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FINAL

GENERIC ENVIRONMENTAL STATEMENT ON THE ROUTINE USE OF PLUTONIUM-POWERED CARDIAC PACEMAKERS

NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL
SAFETY AND SAFEGUARDS

Issued: July 1976

SUMMARY AND CONCLUSIONS

Status: Final Environmental Statement

Responsible Federal Agency: United States Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards

Environmental Project Manager:

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1. Name of Action: Administrative

2. Description of Action: The major Federal action proposed, for which this Environmental Statement is prepared, is the authorization for routine use of plutonium-powered pacemakers by appropriately qualified and licensed physicians who, in their medical treatment of a pacemaker patient, deem it beneficial to their patient. Nuclear-powered cardiac pacemakers have been developed that use plutonium (primarily the plutonium-238 isotope) as a heat source in a thermoelectric converter battery. The relatively long half-life of plutonium-238 (87.8 years) provides batteries that have the potential to provide pacemaker patients with lifetime units. The routine use of any particular nuclear pacemaker model is based on the requirement that its reliability and safety have been demonstrated.

This Environmental Statement defines the safety and reliability standards that nuclear-powered pacemakers are required to meet. All aspects of the risks to the patients, to the public, and to the environment are evaluated for both the routine use of plutonium-powered pacemakers and for postulated accidents involving pacemaker patients. Benefits derived from the use of plutonium-powered units are discussed and weighed against the risks in order to determine whether routine use is justified. Available alternative pacemakers with various performance characteristics are compared with respect to costs and needs of pacemaker patients.

The Nuclear Regulatory Commission has specifically licensed the implantation of limited numbers of plutonium-powered cardiac pacemakers under a rigidly controlled investigational program. This investigational program was preceded by a determination that this limited use would not subject the patients or the public to any undue risk. In addition, the manufacturers were required to demonstrate the safety of their units before their nuclear-powered pacemakers were licensed for implantation in patients. Experience from these investigational programs has been used to evaluate the reliability of plutonium-powered pacemakers.

If routine use is authorized, plutonium-powered pacemakers will be available to many physicians and hospitals, and a patient population of about 10,000 may be reached within a few years. It is expected that plutonium-powered pacemakers would be selected by physicians for only 5 to 10% of all pacemaker patients.

3. Safety and Reliability Requirements:

   a. The nuclear-powered pacemaker is the only type of pacemaker that is required by the Federal government to be designed and tested to standards that assure that the material contained in its power supply will not be released to the environment under conditions of normal use or accidents involving pacemaker patients. These standards include the following:

      (i) The physical and chemical form of the fuel are required to be as nondispersible (in the environment) and nontransportable (in the human body) as is practicable. In order to meet these requirements, the heat source used in all plutonium-powered pacemakers now being manufactured is plutonium dioxide sintered into a hard ceramic pellet and encapsulated to ensure integrity.

(ii) Fuel capsules are required to maintain their integrity when subjected to stresses associated with impact, crush, and fire that could result from credible accidents involving a pacemaker patient. Specific prototype tests and engineering analyses are conducted on each pacemaker model to demonstrate this integrity. The specified test conditions are as follows: (1) impacting a fuel capsule against an unyielding surface at a velocity of 50 m/sec; (2) imparting a static force (crush) of 1000 kg (2200 lb) to the fuel capsule; (3) heating the pacemaker, with the fuel capsule pressurized to the maximum pressure that could develop during its useful life, to 800°C in an oxidizing atmosphere for 30 min followed by quenching in water and a static stress test; and (4) heating the pacemaker with a pressurized fuel capsule in an oxidizing atmosphere for 2 hr at a minimum temperature of 800°C, during which there shall be a sustained temperature of 1300°C for at least 90 min.

(iii) The outer surface of each pacemaker is conspicuously engraved with fire- and corrosion-resistant markings including the trefoil radiation symbol; the words "Radioactive Pacemaker"; identification, quantity, and date of sealing of the contained radioactive fuel; name of the manufacturer; serial number; and the words "Notify Health Authorities for Disposal."

b. Medical institutions that implant nuclear-powered pacemakers and patients who are bearers of nuclear-powered pacemakers are required to comply with specified administrative procedures to assure that the pacemakers are accounted for and that they are recovered for controlled disposal upon the death of the patient or upon removal for any reason prior to death. During the limited investigational use of pacemakers, those administrative requirements for accountability, recovery, and disposal are imposed by conditions of licenses issued to the medical institutions. For routine use, regulations and procedures for licensing will be developed to provide equivalent requirements for pacemaker accountability, recovery, and disposal.

c. Procedures based on statistical techniques have been developed for evaluating the reliability of nuclear-powered pacemakers using information obtained from the investigational programs. Any pacemaker being evaluated in an investigational program or any new model introduced will be required to demonstrate acceptable performance before its routine use will be authorized.

4. Summary of Benefits:

a. Plutonium-powered pacemakers have sufficient longevity to eliminate the need for surgical replacement operations that are necessitated by depletion of chemical batteries. The avoidance of such replacement operations eliminates or reduces:

i. repeated hospitalization of the patients;

ii. patient pain and suffering that is associated with surgery;

iii. patient anxiety associated with anticipated pacemaker wearout and replacement surgery;

iv. complications that can develop after surgery; and

v. damage to pacemaker leads that can result from manipulation during surgery.

b. Plutonium-powered pacemakers can provide long-term maintenance-free pacing to patients for whom the rechargeable pacemakers are physically and/or psychologically unacceptable.

c. Plutonium-powered pacemakers will provide physicians with an alternative choice of medical treatment for patients who require long-term pacing.

d. The use of plutonium power sources will have a positive impact on pacemaker technology. New or additional pacemaker functions that have high power-drain requirements can be more readily accommodated by plutonium-powered batteries without significantly reducing battery life. Such additional functions may also be accommodated by rechargeable batteries, but, currently, would most likely shorten the interval between recharges or lengthen the recharge period.

Currently, plutonium-powered pacemakers have a higher initial cost than nonnuclear alternatives, but this cost is partially or completely offset when one or more replacement implants of alternative pacemakers are necessitated. However, in the selection or prescription of medical treatment

for patients, when health and life are the primary concerns, cost is not necessarily a limiting factor. The lowest-cost alternative is not always the best choice of treatment. Pacemakers are chosen to best meet the medical needs of each individual patient; therefore, all of the different types of pacemekers should be available.

5. Summary of Environmental Impacts: The impact on the environment from routine use of plutonium-powered pacemakers, expressed in terms of effects per 10,000 pacemakers, is as follows:

   a. Radiation exposure to families and all others in the population, excluding the pacemaker patients, involves a dose equivalent to individual spouses of up to 7.5 millirems/year and a dose to the U.S. population of 128 man-rems/year, which is compared with the average natural background dose equivalent of 102 millirems/year to individuals and a total natural background dose to the U.S. population of about 20 million man-rems/year.

   b. Total body and critical organ doses received by pacemaker patients are well below the 5 rems/year that are permitted for occupational exposures of individuals. The integrated dose equivalent to 10,000 patients is 1650 man-rems/year.

   c. The surface dose rate from a pacemaker is about 5 to 15 millirems/hr. The attachment of the pacemaker to leads and the placement of the pacemaker into the prepared pocket usually requires less than 10 min. The permissible occupational exposure to the hands and forearms of radiation workers is 18,750 millirems per calendar quarter. Therefore, the implantation or removal of pacemakers would add only a minute exposure to physicians or other medical personnel.

   d. The radiation exposure rate from a package used for shipment of plutonium-powered pacemakers is less than 0.1 millirem/hr at the surface and is less than ambient background radiation at a distance of 3 ft from the pacemaker. Therefore, exposure to the public and to transportation workers from pacemakers is insignificant.

   e. Potential accidents to plutonium pacemaker patients are evaluated from the standpoint of probability of accident occurrence, types of stresses involved, probability of a fuel capsule being breached, quantity and form of plutonium that would be released from a breached capsule, and pathways to man for the released plutonium. Any plutonium released to the environment would be confined to a finite area and any intake of plutonium by humans would be limited to a small segment of the population. The calculated radiation exposure to the U.S. population for one year of availability of 10,000 plutonium-powered pacemakers is 15 man-rems, which is compared with the total natural background dose to the population of about 20 million man-rems/year. Releases of plutonium from breached fuel capsules are calculated to occur approximately once every 20 years.

   f. The cost of cleaning up plutonium released in the unlikely event of accidental breaches of plutonium-powered pacemakers is calculated to be $20,000 per occurrence.

6. Major Alternatives Considered:

   a. Mercury battery pacemakers
   b. Promethium-powered nuclear pacemakers
   c. Lithium battery pacemakers
   d. Rechargeable pacemakers

7. The following Federal agencies were requested to comment on the Draft Environmental Statement:

   Department of Commerce
   Department of Health, Education, and Welfare
   Department of Transportation
   Environmental Protection Agency

The Draft Statement was also sent, with a request for their comments, to the twenty-five Agreement States that license certain radioactive materials. In addition, announcements of the availability of the Draft Statement and copies of the "Summary and Conclusions" were sent to the State Clearinghouses established pursuant to Office of Management and Budget Circular No. A95 (Revised).

8. The following organizations or individuals (not necessarily representing the organization of their affiliation) submitted comments on the Draft Environmental Statement, which was published in January 1975 (listed in order of receipt):

1. L. Douglas DeNike, Zero Population Growth
2. State of Oklahoma, Grant-in-Aid Clearinghouse
3. State of Kansas, Division of the Budget
4. Harald H. Rossi, College of Physicians and Surgeons of Columbia University
5. Nicholas P. D. Smyth, M.D., Washington, D.C.
6. Stephen R. Parchner, Bakersfield, California
7. Commonwealth of Massachusetts, Office of State Planning and Management
8. State of Nebraska, Human Resources Coordinator
9. Karl Z. Morgan, Georgia Institute of Technology
10. United States Coast Guard, Office of Marine Environment and Systems
11. U.S. Environmental Protection Agency, Office of Federal Activities
12. Sidney M. Wolfe, M.D., Public Citizen Health Research Group, and John Abbotts, Public Interest Research Group
13. R. B. Kershner, Johns Hopkins Applied Physics Laboratory
14. Herman R. Levine, M.D., San Antonio, Texas
15. Dean E. Abrahamson, M.D., Ph.D., University of Minnesota
16. David L. Frank, Fresno Committee for Scientific Information
17. Allen C. Nadler, M.D., Scientists' Institute for Public Information
18. State of Nebraska, Human Resources Coordinator
19. Wilson Greatbatch, Wilson Greatbatch, Ltd.
20. Bobby I. Griffin, Medtronic, Inc.
21. State of Tennessee, Office of Urban and Federal Affairs
22. Donald P. Geesaman, University of Minnesota
23. J. G. Speth, Natural Resources Defense Council, Inc.
24. Patricia Joralemon, Livingston, New Jersey
25. Ron Guenther, Venice, California
26. State of Texas, Division of Planning Coordination
27. F. N. Flakus, International Atomic Energy Agency
28. Department of Health, Education, and Welfare, Office of Environmental Affairs
29. State of Nevada, State Planning Coordinator
30. J. K. Frenkel, M.D., Overland Park, Kansas
31. R. Marriner Orum, Eugene, Oregon
32. Alfred E. Mann, Pacesetter Systems, Inc.
33. W. Albert Sullivan, Jr., M.D., University of Minnesota
34. Gregg S. Everhart, Stanford, California
35. New York State, Department of Environmental Conservation
36. Martin Sonenberg, M.D., Ph.D., Memorial Sloan-Kettering Cancer Center
37. W. Hunzinger, Federal Office of Public Health, Switzerland
38. Thomas S. Bustard, Hittman Nuclear Battery Corporation
39. Victor Parsonnet, M.D., Newark Beth Israel Medical Center
40. L. D. G. Richings, National Radiological Protection Board, Great Britain
41. Thomas S. Bustard, Hittman Nuclear Battery Corporation
42. L. Douglas DeNike, Zero Population Growth
43. Victor Parsonnet, M.D., Newark Beth Israel Medical Center
44. Richard B. Spohn, People for Proof
45. State of Florida, Division of State Planning
46. Dermot A. Nee, Potomac, Maryland
47. N. R. Arthur, Silver Spring, Maryland
48. N. W. Hauser, Edgewater, Maryland
49. Evelyn Bauer, District Heights, Maryland
50. Simone Fouquet, Silver Spring, Maryland
51. Marie Colbert, Washington, D.C.
52. Stephen Cookston, Cordis Corporation
53. Mary P. Jackson, Washington, D.C.
54. Roger G. Powers, Brentwood, Maryland
55. Loyetta C. Wheelbarger, Hyattsville, Maryland
56. Juliet Phillips, Washington, D.C.
57. Martin J. Krauthamer, M.D., Darien, Connecticut
58. Marion R. Lawler, Jr., M.D., Harlingen, Texas

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59. Max Spieler, Pacemaker Foundation, Inc.
60. Victor Parsonnet, M.D., Newark Beth Israel Medical Center
61. Fred Hittman and Thomas S. Bustard, Hittman Nuclear Battery Corporation
62. Stanley J. Runsky, Dover, New Jersey
63. Peter M. Jacobson, Coratomic, Inc.
64. Victor Parsonnet, M.D., Newark Beth Israel Medical Center
65. Peter M. Jacobson, Coratomic, Inc.
66. David L. Purdy, Coratomic, Inc.
67. L. Douglas DeNike, Zero Population Growth

9. On the basis of the analysis and evaluations set forth in this Statement, it has been concluded that the benefits to be derived from the use of plutonium-powered cardiac pacemakers are greater than the risks to the environment and that the routine use of plutonium-powered pacemakers should be authorized subject to the following conditions:

   a. Present administrative practices of nuclear pacemaker inventory control and accountability shall be continued under specific licensing procedures until regulations applicable to routine use are developed and implemented by the NRC.

   b. Nuclear-powered pacemakers implanted during the investigational phase shall continue to be followed and reported, pursuant to the investigational protocols, until they are removed, so that, should an unexpected mode of wearout or failure occur, the NRC and the manufacturer would be promptly informed.

   c. The reliability of any new nuclear pacemaker model shall be monitored by the Commission prior to its release for routine medical use. This reliability determination will be evaluated in the same manner as the reliability of other pacemaker models implanted under the investigational protocols.

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FOREWORD

This Environmental Statement was prepared by the U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, in accordance with the Commission's regulation, 10 CFR Part 51, which implements the requirements of the National Environmental Policy Act of 1969 (NEPA).

The NEPA states, among other things, that "[it] is the continuing responsibility of the Federal Government to use all practicable means, consistent with other essential considerations of National policy, to improve and coordinate Federal plans, functions, programs, and resources to the end that the nation may:

- Fulfill the responsibilities of each generation as trustee of the environment for succeeding generations.
- Assure for all Americans safe, healthful, productive, and aesthetically and culturally pleasing surroundings.
- Attain the widest range of beneficial uses of the environment without degradation, risk to health or safety, or other undesirable and unintended consequences.
- Preserve important historic, cultural, and natural aspects of our national heritage, and maintain, wherever possible, an environment that supports diversity, and variety of individual choice.
- Achieve a balance between population and resource use that will permit high standards of living and a wide sharing of life's amenities.
- Enhance the quality of renewable resources and approach the maximum attainable recycling of depletable resources."

Further, with respect to major Federal actions significantly affecting the quality of the human environment, Section 102(2)(C) of the NEPA calls for preparation of a detailed statement on:

(i) the environmental impact of the proposed action;

(ii) any adverse environment effects that cannot be avoided should the proposal be implemented; and

(iii) alternatives to the proposed action.

This Statement has been prepared to be responsive to the Nuclear Regulatory Commission's responsibilities under the NEPA. In writing this Environmental Statement, the staff communicated with the manufacturers of plutonium-powered pacemakers to seek information that was needed for an adequate assessment and, in general, to ensure that the staff had a thorough understanding of the proposed project. In addition, the staff sought information from consultants, literature, and the medical community that would assist in the evaluation. On the basis of all the foregoing and other such activities or inquiries as were deemed useful and appropriate, the staff made an independent assessment of the considerations specified in Section 102(2)(C) of the NEPA and in 10 CFR Part 51.

This evaluation led to the publication of a Draft Environmental Statement, which was then circulated to Federal, state, and local governmental agencies for comment. A summary notice of the availability of the Draft Environmental Statement was published in the *Federal Register*. Interested persons were requested to comment on the proposed action and the Draft Statement.

In January 1975 the Atomic Energy Commission (now the Nuclear Regulatory Commission) issued the *Draft Generic Environmental Statement on the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers* for comment. A number of the comments received stated that a more complete discussion of the alternatives available and of the need for nuclear-powered pacemakers should be included in the Final Environmental Statement. Some of the comments expressed the opinion that, in view of the availability of nonnuclear pacemakers with long useful service lives, the use of nuclear pacemakers is not necessary or justified.

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In order to prepare an analysis of the need for nuclear pacemakers vs nonnuclear alternatives, the Commission prepared two questionnaires — one requesting information from physicians who have broad experience with pacemakers in their practice and the other requesting information from pacemaker manufacturers on the projected longevity of their various pacemakers and the bases on which the projections were made.

After receipt and consideration of comments on the Draft Statement and the information from the questionnaires, the staff prepared this Final Environmental Statement, which includes a discussion of questions and objections raised by the comments and the disposition thereof, and a final cost-benefit summary which considers the environmental effects and the alternatives available. The action called for is the authorization with conditions or the refusal to authorize the routine use of plutonium-powered pacemakers.

In summary, this Final Generic Environmental Statement is an attempt to place the projected routine use of plutonium-powered cardiac pacemakers in perspective. This Statement addresses the reasonably foreseeable environmental, social, and economic costs and benefits of routine use of plutonium-powered pacemakers; and available alternatives and their reasonably foreseeable costs and benefits. These evaluations are made to determine whether benefits of plutonium-powered pacemakers compared with existing alternative pacemakers justify their use and their availability to broaden the selection for medical treatment of pacemaker patients.

1. INTRODUCTION

1.1 BACKGROUND

There are currently about 100,000 citizens of the United States who rely upon sophisticated pacemakers to treat a defective electrical conductive system in their hearts. In the normal circumstance, a bundle of nerves in the upper heart chambers (atria) transmits electrical impulses to the lower chambers of the heart (ventricles) in such a fashion that the chambers beat in a synchronized way, pumping blood through the circulatory system in an efficient manner. In many disease conditions, including deterioration that accompanies age, infection, or injury, the impulses are blocked, and the normal heart rhythm is interrupted. This interruption causes the lower chambers to beat at a rate that is too slow to pump enough blood to meet the needs of the body (particularly the brain). This frequently results in dizziness and blackout. For many of these conditions, a cardiac pacemaker can deliver an electrical impulse to the lower chambers of the heart, thereby inducing a heartbeat. Depending upon the particular condition, one of the various types of pacemakers can be used. The various types include asynchronous pacemakers, which deliver impulses at a fixed rate; synchronous pacemakers, which sense the impulses in the upper chambers then transmit pulses to the lower chambers so that the proper rhythm is maintained; and demand pacemakers, which deliver an impulse only if the lower chambers do not have a natural beat during a certain period of time. Several thousands of people currently conduct their daily activities with the assistance of these devices.

Most pacemakers are implanted under local anesthetic in a 45-min procedure. In about 10% of the procedures, the wire (lead) is sutured directly to the heart under general anesthesia, but the more common procedure is to insert a catheter lead into a vein in the shoulder region and to thread the lead into the apex of the heart. A pocket is constructed in the tissues of the upper chest, and the pacemaker (pulse generator) is implanted and connected to the lead. Occasionally it is necessary to implant the pacemaker subcutaneously in the abdomen rather than above the pectoralis muscle of the chest.

The ability of muscle to respond to electrical stimulation and the production of electrical energy during cardiac and other muscular contraction has been known for some time. Experiments with electrical stimulation of heart muscle were conducted during the 1920's. In 1932, Hyman first constructed an apparatus that was conceived as a substitute for defective pacing of the heart and referred to as an artificial pacemaker.[1,2] In 1952, Zoll demonstrated the clinical feasibility of closed-chest electrical cardiac stimulation to cause the lower chambers of the heart to contract and pump blood to the body.[1] The technique saved life-saving and opened an era of widespread use of electrical stimulation of the heart using skin electrodes. Several years later, better results were obtained when electrodes were placed directly on the wall of the lower heart chamber or inserted via the veins into the lower right chamber of the heart.

Because some components of the electronic circuit were large, early models of heart-stimulating devices had to be placed outside the body. However, the development of transistors and other solid-state electronic components made possible the production of devices small enough to be implanted internally. In 1959, Elmquist and Senning reported the first implanted pacemaker.[3] The unit used a rechargeable nickel-cadmium battery as its power source. This unit was not widely accepted. Shortly thereafter, Chardack and Greatbatch implanted the first pacemaker powered with mercury batteries, the forerunner of the cardiac pacemakers that are now widely used throughout the world.

Mercury-zinc batteries have been improved to increase their cell life. Also, careful monitoring for indications of impending battery depletion has extended the period between surgical implantations of replacement pacemakers.

Until recently, conventional pacemakers used the mercury-zinc battery as a power source. Due to battery depletion, replacement surgery was required every 18 to 36 months.

1.2 PLUTONIUM-POWERED PACEMAKERS

The cardiac pacemaker is the first prosthetic device powered by nuclear energy to achieve practical application in man. Nuclear batteries in pacemakers have the potential of providing significant benefits to patients by extending the operating lives of pacemakers well beyond that which can be achieved by the current generation of chemical batteries.

The need for longer-lived power sources for pacemakers was recognized early in the development of implanted pacemakers. In response to this need, the Atomic Energy Commission initiated a request in 1966 for proposals from industry to develop a long-lived pacemaker using a radioisotope as the heat source in a thermoelectric converter battery. The primary objective of that program was the development of a nuclear-powered pacemaker with a minimum operating lifetime of ten years. Other important objectives were (1) mitigation of the radiation exposure to the user to a medically acceptable level, (2) containment of the radioisotope fuel, and (3) sufficient reduction of the size and weight of the pacemakers to make surgical implantation practicable.

To achieve the specified operating lifetime and at the same time to minimize size, weight, and radiation exposure to the patients and to the public, the radioisotope used should have a relatively long half-life, a sufficient thermal power density, and low shielding requirements. Plutonium-238 meets these requirements.

The technology for use of this isotope in radionuclide power sources was developed by the AEC for space nuclear power systems and has been successfully applied in a number of lunar and deep-space missions. Using advanced technology and materials, these long-lived heat sources contained in thermal electric generators have been designed and developed to withstand high operating temperatures of approximately 800°C (1475°F), extreme thermal stresses that could be encountered upon reentry to the earth's atmosphere, and extreme mechanical stresses resulting from possible impact onto a hard surface such as granite. Well-known missions include the Apollo lunar series, the Pioneer missions to Jupiter, and the Viking mission to Mars.

Even though the nuclear batteries used in space flight contain about 30,000 times more plutonium than present pacemaker batteries, the materials of construction and basic technology of space batteries were applied by the AEC contractor and private industry to the development and fabrication of plutonium-powered batteries for use in cardiac pacemakers.

Several models of pacemakers that use plutonium-238 power sources have been developed both under the AEC contract and independently by private industry in the United States, England, and France. Five pacemaker manufacturers are now distributing plutonium-powered pacemakers in the United States for clinical evaluation.

1.3 NRC REGULATIONS

The Nuclear Regulatory Commission is authorized by Sect. 53 of the Atomic Energy Act of 1954, as amended, to regulate the possession and use of plutonium. Section 161 of the Act states, in part:

> In the performance of its functions the Commission is authorized to....
>
> b. establish by rule, regulation, or order, such standards and instructions to govern the possession and use of special nuclear material, source material, and byproduct material as the Commission may deem necessary or desirable to promote the common defense and security or to protect health or to minimize danger to life or property....

Plutonium-238 is, by definition, "special nuclear material," and pacemakers containing highly enriched plutonium-238 (>80% plutonium-238) are subject to the NRC regulations in 10 CFR Part 70.* However, the guidelines of the International Atomic Energy Agency exempt plutonium containing more than 80% of plutonium-238 from safeguards requirements that have been set forth in agreement between the IAEA and member countries in connection with the Treaty on the Non-Proliferation of Nuclear Weapons.

The basic elements of the current policy of the NRC relating to the limited licensing of pacemakers for investigational use are stringent requirements to assure (1) safe levels of radiation for patients and the public; (2) safe containment of the plutonium during normal use, during

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*The Commission has entered into agreements with some states under which the Commission has discontinued, and the state has assumed, authority for regulating certain nuclear materials. The regulatory requirements of the Agreement States are equivalent to those of the Commission.

accidents involving pacemaker patients, and during pacemaker disposal; and (3) accountability, recovery, and controlled disposal of pacemakers. Safe containment of the plutonium is provided by requiring pacemakers to be designed, manufactured, and tested in accordance with rigid standards and criteria.

The NRC is currently licensing the implantation of plutonium-powered pacemakers only on a limited investigational basis under a research protocol to establish that nuclear pacemakers are reliable. This program was preceded by a determination that this limited use would not subject the patients or the public to any undue risk. The current practice in licensing the investigational use of pacemakers and the development of a regulatory framework to accommodate the routine use of plutonium-powered pacemakers is discussed in Sect. 2. It is the purpose of these investigational programs to determine whether the reliability of these pacemakers justifies their routine use.

1.4 PROPOSED AUTHORIZATION OF ROUTINE USE OF PLUTONIUM-POWERED PACEMAKERS

The major Federal action proposed for which this Environmental Statement is prepared, is the authorization for routine use of plutonium-powered pacemakers in the medical treatment of cardiac patients; that is, that nuclear pacemakers are justified and acceptable for use by appropriately qualified and licensed physicians who, in their medical treatment of pacemaker patients, deem it benefical to the patients. The routine use of any particular nuclear pacemaker model is based on the requirement that its reliability and safety have been demonstrated.

Prior to taking Federal actions that may affect the quality of the human environment, the NRC is required by the National Environmental Policy Act of 1969 (NEPA), Public Law 91-190, to assess the potential environmental impact of such actions. The regulation under which the NRC implements NEPA is 10 CFR Part 51, "Licensing and Regulatory Policy and Procedures for Environmental Protection." Authorizing the routine use of nuclear-powered pacemakers (beyond the present investigational use of limited numbers of pacemakers) is considered to be a major Federal action that could affect the quality of the human environment. Therefore, this Environmental Statement describes and evaluates the potential environmental consequences of routine use of plutonium fuel in cardiac pacemakers.

The content of environmental statements is specified in 10 CFR Part 51. The three major objects identified from these regulations as being pertinent to this Environmental Statement are as follows: (1) potential impacts on the environment resulting from routine use of plutonium-powered pacemakers, (2) a benefit-cost analysis of such routine use, and (3) available alternatives to such use.

Three environmental impacts are: (1) radiation exposure to the patients from the implanted pacemakers, (2) exposure to the public from normal use of pacemakers, and (3) potential release of plutonium from accidental or abnormal events. These impacts are discussed in Sect. 3.

The benefits from the long service life of plutonium-powered pacemakers are assessed in Sect. 4. The principal benefit from plutonium-powered pacemakers is the lifetime assistance given to cardiac patients requiring pacemakers. Secondary to this benefit is the reduction of the frequency of surgery and postoperative complications and the consequent reduction of patient pain, suffering, and anxiety associated with pacemaker reimplantations.

In addition to the plutonium-powered pacemaker and the improved mercury batteries, pacemakers with other new power sources, such as the lithium and rechargeable batteries, are being developed and evaluated. A discussion of these alternatives is included in Sect. 4.

This Statement considers the impact of plutonium-powered pacemakers on the environment during normal conditions and under potential accident and loss conditions. The production of plutonium, the manufacture of nuclear batteries and pacemakers, and the controlled disposal of any associated radioactive wastes are conducted as a part of other licensed or ERDA contract operations. The amount of plutonium that would be required for routine use of pacemakers would be small compared with that which is produced for other purposes. Since the environmental impact of the production and disposal of plutonium is considered in conjunction with the licensing or authorization of such operations, when required by the NEPA, this Statement does not consider their environmental impact.

REFERENCES FOR SECTION 1

1. S. Furman and D. J. W. Escher, *Principles and Techniques of Cardiac Pacing*, Harper and Row, New York, 1970.

2. H. J. T' len, "The Artificial Cardiac Pacemaker," *Am. Heart J.* 81: 583 (1972).

3. G. A. Rahmoeller and J. R. Veale, "Pacing the Heart Electrically," *FDA Consumer* 7: 18 (November 1973).

2. LICENSING OF NUCLEAR-POWERED PACEMAKERS

2.1 INTRODUCTION

The normal use of nuclear-powered cardiac pacemakers entails some degree of radiation exposure to patients, to members of their households, and to the general public as a result of the radioactivity of the plutonium contained in the pacemakers. There is also a potential for radiation exposure if radioactive material is released in an accident that damages the radioactive source in a pacemaker. In order to acquire information on the actual performance of nuclear-powered pacemakers in patients and to determine whether their longevity and reliability characteristics justify the associated risks, nuclear pacemakers are presently licensed in the United States for limited investigational use. This limited investigational use is recommended by the Nuclear Energy Agency* (NEA) and is followed, in practice, by a number of countries in addition to the United States.

2.2 NUCLEAR ENERGY AGENCY STANDARDS

The NEA had developed "Interim Radiation Protection Standards for the Design, Construction, Testing and Control of Radioisotopic Cardiac Pacemakers."[1] The standards were concerned with protecting the public health and safety but not with medical considerations relating to individual pacemaker patients. The purpose of the NEA standards is to provide a uniform basis for national authorities to establish practices and procedures by which the radiation risks of nuclear-powered pacemakers to the public can be kept to a minimum and to permit non-restricted international travel of pacemaker patients. A member of the Nuclear Regulatory Commission (NRC) staff represented the United States in the NEA group of experts, which developed these standards. The present NEA standards are designated as interim standards applicable during limited clinical investigations using pacemakers. These interim standards may be continued in use or modified for routine use of pacemakers as indicated by experience gained from the investigations.

The NEA standards were drawn up "on the principle that, so far as is practicable, the requirements of radiological safety shall be incorporated into the design of the pacemaker and that the radioactive material will ultimately be recovered and disposed of under controlled conditions."[1] The standards contain guidance on (1) design and testing of pacemakers to assure continued and reliable containment of the radionuclide fuel during normal use and in accident conditions, (2) control of external radiation levels, (3) identification of pacemaker patients, (4) accountability for pacemakers in circulation, and (5) collection and disposal of radioactive source capsules at the end of their useful lives.

The possession and use of plutonium in pacemakers is licensed pursuant to 10 CFR Part 70, "Special Nuclear Material," of NRC regulations. Two licensing guides have been issued to assist manufacturers and clinical users of pacemakers in preparing their applications for licenses. One of the licensing guides, "Interim Safety Guide for the Design and Testing of Nuclear-Powered Cardiac Pacemakers" (Appendix B of this Statement), contains standards for designing, testing, and manufacturing nuclear-powered pacemakers. The second, "Guide for Licensing the Investigational Use of Nuclear-Powered Cardiac Pacemakers" (Appendix C of this Statement), contains conditions for a standard protocol to be followed by all clinical investigators and for the licensing of hospitals to participate in the investigation.

The standard protocol should describe those aspects of the clinical implantation and follow-up program that are to be followed by all of the participating invesitgators. This protocol, when accepted for licensing by the Commission and the Agreement States, can be furnished to all of the participating medical institutions and incorporated by them into their applications for licenses.

2.3 NRC LICENSING OF INVESTIGATIONAL USE

The Nuclear Regulatory Commission, in discharging its statutory responsibility for assuring the public health and safety in the use of atomic energy materials, is presently licensing hospitals

*An agency (formerly the European Nuclear Energy Agency) of the Organization for Economic Cooperation and Development.

to implant nuclear-powered pacemakers for limited investigational use only. The purpose of the investigation is to obtain data to establish whether the pacemakers are reliable for routine use. Data from these investigations will also be used in the development of criteria for routine use of nuclear-powered pacemakers.

Under the present licensing program, both the number of nuclear pacemakers and the number of medical institutions participating in the investigation are being limited. A total of approximately 700 plutonium-powered pacemakers from five manufacturers have been implanted under this investigational program. More than 85% of these pacemakers (4 of the 5 manufacturers) contain 250 mg or less of plutonium. One manufacturer uses 500 mg (about 8 Ci) of plutonium.

There are three principal elements in the present NRC licensing program: (1) control of pacemaker design and manufacture to assure safe containment of radioactive material under anticipated normal and credible accident conditions, (2) control of pacemaker use to assure accountability and recovery for controlled disposal of nuclear sources contained in pacemakers, and (3) collection of data for the evaluation of nuclear pacemaker reliability.

2.3.1 Standards and criteria

The NRC has developed interim safety design and testing criteria that have been coordinated with the NEA standards for nuclear-powered pacemakers for investigational implantation. These criteria, discussed in detail in the "Interim Guide for the Design and Testing of Nuclear-Powered Cardiac Pacemakers" (Appendix 3), include requirements for testing prototype plutonium sources, batteries, and pacemakers under conditions that are more severe than contemplated in their use. Passing the test requires that no radioactive fuel be leaked or released following exposure of the sources and pacemakers to the test stresses. The test requirements, the types of accidents considered in establishing the prototype test conditions, and the rationale for the tests are summarized in Table 2.1.

It is extremely unlikely that accidents involving stresses more severe than the prototype tests would occur. Therefore, the ability to meet these criteria and to successfully complete the tests provides a high degree of assurance that the plutonium fuel will be contained during normal use and under any credible accident condition involving a patient with an implanted pacemaker or involving a pacemaker during handling and transportation before implantation or after removal.

The criteria also require that the physical and chemical form of the fuel be such that it will be as nondispersible (in the environment) and nontransportable (in the human body) as is practicable. The fuel form chosen for all of the presently manufactured plutonium-powered pacemakers is plutonium dioxide. This oxide is a nearly chemically and metabolically inert form of plutonium which is compressed and fired into a hard ceramic pellet to minimize the likelihood of dispersal and subsequent intake and retention in the human body, even in the unlikely event of an accidental breach of the containment system.

The properties of plutonium-238 and the fabrication of plutonium sources are discussed in Appendix D.

2.3.2 Manufacture of nuclear-powered pacemakers

Any pacemaker manufacturer or importer who desires to distribute pacemakers for investigational use must demonstrate, in his application for licensing approval of such distribution, that his pacemaker satisfies all of the safety design and test criteria outlined in Appendix B. In order to meet all of the design and test criteria, plutonium heat sources are fabricated using multiple layers of containment. The construction materials, dimensions, and methods of fabrication of heat sources are chosen so that the combined properties of the multiple envelopes will provide the necessary mechanical strength for fuel containment under the temperatures, pressures, and stresses required by the design and test standards. The materials must also be (1) compatible with all other materials with which they will come in contact in normal use and under test conditions, (2) resistant to oxidation and reaction with other materials during thermal tests, and (3) resistant to long-term corrosion. The adequacy of pacemakers to meet the criteria is determined by engineering analysis of the design and by the demonstration that prototype pacemakers, batteries, and radionuclide sources pass the prototype tests.

2.3.2.1 Quality assurance

Prior to authorizing the licensing of a new pacemaker model, the NRC requires the domestic manufacturer or importer to provide and implement a quality control program to ensure that each production unit is a replica of units that have successfully passed the required safety tests, as outlined previously, and that each unit will conform to the specifications furnished to the NRC.

Table 2.1. Interim safety performance tests for plutonium-powered cardiac pacemakers[a]

Mechanical	
Impact:	Impact the source at a velocity of 50 m/sec onto a flat essentially unyielding surface. This test has evolved out of consideration of the maximum impact expected for a pacemaker implanted in the body of a person involved in a transportation accident or a fall. The 50-m/sec velocity is based on the terminal velocity of a body in free fall following collision of aircraft in midair.
Static stress:	The source shall be subjected to a static stress (crush) load of 1000 kg between roughened steel jaws. This test is related to the forces resulting from an individual being caught under falling masonry or pinned by a steel girder. The 1000-kg test load is based on the possible weight of the girder.
Thermal	
Fire:	The battery shall be subjected to a temperature of 800°C in air for 30 min, followed by quenching in water at room temperature and a 1000-kg static stress (crush) test. This test is based on temperatures experienced in building or transportation fires. The water quench is needed to ensure that the pacemaker will withstand thermal shock resulting from water being used to extinguish a fire, and the static stress test is to ensure that it would withstand being crushed by a collapsing building following the thermal stresses of fire and water quench.
Cremation:	The pacemaker shall be subjected to a cremation cycle of two hours in an oxidizing atmosphere with a minimum temperature of 800°C and a sustained temperature of 1300°C for at least 90 min. This test is based on measured cremation temperatures. The average temperature for cremation is substantially lower than 1300°C.
Corrosion	
Seawater:	It shall be demonstrated that the radionuclide fuel will be contained for 10 half-lives in seawater, including consideration of possible pressure buildup inside the fuel capsule. This corrosion capability shall be determined by corrosion tests, engineering analyses and extrapolations considering the linear rate of corrosion for each material constituting the fuel capsule and each fuel containment envelope. A program plan for corrosion tests of each fuel containment envelope, including possible galvanic reactions, shall be submitted and evaluated. This requirement is to ensure that the radioactive fuel will not be released to the environment if a pacemaker is lost or buried. Since seawater is more corrosive than either fresh surface or groundwater, materials that resist corrosion by seawater would resist corrosion if lost in fresh water or buried in soil. Ten half-lives[b] were chosen to ensure that a negligible amount of fuel would be present if the integrity of the containment system was compromised.

[a]The quality control requirements for licensing plutonium-powered pacemakers are described in Sect. B.3 of the *Interim Safety Guide for the Design and Testing of Nuclear-Powered Cardiac Pacemakers*, which is Appendix B of this Environmental Statement.

[b]Ten half-lives of plutonium-238 are 878 years, during which time the Pu-238 will decay to 1/1000 of the original activity (8 mCi maximum from an initial 500-mg, 8-Ci, plutonium source). Plutonium used in pacemakers contains 10% by weight of Pu-239, which is only 0.04% of the total plutonium by activity. After ten half-lives of Pu-238 decay, the remaining Pu-239 is less than half of the remaining Pu-238 activity.

Quality control procedures must be found acceptable by the Commission as applied to design, material control, fabrication, and product qualification testing. The quality control requirements for licensing plutonium-powered pacemakers are described in Appendix B (Sect. B.3).

2.3.2.2 Labeling

The labeling, as specified in Appendix B, requires that the fuel capsule (or battery housing in the case where the fuel capsule is permanently sealed within the battery housing) and the pacemaker housing be conspicuously and legibly marked by means resistant to fire and corrosion. The purpose of this labeling is to facilitate retrieval of the pacemaker, in case of an accident, by alerting individuals to the fact that the pacemaker and component parts (e.g., the source capsule or battery) contain plutonium and that health authorities should be notified for disposal of the pacemaker.

2.3.3 Limited clinical investigation programs

The primary purpose of the limited clinical investigation of plutonium-powered pacemakers is to determine their reliability under conditions of actual use in man. To provide the most effective evaluation of pacemakers while minimizing the necessary number of investigational subjects, a pacemaker manufacturer or a distributor of imported pacemakers (hereinafter referred to as the sponsor) is required to submit an overall plan for the clinical investigation of each model of nuclear pacemaker and to develop a standard protocol to be followed by all participating investigators.

2.3.3.1 Standard protocol for clinical use

The use of a standard protocol assists in obtaining a uniform approach to the evaluation of plutonium-powered pacemakers and simplifies licensing for the applicant medical institutions participating in the sponsor's study, the sponsor, and the licensing agency (NRC and Agreement States). In addition, conformity to a standard protocol provides a high level of operational control of the plutonium-powered pacemaker within the public sector and a high assurance of recovery following use. The required contents of a standard protocol are described in Appendix C. These provisions are discussed in the following parts of this section.

2.3.3.2 Patient information and consent

The patient shall be informed of, and shall provide written agreement to, the following:

1. Radionuclide-powered pacemakers are under investigation, there are alternative treatments, and the patient is willing to participate in the investigation.

2. To avoid burial, cremation, or loss to the environment of a radionuclide source, the pacemaker shall be removed from the body upon the death of the patient and, when removed at death or for any reason prior to death, shall be returned to the sponsor of the clincial investigation for disposal.

3. The patient shall carry, at all times, an identification card containing the patient's name, the word "Radioactive," the radiation symbol, identification of the patient as a bearer of a radionuclide-powered cardiac pacemaker, identification of the pacemaker by manufacturer's name and model number, the amount and type of contained radionuclide, the words "In case of emergency or death, call collect (name and telephone number of the participating institution)," and information pertaining to the patient's consent to remove the pacemaker in case of death.

4. The patient shall wear, at all times, a durable, fireproof bracelet or other approved form of jewelry engraved with the patient's name, the words "Radioactive Pacemaker," the radiation symbol, identification of the radionuclide, and the words "In case of emergency or death, call collect (telephone number)."

5. Long-term follow-up examinations shall be conducted as scheduled by the participating medical institution.

6. The patient shall notify the hospital of any change in his address or telephone number or if there is any change with respect to the person to be contacted in case the patient cannot be located.

7. The patient shall notify, through the hospital and sponsor, the appropriate licensing authority prior to any travel outside of the United States.

2.3.3.3 Registration reports and records

The implanting hospital reports to the sponsor, and both the hospital and the sponsor keep records on each implanted pacemaker. These reports include the name and address of the patient, names and addresses of at least two persons to be contacted if the patient cannot be located, and pacemaker identification by model and serial number.

2.3.3.4 Follow-up reports

The implanting hospital reports to the sponsor the data on each follow-up examination of nuclear-powered pacemaker patients. Such follow-up examinations are required at intervals not to exceed six months. The report on each follow-up states whether the patient is wearing the required bracelet or other approved identification jewelry, whether the patient is carrying the identification card, and whether satisfactory contact has been maintained since the last follow-up examination.

2.3.3.5 Reports of replacement or removal

The implanting hospital reports to the sponsor any pacemaker that is replaced or removed for any reason. In case of death of the patient, the pacemaker shall be removed and returned to the sponsor for evaluation and approved disposal unless retention and reuse are authorized by the licensing agency. Some pacemakers that have been removed because of death of the patient from causes unrelated to the pacemaker have been retained by the hospital for reuse in other patients. In these cases, the subsequent reimplantations are subject to the same protocol and accountability procedures.

2.3.3.6 Reports of death or loss of contact

The implanting hospital reports to the NRC or the Agreement State licensing agency within 24 hours of occurrence, the death of any bearer of a nuclear-powered pacemaker and, within ten days of the hospital's knowledge, the loss of contact with any pacemaker patient.

2.3.4 Licensing of hospitals

To facilitate continuity of patient follow-up during the investigational phase of plutonium-powered pacemaker use, special nuclear material licenses are issued only to hospitals and not to individual physicians. A hospital, once selected by a sponsor to participate in his clinical study, may apply for a special nuclear material license to possess and implant the sponsor's nuclear-powered pacemaker under an approved standard protocol. Participation by the implanting institution in such a clinical research study is conditioned upon following the standard protocol.

Hospitals must show evidence of and/or agree to the following:

1. The hospital must have an ongoing pacemaker implantation and follow-up clinic.

2. The hospital must use a team approach to the study of implantation, evaluation, and follow-up. A thoracic surgeon(s) specializing in cardiovascular diseases and a cardiologist(s) will be included in the team.

3. The hospital and its study team must agree to follow the sponsor's protocol for the study.

4. Records on patients with nuclear-powered pacemakers must be maintained separately from routine hospital records.

5. The hospital must develop a system of accounting for all nuclear pacemakers within the hospital by serial number and must keep them under lock and key when in storage or otherwise not in use.

6. The hospital must develop a rapid response capability for handling emergency reports or inquiries concerning a bearer of a nuclear-powered pacemaker.

7. The hospital must agree to continue follow-up of the patient, periodic reporting, and recovery procedures until the device is recovered and returned for controlled disposal of the radioactive material.

2.3.4.1 Responsibility of hospital for accountability and recovery

Under a special nuclear material license issued for implanting pacemakers during the investigational study, the responsibility for the plutonium and its control, accountability, and recovery rests with the hospital. The specified possession limit for special nuclear material (plutonium), under a license issued to the hospital, includes all special nuclear material possessed by the licensee whether in storage, implanted in patients, or otherwise in use. License conditions intended to ensure accountability of pacemakers in patients are placed on special nuclear material licenses issued to hospitals. These conditions are as follows:

1. The licensee shall not receive or transfer in any single transaction one gram or more of plutonium contained in nuclear-powered pacemakers without notifying the Division of Safeguards, U.S. Nuclear Regulatory Commission (Washington, D.C. 20555) and, in addition, completing and distributing Form NRC-741 as required by Section 70.54 of 10 CFR Part 70.

2. The licensee shall report to the Radioisotopes Licensing Branch of the U.S. Nuclear Regulatory Commission (Washington, D.C. 20555) within 24 hr of occurrence, the death of any nuclear-powered pacemaker patient.

3. The licensee shall report to the Radioisotopes Licensing Branch of the U.S. Nuclear Regulatory Commission (Washington, D.C. 20555) within ten days, the loss of contact with a nuclear-powered pacemaker patient.

2.3.5 Periodic reports by sponsors

The sponsors of the clinical investigations (manufacturers or importers of the plutonium-powered pacemakers) are required to report to the NRC, at intervals of not more than six months, summary data that they receive from the participating investigators. To date, the sponsors of the investigation programs have reported 100% accountability of implanted plutonium-powered pacemakers.

2.4 STATISTICAL EVALUATION OF PACEMAKER RELIABILITY

Procedures have been developed for evaluating the reliability of nuclear-powered pacemakers using information on clinical experience obtained from the investigational programs. The proposed routine use of nuclear-powered pacemakers is based on the requirement that suitable performance of these units will be clinically demonstrated.

These evaluation procedures, based on statistical techniques, provide a systematic means to determine the acceptability or nonacceptability of nuclear pacemakers as rapidly as possible. Suitable criteria are met when it is established, with a high degree of confidence, that the failure rate of nuclear units is less than or equal to an acceptable standard.

For the investigational program, a limitation is imposed on the monthly implantation rate, which is aimed at controlling the number of units in circulation until routine use is authorized (unrestricted distribution would be tantamount to routine use). Also, constraints are placed on the number of pacemaker-patient-months that are allotted to any one manufacturer for the evaluation of his unit's performance.

Computer programs were developed for the Commission (by Drs. D. Kleitman and A. Barnett, of the Massachusetts Institute of Technology; D. Rosenbaum, of Mitre Corporation; and B. Singer of Columbia University) to evaluate pacemaker performance. These programs require as input the following predetermined parameters: (1) the maximum acceptable failure standard; (2) the confidence level on the maximum acceptable failure standard; (3) the total accumulated number of pacemaker-patient-months in which a decision must be reached; (4) a desired confidence level to terminate a unit's evaluation due to an excessive number of pacemaker failures and (5) a parameter concerned with determining whether pacemakers are failing at a constant rate. The output from these programs provides the means to determine if one of the following circumstances exists:

(1) There is a high degree of confidence that the unit's failure rate is less than the acceptable standard and the test can be discontinued, because acceptability is demonstrated.

(2) The number of device failures has become so large that, to a high degree of confidence, pacemaker acceptability cannot be demonstrated, even if the investigation is run to conclusion. In this case, the test should be discontinued, and this pacemaker model should not be used in future implantations.

(3) Not enough data has been collected to establish one of the above conditions, and the experiment should continue.

For purposes of this evaluation, a pacemaker is considered to fail if, for any reason, the pulse generator fails to provide satisfactory pacing to the patient. In these investigational programs a failure standard is selected that is equivalent to other types of (nonnuclear) pacemakers on which data have currently been reported. The maximum acceptable failure standard currently being used, with which nuclear pacemaker acceptability is compared, is 0.15% failures per month. This standard is compatible with the electronic capabilities of conventional pulse generators.[2-4]

The accumulated months of pacemaker experience adopted, in which pacemaker evaluation must be made, is 25,000 pacemaker-patient-months. The evaluation may be completed or terminated before the maximum number of pacemaker-months if one of the following circumstances exists:

(1) The pacemaker is found to meet the reliability requirement with 90% confidence, or

(2) There is a 95% confidence that the required pacemaker performance cannot be attained even if the clinical investigation is continued.

To date, the evaluation of the accumulated pacemaker experience from the investigational programs indicates a plutonium pacemaker performance better than required specifications. A detailed discussion of the supporting data is contained in Sect. 4. Although one plutonium-powered pacemaker model has successfully demonstrated acceptability, its performance will continue to be evaluated until a decision on routine use is made by the NRC.

If routine use is authorized, any pacemaker model in an investigational program or any new model introduced on the market will be required to demonstrate acceptable performance using the previously outlined procedures and to report the results to the NRC. The NRC will consider authorizing the routine use of this unit at that time. A more comprehensive discussion of the statistical procedures used in evaluating pacemaker performance is contained in Appendix E.

2.5 REGULATION OF ROUTINE USE

If routine use is authorized, plutonium-powered pacemakers will be used by many physicians and hospitals, and a patient population of about 10,000 may be reached within a few years. It is not expected, however, that plutonium-powered pacemakers would be selected by physicians for more than 5 to 10% of all pacemaker patients.

2.5.1 Manufacture of pacemakers

Regulation of the manufacturers and importers of plutonium-powered pacemakers would continue during routine use essentially as described earlier in this section. Both the NEA standards and the NRC guide for design and testing of nuclear-powered pacemakers are designated as interim documents subject to revision if experience indicates that revision is necessary. However, no need for change in the standards or criteria for safety of plutonium-powered pacemakers is now indicated or planned. Thus, as with present licensing for investigational use, pacemakers that will be licensed for routine distribution and use would have to be designed, manufactured, tested, and quality controlled to assure that radiation levels from pacemakers will not cause unacceptable radiation exposures to the patients or the public and that plutonium will be contained in the pacemaker in normal use and under conditions of possible accidents or loss.

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2.5.2 Authorization for implantation and possession

During the limited investigational use of plutonium-powered pacemakers, the licensed hospitals are responsible for (1) the possession of the plutonium-powered pacemakers by the patients, (2) the maintenance of contact with the patients for continuing accountability of the plutonium sources, and (3) recovery of the plutonium sources upon the death of a patient or the removal of a pacemaker from a patient. These procedures are effective and practical during the investigations because close contact with patients is necessary for obtaining investigational data on the pacemakers. Patients are selected, in addition to their medical need for pacemakers, on the

basis of their agreement and availability to participate in the investigation, required follow-up, and recovery of their pacemakers. However, in routine use, relatively large numbers of patients and hospitals may become involved. These patients can be expected to lead essentially normal lives and be highly mobile, as is the case for the rest of the American population. For these reasons, it may not be acceptable to the medical community, or practical, to have the responsibility for accountability and control of nuclear-powered pacemakers rest primarily with the implanting hospitals and medical institutions.

Although the mechanism used for assuring accountability and recovery of plutonium-powered pacemakers during investigational use may not be appropriate during routine use, an equivalent level of control and recovery by means appropriate to their routine use will be imposed.

A regulatory accountability and recovery system for routine use of pacemakers will consider the following:

1. establishment of a system for registering pacemaker patients;

2. assurance that patients and their survivors will permit recovery and appropriate disposal of plutonium-powered pacemakers in case of death of the patient or removal of the pacemaker for any other reason;

3. requirement that patients wear and carry appropriate identification that they have an implanted plutonium-powered pacemaker and instructions to be followed in case of death or emergency to assure safe handling and recovery of the pacemaker;

4. establishment of a system of periodic contact with patients to update registry information, to remind them and their families of the requirements for accountability and recovery of pacemaker sources, and to follow up on unrecovered pacemakers; and

5. establishment of a system for the collection and controlled disposal of plutonium pacemaker sources after use.

REFERENCES FOR SECTION 2

1. "Interim Radiation Protection Standards for the Design, Construction, Testing and Control of Radioisotope Cardiac Pacemakers," C. (74)101 (Final), Nuclear Energy Agency, Organization for Economic Cooperation and Development, Paris, France, 23 August 1974.

2. Medtronic, Inc., *Medtronic Laurens-Alcatel Model 9000 Pulse Generator Clinical Investigation Plan*, March 1973.

3. Medtronic, Inc., *Medtronic Product Performance Report*, MC 74-51, September 1974.

4. Medtronic, Inc., *Implantable Demand Isotopic Pulse Generator, Third Semi-Annual Clinical Evaluation Report to the USAEC*, November 1974.

3. ENVIRONMENTAL IMPACT ASSESSMENT

3.1 INTRODUCTION

The routine use of nuclear power sources in cardiac pacemakers involves three types of potential risks to the public: (1) the radiation exposure to the patients from the implanted pacemakers (Sect. 3.2), (2) the radiation exposure to the public from implanted pacemakers (Sect. 3.3), and (3) the potential release of radioactive fuel from accidental or abnormal events (Sect. 3.7).

Five manufacturers* are currently using radioactive plutonium-238 as fuel for pacemakers. Of the five manufacturers, four are using batteries containing 250 mg or less of plutonium; therefore, this assessment will be based on pacemakers containing 250 mg of plutonium.† The fifth manufacturer's pacemaker contains about 500 mg of plutonium; thus, the impacts for this pacemaker are double those determined for a pacemaker containing 250 mg.

Assuming the availability of nuclear-powered pacemakers, the decision to implant a nuclear-powered pacemaker rather than a conventional battery-powered pacemaker will be made by the physician and the patient case-by-case. According to current estimates, 100,000 to 200,000 patients in the United States are pacemaker bearers. Most physicians queried have indicated that about 5 to 10% of this population could use a long-lifetime pacemaker (i.e., with a lifetime of 10 years or more), and this market for long-lived pacemakers will be shared by nuclear-powered pacemakers, rechargeable pacemakers, and improved types of chemical battery powered pacemakers. This environmental impact assessment is based on an assumed nuclear-pacemaker population of 10,000 patients. Using the base figure of 10,000 pacemakers, the impacts of the pacemakers can easily be scaled up or down for other numbers of implanted nuclear pacemakers.

3.2 DOSE RATE TO PATIENTS FROM IMPLANTED NUCLEAR-POWERED PACEMAKERS

Derivation of the radiation dose to patients from implanted nuclear-powered pacemakers is based on a study by Battelle Pacific Northwest Laboratories. The radiation doses from a Medtronic model 9000 pulse generator containing 173.2 mg of plutonium of 90.14% by weight plutonium-238 (156.1 mg) and 0.26 ppm of plutonium-236 were determined.[1] The dose-equivalents to various organs from a pacemaker containing 250 mg of plutonium have been linearly scaled from the Battelle report and are given in Tables 3.1 and 3.2 for pacemakers located above the left pectoral muscle and near the surface of the abdomen respectively. Additional information on determining patient dose-equivalents has been abstracted from the Battelle study and is presented in Appendix F. Information on the properties of the plutonium fuel and the fabrication of plutonium sources is given in Appendix D. Derivation of radiation dose-equivalents to the patients and to the public is based on fuel containing 0.26 ppm plutonium-236, which is the approximate assay of all plutonium used to date in pacemakers. Should the assay of plutonium-236 increase to 0.6 ppm (the maximum plutonium-236 impurity in the specifications for plutonium-238 by the pacemaker battery manufacturers), the gamma dose rate can double over a period of years, as shown in Fig. F.5 in Appendix F. The net effect would be an increase by 25 to 50% in the dose-equivalents (total gamma and neutron) to various organs, as shown in Tables 3.1 and 3.2.

3.2.1 Assessment of radiation exposure to patients

There are four areas of concern relative to the radiation effects on patients: (1) the radiation dose to tissues in immediate contact with the pacemaker, (2) dose to radiosensitive tissues such as red bone marrow and gonads, (3) genetic effects, and (4) prenatal irradiation. Dr. H. H. Rossi, Professor of Radiology, Radiological Physics Laboratories, College of Physicians and Surgeons of Columbia University, has addressed these four areas, and an abstract of his comments follows:[2]

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*American Optical Co.; ARCO Medical Products Corp.; Coratomic, Inc.; Cordis Corp.; and Medtronic, Inc.

†The marketplace will determine the eventual sales volume of the different manufacturers' pacemakers. Also, improvements in thermal-electric conversion systems may reduce fuel loading. A pacemaker containing 250 mg of plutonium is representative of the present market.

Table 3.1. Dose equivalents to organs for 5-, 10-, 15-, and 20-year periods from a pulse generator that contains 250 mg of PuO_2 and is located above the left pectoral muscle

Location	Dose equivalent, rems (neutron and gamma)			
	5 years	10 years	15 years	20 years
Thyroid	3.9	7.9	12.9	17.3
Left axillary lymph nodes	3.5	7.4	11.7	15.9
Right axillary lymph nodes	0.48	1.3	1.7	2.5
Sternum	3.3	6.8	11.3	14.4
Left pectoral muscle (base of breast)	1.1	2.6	3.9	5.2
Right pectoral muscle (base of breast)	0.45	1.2	1.7	2.5
Heart	1.0	2.5	3.7	4.6
Liver	0.33	0.92	1.4	2.0
Spleen	0.43	1.9	2.7	3.5
Stomach	0.42	1.2	1.7	2.3
Left kidney	0.29	0.75	1.2	1.7
Right kidney	0.27	0.69	1.1	1.6
Left ovary	0.16	0.36	0.59	0.87
Right ovary	0.16	0.35	0.58	0.84
Uterus	0.14	0.33	0.55	0.78
Testes	0.13	0.29	0.46	0.62
Spine (average)	1.0	2.3	3.5	4.8
Torso (average)	1.0	2.5	3.6	4.8
Whole body (average)	0.52	1.4	1.9	2.6

1. Tissues in immediate contact with pacemakers — This is the only category in which the maximum permissible doses stipulated by NCRP and ICRP for radiation workers might be exceeded. The term "might" is employed since the maximum for tissues other than the critical ones is a limit for the average organ or tissue dose of 15 rems/year. These limits have been set with the expectation that effects could not be statistically detected in a large population. The muscle and connective tissues in intimate contact with the pacemaker are considered to be especially radiation resistant.[3] There is a great amount of experience relating to the irradiation of normal tissues in beams directed at malignancies. Usually the doses employed are several thousand rads, although, in multiple-portal treatments and near the edge of the beam, lower doses may also be imparted. These doses are invariably delivered at far higher time rates, which should substantially increase their biological effectiveness. The incidence of neoplasms in such tissues is extremely rare, and it is uncertain whether the few cases on record are due to radiation. There appears to be an equally small incidence following surgery,[4] and, in a careful study,[5] no incidence of such neoplasms could be found in individuals irradiated in infancy with acute doses up to 1000 rads.

2. Bone marrow — The major hazard of large doses to bone marrow is the induction of leukemia. However, the dose from the pacemaker is less than one-fifth of the dose permitted for radiation workers and quite likely near that permitted for members of the general population.

3. Gonads — Irradiation of the gonads is assumed to represent a genetic risk. According to current estimates,[6,7] the dose that results in doubling the naturally occurring genetic defects is about 100 rads. Doubling occurs if the gonads of all parents in a population receive this dose prior to conception. In view of the small doses and the small fraction of the reproductive population that can be expected to wear nuclear-powered pacemakers, the hazard is miniscule. About 1% of the deleterious genetic

effects are expressed in the first generation. In this case, only the dose to the parents is of importance. Calculations indicate (even assuming that the pacemaker is worn 20 years prior to reproduction) a maximum increase of 0.2% above naturally occurring deficiencies in children of pacemaker patients.

4. Prenatal irradiation – During the nine-month gestation period the dose is less than the limit recommended by NCRP.

Aside from the fact that no deleterious effects have appeared in patients using plutonium-powered pacemakers, it should be noted that medical radiation exposures are not subject to the same radiation guidelines that are imposed on occupational radiation workers by NCRP, ICRP, and NRC, because of the off-setting patient benefits from the use of radiation for medical purposes. It may be noted that the diagnostic x-ray and fluoroscopic examination incidental to evaluation and implantation of any pacemaker will deliver dose equivalents to many organs in excess of those given in Tables 3.1 and 3.2.

Table 3.2. Dose equivalents to organs for 5-, 10-, 15-, and 20-year periods from a pulse generator that contains 250 mg of PuO_2 and is located on the left side of the abdomen

Location	Dose equivalent, rems (neutron and gamma)			
	5 years	10 years	15 years	20 years
Thyroid	0.16	0.38	0.62	0.89
Left axillary lymph nodes	0.27	0.72	1.1	1.6
Right axillary lymph nodes	0.23	0.55	0.91	1.3
Sternum	0.29	0.81	1.3	1.7
Left pectoral muscle (base of breast)	0.26	0.68	1.1	1.4
Right pectoral muscle (base of breast)	0.25	0.61	0.98	1.4
Heart	0.55	1.4	2.0	2.7
Liver	0.72	1.8	2.7	3.5
Spleen	0.71	1.7	2.6	3.6
Stomach	1.6	3.5	5.3	7.2
Left kidney	1.3	3.0	4.6	6.1
Right kidney	0.85	2.4	3.6	4.6
Left ovary	1.6	3.8	5.8	7.7
Right ovary	1.1	2.6	3.9	5.2
Uterus	0.77	2.0	2.9	3.8
Testes	0.42	1.2	1.7	2.3
Spine (average)	1.3	3.0	4.9	6.2
Torso (average)	1.3	3.0	4.6	6.2
Whole body (average)	0.77	1.9	2.9	3.8

3.3 PUBLIC EXPOSURE FROM PACEMAKER PATIENTS

When a pacemaker is implanted in a patient, the radiation level at the surface of the patient (about 2 cm from the plutonium) is 1-2 millirems/hr. Since the radiation level decreases as the inverse square of the distance, at 20 cm (8 in.) from the patient's body the radiation from a pacemaker is less than the ambient background radiation.

The spouses of pacemaker patients will receive the largest radiation exposure, since their contact with the patients is more frequent and closer than contacts by other persons. The average exposure to the spouse from the patient is calculated to be 5 to 7.5 millirems/year, and most of this exposure is received during the sleeping hours when the spouse is usually within a few feet of the patient.[8] This exposure is relatively low compared with naturally occurring background radiation.

All other individuals associating with pacemaker patients will be exposed to much lower levels of radiation. Calculations of doses for various categories of people with whom pacemaker patients are likely to come into contact during their daily activities are shown in Table 3.3.

The radiation dose to the U.S. population from 10,000 pacemaker patients is 128 man-rems/year, which is insignificant when compared with about 20,000,000 man-rems/year of natural background radiation that is received by the same population. This additional radiation dose to the individuals who are closely associated with patients is of little significance. The radiation dose to the general public that is attributable to the presence of pacemaker patients will be negligible.

Table 3.3. Radiation doses to critical groups from cardiac pacemakers (Assuming 10,000 implanted cardiac pacemakers with plutonium batteries)

Relationship to pacemaker patients	Group population	Individual dose (millirems per person per year)			Total dose to group (man-rems/year)	
			Average dose			
		Dose from pacemaker[a]	Medical x rays	Natural background radiation	Dose from pacemaker[b]	Natural background radiation
Spouses	6,430	5-7.5	73	102	42	646
Household members	8,950	1-1.5	73	102	12	912
Work associates[c]	72,000	0.1-0.2	73	102	10.5	7,344
Nonwork associates[c]	218,000	0.05-0.1	73	102	14.5	22,378
Total in U.S. populace not included above		<<0.01	73	102	49	21,400,000
Total dose to U.S. population excluding dose to patients[d]					128	

[a]Dose will vary depending upon the plutonium content, fuel characteristics, and shielding effects of a particular pacemaker model.

[b]Integrated dose using 4 Ci of plutonium which is the average amount of plutonium used in any battery.

[c]A patient is predicted to associate with about 30 persons during his daily activities.

[d]U.S. population of 210,000,000.

3.3.1 Public risk resulting from exposure to pacemaker patients

The National Academy of Sciences – National Research Council (NAS-NRC) Advisory Committee on the Biological Effects of Ionizing Radiations (BEIR) recently reviewed the extensive data on human cancer mortality risks from exposure to ionizing radiation.[7] From these data, factors were derived relating dose to estimated risk for various cancer types. The Committee's derivation assumed that the human experience, largely with external irradiation at relatively high dose rates and high total doses, could be linearly extrapolated to zero effect at zero dose. While these cancer risk estimators from the BEIR report have the advantage of being based on human data, they share with the animal studies the uncertainty of linear extrapolation from high-dose observations. In order to be particularly conservative, these BEIR report recommendations have been used as risk estimators for this Environmental Statement despite the fact that many scientists and the NCRP consider these estimators to be excessive.

Table 3.4 lists cancer mortality predictions for exposures to pacemakers, based on the BEIR report risk estimators. The cancer risk estimator of 50-165 deaths per 1,000,000 man-rems is used for external radiation exposures. As shown in Table 3.4, the risk of cancer induction in non-patients from external exposure to the plutonium in pacemakers is essentially zero.

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3.4 EXPOSURES DURING PRODUCTION AND MANUFACTURE

The fabrication of nuclear-powered pacemakers is a multistep process. Generally, pacemaker manufacturers buy the nuclear battery, which they attach to an electronic circuit and then encase. The construction of the nuclear battery is part of routine industrial production performed by occupational workers. Permissible occupational exposures of radiation workers are

Table 3 4. Radiation risks to critical groups from cardiac pacemakers (Assuming 10,000 implanted cardiac pacemakers with plutonium batteries)

Individual risk

Relationship to pacemaker patient	Radiation dose (millirems per person per year)	Risk estimator (deaths per rem)	Chance of death per year per person at risk
Spouse	5-7.5	50-165 x 10^{-6}	2.5-12.4 x 10^{-7}
Household member	1-1.5	50-165 x 10^{-6}	0.5-2.5 x 10^{-7}
Work associate	0.1-0.2	50-165 x 10^{-6}	0.5-3.3 x 10^{-8}
Nonwork associate	0.05-0.1	50-165 x 10^{-6}	0.3-1.7 x 10^{-8}

Total group

Relationship to pacemaker patient	Radiation dose to group (man-rems/year)	Risk estimator (deaths per rem)	Risk (additional deaths per year)
Spouses	42	50-165 x 10^{-6}	2-7 x 10^{-3}
Household members	12	50-165 x 10^{-6}	0.6-2 x 10^{-3}
Work associates	10.5	50-165 x 10^{-6}	0.5-1.7 x 10^{-3}
Nonwork associates	14.5	50-165 x 10^{-6}	0.7-2.4 x 10^{-3}
U.S. populace	49	50-165 x 10^{-6}	2.5-8 x 10^{-3}
Total	128		6-21 x 10^{-3}

limited by NRC and Agreement State regulations, and actual exposures of radiation workers are usually only a small fraction of permissible exposures. It would be difficult if not impossible, to measure the fraction of radiation exposure to the occupational workers that could be directly attributable to the plutonium used in pacemakers; however, the workers will be covered under the different plants' radiation protection and monitoring programs.

3.5 EXPOSURES DURING IMPLANTATION AND REMOVAL

The surface dose rate from a pacemaker is about 5 to 15 millirems/hr. The attachment of the pacemaker to leads and the placement of the pacemaker into the prepared pocket usually requires less than 10 min. The permissible occupational exposure to the hands and forearms of radiation workers is 18,750 millirems per calendar quarter. Therefore, the implantation or removal of pacemakers would add only a minute exposure to these individuals. Most of the time required for an implantation involves placement of the electrode leads and preparation of the surgical pocket for the pacemaker, during which time the pacemaker is not in the operating area.

3.6 EXPOSURES DURING TRANSPORTATION

The radiation exposure rate from a package used for shipment of plutonium-powered pacemakers is less than 0.1 millirem/hr at the surface and is less than ambient background at a distance of 3 ft from the pacemaker. Plutonium-powered pacemakers meet the Department of Transportation's requirements for "special form" radioactive material (Sect. 173.394 of Title 49 Part 173, Code of Federal Regulations) and may be shipped in Type A packages designed to withstand normal conditions of transport. Pacemakers are exempt from the prohibition in Public Law 94-79 against shipment of plutonium by air.

In order to insure a shipment for more than $1000, the package is required to be more than 1 cu ft in volume. Thus, for insurance reasons, the package used is larger than would be required by transportation regulations for radiation safety, and the surface of the package is further from the radiation source than would be the case for most shipments of equivalent quantities of radioisotopes. The shipment of several thousand pacemakers per year would add only an insignificant amount of radiation exposure to transportation workers and the public.

3.7 HAZARD EVALUATION FOR PLUTONIUM-POWERED PACEMAKERS

The primary requirement for nuclear-powered pacemaker fuel capsules is that they be designed and constructed to withstand the severe stresses in excess of those resulting from all credible accidents. For that purpose, design criteria have been established by the Commission that require each pacemaker manufacturer to demonstrate that his pacemaker unit, containing a nuclear battery, would successfully complete specific tests which provide stresses that exceed those conceivable from such accidents.

Notwithstanding that fuel capsules, batteries, and pacemakers are designed and prototypes are tested to standards that assure containment of the plutonium under all credible accidents, for purposes of this Environmental Statement, certain breaches of the containment have been assumed in order to assess the radiation risks that would occur in the unlikely event of a fuel containment breach. A risk-logic model was developed to establish the probabilities of potential hazards involving such postulated breaches. A block diagram of this model is presented in Fig. 3.1 (see pocket insert on back cover). This block diagram provides a delineation of potential accidents, potential fuel capsule breaches, source terms, and population exposures for an equilibrium population of 10,000 nuclear pacemaker patients.

In this assessment of risks, most situations have not occurred and/or data relative to pacemaker patients are not available. Consequently, calculations are necessarily based on approximations of the probabilities relative to accident situations and potential fuel containment breach. Annual statistics are published in the United States that give reliable probability values for the likelihood of the involvement of an individual in an automobile accident. However, for postulated events of very low likelihood, particularly where there are no data from actual events (e.g., a plutonium release from a pacemaker), there is obviously no basis for statistical analysis. The determination of the probabilities of accidents more severe than the spectrum of design-base accidents (e.g., a fuel capsule breach) is necessarily a matter of judgment and estimates. In this assessment it has been necessary to postulate numbers for probabilities of fuel capsule breach and for losses of pacemakers For clarity, these postulated numbers are enclosed in parentheses in Fig. 3.1.

3.7.1 Risk-logic model

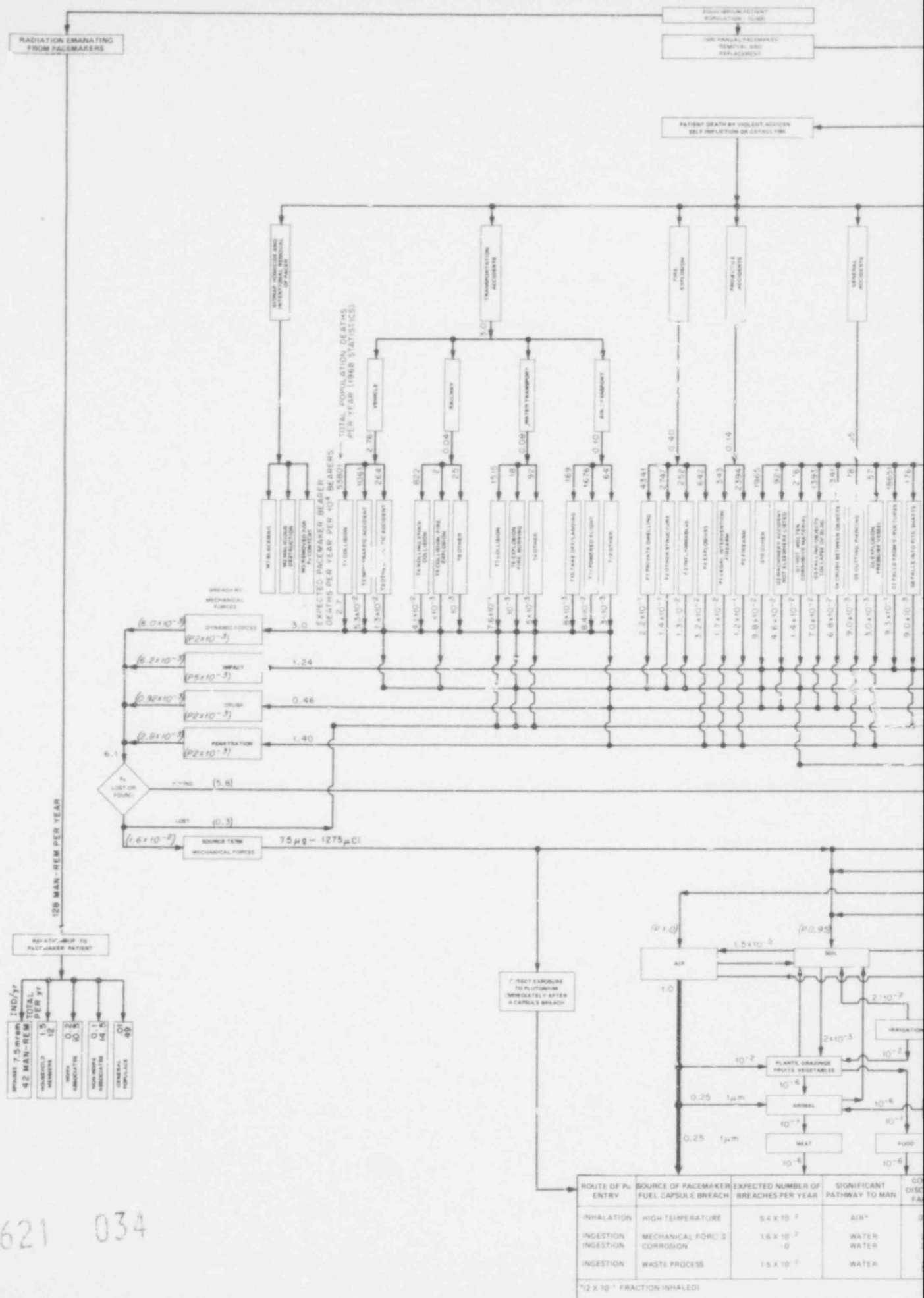
This study assumes the yearly implantation of 1500 nuclear-powered pacemakers to maintain an equilibrium patient population of 10,000. Of the 1500 pacemaker implants 1300 are placed in new patients to balance an equivalent number of deaths and 200 are replacements because of failure or wearout (based on a 0.15% per month pacemaker failure rate).

The probability that a pacemaker patient will be involved in a particular accident situation has been estimated by scaling down accident statistics from mortality tables.[9] Accident statistics from the 1968 mortality tables were used in the draft Statement since they were the most recent available at that time. These same statistics are used in this final Statement for consistency because more recent mortality tables do not appear to change the final assessments of risks. The scaling factor is the ratio of the number of pacemaker patients to the total population. Out of a population of 10,000 patients, 6.6 are predicted to die each year as a result of violent accidents, suicides, or natural disasters.

The remaining 1293.4 pacemakers removed from the deceased and the 200 replacement implants are treated on the right-hand side of Fig. 3.1. Of the 1500 pacemaker removals involved in the annual program, 1472 are expected to be disposed of in a licensed facility and 26 to be accounted for by burial or cremation of the pacemaker intact. Therefore, the overall predicted probability (p) of losses involves two pacemakers annually ($p = 1.3 \times 10^{-3}$).

For the annual 6.6 patient deaths by violent means, Fig. 3.1 delineates the major forms of disasters and the fraction of the 6.6 patients involved in each type of event. Fig. 3.2, an excerpt from Fig. 3.1, illustrates the progressive development of the risk-logic model.

Prior to a further delineation of causative factors for the death of the 6.6 patients, note the column in Fig. 3.1 that contains the numbers of annual deaths for specific events from a population of approximately 200,000,000 people. For example, 53,801 people were killed by vehicular collisions in 1968.



ROUTE OF Pu ENTRY	SOURCE OF PACEMAKER FUEL CAPSULE BREACH	EXPECTED NUMBER OF BREACHES PER YEAR	SIGNIFICANT PATHWAY TO MAN	CO... DISC... FA...
INHALATION	HIGH TEMPERATURE	5.4×10^{-7}	AIR*	
INGESTION	MECHANICAL FORCES	1.6×10^{-7}	WATER	
INGESTION	CORROSION	0	WATER	
INGESTION	WASTE PROCESS	1.5×10^{-7}	WATER	

*1/2 X 10^{-1} FRACTION INHALED

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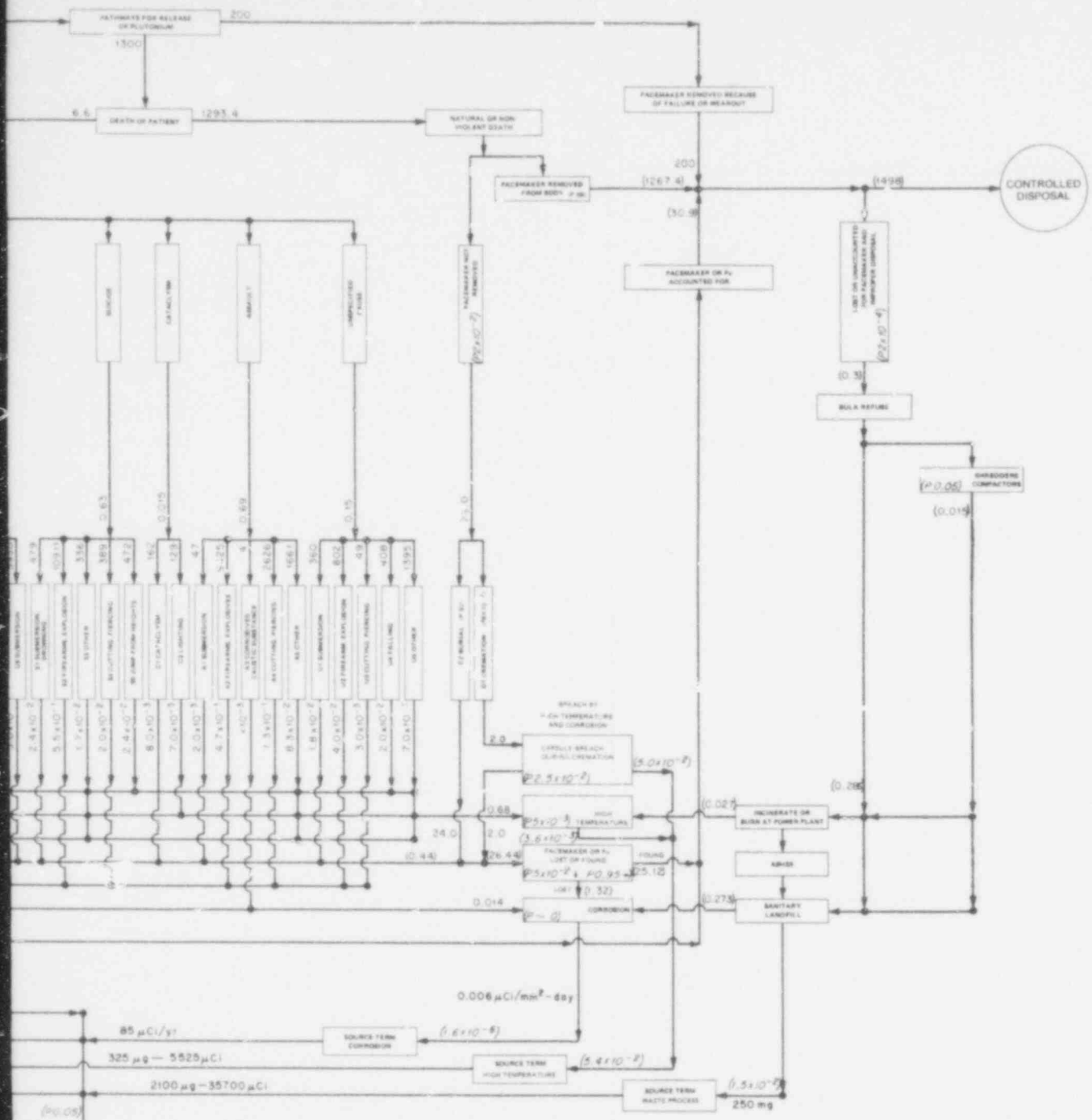

	INTEGRATED DOSE TO POPULACE 250 YEAR DOSE COMMITMENT	DOSE COMMITMENT PER ONE YEAR OF AVAILABILITY
	205 MAN-REM	1.1 MAN-REM
	24 MAN-REM	0.4 MAN-REM
	0 MAN-REM	0 MAN-REM
	241 MAN-REM	3.6 MAN-REM
		15 MAN-REM

PLUTONIUM POWERED CARDIAC PACEMAKER RISK LOGIC MODEL

RISKS DUE TO AN EQUILIBRIUM POPULATION OF 10,000 PACEMAKER PATIENTS

FIG. 3.1

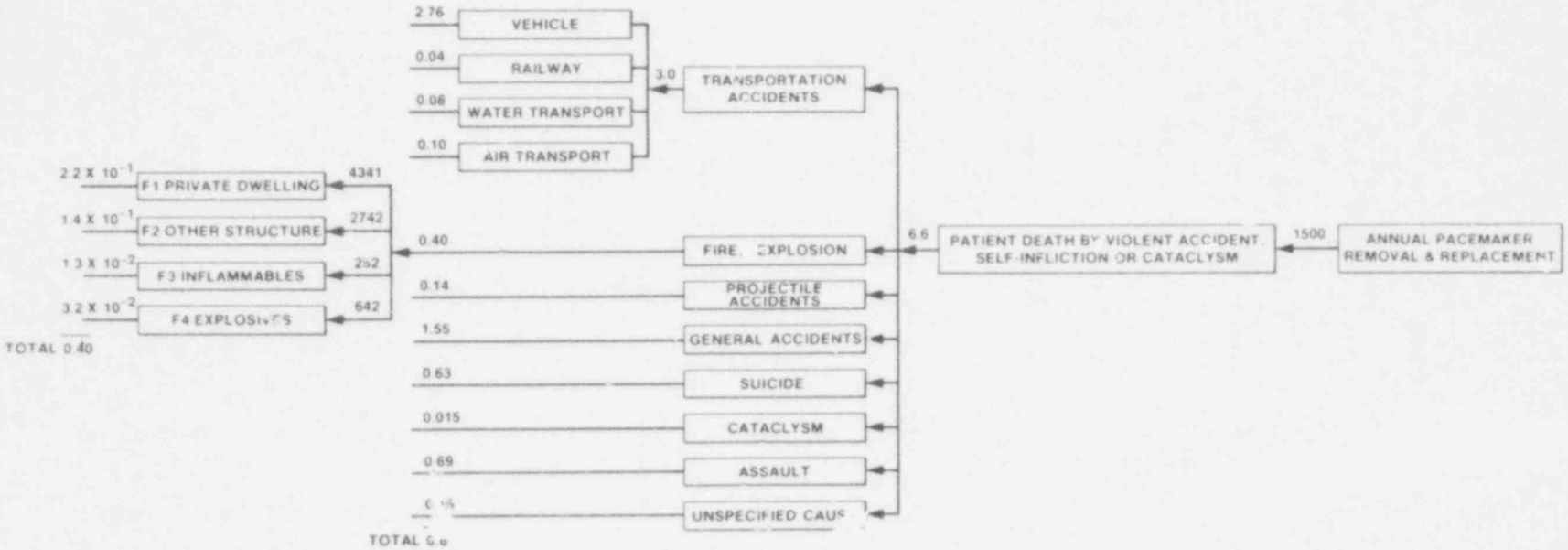

Fig. 3.2. Example of risk-logic development.

Following the specific cause of death in the population, there is a further breakdown of the number of subevents for the same 6.6 patients. For example, the pacemaker patient deaths due to fire or explosion are treated in four blocks of the logic diagram as (1) private dwelling, (2) other structure, (3) motor vehicles, and (4) explosives. The predicted number of patient deaths per year is shown to the immediate left of the block, and the summation for the four blocks is 6.4 (see Fig. 3.2).

The subgrouped elements were grouped according to the types of events that could potentially cause a breach of the capsule. The two major types of events were classified as mechanical forces (left side of accident subgroups in Fig. 3.1) and high temperature and corrosion (opposite side of the accident subgroups). These classifications are similar to those being used by the Nuclear Energy Agency.[10]

The cumulative number of patients that would be subjected each year to forces that could potentially cause a breach of capsule is shown before each of the boxes involved. Transportation accidents are distinguished from the other mechanical forces by a separate heading. The effect of these forces is extremely difficult to assess, because fatalities resulting from transportation accidents may be caused by a combination of impact, penetration, percussion, and crush and are, therefore, referred to as dynamic forces. The lethality of these forces will depend upon the duration, area, and depth of their thrust. Reports show that the human body has the ability to tolerate crushing loads on the chest between 1500 to 2500 lb without producing even moderate injury.[11-12] The flesh of the body may absorb most of this energy, and any real danger to a pacemaker will occur only if it is pinned between objects (e.g., under a vehicle).

Multiplying the postulated probability of breach per event by the number of patient deaths gives the expected number of capsule breaches per year (e.g., for dynamic forces, a probability of 0.002 multiplied by three deaths per year gives 0.006 capsule breach per year). A probability was established for the number of pacemakers that could be dismembered from the patients' bodies. The pathway to this block on Fig. 3.1 shows a cumulative number of 26.44 pacemakers. Of this number, there is an assumed probability that 25.12 would be found and 1.32 would be lost. The 26.44 pacemakers is an accumulation of 26 patients' bodies that may be buried or cremated with their pacemakers still intact and 0.44 patient's body unaccounted for after cataclysms or disasters.

The probability of a patient being lost in a natural disaster or an accident is based on compiled statistics of bodies not being recovered after cataclysms.[13] Most of the unrecovered bodies are lost as a result of floods or hurricanes, and the disposition of these bodies is assumed to be in an aquatic environment.

The risk-logic model indicated that, of 1500 pacemakers removed, 1498 will undergo controlled disposal; of these, 1472 will be retrieved and shipped through appropriate channels to a licensed facility for disposal, and the remainder will be buried. Food and Drug Administration records of radiopharmaceutical shipments indicate that of 100,000 shipments one could not be accounted for. To be conservative, the probability of loss was assumed to be 2 out of 10,000 (a factor of 20 greater). This factor multiplied by the number of shipments yields 0.3 pacemaker per year. The lost pacemakers were then assumed to reach channels for bulk refuse disposal, which could involve shredding and/or compacting. It was assumed that 5% of the lost pacemakers would be breached by trash processing.

In summary, the following occurrences may prevent disposal of a pacemaker in a licensed facility: (1) failure to remove the pacemaker following the death of the patient, (2) failure to recover a patient's body following cataclysms or accidents, or (3) loss in shipment.

If these pacemakers are lost, they most likely will enter normal waste disposal channels. The most innocuous form of disposal will be in a sanitary landfill, where the pacemaker is expected to remain intact in the ground. It is highly unlikely that the integrity of the capsule would be breached in these environments. However, these pacemakers could be processed through commercial waste disposal techniques such as incineration, shredding, or compacting. It is in the realm of possibility that any one of these techniques could breach a fuel capsule.

In the evaluation of the dispersion or movement of plutonium dioxide particulates (fines) into the environment, "source term" data are used. A "source term" is defined as the fraction and form of radioactive material that may escape from a breached capsule under specified conditions. This report uses four source terms for calculating the potential spread of plutonium; these are for releases caused by mechanical forces, corrosion, high temperature, and waste processing. Following each source-term box in Fig. 3.1, the calculated quantity of plutonium dioxide fines is indicated in terms of its mass and its equivalent radioactivity.

The source terms used in this Environmental Statement to describe plutonium releases were established using data on breached plutonium dioxide fuel capsules that were developed under research sponsored by the space nuclear program (SNP). Table 3.5 represents the mechanical damage source term obtained in an SNP study. Capsules containing sintered plutonium dioxide pellets were impacted onto a concrete surface at a velocity of 84 m/sec. At the time of impact,

the capsules were at a temperature of 1365°C. A 1.5 mm breach occurred in the capsule and only 0.3% of the fuel was released in the form of plutonium dioxide particulates that were smaller than 177 μm in size. Of the released material, 15% was in particles of respirable size, 10 μm or smaller. This study was deemed to be representative for the plutonium capsules used in pacemakers.

Table 3.5. Mechanical damage source term
(250-mg sintered PuO_2 fuel pellet, 0.3% release)

Particle size (μm)	Weight fraction	Release within patients body		Assumed release to environment	
		(μg)	(μCi)	(μg)	(μCi)
177	0.00048	120	2040	12.0	204
125	0.00014	35	595	3.5	60
74	0.00028	70	1190	7.0	119
44	0.00071	177	3010	17.7	301
30	0.00052	130	2210	13.0	221
20	0.00042	105	1785	10.5	179
10	0.00029	73	1240	7.3	124
<10	0.00016	40	680	4.0	67
Total	0.003	750	12750	75.0	1275

The released plutonium in the four previously described source terms has pathways to man via the air, soil, and water. The important plutonium pathways to man are shown in the lower section of Fig. 3.1. Individual discrimination factors (IDF) are provided for each medium-to-medium plutonium transfer link and are defined as Ci/g (recipient) ÷ Ci/g (donor) or as a fraction of incident contamination taken up by recipients.[14] Critical exposure pathways are identified by calculating the combined discrimination factor,

$$CDF = \prod_{i=1}^{n} (IDF)_i ,$$

for intake of plutonium dioxide by inhalation and ingestion. The critical pathways for which the combined discrimination factor has the largest value are indicated by heavy lines on Fig. 3.1.

The relative importance of each critical pathway is determined by considering the CDF for each route in combination with (a) the relative amounts of plutonium that might be introduced into the pathway by the maximum credible environmental release and (b) the relative extent to which components of each pathway are utilized by the population. Hence, the most critical pathway is identified as direct inhalation of airborne material. The second most critical pathway, water, is considered significant only for soluble plutonium compounds[15] (i.e., compounds other than plutonium dioxide). The discrimination factor for drinking water will be mitigated by filtration procedures at water-processing plants. These plants are believed to remove most plutonium dioxide fines, and the IDF is assumed to be 10^{-3}. The principal conclusion of Fig. 3.1, summarized in Table 3.6, is that the dose commitment to the entire U.S. population from one year of availability of 10,000 pacemakers resulting from postulated releases of plutonium fines is 15 man-rems. This is an exceedingly small fraction of the background radiation exposure to the populace, which is about 20,000,000 man-rems per year.

3.7.2 Accident analysis

3.7.2.1 Cremation

The cremation of a patient without the removal of the pacemaker is deemed to be the incident most likely to result in the dispersion of plutonium dioxide fines to the environment. Therefore, this incident was selected to demonstrate the methods used to establish the probabilities and eventual source terms illustrated in Fig. 3.1.

The possibility of a fuel capsule breach resulting from high temperature will depend upon both the temperature and duration of the pacemaker's exposure to high temperature. Thermal environments to which a pacemaker may be exposed are crematory furnaces, incinerators, and building (or other) fires.

Table 3.6. Plutonium-powered cardiac pacemaker risk assessment and radiological impact on man

Route of plutonium entry	Source of pacemaker fuel capsule breach	Expected number of breaches per year	Plutonium dioxide released per breach (μCi)	Integrated dose to populace (50-year dose commitment per event) man-rems	Dose commitment from 1-year availability, man-rems
Inhalation	Thermal	5.4×10^{-2}	5,525	205	11
Ingestion	Mechanical	1.6×10^{-2}	1,275	24	0.4
Ingestion	Corrosion	~0	85[a]	~0	~0
Ingestion	Trash process	1.5×10^{-2}	35,700	241	3.6
				Total	15

[a]Per year.

The probability of fuel capsule breach in a crematory furnace is dependent upon the following factors: (1) the probability of patient death per year (p = 0.13), (2) the probability of cremation after death (p = 0.08), (3) the probability that the pacemaker will not be removed prior to cremation (p = 0.02), and (4) the probability that the crematory furnace may exceed the prototype test temperature for a sufficient period of time to rupture the fuel capsule (p = 0.025). These four probabilities combine to an overall expectation of one breach in 20 years from 10,000 patients. Figure 3.3 is abstracted from Fig. 3.1 to show the risk logic for a fuel capsule breach during cremation.

Using information from life tables in the United States[16] and age distribution of pacemaker patients,[17] the proportion of patient deaths per year is estimated to be 13%; that is, there will be approximately 1300 patient deaths per year in an equilibrium pacemaker population of 10,000 pacemaker patients (see Fig. 3.1). If approximately 8% of those who die are cremated, about 100 patient bodies will be cremated each year. Note, it is recognized that the present age distribution of nuclear pacemaker patients is different then the age distribution used above. This is in part due to protocol restriction of the investigational programs. Pacemaker patient age distributions are discussed in detail in Sect. 4.

Data furnished by the Cremation Association of America[18] show a steadily increasing percentage of bodies being cremated in the United States. Approximately 4.4% of the bodies from deaths occuring in 1968 were cremated by member crematories. The association represents about 75-90% of the crematories in the United States. Using these data, it is believed that 8% is a high estimate of bodies currently being cremated. However, factors such as a scarcity of cemetery plots may result in increases in the number of bodies being cremated in the future. In England, for example, over 50% of the bodies are currently being cremated.[12]

Although 100 patients may be cremated each year, there is a high probability that a pacemaker will be removed prior to disposition of the body. Control measures require that pacemaker patients carry identification cards and jewelry in order to be easily recognized as nuclear-powered pacemaker patients. The effectiveness of this control program will depend upon the recognition by physicians, coroners, and morticians of their responsibilities for retrieving and returning the pacemaker to appropriate authorities.

Bodies to be cremated are enclosed in a coffin of wood or other combustible material and are placed directly on the firebrick floor of the furnace. The flame jets are generally located in the top of the furnace pointed downward or in a trench in the furnace floor angled upward. In such an arrangement, with large quantities of air passing through, there is often a temperature differential of several hundred degrees between the hottest and coldest regions. The temperature to which a pacemaker may be exposed depends mainly on its location with respect to the flame. In 63 actual measurements of temperatures in 37 different crematory furnaces, the highest of 62 temperature readings in 36 of these furnaces was found to be 1200°C, and the average temperature measured was 1120°C. One furnace was measured to be 1370°C, but on a second test this furnace produced a peak reading of 1150°C.

The usual cremation cycle is 2 hr; maximum temperature is reached in 15-35 min after the start and is maintained for about 90 min. NRC and NEA criteria require that prototype pacemakers withstand a temperature of 1300°C (2372°F) for 90 min without allowing fuel to escape. This is believed to provide sufficient conservatism to assure capsule integrity. However, on the presumption of a breach, the dispersal of plutonium dioxide fuel has been calculated using test data from the space nuclear systems program (see Table 3.7). In these tests, a plutonium fuel capsule was breached following 2145 hr of heating at 1420°C. The breach resulted in the release of 0.13% of the fuel in particulate form, and 7% of the released material was in particles of respirable size (10 μm or smaller). The temperature and time necessary to deliberately breach this capsule are much greater than the temperature and time conditions of cremation.

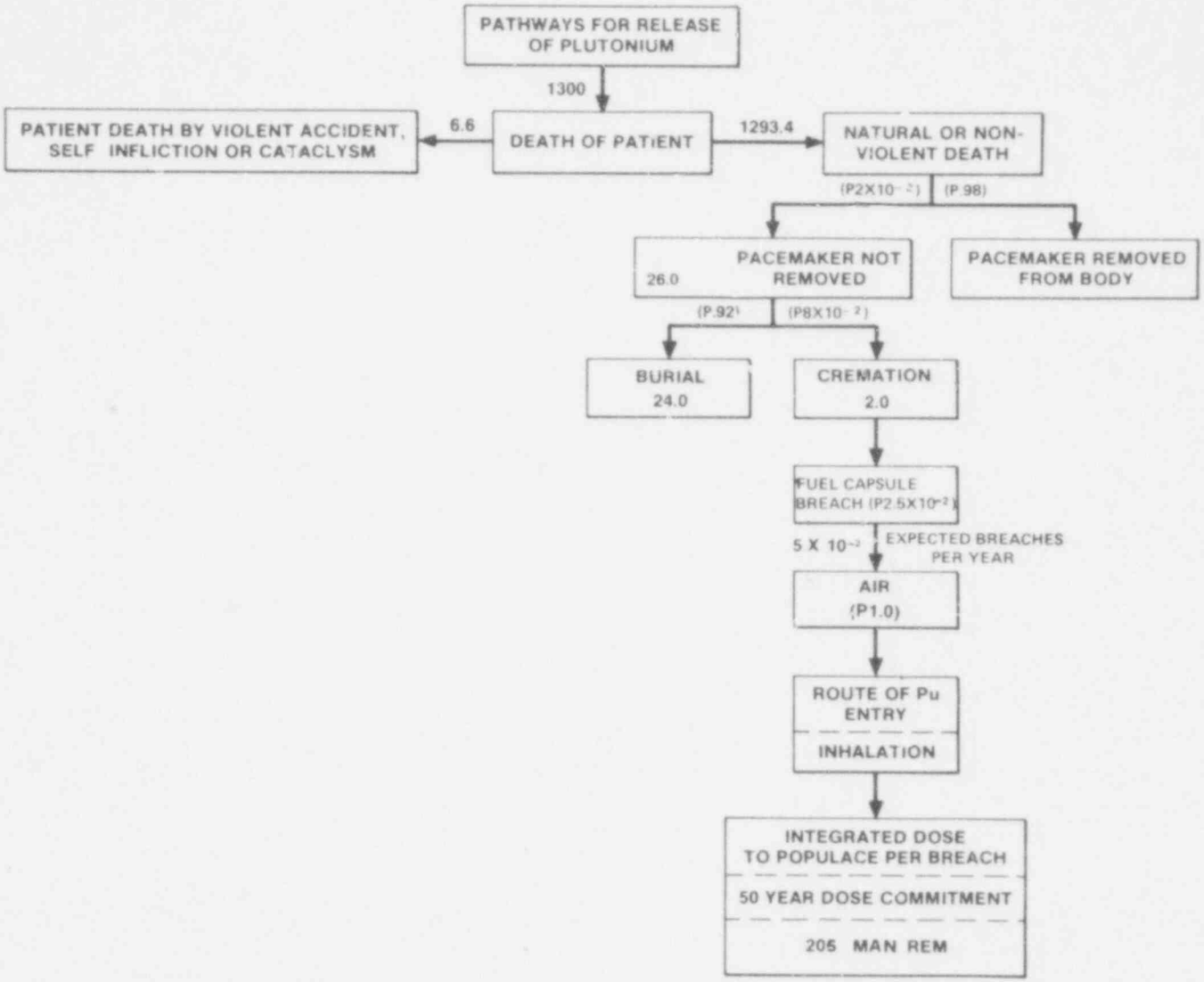

Fig. 3.3. Risk logic for a fuel capsule breach during cremation.

Table 3.7. High-temperature source term
(250-mg sintered PuO_2 pellet, 0.13% released over 1 hr)

Particle size (μm)	Weight fraction	Settling velocity (cm/sec)	Release into atmosphere		
			micrograms	microcuries	microcuries per second
177	0.0002	76.0	50	850	0.24
125	0.0002	49.0	50	850	0.24
74	0.0002	22.0	50	850	0.24
45	0.0002	15.2	50	850	0.24
30	0.0001	9.5	25	425	0.12
20	0.0001	3.8	25	425	0.12
10[a]	0.0002	0.92	50	850	0.24
≤10[a]	0.00002	0.16	5	85	0.03
≤4[a]	0.00008	0.01	20	340	0.10
Total	0.0013		325	5525	

[a]Respirable size (75 μg, 1275 μCi).

Assuming release of plutonium dioxide from a pacemaker containing 250 mg of fuel to be the same percentage as the release from the test source, the maximum dose to an individual in the vicinity of a crematorium from the plutonium dioxide released by a single breach is calculated to be 175 millirems (50-year dose commitment*). This dose would be incurred by an individual exposed in the gaseous plume at a distance of 200-250 m.

The Gaussian plume model developed by Pasquill and Gifford is used to calculate downwind ground-level plutonium concentrations. These concentrations are calculated from a computer code given a settling velocity and release rate for plutonium fines.[15-19] A 10-m stack height for the crematorium is assumed. Zero plume rise is used, since this will result in least dispersion and will yield a maximum radiation dose to an individual. Nearly neutral weather stability and a wind velocity of 4 m/sec are used in the calculation, since they are reasonably representative of average U.S. meteorological conditions. The wind direction is immaterial, since the crematorium is assumed to be located within an area where the population density is isotropic.

The inhalation model employed to calculate the dose is a mathematical representation of the lung model developed by the ICRP Task Group on Lung Dynamics.[20] Not all of the plutonium dioxide fines in the ambient air taken through the respiratory system will be deposited in the lung. Many particles will be filtered out in the nose, mouth, or tracheobronchial regions, while larger particles may be aerodynamically excluded from entering the nose. The quantity of the material deposited in the respiratory system will be a function of the concentration of the material in the air, a depletion factor for the air due to the settling velocity of the particle, and the fraction of the material deposited once inhaled. The depletion factor is based on the presumption that if the fall velocity of a particle is greater than the velocity of air through the nose during inhalation, the particle will not be inhaled. The particles that are settling sufficiently slowly in the air to be inhaled but are larger than 10 μm will be filtered out and deposited in the nose. Hence, the quantity of inhalable material that may reach the pulmonary region of the lung is determined by the number of particles 10 μm in size or smaller.[20] The results of these calculations are shown in Figs. 3.4 and 3.5 and are summarized in Table 3.8.

The maximum 50-year dose commitment of 175 millirems to an individual exposed to plutonium dioxide particles is to the bone, which is the part of the body that receives the highest dose from inhaled plutonium. The average 50-year dose commitment (bone) to individuals exposed to particles of plutonium in the gaseous plume out to 2000 m from the crematorium is 4 millirems. These maximum and average doses are well below the 5000-millirem dose an individual would receive from background radiation over a 50-year period.

Data from Fig. 3.5 on individual doses are combined with data on population densities to calculate the total radiological impact within the area of the plume. Population densities in the United States vary over a broad range, as shown in Table 3.9. The average metropolitan population density (1760 people/sq km) is chosen as representative of the population density of cities in which crematoria are located. The total 50-year dose commitment (bone) to an average metropolitan population exposed in the sector downwind from the crematorium within a radius of 2000 m is 205 man-rems per postulated breach. The population in this sector is 4500 persons and the 50-year natural background dose to this population is 22,500 man-rems. The population of this sector is about 0.002% of the U.S. population, and the dose commitment to this population from a breach would be approximately 1% of their ambient background dose.

For the summary in Sect. 4, an annual dose commitment to the populace from one year of availability of 10,000 nuclear pacemakers is calculated by multiplying the 50-year dose commitment by the expected number of breaches per year. This would be about 15 man-rems per year per 10,000 pacemaker patients (Table 3.6). It is noted, however, that crematoria are usually located in cemeteries and operated by cemetery owners. Consequently, the region of maximum plutonium concentration (200 to 250 m) may be within the cemetery grounds, thus significantly reducing radiological consequences to the populace.

3.7.2.2 Transportation accidents and firearms

Two accident situations in which mechanical forces are exerted on a pacemaker and/or fuel capsule will be discussed briefly: (1) transportation accidents, which account for more deaths than any other group of accidents, and (2) firearms, impact of firearm bullets being the most credible accident to which a pacemaker could be exposed and suffer extensive mechanical damage and breach.

Although it was not required, several manufacturers have subjected their pacemakers to firearm ballistic tests.[21-23] Fuel capsules maintained their integrity in tests using all types of

*The 50-year dose commitment is the radiation exposure that will be received over a 50-year period as a result of one event, taking into account the retention of plutonium in the body, the portion eliminated, the radioactive decay of the plutonium, and the buildup of the radioisotopes into which plutonium decays.

FS-2517

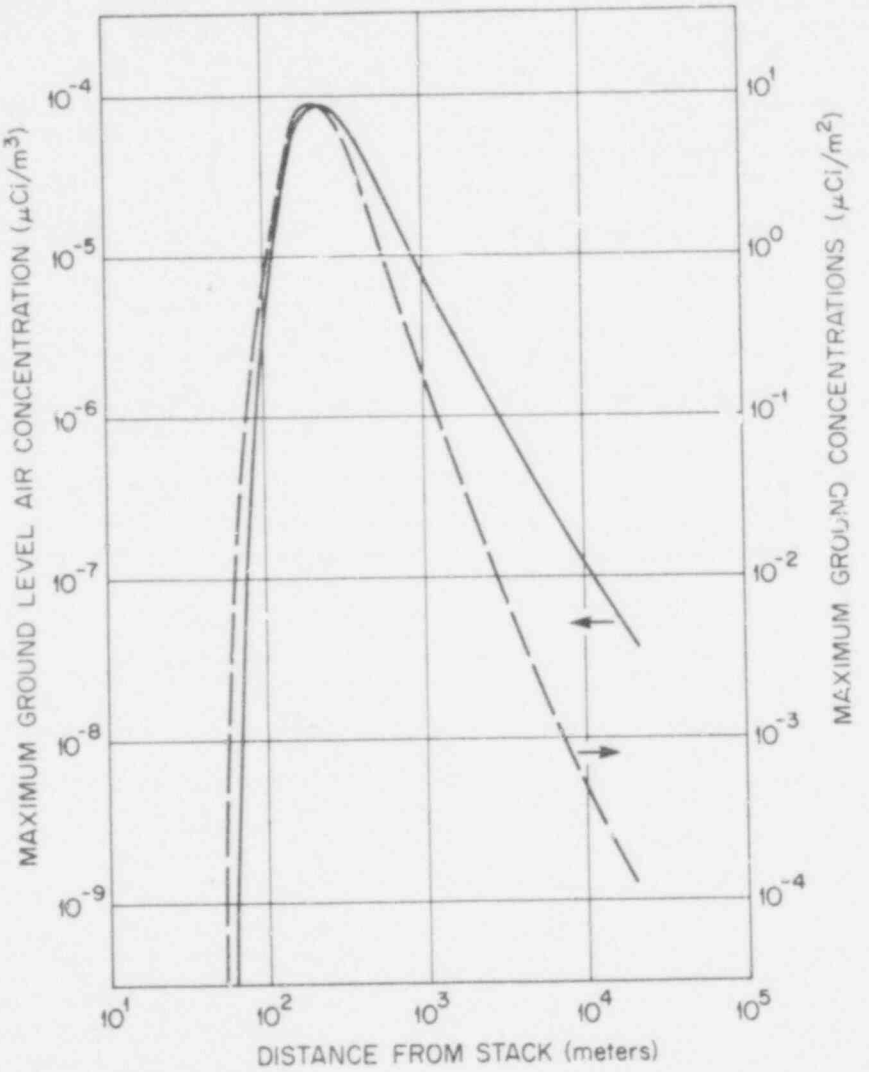

Fig. 3.4. Plutonium concentration as a function of distance from stack.

ES-2514

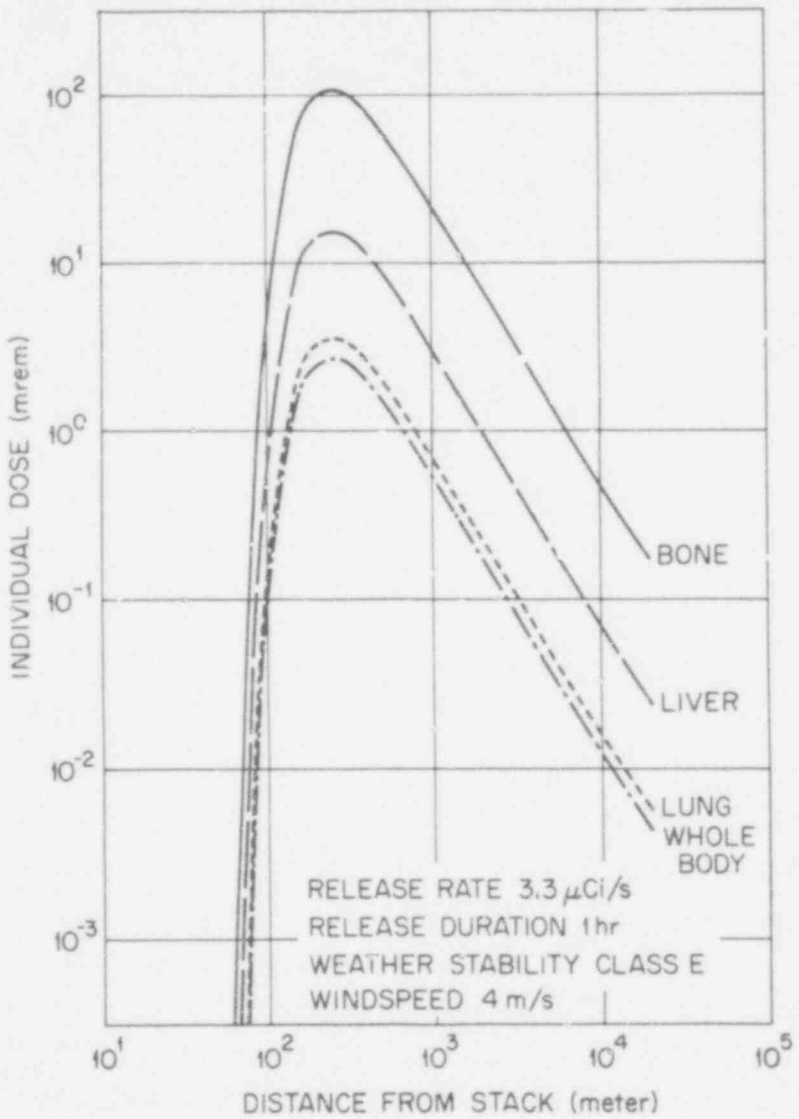

Fig. 3.5. Dose for plutonium dioxide particles (10 μm or less) as a function of distance.

Table 3.8. Summary of radiation doses from a postulated pacemaker breach in a crematory furnace

Organ	Individual dose (millirems)	Total exposure (man-rems)	Total exposure from 1-year availability (man-rems)
Lung		1	0.054
Liver		4	0.22
Bone	4[a]	205	11
Gonads		1.3	0.070

[a]Maximum individual dose, 175 millirems.

Table 3.9. Population densities

City	Rank	Density (people/km^2)
	Large metropolitan area	
New York, N.Y.	1	10,188
Los Angeles, Calif.	2	2,349
Chicago, Ill.	3	5,850
Philadelphia, Pa.	4	5,865
Detroit, Mich.	5	4,236
	Average	5,700
	Average metropolitan area	
Grand Rapids, Mich.	65	1,702
Syracuse, N.Y.	66	2,956
Flint, Mich.	67	2,279
Mobile, Ala.	68	630
Shreveport, La.	69	1,238
	Average	1,760
	Average U.S. land area	
	Average	22

handguns, shotguns, and low-caliber rifles, and they were breached only upon direct hits by high-powered hunting rifles such as the .30-06 caliber.

Analysis of firearm-related deaths shows that 85% of the deaths are caused by handguns, 8% by shotguns, 3.5% by .22-caliber rifles, and 2.5% by other types of rifles.[24] Almost all of the suicide deaths are caused by handguns, most of the fatal injuries being inflicted to the head area, and 82% of all fatal firearm-related assaults involve the use of handguns. Ten percent of firearm-related deaths are accidental; and of these, 37% are caused by handguns, 33% by shotguns, and the remaining deaths by rifle.

The most penetrating .22-caliber long-rifle ammunition develops a muzzle energy of 285 J. Since this energy is well below that produced by handgun (1560 J) and shotgun (3370 J) loads, capsule penetration by a .22-caliber rifle is highly unlikely.

Deaths from high-powered rifles account for 2.5% of all firearm-related fatalities (approximately 1.2 predicted patient deaths per year for 10,000 implants). The maximum number of predicted patient deaths that would be caused by high-powered rifles is 0.03 per year. If the fuel capsule were to breach when struck by a projectile from a high-powered rifle, the frequency of occurrence, patient deaths times the probability of directly striking the fuel capsule, would be once every 17,000 years. The probability of a firearm projectile directly hitting a pacemaker's fuel capsule is calculated from the ratio of the surface area of the capsule to the vital surface area of an adult (head and trunk regions). The plutonium dioxide fines would most likely be confined to the body of the patient and/or his blood and would not spread to present a radiological problem.

Detailed interest has been concentrated on studying the mechanics of the stresses resulting from severe transportation accidents. For example, theoretical analysis shows that a 700-mph impact velocity of a patient against aircraft materials in the crash of a plane against rock is equivalent to impacting a plutonium fuel capsule into granite at a velocity of 64 m/sec.[25] Energy is absorbed by intervening materials on the plane, by the body of the patient, and by the pacemaker housing and materials. Such accidents would rarely occur, and velocities involved in actual accidents are likely to be considerably less than 700 mph. This example is presented to illustrate the relatively low energy of the stresses on a fuel capsule in even the most severe accidents. Three significant points can be made: (1) even under the most severe hypothetical transportation accidents the actual impact the fuel capsule will experience is small relative to the apparent velocities involved, (2) although fuel capsules are required to be impact tested at 50 m/sec, some manufacturers have tested theirs at speeds greater than 70 m/sec, without a subsequent breach, and (3) any plutonium dioxide fines that may escape from a pacemaker assembly will most likely remain confined to the body of the patient.

In summary, the design criteria for pacemaker fuel capsules and fuel form are comprehensive and have a large inherent margin of safety.

3.8 RADIOBIOLOGICAL HAZARDS OF PLUTONIUM

Before the world's supply of plutonium was as much as 1 g, research on the radiobiological hazards of plutonium had been started. The radiobiological hazards of plutonium have been the subject of continuing research under the atomic energy program, and an extensive body of information now exists as the result of 30 years' work by many scientists.

Except in highly specialized and relatively uncommon situations, the greatest radiobiological hazard from plutonium results from its presence inside the body. The most likely routes of intake into the body are (a) deposition in the lung via inhalation and subsequent absorption into body fluids from the lung, (b) absorption through the skin or entry through wounds, and (c) ingestion and subsequent absorption from the gastrointestinal tract. The route of entry of plutonium into the body has a significant effect on its deposition and distribution in tissues (particularly bone).

Experiments with laboratory animals have identified the general metabolic behavior of the plutonium compounds. When plutonium compounds are injected intravenously, they deposit primarily in the liver and skeleton; but, when ingested, only very small quantities are absorbed and deposited in the liver and skeleton. Inhaled plutonium that is deposited in lung tissue is retained for a variable time period related to the solubility of the inhaled material. The material that leaves the lung is translocated to thoracic lymph nodes, the liver, or the skeleton. Lesser burdens have been detected in the thyroid gland, kidneys, and other soft tissues.

Existing laboratory animal data indicate that the lungs, the liver, and the skeletal system are most likely to suffer either neoplastic or degenerative changes. No significant health consequences have been shown to occur in other organs or tissues. Although the gastrointestinal tract and the bone marrow receive some exposure, the dose commitment to these tissues is 1/1000 to 1/100,000 of that to the skeletal system, liver, and lungs.

The quantititative estimation of the expected pathological risks uses data derived from medical, accidental, or occupational exposure of humans to different radiation sources. These studies have been summarized recently by a NAS-NRC committee[7] and by the United Nations Scientific Committee on the Effects of Atomic Radiation.[6] Both reports have arrived at comparable risk estimates of the expected mortality from radiation-induced cancer, but the NAS-NRC document, referred to as the BEIR report (Sect. 3.3.1), presents these estimates in a form that is more appropriate to the estimation of risks in populations that include the normal age distribution. Therefore, to be conservative, the BEIR report has been used as the source document for this Statement with respect to cancer risk estimates despite the fact that many scientists and the NCRP consider its risk estimates to be excessive.

The BEIR report was also used to derive genetic risks that might be attributed to irradiation of the gonads. Genetic risks are translated entirely from experience with external irradiation of laboratory animals. However, the available limited human experience with external irradiation is consistent with these observations.[7]

The purpose of this section is to determine whether the effects on humans of postulated plutonium releases from the use of nuclear pacemakers constitute a risk. This risk is unfamiliar and has certain unusual features. For this reason, it is a cause of public concern and deserves special attention. Among the unusual features of this risk are the following: (1) control of and accountability for the nuclear material used in these pacemakers cannot be absolutely assured; (2) the radioactive half-life of plutonium is long, and risks may persist for several hundred years; (3) although the toxicity of these materials is well demonstrated in experiment animals, there is less direct knowledge of its effects in man; and (4) such effects as might conceivably occur will be indistinguishable from the normal ills of mankind. Some of these and other related concerns were expressed by many who commented on the plutonium toxicity problem in the DES and the LMFBR Environmental Statement.[26] For this reason, much of the material in this subsection is abstracted from the LMFBR Environmental Statement.

Since no restrictions will be placed on the movements of nuclear pacemaker patients, rigorous design criteria are imposed on the fabrication of the fuel capsules (Sect. 2.3) to ensure fuel capsule integrity under all credible accident conditions. However, for redundant protection in the unlikely event that a fuel capsule would be ruptured, additional restrictions are placed on fuel form to mitigate any health impacts. An extensive accident analysis was performed, and man-rem dose estimates were determined (Sect. 3.7).

The estimation of health consequences, based on the risk-logic model prediction of radionuclide accumulation in the environment and in man, is an uncertain procedure because of the very low exposure levels predicted, the lack of direct experimental data on effects at these low exposure levels, and the lack of any well-established mechanism of effect on the basis of which one might extrapolate from data obtained at much higher exposure levels. Therefore, predictions of risk have been based on comparison of predicted radiation doses in man with the dose-response data from animal experiments with plutonium and with the dose-response data from human exposure to other forms of radiation. Relative risk comparisons involving fewer extrapolation uncertainties have been made between the predicted doses due to releases from nuclear pacemakers, exposure to particulate plutonium from weapons test fallout, and exposure to natural background radiation. These comparisons of health consequences are summarized in this section.

3.8.1 Metabolism and dosimetry in man

With a few exceptions noted below, the assumptions of the International Commission on Radiological Protection (ICRP) are used for modeling the behavior of plutonium in man and for calculating radiation doses to organs.[20,27-28]

For the case of inhaled radionuclides, the ICRP lung model distinguishes between various solubility categories.[20] For calculating the dose to the lungs, plutonium dioxide particles fall in the least soluble class, thus maximizing retention in the lungs and thoracic lymph nodes and, consequently, maximizing radiation doses to these organs. In accordance with the ICRP, it is assumed that 1×10^{-6} of ingested plutonium dioxide will be absorbed from the gastrointestinal tract, and, of the plutonium translocated to the systemic circulation system, 45% is deposited in bone and 45% in the liver; the material in bone is retained with a half-time of 100 years and the material in liver with a half-time of 40 years. All of these numbers conform to ICRP recommendations.[28]

Using the dose calculation procedures of the ICRP, estimates were made of the total 50-year dose commitment to several organs resulting from the inhaled and ingested fractions of the initial source term. Briefly, the calculations consider the physical decay and biological retention of the radionuclide, including daughter radionuclides where pertinent, and sum the dose over 50 years following initial deposition. Dose estimates for lung, bone, and liver are calculated, but only the bone doses are shown in Fig. 3.1 since bone is considered to be the critical organ.

3.8.2 Estimates of health effects

The various estimates of exposure to plutonium released from nuclear-powered pacemakers are summarized in Fig. 3.1. Relating these estimates to health effects must necessarily be done indirectly, since, in spite of the occupational exposures to plutonium discussed in Section 3.8.3 below, there are no observed health effects from transuranic elements in man. The relationship must also be quite uncertain, since the estimated levels of exposure are far lower than can be studied experimentally, and since no proven theory exists to support the prediction of radiation effects at such levels. A number of comparisons have been made, however, that give an indication of the probable magnitude of the effects (ref. 26, Appendix II.G.5).

3.8.2.1 Comparison with current levels of alpha emitters

Radiation doses from the naturally occurring alpha-emitting radionuclides dwarf those from either fallout plutonium or predicted pacemaker releases.[29] The average, lifetime, dose-equivalent to an individual from internally deposited naturally occurring alpha emitters is about 1 man-rem, compared with lifetime dose commitments of about 0.01 man-rem from postulated pacemaker releases and plutonium fallout from weapons tests.[26, 30]

Compared with the global effects of plutonium fallout from weapons tests or naturally occurring alpha emitters, the effects of plutonium dioxide released from a pacemaker branch in a crematorium would be restricted to an area of about five acres and could involve as many as 4000 to 5000 people. The dose commitment to these individuals would be approximately equivalent to the dose commitment resulting from global plutonium fallout.

These comparisons provide no measure of the absolute risk of health effects of plutonium releases from pacemakers, but they indicate that such effects will be small compared with the effects of fallout plutonium. They also suggest that any effects from pacemaker releases would be obscured by a larger incidence of effects resulting from naturally occurring alpha emitters, if any effects are to be expected from any of these sources.

3.8.2.2 Comparison with animal toxicity studies

Direct information on the toxicity of plutonium is available only from studies of experimental animals. Literature suggests that the biological effects observed in such animal experiments will approximate those that would occur in man if exposed under the same conditions. For this reason, it is justifiable to look to the results from extensive animal experimentation for guidance in estimating the health risks from exposure of man to transuranic elements.

These studies (reviewed in ref. 26, Appendix II.G.3) suggest that bone and lung cancers are the most important effects of exposure to the lowest levels of radiation from transuranic elements studied.[31] The levels employed in these studies were much higher, however, than the estimated exposure from pacemaker releases. The lowest average radiation dose to tissue that has shown a significantly increased cancer incidence in experimental animals is about 300 rems to lung and 1500 rems to bone, doses that are about 10,000 times the estimated average lifetime dose to a resident of the United States from plutonium releases from pacemakers. The dose to any given individual may be larger or smaller than the average but is, in any case, much lower than the smallest doses that have produced observable effects in animals. To extrapolate over this range of doses without a proven theory relating dose to effect is clearly a very uncertain operation. At present there is little choice but to conservatively assume that health effects are linearly related to dose. Such linear projections were used in obtaining the cancer risk estimates summarized in Table 3.10. The data on which these estimates are based are summarized in ref. 26, Appendix II.G.5.3.

The reasonable agreement between statistics relating to the few species for which data are available, particularly with respect to bone cancer incidence, lends some credence to the usefulness of the risk estimates in Table 3.10. However, quantitative extrapolation of the results of animal experiments to man is uncertain. For example, in the case of radium-226, where cancer risks can be computed for both experimental animals and man, the risk to man per rem is only one-tenth of the risk to dogs or mice.[32]

Animal data on liver cancers are too limited to permit dose-response estimates, but liver cancers seem less probable than bone or lung cancers. Despite the relatively high radiation doses to thoracic lymph nodes, there is no indication from animal studies of significant tumor production in the lymphatic system.

Table 3.10. Cancer incidence predictions based on plutonium toxicity studies in experimental animals

Animal data[a]			Predictions for pacemaker releases			
			Per postulated release		Per year of availability	
Animal	Pu compound and route of administration	Increased cancer incidence per rem	Man-rems[b]	Cancer[c]	Man-rems[b]	Cancer[d]
		Bone exposure				
Dog	citrate, intravenous	7×10^{-5}	205	1.4×10^{-2}	11	7.7×10^{-4}
Mouse	citrate, intravenous	2×10^{-5}		4.0×10^{-3}		2.2×10^{-4}
		Lung exposure				
Dog	oxide, inhaled	7×10^{-5}	1	7×10^{-5}	0.6	4.2×10^{-5}
Rat	Pu-238 oxide, inhaled	7×10^{-4}		7×10^{-4}		4.2×10^{-4}

[a]Condensed from Tables II.G.5-9, Appendix II.G.5.3, LMFBR FES, WASH-1535.

[b]From Table 3.8.

[c]Product of columns 3 and 4.

[d]Product of columns 3 and 6.

3.8.2.3 Comparison with human cancer risk data

The National Academy of Sciences – National Research Council Advisory Committee on the Biological Effects of Ionizing Radiations (BEIR) recently reviewed the extensive data on human cancer mortality risks from exposure to ionizing radiation.[7] From these data the committee derived factors relating dose to estimated risk for various cancer types Their derivation assumed that the human experience, largely with external irradiation at relatively high dose rates and high total doses, could be linearly extrapolated to zero effect at zero dose. While these cancer risk estimators from the BEIR report have the advantage of being based on human data, they share with the animal studies the conservatism of linear extrapolation from high-dose observations.

Table 3.11 lists cancer mortality predictions for pacemaker releases, based on the BEIR report risk estimators. The rather close agreement between these estimates and the estimates from animal data in Table 3.10 should not be taken as evidence for the absolute accuracy of the estimates. The agreement more likely reflects the assumptions made in the derivation of both estimates, especially the assumption of a linear mechanism of effects. Nevertheless, the agreement increases the confidence with which the results from animal experiments are applied to the prediction of health effects in human beings. However, to establish the validity of this application requires further animal and human data from comparable exposure situations.

3.8.2.4 Comparison with genetic risk data

The genetic risks include the full spectrum of genetic defects that occur in the United States and other nations. Their effects upon the carrier may range from lethality at or near birth to minor metabolic consequences that may be nearly undetectable. The genetic spectrum ranges from dominant single-gene mutants, whose effects may be categorically recognized, to subtle genetic contributions to disease conditions that are predominantly of environmental or nongenetic origin. As a consequence, it is not appropriate to compare or equate estimates of genetic risk directly with the cancer risks. The latter are health consequences where case incidence and case mortality are substantially one-to-one. (This is certainly the situation for the lung and bone cancer risks described in this Statement, though it is not the situation for many other cancers that are known to have a lower risk of mortality.) This disparity between genetic and cancer risks is further clarified by noting that the genetic risk estimate incorporates two distinctly different types of genetic defects.[7] The first relates to categorical or specific genetic conditions usually attributed to single genes; and, the second type of genetic disability concerns the diseases of complex etiology, such as congenital anomalies and constitutional or metabolic diseases, that have an obscure genetic component. The uncertainty of risk estimation has a tenfold range for both types that is a function of the uncertainty of the magnitude of the genetic doubling dose. The second type of defect has an additional tenfold uncertainty (100-fold total) attributable to the lack of precise knowledge of the magnitude of the genetic component. Some of this uncertainty may have been resolved by recent data reported by Newcombe, who suggests a total risk of hereditary defects of 20×10^{-6} per man-rem.[33] Table 3.12 lists predictions of genetic defects attributable to plutonium releases from pacemakers, based on the two BEIR categories and on Newcombe's more recent data.

3.8.3 Human experience*

Over the years a number of workers in the nuclear industry have received exposures that have resulted in detectable plutonium deposition. Some exposures have led to deposition at or above the maximum permissible body or lung burden. In spite of uncertainty in measurements of deposition because of technological difficulties, studies conducted on such workers represent a valuable information resource. Relevant data for this Transuranium Registry are now being accumulated for later study. These investigations are described briefly in this section.

Estimates of the average accumulation of plutonium in the world population from previous and current atmospheric detonations of nuclear weapons are also presented here.

3.8.3.1 Followup studies of plutonium deposition cases

Personnel exposures date to the period shortly after the discovery of plutonium three decades ago. One group of persons who were exposed at the Los Alamos Scientific Laboratory (LASL) has been studied at intervals since 1945 and is of sufficient interest to be described in some detail.

*Abstracted in part from GESMO (ref. 34).

Table 3.11. Cancer mortality predictions for plutonium pacemakers based on human irradiation experience

Tumor type	Risk model[a]	Cancer deaths per man-rem[b]	Man-rems	Per pacemaker breach in crematory		Per year of availability	
				Additional cancer deaths[c]		Man-rems	Additional cancer deaths[d]
Lung	Absolute	16×10^{-6}	1	1.6×10^{-5}		0.08	1.3×10^{-6}
	Relative	110×10^{-6}	1	1.1×10^{-4}		0.08	8.8×10^{-6}
Bone	Absolute	2×10^{-6}	205	4.1×10^{-4}		16.6	3.3×10^{-5}
	Relative	71×10^{-6}	205	1.5×10^{-2}		16.6	1.2×10^{-3}
Liver	Absolute	1×10^{-6}	4	4×10^{-6}		0.03	3×10^{-8}
	Relative	7×10^{-6}	4	2.8×10^{-5}		0.03	2.1×10^{-7}

[a]The different assumptions of these two models are explained in the BEIR report and in Appendix II.G.5.4 of WASH-1535.

[b]The risk estimates for lung and bone are taken directly from the BEIR report. No risk estimate for liver cancer is given in the BEIR report. The values listed were derived by procedures described in Appendix II.G.5.4 of WASH-1535.

[c]Product of columns 3 and 4.

[d]Product of columns 3 and 6.

Table 3.12. Predictions of genetic defects

Type of risk	Incidence per man-rem	For pacemaker breach in crematory		Per year of availability	
		Man-rems to gonads[a]	Genetic defects[b]	Man-rems to gonads[a]	Genetic defects[c]
Specific genetic defect[d]					
Lower limit of estimate	50×10^{-6}	1.3	6.5×10^{-5}	0.07	3.5×10^{-6}
Upper limit of estimate	500×10^{-6}	1.3	6.5×10^{-4}	0.07	3.5×10^{-5}
Defects with complex etiology[d]					
Lower limit of estimate	10×10^{-6}	1.3	1.3×10^{-5}	0.07	0.7×10^{-6}
Upper limit of estimate	1000×10^{-6}	1.3	1.3×10^{-3}	0.07	0.7×10^{-4}
Newcombe estimate of total genetic defects[e]	20×10^{-6}	1.3	2.6×10^{-5}	0.07	1.4×10^{-6}

[a]From Table 3.8.

[b]Product of columns 2 and 3.

[c]Product of columns 2 and 5.

[d]Estimates from BEIR Report.

[e]Estimate of H. B. Newcombe.

The group consists of 25 male subjects who worked with plutonium during World War II under very crude working conditions judged by current standards. Twenty-one of these men have recently had complete physical examinations at LASL. In addition to physical examinations and laboratory studies (complete blood count, blood chemistry profile, and urinalysis), roentgenograms were taken of the chest, pelvis, knees, and teeth. Chromosomes of lymphocytes cultured from peripheral blood and cells shed from the pulmonary tract were also studied. Urine specimens assayed for plutonium yielded calculated body burdens that ranged from 0.005 to 0.42 μCi. These estimates of body burden were generally higher than earlier estimates based on radioassay of urine samples performed many years ago, perhaps reflecting uncertainties in the models used to estimate body burden from excretion data.

To date, none of the medical findings in the group can be attributed to internally deposited plutonium. Except for the ailments that one would expect in a group of men who are mostly in their early fifties, all subjects examined were in reasonably good health and were actively working. Of the original group, one man had previously suffered an occlusion but recovered. Another of the original group died in 1959 (at age 38) from a coronary occlusion. Another had a benign hematoma of the lung, which was removed surgically without complication in 1971. A third had a malignant melanoma of the chest wall; the regional lymph nodes showed no malignancy. A fourth had a partial gastrectomy for a bleeding ulcer. Several have mild hypertension and moderate obesity, and one has gout.

3.8.3.2 Analysis of plutonium in tissues not included in the Transuranium Registry

The collection and analysis of tissues from the general and non-registry worker population is conducted by Pacific Northwest Laboratory (PNL) and LASL. Tissue analysis has been completed on about 376 autopsies at PNL, all on individuals who died in the Richland area. Los Alamos Scientific Laboratory has obtained tissues from 512 autopsies in several geographic areas. The following are the locations and numbers of autopsies for which specimens have been analyzed at LASL: Los Alamos area, 170; New Mexico, other than Los Alamos, 104; Colorado, 173; New York, 236; Savannah River area, 21; Chicago, 6; Oak Ridge, 2. In addition to members of the general population, these autopsies included 160 workers at Hanford and 75 at Los Alamos, some of whom were exposed to plutonium in their work. Since these employees were not enrolled in the registry prior to death, they are not included in the registry statistics.

No effects attributable to plutonium have been observed in any of the human populations studied. However, the studies are recognized to be incomplete in view of the brief follow-up period (30-year maximum) and the small numbers of humans definitively studied to date.

3.8.3.3 Plutonium levels in the general population

Plutonium is currently present in extremely small quantities in various organs of the human body. Although dissemination of most of the widely distributed plutonium resulted from atmospheric testing of nuclear weapons by several countries prior to the 1963 limited test ban, some material from contemporary atmospheric weapons testing by China and France has added to the total human burden. Currently, the median plutonium lung burden of persons in the United States is estimated to be about 0.4 pCi (1 pCi = 10^{-12} Ci). A rough estimate of the average amount in the entire body is about 5 pCi. Estimates of the total release of plutonium from weapons testing vary. A value of about 0.5 MCi (1 MCi = 10^{6} Ci) probably is quite reasonable. Of this amount, very little (about 10^{-8}) has found its way into the population (3×10^{9} people). The fraction of the estimated quantity in the biosphere to be found in an individual human is about 10^{-17}.

3.8.3.4 Plutonium hot-particle issue

On the basis of available evidence, the NRC believes that irradiation of the lung by particles of plutonium is not likely to be markedly more carcinogenic than when the same activity is uniformly distributed.[35] After 30 years of experience with plutonium in laboratory and production facilities, there is no evidence that the lung model on which occupational radiation protection standards for plutonium are based is grossly in error or leads to hazardous practices. Currently available data from occupationally exposed persons indicate that the nonuniform dose distribution from inhaled plutonium does not result in demonstrably greater risk than that assumed for a uniform dose distribution. Thus, empirical considerations lead to the conclusion that the nonuniform dose distribution of plutonium particles in the lung is not more hazardous and may be less hazardous than if the plutonium were uniformly distributed and that the mean-dose lung model is a radiobiologically sound basis for establishment of plutonium standards.[36]

For additional information on this subject, the reader is referred to refs. 4, 35, 36, and 37.

3.9 TERRORISM AND DELIBERATE DISPERSAL

The use of plutonium-powered pacemakers for medical treatment has been questioned in some of the comments in Appendix A because of the hypothetical hazard of deliberate dispersal of the plutonium fuel by malefactors who would illegally obtain such a pacemaker. Implied risks may have intensified public concern with regard to the use of plutonium-powered pacemakers.

The alleged toxicity of plutonium (Sect. 3.8) and its use for terrorist purposes is overstated by some commentors. For perspective, this section will discuss the following issues qualitatively: (1) plutonium fuel used in pacemakers has no military significance; (2) the conversion of this fuel into a dispersal weapon is not a simple procedure, and a person attempting such a conversion may place himself in the greater danger; and (3) regulatory controls on these pacemakers will offer safeguards. The requirement that the fuel form be as nondispersible and nontransportable as possible and the fact that the quantity of fuel is limited will deter any subversive attempts at dispersal.

3.9.1 Military weapon significance

The plutonium fuel in a pacemaker (about 90% by weight plutonium-238) has no military weapon significance. At least 25 kg of plutonium-238 dioxide would be needed to achieve a critical configuration. This amount of material generates over 12 kW of heat, an amount that would present thermal engineering problems of a magnitude that would eliminate practical explosive devices from consideration. For example, the 256-g plutonium-238 radioisotopic thermoelectric generators for the space program develop temperatures higher than 1300°C. In essence, there are far more practicable alternatives.

3.9.2 Dispersal

A plutonium-238 fuel capsule is of high integrity, but, given the "tools" and sufficient determination, it can be breached. However, opening the fuel capsule without contaminating oneself would not be easy, even using specialized tools. In response to a comment by a reviewer, an experiment was performed to test the resistance of pacemaker fuel capsule cladding materials to inorganic acids.[38] In summary, the data show that successful dissolution of the cladding from a pacemaker fuel pellet in a manner suggested by this commentor would never occur. Seven samples of different fuel pellet cladding materials were exposed, in vigorous mechanical motion, to solutions of concentrated aqua regia for over 300 hr and over 100 hr to solutions of aqua regia and sodium fluoride. It is concluded from these test results that plutonium pacemaker fuel cladding could not be readily dissolved in inorganic acids. For pellets clad with platinum-iridium, it is virtually impossible to dissolve the capsule even in heated aqua regia with sodium fluoride added.

The calculated penetration rates are small, requiring a long time span to dissolve fuel pellet cladding, but this may not be the limiting factor in discouraging such attempts. Handling of concentrated acids is hazardous and must be approached carefully in order to avoid acid burns, especially if spills occur. Noxious hydrogen chloride fumes are given off in the handling and use of hydrochloric acid. A mechanical failure of the hood used in this experiment required an immediate temporary evacuation of the laboratory.

Metals and alloys used in the fabrication of pacemaker fuel capsules to give them substantial mechanical and high-temperature strength also provide very high corrosion protection to the fuel pellet even in the event of deliberate attempts to dissolve the cladding. This does not imply that it is impossible to open a pacemaker's fuel capsule using inorganic acids but that it would not be a practical choice.

Assuming that an individual has obtained a plutonium heat source from a pacemaker, even by an act of murder as postulated by the comments, and has managed to breach the capsule, it is important to note that the fuel is in the form of a solid pressed and sintered ceramic pellet of plutonium dioxide. At this stage the only identifiable potential casualty would be the person opening a pellet's cladding. Distribution of the contents, to be effective, would require conversion of the fuel to inhalable fines, a task that would probably be more formidable than the initial opening of the capsule. The method proposed by commentor 41 would not be feasible because of the relative insolubility of plutonium dioxide sintered pellets.[39]

Any significant dispersion of fuel from a breached fuel capsule that might interact with man would require the fuel to be in the form of fines less than 10μ in diameter, since the primary damage mode is through inhalation and retention in the lungs. Plutonium dioxide has low solubility, and tests have indicated that ingested particles pass through the gut and are eliminated with minimal effects. Thus, the breaching of the capsule per se is not as significant as the amount of inhalable particulates released. Studies show that of inhalable particulates released, only a small fraction (2×10^{-5}) would be taken up by man.[26] Hence, the most taxing problem may be the dispersal.

For plutonium dispersal to be effective, it must reach a group of people without their knowledge. This essentially eliminates the dispersal of plutonium with explosive devices. Any personal injury by this method would most likely be caused by the explosive.

If there was a threat of plutonium dispersal in an enclosed building or public gathering area, such as a coliseum or stadium, the air conditioning system could be shut down and the area evacuated. Also, the people could be instructed to breathe through several layers of a handkerchief or clothing, which would mitigate, if not prevent the inhalation of plutonium.

3.9.3 Safeguards

As discussed in Sect. 1, the guidelines of the International Atomic Energy Agency exempt plutonium containing more than 80% of plutonium-238 from the safeguard requirements normally imposed on fissile material that have been set forth in agreement between the IAEA and member countries in connection with the Treaty on the Non-Proliferation of Nuclear Weapons. Also, by-product nuclear materials and small quantities of special nuclear materials, such as the plutonium used in the manufacture of pacemakers, are considered to have adequate protection against sabotage or theft, which could have high levels of consequence. The rules governing the protection of these materials are set forth in 10 CFR Part 20. In substance, these rules require that access to the materials be controlled, that materials in storage be secured against unauthorized removal, and that thefts or losses be reported immediately to NRC. The application of more specific physical protection conditions is not considered necessary at this time. The regulatory process provides for periodic review of these requirements, and regulations will be modified appropriately if a review indicates a need.

One issue that is generally taken for granted by some commentors is that plutonium pacemakers are easily obtained. Although it is recognized that it is not impossible to obtain such a pacemaker, gaining possession of a unit may be an arduous task due to stringent controls that will be implemented to govern their handling, transportation, storage, possession, and use. The malicious removal of a pacemaker from a patient will require prior identification of the patient as a bearer of a plutonium-powered unit and will involve an act of murder. To acquire a plutonium pacemaker by other methods will require knowledge of the handling, accountability, and security of the different institutions using these pacemakers, and it would be improper at this time to discuss present procedures.

There is no past experience of terrorist use of radioactive materials for subversive purposes; hence, discussion of any such use in the future is purely speculative. Although terrorist use of plutonium is suggested in some of the comments, deliberate dispersal of plutonium obtained from a pacemaker is not believed to be a viable threat to mankind for the reasons already discussed (Sect. 3.9.2).

An additional point of primary importance, which is often not taken into consideration, is that any detrimental health effects from inhaling plutonium will not manifest themselves for a number of years. There is a 15-year latency period, at the minimum, before somatic health effects, if any are incurred, can be diagnosed. Terrorist threats have not, in the past, involved a threatened action with such delayed results.

There are clearly far more practicable and effective alternatives than using plutonium fuel from a pacemaker for terrorist purposes.

3.10 ENVIRONMENTAL CLEANUP COSTS

If a pacemaker fuel capsule is breached accidently, plutonium dioxide fines may escape into the environment. The routes of entry were discussed in the risk-logic sections. The most likely situation in which plutonium dioxide would reach the environment and possibly require decontamination is the airborne release postulated for a breached capsule in a crematorium (Sect. 3.7.1.2).

In the unlikely event of a capsule breach occurring during cremation, it is calculated that only 0.13% of the fuel would be released in the form of plutonium dioxide particulates. Of

that small fraction, more than 95% would be deposited on the ground within 350 m of the crematorium stack encompassing an area of approximately 5 acres. This area may require decontamination. Estimated costs for 20 people, equipment, and transportation to decontaminate the area is of the order of $4000/acre, or a cost of $20,000 per event. Such an event is calculated to occur once every 20 years.

At distances further than 350 m from the crematorium stack, the calculated amount of plutonium dioxide particulates deposited in the area would be too low to warrant decontamination.

3.11 INVENTORY CONTROL

To ensure that the possibility of pacemaker loss will be minimized and that they will be properly disposed of in licensed facilities, the administration of uniform procedures for their accountability, surveillance, recovery, and disposal will be implemented. Details of control programs appear in Sect. 2. A central registry of pacemaker bearers will most likely use a computerized system.

The estimated cost of operating a central computerized records system is based primarily on the cost of operating the Commission's Centralized Ionizing Radiation Exposure Records and Reports System. The types of data kept by the contractor, the Oak Ridge Computing Technical Services, are somewhat similar in nature and covered 203,210 monitored individuals in 1972. The operating cost of this contract for 1973 was about $25,000. With the increased amount of data required per pacemaker patient, a proposed six-month periodic mailing for data verification, initial programming costs, etc., it is estimated that the average yearly cost for 5000 new or deleted patient entries would exceed this $25,000 contract cost by a factor of 4. Therefore, it is estimated that $100,000 would be required for the average yearly operating cost of the centralized records system for the first five years. For 10,000 pacemaker patients, this cost would translate to approximately $10 per year per patient. The initial programming cost may well make the cost for the first year's operation exceed $100,000, but the cost should average out over the first five-year period.

In the present investigational program, the cost of record keeping is the responsibility of the hospitals and the manufacturers, and these costs are included in their fees and charges. If this system of record keeping changes for routine use of nuclear pacemakers and a central computerized system is implemented, as discussed previously, these costs would be covered by registration fees that would be included in the purchase cost of the pacemaker.

3.12 RECOVERY AND DISPOSAL

The recovery and ultimate disposal of nuclear-powered pacemakers will be the responsibility of the manufacturer and will be regulated by the NRC. No additional costs are calculated for recovery and disposal, since they would be included in the purchase price of the pacemaker. Also, pacemakers, when returned to the manufacturers, may have some recycle value, which would be reflected in the manufacturers' price determination.

REFERENCES FOR SECTION 3

1. L. W. Brackenbush, G. W. R. Endres, and B. I. Griffin, *Radiation Doses from the Medtronic Laurens-Alcatel Model 9000 Pulse Generator*, Report 2211201653, Amendment 2, Battelle Pacific Northwest Laboratories, October 1973.

2. H. H. Rossi, letter to B. Singer of May 16, 1975.

3. P. Rubin and G. W. Casarett, *Clinical Radiation Pathology*, vols. I and II, W. B. Saunders Co., 1968.

4. H. D. Kogelnik, G. H. Fletcher, and R. H. Jesse, "Clinical Course of Patients with Squamous Cell Carcinoma of the Upper Respiratory and Digestive Tracts with No Evidence of Disease 5 Years after Initial Treatment," *Radiology* 115(2): 423-427 (May 1975).

5. L. H. Hempelmann, W. J. Hall, M. Phillips, R. A. Cooper, and W. R. Ames, "Neoplasms in Persons Treated with X-Rays in Infancy: Fourth Survey in 20 Years," *J. Nat. Cancer Inst.* 55: 519-530 (1975).

6. United Nations Scientific Committee on the Effects of Atomic Radiation, "Ionizing Radiation Levels and Effects," Report to the General Assembly, vol. II: *Effects*, United Nations, New York, 1972.

7. National Academy of Sciences — National Research Council, Division of Medical Sciences, Report of the Advisory Committee on the Biological Effects of Ionizing Radiations, *The Effects on Populations of Exposure to Low Levels of Ionizing Radiation*, National Academy of Sciences, Washington, D.C., November 1972.

8. R. W. McKee, L. C. Clark, B. M. Cole, and R. A. Libby, *Dose to the Population: Estimates for Use of Radioisotope Powered Cardiac Pacemakers*, BNWL-1858 (Draft), Battelle Pacific Northwest Laboratories, September 1974.

9. *Vital Statistics of the United States — 1968*, vol. II, *Mortality*, U.S. Department of Health, Education, and Welfare, Public Health Service.

10. *Interim Radiation Protection Standards for the Design, Construction, Testing and Control of Radioisotopic Cardiac Pacemakers*, Nuclear Energy Agency, (74)101 (Final) Aug. 23, 1974.

11. *Human Tolerance to Impact Conditions as Related to Motor Vehicle Design*, SAEJ 885a (October 1966), p. 945.

12. E. M. Wurzel et al., "Measurements of the Loads Required to Break Commercial Aviation Safety Belts as an Indication of the Ability of the Human Body to Withstand High Impact Forces," Naval Medical Research Inst. Report NMRI-630-12.

13. "Chronology - Disasters," *1972 World Almanac* and *1973 World Almanac, The Washington Daily News*.

14. *Study of Potential Magnitude and Radiological Consequences of Plutonium and Fission Product Releases for a Production Scale Mixed Oxide Fuel Fabrication Plant*, Battelle Pacific Northwest Laboratories-1697, 1973.

15. M. Eisenbud, *Environmental Radioactivity*, Academic Press, 1973, p. 29.

16. *Vital Statistics of the United States--1969*, vol. II, *Life Tables*, U.S. Department of Health, Education, and Welfare, Public Health Services.

17. "Benefits Resulting from the Use of the Isotopic Pulse Generator," Medtronic, Inc., Dec. 17, 1973.

    Marie-Francoise Le Febre, Attachee au Centre Hospitalier Regional de Lille, "Long-Term Survival of the Bearers of Cardiac Stimulators," January 1963 — July 1972.

18. Telephone conversation on July 16, 1973, with H. R. Hargrave, Secretary, Cremation Association of America.

19. *Inhalation Risks from Radioactive Contaminants*, Technical Reports Series No. 142, International Atomic Energy Agency, 1973.

20. International Commission on Radiological Protection, Task Group on Lung Dynamics, "Deposition and Retention Models for Internal Dosimetry of the Human Respiratory Tract," *Health Phys.* 12: 73-208 (1966).

21. *Radioisotope-Powered Cardiac Pacemaker — Safety and Radiation Report*, NUMEC 3731-23, Nuclear Materials and Equipment Corp., June 1970.

22. "The Mechanical Resistivity of the Fuel Capsule of Radioisotopic Powered Cardiac Pacemakers against Bullets of Firearms," *Second International Symposium on Power from Radioisotopes, Madrid, Spain, May-June, 1972*, p. 849.

23. Hittman Nuclear Battery Corp., "Comments on the Nuclear Regulatory Commission Draft Generic Environmental Statement on the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers," Aug. 21, 1975.

24. ARCO Nuclear Company, "Analysis of Firearm Deaths, Radioisotope-Powered Cardiac Pacemaker," Leechburg, Pennsylvania.

25. *Parametric Analyses for an Artificial Heart Device*, TRW Report No. SAN-858-22, 1972, pp. 10-15.

26. Environmental Statement, "Liquid Metal Fast Breeder Reactor Program," WASH-1535, December 1974, Sect. 4.7.

27. International Commission on Radiological Protection, *Report of Committee II on Permissible Dose for Internal Radiation*, ICRP Publication 2, Pergamon Press, New York, 1959.

28. International Commission on Radiological Protection, Task Group of Committee 2, *The Metabolism of Compounds of Plutonium and Other Actinides*, ICRP Publication 19, Pergamon Press, New York, 1972, p. 59.

29. U.N. Scientific Committee on the Effects of Atomic Radiation, *Ionizing Radiation: Levels and Effects*, vols. I and II, United Nations, New York, 1972.

30. E. P. Hardy, P. W. Krey, and H. L. Volchok, *Global Inventory and Distribution of Pu-238 from SNAP-9A*, USAEC Report HASL-250, Health and Safety Laboratory, New York, 1972.

31. W. J. Bair, "Toxicology of Plutonium," *Advances in Radiation Biology*, vol. 4, Academic Press, New York, 1974, pp. 255-315.

32. C. W. Mays and R. D. Lloyd, "Bone Sarcoma Incidence vs. Alpha Particle Dose," in *Radiobiology of Plutonium*, B. J. Stover and W. S. S. Jee Eds., J. W. Press, Salt Lake City, 1972, pp. 409-430.

33. H. B. Newcomb, "Mutation and the Amount of Human Ill Health," *Radiat. Res.* 59: 74 (1974).

34. *Generic Environmental Statement, Mixed Oxide Fuel*, WASH-1327 (Draft), August 1974, chap. IV.

35. "The Toxicity of Plutonium," Medical Research Council, London, 1975.

36. W. J. Bair, C. R. Richmond, and B. W. Wachholz, "Radiobiological Assessment of the Spatial Distribution of Radiation Dose from Inhaled Plutonium," WASH-1320, U.S. Atomic Energy Commission, September 1974, p. 1.

37. C. R. Richmond, "Current Status of the Plutonium Hot Particle Problem," *Nucl. Safety* 17 (in press, 1976).

38. R. L. Shoup, *Nuclear Powered Pacemaker Fuel Cladding Study*, ORNL TM-5127, Oak Ridge National Laboratory, 1976.

39. A. L. Uriarte and R. H. Rainey, *Dissolution of High Density UO_2, PuO_2, and UO_2-PuO_2 Pellets in Inorganic Acids*, ORNL-3695, Oak Ridge National Laboratory, 1965.

40. "Medical Uses of Radium and Radium Substitutes," conference at University of Chicago, Sept. 3-4, 1964.

4. ALTERNATIVES, BENEFITS, AND BENEFIT-COST SUMMARY

4.1 INTRODUCTION

The service life of a pacemaker is dependent on the life of its batteries, failure of electronic components, and integrity of the package. Component failures are random (time-independent) and sometimes occur before battery failure, but their occurrence is so infrequent that the limiting factor on the service lives of pacemakers with conventional chemical batteries is current drain, which is dependent upon the pulse-generator design, the lead used, the impedance of the interface between the electrode and the cardiac tissue, and, in the case of demand pacemakers, the fraction of time during which the pacemaker is inhibited by the natural pulses of the heart. The random failure rate of conventional pacemakers, including premature battery wearout, is typically 0.15% per month.[1-3] The principal power source for implantable cardiac pacemakers has been mercury batteries (mercuric oxide-zinc). Improvements are being made in mercury-battery-powered pacemakers, but, until 1973, their service lives were generally 1-1/2 to 3 years.[4-8]

Cardiac Datacorp, Inc., Philadelphia, provides telephone monitoring of pacemakers of all types. Their analysis of data on 4111* pacemakers monitored from 1970 through September 30, 1974[9] showed 1179 removals for all causes, including 642 elective replacements. Excluding the elective replacements, 438 of the remaining 537 removals (81.6%) were due to battery depletion, and the mean time to removal was 25.3 months. The total of 1080 removals for battery depletion and elective replacements, performed for the most part on the basis of the manufacturers' recommendations or anticipation by the physician of impending battery depletion, accounted for 91.6% of the total removed. Of the remaining 2932 pacemakers, there were 462 units still functioning past 24 months, averaging 31.37 months. It is noted (comment HNB-A34) that this is not the average for all pacemaker lifetimes but is restricted to those still functioning in excess of 24 months.

Patients are examined periodically by their physicians to have their pacemakers checked for signs of impending loss of battery effectiveness. When such signs are evident, the patients return to the hospital for surgical implantation of a new pacemaker. To avoid the necessity of frequent replacement surgery, and its attendant risks, costs, and inconveniences, pacemakers with longer service lives have been and are being developed. The most desirable pacemaker would be a unit that would function without replacement for the remaining lifetime of the patient.

When the development of nuclear-powered pacemakers began in 1966, existing pacemaker batteries were lasting about 18 months.[10] The use of improved electrodes, improved microcircuitry, and adjustable output circuitry has reduced the power requirements of pacemakers and extended the service lives of chemical batteries used in pacemakers. Electronic and telephonic analysis of pacemaker function permits the continued use of a pacemaker until an "end-of-life indicator" is observed, thus obtaining a longer pacemaker service life than if elective replacements are made on a predetermined schedule, which sometimes results in the replacement of pacemakers that still have a considerable remaining useful life. Concurrently with the development of nuclear pacemakers, during the past ten years, there have been substantial developments in other types of pacemaker power supplies. Improvements have also been made relative to the reliability and longevity of pacemaker electronics and electrodes.

New power supplies currently being used in pacemakers include lithium-iodine batteries, rechargeable batteries, and improved mercury-zinc batteries. These are discussed in Sect. 4.2 as alternatives to nuclear-powered pacemakers.

Results of the current clinical investigations of nuclear-powered pacemakers are presented in Sect. 4.3.

Some of the comments received on the draft Environmental Statement expressed the opinion that, in view of the availability of nonnuclear pacemakers with long useful service lives, nuclear-powered pacemakers are not needed. In order to appraise the need for, and choice of, long-lived pacemakers in medical practice, a questionnaire was distributed to a number of physicians throughout the United States who have extensive experience in the use of cardiac pacemakers. The questions and a summary of the replies are given in Appendix G.

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*Deceased patients with functioning pacemakers were not included in this analysis.

4.2 ALTERNATIVE PACEMAKERS

4.2.1 Pacemakers powered by mercury batteries

While most of the experience and longevity data for conventional pacemakers powered by mercury batteries is based on pacemakers using Mallory RM-1 Group I cells, a new and improved RM-1 Group II cell has recently become available and is used in pacemakers now being manufactured and implanted. The lifetime of pacemakers with the RM-1 Group I cells was generally in the range of 1-1/2 to 3 years (Sects. 1.1 and 4.1).

Documented failure mechanisms[11] for mercury-zinc batteries include dendritic mercury growth, zinc oxide migration, leaky separators, and corroded welds. Most of the failure modes are traceable directly or indirectly to the mobile, corrosive, liquid electrolyte (sodium hydroxide). Premature cell failure with shorting of the cell frequently occurred before the chemical capacity of the cell was exhausted. The addition of a second barrier in the RM-1 Group II cells has all but eliminated premature failures and is said to have more than doubled the life of the mercury-zinc cell.[12]

According to recent data from Medtronic, Inc.,[2] pacemakers with RM-1 Group II cells have projected replacement times ranging from 30 months to 114 months. Supporting clinical data relating to these batteries are mostly less than 36 months old. The pacemakers (pulse generators and leads), for which replacement times are projected, include 13 models of pulse generators and 11 models of leads. While many pacemaker systems are available, most of the pacemaker systems implanted have recommended pulse generator replacement times near the middle of the time range (from 60 to 76 months).

Although improvements in electronics and electrodes have reduced the power requirements of pacemakers and extended the service lives of chemical batteries (Sect. 4.1), some of the high-power-requirement pacemakers, which have short service lives even with the improved mercury cells, are needed to meet the pacing requirements of some patients. The pacemakers with low power requirements, and, thus, long service lives, are not suitable for pacing all patients.

Since mercury batteries release hydrogen gas, they are not hermetically sealed. Most mercury-battery pacemakers are encapsulated in epoxy. The epoxy acts as a barrier to salt ions but does permit the passage of water. Consequently, the pacemaker circuitry operates in a warm-water environment, which is unfavorable for electronics reliability (comment HNB-A34). The newer pacemakers discussed in the following sections are, or can be, hermetically sealed to prevent the entry of moisture into the electrical system.

4.2.2 Nuclear-powered pacemakers

Pacemakers using plutonium-238 and promethium-147 power sources have been developed and are now under clinical investigation and evaluation. An advantage of these nuclear sources is that pacemakers with a relatively high current drain, as well as pacemakers with average or relatively low current drain, can be powered for longer times than conventional-battery-powered pacemakers. This is due to the higher available energy density of nuclear sources as compared with the chemical-fuel batteries and to the fact that nuclear battery output decreases with the decay of the radioisotopes rather than with the consumption of a chemical fuel.

4.2.2.1 Plutonium-powered pacemakers

The plutonium-powered pacemakers considered for routine use in this Environmental Statement use encapsulated plutonium heat sources and thermoelectric converters to produce electrical power for the pacemakers. Plutonium-238, the principal isotope in the plutonium fuel, has a half-life of 87.8 years. Experience has shown that the decrease in electrical output from plutonium batteries used in pacemakers is proportional to the radioactive decay of the plutonium fuel and that there is no observed degradation in the thermoelectric converters at the low operating temperatures involved in pacemaker power sources. There has been no wearout mode observed or postulated in these power sources other than the radioactive decay of the plutonium fuel. Because of relatively long half-life and relatively low radiation from plutonium-238, these power sources can be built for any useful life desired by using an appropriate amount of plutonium fuel to allow for its radioactive decay during the designed life of the power source.

The Model 9000 isotopic pulse generator manufactured by Medtronic, Inc., has been in clinical use in Europe since April 1970 and in the United States since July 1972. The "Semiannual Clinical Evaluation Report" submitted by Medtronic, Inc., to the Nuclear Regulatory Commission in May 1975 contained data on 324 pacemakers implanted in patients in the United States between July 18, 1972, and May 12, 1975, and on 677 pacemakers implanted outside of the United States since April 1970. In the United States, one pulse generator failure occurred (because of a defect not related to the

battery) in 5292 device-months of clinical use, and outside the United States one pulse generator malfunction occurred (because of a random electronic component failure) in 9227 device-months. By combining these worldwide data, a random failure rate of 0.04% per month was determined. Medtronic[13] interprets these data to mean that 90% of all Model 9000 pulse generators would still be operable after 263 months (21.9 years). The power output from the battery is projected to be greater than 150 μW at 20 years, and the energy output per pulse from the generator is projected to be greater than 30 μJ at 20 years. Medtronic considers this pulse generator to have a 20-year service life.[13]

The ARCO Medical Products Company claims that their NU-5 pacemakers will remain within specification limits for 40 years.[14] In October 1975, this pacemaker model had accumulated 1598 unit-months of clinical use. One pacemaker was removed because of a rate shift caused by a substandard capacitor; another pacemaker was removed because of an electrode failure and was found to have the same rate shift and substandard capacitor. ARCO claims that these failures are not random and that their causes have been corrected by improved quality control procedures.

American Optical Corporation's Model 281343 pacemaker contains a nuclear battery manufactured by Hittman Nuclear Battery Corporation. The electronic components in this pacemaker are predicted to have a mean time to failure of about 40 years. American Optical has arbitrarily selected 20% voltage reduction as their cutoff point for replacement and calculates that this will occur in 28.8 years. The circuitry has a test mechanism to determine the point at which 20% voltage reduction has occurred. American Optical states[15] that the battery is expected to provide for the power demands for the system for a minimum period of 20 years.

Coratomic, Inc., has reported[15] their calculation of random failure analysis for their nuclear-powered pacemaker using the methods documented in the *Military Standardization Handbook* ("Reliability Prediction of Electronic Equipment," MIL-HDBK-217B, 20 September 1974). These calculations project a reliability, from random failure, of 0.98 at 30 years for the electronic module and 0.95 at 30 years for the isotopic battery for a combined system reliability of 0.92 at 30 years. Coratomic has also calculated, from the combined electrical parameters of pacemakers assembled from production batteries and electronic modules and from the radioactive decay rate of the plutonium fuel, that wearout failures due to fuel decay will begin to occur after 28 years.

4.2.2.2 Promethium-powered pacemakers

In a promethium battery, decay electrons from promethium-147 directly excite a semiconductor to produce electrical energy by the betavoltaic conversion process. The promethium pacemaker battery is limited in design lifetime by the power decay of the relatively short (2.62 years) half-life of promethium-147 and by the amount of promethium that can be used because of the radiation emitted by promethium-146, a contaminant in promethium-147. The manufacturers of the promethium battery and the pacemakers using this battery claim that an eight- to ten-year lifetime can be expected.

The manufacturer of the promethium battery has recently announced the discontinuance of this battery. Therefore, this pacemaker is not an available alternative at this time. The draft of this Environmental Statement indicated that a separate statement on promethium-powered pacemakers was under preparation. However, since this pacemaker is no longer manufactured or available for use, preparation of the Environmental Statement has been stopped.

4.2.3 Lithium-battery-powered pacemakers

Batteries containing lithium have been developed for pacemakers with the objective of producing a longer-lived power source for pacemakers than can be obtained from conventional mercury batteries.

The model 702-E lithium-iodine cell, manufactured by Wilson Greatbatch, Ltd., has a rated capacity of more than 3.5 A-hr with available energy of 8.75 Whr, calculated at 2.5 V. The manufacturer has calculated, using extrapolations based on chemical content and accelerated rundown data, that this battery has sufficient chemical capacity to last more than 12 years before the voltage decreases to 1.8 V (their arbitrarily chosen end-of-life indicator) under a 30-uA load. A later lithium-iodine battery, model 743-A, has been developed[16,17] by Greatbatch that has a rated capacity of 4 A-hr and 10 Whr of available energy, calculated at 2.5 V. This battery has 63% of the weight and 58% of the volume of the model 702-E.

The life-limiting factor for the original single-anode lithium-iodine cell was a decrease of voltage due to internal resistance buildup in the lithium iodide electrolyte, which resulted in a gradual linear rate change of the pulse generator. The later-model double-anode cells are life-limited by iodine exhaustion. The change in pulsing rate with the decrease in cell voltage can be used as an end-of-life indicator for a pulse generator.

Cardiac Pacemakers, Inc., uses lithium cells manufactured by Wilson Greatbatch, Ltd., in their pacemakers. They report[18] that the theoretical projected longevity for their pacemakers, under the conditions of 100% pacing and 500-ohm load, is 14 years. This value is calculated on the basis of performance characteristics of the lithium-iodine cell and does not take into account unknown premature battery failure mechanisms. No such premature battery failures have occurred in more than four years of testing. Data from over 5000 implanted CPI lithium-battery pacemaker implants indicate that these pacemakers should attain 91% survival at six years with a 95% confidence level.

Dr. G. Frank Tyers of the Milton S. Hershey Medical Center (HMC), Pennsylvania State University, reports[17] that the HMC pacemakers, with Greatbatch lithium-iodine batteries, will have a 95% longevity of 18 years for fixed-rate pacemakers and 95% longevity of 14 years for demand pacemakers. The HMC pacemakers are not yet in production, and these projections of longevity appear to be calculated from the investigational rechargeable pacemakers discussed in Sect. 4.2.4 and from the electrical capacity of the lithium batteries.

Notwithstanding their calculations of electrical capacity, the absence of any experienced or postulated sudden-failure mechanism and zero failure of these batteries in clinical use (begun in March 1972), Greatbatch does not make any statistical claim beyond six years for their batteries (comment WG-A128). They believe[20] that six years is a conservative estimate based on sound statistical evaluation of documented performance and that other projections of longer performance are based on theoretical extrapolations of chemical capacity that do not take into account the possibility of packaging failures that may occur and have typically occurred in other chemical batteries.

ARCO Medical Products Company's model Li-2 pacemaker uses two lithium inorganic batteries connected electrically in a parallel fashion. ARCO claims[14] that the projected longevity of this pacemaker is about ten years, based on accelerated tests of the lithium batteries over a two-year period. They state that the actual longevity, however, remains to be proven since lithium pacemakers have only been in use for about three years.

4.2.4 Rechargeable pacemakers

A rechargeable pacemaker was first implanted in Sweden in 1958. Others were implanted in England, the United States, and Japan, but all of these early rechargeable cells, which used a commercially available nickel-cadmium cell, failed in a comparatively short time, because of a decrease in energy storage capacity when the cells are operated at body temperature.[21]

Work has been under way since 1967 at the Johns Hopkins University Applied Physics Laboratory and School of Medicine, and since 1969 at Pacesetter Systems, Inc., to develop a rechargeable pacemaker that will not require replacement during the patient's lifetime.[21] This pacemaker uses a hermetically sealed nickel-cadmium cell of the type developed for space applications.

The Pacesetter Systems, Inc. (PSI) pacemakers, using the rechargeable nickel-cadmium cells developed at Johns Hopkins University (JHU), have been implanted in patients since February 1973, and, through December 1974, they report 1000 clinical implants with only one known malfunction (due to a transistor that was not part of the rechargeable power system).

The capacity of the nickel-cadmium cell is sufficient to operate the pacemaker for six weeks without recharge. The normal regimen for recharge is for the patient to recharge his own unit at weekly intervals for 90 min, using a recharger that attaches to a Velcro vest worn over the patient's chest. Some patients are recharging their pacemakers at monthly intervals using a correspondingly increased charging time.

Information furnished by PSI[22] claims that their battery has a projected reliability of 95.5% at 30 years, with a confidence estimate of 60%. The pacemakers containing this battery are claimed to have a projected 30-year reliability of 91.5% with a mean time to failure (MTTF) of 71 or 74 years (depending on the model).

One of the comments (HNBH-A39) states that there is a "memory" effect problem related to nickel-cadmium batteries that could prove to be troublesome. Low discharge rates cause crystalline growth in the cadmium electrode, thereby decreasing its effective surface area and making the battery progressively more difficult to charge. Elevated temperature tends to increase the severity of this effect. To allevaite this problem, the battery must be periodically discharged at a high rate, which is difficult, if not impossible, with an implanted pacemaker. This comment also states that, while this effect may or may not prove to be a difficulty with the nickel-cadmium batteries presently being used in pacemakers, it indicates that present judgment on the lifetime of this power system may be premature. PSI[21] states that this effect has not appeared in more than five years of intensive cycling and testing of PSI cells.

The January 1975 draft of this Environmental Statement stated (Sect. 4.2.3.2) "It has been reported that *some* elderly patients cannot be relied on to recharge their pacemakers and that physicians cannot, *in many cases*, burden such a patient with the responsibility of recharging his pacemaker" (emphasis added). This statement was not intended to indicate that the rechargeable pacemaker was not an acceptable and appropriate pacemaker for many patients; rather, it was intended to indicate that the rechargeable pacemaker was not acceptable to physicians to such a complete extent as to preclude the usefulness of, and need for, other pacemakers.

Two comments took strong issue with this statement of nonacceptability for some patients, and they state that the acceptance of the rechargeable pacemaker by the patients has been very favorable. However, these comments also acknowledge that there are some limits on the acceptance of the rechargeable pacemaker; this acknowledgment of such limits on acceptance is not in disagreement with the above quoted statement in the Draft Environmental Statement.

Alfred E. Mann (PSI-A109) stated:

> In challenging your presentation, I do not contradict the existence of the conviction by a large number of physicians that recharging is undesirable or unacceptable. There are a number of opinions underlying this feeling and it will be a matter of time, education, social and peer pressure, and patient demand before this argument will be put into proper perspective and cease to be a factor. In the meantime, one approach to eliminating the objection is the extension of time between charges and the reduction of the charging time. Significant progress is being made in both of these areas so that much of the opposition will ultimately be laid to rest. For example, in an extensive market survey of this subject some 75% of the physicians indicated that given a six-month recharging interval they would consider the system suitable for their entire patient population. This result compares to only 25% of the physicians who would consider our system for the majority of their patient population with the present regimen of weekly or monthly recharging.

In a paper enclosed with comment JH-A57, the Johns Hopkins University stated, as disadvantages associated with the rechargeable pacemaker, "Patients who are mentally unfit and who have no assistance from others are not suitable candidates for this system," and "The mental state of a small minority of patients may be such that, even though they are able to perform the charging function, they might resent the comparatively short time each week that is required for that purpose."

In the responses to the questionnaire on the need for, and choice of, long-lived pacemakers, *some, but not all,* of the responding physicians indicated that the rechargeable pacemaker was not acceptable for *some, but not all,* patients. Various comments were made on the reasons for such unacceptability, including dependence on patient and family for recharging, the constant reminder of dependence on pacemaker, patient reluctance, patient inconvenience, brevity of the recharge interval, and incomplete rehabilitation of the patient.

Notwithstanding the comment that present judgment on the lifetime of this power system may be premature, it is accepted for purposes of this Environmental Statement that the rechargeable nickel-cadmium pacemaker can essentially provide lifetime pacing for the patients for whom it is selected. Nevertheless, by the acknowledgment of the developer and manufacturer of this pacemaker power source, it is not acceptable to all physicians and all patients; thus, the need exists for other long-lived pacemakers in addition to the rechargeable nickel-cadmium pacemakers.

It would be inappropriate to restrict a physician's decision on choice of pacemakers by the arbitrary limitation of alternatives such as would occur if nuclear or rechargeable pacemakers were denied to the medical community without adequate cause or basis.

Dr. G. Frank Tyers of the Milton S. Hershey Medical Center, Pennsylvania State University, reports[19] that 12 hermetically sealed pacemakers developed at Pennsylvania State University with rechargeable silver-mercury-zinc cells have been tested in animals and clinically for over two years. Longevity estimates, based on rapidly accelerated tests of batteries, which simulated 200 years of pacing; modestly accelerated tests, which simulated over 50 years of pacing; and real-time tests, which continue after 6 to 7 years without failure; indicate a pacemaker longevity greater than 20 years with 95% reliability. Dr. Tyers provided additional information in a telephone conversation with an NRC staff member on September 11, 1975. The mean time to run-down, without recharging, of thirteen test units was 4.8 years, and the recharge interval is not critical. Of the four units now in patients, two are recharging daily for 2-1/2 min per day, one is recharging weekly for 20 min, and one has not recharged for a year and is deferring recharge until needed. Of the eight units being tested in dogs, three are being recharged weekly, three monthly, one every six months, and one is not being recharged until the battery is discharged. This rechargeable pacemaker is not yet commercially produced or available for clinical use; however, if a reliable rechargeable pacemaker with a long recharge interval becomes available for routine use, it may well be chosen by physicians for many patients.

4.3 RESULTS OF CLINICAL INVESTIGATIONS OF NUCLEAR PACEMAKERS

From July 18, 1972, to November 5, 1975, 389 Medtronic Model 9000 plutonium-powered pacemakers were implanted in patients in the United States. Medtronic has reported[23] that as of November 5, 1975, these pacemakers had accumulated 7188 device-months of use. One pacemaker failed after 12 months of service, at which time there were 2504 accumulated device-months of use. The failure resulted from a void in the plastic potting material, which allowed body fluids to enter the pacemaker around the output tab and to corrode the tab. The device failure was not related to the plutonium power source, and quality assurance procedures have been revised to prevent recurrence of this mode of electrical failure.

ARCO Nuclear Company has reported (enclosure A of ref. 19) the implantation of 91 Model NU-5 plutonium-powered pacemakers since April 1973. As of October 1975, these pacemakers have accumulated 1598 device-months of use. Two of these pacemakers failed after 166 and 303 days in service, respectively, because of an increase in rate to approximately 90 pulses per minute, due to delamination of a capacitor. ARCO has corrected this problem by using a capacitor that has foils made from a special alloy of gold, platinum, and palladium to preclude delamination.

During the period from Sept. 1, 1974 to Oct. 20, 1975, 92 Coratomic Model C-100 demand pacemakers were implanted. This pacemaker was designed to be insensitive to electromagnetic interference and to electrical signals from skeletal muscle contractions; however, this design caused a problem in that the pacemaker failed to sense the r-wave of natural heartbeats when the r-wave had an unusually low amplitude and long duration. Seven of these pacemakers have been removed from patients because of this sensing problem, and Coratomic has discontinued the distribution of this model. All of the removed pacemakers have been returned to Coratomic, Inc., and are still (December 1975) performing to design specifications, with no component failures.

This model failed to meet the reliability requirements for possible routine use because of a design-judgment error rather than because of electronic or mechanical failure of the pacemaker or its components. The remaining pacemakers implanted in this series are continuing to be followed under the investigational protocol.

Coratomic, Inc., is now distributing Model C-101 pacemakers, which have a revised sensing circuit that overcomes the sensing problem but are otherwise identical to the Model C-100. Twenty-five Model C-101 pacemakers have been implanted with an accumulated experience, as of December 19, 1975, of 42 pacemaker-months, with zero explantations or failures. The investigation of this model continues, but the number and duration of implants to date is insufficient for statistical analysis.

The reported clinical data on the Medtronic Model 9000 and the ARCO Nuclear Model NU-5 pacemakers have been evaluated by the statistical method described in Sect. 2.4 and Appendix E to determine their reliability. The performance standard adopted for these devices specifies that testing must demonstrate, in not more than 25,000 device-months of experience and with 90% confidence, that the random failure rate is not more than 0.15% per month, which is the norm random failure rate of conventional pacemakers (Sects. 2.4 and 4.1 and refs. 1-3).

On the basis of one failure in over 7000 device-months for the Medtronic Model 9000 pacemakers (an observed failure of 0.02% per month), it is statistically demonstrated with 90% confidence that the failure rate is no more than 0.15% per month. Medtronic has also reported[23] that more than 700 Model 9000 pacemakers implanted in Europe have accumulated 13,000 device-months of effective experience: there has been one pulse generator malfunction due to a random failure of an electronic component. The European data are consistent with the results from the U.S. clinical tests. By combining data from all Medtronic Model 9000 units implanted worldwide, a random failure rate of 0.03% per month, with a 95% confidence, is calculated.

The 1598 pacemaker-months of clinical experience, with two failures, of the ARCO Nuclear Model NU-5 pacemaker are not sufficient to demonstrate with 90% confidence whether this pacemaker will achieve a failure rate of no more than 0.15% per month. The clinical investigation of this pacemaker is continuing.

Since the plutonium battery, with an isotopic half-life of 87 years, has such a high theoretical life expectancy (greater than 20 years), it should function as a nondepleting power source for many years following implantation. As long as no systematic failure or wearout mode occurs, the cumulative probability of generator failure will be solely dependent upon random component failures. No systematic failure or wearout mode has occurred, and experience with thermoelectric conversion of nuclear decay heat to electrical power in the space nuclear systems and Navy underwater power systems programs has demonstrated that this type of power source can function for periods in excess of ten years. These other power sources have power levels many times higher than the power levels of pacemaker batteries.

4.4 MEDICAL CONSIDERATIONS

Implantation of pacemakers for treatment of various types of cardiac arrhythmias is a widely accepted medical procedure. Because the procedure is relatively new (about 17 years old), surgical techniques and pacemaker hardware are continually evolving. Ideally, this evolution will make available a pacemaker that will function with minimal maintenance and follow-up requirements for the remainder of the patient's life. Achievement of this ideal depends on the medical requirements of pacemaker patients and on developing the technology of pacing systems.

4.4.1 The patients

Permanent cardiac pacemakers were implanted, initially, in patients with indications of complete atrioventricular heart block (lack of coordination between atrial and ventricular contractions). Although heart block (complete, incomplete, and intermittent) remains to be the major medical indication for pacemaker implantation, physicians have recognized the utility of cardiac pacemakers in the treatment of other types of cardiac conduction disturbances (e.g., sino-atrial blocks, bundle branch blocks, various arrhythmias).[5,24-26] A detailed analysis of the indications for pacemaker implantation in a study of 579 patients is available to the interested reader.[26]

Approximately 120,000 persons underwent primary pacemaker implantation between 1958 and 1972 (an average of about 8600 per year), and about 90,000 of these persons were estimated to be alive in 1974.[24] The current (1975) annual rate of primary implantation is unknown, but likely exceeds the older average because of increased diagnostic awareness and the diversity of indications for pacing.

The age distribution of pacemaker patients differs from that of the general population of the United States. Table 4.1 gives typical age distributions for pacemaker patients. The first distribution (column 2) is based on a study of 1989 patients[27] and is typical of age distributions reported up to 1973.[28-30] A trend toward a younger age distribution is developing[31] and is evidenced by a recent, less comprehensive (579) patient study (column 3).[26] A breakdown of the patients, in the more recent study, according to the type of power source used shows that nuclear-powered pacemaker patients (column 5) generally have been younger than patients with chemically powered pacemakers (column 4). However, this may be artificial due to the restrictions of the investigational research protocols.

Many pacemaker patients are expected to lead relatively normal lives; that is, to engage in activities normally carried out by persons their age and to have the normal longevity patterns of their age group (refs. 4, 5, 10, and 30-34).

4.4.2 Pacemaker systems

A pacemaker system consists of three components: the power supply (battery), the electronics, and the leads. Each component is important because it may determine how well the entire system functions and may limit the useful life of the system. Battery systems were discussed in Sects. 4.1, 4.2, and 4.3.

4.4.2.1 Electronics

The electronic components of a pacemaker are encapsulated with the battery in a pulse generator. Several types of pulse generator electronic circuits are in use. Asynchronous (fixed rate) generators have a stimulating circuit that delivers electrical pulses only at a constant rate to stimulate the heart. Demand pacemakers sense natural contractions of the heart and either inhibit the pacing pulse or deliver the pacing pulse in appropriate synchronization when a natural pulse occurs. When a natural pacing pulse does not occur, the demand pacemaker delivers a pacing pulse at a preset rate. The most common type of demand pacemaker senses natural ventricular contractions and inhibits the pacing pulses. Other types of demand pacemakers sense atrial contraction and deliver triggered ventricular pulses. Most pulse generators are the demand type and are noncompetitive.[24] Descriptions of available pulse generator functions are available in the literature.[24] Additional useful functions are being developed, but their successful application will depend on the capacity of available batteries. As the sensing and stimulating functions of a pulse generator are increased, the power drain on the battery increases. Power drain is a limiting factor for the life of chemically powered batteries but is not limiting for nuclear-powered batteries and may not be limiting for rechargeable units.[24,31]

Table 4.1. Age distribution of pacemaker patient population

Age group, years	Percentage of total population 1963-72[a]	Percentage of total population 1972-75[b]	1972-75 patients[b] by power source, % Chemical	1972-75 patients[b] by power source, % Nuclear
1-10	0.5	0.7	1.2	0.3
11-20	0.5	2.8	0.8	4.3
21-30	0.5	6.7	1.2	11.1
31-40	0.7	6.0	1.6	9.6
41-50	3.1	13.1	3.1	21.0
51-60	8.9	25.6	14.1	34.6
61-70	31.1	21.4	27.4	16.7
71-80	39.1	15.9	33.3	2.1
81-90	15.0	6.7	14.9	0.3
91-up	0.6	1.0	2.4	0.0
Average age, years	66.8	57.6	69.0	48.7

[a]Source: Medtronic, Inc., *Benefits Resulting from the Use of the Isotopic Pulse Generator*, December 17, 1973, with enclosure, "Long-Term Survival of the Bearers of Cardiac Stimulators," by Marie-Francoise LeFebvre, Attachee au Centre Hospitalier Regional de Lille, January 1963-July 1972. Includes 1989 patients.

[b]Source: Medtronic, Inc., *Medtronic™ Implantable Demand Isotopic Pulse Generator, Laurens-Alcatel Model 9000, Fourth Semi-Annual Clinical Evaluation Report to the United States Nuclear Regulatory Commission*, May 24, 1975. Includes 573 patients; 324 nuclear and 255 chemical.

4.4.2.2 Leads

Several comments on the draft Environmental Statement have expressed the belief that lead life would limit the useful system life of pacemakers. Two factors that are important to the consideration of the influence of lead problems on the useful life of pacemaker systems are the history of lead development and the causes of lead problems.[35]

Until recently, leads were not considered to be limiting factors on pacemaker system life. The major limiting factor was chemical battery depletion. As a result, special attention was not given to the development of long-lived leads. Steady improvements in lead reliability have occurred since 1965, and continued improvements can be expected as availability of longer-lived pulse generators is realized. A pacemaker patient follow-up clinic has observed that lead failures in their patients were the cause of 16% of the pacemaker replacements in 1967, 8% in 1968, 3.3% in 1969, and 5.7% in 1970.[7]

Lead problems are frequently reported to be the cause of complications in pacemaker patients.[36,37] Most of the problems are not caused by the leads themselves, but by the techniques of lead insertion and attachment (Sect. 4.4.3). Problems attributable solely to the leads are largely restricted to fracture of the lead or loss of insulation.

A recent survey of lead fracture experience[38] shows that 1.9% of 2361 leads have fractured. The average use time of these leads varied between 24 and 40 months, with the longest use times between 70 and 146 months. (Use time is the reported duration of use, not the time to failure.) Annual lead fracture rates were between 0.15 and 3.2% per year.

An analysis[38] of lead fracture data from detailed clinical follow-up of 579 pacemakers implanted by 109 physicians between July 8, 1972, and May 12, 1975,[26] shows that 7 (1.3%) of 553 leads fractured. The annual rate of fracture was about 0.5%, and cumulative lead failure estimates indicate that about 80% of the leads would be functional after 10 years of use.[38]

4.4.3 Surgical factors

Physicians consider the surgical procedures used to implant cardiac pacemakers to be simple and relatively free of risk. However, any surgical procedure, no matter how simple, may have unexpected consequences such as medical complications and even death.[39]

Patient mortality rates from surgical pacemaker-implantation procedures, including early postoperative follow-up, of 1 to 4% have been reported (refs. 4, 28-29, 32, and 39-40). A recent survey of physicians (Appendix G) indicates an expected mortality rate of approximately 0% for routine reimplantation procedures.

Complications do occur, and historical data on complications are summarized in Table 4.2; no attempt was made to distinguish between abdominal and pectoral implantation or between methods of lead insertion. These reported values reflect a wide variation in clinical experience.

Since the definition of a complication varies among physicians, the reported values are meaningful only in that they demonstrate the occurrence of complications and indicate their frequency of occurrence. The complications mentioned in the literature vary in severity from those requiring little, if any, treatment to those requiring a reimplant procedure. Some complications have resulted in mortality. Most physicians, in responding to the recent survey (question No. 12, Appendix G), indicated morbidity rates between 1 and 5%.

4.5 COSTS

Both societal and private (to patients and their families) costs are incurred from the use of plutonium-powered pacemakers. The potential societal costs, which arise largely from the presence of plutonium-238 in the pacemakers, are discussed assuming (1) that 10,000 pacemakers will be in use at all times and (2) that 1500 pacemakers will be implanted per year (Sect. 3.7.1).

4.5.1 Radiological

Potential radiation doses to the whole body of a patient (Sect. 3.2) are estimated to be between 0.52 and 0.77 rem for five years of use and between 2.6 and 3.8 rems for 20 years. Doses to the gonads vary from 0.13 to 1.6 rems over five years and .62 to 7.7 rems over 20 years. Patients who receive these doses would have freely chosen to do so in anticipation of benefits received from use of a plutonium-powered pacemaker. This is a private choice and would result in little, if any, somatic health risk to the patient. If all potential patients of reproductive age wore a pacemaker for 20 years prior to reproduction, an increase in genetic deficiencies (a societal cost) by no more than 0.2% over naturally occurring deficiencies is predicted to occur in their children.

Potential annual population doses to groups of persons from pacemakers implanted in patients were discussed in Sect. 3.3.

Disposal requirements for explanted pacemakers would involve additional costs. Records would be kept of each pacemaker from the time of manufacture until the time of disposal (Sect. 3.11). If a centralized records-keeping system were implemented, it is estimated to cost about $100,000 per year or $10 per year per pacemaker. This cost would be included in the purchase price of the pacemaker. The costs of recovery and disposal of pacemakers, offset by values for reuse and recycle of pacemakers of their components, would also be reflected in the purchase price (Sect. 3.12).

Environmental contamination could occur if the fuel capsule of a pacemaker is breached. The extent and the cost of such a breach is highly site-specific and is discussed in Sect. 3.7.

Although not discussed explicitly, alternative batteries may also produce societal costs that are qualitatively similar to those considered for plutonium-powered pacemakers. For example, some of the materials used are chemically toxic elements, as indicated by suggested maximum ambient environmental levels given in Table 4.3.[41]

Table 4.2. Summary of data on complications resulting from pacemaker reimplantation

Complication	Patients affected, %
Infection	2.6,[a] 12.2,[b] 0-20,[c] 2.4,[d] 10.5,[e] 10,[f] 0.15,[g] 5.5[h]
Hematoma, bleeding	1.0,[a] 4.1,[b] 1.5,[i] 4.2[j]
Extrusion of pacemaker, skin erosion, etc.	0.9,[a] 2.0,[b] 14.1,[f] 0.3,[g] 0.7,[i] 2.4,[j] 16,[k] 5.5[l]
Malposition or component movement	2.0,[b] 11.5,[e] 3.0,[g] 1.5,[i] 6.3[m]
Sensing problems - threshold, competition, etc.	2.2,[a] 8.2,[b] 3,[c] 6,[f] 1.1,[i] 17,[j] 6,[l] 10.9,[m] 1.7,[n] 4.3[g]
Miscellaneous	10.4,[a] 0.3,[c] 10.4,[h] 4.8,[i] 3.6,[j] 1.6,[m] 12.9[n]
Electrode related (excluding fracture)	
Displacement	2.2,[a] 16.3,[b] 3.3,[c] 8,[f] 3.7,[i] 19,[k] 1.5[l]
Ventricular perforation	0.9,[a] 0.7,[i] 1.2,[j] 9,[k] 6.3[m]
Extrusion	0.3,[a] 10.2,[b] 0[g]

References:

[a]Medtronic, Inc., *Medtronic™ Implantable Demand Isotopic Pulse Generator, Laurens-Alcatel Model 9000, Fourth Semi-Annual Clinical Evaluation Report to the United States Nuclear Regulatory Commission,* May 24, 1975, attachment to letter from T. Stewart and B. Griffin, Medtronic, Inc., to J. R. Mason, NRC, September 25, 1975.

[b]M. V. Inberg et al., "Permanent Endocardial Pacing," *Acta Med. Scand.* 189: 87-91 (1971).

[c]G. A. Geruglio, "La Stimolazione Endocardica Permanente in Italia: Risultati Clinici Nei Primi 2,324 Cosi Trattati," *Giorn. Ital. Cardiol.* 2: 271-82 (1972).

[d]Medtronic, Inc., "Benefits Resulting from the Use of the Isotopic Pulse Generator," December 17, 1973, with enclosure, "Long-Term Survival of the Bearers of Cardiac Stimulators," by Marie-Francoise Le Febure, Attachée au Centre Hospitalier Regional de Lille, January 1963-July 1972.

[e]G. Green et al., "Pacemaker Lifetimes-A Review and Definitions," *Amer. Heart J.* 80: 414-421 (1970).

[f]E. Sowton, G. Hendrix, and P. Roy, "Ten-Year Survey of Treatment with Implanted Cardiac Pacemaker," *Brit. Med. J.* 3: 155-160 (1974).

[g]E. F. Conklin, G. Giannelli, and T. F. Nealon, Jr., "Four Hundred Consecutive Patients with Permanent Transvenous Pacemakers," *J. Thorac. Cardiov. Surg.* 69: 1-7 (1975).

[h]B. S. Golman et al., "Critical Analysis of Pulse Generator Replacement," *Ann. Thorac. Surg.* 2: 156-163 (1974).

[i]M. G. Seremetis et al., "Cardiac Pacemakers," *Amer. Heart J.* 85: 739-748 (1973).

[j]F. L. Grove, M. J. O'Sullivan, and R. G. Fosbring, "Demand on Fixed-Rate Pacemakers?" *J. Thorac. Cardiov. Surg.* 67: 142-147 (1974).

[k]A. M. Imparato and G. E. Kim, "Electrode Complications in Patients with Permanent Cardiac Pacemakers," *Arch. Surg.* 105: 705-710 (1972).

[l]V. Parsonnet, "Power Sources for Implantable Cardiac Pacemakers," *Chest* 61: 165-173 (1972).

[m]D. R. McConahay et al., "Clinical Experience with Permanent Demand Pacers," *Mayo Clin. Proc.* 46: 44-47 (1971).

[n]S. Specht and W. Weinlander, "Statistical Methods for the Determination of Pu-238--Demand for Medical Application," pp. 171-184.

4.5.2 Medical

Selection of a pacemaker for a patient should be based on the patient's needs and the physician's judgment with respect to the optimum pacemaker required to fill those needs. Factors that will influence the selection process include the patient's physical condition, expected longevity, and mental attitude. The price of a pacemaker and its implantation are not usually the determining factors in the selection of a pacemaker. However, estimates of these costs are presented.

Monetary costs arise from the price of the pacemaker, surgical procedures, hospital and medical costs, complications, and loss of work (income to the patient and productivity to society). Table 4.3 summarizes these estimated costs. Pacemaker costs are based on 1975 prices. Surgical and medical costs are based on those supplied by physicians. Hospital costs are based on the average per diem charges as reported from almost 6000 hospitals.[31] Costs associated with complications are based on the assumptions that 2.5% of all implant procedures will be followed by complications, which will require an average of five days of additional hospitalization, and that 5% of the patients will require additional surgery (at $425 per occurrence). Loss-of-work costs are associated with the length of hospitalization (5 to 10 days for surgery and 1.5 days for complications) and outpatient recovery (14 days). The time loss from work can be adjusted to a five-day work week using an average income of $60 per day (based on an annual income of $15,000) for patients in the work force; however, many patients will be retired.

Previous considerations (Sects. 4.2 to 4.4) indicate that rechargeable and nuclear pacemakers may have comparable lifetimes (20 years or more). At current prices, rechargeable battery-powered pacemakers have an initial monetary cost advantage of about $3000. This is somewhat offset by the need for medical supervision and, frequently, the use of telephone monitoring of recharging.

4.6 BENEFITS

Plutonium-powered pacemakers fill the need for a long-lived pacemaker by providing physicians with a unit that is capable of long-term maintenance-free pacing of cardiac patients whose life expectancy exceeds the useful lifetime of chemical batteries and for whom the recharging regimen of rechargeable pacemakers is unacceptable. Benefits to the patients from long-lived pacemakers are derived from the elimination or reduction of the need for surgical implantation of replacement units because of pacemaker battery wearout. Avoidance of replacement operations eliminates or reduces the following:

(a) Exposure of patient to repeated surgery and hospitalization.
(b) Pain and suffering (associated with surgery) of the patient.
(c) Complications to patients. The severity and frequency of complications increase with repeated implantations since a reopened "pocket" has more problems with scar tissue, wound healing, infection, inflammation, etc.
(d) Damage to pacemaker leads. The manipulation of leads during their removal from worn-out pacemakers and attachment to replacement units increases the likelihood of lead fracture or damage.

In addition to the benefits derived from the avoidance of risks associated with pacemaker replacement operations, an additional important benefit of long-lived pacemakers is the avoidance by the patient of the anxiety associated with the anticipation or contemplation of pacemaker wearout and replacement surgery.

In the questionnaire to physicians, they were requested to reply to the question *"What is the value to the patient to avoid or extend the interval between pacemaker replacements?"* One physician (respondent 104, Appendix G) replied as follows:

Table 4.3. Monetary costs associated with pacemaker implantation

Item	Cost, Dollars	Bases
Pacemaker		
Long-lived (>10 years)		
Plutonium	5000	1975 cost
Rechargeable	2000	" "
Medium-lived (8-10 years)	1500	" "
Short-lived (4-6 years)	1000	" "
Initial Implant		
Surgery	850	Physician responses
Hospital	1270	Average cost per day in ~6000 hospitals, 10 days in hospital
Medical	270	Physician responses
Complications	20	Occur in 2.5% of cases, require 5 days in hospital, 5% require additional surgery
Loss of work	1080	18 days at $60 per day
Total	3490	
Reimplant		
Surgery	425	Physician responses
Hospital	635	5 day hospitalization
Medical	270	Physician responses
Complications	20	As above
Loss of work	780	13 days at $60 per day
Total	2130	

"The value to the patient of avoiding or extending the interval between pacemaker replacements is almost incalculable. While the operation is a small one and a safe one, it is surgically inappropriate. It is the nature of a surgical procedure that it be definitive and hopefully provide a cure. The concept of a patient returning repeatedly for repetition of the same surgical procedure is not readily acceptable either to the patient or the surgeon. Apart from the inconvenience and the discomfort and the cost to the patient there is a real psychological factor involved. Patients are unusually and unexpectedly reluctant to undergo these small repeated operations and all of them in my experience would welcome a single procedure and a life-time pacemaker. I think it is fair to say that this is the overpowering concern, namely the avoidance of repeated operations, of any patient who has a permanent pacemaker."

The satisfaction and sense of "well-being" of patients with implanted plutonium-powered pacemakers was expressed in several of their letters to the NRC (see Appendix A) in response to the DES.

Another benefit from the use of plutonium-powered pacemakers is their impact on pacemaker technology. Since nuclear decay is a predictable physical process, nuclear batteries are not subject to chemical anomalies, and power output is not drain-limited during their useful lifetime. New or additional pacemaker functions, which may require higher power drains, could be more readily incorporated into a unit with a nuclear battery than in a unit with a chemical

battery. Such additional functions may also be accommodated by rechargeable batteries but, currently, would most likely shorten the interval between recharges or lengthen the recharge period.

Rechargeable chemical batteries require a continual recharging regimen but may provide a long service life. However, some physicians (Sect. 4.2 and Appendix G) consider the recharging regimen to be unsatisfactory for some patients because of physical, psychological, or emotional factors. These factors are very real to these patients, and, therefore, rechargeable pacemakers are not considered to be acceptable or suitable for all patients that need long-lived pacemakers. Plutonium-powered pacemakers can meet the needs of such patients. Thus, the availability of all types of long-lived pacemakers would permit physicians to choose the system that is best suited to their patients' needs.

4.7 COST-BENEFIT ANALYSIS

Direct monetary costs are only associated with purchase prices of pacemaker units, medical charges for implantations (and replacement implants), and costs incurred for the environmental cleanup of any released power-source materials. In a cost-benefit analysis, the cost advantage of any one pacemaker model is derived by comparing it, over a period of time, with the alternatives.

A cost-benefit determination for plutonium-powered pacemakers is derived from the elimination or reduction of the need for surgical implantation of replacement units because of battery wearout. Currently, plutonium-powered pacemakers have a higher initial price than nonnuclear alternatives; however, this price is partially or completely offset when one or more replacement implants of alternative pacemakers becomes necessary. For example, the cost accrued after a replacement implant of a medium-lived pacemaker [$1500 + $3490 + $1500 + $2130 = $8620 (from Table 4.4, Sect. 4.6)] exceeds (even neglecting inflation) the cost of initial implantation of a plutonium-powered pacemaker ($5000 + $3490 = $8490). The additional costs incurred due to postulated environmental contamination, about $2 per pacemaker (Sect. 3.10), are of minor importance when compared with the cost of the initial implantation of a plutonium-powered pacemaker.

4.8 SUMMARY

Benefits, costs, and safety and reliability requirements associated with the routine use of plutonium-powered pacemakers, which are identified and discussed throughout this Statement, are listed in Tables 4.4-4.6 and, where possible, are quantified. Sections containing discussions of each item are indicated.

Plutonium-powered pacemakers will broaden the basis for the physician's selection of the proper medical treatment of pacemaker patients by offering them a maintenance-free lifetime unit. There are alternative pacemakers available with various performance characteristics; however, these alternatives are not always preferred or acceptable and do not always offer the best treatment of a patient. The decision is necessarily the choice of the physician. Plutonium-powered pacemakers are acceptable to the medical community, as evidenced by physicians' comments on the draft Environmental Statement (Appendix A) and their responses to the physicians questionnaire (Appendix G). These physicians, for the most part, considered the plutonium pacemakers' higher initial cost to be the most serious disadvantage. However, in the selection or prescription of a medical treatment, when life and health are at stake, monetary costs are not necessarily a limiting factor, and the lowest cost alternative is not necessarily chosen or required nor does it necessarily offer the best treatment.

An advantage of using plutonium-powered batteries in some types of pacemakers is that power drain requirements of the pacemaker's electronics is not a limiting factor on the life of the unit, as it is with chemical-battery-powered pacemakers. The electrical sensing and stimulating functions of the pacemakers can be increased or additional functions added, as is desirable for some patients without sacrificing the service life (or decreasing the interval between recharges) of the unit.

Plutonium-powered pacemakers are, by statutory authority, regulated by the Nuclear Regulatory Commission because they contain special nuclear material. It is only after a satisfactory appraisal of safety and performance considerations that the Commission would allow them to be available for routine medical use by appropriately licensed and qualified physicians. An evaluation of the cumulative experience with plutonium-powered pacemakers, from the investigational programs, indicates satisfactory performance capabilities.

Table 4.4. Summary of safety and reliability requirements

Requirement	Section reference
The nuclear-powered pacemaker is the only type of pacemaker that is required by the Federal government to be designed and tested to standards that assure that the material contained in its power supply will not be released to the environment under conditions of normal use or accidents involving a pacemaker patient.	2.2, 2.3
Medical institutions that implant nuclear-powered pacemakers and patients who are bearers of nuclear-powered pacemakers are required to comply with specified administrative procedures to assure that the pacemakers are accounted for and that they are recovered for controlled disposal upon the death of the patient or upon removal for any reason prior to death. For routine use, regulations and procedures for licensing will be developed to provide equivalent requirements for pacemaker accountability, recovery, and disposal.	2.3, 2.5
Procedures have been developed, based on statistical techniques, for evaluating the reliability of nuclear-powered pacemakers using information obtained from the investigational programs. Any pacemaker model being evaluated in an investigational program or any new model introduced will be required to demonstrate acceptable performance before its routine use will be authorized.	2.4

Table 4.5. Summary of benefits associated with the routine use of plutonium-powered pacemakers

Benefit	Section reference
Plutonium-powered pacemakers have sufficient longevity to eliminate the need for surgical replacement operations that are necessitated by depletion of chemical batteries. The avoidance of such replacement operations eliminates or reduces: i. repeated hospitalization of the patients; ii. patient pain and suffering that is associated with surgery; iii. patient anxiety associated with anticipated pacemaker wearout and replacement surgery; iv. complications that can develop after surgery, and v. damage to pacemaker leads that can result from manipulation during surgery.	3.7.1, 4.5, and 4.6
Plutonium-powered pacemakers can provide long-term maintenance-free pacing to patients for whom the rechargeable pacemakers are physically and/or psychologically unacceptable.	4.6
Plutonium-powered pacemakers will provide physicians with an alternative choice of medical treatment for patients who require long-term pacing	4.6
The use of plutonium power sources will have a positive impact on pacemaker technology. New or additional pacemaker functions that have high power drain requirements can be more readily accommodated by plutonium-powered batteries without significantly reducing battery life. Such additional functions may also be accommodated by rechargeable batteries, but, currently, would most likely shorten the interval between recharges or lengthen the recharge period.	4.4, 4.6

Table 4.6. Summary of environmental impacts associated with the routine use of plutonium-powered pacemakers

Impacts assuming 10,000 implanted cardiac pacemakers with plutonium batteries		Section reference
Potential radiation doses to man from routine use, man-rems/year		
Patients	1,650	3.2.1, 4.5
Spouses	42	3.3, 4.5
Members of patients' households	12	3.3, 4.5
Associates of patients	25	3.3, 4.5
Remainder of population	49	3.3, 4.5
Postulated accidents	15	3.7
Environmental contamination clean-up cost, $/occurrence	20,000	3.10

Since no restrictions will be placed on the movement of plutonium pacemaker patients, rigorous design criteria are imposed on the fabrication of the fuel capsules to ensure fuel capsule integrity under all credible accident conditions. However, for redundant protection in the unlikely event that a fuel capsule would be ruptured, additional restrictions are placed on fuel form to mitigate any radiological impact on the environment.

A comprehensive risk assessment was performed to determine the environmental impact of routine use of plutonium-powered pacemakers, and it was concluded that the radiation risk from these pacemakers would result in an insignificant additional radiation exposure to the public. These radiation risks are so small that, even if the benefits are less than expected, the routine use of plutonium-powered pacemakers is still justified.

The benefits to patients of avoiding or extending the interval between pacemaker replacements is almost incalculable. It is the nature of a surgical procedure that it should be definitive and, hopefully, provide a cure. Apart from the inconvenience, discomfort, and cost to the patient, there is a real psychological factor involved. Patients are usually and expectedly reluctant to undergo repeated operations, and all of them would welcome a single procedure and a lifetime pacemaker. Both the rechargeable and plutonium-powered pacemakers have the potential of offering a patient lifetime service, but the treatment of pacemaker patients with the rechargeable unit is considered by some physicians to be "incomplete rehabilitation" of the patient, due to the necessity of and dependence on periodic recharging of the unit.

Since pacemakers are chosen to best meet the medical needs of each individual patient, all of the different types of pacemakers are needed. In view of the regulatory requirements on nuclear pacemakers, which do not apply to other pacemakers and the higher initial cost of nuclear pacemakers, it is not likely that nuclear pacemakers will be used frivolously or that they will be selected for use by physicians or patients except in those cases in which the longer maintenance-free service lives of the nuclear pacemakers offer a significant advantage in the medical care of the patient.

REFERENCES FOR SECTION 4

1. Medtronic, Inc., *Medtronic Laurens-Alcatel Model 9000 Pulse Generator Clinical Investigation Plan*, March 1973.

2. Medtronic, Inc., *Medtronic Product Performance Report*, MC 74551, September 1974.

3. Medtronic, Inc., *Implantable Demand Isotopic Pulse Generator, Third Semi-Annual Clinical Evaluation Report to the USAEC*, November 1974.

4. S. Furman et al., "Results of Long-Term Pacemaker Implantation," *Cardiac Arrhythmias*, D. Leonard and W. Litaff, Eds., Grune & Stratton, New York and London, 1973, p. 599.

5. V. Parsonnet, "A Decade of Permanent Pacing of the Heart," *Cardiovasc. Rev.* 2: 181 (1970).

6. V. Parsonnet et al., "Prediction of Impending Pacemaker Failure in a Pacemaker Clinic," *Amer. J. Cardiol.* 25: 311 (1970).

7. S. Furman et al., "The Pacemaker Follow-up Clinic," *Progress in Cardiovascular Disease*, vol. XIV, 1972, p. 515.

8. R. Rockland et al., "Failure Modes of American Pacemakers - In Vitro Analysis," *Amer. Heart J.* 83: 481 (1972).

9. Cardiac Datacorp Inc., "Analysis of the Data on 4,111 Pacemakers," Sept. 30, 1974, Attachment 1 to letter from T. S. Bustard, Hittman Nuclear Battery Corp., to NRC, April 2, 1975.

10. V. Parsonnet et al., "Clinical Experience with Nuclear Pacemakers," presented before the Society for Vascular Surgery, Boston, June 21, 1975, Attachment to Comment 60.

11. Wilson Greatbatch, "Chemical Power Supplies for Implanted Cardiac Pacemakers," Fourth International Symposium on Cardiac Pacing.

12. Medtronic, Inc., Brochure MC74460, 1974.

13. T. Stewart and B. Griffin, Medtronic, Inc., letter to J. R. Mason, NRC, Sept, 25, 1975 (Response to Pacemaker Manufacturer's Questionnaire).

14. S. A. Kolenik, ARCO Nuclear Co., letter to B. Singer, NRC, Aug. 4, 1975 (Response to Pacemaker Manufacturer's Questionnaire).

15. P. Damour, American Optical Corp., letter to B. Singer, NRC, Aug. 6, 1975 (Response to Pacemaker Manufacturer's Questionnaire).

15a. Peter M. Jacobson, Coratomics, Inc., letter to J. R. Mason, NRC, Oct. 6, 1975 (Response to Pacemaker Manufacturer's Questionnaire).

16. Wilson Greatbatch, Ltd., *Newsletter*, Apr. 1, 1975.

17. Wilson Greatbatch, Ltd., *Newsletter*, July 1, 1975.

18. M. Mosharrafa, Cardiac Pacemakers, Inc., letter to B. Singer, NRC, Aug. 12, 1975 (Response to Pacemaker Manufacturer's Questionnaire).

19. G. F. Tyers, Milton S. Hershey Medical Center, Pennsylvania State University, letter to B. Singer, NRC, Aug. 12, 1975 (Response to Pacemaker Manufacturer's Questionnaire).

19a. ARCO Medical Products Company, Technical Memorandum Report VII on the Status of the Clinical Studies of the Nuclear Pacemaker Model NU-5, Oct. 15, 1975.

20. Wilson Greatbatch, telephone communication with NRC staff member, Sept. 15, 1975.

21. R. E. Fischell, K. B. Lewis, and J. W. Love, "A Long-Lived, Reliable, Rechargeable Cardiac Pacemaker," presented at the International Symposium on Advances in Pacemaker Technology, Erlangen-Nuremberg, West Germany, September 26, 1974 (revised and updated Dec. 31, 1974), attachment to Comment 13.

22. A. E. Mann, Pacesetter Systems, Inc., letter to B. Singer, NRC, July 28, 1975 (Response to Pacemaker Manufacturer's Questionnaire).

23. Medtronic, Inc., *Medtronic™ Implantable Demand Isotopic Pulse Generator, Laurens-Alcatel Model 9000, Fifth Semi-Annual Clinical Evaluation Report to the United States Nuclear Regulatory Commission*, November 24, 1975.

24. V. Parsonnet, S. Furman, and N. P. D. Smyth, "Implantable Cardiac Pacemakers, Status Report and Resource Guideline," *Amer. J. Cardiol.* (1974).

25. E. Sowton and J. Flores, "Natural History of Pacemaker Patients," *Bull. N.Y. Acad. Med.* 47: 999-1010 (1971).

26. Medtronic, Inc., *Medtronic™ Implantable Demand Isotopic Pulse Generator, Laurens-Alcatel Model 9000, Fourth Semi-Annual Clinical Evaluation Report to the United States Nuclear Regulatory Commission*, May 24, 1975, attachment to letter from T. Stewart and B. Griffin, Medtronic, Inc., to J. R. Mason, NRC, September 25, 1975.

27. Medtronic, Inc., "Benefits Resulting from the Use of the Isotopic Pulse Generator," December 17, 1973, with enclosure, "Long-Term Survival of the Bearers of Cardiac Stimulators," by Marie-Francoise Le Febre, Attachée au Centre Hospitalier Regional de Lille, January 1963-July 1972.

28. M. V. Inberg et al., "Permanent Endocardial Pacing," *Acta Med. Scand.* 189: 87-91 (1971).

29. M. G. Seremetis et al., "Cardiac Pacemakers," *Amer. Heart J.* 85: 739-748 (1973).

30. S. Specht and W. Weinlander, "Statistical Methods for the Determination of Pu-238--Demand for Medical Application," pp. 171-184.

31. F. Hittman and T. S. Bustard, "Comments on the Nuclear Regulatory Commission Draft Generic Environmental Statement on the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers," enclosure with letter to B. Singer, NRC, August 21, 1975.

32. G. A. Geruglio, "La Stimolazione Endocardica Permanente in Italia: Risultati Clinici Nei Primi 2,324 Cosi Trattati," *Giorn. Ital. Cardiol.* 2: 271-82 (1972).

33. H. Thalen, "The Artificial Cardiac Pacemaker," *Amer. Heart J.* 81: 583-590 (1971).

34. D. M. Davidson et al., "Permanent Ventricular Pacing," *Ann. Intern. Med.* 77: 345-351 (1972).

35. V. Parsonnet, L. Gilbert, and I. R. Zucker, "The Natural History of Pacemakers Wires," *J. Thorac. Cardiov. Surg.* 65: 315 (1973).

36. A. S. Brenner et al., "Transvenous, Transmediastinal, and Transthoracic Ventricular Pacing: A Comparison After Complete Two-Year Follow-Up," *Circulation* 49: 407-414 (1974).

37. A. M. Imparato and G. E. Kim, "Electrode Complications in Patients with Permanent Cardiac Pacemakers," *Arch. Surg.* 105: 705-710 (1972).

38. T. Gibbons, "Longevity of Leads," memo to T. Stewart, Medtronic Inc., attachment to letter from T. Stewart and B. Griffin, Medtronic Inc., to J. R. Mason, NRC, September 25, 1975.

39. F. L. Grove, M. J. O'Sullivan, and R. G. Fosbring, "Demand or Fixed-Rate Pacemakers?" *J. Thorac. Cardiov. Surg.* 67: 142-147 (1974).

40. S. Furman, D. J. W. Escher, and B. Parker, "Pacemaker Longevity," *Amer. J. Cardiol.* 31: 111-113 (1973).

5. DISCUSSION OF THE COMMENTS RECEIVED ON THE DRAFT ENVIRONMENTAL STATEMENT

Pursuant to 10 CFR Part 51, Sect. 51.25, the *Draft Generic Environmental Statement on the Wide-scale Use of Plutonium Powered Cardiac Pacemakers* was transmitted with a request for comments to the following:

Council on Environmental Quality
Department of Commerce
Department of Health, Education, and Welfare
Department of Transportation
Environmental Protection Agency

This Statement has been sent, with an invitation for comments, to the Agreement States, companies in the nuclear industry, and the Association for Advancement of Medical Instrumentation. An announcement of the availability of the Statement and a copy of the summary and conclusions have been sent to the state clearinghouses. In addition, the NRC requested comments on the draft Environmental Statement from interested persons by a notice published in the *Federal Register* on January 16, 1975 (40 F.R. 2863), and the Council on Environmental Quality published a notice of availability of the draft Environmental Statement in the *Federal Register* on January 24, 1975 (40 F.R. 3799). Comments in response to these requests were received within the specified 45-day comment period from the following:

Sheldon Meyers, U.S. Environmental Protection Agency (EPA)
W. E. Caldwell, U.S. Coast Guard (USCG)
James W. Bibb, Department of Administration, State of Kansas (SOK)
Adriana Gianturco, Executive Office for Administration and Finance, The Commonwealth of Massachusetts (COM)
Joseph S. Golden, Office of Planning and Programming, State of Nebraska (SONB)
Don N. Strain, State Grant-In-Aid Clearinghouse, State of Oklahoma (SOO)
Harald H. Rossi, College of Physicians and Surgeons of Columbia University (HHR)
David L. Frank, Fresno Committee for Scientific Information (FCSI)
Karl Z. Morgan, Georgia Institute of Technology (KZM)
R. B. Kershner, Johns Hopkins Applied Physics Laboratory (JH)
Herman R. Levine (HRL)
Dean E. Abrahamson, University of Minnesota (UOMA)
Stephen R. Parchner (SRP)
Sidney M. Wolfe and John Abbotts, Public Citizen Health Research Group (PC)
Nicholas P. D. Smyth (NPDS)
L. Douglas DeNike, Zero Population Growth (ZPG)

Comments were received after the expiration of the comment period from:

Charles Custard, Department of Health, Education, and Welfare (HEW)
E. E. Maroney, Department of Administration, State of Florida (SOF)
Bruce D. Arkell, Office of the State Planning Coordinator, State of Nevada (SONV)
Terence P. Curran, New York State Department of Environmental Conservation (NYS)
Stephen N. Norris, Office of Urban and Federal Affairs, State of Tennessee (SOTN)
James M. Rose, Division of Planning Coordination, The State of Texas (SOTX)
N. R. Arthur, pacemaker recipient (NRA)
Evelyn Bauer, pacemaker recipient (EB)
Marie Colbert, pacemaker recipient (MC)
Peter M. Jacobson, Coratomic, Inc. (CI)
David L. Purdy, Coratomic, Inc. (CI)
Stephen Cookston, Cordis Corporation (CC)
Gregg S. Everhart (GSE)
W. Hunzinger, Department of Radiological Protection, Federal Office of Public Health, Switzerland (FOPH)
Simone Fouquet, pacemaker recipient (SF)
J. K. Frenkel (JKF)
Ron Guenther (RG)
N. W. Hauser, pacemaker recipient (NWH)
Thomas S. Bustard, Hittman Nuclear Battery Corporation (HNB, HNBB)
Fred Hittman, Hittman Nuclear Battery Corporation (HNBH)
F. N. Flakus, International Atomic Energy Agency, Austria (IAEA)

Mary P. Jackson (MPJ)
Patricia Joralemon (PJ)
Martin J. Krauthamer (MJK)
M. R. Lawler (MRL)
Bobby I. Griffin, Medtronic, Inc. (MI)
Martin Sonenburg, Memorial Sloan-Kettering Cancer Center (MSK)
Donald P. Geesaman, University of Minnesota (UOMG)
W. Albert Sullivan, University of Minnesota (UOMS)
T. D. G. Richings, National Radiological Protection Board (NRPB)
J. G. Speth, Natural Resources Defense Council, Inc. (NRDC)
Dermot A. Nee, pacemaker recipient (DAN)
Victor Parsonnet, Newark Beth Israel Medical Center (NBI)
R. Marriner Orum (RMO)
Max Spieler, Pacemaker Foundation, Inc. (MS)
Alfred E. Mann, Pacesetter Systems, Inc. (PSI)
Richard B. Spohn, People for Proof (PP)
Juliet Phillips, pacemaker recipient (JP)
Roger G. Powers, pacemaker recipient (RGP)
Stanley J. Runsky, pacemaker recipient (SJR)
Allen C. Nadler, Scientists' Institute for Public Information (SIPI)
Loyetta G. Wheelbarger, pacemaker recipient (LGW)
Wilson Greatbatch, Wilson Greatbatch, Ltd. (WG)
L. Douglas DeNike, Zero Population Growth (ZPG)

Consideration of comments received and the disposition of substantive issues involved are reflected in part by revised text in other sections of this Final Environmental Statement and in part by the following discussion. Reference will be made to the comments using the abbreviations indicated above. All comments received by October 20, 1975, are included in Appendix A of this Statement.

5.1 RESPONSES TO COMMENTS ON SECTION 1

(UOMA-A76, NRDC-A102)

This final generic Environmental Statement has been prepared in accordance with the procedures in 10 CFR Part 51 of the Commission's regulations. Part 51 implements published guidelines of the Council on Environmental Quality pertaining to the preparation of environmental impact statements pursuant to the National Environmental Policy Act of 1969 (NEPA).

5.2 RESPONSES TO COMMENTS ON SECTION 2

(EPA-A3, HEW-A4, SOF-A7, UOMG-A70, UOMA-A76, NRDC-A102, PSI-A109)

The DES does not discuss in detail the regulatory framework that NRC will implement to govern the routine use of plutonium-powered pacemakers. These regulations are currently being drafted. When completed, these proposed regulations will be available for public comment, and a notice to this effect will be published in the *Federal Register*. In the interim, the existing controls program (discussed in Sect. 2) will remain in effect.

5.3 RESPONSES TO COMMENTS ON SECTION 3

More information has been added to many of the subsections, and two new subsections were added.

5.3.1 Radiation doses to patients

(KZM-A31, UOMA-A76, NRDC-A102, PC-A115)

It is acknowledged that the absorbed radiation dose to patients was somewhat underestimated due to the use of a smaller plutonium loading as reported in the PNL report, but the differences are not large enough to cause any changes in the conclusions drawn in the draft Statement. The data reported in the DES were based on 173 mg of plutonium in a Medtronic pacemaker. This has been corrected in Sect. 3.2 by calculating the absorbed radiation doses on the basis of a pacemaker containing 250 mg of plutonium, which represents the average quantity of plutonium used per pacemaker. All subsequent risk analyses are also based on this quantity.

The absorbed radiation doses are also based on 0.26 ppm of plutonium-236 impurity in the fuel, which is the approximate assay of all plutonium used to date in pacemakers. The decay of this impurity accounts for a major portion of the emitted gamma radiation. Should the plutonium-236 impurity be increased to 0.6 ppm (the maximum plutonium-236 impurity in the specifications for plutonium-238 by the pacemaker battery manufacturers), the gamma radiation component would double over a period of years (Appendix F).

The plutonium fuel available in the future may vary up to 0.6 ppm of plutonium-236. If anticipated needs of plutonium-238 fuel are known in advance, the plutonium-236 component in newly produced fuel can be allowed to decay before it is marketed.

Because of the relatively low amount of radiation emitted from pacemakers, the suggested future isotopic enrichment of plutonium-238 fuel to nearly 100% assay is not anticipated. In terms of cost effectiveness, such a high degree of enrichment is not warranted. On the other hand, because of the radioactive impurities in plutonium separated in power-reactor fuel reprocessing, the use of this fuel in pacemakers is not justified or contemplated. High-grade plutonium-238 fuel from separated and reirradiated neptunium is available, and its cost is minor compared with the cost of source encapsulation and other fabrication processes.

5.3.2 Exposures to persons under 18 years of age

(HEW-A4, KZM-A31, HRL-A61, MRS-A69, UOMG-A70, UOMA-A76, NRDC-A102, PC-A115)

It is acknowledged that younger pacemaker patients will receive a comparatively greater accumulated radiation dose because of their smaller size and longer cumulative exposure. The accumulated dose for children may be 2 to 5 times as large as for adults, which is still within acceptable limits.

Approximately 0.5% of all implanted pacemakers are implanted in persons under 18 years of age. This is an extremely small percentage of the market, even if nuclear-powered pacemakers are used more frequently than conventional pacemakers in minors. The medical conditions that require pacemaker implantation are more prevalent in the aged than in children.

In medical diagnosis and treatment using radiation and radioisotopes (e.g., diagnostic x ray, radiation therapy, and nuclear medicine procedures), occupational and population radiation standards are not strictly applicable because of offsetting medical benefits. Studies have shown that nonradiosensitive soft tissues, such as muscular tissue in close contact with implanted pacemakers, can receive several hundred rads of protracted radiation exposure without manifestation of somatic effects. (Additional information is given on those topics in Sect. 3.2.1.)

5.3.3 Occupational exposures related to plutonium production and disposal

(UOMA-A76, NRDC-A102, PC-A115)

Section 3.4, "Exposures during Production, Manufacturing, and Disposal," has been added to Sect. 3. However, the purpose of this Statement is the assessment of the effects on the environment and population from the routine use of plutonium-powered pacemakers. Occupational workers are routinely covered by the radiation control and monitoring programs of individual plants, which are already under State or Federal control.

5.3.4 Accidents involving pacemaker patients

(JKF-A30, MRS-A69, UOMA-A76, NRDC-A102)

Additions have been made to Sect. 3.7.2 that discuss patient deaths due to firearms- and transportation-related deaths.

5.3.5 Plutonium toxicity

(NRA-A15, FSCI-A30, JKF-A30, RG-A32, JH-A57, HRL-A61,
MRS-A69, UOMA-A76, UOMS-A100, NRDC-A102, RMO-A108,
PSI-A109, PP-A113, SRP-A113, SIPI-A125, ZPG-A130, AP-32)

Section 3.8, "Radiobiological Hazards of Plutonium," has been added, which discusses the aspects of plutonium toxicity in detail.

5.3.6 Relative risks of plutonium-238 compared with plutonium-239

(RG-32, SIPI-A125, ZPG-A130)

It is acknowledged that one gram of plutonium-238 is potentially more hazardous than one gram of plutonium-239 due to differences in specific activity (curies per gram). However, all risk assessments were based on measured radiation emitted from actual pacemakers or on the number of microcuries that could be released in postulated accidents.

5.3.7 Somatic and genetic effects of radiation

(KZM-A31, MRS-A69, UOMA-A76, NRDC-A102, PSI-A109, PC-A115, ZPG-A132)

Sections 3.2.1, 3.3.1, 3.8.2, and 3.8.3 have been added. They discuss the somatic and genetic effects of radiation exposure from plutonium-powered pacemakers.

5.3.8 Terrorism and deliberate dispersal

(GES-A28, JKF-A30, FSCI-A30, RG-A32, PJ-A60, HRL-A61, UOMG-A70, UOMS-A100, RMO-A108, PP-A113, SPP-A113, PC-A115, SIPI-A125, ZPG-A130, A131, A132)

Section 3.9, "Terrorism and Deliberate Dispersal," has been added.

5.3.9 Patient identification

(KZM-A31, HRL-A61, UOMA-A76, NRDC-A102, ZPG-A130)

Patient identification jewelry and wallet cards are for the identification of pacemaker patients by proper authorities in the event a patient is involved in an accident or needs emergency help. Such jewelry is in common use by persons with various types of medical problems requiring special attention.

These identifications are sufficient for authorities to identify a patient's body in the event of his demise. If this identification is missing from a body, a coroner will notice the scar and bulge of a pacemaker under the skin of the body. Tattooing a patient is not considered necessary, and a tattoo can be obscured if the patient is burned in an accident.

On the other hand, the patient's jewelry could serve as identification if sought out by a terrorist; however, there will be very few patients in the U.S. population, and similar types of jewelry are used for other medical purposes. It should also be noted that medical records on nuclear pacemaker patients will remain confidential, as is typical with all medical records.

5.3.10 Nuclear gadgets

(PC-A115, ZPG-A130)

Plutonium-powered pacemakers were developed for specific medical treatment of cardiac patients. Any new uses of radioisotopes will be licensed only on the merits of their proposed use.

5.3.11 Estimation of contamination and cleanup costs

(SOTN-A13, MRS-A69, UOMG-A70, UOMA-A76, NRDC-A102, PC-A115, ZPG-A130, A132)

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A commentor suggested that estimated costs of cleaning up environmental contamination from a pacemaker breach should be based on the costs of the cleanup of plutonium from incidents at Thule, Palamares, and Rocky Flats, and from the contaminated residence of Karen Silkwood. The Thule, Greenland, and Palamares, Spain, incidents involved the dispersal of metallic plutonium from a military weapon in a foreign country. The Rocky Flats, Colorado, plutonium release was caused by an industrial fire and involved a much larger quantity of metallic plutonium. The estimation of cleanup costs is based on plutonium dioxide and not on metallic plutonium. The postulated releases discussed in Sect. 3.7.2 involve a very small amount of plutonium dioxide that is confined to a relatively small area. Cleanup costs are based on these considerations (Sect. 3.10).

Costs due to deliberate plutonium dispersal are not considered because of the difficulty associated with the conversion of the plutonium dioxide used in pacemakers to dispersable fines. (Additional information is given in Sect. 3.9.)

5.3.12 Accountability and disposal

(SONB-A11, NYS-A12, KZM-A31, UOMA-A76, NRDC-A102)

The regulatory framework governing the use, accountability control, and disposal of plutonium-powered pacemakers is currently being developed.

Prior to disposal, the plutonium heat sources may have some recycle value, and if a manufacturer does choose to recycle his heat sources, his recycle procedures will be regulated by the NRC or an Agreement State. The disposal of plutonium fuel from pacemakers will be done in accordance with regulatory requirements in existence at the time. It is contemplated that the Federal government will be responsible for the management of such wastes.

The plutonium-239 content in the pacemaker-grade fuel is immaterial when it is disposed of properly. If a pacemaker is lost, it would be difficult to determine its fate in several hundred years. It would most likely remain buried, and any fuel capsule rupture would add an insignificant amount of plutonium to the terrestial environment as compared with the estimated inventory of plutonium currently in the biosphere. (See, for example, Table 3.10.)

The intended routine use of plutonium-powered pacemakers, enabling a patient to move about and carry on daily activities without regulatory restrictions, is predicated on rigid design and construction requirements for the fuel capsules and fuel form. In other words, a pacemaker could be lost or damaged without significantly affecting the environment. To date, no losses of or releases from plutonium-powered pacemakers have occurred.

The cost of pacemaker control and accountability is based on record-keeping systems presently in use. If a centralized record keeping system is established such costs may be recovered from licensing fees or registration fees. Presently, the accountability of plutonium-powered pacemakers is, by protocol, the responsibility of the participating medical institutions and manufacturers, and no additional costs have been incurred by the Commission other than the cost of reviewing the regular semiannual reports.

5.3.13 Other comments related to Section 3

(SOTN-A13)

Absorbed radiation doses are given for both individuals and groups for normal and postulated accident situations. The calculated risks are a composite of the yearly group exposures.

(EPA-A3)

Dose commitment data from postulated accidental plutonium releases have been corrected to facilitate comparison and are redefined in terms of exposure from one year of nuclear pacemaker availability.

Patients' absorbed radiation doses to the lungs were not considered in the draft Statement. However, absorbed doses to the axillary lymph nodes were considered because of their proximity to a subcutaneous implant above the pectoralis muscle. The dose to the lymph nodes would be much higher than the lung dose.

The lungs are spread across the chest cavity; hence, there will be a variation in absorbed dose, which varies approximately as the inverse of the square of the distance. The integrated dose-equivalent for ten years to a patient's chest region is shown by the isodose curves in Appendix F. The lung dose will vary from less than 1 rem to approximately 10 rems for a ten-year exposure from a typical pacemaker.

621 080

5.4 RESPONSES TO COMMENTS ON SECTION 4

A major portion of Sect. 4 has been rewritten to reflect new information and comments from reviewers. New information was obtained from literature references cited by reviewers and from a physicians' questionnaire sponsored by the Commission. The physicians' questionnaire was initiated to obtain information from the medical community regarding the need for, and choice of, long-lived pacemakers. The results of this questionnaire are summarized in Appendix G.

It was also suggested in some comments that the alternative of "no action" should be considered. "No action" would involve a continuation of the present investigational licensing of pacemakers in which limitations have been placed on the number of nuclear pacemakers that may be distributed and on the number of medical institutions licensed to use the pacemakers. Sufficient information is available to make an assessment of the routine use of plutonium-powered pacemakers. It would, therefore, be unfair to deprive patients who could derive medical benefits from plutonium-powered pacemakers of the opportunity to receive such benefits and to deny manufacturers the opportunity to commercially distribute pacemakers that have been demonstrated to offer improved performance and a long projected lifetime with low environmental risk. Consequently, the alternative of "no action" is not considered reasonable and is not recommended.

5.4.1 Need for plutonium-powered pacemakers

(UOMG-A70, PSI-A109, SIPI-A125)

The need for a long-lived plutonium-powered pacemaker became apparent in 1966 when the conceptual design of such a unit called for ten or more years of service life.

Notwithstanding the rapid developments in pacemaker power-source technology, the need still exists for the long-lived pacemakers for the lifetime treatment of pacemaker patients. Two types of pacemakers are currently (1975) available which may offer patients lifetime pacing. However, neither pacemaker has a proven longevity and it will take several years of clinical experience to empirically determine average pacemaker service lifetimes. (Plutonium-powered pacemakers are presently subject to licensing restrictions under a carefully regulated clinical investigational program regulated by the Commission.)

Pacemakers will be selected to fulfill a particular need in the medical treatment of pacemaker patients. Therefore, there is a need to broaden the choice of pacemakers to include nuclear pacemakers so that the physicians will be able to make the best selections for their patients.

Time, marketing factors, and new pacemaker developments will determine the eventual acceptability of any lifetime pacemaker. For plutonium-pacemakers, routine use involves physician acceptance, higher unit costs, and some degree of radiation risks; for the rechargeable pacemaker, physician and patient acceptance are prerequisite, since these units demand continuous maintenance on the part of the patient.

5.4.2 Patient selection criteria

(HEW-A4, MRS-A69, UOMG-A70, UOMA-A76, NRDC-A102, PC-A115)

Although discussed in the comments, regulatory restrictions are not anticipated to be placed on the selection of patients receiving plutonium-powered pacemakers. This is a medical decision, and the physician must use his best judgment and preference in selecting treatment, for each of his pacemaker patients, from the available alternatives. In view of the regulatory requirements on nuclear pacemakers, which do not apply to other pacemakers and the higher initial cost of nuclear pacemakers, it is not likely that nuclear pacemakers will be used frivolously or that they will be selected for use by physicians or patients except in those cases in which the longer maintenance-free service lives of the nuclear pacemakers offer a significant advantage in the medical care of the patient.

5.4.3 Alternatives

(EPA-A3, HEW-A4, USCG-A6, SOTX-A14, JH-A57, HRL-A61, MRS-A69, UOMG-A70, UOMA-A76, NRPB-A100, NRDC-A102, PSI-A109, PC-A115)

New information has been added to Sect. 4.2, "Alternatives."

5.4.4 Leads and electronics

(HEW-A4, SONB-A11, UOMG-A70, UOMA-A76, NRPB-A100, NRDC-A102, PSI-A109, PC-A115)

Section 4.4.2 was added to discuss lead and electronic systems.

Any failure of hardware, either pacemaker or leads, will require additional medical treatment to correct the condition. Most random failures are associated with the electronic components of the pacemaker, while problems with leads usually occur in the early months after implantation or after a replacement operation. (Lead problems will be discussed in a later paragraph.)

The NRC is presently monitoring the performance of plutonium-powered pacemakers to determine whether the overall reliability and longevity of the entire pacemaker system can make effective use of the long-lived plutonium batteries. A computer program has been developed to detect, statistically, the development of any systemic failure modes associated with the different models of pacemakers. If any such failure modes that would make the pacemakers unsuitable for use are detected, the particular pacemakers will be removed from the market until the situation is corrected.

It has been argued in some comments that radiation damage to the electronic components would represent a failure mode. However, experience with space satellite hardware and radioisotopic thermoelectric generators, together with other data on radiation damage to semiconductors, indicates otherwise. Plutonium pacemaker manufacturers are aware of these data, and there is no reason to believe that radiation damage will occur to the electronic components at the radiation levels involved in pacemakers.

Lead failure is an independent variable and does not limit the useful lifetimes of all long-lived pacemakers. Most leads in service have exceeded the lifetime of any conventional pacemaker. Most lead failures are caused by stresses on the leads that often occur in conjunction with removal and reimplantation of pacemakers, rather than by wearout from flexion. Therefore, use of longer-lived pacemakers, which would not require replacement, would reduce the possibility of lead failure.

Modern leads, in accelerated flexion tests, have demonstrated an ability to withstand an average of 500 million flexions (equivalent to 15 years of pacing) and as many as one billion flexions (equivalent to 30 years of pacing). The lifetimes of leads have been extended because of improvements in lead design and improved surgical techniques.

5.4.5 Mortality and complication rates

(HEW-A4, FSCI-A30, HRL-A61, JOMG-A70, UOMA-A76, NRDC-A102, PSI-A109, PC-A115, SIPI-A125)

It is acknowledged that the mortality and complication rates for pacemaker reimplantations quoted in the DES are outdated. The comments are supported by the responses in the physician's questionnaire (Appendix G).

In the light of these comments and questionnaires, the approach of assessing benefits on lives saved has been retracted.

5.4.6 Cost considerations

(EPA-A3, SONB-A11, SOTN-A13, JH-A57, UOMG-A70, UOMA-A76, NRPB-A100, NRDC-A102, PC-A115)

The cost analysis of Sect. 4 has been recast to reflect new data and comments by reviewers. (Factors such as assigning a dollar value to a year of life have been dropped.)

The justification for allowing the plutonium-powered pacemaker to be marketed, considering its additional cost over an alternative pacemaker, has been questioned. The purpose of this Statement is to determine whether plutonium-powered pacemakers are safe and reliable and whether they offer unique advantages that cannot be satisfied by an alternative pacemaker. Comparative costs are presented for all pacemakers for the purpose of gaining perspective.

Also, in the selection or prescription of a medical treatment when life and health are at stake, costs are not necessarily a limiting factor, and the lowest cost alternative is not necessarily chosen or required.

5.4.7 Benefit and benefit-cost considerations

(EPA-A3, UOMG-A70, UOMA-A76, NRPB-A100, NRDC-A102, PC-A115)

Assessment of benefits and cost-benefit considerations have been redrafted in Sects. 4.6 and 4.7.

All significant costs are taken into consideration either directly or indirectly. For example, the purchase price of plutonium-238 fuel will include costs due to occupational personnel monitoring, health benefits, etc. If the pacemaker manufacturer is responsible for disposal of the unit's plutonium, this cost will be built into its purchase price.

5.4.8 Risks from chemical battery-powered pacemakers

(WG-A128)

The risks from plutonium-powered pacemakers are discussed in detail in Sect. 3; however, the risks from chemical battery-powered pacemakers have not been discussed. Accidents in which pacemaker patients may be involved (Fig. 3.1) are also applicable to chemical battery-powered pacemakers. However, this is where the similarity ends. Probabilities of pacemaker rupture, source terms, environmental discrimination factors, and dose-response curves will all be different in a risk analysis of chemical batteries.

Qualitatively, probabilities of rupture will be nearer to unity, since chemical battery pacemakers are not required to withstand the same prototype tests as the nuclear-powered pacemakers. Given the same prototype test conditions, all chemical-battery-powered pacemakers would rupture and release their contents to the environment. A detailed analysis of the risk associated with such a rupture is beyond the scope of this report, but any significant risk from chemical-powered pacemakers would tend to enforce the conclusions drawn in the Draft Statement.

Appendix A

LETTERS OF RESPONSE TO THE DRAFT ENVIRONMENTAL STATEMENT

Contents

Contents (continued)

Contents (continued)

Contents (continued)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

1014

5 MAR 1975

Mr. Bernard Singer, Chief
Materials Branch
Directorate of Licensing
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Singer:

The Environmental Protection Agency has reviewed the draft generic environmental statement on the wide scale use of plutonium powered cardiac pacemakers issued on January 16, 1975, and our comments are enclosed.

The Nuclear Regulatory Commission staff is to be complimented on the detailed analysis of the possible accident modes which could result in the release of plutonium from the pacemaker. However, the draft statement does not discuss the materials protection program that would be instituted at hospitals or the disposal facility. In our opinion the materials security measures involved in the program should be discussed in the final statement.

Our other comments discuss the need for additional information and corrections in the cost/benefit analysis and additions to the discussion of alternatives to the plutonium powered cardiac pacemaker.

In accordance with EPA procedures, we have classified the project "LO" (Lack of Objections) and rated the draft statement as "Category 2" (Insufficient Information). We will be pleased to discuss our comments with you or members of your staff.

Sincerely yours,

Sheldon Meyers

Sheldon Meyers
Director
Office of Federal Activities (A-104)

Enclosure

980 029

Additional Comments

1. Lung doses are not calculated or discussed in Section 3. This dose could be substantial for the pulse generator located above the left pectoral muscle. It should also be noted that doses to tissues adjacent to the pacemaker could be greater than 40 rem/year.

2. On page 3-44, it is not proper to define an annual dose commitment by taking one-fiftieth of the 50-year dose commitment times the expected number of breaches per year. This does not account for annual doses from previous breaches. At equilibrium the annual dose commitment is the total 50-year dose commitment from one breach times the expected number of breaches per year. This gives a population dose 50 times larger than reported here.

3. The cost benefit analysis in the draft statement addresses the costs to society but does not appear to include the costs to the individual using the pacemaker. The draft statement does not factor into the cost analysis the additional expense to the individual of a Pu^{238} powered pacemaker which, if included into the overall cost, can make a difference.

4. The value of each additional life saved as a result of the Pu^{238} pacemaker is computed on the basis of income potential and the value which is used is the average value ($15,000) for U.S. population. This value seems unrealistic in light of the fact that 85% of the pacemaker recipients are between the ages of 60-90 years. The average yearly income for people in the age bracket 60-65 years is actually closer to $8,000.

5. The AEC computation accrues the benefits over a 14 year period (average additional expected lifetime of pacemaker recipient) while the costs are figured only over a ten year period (suggested lifetime of Pu^{238} pacemaker). To calculate the costs over a 14 year period would involve adding in the additional cost of second pacemaker implant. The cost analysis in the final statement should be recalculated to include these changes.

A-3

Comments of the U.S. Environmental Protection Agency on the Draft Generic Environmental Statement on the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers

Introduction

The Environmental Protection Agency has reviewed the draft generic environmental statement on the wide-scale use of plutonium powered cardiac pacemakers issued by the Nuclear Regulatory Commission (NRC) on January 16, 1975. Following are our general comments:

1. The information presented on the radiological hazards from wide-scale use of the plutonium powered cardiac pacemaker appears to be comprehensive.

2. The statement does not discuss the need for materials security for the plutonium pacemakers while in storage at the hospital or disposal site. The final statement should discuss the materials protection aspects of the pacemaker program.

Alternatives

The section discussing alternative pacemakers should be expanded to include greater detail of the developmental stages of other power sources for the pacemaker. For example, a pacemaker utilizing a rechargeable chemical battery has been implanted in humans recently. This battery, a mercury-silver one, has been subjected to accelerated life tests and is predicted to be able to operate for three years between recharging and for 20 years before replacement is needed. This should be considered as an alternative.

Still another pacemaker which uses a rechargeable nickel-cadmium battery is beginning its third year of tests. More than 1,200 patients have worn this pacemaker successfully. The total cost of the rechargeable pacer is about $2,200 in addition to the cost of once-only surgery. Recharging is accomplished in a 90 minute, once-a-week session and is done through the patient's skin. Estimated total life of the device is estimated at greater than 25 years.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

MAR 20 1975

Mr. Bernard Singer
Chief, Materials Branch
Fuels and Materials
Directorate of Licensing
Atomic Energy Commission
Washington, D. C. 20545

Dear Mr. Singer:

We have reviewed the Generic Draft Environmental Impact Statement on the environmental considerations relating to the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers. On the basis of our review, we offer the following comments:

1. We found no specific mention as to the possible adverse health effects on patients that might result from radiation dose. Although the average age of the patients is over 66, as shown in Table 16, page 4-10, it may also be seen that they have sufficient life expectancies during which to accumulate dose. Further, those relatively few young patients, age ~0-15, would probably be smaller in stature than the model within which dose rates were measured and thus would accumulate dose at a greater rate than an adult person. As a group, children would tend to be more radiosensitive than adults. These factors should be addressed in greater detail in the final statement.

2. The control and final disposition of the plutonium residual in these devices presents the major potential environmental impact to humans from radiation. Part 2.5.3, page 2-19, describes a proposed system for accountability and recovery, but only in outline. We suggest that physicians and morticians be well informed with regard to the identification of the nuclear device bearer, and be required to report the discovery of the nuclear device in a cadaver to the appropriate authorities for appropriate disposal. Disposal of the radioactive material is an important aspect for safeguarding the public and the environment in the wide-spread use of the plutonium pacemaker.

3. We disagree with the assumption that battery decay is the only systematic failure mode. For non-hermetically sealed pacemakers, moisture absorption over a period of time can eventually result in failure of the unit.

4. Page 4-9 indicates that pacemaker patient mortality rates due to natural attrition are the same as those of the U.S. populace of the same ages. We found no data presented to confirm this statement.

5. Page 4-4. The data on the rechargeable battery appears out-of-date, as many recent publications have indicated.

6. Page 4-15 lists the life expectancy as 14 years. Elsewhere in the document, it is stated that 13% of the population was assumed to die each year. This may be a statistical problem, as the figures are important in calculating the benefit. The actual life data for pacemaker recipients is needed.

7. Page 4-25, Recommendation #2. We feel that the reporting of all failures should be required, at all times, not only during the investigation phase. Additionally, in the risk benefit analysis, a random failure rate of 15%/mo. is assumed. This figure is based in a large extent, on the manufacturers published figures. However, some investigations have shown the actual failure rate to be up to .4-.5%/mo., and one manufacturer has advertised a random failure rate of .37/mo. This implies that the projected figures for conventional powered pacemakers used in the analysis would be seriously affected. Also, if the same random failure rates are assumed for nuclear powered pacers, a 10-20 year lifetime would not be accurate for the majority of the pacers.

8. The draft statement does not mention the fact that with the average life expectancy (average age of 66) being about 8 years, very few patients would have more than one replacement of a 5-6 year life chemical battery unit. However, the possible greater than average risk

to the older population group (i.e. that with a shorter life expectancy) from a replacement operation could tend to reduce the cost disadvantage to the older group.

Thank you for the opportunity to review this draft statement.

Sincerely,

Charles Custard
Director
Office of Environmental Affairs

DEPARTMENT OF TRANSPORTATION
UNITED STATES COAST GUARD

MAILING ADDRESS:
U.S. COAST GUARD (G-WS/73)
400 SEVENTH STREET SW
WASHINGTON, D.C. 20590
PHONE (202) 426-2262

27 FEB 1975

Mr. Bernard Singer
Chief, Materials Branch
Directorate of Licensing
Atomic Energy Commission
Washington, D. C. 20545

Dear Mr. Singer:

This is in response to your letter of 16 January 1975 addressed to Mr. Benjamin O. Davis concerning a Generic Draft Environmental Statement relating to the wide-scale use of plutonium powered cardiac pacemakers.

The concerned operating administrations and staff of the Department of Transportation have reviewed the material submitted. The Coast Guard had the following comments to offer: (The Office of the Chief Medical Officer).

"Plutonium powered cardiac pacemakers do have a great advantage over the conventional powered cardiac pacemaker in that the life of the plutonium pacemaker is approximately five times as long as current batteries in present pacemakers. Its main disadvantage is that it does emit gamma rays and neutrons, and while it is considered inconsequential at the present time, it may not be considered so at some future date. We have many examples of this in medical literature when radiation was considered safe and then proven to be not so 20 years later. Such an example is radiation of thymus in children and now we have increased incidence of thyroid cancers in these individuals.

"Perhaps the U. S. Atomic Energy Commission should compare its cardiac pacemaker to the nickel cadmium battery that is implanted in the patient's chest wall and can be recharged through the skin. To charge the device, the patient puts on a lightweighted jacket, plugs it into a box with electronic components which in turn plugs into ordinary electric socket for 90 minutes daily. It is believed this battery will last for 25 years. It is understood that over 1,000 of these batteries have been implanted.

"Based on current scientific data, it appears that the plutonium powered pacemaker would be much less desirable for many reasons when compared to the nickel cadmium battery which was developed as a refinement of space satellite technology."

The Department of Transportation has no other comments to offer. It is requested that the final statement address the concern of the Coast Guard.

The opportunity to review this generic draft statement is appreciated.

Sincerely,

W. E. Caldwell

W. E. CALDWELL
Captain, U.S. Coast Guard
Deputy Chief, Office of Marine
Environment and Systems
By direction of the Commandant

STATE OF FLORIDA

Department of Administration

Division of State Planning

650 Apalachee Parkway - IBM Building

TALLAHASSEE

32304

(904) 488-2371

April 17, 1975

Reubin O'D. Askew
GOVERNOR

Lt. Gov. J. H. "Jim" Williams
SECRETARY OF ADMINISTRATION

Earl M. Starnes
STATE PLANNING DIRECTOR

APR 30 1975

Mr. Bernard Singer, Chief
Materials Branch
U. S. Atomic Energy Commission
Washington, D. C. 20545

Dear Mr. Singer:

Functioning as the state planning and development clearinghouse contemplated in U. S. Office of Management and Budget Circular A-95, we have reviewed the following draft environmental impact statement:

Atomic Energy Commission: Wide-Scale Use of Plutonium Cardiac Pacemakers (SAI No. 75-1129E).

During our review we referred the environmental impact statement to the following agencies, which we identified as interested: Department of Health and Rehabilitative Services, Environmental Information Center, and the Department of Legal Affairs. Agencies were requested to review the statement and comment on possible effects that actions contemplated could have on matters of their concern. A letter of comment on the statement is enclosed from the Department of Health and Rehabilitative Services. No further comments were received.

In accordance with the Council on Environmental Quality guidelines concerning statements on proposed federal actions affecting the environment, as required by the National Environmental Policy Act of 1969, and U. S. Office of Management and Budget Circular A-95, this letter, with attachments, should be appended to the final environmental impact statement on this project. Comments regarding this statement and project contained herein or attached hereto should be addressed in the statement.

We request that you forward us copies of the final environmental impact statement prepared on this project.

Sincerely,

Ed Maroney

E. E. Maroney, Chief
Bureau of Intergovernmental Relations

Enclosures
cc: Mr. O. J. Keller
Mr. Robert Shiver
Mr. William Partington

0600 129

STATE OF FLORIDA

DEPARTMENT OF HEALTH AND REHABILITATIVE SERVICES

Prior Notification and Review System

DIVISION OF STATE PLANNING
Bureau of
MAR 12 1975
RECEIVED
SAI NO.

O. J. KELLER
Emmett S. Kobert
Secretary

Date: March 10, 1975

MEMORANDUM

REF. NO: DHRS _____ SPDC (SAI) 75-1129E

TITLE Draft Generic Environmental Statement on Widescale Use of Plutonium Cardiac Pacemakers

APPLICANT U.S. Atomic Energy Commission

TO: Kenneth Ireland, Secretary
Department of Administration
E.E.Maroney,
Attn: Chief
Bureau of Intergovernmental Relations
O. J. KELLER

FROM: Emmett S. Kobert, Secretary
Department of Health and Rehabilitative Services

By: Division of Planning and Evaluation

SUBJ: NOTIFICATION OF INTENT TO APPLY FOR FEDERAL FUNDS

The project identified above has been reviewed in accordance with O.M.B. Circular A-95. Action recommended:

☐ The project is consistent with the goals and objectives of the Department of Health and Rehabilitative Services. Favorable action is recommended.

☒ Substantive comments have been received and are summarized in the attached.

☐ Conference with applicant is requested.

☐ The project is not consistent with the goals and objectives of the Department of Health and Rehabilitative Services. Approval is not recommended for reasons described in the attached.

Attachment (s)

DH COMMENTS ATTACHED

Recommendation

A-7

STATE OF FLORIDA

DEPARTMENT OF HEALTH AND REHABILITATIVE SERVICES

Prior Notification and Review System

O. J. KELLER
~~Ernest G. Roberts~~
Secretary

Date: February 28, 1975

MEMORANDUM

REF. NO: DHRS _____ SPDC (SAI) 75-1129E

TITLE Draft Generic Environmental Statement on Wide-Scale Use of Plutonium Cardiac Pacemakers

APPLICANT U.S. Atomic Energy Commission

TO: Robert H. Browning, Chief
Bureau of Comprehensive Rehabilitation Planning

FROM: Federal Programs Coordinator, Division of: [illegible]

The proposal identified above was reviewed by:

Thomas W. Harris, Public Health Physicist III — March 7, 1975
Reviewer's Name and Title — Date Reviewed

Reviewer's Comments: (Use additional sheet if needed)

The draft "Generic Environmental Statement on Wide-Scale Use of Plutonium Cardiac Pacemakers" is well done and covers all conceivable areas which may affect the environment.

The Radiological and Occupational Health Section of the Division of Health of the State of Florida in cooperation with the Materials Branch of the U. S. Nuclear Regulatory Commission (formerly U. S. Atomic Energy Commission) has issued two radioactive materials licenses in Florida authorizing the distribution of nuclear powered pacemakers to medical institutions licensed by the U. S. Nuclear Regulatory Commission or Agreement States. This Section has also licensed 14 institutions authorizing implantation of nuclear powered pacemakers in patients. All areas of concern have been thoroughly explored and it is felt by this Section that adequate safeguards have been provided for the use of nuclear powered cardiac pacemakers on an investigational stage basis. The draft "Generic Environmental Statement on Wide-Scale Use of Plutonium Cardiac Pacemakers" on Page 2-19, Section 2.5.3 Accountability and Recovery, discusses the methods by which accountability and recovery are presently accomplished. It is the opinion of this Section that a National regulatory accountability and recovery system should be established with appropriate regulations prior to wide-scale use. The manufacturers of nuclear powered cardiac pacemakers are predicting a normal life of these pacemakers of between 10 and 30 years. The present requirement places the burden of accountability on the licensees; however, as the use of these pacemakers increases, it may be impossible for institutions to maintain adequate records due to the mobility of patients, also due to the closing of certain licensed institutions, and possibly due to future legal decisions which may nullify the informed consent agreement originally signed by the patient.

160 129

Reviewer Comment

A-8

STATE OF KANSAS

AREA CODE 913
296-2436

Department of Administration

DIVISION OF THE BUDGET

STATEHOUSE—TOPEKA 66612

February 6, 1975

Mr. Bernard Singer, Chief
Materials Branch
Fuels and Materials
Directorate of Licensing
U.S. Atomic Energy Commission
Washington, D. C. 20545

RE: Environmental Statement on the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers
Clearinghouse Number 1637-24.998(ES)

Dear Mr. Singer:

The referenced environmental statement has been processed by the Division of the Budget under its clearinghouse responsibilities described in Circular A-95.

After review by interested state agencies, it has been found that the proposed project does not adversely affect state plans. We are enclosing comments received from the University of Kansas Medical Center concerning this project for your information and referral.

Sincerely yours,

James W. Bibb
Director of the Budget

JWB:REK:rw

Enclosure

760 129

State Clearinghouse
State of Kansas

REQUEST FOR ACTION ON PROPOSAL (UNDER OFFICE OF MANAGEMENT AND BUDGET CIRCULAR A-95)

Agency Name P. R. Schloerb, M.D., Dean of Research, Kansas University Medical Center	
Clearinghouse Number 1637-24.998(ES)	Applicant's Name U.S. Atomic Energy Commission
Expected Filing Date	Project Title Environmental Statement on the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers
RETURN NO LATER THAN February 7, 1975	Return to Division of the Budget, Department of Administration, 1st Floor, Statehouse, Topeka, Kansas 66612

The enclosed proposal has been submitted to the Division of the Budget under its clearinghouse responsibilities described in Office of Management and Budget Circular A-95. Your review of this proposal as it affects the interest of the state will be appreciated. Your appropriate comments concerning the proposal should be submitted to the Division of the Budget no later than the date specified above.

Comments filed on a proposal may include: (1) the extent to which the project is consistent with or contributes to the fulfillment of comprehensive planning within the state; (2) how the proposal relates to state objectives; and (3) the effect of the proposal on your agency's activities.

___ No Objections
___ Objections (discuss below)
___ Request for Additional Information (discuss below)
___ Request for a Conference

COMMENTS:

Lacks appropriate endorsement of Executive Committee.

P. R. Schloerb, M.D.
Signature

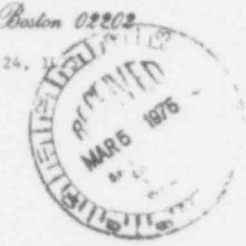
A-9

THOMAS O'BRIEN
DIRECTOR

The Commonwealth of Massachusetts
Executive Office for Administration and Finance
Office of State Planning and Management
Leverett Saltonstall Building, Room 909
100 Cambridge Street, Boston 02202

AREA CODE 617
727-8068

February 24, 1975



Bernard Singer, Chief
Materials Branch
Fuels and Materials
Directorate of Licensing
Atomic Energy Commission
Washington, D.C. 20545

Re: A-95 Review of Draft EIS on Plutonium Powered Cardiac Pacemakers
State Clearinghouse Identifier 75010042

Dear Mr. Singer:

The State Clearinghouse, in accordance with the provisions of OMB Circular A-95 and National Environmental Policy Act, has reviewed the above cited Draft Environmental Impact Statement on the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers.

Comments were requested from the Departments of Natural Resources and Public Health and the Office of Comprehensive Health Planning.

The Department of Natural Resources is satisfied that the Draft EIS adequately treats the subject. No other comments have been received to date. Any comments we may receive in the future will be forwarded for your information.

Sincerely,

Adriana Gianturco

Adriana Gianturco
Acting Director of State Planning

AG/PS/b

cc: Mr. Arthur Brownell, DNR

OFFICE OF PLANNING AND PROGRAMMING

BOX 94601 STATE CAPITOL LINCOLN, NEBRASKA 68509 (402) 471-2414

Governor J. James Exon — Don Nelson, Director

February 26, 1975

Acting Deputy Director for Fuels and Materials
Directorate of Licensing - Regulation
U. S. Atomic Energy Commission
Washington, D. C. 20545

Dear Sir:

Project 75 01 31 38
Plutonium Cardiac Pacemakers

Under the provisions of OMB Circular A-95, this office has conducted a state level review of the generic draft environmental statement on the wide-scale use of plutonium powered cardiac pacemakers.

The proposed program does not appear to conflict with any state level comprehensive plans. No adverse comments were received from state agencies during this review.

Sincerely,

Joseph S. Golden
Human Resources Coordinator

JSG:np

A-10

OFFICE OF PLANNING AND PROGRAMMING

BOX 94601 STATE CAPITOL LINCOLN, NEBRASKA 68509 (402) 471-2414

Governor J. James Exon — Don Nelson

March 4, 1975

Acting Deputy Director for Fuels and Materials
Directorate of Licensing - Regulation
U. S. Atomic Energy Commission
Washington, D. C. 20545

Dear Sir:

Project 75 01 31 38
Plutonium Cardiac Pacemakers

The enclosed comments from the University of Nebraska Medical Center were received after completion of our review of the generic draft environmental statement on the wide-scale use of plutonium powered cardiac pacemakers.

These comments are forwarded for your information and use in the final statement development.

Sincerely,

Joseph S. Golden
Human Resources Coordinator

JSG:np
cc: Conny Nelson

621 094

UNIVERSITY OF NEBRASKA
STANDARD MEMO FC

Date 2-20-75

To Dept. of _____ Attn Chancellor Sparks

From: Drs. Eliot & Dzindzio Dept. Cardiovascular Medicine

Subject: Atomic Energy Commission Notice of Availability of Generic Draft Environmental Statement on the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers

- ☐ Your Information
- ☐ Suggested Reply
- ☐ Appropriate Action
- ☐ Your Recommendation
- ☐ Please Return
- ☐ Your Files
- ☐ Direct Reply
- ☐ Carbon copy for our files

Message:

The following is a list of our opinions as to the usefulness of the plutonium powered pacemakers:

1. Although the plutonium units have considerably longer periods of power supply, this does not reconcile the fact that other sections of the pacemaker unit, i.e. the pacemaker wires, are still a problem to be reckoned with and will require reimplantation at a frequency of five years or less. This means that the patient will have to be exposed to surgical reexploration for insertion of the new pacemaker wires at about a five year or less interval regardless of whether plutonium or a conventional powered pacemaker unit is inserted.

2. We are interested in the cost analysis of the plutonium pacemaker versus the traditional pacemaker battery units. Considering the lifespan of the patient with complete heart block and pacemaker and the number of years required to maintain this patient versus the insertion of a single expensive unit would be interesting. This has not been submitted with the statement and we consider this an inadequacy that should be considered.

3. The need for a unit lasting 90 years is dubious since most patients with symptomatic complete heart block requiring a pacemaker unit certainly do not last this long and live probably an average duration around ten years. This can be easily accomplished with two of the newer pacemaker power units. The 80+ years supplied by the plutonium unit are superfolous.

4. Probably the most important is the difficulty of disposing used plutonium units. Plutonium maintains ability for particle emission in the range of several thousands of years making safe disposal considerably difficult.

Summary: We are not completely convinced that there is any need or use for plutonium powered cardiac pacemakers for the above reasons and if wide-scale use is to be considered feasible we would like to have the above questions more completely answered.

BSD/lgk

RECEIVED
UNIVERSITY OF NEBRASKA
FEB 20 1975
CHANCELLOR'S OFFICE
U of Nebraska Medical Center

A-11

STATE OF NEVADA
OFFICE OF THE STATE PLANNING COORDINATOR
CAPITOL COMPLEX
CARSON CITY, NEVADA 89701
(702) 885-4865

March 14, 1975

Mr. Bernard Singer, Chief
U.S. Atomic Energy Commission
Washington D.C. 20545

RE: DRAFT ENVIRONMENTAL STATEMENT ON WIDE SCALE USE OF PLUTONIUM POWERED PACEMAKERS SAI # NV 75800016

Dear Mr. Singer:

Thank you for the opportunity to review the above mentioned project.

The State Clearinghouse has processed the proposal and has no comment. Based on the information contained therein and the responses of interested parties, the proposed project is, as of this date, found not to be in conflict with the State's plans, goals or objectives.

Sincerely yours,

Bruce D. Arkell
State Planning Coordinator

BDA:bw

New York State Department of Environmental Conservation
50 Wolf Road, Albany, New York 12233

Ogden Reid,
Commissioner

March 26, 1975

U. S. Nuclear Regulatory Commission
Washington, D. C. 20545

ATTENTION: Acting Deputy Director for Fuels and Materials
Directorate of Licensing - Regulation

Dear Sir:

The State of New York has completed its review of the Commission's "Draft Generic Environmental Statement on the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers."

The draft statement discusses in considerable detail the procedures for keeping track of the pacemakers and recovering the pacemaker for controlled disposal. The potential problems of such recovery, including the problem of cremation of a body containing a pacemaker, was adequately reviewed by the Draft Statement.

Based on the prediction of a population of 10,000 patients there could be 1,500 pacemakers recovered every year with up to 8 curies of plutonium in an individual pacemaker. This would amount to approximately 10,000 curies of plutonium per year to be disposed of in an acceptable manner. The draft generic environmental statement did not identify in the report the method of ultimate disposal that would be used. It is recommended that the final generic environmental statement specifically identify the method of ultimate disposal and discuss any possibility of recycling the plutonium.

Very truly yours,

Terence P. Curran
Director of Environmental Analysis

STATE OF OKLAHOMA

State Grant-In-Aid Clearinghouse

4901 N. LINCOLN BLVD. • OKLAHOMA CITY, OKLAHOMA 73105 • PHONE (405) 521-2187

February 5, 1975

Acting Deputy Director for
Fuels and Materials
Directorate of Licensing - Regulation
U. S. Atomic Energy Commission
Washington, D. C. 20545

RE: Notice of Availability of Generic Draft Environmental Statement on the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers

Dear Sir:

The draft environmental statement on the above project has been reviewed in accordance with OMB Circular A-95 and Section 102 (2) (c) of the National Environmental Policy Act by the state agencies charged with enforcing environmental standards in Oklahoma.

The state agencies, comprising the Pollution Control Coordinating Board, have reviewed the proposed project and agree that no adverse environmental impact is anticipated. Therefore, the state clearinghouse requires no further review.

Sincerely,

Don N. Strain
Director

DNS:ma

STATE OF TENNESSEE
OFFICE OF URBAN AND FEDERAL AFFAIRS

SUITE 100
PARKWAY TOWERS BUILDING
NASHVILLE 37219
615-741-2714

March 7, 1975

Mr. Bernard Singer, Chief
Materials Branch
Fuels and Materials
Directorate of Licensing
Nuclear Regulatory Commission
Washington, D. C. 20545

RE: Generic Draft Environmental Statement
Plutonium Powered Cardiac Pacemakers

Dear Mr. Singer:

As the designated State Clearinghouse for Federal development programs, we have reviewed the summary and conclusions from the above captioned draft statement.

The Tennessee Department of Public Health, Division of Occupational and Radiological Health, addresses several areas regarding the subject material, namely:

1. Item 2c, page vii - From the information available, it does not appear that nuclear powered cardiac pacemakers should be considered as items exempt from licensing requirements.

2. Item 3f, page ix - This item appears to give an average or weighted cost for clean-up of a spill of the radioactive material from a pacemaker. The cost for the clean-up of one spill involving plutonium from a pacemaker should be considered.

3. Item 3a, page vii, and item 3e, page ix - Does the "total dose to the U.S. population" include the calculated "total radiation exposure to man from accidents involving nuclear pacemaker patients"? Also, does the fact that the two "totals" differ by only a factor of approximately 125 indicate a relatively large number of accidents involving pacemaker wearers, a very substantial dose to persons near an accident, or some other factors?

4. No data were found to indicate that the original and replacement cost of nuclear and conventional pacemakers were included in the monetary values of benefit-risk comparisons.

These substantive comments merit your responsive consideration in finalization of the environmental statement. Therefore, we request that a response be made to the areas addressed by the above comments in the final statement.

We appreciate the opportunity to review this proposal. We, or other reviewing authorities, may wish to comment further at a later time. If our office, as the State Clearinghouse, can be of further assistance, please do not hesitate to contact us.

Sincerely,

Stephen H. Norris
Grant Review Coordinator

SHN:mn

DOLPH BRISCOE
GOVERNOR

OFFICE OF THE GOVERNOR
DIVISION OF PLANNING COORDINATION

JAMES M. ROSE
DIRECTOR

March 20, 1975

Mr. Bernard Singer
Chief, Materials Branch
Fuels and Materials Directorate
of Licensing - Regulation
The United States Atomic Energy
Commission
Washington, D. C. 20545

Dear Mr. Singer:

A summary of the Draft Environmental Statement, titled, "Draft Generic Environmental Statement of the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers" prepared by the U. S. Atomic Energy Commission (AEC) has been reviewed by the Governor's Division of Planning Coordination and by the Texas State Department of Health as provided for by the National Environmental Policy Act of 1969.

The Texas State Department of Health (TSDH) stated that they had no objection to the widespread use of the plutonium powered pacemakers; however, it was felt that recent developments in battery technology might obviate the need for plutonium powered pacemakers.

This Division suggests that the AEC take note of the comments made by the TSDH which are enclosed for your use. If we can be of further assistance, please let us know.

Sincerely,

James M. Rose

JAMES M. ROSE
Director

JMR/lss
Enclosures
cc: Dr. James E. Peavy, TSDH

P. O. BOX 12428, CAPITOL STATION, AUSTIN, TEXAS 78711
Phone 512/475-2427 Offices Located in Sam Houston State Office Building

204 Mowbray Road
Silver Spring, Maryland 20904
May 21, 1975

Mr. Bernard Singer, Chief
Materials Branch
Nuclear Regulatory Commission
Washington, D. C. 20555

Dear Mr. Singer,

During my 15 years as a nuclear reactor physicist, I learned to respect the benefits and hazards of nuclear radiation. Now, as the recipient of a nuclear pacemaker, I believe I am in a unique position to assess its benefits and hazards.

The major benefit, aside from the fact that is is keeping me alive, is the longevity of the device. A replacement rate of ten years means that I will have to undergo surgery only once every ten years instead of every year with a conventional pacemaker. While I do not know the failure rate for surgery of this sort, I know it is not zero. With the nuclear pacemaker I am not exposed to the hazard of yearly surgery.

Another benefit is reliability. Very few things in nature are as constant and predictable as nuclear decay. Conventional batteries, even the newer types, are subject to manufacturing error. A conventional pacemaker, therefore, would seem less reliable than the nuclear device.

The only hazard that I can see would result from a major catastrophe to me, such as being blown up be a bomb, that would rupture the pacemaker and disburse the plutonium into the environment. I am well aware of the highly toxic nature of plutonium, but I am also aware of the extremely low probability that a catastrophic accident will happen to me or to anyone else wearing a nuclear pacemaker. And note that only a catastrophe of truly magnificent proportions is likely to rupture the device.

Let me extend my heartfelt thanks to those who developed the nuclear pacemaker, and to the AEC for its foresight in licensing the device.

N. R. Arthur

5833 Marlboro Pike
District Heights, Maryland 20028
May 29, 1975

Mr. Bernard Singer, Chief
Materials Branch
Nuclear Regulatory Commission
United States Atomic Energy Commission
Washington, D.C. 20555

Dear Mr. Singer:

I have been informed that your Commission is interested in hearing all points of view regarding the nuclear pacemaker.

I received my pacemaker on June 13, 1973 and have found it to be very satisfactory. I have been very active and have had no problems whatsoever. I should think that this pacemaker would be beneficial to many others.

Very truly yours,

Evelyn M. Bauer
Evelyn Bauer

117 Ingraham Street, N. W.
Washington, D. C. 20011

Barnard Singer
Chief, Materials Branch
Nuclear Regulatory Commission
U. S. Atomic Energy Commission
Washington, D. C. 20055

Dear Mr. Singer:

This is in response to a letter received from Dr. Nicholas Smyth, my surgeon in three pace maker operations, the last of which was nuclear powered. Dr. Smyth stated there were numerous unfavorable comments and opposition to the nuclear pace maker.

First, I would like to say that Dr. Smyth is a very good surgeon. I have the utmost confidence in his ability to make decisions as to the type of pace maker his patients should use and the possible dangers, if any, that may be derived from its use.

I had my nuclear pace maker implanted December 5, 1974. So far I have had no problems at all. I think the longevity and the reliability of nuclear pace makers are very important to the patient recipient. No one knows what it means to have a pace maker replaced every 18 months but those patients that have to have the surgery. Prior to the use of the nuclear pace maker, all you can foresee in years ahead are trips back and forth to the hospital for replacement due to run down batteries or other malfunctioning; anxiety and fear on the part of the recipient and their family; the hazards of having surgery so often — it can really get you down mentally. I speak not only for myself but for my brother, who is not fortunate enough to have the nuclear device but has to have two pace makers due to medical complications. Fortunate or not, we're both glad to be alive due to advancements in the medical sciences. It is far more desirable to be alive, useful and productive than to die or become a financial burdon to your family.

Personally, I believe the nuclear pace maker is a very promising device as it gives hope and encouragement to those people who are fortunate enough to receive one. I certainly would not like to see its curtailment or abolishment due to the "not so knowledgeable public or groups."

Sincerely yours,

Marie Colbert

(Mrs.) Marie Colbert
Patient Recipient

College of Physicians & Surgeons of Columbia University | New York, N.Y. 10032

DEPARTMENT OF RADIOLOGY
Radiological Research Laboratories

630 West 168th Street

February 18, 1975

Dr. Bernard Singer
U.S. Atomic Energy Commission
Washington, D.C. 20545

Dear Dr. Singer:

In response to your request of January 16, 1975 I have reviewed your Draft Generic Environmental Statement on the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers issued in January 1975.

Within my area of competence most aspects of this document are generally satisfactory except for one major problem. This concerns not only the particular document under discussion but involves a broad issue which should be of basic importance to the Nuclear Regulatory Commission. This is the subject of risk benefit balances as carried out in Section 4 of the document.

Apart from any philosophical or moral objections that might be raised, this type of analysis is compromised by a fundamental deficiency of the BEIR report of the National Academy of Sciences. A recently released statement of the National Council on Radiation Protection (NCRP Report #43) examines this subject in some detail and offers the conclusion that the figures in the BEIR report are highly uncertain and very likely gross overestimates of radiation hazards at low doses. It might be argued that this is not important in this particular instance since even use of the figures proposed in the BEIR report leads to a balance which is well in favor of introduction of the radiation producing devices involved. However, once NRC has committed itself to the use of such calculations it will be expected to adopt them in other instances under conditions where the balance is more critical and the conclusions drawn might be erroneous. I have no doubt that this could readily occur. In an environmental assessment report on the performance standard for diagnostic x-ray systems and their major components (21 CFR 1020.30-1020.32) the FDA comes to the conclusion that certain improvements in diagnostic x-ray equipment should be carried out on the basis of a similar risk benefit calculation. Here again I agree with the recommended action. However, the risk benefit balance is much more delicate in this case and if more realistic risk figures were to be employed it would come out in the opposite direction, i.e. against improvement of radiation

safety features. I believe there are also indications that the introduction of such calculations into the practice of radiology and nuclear medicine could quickly lead to ill-advised actions.

For the above reasons I strongly recommend omission of the risk benefit calculations in Section 4. I am aware that this involves a major policy decision.

One additional comment of somewhat lesser importance concerned the terminology in dosimetry and specifically the use of the expression "gamma dose" instead of "absorbed dose due to gamma radiation." Current national and international recommendations do not recognize the term "dose" to represent a physical quantity. The proposed change may be considered unduly formal except that a regulatory agency might take the position that it should employ strict terminology.

In the footnote to page 1-5 the term "barnes" should be replaced by "barns" in two places.

I do not understand the reasons for the restriction to 1 gram of plutonium under 2.3.4.1 (page 2-14). This corresponds to perhaps two pacemakers which seems to be a peculiar limitation.

At the end of the first paragraph on page 2-16 there is a sentence which would appear to need clarification since I do not know what is meant by "frequency significantly greater than the norm."

On page 2-17 and in various other places throughout the document reference is made to a monthly conventional pacemaker failure rate of 0.15%. I would presume that this applies to the device exclusive of its power source (even then it seems surprisingly low). Whatever the meaning this needs to be specified since I cannot believe that it applies to the entire device.

On the same page the first sentence under 2.5 might well be challenged and I would suggest that the word "demonstrates" be replaced by "indicates".

On page 3-1 the term "radiation doses" should be replaced by "absorbed doses" (if desired one might add "of radiation"). Corresponding changes should be made throughout the document.

On page 3-3 the last sentence in the first complete paragraph would better be concluded by "... since tissue attenuates the neutrons emitted more effectively than the gamma emission." This is necessary since neutrons are not always more effectively absorbed by tissue than gamma rays.

On page 3-5 the first sentence should be changed to "All of the organ dose equivalents are below 0.5 rem/year which is the maximum permissible dose equivalent for non-occupational exposure of the whole body and the critical organs including blood forming organs and gonads...."

In the 4th line from the bottom of this page the word "was" suddenly appears while "is" is used throughout the sentence.

A dose equivalent of 660 mrem can be incurred by airplane crews only if they spend all of the 960 hours at an altitude in excess of 40,000 feet at magnetic latitudes beyond 50 degrees. Even then this number represents the maximum galactic rate. The overall average is less. It seems quite unlikely that airplane crews exceed 500 mrem/year.

On page 3-20 the table referred to in the third paragraph is presumably 11.

In the next line the term "integrated dose" is undefined and in line with my comments at the beginning of this letter it may well be eschewed.

On 3-22 the reference to lead aprons might be misleading since these are designed to substantially absorb only x rays at modest energies.

Yours sincerely,

Harald H. Rossi

Professor of Radiology

HHR:lsh

A-17

CORATOMIC, INC.

BOX 434, INDIANA, PENNA. 15701 (412) 349-1811

September 5, 1975

Mr. Bernard Singer
Chief, Materials Branch
Division of Materials & Fuel
Cycle Facility Licensing
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555

Dear Mr. Singer:

I have come across several published items on plutonium safety. These may be of interest to the public with regard to your forthcoming evaluation of radioisotope-powered pacemaking systems. I have enclosed copies of these items, and I suggest these be placed in the Public Document Room.

These articles demonstrate that the hazards of plutonium have been grossly over-exaggerated in the adversaries' comments on the AEC Draft Environmental Statement. There is an item enclosed written by Henry W. Pierce, a Pittsburgh Post-Gazette staff writer. It reviews a report by Prof. Bernard Cohen, Director of the Scaife Nuclear Physics Laboratory at the University of Pittsburgh. Cohen's report concludes that a release from a nuclear reactor, which would involve many orders of magnitude more fuel than a pacemaker breach, would not be anywhere near as disastrous as has been claimed.

One of Cohen's most striking comments is this: "For those who fear that the earth may become contaminated with plutonium, it should be pointed out that there is almost as much radium in every meter of depth of the earth's crust as there would be plutonium in the world if all the world's present power were derived from fast breeder reactors." Radioisotopes naturally occur in the environment in quantities comparable to the most extensive nuclear programs contemplated, and man has developed positively for tens of thousands of years with this natural radiation integrated into his environment. Also enclosed is a rebuttal by Dr. Cohen to L. Douglas DeNike on a letter DeNike presented to "Nuclear News". Cohen's answer is scientifically clear and responsive.

Dr. Ralph E. Lapp is another experienced nuclear scientist who has carefully examined plutonium safety. Dr. Lapp is an energy/nuclear consultant to government and industry, and a Senior Member of Quadri-Science, Inc. Enclosed is an article of his, published in the April, 1975 Readers Digest, entitled: "Nuclear Power Reactors: How Dangerous?" This is a good summary of the advantages of nuclear reactors, and an equally good demonstration that the grossly exaggerated fears of the nuclear adversaries are not founded on facts.

Lapp shows that reactors are safe. The Coratomic pacer program involves a miniscule amount of plutonium by comparison. Many of Dr. Lapp's comments on reactors could be much more strongly stated in terms of the plutonium in pacemakers.

Not only is the quantity of fuel in our isotopic pacemaker very small, but the design of fuel cell in our pacer has evolved during the past ten years to become the safest isotopic containment known.

The Readers Digest article is just a summary of Dr. Lapp's comments. I have also enclosed a booklet entitled, Nader's Nuclear Issues, in which Lapp analyzes in detail, and then disproves many of the adversaries' arguments.

The last article I have enclosed does not treat alleged plutonium hazards, but instead discusses a more real shortcoming of another proposed long-life pacemaking system -- the NiCd rechargeable. This is an item from the Pittsburgh Press, and it concerns the difficulties elderly patients have in checking their pacemakers. This is a common occurrence, and it, in part, explains the reluctance of many physicians to utilize the device with older patients. The other disadvantage, of course, is that the patient is reminded of his ailment and his dependence on a machine once per week, with clock-like regularity.

I feel these ideas are critical in a fair evaluction of the wide-spread use of plutonium powered cardiac pacemakers, and I feel you should make them available to the public. We are proceeding with our formal comments on the Draft Generic Environmental Statement, and will make these available to you shortly.

Sincerely,

Peter M. Jacobson
Applications Engineer

PMJ:dm

Enclosures (5)

A-18

(2 1 10)

The following enclosures were submitted with letter No. 63 and are available for examination in the Nuclear Regulatory Commission Public Document Room, 1717 H Street, Washington, D.C.:

1. B. L. Cohen, "Letters," Nuclear News, August 1975.

2. L. D. DeNike, "Letters," Nuclear News, August, 1975.

3. R. E. Lapp, "Nuclear Power Reactors: How Dangerous?" Reader's Digest, April 1975, pp. 169-174.

4. H. W. Pierce, "Hazards of Plutonium Less Than Believed, Prof Says," Pittsburgh Post-Gazette, June 6, 1975.

5. T. R. Van Dellen, "Pacemaker Needs Care," Pittsburgh Press, August 7, 1975.

L21 102

CORATOMIC, INC.
BOX 434, INDIANA, PENNA. 15701 (412) 349-1811

3703

September 12, 1975

Mr. Bernard Singer
Materials Branch
Directorate of Licensing
U. S. Nuclear Regulatory Commission
Washington, D. C. 20545

Dear Mr. Singer:

Recently, I submitted several published articles to you. These reviewed a technical aspect of the isotopic pacer: they demonstrated that widespread use of plutonium involves only extremely minor risks to man and the environment, due to the radioisotopic fuel. Another article I had enclosed pointed out an important advantage of our isotopic pacemaker, especially in comparison to rechargeable systems -- the patient is no longer constantly reminded of his disease.

This issue of patient comfort, both physical and mental, is very important, and is a major factor in evaluating the efficacy of a pacemaking system. Although patient attitudes are difficult to quantify, a sincere effort should be made to integrate them into your forthcoming evaluation of plutonium pacemakers. With this in mind, I am submitting several published articles, which discuss patients' reactions to the Coratomic C-100 pacemakers. Since this is an essential part of the public reaction to isotopic pacemakers, I also request that you place these articles in the Public Document Room.

Patients and physicians tend to stress certain features of the Coratomic pacer in these articles. The small size, light weight and streamlined contour each enhance the patient's physical comfort. Several patients were happy to find that the Coratomic pacer doesn't restrict their physical activity like the larger and heavier, less advanced pacers they once had to wear. Mainly, however, they value the long projected life of the pacer most highly. All patients under 73 years of age at implant can statistically expect their Coratomic pacer to save them at least one reimplant operation. Many of these patients realize that their Coratomic pacemaker will probably last their lifetime, with very little monitoring or other attention. They are not forced to anticipate the physical discomfort of a replacement operation, as they were with a conventional battery-powered pacemaker. Nor must they be regularly reminded of their ailment, for they don't need to strap on a recharging vest once a week.

A-19

The isotopic pacemaker gives the patient a measure of security and peace of mind which he cannot gain from any other pacer. Many patients know that their isotopic pacemaker has been designed to far more severe standards than any other system, and they realize that their pacer is extremely safe and rugged because of this. No other pacer is so carefully designed, and of course, no other pacemaker has been so extensively te.ted. Most patients learn this when they agree to use a Coratomic pacemaker, and they remain more secure because of this, for the lifetime of the system.

Please consider this in your evaluation: To our knowledge, no patient who has been told he is eligible to have a Coratomic isotopic pacer implanted, has then chosen any other pacer.

Sincerely,

Peter M. Jacobson

Peter M. Jacobson
Applications Engineer

PMJ:mb

Enclosures (8)

The following enclosures were submitted with letter No. 65 and are available for examination in the Nuclear Regulatory Commission Public Document Room, 1717 H Street, Washington, D.C.:

1. "Atomic Pacemakers Implanted," Center Line, Washington Hospital Center 17(7), October 1974.

2. "Doctor Defends Her Plutonium Heart," letters to the editor, The Washington Star, April 10, 1975.

3. "Lutheran to Implant A-Powered Pacemaker," Fort Wayne Journal-Gazette, August 9, 1975.

4. M. Miller, "Nuclear Pacemaker Operation Sign of Times Here," Sun-Tattler, Hollywood,Fla., August 28, 1975.

5. J. Boulough, "New Heartbeat, New Hope," Denver Post, March 30, 1975.

6. "New Type of Pacemaker, New Life for Donna," The Springfield Union, Springfield, Mass., September 4, 1975.

7. News release, Allegheny General Hospital, Pittsburgh, Pa., October 3, 1974.

8. A. Page, "Tonawanda Boy Given Nuclear Pacemaker," Buffalo Evening News, May 1, 1975.

CORATOMIC, INC.

BOX 434, INDIANA, PENNA. 15701 (412) 349-1811

September 12, 1975

Mr. Bernard Singer
Materials Branch
Directorate of Licensing
U. S. Nuclear Regulation Commission
Washington, D. C. 20545

Dear Mr. Singer:

In your forthcoming analysis of the widespread use of radioisotope-powered pacemaking systems, we expect you will concentrate on a risk-benefit comparison of currently available systems. Weiner Associates of Cockeysville, Maryland has performed some applicable work in 1974. Although their study is based on the ARCO/AEC RPCP NU-5, the cost-benefit analysis is generally applicable to isotopic pacemakers.

The Weiner report finds that isotopic pacemakers demonstrate quite a large benefit-risk ratio for all patients with a life expectancy greater than ten years, at implant. This includes seventy percent of all implantees.

We have enclosed a brief summary of this report, as well as a copy of Weiner's document. We ask that the summary and original document be placed in the public document room.

Coratomic is proceeding with a more detailed risk-benefit analysis based on the C-100 Series pacemakers, which we will make available to you shortly.

Sincerely,

David L. Purdy
President

DLP:mb

Enclosures

621 104

The following enclosures were submitted with letter No. 66 and are available for examination in the Nuclear Regulatory Commission Public Document Room, 1717 H Street, Washington, D.C.:

1. Environmental Impact Statement Summary, September 12, 1975.

2. R. I. Weiner, "Systems Safety Analysis of Nuclear Pacemakers," a paper delivered at the Second Annual Systems Safety Society Conference, San Diego, California, July 24, 1975.

CORATOMIC, INC.

BOX 434, INDIANA, PENNA. 15701 (412) 349-1811

September 29, 1975

Mr. Bernard Singer
Materials Branch
Division of Materials and
Fuel Cycle Facility Licensing
U. S. Nuclear Regulatory Commission
Washington, D. C. 20545

Dear Mr. Singer:

In our letter of September 5, 1975, we submitted several published items on plutonium safety. These included references to a report by Professor Bernard Cohen, Director of The Scisfe Nuclear Physics Laboratory at the University of Pittsburgh. Since that time, we have obtained a copy of Dr. Cohen's original paper, "The Hazards of Plutonium Dispersal". The paper develops a comprehensive risk logic model for accidental or deliberate dispersal of reactor fuel in a variety of credible scenarios. Using techniques Cohen developed, we have constructed a parallel risk assessment for dispersal scenarios involving the fuel capsule in a Coratomic pacemaker.

The results are striking. Dispersal of all the plutonium-238 on a pacemaker fuel capsule would most probably contaminate only a small area, less than 100 square meters. This would be low-level contamination, with a carcinogenic risk less than 0.001. If the fuel were released in a crowded city, the carcinogenic risk would still be low, 0.008 if the dispersal took place in daytime, or 0.04 at night. Even if the release took place in a packed sports stadium, the risk of a single cancer being induced is still only 0.22. The additional risk on the wide areas outside the city where dispersal took place is almost negligible -- about 3.4×10^{-5}.

The most hazardous credible scenario is dispersal through the ventilating system of a large building. If no warning were first received, the dispersal of all the fuel in a pacer might result in as many as 1.5 statistical deaths. Cohen makes two comments in this connection. The first is that many more easily obtainable materials would be equally lethal, including nerve gas and biological agents. The second comment is that plutonium dispersal in a building ventilation system could not be used as a blackmail threat, for such a threat could be immediately defused by shutting off the ventilation system or cutting off power to the building.

The effects of plutonium dust inhalation could be reduced substantially by treatment with DTPA (diethylene triamine penta-acetic acid). Cohen estimates this would reduce carcinogenesis by a factor of two. If a warning were issued, as would be likely in a terrorist attack, Cohen estimates that this would further reduce the effects by a factor of ten.

Cohen finds that the risk due to the dispersal of insoluable plutonium like Coratomic fuel in food or water supplies is negligible. In addition, the risk due to buried plutonium-238 is shown to be practically nil.

The point of all this is that the plutonium in a pacemaker would not make an effective terrorist weapon. Dr. Cohen summarizes this in his conclusions:

> "Since nearly all fatalities caused by plutonium dispersal are via cancer, it is pertinent in this study to consider the terror engendered by an increased cancer risk. These cancers generally occur 15 to 45 years after the exposure, and in most victims the increased risk is less than 10 percent. The normal risk of cancer death in the U. S. is 16.8 percent, and this varies considerably with geography. For Kentucky, Tennessee, Alabama, and Mississippi, it is 14.7 percent, whereas in New England, it is 18.4 percent. It is highly doubtful whether this added cancer risk of 3.7 percent is given any consideration by people moving between the two areas.
>
> "When reports first reached the public of the cancer risk of cigarette smoking, millions of Americans were suddenly informed that they had accrued at least a 10 percent increased risk of cancer death. What ensued can hardly be described as terror. There was even little sign of terror among those very heavy smokers whose risk was as high as 50 percent.
>
> "It thus seems reasonable to conclude that inducing a risk of cancer that will not be fulfilled for 15 to 45 years is not likely to prove an effective way to cause terror.

Cohen's paper, and our parallel analysis are based on the most probable combination of circumstances. They are conservative, however, in the sense that they are based on health physics models with considerable built-in conservatism. One conservative assumption used is the "linear-no threshold" theory of the carcenogenic effects of low radiation doses. This is discussed briefly in an attached summary of the Linear Extrapolation Theory.

The figures given in this letter were calculated in the Plutonium-238 Dispersal Risk Assessment, which is attached. It corresponds to Dr. Cohen's calculations, and refers to the original paper by page number. Copies of Cohen's paper are also enclosed. Please place a copy of each of these enclosures in the Public Document Room.

Sincerely,

David L. Purdy
President

DLP:mb

Enclosures: "The Hazards on Plutonium Dispersal", by Bernard L. Cohen
Summary of the Linear Extrapolation Theory
Plutonium-238 Dispersal Risk Assessment

cc: Mr. F. Hittman

SUMMARY OF THE LINEAR EXTRAPOLATION THEORY

September 25, 1975

Cohen's figures are probably conservative.

Cohen's calculations of the somatic effects of plutonium are based on the assumption that the effects of radiation at low dose rates may be determined by extrapolating from data taken at high dose rates. This "linear-no threshold" theory has been widely criticized in the health physics community. Many of the criticisms have been summarized in the National Council on Radiation Protection and Measurements Report, No. 43.

The NCRP points out

> "All national and international groups which have studied the problems of quantitative carcinogenic risk estimates have regarded the practice of linear extrapolation as overestimating the risk, when the extrapolation is made from the rising and fairly linear portion of the dose-effect relationship . . ."

The shortcoming of linear extrapolation is that it does not recognize threshold effects. It is widely held that most, if not all carcinogenic processes involve multi-event mechanisms. These might include cell-killing or tissue disorganization to stimulate or encourage cell proliferation. Remote effects such as hormonal or immunological balances are thought to be critical. The point is that only a small percentage of a population exposed to low doses of radiation will have already experienced the events above which require greater doses. Therefore, only a small percentage of the population exposed to low doses of radiation will develop cancers -- a much smaller percentage than would be indicated by extrapolating from higher dose effects.

The BEIR Committee has indicated that its Report is a "most likely" estimate for the increased risk of cancer to the American population exposed to low dose radiation. The NCRP report points out, however, the body of the BEIR Report makes it clear that

> ". . . careful reading of both the summary and the "most likely" estimate refers to the most reasonable number that can be derived from linear extrapolation from high doses and dose rates, and not that such a procedure necessarily estimates the actual risk at low doses and dose rates . . .
>
> ". . . It seems probable, for example, that if there are induced cancers induced by small doses of radiation, they occur only in a relatively small number of highly susceptible individuals, and with factors other than radiation predominating.

While the results of Dr. Cohen's report are very encouraging, they are also based on what is widely recognized as a conservative hypothesis: the linear extrapolation theory.

A-23

PLUTONIUM -238 DISPERSAL RISK ASSESSMENT

In relating Dr. Cohen's treatment of reactor fuel dispersal to pacer fuel dispersal, it is necessary to compare the two types of fuel. The specific alpha activity of the medical grade plutonium Coratomic uses is 13.8 Curies/gm, a factor of 220 greater than the ^{239}Pu in Cohen's paper, and a factor of 41 greater than the "reactor-Pu" in Cohen's paper. The mean alpha energy of the medical-grade fuel is also greater than the figure for ^{239}Pu, by a factor of 1.07.

The fuel used on the Coratomic pacer would still be less dangerous than Cohen's "reactor-Pu" when released into the environment, however. This is due to its hard sintered ceramic form. The fuel pellet releases only a very small percentage of fines or particles smaller in size than ten microns, due to abrasion during a violent accident. Cohen estimates the production of fines in reactor-Pu to be 50%. The magnitude of fines released from PuO_2 fuel similar to Coratomic fuel has been studied by the Space Nuclear systems branch of United States Atomic Energy Commission. Here, 250 gm of fuel was impacted at 250 feet per second. The data obtained by Sandia and Los Alamos Scientific Laboratory between 1972 and 1974 (N. Goldenberg) indicate that approximately 0.1% by weight of the fuel is released in fines of less than ten microns diameter. This is a factor of 0.002 less than reactor-Pu.

These factors relating Coratomic fuel to the fuel Cohen treats are summarized in the table on the following page.

CONVERSION FACTORS RELATING "PACER-Pu"
TO
"REACTOR-Pu" AND 239-Pu

Alpha activity of fuel:	$\frac{13.8\ Cu/gm}{.062\ Cu/gm} = 220 \times {}^{239}Pu$
Mean alpha energy	$\frac{5.49\ MeV}{5.1\ MeV} = 1.07 \times {}^{239}Pu$
Alpha activity of fuel	$\frac{13.8\ Cu/gm}{.33\ Cu/gm} = 41 \times$ reactor-Pu
Percent fines <10u	$\frac{.1\%}{50\%} = .002 \times$ reactor-Pu

Relating Cohen's Hazards in Plutonium Dispersal to Pacemaker Fuel

Page 5. ^{238}Pu alpha particles are 1.07 times as energetic as ^{239}Pu alpha particles, so the total dose to the lung is (2000 x 1.07) = 2140 rem/μCi. Similarly, the dose rate to bone is (81 x 1.07) = 87 rem/year-μCi.

Page 6. The risk of liver cancer is (6.7×10^{-8} x 1.07) = 7.2×10^{-8}/year-man-rem

Total cancer risk per microcurie of ^{238}Pu inhaled into the lung is:

youth: (9 x 1.07) = 9.6%

average: (4.7 x 1.07) = 5%

Page 7. The number of deaths per μCi of ^{238}Pu inhaled into the lung is (.047 x 1.07) = .05 deaths per μCi. The number of deaths per μg of ^{238}Pu is then:

$$.05 \frac{\text{deaths}}{\mu Ci} \times 13.8 \frac{\mu Ci}{\mu g} \times .25 \text{ fraction retained in lung} = 0.17 \frac{\text{deaths}}{\mu g}$$

Page 10. The cancer-causing inhalation dose of ^{238}Pu is then:

$$1/(0.17 \text{ deaths}/\mu g) = 5.9 \ \mu g/\text{death}$$

Cohen's calculated lethal limit for inhaled "reactor Pu" is 260 μg and for ^{239}Pu, 1400 μg. Therefore, the lethal dose of ^{238}Pu is (5.9/260)=.022 times as small as the figure for reactor - Pu, and (5.9/1400) = .0042 times as small as the figure for ^{239}Pu.

The short term death doses of ^{238}Pu are reduced by this factor:

60 days: 12000 x .022 = 270 μg ^{238}Pu

1 year: 1900 x .022 = 43 μg ^{238}Pu

3 years: 700 x .022 = 16 μg ^{238}Pu

Page 13: The LC-50 figure for ^{238}Pu is also reduced by this factor:

total: .036 x .022 = 8×10^{-4} mg/m^3 ^{238}Pu

short-term: 1.8 x .022 = .04 mg/m^3 ^{238}Pu

The risk of cancer due to ^{238}Pu injected into the bloodstream is increased proportionally, to one death per (.022 x 78) = 1.7 μg ^{238}Pu

Page 14: Cohen's Table II is modified to include the cancer-causing dose in μg intake of ^{238}Pu:

	Reactor-Pu	^{239}Pu	^{238}Pu
Inhalation	260	1400	5.9
Injection into bloodstream	78	420	1.7

(Ingested data is not applicable for the insoluble PuO_2 fuel form)

Page 16: If all 225 mg of ^{238}Pu in a Cordtonic pacemaker's fuel capsule were released, the ratio of lethal inhaled mass to mass released would be:

$$\frac{q}{Q} = \frac{5.9 \times 10^{-6}}{2.25 \times 10^{-1}} = 2.62 \times 10^{-5}$$

Cohen's figures 4 and 5 indicate the area in which the lethal dose would be received, due to an unrestricted fuel capsule breach. During the daytime, it would be a strip about 7 meters wide and 11 meters long --- 80 m^2, approximately the floor area of a two-car garage. At night, when atmospheric conditions are more stable, the lethal dose would be received in a larger area, about 500 square meters, extending 50 meters downwind. This is about the area of the end zone of a football field.

Page 19: If a uniform population distribution extends 5000 meters downwind, the eventual number of cancer deaths, according to equation (1) in Cohen's report, is $\left(1 + 2 \ln \frac{5000}{11}\right)$ = 13.24 times the population in the 80 m^2 lethal area. A high city population density is about 10^{-2}/m^2, so a release at random of all the ^{238}Pu in a pacer capsule would induce a single cancer in the lethal

area with a probability of 0.8 and a total of 11 cancers in the city. At night, the release of all the plutonium in a single capsule would induce cancers in 5 people in the lethal area, and a total of 51 people in the city. These figures are grossly inflated, since they assume that all of the fuel would be released in particles smaller than 10 microns, the upper size limit for particles carried airborne into the lung. As was mentioned previously, Coratomic fuel is highly resistant to the production of fines and even in violent impact, less than 0.1% of the fuel escapes as particles smaller than 10 microns. This yields a dispersal efficiency factor of .001. Cohen also includes a factor of 0.8 to describe dispersal difficulties with PuO_2 dust. This yields a total dispersal efficiency for Coratomic fuel of .0008. This means that the most probable risk of cancer due to a single fuel capsule breach in a populated city is (11 x .0008) = .008 during the day or (51 x .0008) = .04 at night. These low numbers do not include the shielding effect of buildings, or the dose-reducing effect of advance warning, as Cohen does. These would further reduce the risk by a factor of 15-20.

If the release were accomplished in a crowded area, such as a large sports stadium with a population density of about one man per square meter, then the factor [1 + ln (L/R)] is reduced to about 3.4, so the total risk of cancer is 3.4 x 80 x .0008 = 0.22. Thus, release in a crowded stadium would only produce a one-in-five chance of one person eventually developing a cancer.

Page 27: If Coratomic fuel were dispersed in the ventilating system of a large building, the total amount of fuel inhaled by a single person would be:

.0008 dispersal efficiency x .05 fraction inhaled per person x .22 gm = 8.8 µg

Since the lethal mass is 5.9 µg, dispersal in ventilating systems would cause $\frac{8.8}{5.9}$ = 1.5 statistical deaths per pacer fuel capsule dispersal. If a warning were issued, as would be likely in a terrorist attack, Cohen estimates the risk is reduced by a factor of 10, to .15.

Page 27: The maximum permissible concentration of Pu in air for unrestricted use is 10^{-12} Ci/M^3. This is 7.2 x 10^{-8} µg/m^3 for ^{238}Pu, averaged over one year. Using Cohen's model for the resuspension constant K, the allowable ground concentration for the first year is .036 µg/m^2. When K reaches 10^{-5} m^{-1}, the allowable level is 72 µg/m^2. Taking into account Cohen's area coverage efficience of 1%, the dispersal of the 220 mg of ^{238}Pu in one pacer fuel capsule would contaminate 67,000 m^2 on a short-term basis, and 30 m^2 on a long-term basis.

Page 28: For short-term contamination, the total Pu inhaled is 7.2 x 10^{-8} µg/M^3 x 7000 m^3 of air inhaled per year. This is .0005 µg. Since the lethal dose is 5.9 µg, the short-term risk of developing cancer is .0005/5.9, or about one in 12,000. Over a longer term, Cohen shows the risk increases by a factor of ten, to about one in 1200. This assumes that the person spends all his time in the contaminated area, and allows no credit for the fact that the Coratomic fuel is very resistant to the production of inhalable fines. When no fines are produced, the resuspension coefficient K decreases, which, of course, reduces the risk of cancer due to inhalation. This consideration introduces the dispersion efficiency factor of .001 and reduces the contaminated area to about 40 m^2.

Page 29: Since the lethal dose of ^{238}Pu is .022 times as small as the lethal dose of reactor-Pu, Cohen's estimate of the number of fatalities per gram dispersed over a wide area is reduced to one death per (300 x .022) = 6.6 gm. The risk of death per pacer fuel load is then (.225/6.6) = .034, during the first year after release. When the dispersal inefficiency factor of .001, due to limited production of fines is included, the risk is 3.4 x 10^{-5}. This is

nearly negligible. The risk in the city in which the dispersal took place (page 30) is reduced in 10^{-4}. Cohen points out the effects following the first year after dispersal are negligible.

Page 31: Cohen shows that 50 or 60 kilograms of plutonium in soluble form are required to cause cancer through poisoning of food or water supply. This would involve about 250,000 pacemaker fuel capsules, each containing 225 mg ^{238}Pu.

Page 32: The probability of cancer induction for a man digging up ^{238}Pu which has been buried for a short time is about 44 times Cohen's estimate for ^{239}Pu -- about 1.8×10^{-7}. This is comparable to the man's probability of accidental death due to other causes, during the time he is working.

Page 33: As Cohen points out, most of the ^{238}Pu decays within 200 years, so the long-term risk of pacer fuel is negligible.

The following enclosure was submitted with letter No. 67 and is available for examination in the Nuclear Regulatory Commission Public Document Room, 717 H Street, Washington, D.C.:

1. B. L. Cohen, "The Hazards In Plutonium Dispersal," University of Pittsburgh, Pittsburgh, Pennsylvania, July 1975.

2415

cordis

Cordis Corporation
Post Office Box 370428
Miami, Florida 33137, U. S. A.
Telephone 305 834 5411
Cardiovascular Instrumentation

June 5, 1975

U. S. Nuclear Regulatory Commission
Washington, D. C. 20545

Attention: Acting Deputy Director for Fuels and Materials
Directorate of Licensing - Regulation

Gentlemen:

The Cordis Corporation, a recognized leader in the development and manufacture of cardiac pacemakers, most heartily concurs with the purposes and conclusions elucidated in your Draft Environmental Statement, issued in January 1975.

We are in particular agreement with the Statement's conclusion that benefits to be derived from the use of plutonium powered cardiac pacemakers far outweigh any subsequent risks to the environment and, as a consequence of this conclusion, wide-scale utilization of such power should be authorized.

The saving and protraction of human life is prima facie consideration for all manufacturers of cardiac pacemakers and any consequent maturation of that state-of-the-art is indeed a welcome asset if it helps to meet that goal and is within the rigid parameters of safety for all.

Cordis Corporation for some time now has conducted feasability studies and controlled clinical investigations of a plutonium powered cardiac pacemaker under Radioactive Materials License No. 464-3. Such investigations have helped to corroborate the findings and conclusions reached in your Draft Environmental Statement.

Cordis Corporation would like to complement the Directorate of Licensing for the very factual presentation contained in their Draft Environmental Statement. The magnitude of such a report will become apparent and fully appreciated with the introduction of newer and more advanced products which will benefit all humanity.

Sincerely,

Stephen Cookston
Marketing Manager
Nuclear Pacing Program

SC/BAS

621 — 1129

March 27, 1975

Acting Deputy Director for Fuels and Materials
Directorate of Licensing-Regulation
United States Atomic Energy Commission
Washington, D.C. 20545

Dear Sir:

I would like to protest agaoinst the proposeed use of plutonium-powered heart pacemakers. If companies like Kerr-McGee cannot safeguard their plutonium, how is some little old lady to do better? It seems that they would be unnecessarily endangered and also endanger the rest of us. Apparently the draft environmental statement does not even discuss the possible illegal uses of plutonium and how and if they might be avoided. I think that this should be considered and would weigh stronly against such devices.

Please inform me as to your progress in this matter.

Sincerely,

Gregg S. Everhart

Gregg S. Everhart
Box 8548
Stanford, CA 94305

A-28

EIDGENÖSSISCHES GESUNDHEITSAMT
SERVICE FÉDÉRAL DE L'HYGIÈNE PUBLIQUE
SERVIZIO FEDERALE DELL'IGIENE PUBBLICA

Sektion für Strahlenschutz
Section de la radioprotection
Sezione della radioprotezione

[redacted]
3011 Bern, Speichergasse 29

Mr.
Richard E. Cunningham
Assistant Director for
Fuel Cycle
Division of Materials and
Fuel Cycle Facility Licensing
W a s h i n g t o n, D. C. 20555

United States of America

APR 21 1975

Ihr Zeichen / Your reference / Votre référence
Ihre Nachricht vom / Your communication of / Votre communication du
Unser Zeichen / Our reference / Notre référence: 18.3.41 H/da
Bern the 10th March 1975

Gegenstand / Objet / Oggetto

Dear Mr. Cunningham,

I have received a copy of the Draft Generic Environmental Statement on the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers with many thanks.

A first glance at the report showed it to be a marvellous risk analysis, systematic, complete and convincing.

I am sure it will serve as a model for risk analysis, still to be done for many other products containing radioisotopes, and distributed throughout the population without control.

Sincerely

W. Hunzinger

Dr. W. Hunzinger
Chief, Department of Radiological Protection
FEDERAL OFFICE OF PUBLIC HEALTH

621 112

June 1, 1975

JUN 3 1975

Mr Bernard Singer, Chief
Materials Branch, Nuclear Regulatory Commission
United States Atomic Energy Commission
Washington, DC 20555

Dear Sir;

I have been one of the patients recipient of the nuclear Pacemaker since July 24 1973 and in my gratitude I must express my admiration for this great invention. In those 23 months I have had no discomfort nor attacks. I can climb two or three flights of stairs which I could not do with the other pacemakers that I wore before. The other pacemakers had to be changed within two years and for a person my age, the surgery involved was exhausting.

In the first year that I wore the Durant nuclear Pacemaker, I was in touch every week with the Cardiovascular Research Center to record my EKG via telephone. The second year, the telephone checks were reduced to once a month. During my last check-up visit, which visits take place every six months, I was informed that the monthly telephone recordings were no longer needed. It was indicated that the Doctors were confident of the regularity of the nuclear Pacemaker.

In January 1975, I had the great sorrow of losing my dear husband of 46 years. Needless to say that, during his two month illness with cancer, I experienced great anxiety and grief. After returning from a two months stay at my son's, I am now coping with the domestic tasks, shopping, etc., which were once taken care of by my husband. In my life I have had many difficulties and at 69 years of age, I feel life hangs by a very thin thread but concerning my cardiac ailment, I feel perfectly safe and secure.

I pray that this testimonial will be taken in all the seriousness it is given. For elderly persons such as myself who need long lasting and steady regulation, the nuclear Pacemaker must be praised for the great service it offers.

Respectfully yours,

Simone Fouquet

Simone Fouquet

2206 Colston Drive
Silver Springs, Maryland

A-29

J. K. FRENKEL, M. D.
10030 EL MONTE LANE
OVERLAND PARK, KANSAS 66207

AREA CODE 913 648 6650

March 24, 1975

Acting Deputy Director for Fuels & Materials
Directorate of Licensing - Regulation
U.S. Nuclear Regulatory Commission
Washington, D.C. 20545

Dear Sir:

This is to protest use of Plutonium-238 or -239 in cardiac pacemakers, under review in a draft environmental statement. This material is too toxic and too permanent to be disseminated for public use. Since adequate pacemaker batteries are available, there is no clear-cut need for this scientifically and intellectually interesting, but practically dangerous application.

I am concerned about ordinary losses, violent destruction of the apparatus in airplane crashes and fires, as well as criminal abuse of the material. Certainly the benefit to the patient should not be associated by an inordinate risk to society.

Sincerely yours,

J.K. Frenkel, M.D.

JKF:lw

FRESNO COMMITTEE FOR SCIENTIFIC INFORMATION
c/o Department of Chemistry
California State University, Fresno
Fresno, California 93710

#16

March 5, 1975

Acting Deputy Director for Fuels and Materials
Directorate of Licensing and Regulation
U. S. Atomic Energy Commission
Washington, D.C. 20545

Sir:

These comments are directed toward the "Draft Generic Environmental Statement on the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers," dated January, 1975.

The toxicity and radioactive potency of the element Plutonium make its widespread use absolutely irresponsible and intolerable. If this program is approved, 1500 or more pacemaker recipients will each be carrying a half-gram of Plutonium-238. This gram quantity is enough to bring 2.1 square miles of a city to levels of semi-permanent evacuation*, enough to induce thousands of cases of lung cancer if the material is efficiently dispersed in a populated localities area (such as a theater, skyscraper, etc.).

Accidental release of this plutonium may be remote. Deliberate release, not considered by the A.E.C., is in my opinion a far more probable risk. Terrorists would have access to identifiable sources of Plutonium, since each pacemaker recipient is to wear an identification bracelet. Any one of these 1500 or more sources could provide enough Plutonium to make a super-lethal weapon with which entire social systems could be blackmailed.

The program is even more outrageous when one considers the "benefit" from such a project: that the interval between skin-flap surgical operations might be lengthened to 10 years rather than the two to five years representing the useful life of conventional batteries. Such a benefit appears inconsequential compared with the enormous risk involved.

It is unthinkable that the U. S. Atomic Energy Commission would or could violate the public trust and safety by irresponsibly approving any program which could lead to the wide-scale, delocalized use of the highly toxic element Plutonium-238.

Sincerely,
David L. Frank
David L. Frank, Ph.D.
Chairperson

*Deductions from Table 2-2 of Nuclear Theft: Risks and Safeguards, Willrich and Taylor (Ballinger, 1974, p. 25). Although the half-life of Pu-238 is shorter than that of Pu-239, the toxicity is the same or greater.

A-30

621 113

GEORGIA INSTITUTE OF TECHNOLOGY
ATLANTA, GEORGIA 30332

SCHOOL OF
NUCLEAR ENGINEERING

cc: REC/HL/RGP for info

February 26, 1975

cy to Ken & Marian 3/5/75

MAR 5 1975

#9

Office of Nuclear Material Safety
and Safeguards
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555

Gentlemen:

Dr. Dean E. Abrahamson sent me a copy of the draft "Generic Environmental Statement on the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers." I have reviewed this document rather hurriedly and would like to comment as follows:

Perhaps my greatest concern about this proposed cardiac pacemaker program is the fact that 10% of the Pu by weight will be ^{239}Pu. This will correspond to 3110 μCi of ^{239}Pu in a new pacemaker. My concern is emphasized by the fact that this device is designed to contain the fuel for only 10 half lives of ^{238}Pu (or 864 y) in seawater. (Note that the helium pressure in a capsule would be considerable after 864 y.) This would reduce the ^{238}Pu to 0.098% but the ^{239}Pu to only 97.5% of the original activity (i.e. from 3110 μCi to 3030 μCi). This is not much help when it is recalled the present occupational body burden of ^{239}Pu or of ^{238}Pu is 0.04 μCi and I have shown by the enclosed paper this occupational level, when based on the total skeleton as the critical body organ, should be reduced at least by a factor of 240. Of course, the non-occupational levels of Pu should be much less (e.g. 1/240 x 0.04 x 0.01 = 1.7×10^{-6} μCi = 1.7 pCi). We should not forget also that after 10 half lives of ^{238}Pu the ^{238}Pu risk has not completely vanished. The 8.7 Ci of ^{238}Pu is now down to 8500 μCi. In 100 half lives of ^{238}Pu (i.e. 8640 y) the ^{238}Pu would be to a negligible level (i.e. 6.9×10^{-18} pCi) but the ^{239}Pu would have dropped only to 2360 μCi. Thus it seems to me two improvements should be made in the pacemaker: 1) the ^{239}Pu should be reduced considerably below 10% by weight and 2) the fuel capsule should hold up in seawater for more than 10 half lives of ^{238}Pu (16.4 half lives of ^{238}Pu or 1417 y would reduce the activity in a pure ^{238}Pu capsule to 100 μCi, a more acceptable level). Hopefully, 1417 years from now someone finding this capsule containing 100 μCi ^{238}Pu will treat it with some caution.

Of concern also is the amount of $^{241,243}Am$, ^{244}Cm, and $^{240,242}Pu$ that would be contained in a new pacemaker should power reactorgrade plutonium ever be considered as fuel for the pacemaker. The $^{241,243}Am$ content would have to be very low to keep down the γ-dose and the ^{244}Cm content must be low to reduce the neutron emission. I hope serious consideration will never be given to such a "low cost" pacemaker.

I do not believe it is sufficient for the person to carry a card and bracelet indicating he has in his body a radioactive pacemaker. It seems to me, in addition, he should have tatooed on his body near the groin something like "Radioactive Pacemaker--phone 202-408-6618" in which the phone number would be some office of the NRC (Charles Eason's Record Department) that would be on call to provide instructions.

It seems to me it is not sufficient for the hospital to keep records of patients having these pacemaker implants. These records should be in duplicate with copies maintained in Mr. Charles Eason's NRC radiation records. After all, records of a hospital can be destroyed by a fire.

In conclusion, I believe that ^{238}Pu with 10% ^{239}Pu is not a wise choice. I think a very serious effort should be made to obtain relatively pure ^{238}Pu because of its low yield of x- and γ-rays, low spontaneous fission, and relatively short half life. Both the ^{239}Pu and the ^{236}Pu (with its daughter products) introduce serious problems. Why not develop a mass separation of the ^{238}Pu?

It would be wise to encourage or require those having pacemaker implants not to conceive children--especially if the generator is implanted in the abdomen. As a precaution perhaps such persons should be sterilized.

I hope the above comments will be given appropriate consideration.

Yours truly,

Karl Z. Morgan
Neely Professor

KZM:lsg
Enclosure

cc: D. E. Abrahamson

A-31

The following enclosure was submitted with letter No. 9 and is available for examination in the Nuclear Regulatory Commission Public Document Room, 1717 H. Street, Washington, D.C.:

1. K. Z. Morgan, "Suggested Reduction of Permissible Exposure to Plutonium and Other Transuranium Elements" (processed).

Sept. 14, 1975

232 Howland Canal
P.O. Box 247
Venice, California 90291

Acting Deputy Director for Fuels & Materials
Directorate of Licensing-Regulation
USAEC
Washington, D.C. 20545

Dear Sir:

The purpose of this letter is to deliver to you our strongest protests against the use of PU238, or any of the other isotopes of plutonium, in heart pace-makers.

Please include our remarks as part of any official hearing record on this subject.

PU238 is one of the deadliest substances ever introduced into the planetary ecosystem by man. A microscopic particle, if lodged in the lungs, will cause almost certain lung cancer. A tiny amount, if ingested, could be absorbed by the bone marrow and become a radiological poison, emitting heavy charged particles which cause leukemia, other cancers, gene and cell damage, and mutations. It is also a gamma emitter, which means that exposure is the same as exposure to high energy X-rays, bringing massive, irreversible interference with cell metabolism and reproductive processes. The PU239 body burden, the amount that can be maintained indefinitely in an adult without producing significant body injury, is about $\frac{1}{4}$ billionth of a gram. PU238 is 270 times as radiotoxic as PU239, so that this microscopic amount must be reduced even further.

Enough PU238 to cover the head of a pin, if dispersed evenly, would be enough to give the population of San Francisco lung cancer. A few grams dispersed through the air-conditioning system of a large building, would be enough to kill all life in the building. A piece as big as a basketball, if pulverized and spread evenly over the earth's surface, would probably eliminate all life on this planet.

It would be the epitome of madness, in our opinion, to allow ANY possibility of even microscopic quantities of PU238 to be released into the planetary ecosystem. The draft E.I.R. on the heart pace-maker program, incredibly, does not even discuss this possibility, or the results of such a release. To feel that this omission is in blatant disregard of the broad public interest.

We stand strongly against any use of the plutonium isotopes in the heart pace-maker program.

Yours cordially,

Ron Duenther and family

Box 107 Rte. 2
Edgewater, Maryland
21037

May 27, 1975

Directorate of Licensing
Chief, Materials Branch
United States Atomic Energy Commission
Washington, D.C. 20555

Dear Mr. Singer:

"Confidence"

I have been a user of pacemakers since May of 1970. My sixth pacer is a Medtronic Model 9000 isotomic, Serial #4R00057.

It has come to my attention that you are interested in hearing all points of view on the subject of Atomic Pacers.

My reaction is from the patients point-of-view. I finally feel confidence in my present pacer.

1. I was fortunate enough to visit the Medtronic Plants in Minneapolis in September, 1974.
2. The tour gave me confidence in Medtronics ability to put out excellent products thoroughly checked and counter-checked.
3. I had the privilege of being introduced to Dr. Kenneth A. Gasper, Director of Engineering, Pacemaker Systems. Dr. Gasper gave me a history of and projected expectations of the Model 9000, giving me even more confidence.
4. My wife and I made an 11,400 mile trip through Canada's mainland to Vancouver Island then down through Washington, Oregon, California, Baja California and back up through Arizona, Utah, and Wyoming before heading home. I was not allowed to take this trip with my other "pacers" because of altitudes. With the Model 9000 I went over 9000 feet with no side effects driving a 29' motor home.
5. The ability of the doctor who installed the Model 9000 increased my confidence. Dr. Nicholas P.D. Smyth did an excellent job and has followed up closely since the implantation.
6. Two doctors, David A. Morowitz, Gastroenterologist, and Harold H. Haxfield, Surgeon, both of the Physicians Office Building at the Washington Hospital Center, agree that without my Model 9000 Pacer I would have sustained two major surgerical operations that I had this year in a short period of time. On February 27, 1975, I had surgery for the removal of an embolism of my left leg from the knee down saving my left foot. On May 7, 1975, I had an ileitis operation for the removal of part of my small intestine and my appendix.

All of the above spells confidence and believe me I needed confidence after having my heart beat drop to 29 per minute. I am 68 years old and have no problems of mobility or restrictions except over doing that any man my age has.

Please accept this letter as a layman's vote for continued use of the nuclear pacemaker.

Yours very truly,

N.W. Hauser

Hittman Nuclear Battery Corporation
9190 Red Branch Road
Columbia, Maryland 21045
301/730-7800

Refer to:
75-NB247

April 2, 1975

#38

APR 23 1975

Nuclear Regulatory Commission
Washington, DC 20545

Attention: Acting Deputy Director for Fuels and Materials
Directorate of Licensing - Regulation

Subject: Comments on "Draft Generic Environmental Statement on the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers"

Gentlemen:

We have read with interest many of the comments you received on the "Draft Generic Environmental Statement on the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers." The adverse comments made can be categorized into several areas such as pacemaker longevity, nuclear safety, plutonium toxicity, etc. We intend to analyze the adverse comments and submit our "comments on the comments," so to speak, according to these categories. As the longevity of pacemakers is a highly crucial point affecting the benefit-risk analysis, it is the area which we will address initially. Enclosed you will find our information regarding pacemaker longevity.

We could not help but note a striking similarity of terminology in the following documents which you received.

1. "Comments on Draft Generic Environmental Statement on the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers," Dean E. Abrahamson, March 8, 1975.

2. Letter from Scientists' Institute for Public Information, Allen C. Nadler, March 7, 1975.

3. Letter from Fresno Committee for Scientific Information, David L. Frank, March 5, 1975.

4. Letter from Public Citizens, Sidney M. Wolfe and John Abbotte, March 10, 1975.

5. Letter from Zero Population Growth, L. Douglas DeNike, January 31 1975.

Indeed, it should be noted that Dean Abrahamson, H. Jack Geiger, Dan W. Lufkin, David W. Swetland, Margaret Mead, Barry Commoner, Donald Dahlsten, Allen C. Nadler, Glen Paulson, and Martin Sonneberg are all members of both the Scientists Institute for Public Information and the Fresno Committee for Scientific Information. Based upon the similarity of terms utilized such as "skin flap surgery," "nuclear gadgets," etc. it would not be surprising to find that the same group of persons was in essence responsible for the submission of all five of the above listed submittals. It perhaps reflects the efforts of a small group of persons, under the guise of numerous organizations, to retard progress in the cardiac pacemaker area. However, this is important only as it relates to the quantity of the adverse comments received rather than their quality.

In terms of quality of the adverse comments, we were impressed by the sparsity of quantitative scientific argument. There was much personal feeling expressed and a good bit of "arm waving" was in evidence. In most instances, there was an appalling lack of knowledgeability with regard to implantable cardiac pacemakers. Scientific data and sound analyses were almost totally absent.

As previously stated, this submission is restricted to our initial category of comments, that of pacemaker longevity. Further submission will be made in the near future. We are taking this approach due to the fact that our analyses will necessarily be voluminous. We hope they will be considered in your final determination regarding plutonium powered cardiac pacemakers.

Sincerely yours,

Thomas S. Bustard, Ph.D.
President

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Enclosures

PACEMAKER LONGEVITY

One of the most difficult areas to quantify in the field of implantable cardiac pacemakers is that of longevity. There exist a myriad of power sources presently in use or contemplated for use. The manufacturers of these power sources or the pacemaker manufacturers utilizing them make numerous claims based upon what they think they have or will have in the "near future." The issue is further clouded by physicians who publish data on their personal experience with small numbers of a specific pacemaker. Most of these non-quantitative claims are clouded by a vested interest of one sort or another.

Our analysis and comments with regard to pacemaker longevity is separated into several topics. These are power sources, catheters or wires, and electronics. The power sources section is further categorized to discuss several of the specific "new" chemical batteries that have recently come into use.

A. Power Sources

It is generally conceded that prior to the advent of the plutonium powered pacemaker that the power source represented the life limiting factor. The most common power source utilized was the Mallory RM-1 "certified" mercury-zinc oxide cell. Since, and probably as a direct result of the introduction of the plutonium powered pacemaker, a myriad of "new" power sources have appeared. Many lofty claims are made for these devices, all of which are clouded by non-scientific data and vested interest.

1. Presently Available Pacemakers

The only firm, statistically significant pacemaker longevity data of which we are aware and which is generally available may be obtained from:

Cardiac Datacorp, Inc.
Pacemaker Evaluation Systems
1705 Walnut Street
Philadelphia, Pennsylvania 19103
Telephone: (215) 665-0700

This company specializes in telephone monitoring of pacemakers of all types. Attachments 1, 2, and 3 of this submittal are data obtained from Cardiac Datacorp for the periods ending December 13, 1973, June 30, 1974, and September 30, 1974. The data cover thousands of pacemakers.

Note that excluding elective replacements, 80 to 81.5 percent of all pacemaker removals were for battery depletion. The mean time to removal for battery depletion varied only slightly from 24.9 to 25.3 months. The elective replacements, which are made for the most part by pacemaker producer recommendation or physician fear of impending battery depletion, had a mean life of 24 to 25 months and therefore correspond closely to the battery depletion numbers. This lends credence to the fact that the power source still represents the life limiting factor in cardiac pacemakers.

Perhaps more germane to the subject is the lifetime of the pacemakers which were not removed and were still functional at the time of the report. These are as follows:

	Report Date		
	12/31/73	6/30/74	9/30/74
Average Pacemaker Lifetime	31 months	30.6 months	31.4 months

Note that these numbers are not the average lifetime of the total pacemaker population, but are restricted to those still functioning. This is significant in that the units previously failed or electively removed have not been considered to have shortened the average lifetime. The most pertinent point is that the average lifetime of the pacemakers still functioning did not increase significantly between December 31, 1973 and September 30, 1974.

The data from Cardiac Datacorp would indicate that the Nuclear Regulatory Commission was overly optimistic with regard to chemical battery powered pacemaker lifetime in the benefit-risk analysis. Indeed, the data, which covers more than 10,000 patient month of monitoring and over 4000 pacemakers would indicate an average pacemaker lifetime of less than 30 months with 80 percent of the failures being due to battery depletion. These data would indicate a greater benefit-risk ratio in favor of plutonium powered cardiac pacemakers than that given in the "Draft Generic Environmental Statement on the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers."

2. Lithium Powered Pacemakers

Prior to 1971, almost all pacemakers were powered by the Mallory RM-1 "certified" mercury-zinc oxide battery. Since that time, many other chemical power sources have been considered for use. Perhaps the most well known and widely utilized "new" chemical battery is the lithium-iodide cell marketed by Wilson Greatbatch Ltd. of Clarence, New York. The pacemakers manufactured by Cardiac Pacers Inc. of Minneapolis, Minnesota use this power source exclusively.

Several of the adverse comments on the Draft Environmental Statement were directed toward use of the lithium system as a viable and less risky alternate to the plutonium powered pacemaker. Indeed, the comments from Public Citizen seemed critical that this type device had received greater exposure to date than the plutonium powered pacemaker. Perhaps this group is unaware of the restraints that are placed on plutonium powered

pacemakers as compared to the total non-regulation of other types. Be that as it may, Abrahamson indicates that the expected lifetime of these pacemakers is 10 years or greater. He further criticizes that the 10-year life was not utilized in the benefit-risk analysis but rather the 60 to 76 months for the improved mercury cells was employed.

The fact that it is impossible to prove that any of the newly developed chemical power systems will operate for a period of 10 years with only 3 years of clinical experience does not seem to have had any affect on anyones' judgment in this regard with the exception of the manufacturer. Note that in the letter from Wilson Greatbatch to Mr. Melvin Shupe dated March 6, 1975, Dr. Greatbatch points out that the word well in "well beyond the six-year objective" on Page 4-4 of the Draft Environmental Statement should be deleted. He goes on to state that Wilson Greatbatch Ltd. makes no statistical claim (for the lithium-iodide battery) beyond the six-year lifetime.

Other examples of the longevity of the lithium powered pacemaker can be given. Attachment 4 to this submittal is one such publication. Note the underlined conclusion that perhaps the battery will not power a pacemaker for even five years.

3. Rechargeable Pacemakers

Much publicity has been given over the last several years to rechargeable pacemakers. Perhaps the foremost of these units was developed at The Johns Hopkins Applied Physics Laboratory. This device is produced and marketed by Pacesetters Inc. of Sylmar, California. Here is yet another example of an unproven power source for which extended longevity claims are being made. The first such unit was implanted in February 1973 or only slightly more than two years ago. Since that time, more than 1200 of these have been implanted with only two failures reported by the manufacturer. This is indeed an enviable record of progress but it must be pointed out that chemical battery failures are not statistically "random," their failure mode is one of "wear out." That is, operating 1000 units successfully for a year does not prove that one unit will last for 1000 years. Further clinical data is necessary to prove their claimed longevity.

Another point to be made, which is applicable to both solid state and rechargeable pacemakers is that their batteries will wear out due to chemical depletion. It would seem then that longevity could be predicted by examining the internal state of the battery with regard to chemical reactivity. Despite carefully searching the literature, nowhere is there a cross sectional picture of these type batteries comparing an operated unit to one as good as new.

Another consideration with regard to the rechargeable pacemaker has to do with its medical acceptability. Certainly the record for pacemaker longevity is held by a device developed by a group of physicians at Queen Elizabeth Hospital in Birmingham, England. This is the inductively coupled pacemaker. That is, the battery power source is worn externally by the

patient and power is transmitted through the skin to the pacing circuitry. In March 1973, there were 46 patients who had been continuously paced for more than five years and an incredible four who had been paced for more than 10 years by this system without operation. Curiously, this system was not mentioned in the Draft Environmental Statement nor in any of the comments on the Statement. The reason for this is, of course, the small number of patients utilizing this device which relates directly to its medical acceptability. Many physicians do not wish to have their patients carry an external power supply as it retards medical rehabilitation. The same is true of rechargeable pacemakers to some extent.

We are not qualified to comment on medical acceptability and will leave that to the physician community. However, we include an article as Attachment 5 to this submittal where Dr. Seymour Furman of Montefiore Hospital in New York who has experience with these devices and gives some patients' viewpoints.

3. Miscellaneous Power Sources

Other power sources such as biogalvanic, piezoelectric, etc. have been proposed for use with implantable cardiac pacemakers. Recently, a "new" rechargeable pacemaker using a mercury-silver battery has been given some publicity. Not too long ago, General Electric was extolling the sodium-bromine power source for pacemakers. All of these units are very new and have yet to reach clinical trials.

B. Catheters

Presently, as shown by the included data, power sources continue to be the life limiting factor in pacemaker failure. However, it is fact that some pacemakers do malfunction because of the catheter breaking. Little documented data appear in the literature regarding this failure mechanism. Attachment 6 to this submittal is the best piece of documented data concerning this phenomena that we were able to find. Note that the data indicate that transvenous catheters are more stable than myocardial and that stainless steel coil catheters can be expected to have a significant lifetime. Certainly it is in excess of any of the power sources previously discussed.

C. Electronics

Pacemaker electronics reliability have suffered from the environment in which they are required to operate. Most commercially available pacemakers are epoxy encapsulated. The epoxy itself contributes to the hostile environment. Attachment 7 to this submittal is a description of how and why. Further while the epoxy acts as barrier to salt ions, it does permit the passage of water. Therefore, the pacemaker electronic circuitry ends up operating under high stress in warm water. This is not

a problem with chemical battery powered pacemakers in that the electronics, despite the hostile environment have not represented a life limiting factor.

Newer pacemakers, including several models of the plutonium powered variety are hermetically sealed. This negates the previous factors. Further, some of the more advanced models are beginning to employ high reliability, hybrid circuitry. These factors will increase the pacemaker electronic reliability. However, even at present, under adverse conditions, no one has pacing circuits which will last for 10 to 20 years.

D. Summary

We hope that this submittal has shown that many or perhaps all of the adverse comments received on the Draft Environmental Statement concerning pacemaker longevity are without foundation in fact. It would seem that many of the adverse comments were made in the vein that if plutonium powered pacemakers were released to wide-scale use, that they would be universally adopted. We do not believe this to be the case. In fact, it is our anticipation that only 10 to 30 percent of all pacemaker patients are suitable candidates for the nuclear unit. Attachment 8 is a short study performed for us by Dr. Victor Parsonnet indicating this to be a valid range. Larger percentages of the pacemaker patient population are probably more suited to the solid-state, rechargeable, and mercury battery powered devices. We do believe, however, that in certain cases, a plutonium powered pacemaker will be more suitable than any other type and that a positive benefit-risk ratio will be present in these instances.

Several items of information lead us to believe that our conclusion in this regard is sound. First, many of the pacemaker producers are developing a varied line of systems which include all the different power sources. These include the plutonium powered pacemaker as well as the solid state and mercury battery powered units. Second, we are including with this Attachment 9 which is a series of papers on pacemaker energy sources from the IVth International Symposium on Cardiac Pacing. Note particularly the discussion at the end of this attachment amongst some of the leading pacemaker authorities in the world.

The following enclosures were submitted with letter No. 38 and are available for examination in the Nuclear Regulatory Commission Public Document Room, 1717 H Street, Washington, D.C.:

1. Analysis of the Data on 4,111 Pacemakers, Cardiac Datacorp, Inc., September 30, 1974.

2. Analysis of the Data on 3,835 Pacemakers, Cardiac Datacorp, Inc., June 30, 1974.

3. Analysis of the Data on 3,084 Pacemakers, Cardiac Datacorp, Inc., December 31, 1973.

4. D. J. Debney, "Cardiac Pacemaker Encapsulation Investigation," Bio-Medical Engineering, October 1971, pp. 458-462.

5. K. Fester and R. L. Doty, "Solid-State Batteries for Cardiac Pacemakers," Medical Instrumentation 7(3): 172-175, May-August 1973.

6. "New Pacemaker Goes On and On," Medical World News, February 10, 1975, pp. 26-27.

7. V. Parsonnet, L. Gilbert, and I. H. Zucker, "The Natural History of Pacemaker Wires" (processed), Department of Surgery and Cardiodynamics of the Newark Beth Israel Medical Center, Newark, New Jersey.

8. V. Parsonnet, "Potential Patient Users of Radioisotope Thermonuclear Generator," letter addressed to F. Hittman, October 13, 1972.

9. Articles copied from text (reference not given) as follows:

   J. G. Davies, "Pacemaker Power Sources, Past, Present, and Future"
   W. Greatbatch, "Chemical Power Supplies for Implantable Cardiac Pacemakers"
   V. Parsonnet et al., "The Development of Radioisotope Power Sources for Pacemakers in the United States"
   F. Laurens et al., "Clinical Results of the Implantations of an Isotopic Pacemaker"
   O. Z. Roy and R. W. Wehnert, "Biogalvanic Energy Sources"
   J. K. Cywinski et al., "Biogalvanic Power Sources"
   L. D. Abrams and D. O. Williams, "Experience with the Inductively Coupled Cardiac Pacemaker between February 1960 and February 1972"
   L. Cammilli et al., R.F. Impulses Transmission: Clinical Results and Current Status"
   E. Dekker et al., "Discussion: Energy Sources"

Hittman
Nuclear Battery
Corporation
9190 Red Branch Road
Columbia, Maryland 21045
301/730-7800

Refer to:
75-NB251

April 10, 1975

Nuclear Regulatory Commission
Washington, DC 20545
Attn: Acting Deputy Director for Fuels and Materials
Directorate of Licensing - Regulations

Subject: "Draft Generic Environmental Statement on the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers"

Dear Sir:

On April 2, 1975 we submitted comments on the subject document pertaining to pacemaker longevity. Since, an article has appeared in the "Medical World News" dated March 24, 1975 pertaining to pacemaker longevity. This article, enclosed, also indicates that pacemakers are presently lasting 24 to 36 months.

We thought this might also be of some interest to you.

Sincerely yours,

Thomas S. Bustard, Ph.D.
President

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Enclosure

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The following enclosure was submitted with letter No. 41 and is available for examination in the Nuclear Regulatory Commission Public Document Room, 1717 H Street, Washington, D.C.:

1. "Pacemaker Life: The Price Is Right," Medical World News, March 24, 1975, p. 63.

HITTMAN

Hittman
Nuclear Battery
Corporation
9190 Red Branch Road
Columbia, Maryland 21045
301/730-7800

August 21, 1975

Mr. Bernard Singer, Chief
Materials Branch
Directorate of Licensing
U. S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Singer:

Considerable time has now passed since your issuance of the "Draft Generic Environmental Statement on the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers" in January of 1975. We believe that certain new and more complete information should be considered for inclusion in your final statement. In addition, we consider it important to address ourselves to some of the comments made on the "Draft Statement" and its conclusions and recommendations, since its issuance.

Approximately 1400 nuclear pacemakers have been implanted in humans since April of 1970 (about one-third of them in the United States), without a single battery failure. The median age of the nuclear powered pacemaker recipients to date is approximately 46 years. The life expectancy of the median aged nuclear pacemaker recipient is 29 years (based on the latest U.S. life expectancy and mortality data). The nuclear thermoelectric technology upon which nuclear batteries for pacemakers are based was developed primarily in the United States, since 1955, and has been utilized in nuclear space power supplies wherein one of the earlier nuclear batteries (SNAP-3) has been producing power in a TRANSIT satellite for 15 years. The performance history to date gives credence to the projections of expected nuclear battery lifetimes of 20 years or more. It may, in fact, be possible to ultimately produce a pacemaker power supply that will operate for the lifetime of the youngest patients.

Nevertheless, it would be unrealistic to contemplate that all pacemaker recipients should receive nuclear powered pacemakers. This has never been contemplated. However, for patients in the younger age group with long life expectancy and free from known major disease such devices should be available for the free choice of the physician and patient.

Independent studies indicate that based on today's patient population no more than 15 percent of the patient population would be suitable candidates for nuclear pacemakers. Improved mercury cells, lithium cells, rechargeable batteries, etc., as well as nuclear batteries, will all play a role in satisfying the varied needs of future pacemaker patients. No single power supply is a panacea. Just as there are many different types of pulse generator and pacemaker models in use today, different power supplies should be available to optimize the solution of the pacing problem of the patient.

The laborious administrative burden imposed on nuclear pacemakers by regulatory and licensing restrictions has, and will deter frivolous use of nuclear pacemakers. Allowing the medical community the freedom to choose a nuclear pacemaker for their patients will make certain that this technological advance will not be denied to patients best served by them.

We believe it important that the final environmental statement emphasize the fact that nuclear pacemakers are contemplated for use in a very specific portion of the patient population and that based on today's projections this will represent a small fraction of the overall population. The benefit analysis should then reflect the rewards to this specific patient population as compared to other alternatives and the negligible attendant risks to the general population.

We fully agree with the conclusion contained in the "Draft Statement" that recommends the wide-scale use of plutonium powered cardiac pacemakers under certain administrative and licensing controls. We also believe that after the intense testing program performed on nuclear pacers (more severe than that for any conventional pacer) that the NRC should move as quickly as possible to allow pacemaker patients to benefit from this development. Further delay in carrying out your recommendations would not only destroy the capability for production of such devices, but unfortunately prevent the youngest and healthiest members of the pacemaker bearing population from ever benefiting from this unique development.

Our comments are presented in the enclosed memorandum entitled Comments on the Nuclear Regulatory Commission "Draft Generic Environmental Statement on the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers." If there is any clarification required on the data presented, please feel free to call upon us.

Sincerely yours,

Fred Hittman

Fred Hittman, P.E.
Chairman of the Board

Thomas S. Bustard

Thomas S. Bustard, Ph.D., P.E.
President

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Enclosure

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COMMENTS ON THE NUCLEAR REGULATORY COMMISSION
"DRAFT GENERIC ENVIRONMENTAL STATEMENT
ON THE WIDE-SCALE USE OF PLUTONIUM POWERED
CARDIAC PACEMAKERS"

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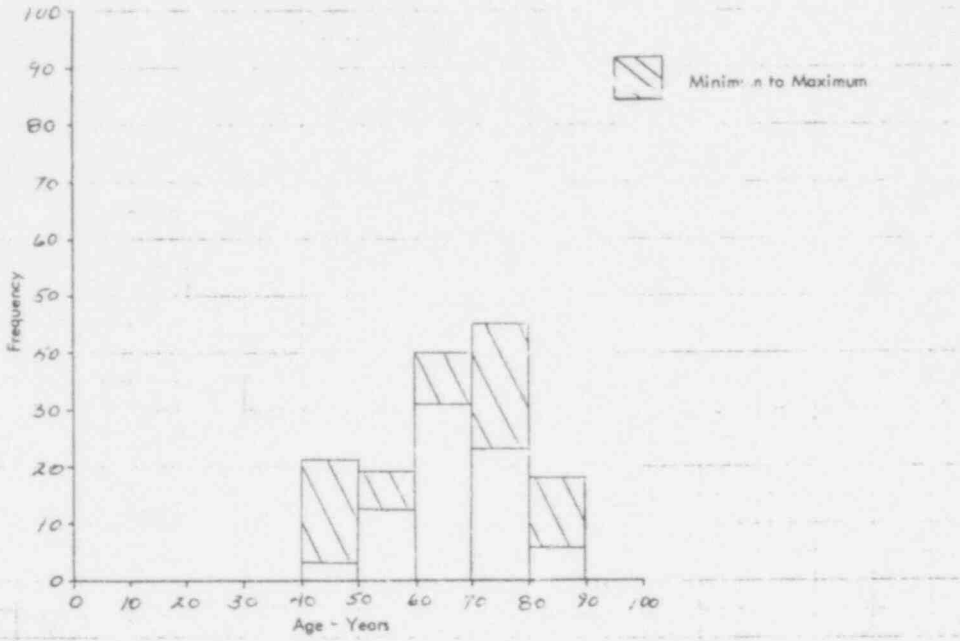
Benefit Analysis - Pacemaker Population Considerations

As the primary benefit of a plutonium powered pacemaker is its long life, all factors affecting the benefits resulting from longevity must be carefully considered. One of the more important of these factors is the age of the patient population. Figure 1 shows the age frequency of typical pacemaker bearers from four surveyed populations.(1) These populations are for all pacemaker bearers and probably represent primarily mercury cell powered pacers because the data was published in 1973. Shown on Figure 1 are the maximum and minimum percentages of the four populations for each of the 10-year age groups. Of particular note is the fact that below age 40, there is no 10-year grouping with a level of even 1 percent.

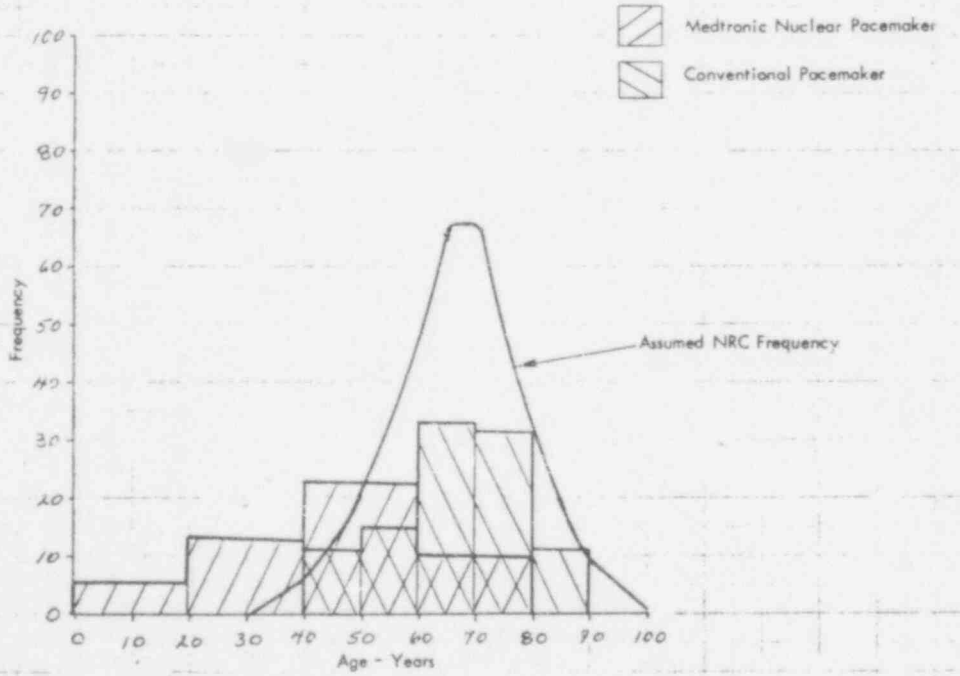
Figure 2 shows the normalized age group of the four populations previously discussed with the assumed NRC frequency(2) utilized in the benefit analysis. Also shown on Figure 2 is the age frequency for nuclear pacemakers as experienced by Medtronic Inc.(3) It is important to note that the age frequency for nuclear pacemakers is for a much younger patient population than either the surveyed populations (Figure 1) or the NRC assumed age distribution. This is more readily apparent on Figure 3 which shows the distribution of the age frequency. Note the distribution assumed by the NRC and the four surveyed populations (Figure 1) are identical. However, the age distribution for the nuclear pacemaker population is markedly different. The median age of a conventional pacemaker bearer is 68 years, while the median for a nuclear pacemaker bearer is 46 years! This represents an enormous disparity when considering longevity benefits.

Also shown on Figure 3 are two isolated points for conventional pacemaker bearers.(4) These represent the latest available data on age distribution. They are an indication of a trend generally realized in the pacemaker industry, that the average age of all pacemaker bearers is decreasing.

The ramifications of these data will have considerable impact on the benefit analysis. The NRC analysis utilized a conventional historic pacemaker population for the direct comparison between the nuclear and non-nuclear devices. We believe that this does not present an accurate up-to-date picture. The NRC's benefit analysis should reflect the fact that long-lived pacemakers are implanted in a much younger patient population group than the historical data for chemical powered pacers presents. The nuclear pacemaker age distribution experienced should be utilized for the cost benefit comparisons rather than the



Frequency of Four Pacemaker Populations
Figure 1

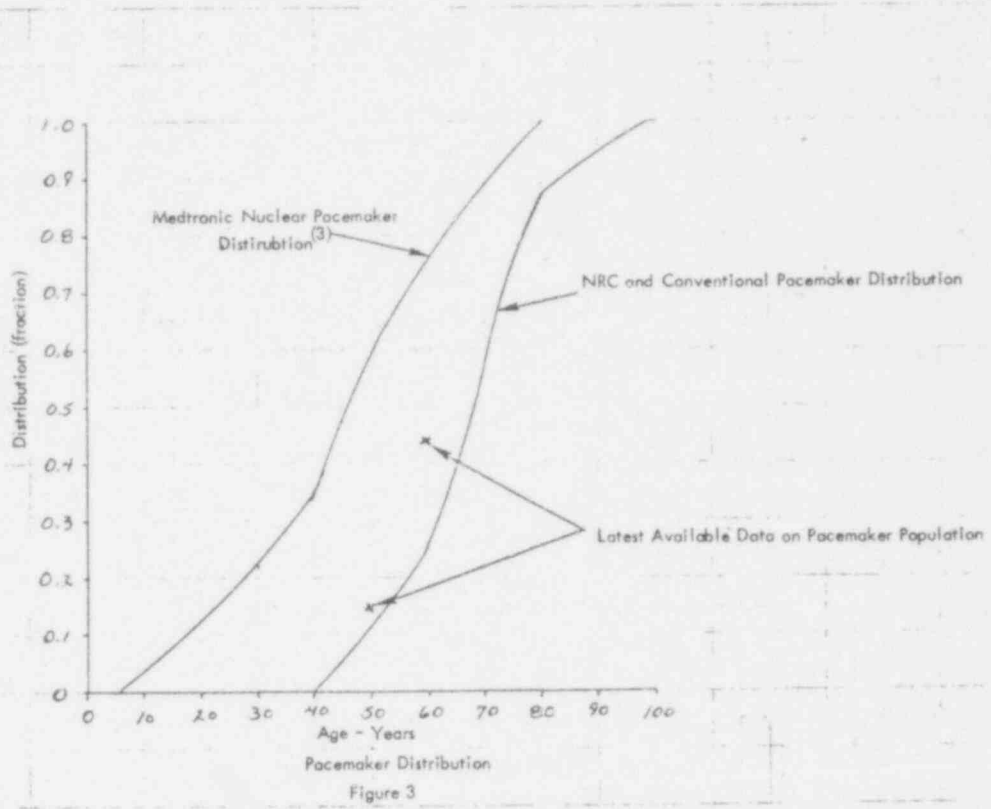


Frequency of Pacemaker Populations
Figure 2

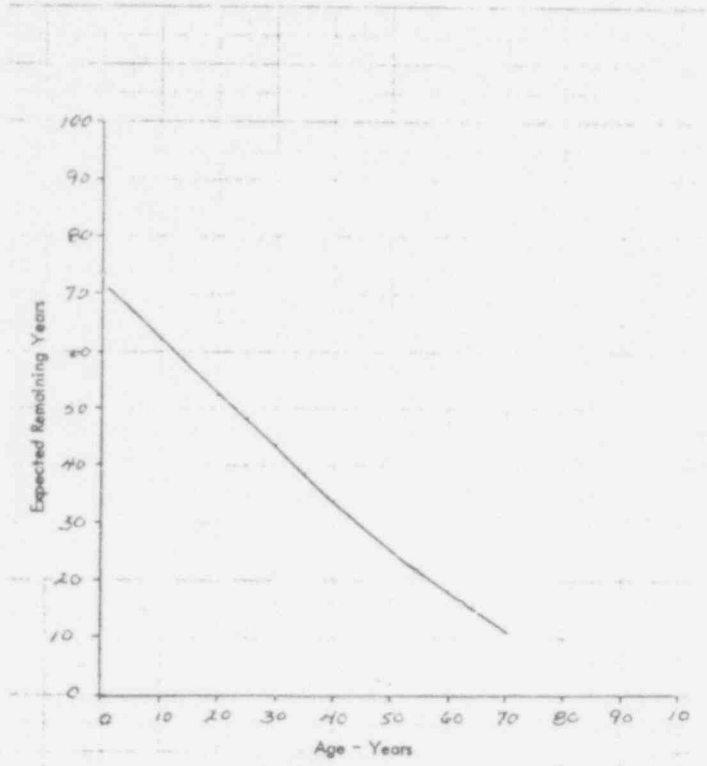
non-nuclear pacemaker age distribution. That is, the nuclear pacemaker is a specialized device applicable primarily to younger patients. Therefore, to reasonably assess its longevity benefit, it is the younger patient population that must be studied and comparisons made with.

In this same regard, it is the younger patients who will derive the maximum benefit because of their increased longevity and life expectancy. This is clearly shown in Figure 4 which indicates that the 46 year old median nuclear pacemaker recipient has an expected remaining life of 29 years while the 68 year old median historical conventional pacemaker patient has an expected remaining life of 13 years. The effect of increasing life expectancy is further emphasized when observing the death rates[5] over the past number of years. Since 1920, the mortality rate for the 65 to 74 year age group has decreased from 52.5 to 36.7 percent. People are living longer than ever before and the trend is continuing. In using the life expectancy and mortality data published by the U.S. Public Health Service[6], the assumption was made that is generally accepted by the medical profession that an otherwise healthy pacemaker recipient has the same life expectancy as the general population. Some of the comments on the "Draft Statement" questioned this assumption. In attempting to assess this assumption, we were able to obtain some further insights. Apparently the basic cause requiring pacing differs in the older versus the younger patient. Ischemic heart disease is present much more often in the older patients. The mortality rate in the older patient groups is 27 percent in the 2 years after receipt of initial implant. Once the older patient survives beyond this point, the mortality rate is apparently similar to that of the overall population. In the younger patient, free of ischemic heart disease, pacers are most likely required because of congenital heart block or as a result of heart surgery. This younger group, of which the nuclear pacemaker bearer is representative, should have a longevity as great as the general population. In fact, since pacemaker bearers are examined regularly, other problems such as high blood pressure, diabetes, and tumors are caught and treated earlier than in the general population so that this group's life expectancy may actually be greater than that of the general population.[7]

It is our believe that the nuclear pacemaker is most beneficial to younger patients and that a free marketplace would reflect this fact. That is, even without NRC restriction, the nuclear pacemaker would be a "specialty" product reserved for the younger and healthier portion of the pacemaker population. This was reflected in a study[8] performed for us by Dr. Victor Parsonnet, Director of Surgery at Newark Beth Israel Medical Center. Dr. Parsonnet reviewed 100 typical pacemaker patients on a retrospective basis and found,



Pacemaker Distribution
Figure 3



Expected Remaining Years as a Function of Age[5]
Figure 4

in his judgment, that 11 to 13 of these persons would have been suitable candidates for a nuclear pacemaker. Most of the 87 to 89 exclusions were based on lack of expected patient life expectancy. More recently, Dr. Parsonnet presented a paper[9] at the Society for Vascular Surgery, reflecting on his experience with 62 nuclear pacemaker implantations. The average patient age was 50.1 years with a range of 12 to 76 years. This compares favorably with the median age of 46 years experienced to date by Medtronics in its nuclear pacer implants.

It is clear that the primary benefit to be derived from the nuclear pacemaker is its long life. In order to achieve long-lived pacing, not only must the pacemaker function properly, but the patient must also survive for a significant number of years. In this regard, we believe the longevity benefit analysis performed in the "Draft Statement" was based on the wrong patient population. The benefit comparisons should not be made using historical conventional pacemaker age distribution and comparing the nuclear units to the conventional units. The age distribution utilized for such comparisons should utilize the characteristics of the nuclear pacemaker bearer population.

Alternative Power Supplies for Pacemakers

Ten years ago when serious development began in this country and Europe to provide a nuclear power supply for pacemakers, the major impetus was the poor performance of the then existing chemical batteries which on the average lasted about 18 months. Since that time, spurred on by the successful development of nuclear batteries and their successful implantation in humans beginning in April of 1970, a whole series of new power supplies has been under development and in some cases used clinically. As mentioned previously, to date approximately 1400 nuclear pacemakers have been implanted in humans throughout the world, the earliest of these has been successfully operating for 5-1/2 years and all have operated without a single failure due to the nuclear battery. In any development, such as a new long-lived power supply for pacemaker application, considerable clinical experience must be obtained before any claims can justifiably be made. Decisions should be made on the basis of facts gathered over a period of time rather than on promises and predictions of wonderful accomplishments to be realized in the future. In that respect, the 5-1/2 year period since the original human implant of a nuclear powered pacemaker gives considerable confidence in the early projections of achieving a lifetime in excess of 10 years. It is also important to note that the success to date with nuclear pacemakers has come despite the problems inherent in the development and use of this device by the arduous testing program and administrative and licensing procedures that had to be followed

in the preclinical tests and in the clinical protocals. The non-nuclear, long-lived power supplies were not under such restrictions and did not require the severe testing prior to use, that has been imposed on the nuclear pacemaker.

As mentioned in the previous section, the advent of the nuclear pacemaker initiated the development of a number of pacemaker power sources other than the Mallory RM-1 mercury cell which had been the standard of the industry for many years. The most prominent, in terms of utilization to date, are the lithium batteries produced by Wilson Greatbatch, Ltd., the rechargeable cell produced by Pacesetters Inc., and the "improved" Mallory mercury cell. Other power sources still in the laboratory stage, recently announced as long-lived power supply possibilities for pacemakers, are the General Electric sodium-bromine, the University of Pennsylvania silver-zinc, and a host of other types of lithium cells. Some of these units may eventually prove to be viable power systems for cardiac pacemakers and may well prove to outlast the Mallory RM-1 mercury cell.

It is premature to make a judgment on the useful life of any of the new power sources. When the RM-1 was initially used, its predicted lifetime was 6 years. Its actual life turned out to be 1.5 to 2 years. This was due to the fact that the life estimate was based upon capacity considerations, but the units failed primarily due to internal shorting while a large chemical capacity still remained. Most chemical batteries have failure modes leading to lifetime limitations other than theoretical capacity limits. Corrosion, reduction of effective electrode surface areas, build up of internal impedance, or shorting, are all factors that can become the actual limits to battery life. Such phenomena could well exist in some of the newer power sources and become the life limiting factor.

Calling the nuclear battery a "battery" is in a sense a misnomer. It is really a generator, converting heat to electricity on a continuous basis. Its output falls with time due to decay of the nuclear heat source. It gets its long life because of the long half-life (87.8 years) of the Pu-238. Therefore, the type of failure modes possible in chemical batteries and the "drain" and shelf life problems inherent to chemical cells are not in evidence in "nuclear generators."

One of the more promising long-lived power sources for pacemakers, in addition to the nuclear generators, that has been developed and put into use in the past several years is the lithium-iodine battery covered in your "Draft Statement." Although the clinical testing of this battery has proceeded since 1972, it has not as yet reached the total lifetime experience of 5-1/2 years to date achieved by the nuclear powered pacemaker. Because the failure mechanism of chemical batteries is not necessarily related to the theoretical

chemical capacity (as previously discussed), the actual life of lithium-iodine batteries will not be able to be determined until large numbers have been used to depletion. Internal packaging considerations are very important to the lithium-iodine cells. Iodine migration could cause premature failure in much the same manner that mercury migration caused premature failure of the RM-1 cells. The largest manufacturer of this type cell, Wilson Greatbatch Ltd., based on laboratory data, shows that these cells will probably have a lifetime of on the order of 6 to 8 years, despite a theoretical lifetime of over 13 years. This matches to some extent the fact that initially mercury cells used in pacemakers which have a theoretical lifetime of 6 years actually performed in the range of 1-1/2 to 3 years, in clinical use. It should also be pointed out in the "Draft Statement" that there is no such thing as a generic lithium battery. In addition to the lithium-iodine battery, there are currently at least 6 different types of lithium cells under development, most of which will be considered as possible power supplies for pacemakers. These cells all use lithium, but vary in type of electrolyte used.[10]

Nickel cadmium rechargeable batteries were considered for pacemaker use since the beginning of the pacemaker industry, approximately 15 years ago. Both in England and Sweden small numbers have been built. Wide-scale use has never developed from these early efforts. More recently, in this country, Pacesetters Inc., utilizing a rechargeable Ni-Cd system developed by the Applied Physics Laboratory of The Johns Hopkins University, has been manufacturing and marketing a pacemaker using a Ni-Cd rechargeable power supply. What the actual life of this system will be, only time and use will determine. Your initial "Draft Statement" referred to certain medical references which consider it difficult to rehabilitate patients who are externally recharge dependent. In addition, there are special problems related to Ni-Cd batteries, which if not solved in the power package currently in pacemaker use, could prove troublesome. This problem relates to the "memory" effect in low drain Ni-Cd systems. Several papers[11], [12] have been published relating to this effect. Apparently, low discharge rates cause crystalline growth in the cadmium electrode thereby decreasing its effective surface area. This makes the battery progressively more difficult to charge. Elevated temperature tends to increase the severity of this problem. To alleviate this phenomena, a high rate of discharge must be periodically effected which is quite difficult, if not impossible, with an implanted pacemaker. While this effect may or may not prove to be a difficulty with the nickel-cadmium rechargeable batteries presently being utilized in pacemakers it serves as an example to indicate that present judgment on the lifetime of this power system may well be premature.

The silver-zinc system is newer than the lithium-iodine or nickel-cadmium cells previously discussed. However, it is interesting to note that many years ago when this cell was formulated as a secondary battery, it was found that mercury addition improved its charging characteristics. As more mercury was added, the recharging became better and better. This subsequently resulted in development of the mercury cell.

The above discussion is not intended as being critical of any of the newly developed chemical pacemaker power sources. Rather, it is given to exemplify the fact that these devices are still new and unproven. Their reliability cannot be estimated from having large numbers of units operating for short time periods as is the case with electronic circuitry. Chemical batteries generally fail due to "wear out" instead of at "random." This is clearly evident from the fact that battery reliability is characterized by a Normal or Chi-Square distribution. Random failures are characterized by an Exponential distribution. Therefore, more time will have to elapse prior to making a final judgment on the true lifetimes and viability of the new chemical power sources for pacemakers.

Radiological Considerations

This subject must be looked at in two parts; the radiological safety from a radiation emanation point of view and the safety of the fuel capsule and fuel form from a contamination point of view.

In the product produced by us, the ATOMCELL® nuclear generator, we have taken great pains to reduce the amount of fuel utilized and to put such fuel in a chemical and isotopic form minimizing both the above mentioned radiological factors. First, our nuclear generator has, to the best of our knowledge, the lowest fuel loading of any of the currently manufactured devices, nominally 140 mgm of Pu-238 or $2.3\ ^{+0.3}_{-0.0}$ curies. Secondly, we use this plutonium in a chemical form proven to be most inert, i.e., sintered PuO_2 with a melting point of 2240°C. Additionally, we utilize "medical grade plutonium," or plutonium greater than 90 percent Pu-238 with the Pu-236 content held at less than 0.3 parts per million as produced. Additionally, the normal oxygen in the PuO_2 is converted to oxygen-16 to further reduce the radiation level. The pressed and sintered pellet of PuO_2^{16}, which is very hard and has a theoretical density greater than 95 percent, is then hermetically encapsulated in the nuclear pacemaker within four welded and hermetically sealed containers fabricated from high strength, high temperature, and corrosion resistant metals.

The nuclear pacemaker fuel capsule has been tested to demonstrate its ability to withstand corrosion, high velocity impact (including being hit by a high velocity rifle bullet),

thermal stresses, crush resistance, and high temperature resistance including cremation at 1300°C, prior to its release by NRC for clinical trials. It is therefore difficult to understand some of the comments and, in our opinion, unrealistic concern relating to the radiological safety of the device. Little cognizance seems to have been taken by some of the critics of the very stringent test criteria imposed on the nuclear pacemakers by the NRC prior to allowing their use in clinical trials. It almost appears as if some of the reviewers assumed that the plutonium-238 is easily released, as if it were contained in a "paper bag."

The administrative controls placed on nuclear pacers by the NRC were also cited by some commentators as examples indicating the hazardous nature of the pacemakers. This was particularly true with regard to recovery of the units upon patient demise. We would like to point out that recovery of these units accomplishes several purposes, only one of which is related to radiological safety. First there is a major benefit to the pacemaker manufacturer in giving him an opportunity to examine the units after extended operation. This enables upgrading the device after practical application. Secondarily, because of the long half-life of the nuclear fuel (87.8 years), there is no reason that the sources cannot be recycled and reused on a repetitive basis. Even after 20 years of use, such a source will have lost only 15 percent of its original heat production capability. Additionally, the recovered sources can be reprocessed and upgraded after their specific power falls to an unacceptable level. This modus operandi would certainly minimize the total quantity of plutonium necessary for nuclear pacemakers and conserve a valuable resource in limited supply.

Other comments received on the "Draft Statement" related to the toxicity of plutonium. Some were stated in emotional terms such as "the most deadly material known to man." As the NRC is aware, this is hardly the case. Many nerve gases and biological agents are far more lethal than plutonium. Authorities such as Chauncey Starr, Dixie Lee Ray[13] and Bernard L. Cohen[14] have all recently commented on the toxicity of plutonium by comparison to other toxic materials. Dr. Ray indicated that botulism is one million times; dyptheria one billion times; and muscarine ten times more toxic than plutonium. Muscarine is the toxin found in the relatively common mushroom. The most cogent consideration, however, remains the fact that to date there is not a single documented account of a fatality due to plutonium poisoning. This is either a strong tribute to the skill of the numerous organizations which handle this material on a routine basis, or perhaps the plutonium is not quite so deadly as some of the adverse comments would lead us to believe.

When reviewing the emanated radiation considerations of a nuclear pacemaker, one

naturally finds that the nuclear pacemaker falls into the "low level radiation controversy" because of the minute amount of radiation it emits. Most of the nuclear pacemakers presently licensed for clinical trials have radiation levels on their surface between 4 and 5 millirem per hour. This level will increase after 10 to 14 years to about 8 to 10 millirem per hour and then begin decreasing. This phenomena is due to the growth of daughter products from the decay of the various plutonium isotopes, primarily Pu-236. The radiation level falls very quickly with distance dropping to less than 0.01 mrem at 50 cm in air.

By any standard, the radiation emanating from plutonium powered pacemakers is low. The total integrated whole body dose received by the patient per year is on the order of that received from a single dental X-ray. We do not believe that we can resolve the low level radiation controversy in this document. However, we can point out that the linear dose extrapolation theory* is not supported by any base of scientific information. It has not been proven. The only thing that can be said with any degree of certainty is that the linear dose extrapolation theory is a worst case condition. Based on the evolutionary aspects of man in a natural radiation environment where great mental and physical improvements have taken place over tens of thousands of years, it is probably an extreme worse case.

Another aspect of the radiation emanating from a nuclear pacemaker not realized by the layman and sometimes even by nuclear experts is that it is so low it is difficult to measure. Determination of this low a radiation level to a reasonable degree of accuracy is a difficult undertaking for a number of reasons. First and foremost is the fact that the radiation dose level is extremely low and consists of a mixture of gammas and neutrons. Second, the plutonium sources are physically very small (ours is a cylinder 0.34 inches in diameter, 0.30 inches long) and the radiation dose is very sensitive to the distance from the source. Therefore, if a reasonably sized TLD chip or piece of Kodak Type A film is placed on the surface of the pacemaker, they will be nonuniformly dosed and are thus difficult to read. They must be scanned to pick up the maximum dose point. Therefore, even the low radiation levels reported for plutonium powered pacemakers occur only at a single point on their surface and the dose rates at all other points are significantly less.

*The linear dose extrapolation theory expounds the notion that the measurable damage done to living organisms can be linearly extrapolated to low radiation doses. This results in the conclusion that any radiation will do some damage. This is in contrast to the threshold theory that below a certain level of radiation, living organisms will be resistant and incur no damage.

Perhaps the best method of putting the radiation levels from the nuclear pacemaker in context is by example. The following low level every day sources of radiation are cited from Reference 15. The radiation dose to even the closest member of a nuclear pacemaker bearer, his spouse, is taken from the NRC's "Draft Statement."

Source	Annual Dose in Millirems
Nuclear pacemaker bearer's spouse	5 to 15
Sea level cosmic (add 1 for every 100 feet of elevation)	40
Breathing air (U.S. average)	5
Water and food (U.S. average)	25
Living in a brick house	85
One transcontinental jet flight	4
One chest X-ray	150
One gastrointestinal tract X-ray	2000

These are relatively common sources of radiation encountered in our every day lives as part of our natural environment. Persons residing in Denver, for instance, receive an additional 53 millirem in a year due to the increased elevation. Does this make Denver an unhealthy area in which to reside? Indeed, it is generally regarded as being just the opposite.

Therefore, placed in the proper context, the plutonium powered pacemaker radiation levels should not be of concern. We previously submitted a fairly extensive report[16] to the NRC showing that based upon all the experimental evidence we were able to find in the literature that there would be no organ effect from radiation up to 25 millirem per hour for a 30-year exposure. This is summarized in Figure 5 of this submittal.

The only other item to be mentioned concerning the radiation level, which also impacts the radiological safety consideration, is the plutonium inventory in a nuclear pacemaker. Many of the examples cited in the NRC "Draft Statement" utilized a pacemaker containing 8.3 Ci of plutonium-238. This is atypical of nuclear pacemakers and again represents a worst case condition. Most plutonium pacemakers have an inventory far lower than this value including the Medtronic, Cordis, and the American Optical units. The inventory in these units is 2.3 to 2.8 curies. Further, these are first generation devices and should the nuclear pacemaker prove successful in the marketplace, the curie level will undoubtedly decrease as more efficient units are developed.

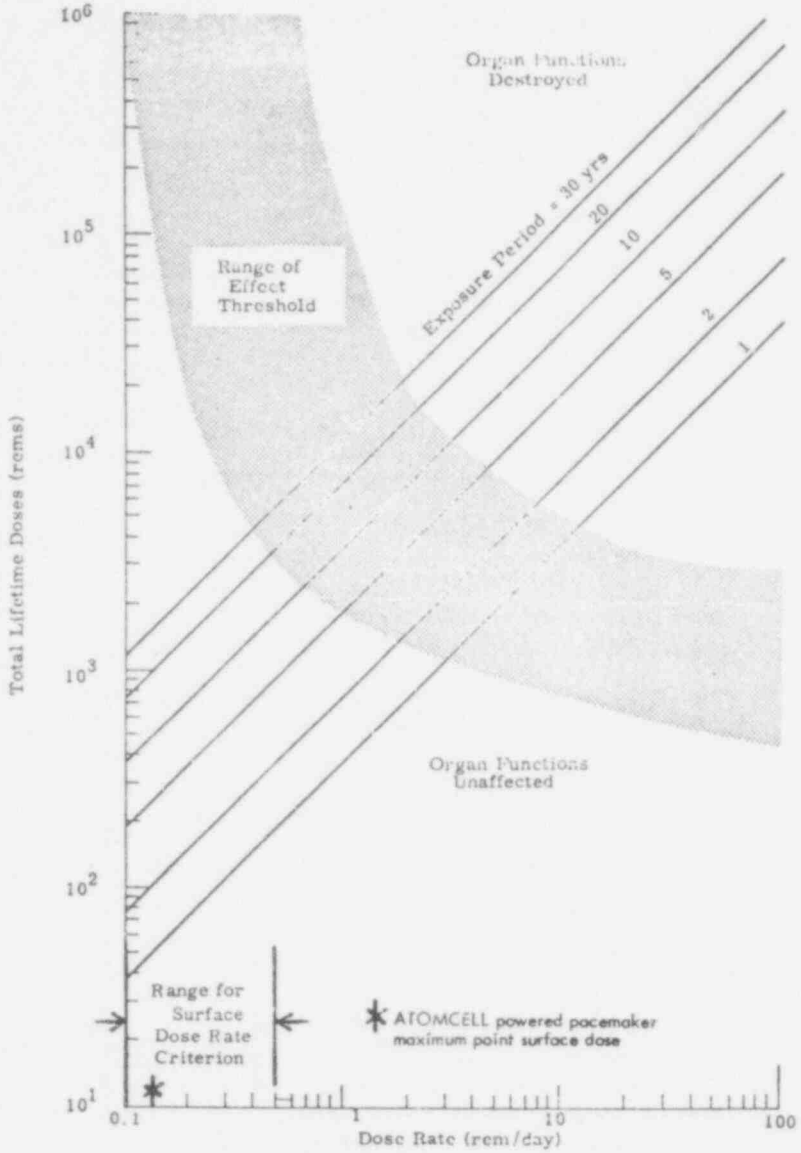


Figure 5. The Dependence of Dose and Dose Rate Regarding the Destruction of Organ Functions

In the environmental impact assessment of the NRC's "Draft Statement," a very thorough job was done to evaluate the radiation emanating from a nuclear pacemaker and its effect on both the patient and the general population. We concur from our own experience in the conclusions that these levels of radiation do not represent doses that should be of concern.

Terrorist Considerations

A number of the comments to the "Draft Statement" addressed themselves to possible terrorist activities utilizing the plutonium contained within the nuclear pacemakers. These comments regarding the possibility of terrorist activity utilizing plutonium extracted from a nuclear pacemaker are difficult to address because logic does not apply to such behavior and one even hesitates to discuss it. Many of the "scenarios" postulated in the comments on the "Draft Statement" appear to us at least as unrealistic. There are, however, certain physical aspects as to what detrimental effects could be induced by terrorists utilizing nuclear pacemakers that can be hypothesized.

One of the improbable scenarios is the construction of a fission "terror" weapon from the plutonium gathered from a number of the nuclear pacemakers. First, Pu-238 is not fissionable in the same sense as Pu-239. Its fission cross-section is not well established, but definitely is not as favorable as Pu-239. However, even if a weapon could be constructed from as little as 5000 grams (approximately eleven pounds) of plutonium-238 which is the estimated amount required for the more easily fissioned Pu-239[17], 30,000 nuclear pacemakers would be required. That is, the terrorist or terrorist group would have to kill more than 30,000 persons in order to collect sufficient plutonium to construct a weapon. They then would have to metallurgically process the PuO_2 fuel to plutonium metal and fabricate the weapon, all the time being hunted by police. This is not only illogical, it would be physically impossible to track down and murder 30,000 persons on a selective basis without being caught.

Another "terror scenario" is that of terrorists obtaining nuclear pacemakers, cutting them open, grinding up the plutonium, and subsequently dispersing it in a crowded or populated area. Not only is such a scenario highly improbable, but it most probably wouldn't result in "terror type" results for a number of reasons. As in the weapon example, the terrorist is faced with locating and killing numerous persons in order to collect the plutonium. To get even a gram of plutonium-238, he would require no less than seven victims. Next the terrorist is faced with the task of opening the pacemaker to extract the plutonium. This

would be a difficult undertaking for even a highly trained individual working with specialized equipment. An untrained individual working with jury rigged facilities and under hunt by the authorities would find this a most arduous undertaking. Next, the pressed and sintered PuO_2 pellets would have to be ground into a powder. This is also not a simple procedure. The PuO_2 pellets are sintered at temperatures in excess of 1300°C and they are strong and dense. Their strength is somewhat akin to granite. However, even supposing the terrorist were able to accomplish all the necessary steps, the results of his subsequent postulated actions must also be examined

Some of the comments raised the spectre of the terrorist releasing the PuO_2 powder in the air conditioning system of a large and heavily populated building. The comments are stated in such a fashion so as to have one believe the material will be whisked almost as a vapor through the maze of duct work, through any filters, and out into the breathable atmosphere of the building. This is hardly the case. PuO_2 is a dense material (i.e., $\sim$10 gms/cc) which is not easily transported even as a fine powder by slow moving air. An attempt at this type dispersal would probably result in little more than a contaminated air conditioning duct. It is improbable that significant harm would be accomplished. In any event, in the sample cited of terrorizing a large building, the use of an easily available poisonous gas in the air conditioning system or the placement of an arsenic based rat poison or insecticide (that can be purchased in any hardware store) in the drinking water supply is probably more likely scenario for this kind of antisocial activity.

Bernard L. Cohen has recently issued a report[14] addressing possible terrorist activity utilizing plutonium. He concludes that plutonium dispersal is a poor mechanism for terrorist activity. He points out that if 160 kilograms per year of reactor grade plutonium was all distributed to plowed soil used to grow grains, only 15 cancer deaths would occur per century. This is hardly conducive to making one believe that plutonium is the "most deadly material known to man."

Terrorists want to frighten people and get quick results. Their main weapon is threat of immediate death; their usual weapons the gun and stick of dynamite. As pointed out by C. Starr[18], "Lucretia Borgia would not have used plutonium to poison her enemies because it takes too long to have any effect, requiring some 15 to 45 years to induce cancer if injected directly into the blood stream. Such a means of introducing plutonium into humans is absurd. Plutonium is certainly much less toxic than many other toxins such as botulism

and anthrox, all of which cause death in a few hours." He points out that about 5 million grams of plutonium have been dispersed in the atmosphere as a result of nuclear weapons, but no adverse public health effects have been noted.

Comparative Safety Considerations

Although it is not fashionable for the NRC to compare comparative risks when looking at alternatives to long-lived nuclear pacemaker systems, it is of interest to note that lithium is a very reactive material and that if body fluids, for instance, would leak into a lithium battery containing the very reactive lithium metal, a violent reaction could ensue with a very rapid release of hydrogen gas and the possible explosion of the cell. In a similar vein, if the release of mercury from mercury cell powered pacemaker bearers cremation were treated with the same attention and on the same basis as that used with nuclear pacemakers, a fairer appraisal of the risk side of the comparative risk benefit analysis might result. For example, as previously indicated, mercury batteries are used in the vast majority of implanted pacemakers. Mercury is highly toxic. It is listed in "Dangerous Properties of Industrial Materials" by N. Irving Sax as having a "3" rating as a local allergen, and injestion hazard; as an acute systemic ingestion, inhalation, and skin absorption hazard; as a chronic local irritant and allergen hazard; and as a chronic systemic inhalation, ingestion, and skin absorption hazard. It is given the "3" rating across the board, so to speak. The "3" rating is defined as "HIGH: May cause death or permanent injury after very short exposure to small quantities." The maximum permissible concentration of mercury in air for safe human consumption is given as 0.1 milligram per cubic meter. Each mercury cell in a pacemaker contains about 5 grams of mercury and each pacemaker contains 5 cells. The mercury in a mercury battery is not very well contained. The cell is designed to leak the hydrogen gas produced in it. Therefore, one mercury battery powered pacemaker cremated with the mercury released is capable of raising 250,000 cubic meters or 8,000,000 cubic feet of air to dangerous levels. Attachment "A" gives some additional insight to the hazard of mercury batteries.

However, as demonstrated in our testing program, cremation of a cadaver containing a nuclear pacemaker would release no dangerous plutonium. Cremation of a cadaver containing a mercury powered pacemaker could result in a potential hazard to the public health and safety if the crematorium were located in a populated area. A consideration such as the relative hazard presented to the population from the use of mercury cells in a conventional pacemaker appears germane in evaluating the use of plutonium powered pacemakers and should probably be factored into the benefit analysis considerations.

Patient Considerations

In the issuance of the "Draft Statement" and the comments thereon, the patients have had the smallest voice and they are perhaps the most concerned group. The patients are not an organized group and the large majority of nuclear pacemaker bearers are not aware of the licensing and regulation process nor even the existence of the "Draft Statement." They do not review the Federal Register on a regular basis nor are they probably aware of the continuing so-called "nuclear controversy."

It would seem that additional emphasis should be given to the role of the patient in selecting the type of pacemaker to be implanted. The risk/benefit analysis must consider the impact on the patient of repeated surgery versus the use of long-lived pacemakers. Pacemaker replacement may be "minor surgery" to the surgeon, but it is viewed entirely different by the patient. The anxiety created in the patient in contemplation of their pacemaker power supply being depleted, as well as the surgery required to replace it, undoubtedly is a burden of considerable significance which cannot be easily or objectively measured. It is interesting to note that nuclear pacemakers have been chosen, despite the administrative controls placed on the patient by current licensing procedures and the scare tactics of nuclear opponents, by people who because of their social and economic position can get the benefit of the best medical advice and treatment. Additionally, a number of these patients are also scientifically or technically trained to make a most rational decision by themselves. Such patients include a female physician who is an expert in the fields of cancer epidemiology and the relation of cancer to the environment; a former chairman of the Pacific Section of the American Academy of Sciences, age 68; a graduate female chemist, age 32; and as has been reported in the January 11, 1975, issue of The New York Times (copy of article enclosed as Attachment "B"), no less a personage than Leonid I. Brezhnev, the leader of the Soviet Union, age 69. It therefore appears that when patients of this type have the free choice, regardless of age, as to what type of pacemaker to receive, that at least in these instances, they chose the nuclear pacemaker; recognizing that whatever the slight risk they may incur in having a tiny nuclear source implanted in their body, that the rewards outweigh the risks.

There is an interesting patient reaction to an article published in The Washington Star recently entitled "Plutonium Makes The Heart Beat" which was attributed to Mr. Ralph Nader. The article was read by Dr. Lucia J. Dunham who is a specialist in the field of cancer epidemiology and herself a nuclear pacemaker bearer. She responded to Mr. Nader's article which The Washington Star also published on April 10, 1975, under the title "Doctor Defends Her Plutonium Heart." (See enclosure, Attachment "C"). In her response,

Dr. Dunham clearly indicates that she is well aware of the technical aspects of the plutonium powered pacemaker and she expounds a staunch defense of these devices. Her response is initiated with the paragraph, "I want to protest Ralph Nader's recent column headed, 'Plutonium Makes the Heart Beat.'" It concludes with the paragraph, "I regret that the Nader article on plutonium use for devices to assist the human heart is not based on sound scientific reporting, and thus does a disservice to the thinking American public."

Dr. Dunham is obviously an atypical pacemaker bearer. She is well educated and very well informed regarding the technical aspects of the nuclear pacemaker. Most significant is the fact that she is a specialist in cancer epidemiology and discounts in her article the possible carcinoma effects described by many of the adversary comments on the "Draft Statement." Another significant point is that Dr. Dunham did not adopt an attitude of, "I have my nuclear pacemaker; let other people worry about getting theirs."

The patient population most important to consider with regard to nuclear pacemakers is that group of persons who are relatively young and healthy, but who will require a pacemaker in the near future. These persons are as yet undefined. As Dr. Dunham expressed the situation in her article, "Five months ago I had the entirely unanticipated experience of having a cardiac pacemaker installed in my chest." The only way this group can obtain the benefits of a nuclear pacer is by allowing their physician to make available, and recommend when indicated, the free choice as to which type of long-lived pacer they prefer. If these persons do not want nuclear pacemakers, it will quickly become apparent in a free and competitive marketplace. If not needed, the nuclear pacemaker would disappear as did the "Edsel" automobile and numerous other unwanted or obsolete and non-competitive products. However, the only mechanism for determining the need for plutonium pacemakers is to allow a free choice when the doctor recommends, and the patient desires, such a device. This can be accomplished only if the devices are released for use as was recommended in the "Draft Statement."

Weak Link Considerations

Some of the comments on the "Draft Statement" questioned the need for a long-lived pacemaker power supply on the basis that other components such as the electrical leads and electronic components would not last the design life of the nuclear power supply and therefore abrogate a need for such a power supply. This is not a valid argument. In the past, before the advent of long-lived power supplies, it was not necessary to have electrical leads that would last 10 or 20 years, nor for that matter electronic components that

would last much more than 2 to 3 years, since the major mode of failure was depletion of the mercury-zinc batteries powering the vast majorities of pacemakers. In addition, because these mercury cells had to be vented to get rid of the gases generated in their discharge, the entire pacemaker was encapsulated in a biocompatible silastic or epoxy material which would "breath" out the gases. Fortuitously, it was found out that these same epoxy materials, although passing water and water vapor, did not allow the salts in the body fluid to interfere with the functioning of the discrete electronic components in use at that time.

Recognizing the need for improved lifetimes, the pacemaker industry worked on methods of reducing the power drain on pacemakers by the design of better circuitry using solid-state electronic components and smaller surface area electrodes to reduce the power required to pace. These more modern and reliable long-lived solid-state electronic components, however, must be enclosed in a hermetically sealed container very much akin to that developed and pioneered for use in every nuclear pacemaker manufactured. In such a setting, with current technology for electronic components, there is every assurance that the pulse generators will last as long as the long-lived power supplies powering them.

In the area of leads, again in the past, it was not necessary to use technology for leads promising lifetimes longer than that of the power supply. Much successful development work has been accomplished in the lead area over the past years as longer-lived power sources have become available and because of the use of pacemakers in younger patients. Leads being implanted at this time have a heart "beat expectancy" greater than one billion times, based on laboratory testing. This is equivalent to a 30 year lifetime for leads. In conversations with our pacemaker customers, who manufacture the leads, it appears that none of them consider this a major problem and thereby a weak link in the use of long-termed pacers. In order to get the latest available data on leads, we would advise that the NRC get in touch with the manufacturers of leads to obtain any corroborating details required.

Technological Development and Other Benefits

Technology is continuously moving and it is most difficult to fairly compare various alternative solutions without a full knowledge of not only the current status but the future potential of a particular device. We have alluded previously to the fact that the development of a nuclear pacemaker power supply stimulated the improvement of existing chemical batteries and new primary and secondary chemical devices. Such technological competition

in a free marketplace is the ideal way to make certain that the best possible solution to the problem is available to the medical profession and the patients. Current nuclear battery technology married to improved electronic components in the pulse generator make it possible to package a nuclear pacemaker smaller in weight and volume than most chemically powered devices. Also, because of the low weight and density of the nuclear battery, it is possible for the manufacturer to design a pacemaker package minimizing the discomfort to the patient and the possibility of extrusion through the skin. All nuclear pacemakers being produced are in hermetically sealed metal cans, thereby aiding in achieving maximum reliability and life for the electronic components and in the shielding of the circuitry from microwave sources.

From our advanced development program, we definitely believe that it will be possible to develop and manufacture a pacemaker in the not unforeseeable future whose total weight would be in the 60 gram range as compared to current ATOMCELL® powered models which are in the 80 gram to 120 gram range. The size would also be further reduced. A pacemaker density approaching that of body tissue (which is ideal for patient comfort), has already been achieved in ATOMCELL® powered pacemaker units. In fact, research work has been done[19] that indicates that ultimately a pacemaker may be possible to be designed that requires no electrical leads, but would achieve the same purpose by the whole pacemaker package being attached into the heart muscle itself thus mimicking as close as possible the "natural pacemaker" of the heart.

For many years the pacemaker manufacturers have been developing pulse generator circuitry and smaller area pacer electrodes requiring less and less power. This was done in an attempt to minimize battery "drain." As the nuclear powered generator is independent of "drain," it may become the ideal power supply for such pacemaker models as the American Optical "Bifocal" (which paces both the atrium and ventricle) and the Cordis "Atricor" (which is an atrial pulsing unit), wherein more power is required. In addition, work has been proceeding for some time on "pacer defibrillators" which would continuously monitor the heart, pace when necessary, and defibrillate the heart when necessary.[20] Such an implanted defibrillator might also benefit from the unique capabilities of a nuclear generator. If power drain is no problem, self-diagnostic features could also be included in pacers to enable in-vivo determination of lead resistance, condition of the electronic circuitry, thresholds, etc. In other words, there may be many beneficial features that can be added to a pacemaker that have not been considered to date so as not to foreshorten its lifetime by draining power from its chemical batteries. Such ideas become feasible with a nuclear generator which is not power drain limited.

In addition, because of our work in nuclear batteries, we have been contacted by physicians with interests in solving other medical problems requiring long-lived electrical power within the body. These include power supplies to be used in brain pacemakers currently under development, and in some cases clinical test, whereby victims of cerebral palsy are helped to lead acceptable and meaningful lives as well as in the use of implantable hearing aids for hearing problems which cannot be solved by the usual external type hearing aids.

It is therefore important to recognize that the nuclear pacemaker power supplies have only begun to make their contribution and that to restrict its use unnecessarily would be a disservice to mankind.

Monetary Considerations

In our opinion, monetary considerations should not be a major factor in selecting the appropriate type of pacemaker for a particular patient. However, in the cost comparisons that are made between nuclear pacers and conventional pacers, several factors seem important.

First, monetary comparisons should be based using a span time reflecting the life expectancy of the patient population most likely to receive a nuclear pacer. This should then be compared to the best chemical long-life system available. Reasonable extrapolation of pacer lifetimes, based on experience to date, should be used. Additionally, since the related surgical, medical, and hospital expenditures are a sizable amount of the total costs and since these costs have been increasing at a faster rate than our overall inflation rate, medical and surgical cost escalation factors should also be considered. The importance of this aspect can be seen from the trend of expenses per patient day in American hospitals as published by the American Hospital Association (see Attachment "D") as compared to the GNP "deflator" published in The Wall Street Journal, August 11, 1975.

Year	Number of Hospitals Included	Expenses Per Patient Day	Percent Increase	GNP "Deflator" (Inflation Rate)
1969	5,853	$ 70.03	---	4.8 percent
1970	5,859	81.01	15.7	5.5
1971	5,865	92.31	13.9	4.5
1972	5,843	105.21	14.0	3.4
1973	5,891	114.69	9.0	5.6
1974	5,977	128.05	11.6	10.6
		OVERALL	82.9	

As an example of our suggested approach, we have prepared a cost analysis using some recent data and certain assumptions. In this example, we assumed that the nuclear pacemaker would have an effective life of 15 years and a current price of $5,500 and compare it to a long-life chemical battery powered pacemaker of the hermetically sealed type, using C-MOS circuitry, with a projected life of 7 years and an estimated current price of $1,800. Approximately half the cost of a nuclear pacemaker is the nuclear generator. This element of cost should not increase as fast as other pacemaker components in the future because as production rates become more than nominal, certain cost elements should decrease A 3%/annum escalation for nuclear pacemaker cost was therefore utilized in comparison to a 5%/annum escalation for chemical powered pacers whose costs will more likely reflect the inflation rate hoped for in future years.

It is probably also true that the rapid increase in hospital patient expenses over the past years was due to large increases in "catch up" labor costs. Hopefully, this rate of increase will moderate. However, in our own State of Maryland, the regulatory agency governing hospital rates recently approved a further increase to most hospitals of over 9 percent for 1975. Nevertheless, in the cost comparison example presented herein, an 8 percent per year escalation rate for the next 10 years decreasing to a 6 percent per year rate from that point forward, was assumed for hospital cost escalation. Hospital costs at date of implant were assumed to be the same as those used in the "Draft Statement," i.e., $1200 for the initial implant and $500 for the replacement.

The trend in surgical expenses is more difficult to ascertain. Utilizing Consumer Price Indexes published by the U.S. Department of Labor related to tonsillectomies and adenoidectomies, the surgical costs were found to increase an average of 6.8 percent per annum from 1969 to 1975. We were not able to get useful data on historical pacemaker implant charges and therefore used a 6.8 percent escalation factor for surgical expenses in our example, starting with the $800 surgical fee for original implant escalated to $850 for 1975 costs and the $400 charge for re-implant used in the "Draft Statement" as the 1975 starting figure for this element of cost. We also assumed that the other "medical" expenses used in the "Draft Statement" would be escalated at the same rate (6.8 percent per annum) as the surgical costs.

We further assumed that the average patient receiving a long-life pacer would be 43 years of age (the midpoint of the 45 to 50 range). At age 40, based on the life expectancy data previously presented on Figure 4, this patient would have a remaining life expectancy of 27 years. Even if this life expectancy is somewhat reduced, in view of the discussion previously presented, our example still would be essentially valid on a comparative basis.

Table I presents our tabulation of cumulative costs based on the assumptions stated, as follows:

TABLE I
EXAMPLE CALCULATION OF CUMULATIVE PATIENT COSTS OF LONG-LIVED PACEMAKERS
(Costs have been escalated in accordance with the assumptions presented in the text)

Occurrence & Year	Item of Cost	Nuclear Pacer, $	Nuclear Cumulative Cost, $	Chem. Battery Powered Pacer, $	Chemical Powered Cumulative Cost, $
Initial implant, 1975	Pacemaker	5,500		1,800	
	Hospital	1,200		1,200	
	Surgery	850		850	
	Other medical	250		250	
		7,800		4,100	
Chemical pacer replacement implant, 1982	Pacemaker	---		2,533	
	Hospital	---		857	
	Surgery	---		634	
	Other medical	---		396	
				4,420	8,520
Chemical pacer replacement implant, 1989	Pacemaker	---		3,564	
	Hospital	---		1,710	
	Surgery	---		1,005	
	Other medical	---		628	
				6,907	15,427
Nuclear pacer replacement implant, 1990	Pacemaker	8,569			
	Hospital	1,748			
	Surgery	1,073			
	Other medical	671			
		12,061	19,861		
Chemical pacer replacement implant, 1996	Pacemaker	---		5,015	
	Hospital	---		2,028	
	Surgery	---		1,592	
	Other medical	---		995	
				9,630	25,057

The difference in total dollar costs for the example cited is $5,196. Of course, this amount to be expressed in 1975 dollars should be discounted to reflect the 21-year overall inflation rate over the period. This rate is difficult to approximate. If one assumes that such rate averages 4 percent, the savings in 1975 dollars is $2,280. Assuming a 5 percent inflation rate, the savings in 1975 dollars is $1,865.

If the nuclear pacer lasts for the entire life of the patient, as may be possible, the savings is ($25,057 to $7,800) = $17,256. This saving discounted at an average rate over the 21 years of 4 percent is $7,573; at a 5 percent discount rate, it would amount to $6,194.

Summary Conclusions

Based upon our studies, we conclude:

1. The benefits resulting from a nuclear pacemaker are primarily derived from its long life and therefore any analysis performed in this regard should consider the younger patient population (median age 46 to 50 years) which will receive nuclear pacemakers.
2. The alternative long-lived power supplies have yet to be proven and if successful will not eliminate the need for the substantially longer life nuclear powered pacemakers.
3. The radiation emanating from nuclear pacemakers is very low and will produce inconsequential effects on the bearer and his closest associates.
4. Possible terrorist acts using the very small amount of Pu-238 in nuclear pacemakers would be almost impossible.
5. Based on arduous testing, the nuclear pacemakers licensed for clinical use are highly safe and will pose very little risk to the environment.
6. Patient considerations have been largely neglected in all studies performed and although somewhat subjective are very important.
7. Present pacemaker leads are probably sufficient to last for many years and data to this effect is available from the pacemaker producers.
8. Further important technology innovations are possible in pacemakers and other medical devices when considering nuclear powered systems.
9. The monetary savings to a younger patient will be substantial from a nuclear pacemaker as compared to long-life chemical pacers.

In summary, we agree with the conclusion contained in the "Draft Statement" that recommends the wide-scale use of plutonium powered cardiac pacemakers under certain administrative and licensing controls. We also consider it only fair that after the intense testing program (more severe than any conventional power supply was ever subjected to) that the NRC move as quickly as possible to allow pacemaker patients to benefit from this development. Further delay in reaching this conclusion would not only destroy the capability existing for production of such devices, but unfortunately most probably stop the whole base of technology and its benefits to mankind.

REFERENCES

1. Thalen, Hilbert J. Th., Cardiac Pacing - Proceedings of the 4th International Symposium, 1973, Van Gorcum & Company, pp. 98, 107, 110, 117.
2. Nuclear Regulatory Commission Pacemaker Industry Meeting, December 18, 1974.
3. Alars, M. et al, "A Plutonium-238 Fueled Cardiac Pacemaker," Nuclear Technology, Volume 26, No. 3, July 1975, p. 317.
4. Telephone Communication, F. Hittman and R. Griffin of Medtronic Inc., July 1975.
5. U. S. Public Health Service, Vital Statistics of the United States, Deaths and Death Rates: 1920 to 1970.
6. U. S. Public Health Service, Vital Statistics of the United States, Expectation of Life and Mortality Rates - 1969.
7. Telephone Communication, Dr. Hilbert Thalen and F. Hittman, August 12, 1975.
8. Letter, Dr. Victor Parsonnet to Mr. Fred Hittman dated October 13, 1972.
9. Parsonnet, Victor et al, "Clinical Experience with Nuclear Pacemakers," Society for Vascular Surgery, Boston, Massachusetts, June 1975.
10. Personal Communication, Dr. A. Salkind, ESB Incorporated, and Mr. F. Hittman, July 1975.
11. Barner, P., "Batteries for Space Power Systems," NASA Report NASA SP-172.
12. Salkind, A., and Bodaner, G., "Changes in Physical Properties of Secondary Battery Electrodes During Cycling," Batteries 2, 59, 1965.
13. Nucleonics Week, May 15, 1975.
14. Nucleonics Week, February 20, 1975.
15. Nuclear Power and the Environment, San Diego Section of the American Nuclear Society Publication.
16. ATOMCELL Safety Report, NB-531, Addendum 3, Nuclear Battery Corp. Sept. 1973.
17. L. Douglas DeNike, Radioactive Malevolence, Bulletin of the Atomic Scientist, 1974.
18. Nucleonics Week, May 15, 1974.
19. Spickler, William J. et al, "Totally Self-Contained Intracardiac Pacemaker," J. Electrocardiology 3, (3-4), 325-331, 1970.
20. M. Mirowski, Morton Mower, Vincent Gott, Robert K. Brawley, "Feasibility and Effectiveness of Low-Energy Catheter Defibrillation in Man," Circulation, Volume XLVII, January 1973.

ATTACHMENT "A"

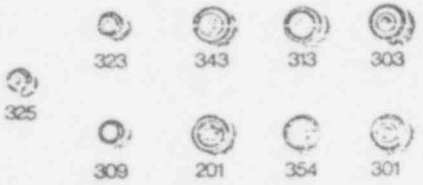
IMPORTANT

WHAT TO DO WITH USED MERCURY BATTERIES?

Sales of electric and electronic watches, alarms and clocks are growing year by year, accounting today for an estimated 10% of total production, a figure which is expected to rise by one-third by 1980. This growth is paced by a corresponding increase in the use of mercury batteries, in keeping with their 1 to 2-year life span. Apart from its energy storage function, mercury as a heavy liquid metal has considerable drawbacks. In the form of vapor or alloyed with other metals, it is a dangerous and even highly toxic polluting agent. When exactly does mercury become dangerous? Not when it forms salt crystals or sponge. Even under conditions of extreme humidity, only the electrolyte will seep out. On the other hand, when batteries short-circuit each other or recharge and explode, when they are split open, misshaped or exposed to excessive heat (as in garbage incineration plants) until they burst, the mercury becomes dangerous.

In Japan, a country where mercury has caused extensive damage, pending legislation stipulates that no person can purchase a fresh mercury battery without handing in a used one. It is therefore imperative that you inform your customers of this matter. Mercury-containing objects must not simply be thrown in the wastebasket. But then what is to be done with them?

We have asked three major mercury battery manufacturers to answer this question.



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Union Carbide Europe SA has been in Switzerland for the last 25 years. Since 1968, the company has actively cooperated with the Swiss watch industry. At the time, Union Carbide supplied its first-generation mercury batteries to manufacturers only. Over the last two years, distributors have begun supplying them directly to retailers.

It has always been the company's policy to take back used batteries which are then stored in a suitable location. When a large enough amount of them has been collected, Union Carbide will turn them over to the Swiss or European metal industry for re-use. Watch manufacturers have been kept informed of company policy regarding the return of used batteries. Union Carbide was the first company in the U.S. and especially in Japan to set up a collection network for used mercury batteries.

A-1

Leclanché SA in Yverdon, Switzerland, was one of the first in the industry to take back used batteries. For the last three years, the company has also been running large-scale information campaigns to warn wholesalers and retailers of the dangers of mercury. Every order acknowledgment, delivery slip and invoice bears a yellow sticker warning, in both French and German, of the dangers of mercury and requesting that used mercury batteries be returned to the company in Yverdon. A similar bilingual warning is printed on the company's battery packagings and catalogues. But Leclanché doesn't stop there. The company helps its clients organize large-scale programs like that of Autophon AG, Zurich, which recently benefited from Leclanché's assistance in developing and distributing its "environmental protection deposit box" for mercury batteries which, once filled, is returned to the factory. The company is willing to provide such boxes to all watch retailers. Just write or phone Autophon AG, Steinstrasse 21, 8036 Zurich (att. Mr. Andreas Meyer). Phone: 01/35 85 35.

Mallory Batteries has been represented in Switzerland since 1962 by Kurt Hirst AG, Zurich. For the last two years or so, all representatives and retailers have been informed that Mallory takes back used mercury batteries. About 200 kilos of used batteries are sent monthly from Zurich to a recycling plant set up at great cost in Belgium. Recycled mercury is more expensive for the company than new mercury but the company regards its policy as a contribution to environmental protection.

Three times a year, Mallory Batteries publishes an information bulletin for wholesalers and manufacturers. Interested retailers can obtain a copy from their wholesale suppliers. From April 1975 on, Mallory is providing used battery containers. These will first be distributed to camera and hearing-aid stores, now the largest users of mercury batteries, and at a later date to watch stores.

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ATTACHMENT "B"

THE NEW YORK TIMES

January 11, 1975

Paris Newspaper Asserts Brezhnev Uses Pacemaker

B-1

WASHINGTON STAR NEWS - 4/10/75

Doctor Defends Her Plutonium Heart

I want to protest Ralph Nader's recent column headed, "Plutonium Makes the Heart Beat."

I have often found myself deeply sympathetic with Nader's attempts to protect the consumer from commercial exploitation and from the associated hazards to consumer health and safety. However, the many responsible and dedicated scientists who are developing the medical uses of atomic energy and trying to improve the quality of life for individual patients should not be accused of exploiting the public. It is seriously biased reporting not to name these men and quote their considered statements, while citing only the names and statements of scientists who on general principles oppose the use of nuclear devices in people.

At this point, I must identify my training and experience as in the fields of cancer epidemiology and the relationship of cancer to the environment. Five months ago, I had the entirely unanticipated experience of having a cardiac pacemaker installed in my chest. This was a health restoring and even lifesaving measure in my case.

My choice of a Plutonium 238 pacemaker (for which my case fortunately proved eligible) was based on a modest understanding of the design and manufacture of this device. The quality control was similar to that demanded of instruments fashioned for use of the NASA space program. High safety standards both for fabricators and users of the units were in effect, just as for nuclear-powered instruments in the NASA progam.

Pellets of plutonium 238 power a pacemaker from this cartridge.

These are the reasons why I consider myself fortunate in having a plutonium-powered pacemaker.

(1) It is reliable and safe. The energy derived from it for regulating the heart beat is electronic, as with other pacemakers. The electronic energy is derived through heat energy developed from the well-shielded atomic source. The escape (to me) of ionizing radiation for one year has been determined at about that of a single dental X-ray. The exposure per year of my husband, relatives and friends has been found to be much less than this, and essentially negligible. The energy sources of the pacemakers are well-protected against the effects of mechanical shock, fire and erosion.

(Here I have another serious quarrel with the Nader article: its arguments about the plutonium pacemaker, and a plutonium-powered heart that has been considered but is not manufactured or in use, are presented as if the artificial heart might already be a fact, its hazards tested, and its safety found wanting. The author makes no mention of the carefully controlled laboratory studies of the safety of the plutonium pacemaker devices both for their bearers and for future generations.)

(2) The plutonium-powered device is long-lived. This improves its usefulness and the comfort of the patient. Though the operation for reinsertion is not usually life-threatening, it is often unpleasant and always costly.

(3) This pacemaker is not sensitive to stoppage or change of pace when exposed to electromagnetic forces, as are the strictly electronic pacemakers. Nearby blasting, microwave ovens, and some devices used in hospital operating rooms are examples of such influences.

(4) The pacemaker is extremely small and light in weight.

(5) The radioactive material in the pacemaker remains the property of the United States government to which it is returned when the patient no longer needs it.

It might be recalled that there is good and bad in all major physical forces, and that what is really important is how men use them. For example the sun, and fire, can be among the most beneficial of forces, unless man's relationship with them is carelessly handled. If so, the possibility arises that either force will seriously damage him.

I regret that the Nader article on plutonium use for devices to assist the human heart is not based on sound scientific reporting, and thus does a disservice to the thinking American public.

Lucia J. Dunham M.D.
Bethesda, Md.

ATTACHMENT "C"

C-1

ATTACHMENT "D

AMERICAN HOSPITAL ASSOCIATION
840 NORTH LAKE SHORE DRIVE CHICAGO, ILLINOIS 60611 TELEPHONE 312-645-9400
TO CALL WRITER, PHONE 312-645- 9743

August 7, 1975

Ms. J. Griffin
Hittman Associates, Inc.
9190 Red Branch Road
Columbia, Maryland 21045

Dear Ms. Griffin

Here are the figures you requested for hospital expenses per patient day and per adjusted patient day, 1969-1974. These figures pertain to "nonfederal, short-term, general and other special hospitals". Basically, these hospitals are "community hospitals", plus a few hospital units of institutions.

Year	Number of hospitals included	Expenses per patient day	Percent increase	Expenses per adjusted patient day	Percent increase
1969	5,853	$ 70.03		$ 64.26	
			15.7%		14.7%
1970	5,859	81.01		73.73	
			13.9		13.2
1971	5,865	92.31		83.43	
			14.0		13.4
1972	5,843	105.21		94.61	
			9.0		7.6
1973	5,891	114.69		101.78	
			11.6		11.2
1974	5,977	128.05		113.21	
		Overall	82.9%		76.2%

"Adjusted patient days" are an aggregate measure of inpatient care plus an estimate of the volume of outpatient services in units equivalent to an inpatient day in level of effort. A complete definition is available in the copy of Hospital Statistics you have ordered.

Sincerely
David M. Kozak
David M. Kozak
Bureau of Research Services

D-1

lg

CABLE ADDRESS AMHOSP

621 139

INTERNATIONAL ATOMIC ENERGY AGENCY
AGENCE INTERNATIONALE DE L'ENERGIE ATOMIQUE
МЕЖДУНАРОДНОЕ АГЕНТСТВО ПО АТОМНОЙ ЭНЕРГИИ
ORGANISMO INTERNACIONAL DE ENERGIA ATOMICA
KARNTNER RING 11, P.O. BOX 590, A-1011 VIENNA, AUSTRIA
TELEPHONE 52 45 11
52 45 15
TELEX 01-3645
CABLE INATOM VIENNA

IN REPLY PLEASE REFER TO Sc/642-3
1975-03-27

MAR 26 1975

Dear Mr.Cunningham,

Thank you very much for your letter, dated 25 February 1975, and the copy of the Draft Generic Environmental Statement on the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers.

I find the report very interesting and most useful and I do not have any specific comments to offer. I would very much appreciate receiving a copy of the final version of this report when it becomes available.

With kindest regards,

Sincerely
F.N.Flakus
Division of Nuclear Safety and
Environmental Protection

Mr.R.E.Cunningham
Nuclear Regulatory Commission
Division of Materials and
Fuel Cycle Facility Licensing
Washington, D.C. 20555
USA

A-56

4506 Georgia Avenue, N.W.
Washington, D. C. 20011

June 4, 1975

Mr. Bernard Singer, Chief
Directorate of Licensing
Materials Branch
Nuclear Regulatory Commission
United States Atomic Energy Commission
Washington, D.C. 20555

Dear Mr. Singer:

I understand that you are interested in comments about the atomic pacemaker. I think it is an excellent pacemaker as it lets the patient go for years without the need for more surgery.

Yours sincerely,

Mary P. Jackson

Mrs. Mary P. Jackson

THE JOHNS HOPKINS UNIVERSITY
APPLIED PHYSICS LABORATORY
8621 GEORGIA AVENUE
SILVER SPRING, MARYLAND 20910

TELEPHONE
953-7100
589-7700
AREA CODE 301

TSD-5008
7 March 1975

U. S. Atomic Energy Commission
Washington, D. C. 20545

Attention: Acting Deputy Director for Fuels and Materials, Directorate of Licensing - Regulation

Reference: "Draft Generic Environmental Statement on the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers," January 1975, U. S. Atomic Energy Commission, Fuels and Materials, Directorate of Licensing

Gentlemen:

This letter is in response to the Atomic Energy Commission's letter, dated January 10, 1975, which solicits comments on the "Draft Generic Environmental Statement on the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers." Since the Applied Physics Laboratory has had considerable experience in the development of cardiac pacemakers and in the development and use of plutonium powered, thermoelectric generators for satellites, we feel that we are competent to comment on the above referenced Draft Environmental Statement.

Enclosed for your information is a reprint of a recent publication which describes in detail the design and many performance features of the rechargeable pacemaker that was developed at this Laboratory. To summarize the most pertinent results: As of March 1, 1975, there have been more than 1200 rechargeable pacers implanted in patients over a period of two years, with only two failures of any kind, neither of which caused a patient fatality. There are no known patient deaths due either to pacemaker malfunction or due to the patient's failing to recharge the pacemaker.

On Page 4.4 of the referenced Draft Environmental Statement the following is stated:

> It has been reported that some elderly patients cannot be relied on to recharge their pacemakers[12] and that physicians cannot, in many cases, burden such a patient with the responsibility of recharging his pacemaker.[13]

This Laboratory has obtained both references cited in this quotation. The first of them (Ref. 12) was written by a group of doctors in the Washington, D. C. area who, to the best of our knowledge, at the time of publication, had never used or had any experience with the rechargeable pacemaker. Contrary to their findings, none of the patients known to us has failed to recharge his pacer because of a lack of capability to do so. Since the publication of Ref. 12, one of the doctors who was a co-author of that paper has now begun to use, and continues to implant the rechargeable pacer in some of his patients. Ref. 13 from the above referenced Draft Environmental Statement was found to be an extract from a Wall Street analyst's report. Presumably, it was written, not by a person experienced in medicine, but rather by a financial analyst. It is doubtful that a financial analyst would have sufficient expertise in the area of the psychology of pacemaker patients to be authoritatively quoted on this subject. Furthermore, a study currently being performed by a trained professional in the field of patient psychology has indicated that in 47 patients who are using a rechargeable pacemaker, the vast majority, 94%, either were unconcerned about recharging, or actually looked forward to the process. Many elderly patients have reported that the recharging process gives them a feeling of security that their heart pacers are operating properly.

In the Opening Address to the IVth International Symposium on Cardiac Pacing, held in the Netherlands in the spring of 1973, Dr. Paul Zoll, of the Harvard Medical School, who is regarded as one of the world's leading authorities in the field of electrical stimulation of the heart, explicitly stated a preference for rechargeable pacemakers in clinical use as compared to those that are nuclear powered. In a February 1975 publication,[1] Dr. Zoll reiterated his perspective on this matter by stating:

> Radioisotope-powered cells are being tried clinically, but at present rechargeable nickel-cadmium cells appear to offer more clinical advantages.

Any possible objections to the rechargeable pacer as raised in Refs. 12 and 13 will, in the near future, be relieved by a new rechargeable pacer that is now operating in the laboratory. This new design is capable of being recharged by a

[1] P. M. Zoll, "Countershock and Pacemaking in Cardiac Arrhythmias," Hospital Practice, February 1975, pp. 125-132.

medical technician or nurse in the doctor's office at six-month intervals, with a recharge time of two to three hours. It is expected that this device will be available to the public in less than two years and should answer any objections relative to the alleged inability of the patient to recharge his own pacemaker.

In addition to the work on rechargeable nickel-cadmium, battery powered pacemakers which is being accomplished at this Laboratory, Dr. O. Frank Tyers of the Hershey Medical Center, has developed a rechargeable pacer using a mercury-silver cell which is able at the present time to be recharged at six-month or longer intervals.[2] A February 1975 publication[3] indicates that two of these pacemakers, with a claimed capability of being recharged only once every three and a half years, have been implanted in patients at the Hershey Medical Center.

A significant consideration in this matter is the additional medical cost that the public will have to bear if nuclear powered pacers are allowed to be used extensively in the United States. The average cost of a nuclear pacer system today is $5200. (Some are a few hundred dollars less, some a few hundred dollars more.) The cost of the rechargeable pacemaker system is $2200. The difference in cost, therefore, is $3000 per implantation. Since inflation has increased the cost of all devices of this sort by approximately 10% a year, it would not be unreasonable to assume that the difference in cost would increase in years to come by about the inflation rate. However, even based on a fixed difference for years to come of $3000 per implant, the additional cost to the United States public per ten thousand implants would be $30 million per year—a most appreciable sum. It has been estimated that there will be 75,000 pacers implanted in the United States in 1976. If half of these were nuclear powered, as opposed to the rechargeable pacer, and even assuming no inflationary rise in the cost difference, the additional dollar burden to the public would be $112,500,000 each year. In these times when the medical costs are already excessive, this additional expense does not appear to be warranted.

[2] O. F. Tyers, R. A. Foreman, Jr., H. C. Hughes, Jr., H. A. Toman, "Comprehensive Studies to Achieve Long-Term Internal Cardiac Pacemaking Without Frequent Reoperation," The Journal of Thoracic and Cardiovascular Surgery, Vol. 66, No. 5, November 1973, pp. 778-781.

[3] "New Pacemaker Goes On and On," Medical World News, February 10, 1975, pp. 26-27.

Because there are also some potential risks in the wide distribution of a radioactive and highly toxic material such as Plutonium 238, and since there are viable alternatives, it would appear that the wide scale use of plutonium powered pacers is not in the public interest.

If you would like any further information on this subject, please contact Mr. Robert E. Fischell at this Laboratory on Extension 3091.

Very truly yours,

R. B. Kershner
Assistant Director

RBK:REF:mo'm
Enclosure

The following enclosure was submitted with letter No. 13 and is available for examination in the Nuclear Regulatory Commission Public Document Room, 1717 H Street, Washington, D.C.:

1. R. E. Fischell, K. B. Lewis, and J. W. Love, A Long-Lived, Reliable, Rechargeable Cardiac Pacemaker, The Johns Hopkins Applied Physics Laboratory, Silver Spring, Maryland, December 31, 1974.

81, Irving Ave
Livingston.
N. J. 07039.
March 16th 1975

Acting Deputy Director for Fuels & Materials.
USAEC
Dear Sir,

I wish to place on record my strong opposition to the insane idea of the plutonium pacemaker. It would be a relief to know that it is a hoax but I think not.

The possibilities for the illegal use of the objects are boundless & people could be killed for possession of them. Several of them in the hands of a nut offer us a nightmare. I have written my representatives to advise them of the plan, and being sensible people I am sure they will oppose it.

Sincerely.

MS PATRICIA JORALEMON Pat Joralemon

621 143

CARDIOLOGY ASSOCIATES, p.c.

MARSHALL FRANKLIN, M. D.
MARTIN J. KRAUTHAMER, M. D.
A. RAZZAK TAI, M. D.
RICHARD LANDESMAN, M. D.
JESUS P. YAP, Jr., M. D.

17 OLD KING'S HIGHWAY SOUTH
DARIEN, CONNECTICUT 06820
Telephone 203 — 655-1404

June 12, 1975

Nuclear REgulatory Commission
Washington, D. C. 20545

Attention: Acting Deputy Director
Material, Fuel Cycle Facility Licensing

Dear Sirs:

It has come to my attention that there is a rumor that negative comments have been received by the Nuclear Regulatory Commission in regard the wider scale usage of nuclear powered pacemakers. I would be interested in knowing if this is actually true or if this qualifies as another "rumor".

There is no question of plutonium powered units have a definite risk. As a physician very much involved in implanting pacemakers, I think that each case has to be handled on its own merit. I would be shortchanging my patients if each one did not get this kind of individualized care. Accordingly, should a person best be benifited, in my opinion, by an atomic powered unit I would hope that such would be available at some point in the future should I wish to utilize one. The actual cost of such units may be a greater "deficit" in their use on an ongoing basis than the "risk" of the atomic fuel.

Should there be any way that I could assist in future involvement in relation to the nuclear powered units, please do not hesitate to contact me.

Respectfully,

Martin J. Krauthamer, M.D.

Martin J. Krauthamer, M. D.

MJK:DYI (Signed by secretary to expedite mailing.)

A-60

MARION R. LAWLER, JR., M. D., P. A.
MEDICAL CENTER BUILDING - SUITE 3
610 ED CAREY DRIVE
HARLINGEN, TEXAS 78550

GENERAL THORACIC AND
CARDIOVASCULAR SURGERY

June 19, 1975

Nuclear Regulatory Commission
Washington, D. C. 20555

Attention: Acting Deputy Director
Materials Fuel Cycle Facility
Licensing

Gentlemen:

After extensive and lengthy experience with clinical implantation of cardiac pacemakers, this comment is sent to you to encourage continued clinical investigation of the use of nuclear powered cardiac pacemakers. Particularly in our area, we find many patients who are unable or undependable such that not only do they fail to return for follow up visits at prescribed intervals, they are unable to return for replacement until symptoms return and it is highly doubtful that they would be able to remember to recharge when necessary. There is an increasing number of younger patients in the teen age or early adult age group which lead very active lives and have need for a small long lasting pacer with which they can carry on full activity and travel without physical or mental concern with the paraphernalia of recharging. In many patients, of course, an initial nuclear pacemaker would outlast their life span and never have to be replaced.

Your continued support for clinical investigation in nuclear pacers is encouraged.

Sincerely,

M. R. Lawler, Jr.

Marion R. Lawler, Jr., M. D.

MRL/lw

621 1A4

HERMAN R. LEVINE, M.D.
1017 DONALDSON AVENUE
SAN ANTONIO, TEXAS 78228
TELEPHONE
735-4161

March 5, 1975

Deputy Director for Fuels and Materials
Directorate of Licensing
United States Atomic Energy Commission
Washington, D.C. 20545

Dear Sir:

Re:"A.E.C. issues Draft Generic Environmental Statement on Wide-scale use of Plutonium Powered Cardiac Pacemakers", as released, E.R.D.A., weekly summary, week ending January 22, 1975.

1. Paragraph 2 gives incorrect information. Contrary to what is stated, we now have conventional pacemakers with batteries that can be charged in situ, without periodic surgical replacement.

2. The time-lag between exposure to radioactivity and cancer development could be 20 to 30 or more years. The hazard to young persons who will be receiving long term radioactive exposure to plutonium pacemakers has not been researched for long enough periods to consider this pacemaker a safe or desirable substitute for conventional pacemakers.

3. The surgical procedure required for implanting pacemakers is a very simple one and does not pose a risk to the health or safety of the patient or to the environment. Any temporary discomfort from repeated transplants (if required) certainly makes up for possible future detrimental radiation effects to the patient and the environment.

4. My personal inquiry of persons in charge of activities in mortuaries and crematories in San Antonio where I reside, revealed a total lack of knowledge or concern regarding the need for special precautions required re: plutonium pacemakers. The general attitude was that the radioactive material in plutonium pacemakers was negligible and of no real consequence. However, I did sense that there was interest in any precious metals that could be salvaged from pacemakers. This reveals a temptation to strip such metals from the pacemaker. In view of the "thousands of pacemakers"that have already been implanted in patients, this apathy towards plutonium pacemaker hazards demonstrates that educational efforts by the A.E.C. have been ineffectual.

In view of this record, the widespread use of plutonium pacemakers could compound the problem of negligence.

The news media, with information provided by the A.E.C. and the plutonium pacemaker producers, is partly responsible for this attitude, since they repeatedly

A-61

HERMAN R. LEVINE, M.D.
1017 DONALDSON AVENUE
SAN ANTONIO, TEXAS 78228
—
733-4181

reassure the public that the plutonium pacemaker is completely safe and innocuous.

5. In view of the above, it is, in my serious judgment, essential that presently implanted plutonium pacemakers be researched for damaging health effects for the next 30 years, before licensing them for widespread use. In the meantime, conventional pacemakers may continue to give safe, effective help for cardiac patients.

Very sincerely yours,

Herman R. Levine, M.D.

Medtronic, Inc.
3055 Old Highway Eight
Minneapolis, Minnesota 55418 USA
Telephone [illegible]
Cable [illegible]

1074

March 10, 1975

U. S. Nuclear Regulatory Commission
(formerly U. S. Atomic Energy Commission)
Washington, D. C. 20545

Attention: Acting Deputy Director for Fuels and Materials,
Directorate of Licensing - Regulation

Gentlemen:

In response to the notice published in the Januar[illegible]5, 1975 Federal Register (Vol. 40, No. 11, p. 2863), Med[illegible]ic submits the enclosed comments on the "Draft Generic Envi[illegible]ntal Statement on the Wide-Scale Use of Plutonium Powered Cardiac [illegible]cemakers" prepared by the Commission's Directorate of Licensi[illegible]

Medtronic, a leading manufacturer of cardiac pacemak[illegible] including the Medtronic® Laurens-Alcatel Model 9000 plutonium p[illegible]wered pulse generator, agrees with the Draft Environmental Statem[illegible]s conclusion that the benefits to be derived from the use of plutonium powered cardiac pacemakers are substantially greater than the risks to the environment and that wide-scale use should be authorized.

Medtronic has been conducting a controlled clinical investigation of its Model 9000 plutonium powered pulse generator under a Special Nuclear Materials License (SNM 1156). Since July 18, 1972, 311 Model 9000 plutonium powered pulse generators have been implanted in the United States under this clinical investigation.

Medtronic compliments the staff of the Directorate of Licensing for the tremendous task of collecting, organizing and evaluating the information presented in the Draft Environmental Statement. The pacemaker industry and medical community which it serves deeply appreciate all the efforts that the Statement represents. Medtronic is hopeful that the results of the efforts of all concerned will be the introduction of a superior product to serve the needs of mankind.

Sincerely,

MEDTRONIC, INC.

Bobby I. Griffin
Nuclear Programs Manager

RIG/ka

A-62

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Comments by Medtronic, Inc.
on Draft Environmental Statement
March 10, 1975

I. Summary and Conclusions

The Draft Generic Environmental Statement on the Wide-Scale Use of Plutonium Fowered Cardiac Pacemakers, issued January, 1975, ("Statement") represents an attempt to evaluate and set forth in a comprehensive manner the benefits and costs to the public and pacemaker patients of plutonium pacemakers. Medtronic feels that, overall, the Statement succeeds in making a fair and objective analysis, and Medtronic is in basic agreement with its conclusions and recommendations. The comments that follow are intended to assist in preparation of as accurate as possible final Statement and not to detract from the overall excellence of the Statement.

In addition to the General and Specific Comments submitted below, Medtronic has attached an Appendix A with errata which came to its attention in reviewing the Statement.

II. General Comments

A. Conservative Approach:

While Medtronic recognizes the needs in preparing an Environmental Statement to take a conservative approach, it feels that the Statement assumes a "worst case" analysis. That the benefits still outweigh the costs under such an approach only demonstrates the tremendous value that plutonium powered pacemakers represent to pacemaker patients. Medtronic wishes to point out and emphasize that, if more moderate assumptions were made, the benefits from plutonium powered pacemakers in restoring health and prolonging life in man would further exceed the environmental and societal costs associated with their use.

In addition, no attempt is made in the Statement to quantify the possibly most important benefits of reduction in pain and suffering associated with replacement surgery and reduction in anxiety associated with anticipation of repetitive surgery. The monetary comparisons contained in the Statement may be misunderstood because they do not reflect substantial intangible benefits such as these. Medtronic feels that these are significant and substantial benefits.

B. Future Developments:

Although the Statement makes an analysis of alternative pacemakers under development, it should also point out the potential benefits of plutonium powered pacemakers resulting from future research and improvements. The plutonium power source offers the potential for substantial reduction in the size and weight of pacemakers, for higher output units with long service lives, and for the sophisticated circuitry that may be needed in new applications of pacemakers in the fight against heart disease. These potential benefits cannot be quantified or predicted but offer another reason, in addition to the benefit-risk analysis, why Medtronic supports the wide-scale use of plutonium powered pacemakers, subject only to the requirements of accountability, recovery and disposal.

C. Ownership After Death:

Upon the death of a plutonium powered pacemaker patient, it is unclear under the various state laws who has title to the device and who can convey marketable title. The next of kin, heirs at law, heirs under a will or the executor or administrator of the deceased patient's estate may each claim some interest or right in the device. Since there will be economic value to the recovered device, the manufacturer may be willing to pay the cost of recovery or otherwise pay value for title to the device. This would assure proper handling and recovery of explanted nuclear pulse generators. However, unless the regulatory scheme for accountability, recovery and disposal of the device clarifies the question of ownership, the manufacturer will be reluctant to attempt to acquire title to the device because of the various possible claims on the device that cloud the title and make it uncertain, or at least difficult because of the numerous parties involved, to acquire clear title.

Medtronic recommends that the regulatory scheme anticipate this potential difficulty in recovery.

III. Specific Comments

A. P. iv, Section 2, 1st paragraph, last sentence:

In order to be consistent with terminology recommended by the Association for Advancement of Medical Instrumentation (see Medical Instrumentation, Vol. 7, No. 1, p. 22, 1973), the words "pulse generator" should be inserted in place of "entire pacemaker". Medtronic recommends that all terms in the Statement be consistent with the standard definitions adopted by AAMI.

B. P. vi, paragraph c:

The second sentence listing the specific tests for credible accidents should also include reference to the corrosion test to be complete (see Table I, pages 2-6 and 7).

C. P. viii, paragraph d:

Public and worker exposure to transporting radiopharmaceuticals and radioisotopes may be considered by some to be unsafe and therefore not a valid comparison. The Statement should point out that the exposure is well below safe levels and is allowed under the Transportation Safety Act of 1974 for passenger carrying aircraft as long as it meets the packaging and labeling requirements of that Act.

D. P. ix, paragraph e:

In order to clarify calculation of total costs to the public of $295,000, it is suggested that the following clause be added to the last sentence:

". . .and, at a risk value of $250 per man-rem, is valued at $500 per year."

E. P. ix, paragraph g:

This cost could be passed on to the patient by requiring an initial registration fee. Therefore, not all these costs need be borne by the public.

F. P. ix, paragraph h:

This cost could be offset, in some cases, by the recovery value of the plutonium pulse generator and therefore is a conservative estimate.

G. P. x, paragraph 4:

Mention should be made in this summary that no attempt was made to quantify the very substantial benefits in reducing pain, suffering and anxiety because of the less frequent replacement surgery with plutonium pacemakers. Since the majority of pacemaker patients are elderly (the median age of a pacemaker patient is over 66), even the thought of minor surgery creates severe anxiety. The summary of benefits should make reference to these intangible benefits which were not quantified. Although these benefits are difficult to quantify, Medtronic also feels that an attempt should be made (see comment 7).

H. P. xi, paragraph 6:

The Food and Drug Administration should be asked to comment on the Statement to insure that requirements for plutonium pacemakers are consistent with medical device labeling regulation. Federal Aviation Agency should also be requested to comment on safety of transporting plutonium pacemakers on passenger carrying aircraft if properly labeled and packaged.

I. P. 1-1, Section 1.1, first sentence:

Medtronic suggests using "essentially normal" in place of "normal" as a more accurate description of the expectant state of health of pacemaker patients.

J. P. 1-1, Section 1.1, 2nd paragraph, last sentence:

This sentence describes an atrial synchronous pulse generator. A more common type of demand pacemaker by far is the ventricular inhibited pulse generator. Medtronic recommends that this sentence be redrafted to describe the more commonly used demand pacemaker as follows:

"Depending on the electrical circuits used in a pacemaker, the pacemaker may sense the natural beat of the lower chambers and time its electrical pulses to contract the lower heart muscles only in the absence of a natural contraction or the pacing pulses may be delivered at a fixed rate, not synchronized with the natural beat."

K. P. 2-3, line 7:

In order to be consistent with the last sentence of the first paragraph of Section 2.3.3.1, the word "suggestions" should be replaced by "requirements".

L. P. 2-7, second footnote:

Example in parenthesis should read:

". . .(8 mCi maximum from an initial 8 Ci plutonium source that weighs 500 mg). . ."

M. P. 2-16, line 3:

"Experimental" should be replaced with the word "investigational".

N. P. 2-16, last sentence of first full paragraph:

The definition should be clarified because a pacemaker may be giving normal pacing pulses but they may not be satisfactory to the patient for physiological reasons unique to that patient. Medtronic suggests this read as follows:

"A pacemaker failure is indicated if, for any reason, a pacemaker needs to be replaced due to unavailability of normal pacing pulses from the pacemaker."

O. P. 2-16, last sentence which continues on top of p. 2-17:

Medtronic feels that the appropriate criteria for failure rate should be "not significantly greater than the norm" instead of "significantly less than the norm."

P. P. 2-17, line 3:

Footnote to asterisk is omitted. Medtronic experience indicates that a random component failure rate of 0.15% per pulse generator month with a 90% confidence level is a conservative standard for conventional pulse generators. It is recommended that "0.15% pacemaker failures per month" be restated as "a random component failure rate of 0.15% per pulse generator month with a 90% confidence level." (See "Medtronic Product Performance Report", MC 74551, Medtronic, Inc., September, 1974, p. 6).

Q. P. 3-5, 5th sentence:

Is it the conclusion of the Statement that no restriction be placed on implantation of plutonium powered pacemakers in women in their pre-child bearing and child bearing years? Or that the pulse generator be located above the left pectoral muscle in these cases? Medtronic recommends that the Statement state that these are medical decisions to be made by the physician and patient and that the Statement recommend that no restrictions be made on patient selection or pulse generator placement in wide-scale use.

R. P. 3-23, Section 3.5, last sentence:

Same comment as C above.

S. P. 3-29, 8th line:

Should be clarified to read:

". . .that 5% of the fuel capsules of the 0.3 pacemakers. . ."

There would be no release of radioactive material unless the fuel capsule itself was breached and not just the pacemaker.

T. P. 3-34, footnote 14:

Medtronic suggests that this data be documented in written form.

U. P. 3-36, 1st paragraph:

Since conventional pacemakers must be removed from the deceased patient prior to cremation to avoid possible bursting of the pacemaker or escape of chemicals, the removal of pacemakers should be a familiar and routine procedure for morticians, coroners and physicians. Medtronic is aware of only one incidence of cremation without prior removal of a pacemaker. In this case the titanium can housing the pacemaker burst open to allow internal gases to escape. Some damage to the crematory resulted. Medtronic's Model 9000 plutonium pacemaker has been tested to show that the bursting of the pacemaker during cremation will not breach the fuel capsule and expose radioactive material. Therefore, the bursting of the pacemaker actually acts as an additional safety factor, warning and alerting the crematory that something is amiss.

V. P. 4-1, 1st paragraph, line 8:

The word electrode should be deleted.

W. P. 4-1, 1st paragraph, line 12:

The random failure rate should read:

". . .0.15% per pulse generator month. . ."

X. P. 4-2, Section 4.2.1, 3rd sentence:

Medtronic recommends that this sentence be clarified by adding the following statement:

"Medtronic recommends prophylactic replacement of its highest volume pulse generator (Model 5944) depending on the type of lead used, at times, ranging from 52 to 72 months. Its recently introduced bipolar demand pacemaker (Xytron Model 5950, January 1, 1975) has similar recommended replacement times."

Y. P. 4-6, Section 4.3.1.1, 1st paragraph:

The additional references contained in Appendix B also substantiate the rate of mortalities from surgical procedures reported in the literature and referred to in the Statement (References, 4, 15-19).

The Van der Heide article also substantiates that the Statement's assumption of 1% surgical mortality rate for reimplantations is conservative. This article reports that in the 1961-1973 period, 547 reimplantation operations took place with 11 postoperative deaths; 11 of 547, or a 2% rate.

The mortality rate observed by Medtronic in its clinical investigation studies may be summarized as follows:

Model 5842/5942 clinical study, Duke University: 188 implants, 4 deaths within one month; 4 of 188, or 2%.

Model 5944/5945 long-term follow-up study: 185 implants, no deaths.

Model 9000 clinical investigation: 272 implants, one death; 1 of 272, or a 0.4% rate.

Total for clinical studies: 645 implants, 5 deaths; 5 of 645, or a 0.78% rate.

Z. P. 4-11, Section 4.3.1.3:

Medtronic agrees that the intangible benefits from reduced pain, suffering and anxiety are difficult to quantify. However, in order to properly evaluate and compare the benefits of plutonium pacemakers, an estimate in quantifiable terms should be made. Juries are charged with quantifying such intangibles regularly, and an analysis of jury verdicts would provide a rough yardstick. Medtronic feels that these benefits are substantial and failure to quantify them does not accurately reflect the relative advantages of plutonium pacemakers over conventional pacemakers.

AA. P. 4-16, last paragraph:

The Statement assumes an extremely conservative value for measuring the economic cost of radiation. This assumption makes the total value of risks and costs to the public appear greater than what they actually may be.

BB. P. 4-24, last paragraph:

Medtronic agrees that plutonium powered pacemakers will become the pacemaker of choice for only a limited portion of all patients. Since the history of pacing with implantable devices goes back only fifteen years, the only way to determine the percent of pacemaker patients that will survive beyond fifteen years is by extrapolation of data presently available. Medtronic data indicates that between 20% and 40% of pacemaker patients survive 10 years or more after receiving a pacemaker. Selection of the most appropriate pacemaker, Medtronic agrees, would be up to the physician's judgment of the medical needs of each individual patient. Medtronic would like to point out that concerns expressed by some that all pacemakers in the future will be plutonium powered are not in accordance with Medtronic's evaluation of the market needs for pacemakers.

Reference	Comment
p. 3-39, l. 23	Insert the word "be" between "not" and "inhaled".
p. 3-40, l. 2	Typographical error. Should read "pulmonary".
p. 3-48	Reference 6 should read the same as the second footnote on p. 2-1.
p. 3-49	Reference 13. Proper spelling of the name in the 4th line should be "Marie-Francoise Le Febvre".
p. 4-5	It is suggested that heading on Section 4.2.3.4. read "Other Batteries".
p. 4-6, l. 12	Postoperative is spelled without a hyphen.
p. 4-6	In last line, figure should be 373 lives, not 372.
p. 4-20	Table 20, last section under "Benefits": the "20 year" and "10 year" references should be reversed.
p. 4-27	Reference 24. Misprint, leaving "t" out of "Smyth" in second line.
p. 4-27 and 28	References 26 and 33 are identical. Reference 33 may be omitted and the text corrected to refer to Reference 26.

APPENDIX A

Errata

Reference	Comment
p. iv, l. 20	"widescale" should be spelled with hyphen, "wide-scale"
p. xiii and p. 2-17	It is suggested that heading for Section 2.5.1 read "Manufacturing of Nuclear Pacemakers".
p. xiv and p. 4-4	It is suggested that heading for Section 4.2.3. read "Other Pacemakers Under Development".
p. xix, l. 12	Insert the words "from" before and "who" after the word "consultants".
p. 1-3, l. 15	"Nuclear powered" without a hyphen.
p. 1-5, last line	Last word of footnote should refer to Appendix C.
p. 1-8, l. 2	"Plutonium powered" without a hyphen.
p. 2-7	Reference at top of page should use Roman numeral, "Table I".
p. 2-14, l. 8	"Follow-up" with hyphen.
p. 3-20, l. 18	Last word of third paragraph should be "Table II" - not "Table 10".
p. 3-25, l. 10	Typographical error. Should read "... right hand side..."
p. 3-27, l. 18	It is suggested that the dash be replaced by a comma.

APPENDIX B

Mascarenhas, Eugene and Sol Center. Results of permanent pacemaker therapy. in: Cardiac pacing. Edited by Philip Samet. New York: Grune & Stratton, 1973. pp. 175-200.

Bello, Alexis, et al. Comparative experience with endocardial and epicardial pacemakers. J Cardiovasc Surg 15:528-531, 1974.

Homan Van Der Heide, J. N., et al. Results with pacemaker implantations; is the transthoracic approach and implantation of intramural electrodes still justified? in: Symposium on Cardiac Pacing, 4th, Gronigen, 1973. Proceedings. Cardiac Pacing. Edited by Hilbert J. Th. Thalen. Assen, The Netherlands: Van Gorcum, 1973. pp. 253-267.

Conklin, E. Foster, Stanley Giannelli, Jr., and Thomas F. Nealon, Jr. Four hundred consecutive patients with permanent transvenous pacemakers. J Thorac Cardiovasc Surg 69:1-7, 1975.

MEMORIAL SLOAN-KETTERING CANCER CENTER
1275 YORK AVENUE, NEW YORK, NEW YORK 10021
(212) 879-3000

March 31, 1975

Deputy Director for Fuels and Materials
Directorate of Licensing - Regulation
Energy Resources Development Agency
United States Atomic Energy Commission
Washington, DC 20545

RE: Draft generic environmental statement - plutonium powered cardiac pacemaker.

Gentlemen:

I urge you to delay licensing of the plutonium powered cardiac pacemakers since the generic environmental statement is inadequate and there has not been adequate time for the medical community as well as others to respond to this statement. Since this will represent the first general licensing of plutonium and such action may set important precedents, it is important that the environmental statement and related information be fully discussed by interested individuals.

In the case of a plutonium powered cardiac pacemaker where there are excellent alternatives, it would appear that the case has not been made for licensing a plutonium powered cardiac pacemaker. The alternatives avoid the hazards of plutonium both to the patient and the environment.

It should be emphasized that cardiac pacemakers are generally implanted in patients of 60-70 years of age. With the limited life expectancy of such patients for whom pacemakers are indicated, it would appear that the present battery powered pacemakers are more than adequate. The generic environmental statement suggests that the plutonium powered pacemaker would be particularly indicated in the younger patient. However, it is the younger patient who would be more subject to somatic and genetic risks of radiation. Since the surgical mortality is essentially zero and even if it were necessary to have a second implantation in the younger patient, it is obvious that this is more desirable than implanting a plutonium powered pacemaker.

Additionally, it is obvious that the follow-up on pacemaker patients is most difficult. With 0.15 - 0.5 grams of plutonium in these pacemakers, the community should be assured that each and every patient and his pacemaker can be completely followed from the point of view of environmental contamination. The possibility of contamination, to an accident of the patient, or disposition of the pacemaker upon death are very real ones. Since plutonium is a known carcinogen in animals and would very likely be so in man, it is most important that the toxicity of this material be further established.

Memorial Hospital for Cancer and Allied Diseases
Sloan-Kettering Institute for Cancer Research
Sloan-Kettering Division, Graduate School of Medical Sciences, Cornell University

Since there are dubious bene[illegible] a plutonium powered pacemaker and these are significantly overshadowe[illegible] risks and because alternatives are available which have significant benefi[illegible] without such risks or other alleged risks as stated in the generic environmental statement, I think it most important that there is a wider discussion and dissemination of information about this development.

Sincerely yours,

Martin Sonenberg

Martin Sonenberg, M.D., Ph.D.
Member, Sloan-Kettering Institute for Cancer Research
Professor of Medicine, Cornell University Medical College

MS/nog

UNIVERSITY OF MINNESOTA
TWIN CITIES

School of Public Affairs
Social Sciences Building
Minneapolis, Minnesota 55455

#22 1109

7 March 1975

Atomic Energy Commission
Washington, D.C. 20545

ATTN: Acting Deputy Director for Fuels and Materials
Directorate of Licensing-Regulation

RE: Draft Generic Environmental Statement
Plutonium Powered Cardiac Pacemaker

Dear Sir:

Enclosed are my comments on the above.

Yours truly,

Donald P. Geesaman
Associate Professor

DPG/lam

Encl.

COMMENTS ON THE

DRAFT GENERIC ENVIRONMENTAL STATEMENT

ON THE WIDE-SCALE USE OF

PLUTONIUM POWERED CARDIAC PACEMAKERS

March 7, 1975

Donald P. Geesaman
School of Public Affairs
University of Minnesota
Minneapolis, Minnesota 55455

SUMMARY AND CONCLUSIONS

In summary, the Draft Generic Environmental Statement on the Wide Scale Use of Plutonium Powered Cardiac Pacemakers is inadequate in its justification of that program because:

1) It does not establish an absolute need for a long-lived pacemaker power source (see Comments #1, #2);

2) even given that such an absolute need does exist, it does not establish the superiority of nuclear power sources over chemical power sources (see Comments #3, #4); and

3) even given that such an absolute need does exist, and even given that nuclear power sources are relatively superior, then it does not establish that a nuclear power source will, in fact, result in reduced mortality, morbidity, anxiety or expense for the patient (see Comments #5, #6, #7, #8).

By not establishing these critical bases for proceeding with this program, the residual impression is left that the draft statement simply describes a technology in search of a need. This in itself is not objectionable. Even in the case where the need is contrived, there is still considerable precedent for support of technological welfare projects. Unfortunately in this instance, the program runs contrary to the more profound tradition of exacting control of the material flows associated with radiologically toxic nuclear fuels, such as Pu-238. What is implied by the wide scale usage of plutonium powered pacemakers is that some tens of thousands of plutonium power sources will move in a relatively noisy uncontrolled manner through society,

containing a few curies of Pu-238 individually, and some 10^5 curies in the aggregate. This is a far cry from the rigidly constrained material flows of the nuclear fuel cycle, and such a situation becomes a precedential action gravid with social implications when one recognizes that there are various other devices utilizing much larger inventories of Pu-238 which may then be advanced for similar public dissemination.

To emphasize the significance of a few curies of Pu-238 (half-life 89 years), such as would fuel a nuclear powered pacemaker, it is sufficient to indicate that current standards prescribe a maximum permissible lung burden (general public) of $\sim 10^{-9}$ curies and are of very doubtful conservatism even at that level. In addition, the only existing governmental guidelines for soil contamination by plutonium have been imposed by the State of Colorado, the acceptable level being $\sim 10^{-2}$ curies per square-kilometer. These numbers give the scale for the disruptive potential associated with the release of the contents of one nuclear pacemaker power source, and point up the crematorium plume calculation (3.7 Accident Analysis) for what it is, a morbid exercise in irrelevence. As has been said elsewhere, the primary causal agent for technological events in our society is human intelligence. When people decide to steal a nuclear pacemaker and disperse its contents it will happen. The disruptive potential is substantial and disruption may be politically appealing.

In conclusion, neither absolute, nor relative need have been established for the nuclear powered pacemaker, nor have relative benefits. The adverse implications are real and obvious. In this context, a decision to proceed with the wide scale usage of nuclear powered pacemakers would be an arbitrary and irresponsible exercise of bureaucratic authority.

COMMENT #1: Time Scale of Need

The design objective for the lifetime of the pacemaker power source should be determined by the time scale of need. This time scale will be determined both by patient's needs, and by the component performance of the pacemaker, the power source excepted. Nowhere is this issue explicitly addressed in the Draft Generic Environmental Statement.

One can infer from the cited random failure rate of 2% annually for conventional pacemakers (p. 4-8) that the pacemaker components, exclusive of power source, comprise a relatively stable system. Considering only random failure modes, the fraction of functioning devices after N years would be $(.98)^N$, i.e., after 10 years slightly more than 80% would be functioning. If instead the random failure rate were 5% annually, the fraction of devices functioning after N years would be given by the expression $(.95)^N$, and after 10 years slightly more than 50% would be functioning. Also, if the random failure rate were to exhibit some time dependence associated with a rapidly increasing failure mode after several years, such as, perhaps, electrode degeneration, then the fraction of functioning devices could be much less than that predicted by the above expressions. The point is that a sine qua non for the demonstration of need of a long lived power source is that the ancillary components of the pacemaker have a similar functional lifetime. Therefore, to demonstrate that this requirement is roughly satisfied it is important to document the accuracy of the 2% random failure rate, and to argue that the failure rate can not increase substantially at times a few years after implantation. A long lasting power source would have little utility if pacemaker systems decayed to a small fraction of functioning devices in less than the power source lifetime, thus necessitating reimplantation, independent of power source lifetime.

Moreover, it is not clear from the text of the Draft Generic Environmental Statement, what sort of failures are included in random failure. Would it include broken leads, or corroded electrodes, for instance? Does it, in fact, include all malfunction modes, excepting power source failure, that might limit the lifetime of the pacemaker?

In addition, what are the time scales imposed by the clinical responses and needs of the patients. If one considers the very young, will a pacemaker implanted at age two be adaptable to the growth of the child over the next 10 years without some surgical adjustment? The pacemaker is not a part of the body and has no organic adaptability without surgical intervention. It would not be surprising, if long term tissue response to a foreign system (pacemaker, electrodes, leads), or changing of the patient's cardiac pathology with time, or physical changes in the patient's size with time would impose a natural time scale of need much less than the patient's expected lifetime. This point is not addressed in the Draft Generic Environmental Statement. It should be, if need of a long lifetime power source is to be established rather than assumed.

COMMENT #2: Nuclear Pacemaker Implantation in the Young

Because of the projected long lifetime of the nuclear-powered pacemakers, young patients are often identified as the most likely recipients. On p. 3-22 the radiation rate at the pacemaker surface is cited as "only 5-15 mrem/hr." This converts to 40-120 rems/yr or 1200-3600 rems over a 30 year period. By any standard this is a very large dose to the contiguous tissue which will be several square-inches in cross-sectional extent. When a protracted dose of this magnitude is delivered to a localized and disturbed

tissue region in young patients, a substantial incidence of cancers should be expected unless the contiguous tissue has no carcinogenic potential.

Implantation of nuclear powered pacemakers in the young also raises the issue of genetic damage. Figure 4 (p. 3-9) and Figure 5 (p. 3-10) show the 10 year dose to the ovaries for pectoral muscle and abdominal implantation. For a mature woman the doses are ∿ .3 rem and ∿ 2 rem respectively. A child during the period 4-14 years would suffer an exposure 2 to 3 x larger. A pacemaker with 8 curies instead of 2 1/2 curies would increase this dose another factor of 3. A source material containing .6 ppm of Pu-236 instead of .26 ppm would increase the dose by another factor of 2. Hence as a rough estimate the possible 10 year genetic doses to a female child would be in the ranges 1-5 rem for pectoral muscle implantation, 6-30 rems for abdominal implantation. Doses of this magnitude are recognized as producing significant genetic damage.

The two preceding considerations are likely to limit the widespread use of nuclear powered pacemakers in the young; in the first case, because of the significant risk of local cancer induction, in the latter case because of the social implications associated with constraints on childbearing.

COMMENT #3: Chemical Batteries

The following statement is made in Appendix C (p. C-12):

> "The output of the nuclear battery is in the range of 250-600 micro-watts..."

Hence the electrical energy provided by a nuclear battery over a period of 10 years is 20-50 watt-hrs. Oxidation of an ounce of chemical fuel produces 500 watt-hrs, which demonstrates that energies available in chemical reactions

do scale like the energy requirements of the pacemaker. This is obvious and has been obvious from the first recognition of the need for a pacemaker. Hence many tens of thousands of chemically powered pacemakers have already been implanted. This should be remembered when evaluating the nuclear powered pacemaker because the alternative to nuclear is, in fact, the proven technology, the chemically powered pacemaker. Moreover, it seems probable from the brief discussion in 4.2.1 and 4.2.3 that market pressure in this technology has already upgraded chemical battery (including rechargeable) lifetimes to the range 5-10 years, which if so, makes very arbitrary, any distinction between chemically powered and nuclear powered pacemakers on the basis of power source lifetime.

Moreover, the following remark is made in 4.2.3.2 Rechargeable Nickel-Cadmium Battery (p. 4-4):

> "It has been reported that some elderly patients cannot be relied on to recharge their pacemakers[12] and that physicians cannot, in many cases, burden such a patient with the responsibility of recharging his pacemaker."

Two points: 1) This is a long-lived pacemaker, and like the nuclear powered pacemaker would not be particularly suggested for elderly patients, and 2) many elderly patients with cardiac disorders are on far more complicated pharmaceutical regimens, than the regimen implied by inductive charging of a pacemaker. The cited remark therefore seems of questionable relevance and of doubtful general validity.

COMMENT #4: Clinical Investigation of Nuclear Powered Pacemakers Reliability

Section 4.5 Results of Clinical Investigations (p. 4-19, 4-23) evaluates the clinical experience with nuclear powered pacemakers during their

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investigational use. Since the Interim Safety Guide for the Design and Testing of Nuclear Powered Cardiac Pacemakers is dated March 26, 1974, one may assume that implantation did not substantially precede this date. Taking the most extensive history of clinical experience (Medtronic Model 9000), there have been 272 implanted pacemakers which have accumulated 2776 device months of function, or approximately 10 months per device. Analysis of reliability strictly on a total device month history seems extremely tenuous since it ignores the possibility of any time dependent failure modes associated with the device, such as for example the possible effects of high neutron presence on semi-conductors. In effect, what is known at the present stage of the investigation is that this pacemaker has functioned within specifications during the first year of investigation. Moreover, this investigatory stage has been conducted under rigorous regulation with presumably only a few major hospitals involved. In comparing this history with that of chemically powered pacemakers, cognizance should be taken of the fact that the integrated history of the latter has evolved in a more technically uncertain time and in a less rigidly controlled situation. Direct comparison with recent and equivalently controlled chemically powered pacemaker implantations is the meaningful comparison.

COMMENT #5: Reimplantation Mortality Rates

The following statement is made in Summary and Conclusions, 4. Summary of Benefits, (p. X):

> "The principal benefit of nuclear pacemakers is the lives saved by the decreased surgical mortality associated with decreased need for replacement operations. If the useful life of plutonium batteries is 10 years and the random failure rate of plutonium powered pacemakers is the same as the random failure rate, exclusive of battery depletion, of conventionally powered pacemakers, 5.9 lives will be saved per year per 10,000 pacemaker patients. ...If the useful life of plutonium batteries is 20 years 9 lives would be saved per year...."

The following statement is made in 4.3.1.1 Reduction in Surgical Mortality (p. 4-6):

> "A surgical mortality rate of 1% is assumed for reimplantations."

The stated principal benefit, i.e., the number of lives saved per year relative to chemical pacemakers, is linearly dependent on the mortality rate associated with reimplantation. That rate appears to have been arbitrarily assumed to be 1%. If it had been assumed to be 0% the principal benefit would have vanished, or if assumed to be 0.1% the principal benefit would have fallen to less than 1 life per year. What in fact is the hard basis for 1%? The conclusions on the principal benefit are sensitive to the mortality rate for reimplantation; that rate can not be arbitrarily assumed if the evaluation is to have merit. Considering the nature of the surgical procedures for reimplantation, the assumption of 1% mortality seems inordinately high.

COMMENT #6: Reimplantation Morbidity Rates

The following statement is made in 4.4 Benefit-Risk Balance (p. 4-15):

> "It is assumed that complications occur in 33% of reimplantations...."

Any reduced morbidity relative to chemically powered pacemakers would be a benefit to the patient. This benefit would be proportional to the morbidity rate for reimplantation. That rate appears to have been arbitrarily assumed to be 33%. The evaluation of this program is sensitive to this assumption. What is the hard basis for this assumption? A morbidity rate of 33% seems

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remarkably large considering the nature of the surgical procedure, and the level of sophistication in current surgical practice.

COMMENT #7: Pain, Suffering and Anxiety

The following statement is made in 4.3 Benefits (p. 4-5):

> "The major advantage of long-lived pacemakers are medical benefits to the patients. They are: 1) a reduction in patient deaths due to reimplant surgery, 2) a reduction in surgical and medical complications, and 3) a reduction in pain, suffering and anxiety."

Reduction of pain, suffering and anxiety (3 above) are real benefits for the patient. It should be recognized, however, that 1), 2) and 3) are not independent, and, in fact, the most substantive portion of 3) derives directly from 1) and 2), i.e., anxiety over reimplantation mortality and morbidity is the most real basis for anxiety and suffering, both to the patients and to their family. Therefore, the questions raised in Comment 5 and Comment 6 about the validity of the assumed mortality and morbidity rates for reimplantation, bear directly on the issues of pain, suffering and anxiety. Should mortality and morbidity rates prove to be much lower than conjectured in the Draft Generic Environmental Statement, then the issue of suffering and anxiety will do little to discriminate between nuclear powered and chemically powered pacemakers, especially against the significant residuum of anxiety associated with the patient's given situation of having a pacemaker.

COMMENT #8: Cumulative Cost of Pacemaker to Patient

Table 18 (p. 4-14) purports to be a comparison of the cumulative

costs to a patient for a nuclear powered and a periodically replaced chemically powered pacemaker. The tabulation as shown is misleading because it does not demonstrate the sensitivity of this calculation to factors such as replacement time, discount rates, etc. How would a more specific tabulation read if it were based on the assumption of a 6 year replacement time and a 7% discount rate? This is a minor defect in the discussion, but it is one that should be corrected, since it would be improper to create the illusion that in the long run the nuclear pacemaker will necessarily or even probably be cheaper for the patient.

COMMENT #9: Benefit-Risk Calculation

The economic benefit risk calculus employed in 4.4 Benefit-Risk Balance (p. 4-12 to p. 4-19) and tabulated in Table 20 (p. 4-20) is morally offensive. The assignment of a value of $15,000 for each year of life is a blasphemy, and an arbitrary blasphemy at that. It would suggest a particularly sordid extension of the calculation in which the benefits were maximized by preferential implantation in those of greatest economic worth.

The designated equivalence between $250 and a man-rem of exposure (p. 4-16) is a more convoluted, but similar and equally despicable technique for placing a price on human life.

There are irreducible classes of human experience into which economics and systems analysis can not properly intrude. The policy lesson of the 1960s was that quantification was not a necessary condition for existence. Custom, history, ethics are the unreckoned sums that will remain uncountable.

The good purposes espoused by this program are desecrated by resorting to these degenerate numerical machinations.

UNIVERSITY OF MINNESOTA
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School of Public Affairs
Social Sciences Building
Minneapolis, Minnesota 55455

20 March 1975

Atomic Energy Commission
Washington, D.C. 20545

ATTENTION: Acting Deputy Director for Fuels and Materials
Directorate of Licensing-Regulations

Re: Draft Genertic Environmental Impact Statement
Plutonium Powered Cardiac Pacemaker

Dear Sir:

On 9 March 1975 I sent you my comments on the above draft impact statement.

When, after the rush of completing the statement before the final date for comment was past, we again read the statement, several minor errors were found.

These have now been corrected. I am enclosing the corrected copy and ask that the first copy sent to you be discarded and replaced by this one. There have been no substantive changes, just correction of typographical and transcription errors.

Thank you very much.

Sincerely yours,

Dean E. Abrahamson, M.D., Ph.D.
Professor

DEA/cc

cc: J. G. Speth, Natural Resources Defense Council, Inc.

9211 159

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COMMENTS ON

DRAFT GENERIC ENVIRONMENTAL STATEMENT ON THE WIDE-SCALE USE OF PLUTONIUM POWERED CARDIAC PACEMAKERS

ISSUED BY
U.S. ATOMIC ENERGY COMMISSION, FUELS AND MATERIALS,
DIRECTORATE OF LICENSING
JANUARY 1975

BY

DEAN E. ABRAHAMSON, M.D., Ph.D.
PROFESSOR, SCHOOL OF PUBLIC AFFAIRS
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March 8, 1975

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ABSTRACT

The following comments are made in response to the issuance of a draft environmental impact statement on the AEC's proposed action of licensing for wide-spread use of the plutonium powered cardiac pacemaker.

These comments demonstrate that:

- There are environmental and social hazards associated with the radiation exposures which would result from the use of plutonium powered cardiac pacemakers
- That official guidance requires that any exposure to ionizing radiation be regarded as harmful, that any unnecessary exposure to ionizing radiation should be avoided, and that exposure to radiation shall result from a real determination of its need
- That there are no significant benefits that would be derived from the use of the plutonium powered cardiac pacemaker
- That there are alternative pacemakers available having operational life at least as long as the proposed plutonium powered cardiac pacemaker
- That these alternatives not only avoid the hazards which are unavoidably associated with the plutonium powered pacemaker but also have no environmental or other hazards of their own
- That there are grievous errors of commission and omission in the draft impact statement
- That the draft impact statement does not satisfy the criteria specified in the guidelines of the Council on Environmental Quality

It is demonstrated that the only appropriate conclusion which can be reached is that the approval for wide-spread use of plutonium powered cardiac pacemakers must be denied.

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SECTION I

THERE ARE HAZARDS ASSOCIATED WITH THE USE OF PLUTONIUM POWERED CARDIAC PACEMAKERS

The draft generic environmental statement on the wide-scale use of plutonium powered cardiac pacemakers (hereafter referred to as "the draft") acknowledges that there are environmental and other hazards which would unavoidably result from the wide-spread use of plutonium powered cardiac pacemakers. Among the hazards acknowledged in the draft are:

1. Radiation exposures to hospital personnel
2. Radiation exposure to the pacemaker patient
3. Radiation exposure to the patient's family
4. Radiation exposure to the general public
5. Environmental releases of plutonium from various accidents and from cremation of pacemaker-containing bodies.

Other hazards certain to be associated with the plutonium pacemaker program were it to be undertaken, but not considered in the draft, include:

1. Occupational exposures to radiation during preparation of the plutonium
2. Occupational exposures to radiation during fabrication of the plutonium power source
3. Environmental releases of plutonium during normal and accident conditions during preparation of the plutonium
4. Environmental releases of plutonium during fabrication of the plutonium power source
5. Environmental releases and/or occupational exposures to radiation associated with collection and processing of used radioactive pacemakers and disposal of the used plutonium.

SECTION II

OFFICIAL GUIDANCE REQUIRES THAT "EXPOSURE TO RADIATION SHALL RESULT FROM A REAL DETERMINATION OF ITS NECESSITY"

All official standards and guidances emphasize the desirability and importance of minimizing human radiation exposure. The Federal Radiation Council has made the following policy statement (ref. 1):

> There can be no single permissible or acceptable level of exposure without regard to the reason for permitting the exposure. It should be general practice to reduce exposure to radiation, and positive effort should be carried out to fulfill the sense of these recommendations. It is basic that exposure to radiation should result from a real determination of its necessity. (emphasis added)

The United States Public Health Service has used the following language (ref. 2):

> The effects of human radiation exposure are viewed as harmful and any unnecessary exposure to ionizing radiation should be avoided. (emphasis added)

SECTION III

THE BENEFIT CLAIMED FOR NUCLEAR PACEMAKERS DOES NOT EXIST (I.E. IS FICTIONAL)

The draft asserts that (page x and elsewhere):

> The principal benefit of nuclear pacemakers is the lives saved by the decreased surgical mortality associated with decreased need for replacement operations. If the useful life of plutonium batteries is 10 years and the random failure rate of plutonium powered pacemakers is the same as the random failure rate, exclusive of battery depletion, of conventionally powered pacemakers, 5.9 (sic) lives will be saved per year per 10,000 pacemaker patients. (emphasis added)

Although called the "principal benefit", the AEC in fact claims no other benefit (Table 20, p. 4-20) for the plutonium powered pacemaker. This is the sole benefit against which must be weighed the monetary costs of the program, the monetary costs to the patient and to society, and the hazards mentioned in previous sections of this comment.

Let us examine this purported "benefit" in some detail. The advantage claimed for the plutonium powered pacemaker is its assumed long battery life. It is argued that "if the useful life of the plutonium batteries is 10 years" and if certain other conditions are assumed, then there will be fewer surgical procedures for replacement of the pacemaker than with pacemakers having alternative batteries. The assumptions include: (a) that the plutonium battery life is indeed 10 years or more; (b) that battery life determines the operational life of the pulse generator; (c) that other components of the pacemaker system – principally the electrodes – have at least as long operational lifetimes as the pulse generator; and (d) that the life expectancies of pacemaker patients is such that longer lasting pacemakers have significance.

Each of these assumptions is examined in later sections of this

comment. If for the purpose of further discussion in this section we join the AEC in assuming that pacemaker replacement intervals are determined by the theoretical life of the pacemaker power supply, then what are the implications? Are the values claimed by the AEC as benefits in the cost benefit analysis (summarized in Table 20, page 4.20 of the draft) as "Lives saved by reduction of surgical mortality" and the associated "Estimated monetary value of the above shown lives saved" valid? By the AEC's own calculus of decision making, the justification for the entire plutonium pacemaker program rests solely upon those values.

THE AEC'S "BENEFIT" COMPUTATION IS SUMMARIZED

The method used in the draft impact statement to determine "Benefits to the public" because of "lives saved by reduction of surgical mortality" is summarized below:

(a) An age distribution for pacemaker recipients was determined (Table 6, page 4-10).

(b) It was assumed that the average remaining lifetime (age specific mortality rate) was the same for pacemaker patients as for members of the general public of the same age.

(c) It was assumed that the operational life of a plutonium powered pacemaker would be at least ten years, and that plutonium pacemakers would be replaced each ten years.

(d) Using the data produced by steps (a) through (c) above, the number of replacement operations was computed, apparently assuming that patients in all age classes would receive nuclear pacemakers.

(e) For comparison with "conventional pacemakers" a six year service life was assumed. (No comparison was made with non-conventional alternatives to the plutonium powered pacemaker. Some of these alternatives have at least the service life of the nuclear option (see below Section IV)).

(f) It was assumed that there was a one percent (1%) mortality rate associated with pacemaker replacement.

(g) It was assumed that associated with each surgical mortality, fourteen years of "life expectancy" would be lost.

(h) A monetary benefit to the public of $15,000 per year of unrealized life expectancy was assumed.

The result of this series of operations (detailed in Section 4 of the draft) is said to be a "saving" of 5.8 (sic) lives per year due to the assumed four year differential service life between the nuclear pacemaker and the "conventional pacemaker". Assuming then a "saved" life expectancy of 14 years per "saved" life, and a "value of each life saved of $15,000 per year", the "estimated monetary value of the above shown life saved" is:

> (5.8 "saved lives per year") X (14 years "saved life expectancy per life "saved") X ($15,000 "public benefit" per year of life expectancy "saved") = $1,218,000 per year "benefit to the public from the use of plutonium powered pacemakers".

The computation contained in the draft impact statement, and reproduced in outline form above, is fiction. The evidence is briefly outlined below.

THE AEC'S "BENEFIT" COMPUTATION IS SUBJECTED TO REVIEW

The remainder of this section of the comment is a step by step review of the AEC's "benefit" analyis. Beginning with a review of the surgical mortality rate, which appears in fact to be zero percent, each assumption used in the AEC's analysis is shown to be unsupported and/or unsupportable.

Surgical mortality associated with pacemaker replacement is virtually zero

The draft statement assumes a surgical mortality rate of one percent. The available clinical reports show that this mortality rate is zero.

Conklin et al (ref. 3) report on 400 consecutive patients with permanent transvenous pacemakers. Their series includes 400 initial implantations and 326 replacements. There was one death associated with the initial implantation (caused by perforation of the myocardium associated with electrode placement) and no deaths associated with the replacements. In addition, there was only one infection (the most serious surgical complication) associated with initial implantation (and that acknowledged by the authors as being

associated with "ill-advised efforts to aspirate a pouch hematoma with large-bore needles") and no infections associated with the 326 pacemaker replacements.

Sowton, et al (ref. 4) report ten years of experience with implanted cardiac pacemakers. This series includes 374 patients and 233 pacemaker replacements. There were no deaths associated with either initial placement or replacement of the pacemakers.

Abrahamson and Trigg (ref. 5) have reviewed the past three years' (1972-1975) experience at the University of Minnesota Hospitals. During that period there have been a total of 159 pacemaker replacements with no deaths associated with the replacements.

It might also be noted that nowhere in the several articles which could be found reviewing clinical experience with nuclear-fueled cardiac pacemakers have the authors claimed as benefits a reduction in surgical mortality associated with pacemaker replacement. A typical statement, from a 1974 review article (ref. 6) is:

> In addition to expense and anxiety, pacemaker replacement constitutes a small but finite risk of infection and/or prolonged hospitalization.

The conclusion must be that in the absence of surgical mortality associated with pacemaker replacement, the benefits, as defined by the AEC in the draft impact statement on the plutonium powered cardiac pacemaker, are zero. The AEC's entire analysis is fiction.

Although the above discussion, by itself, is sufficient to demonstrate that there is no justification for proceeding with the proposed licensing of the plutonium powered pacemaker for wide-scale use, other of the assumptions and data used in the AEC's "benefit" analysis are also unsupported and/or unsupportable. A brief review of these other points follows.

The age distribution for nuclear pacemaker recipients would not be that of the general population of pacemaker recipients

There is a large literature dealing with long lived cardiac pacemakers, nuclear and non-nuclear. Throughout this literature reference is made to the short life expectancy of the average pacemaker patient at the time of initial implantation. The literature is not uniform, but the average age

at implantation is typically near 70 years with the vast majority of pacemakers implanted in patients in excess of 60 years of age.

As would be expected, discussions in the medical literature of the need for long lasting pacemaker systems focus on the relatively small fraction of total pacemaker patients who are sufficiently young so that several replacements would be anticipated during their life expectancy. A representative statement is that of Huffman et al (ref. 6):

> For those patients with relatively short longevity expectations, improved chemical batteries will probably be used. The primary application of nuclear pacemakers is likely to be for the younger patients in whom they are most cost effective.

The assumption apparently used in the AEC's benefit analysis — namely that the age distribution of nuclear pacemaker patients would be the same as that of all pacemaker patients — would appear, at first glance, to be biased against the nuclear pacemaker. This is because were a younger patient population postulated, more pacemaker replacements would be expected, more surgical "mortality", and hence increased "public benefits" as defined in the draft statement. However, the bias is in fact in favor of the nuclear pacemaker when radiation exposures to the patient are considered. As will be discussed in greater detail below (Section V) the radiation doses to the plutonium pacemaker recipient are quite large. Radiation exposure involves somatic risk (induction of malignancies) and genetic risk. There is a several year latent period associated with the production of cancers due to radiation exposure. This is of lesser importance in the older patient whose life expectancy is probably not sufficiently long for cancer production to be manifest. Such is not the case for the younger patient. Likewise in the older patient there is relatively little chance that the genetic effects of radiation will be manifest. Such is not the case with the younger patient.

The life expectancy of pacemaker recipients is not equal to that of the general public

Patients who receive cardiac pacemakers have serious cardiac or cardiovascular disease. While the record clearly shows that patients who meet certain criteria do better if they receive a pacemaker than if they do not (see e.g. ref. 7),

no evidence could be found to support the draft statement that (p. 4-9):

> The mortality rate from natural attrition for each age subgroup was assumed to be the same as the U.S. mortality rate for the subgroup. (emphasis added)

The only evidence offered in the draft is (p. 4-9):

> This appears to be a valid assumption. Physicians have reported that many patients for whom pacemakers were implanted return to a relatively normal life... .

Casual reports of physicians' impressions are notoriously unreliable and can hardly be taken as sufficient documentation for input in what purports to be a serious, statistically significant, benefit-risk analysis. This is particularly true when the assertion runs counter to common sense expectations. This is a point that would be so obvious to the physician that one would not expect an extensive medical literature. There is, however, some documentation in the literature, for example the 1974 review of Svendsen, et al (ref. 13). A pacemaker is palliative at best, and its implantation does nothing to correct the serious underlying disease processes that necessitated its use.

The draft statment analysis has been biased in favor of the longer lasting pacemaker systems.

Alternatives to the plutonium pacemaker have an anticipated operational life well in excess of six years and may exceed that of the plutonium pacemaker

The benefit "analysis" purports to show the differential benefits associated with a plutonium pacemaker having an assumed operational life of ten years contrasted with a "conventional pacemaker" having an operational life of six years. As discussed below, there is no evidence to support the assumption of a ten year operational life for the nuclear pacemaker — ten years is simply the design objective of the promoters. On the other hand, six years is the anticipated lifetime of conventional battery powered pacemakers which have undergone years of development and clinical use.

At issue here is a comparison of alternatives to the nuclear powered pacemaker and these alternatives include a variety of battery powered pacemakers and also a variety of technical changes involving reduction of the energy per

pulse delivered by the pacemaker. As is discussed in greater detail below (Section IV) there are several alternative chemical batteries, some of which are rechargeable, which promise a life expectancy far in excess of six years. It is completely unrealistic, and a blatent attempt to subvert the very purpose of the discussion of alternatives in an environmental impact statement, to compare the nuclear pacemaker with readily available conventional pacemakers. The appropriate comparison, and that required by the National Environmental Policy Act, is with all alternative pacemaker systems — whether or not they are commercially available.

Plutonium pacemaker life of ten years has not been demonstrated

Clinical and operational experience with plutonium powered cardiac pacemakers is very limited. The draft attempts, through elaborate statistical machinations, to demonstrate on the basis of very little data, that the failure rate will not exceed 0.15% per month. The assumption was made that failure rates are not time-dependent — an assumption that is of doubtful validity for any pacemaker system. In addition, there is at least one failure mode that is unique to the nuclear pacemaker and which, if operative, would lead to time-dependent failure rates. More information on neutron fluxes, pacemaker geometry and electronic design than is provided in the draft would be necessary to fully evaluate this time-dependent failure mode. However, rough computation shows that the electronic components of the pacemaker could be exposed to 10^{11} or 10^{12} neutrons over the projected ten year life. In addition, there is a high gamma irradiation of components. These neutron and gamma exposures may well be sufficient to cause serious deterioration of the pacemaker circuitry. These deleterious effects are not dependent on dose rate, are cumulative, and would lead to increasing failure rates with time.

Much more operational experience is needed to demonstrate a ten year life for the plutonium pacemaker and much more information than is provided in the draft is needed to support the assumption that failure rates are not time-dependent.

The operational life of a pacemaker system is not necessarily limited by power supply life

While it is true that the reliability of all components of pacemaker

systems has shown improvement with time (see e.g. ref. 8), it is by no means clear that battery life limits the operational life of the system. The literature is replete with discussions of failures of electronic components, electrode failures, infections/erosion and other failures associated with patient/pacemaker system interactions, and other system failures (see e.g. refs. 9, 10, and 11). System failure rates approximating one per cent per month from other than battery failures are reported. Several authors have speculated as to whether or not electrode life will limit pacemaker system life given the new longer lasting power sources — nuclear or non-nuclear (see e.g. refs. 3 and 12).

Hence, it is not valid to assume that the frequency of replacement surgery, or surgical intervention equivalent to the procedures necessary for pacemaker replacement, is only determined by pacemaker power supply longevity. The benefit analysis in the draft is again based on unsupported and unsupportable assumptions.

It is inappropriate to assign a value of $15,000 per year of unrealized life expectancy

Even were it to be agreed, which it is not, that the method used to assign value to life is valid, the value used for public cost of life lost (or public benefit from lives saved) is grossly inappropriate. The draft statement supports the figure of "$15,000 per year of life expectancy" with the glib and totally fallacious comment (page 4-15):

> based on average annual earnings of individuals in the work force and used here as a value of life even though many pacemaker patients are of retirement age or otherwise not in the work force.

This is ridiculous. The vast majority of pacemaker recipients are past retirement age and another large fraction are not in the work force for other reasons. The average per capita income for individuals in the U.S. is less than a third of the value assumed by the AEC and even that figure is substantially in excess of the average net income for individuals of age characteristic of pacemaker patients.

Once again the analysis has been biased to a point that no semblance of credibility or objectivity has been preserved.

Summary of "public benefit" analysis in the draft impact statment

The computation included in the draft impact statement is totally without value. Considering the surgical mortality rate alone shows that the benefits as defined by the AEC are zero. In addition, virtually every other parameter used in the analysis is either an unsupported and unsupportable assumption biased to favor the nuclear pacemaker or is a misrepresentation of the data presented in the medical literature. The CEQ guidelines for the preparation of environmental impact statements (discussed more completely in Section VI) contain the following language (Sec. 1500.7):

> In particular, agencies should keep in mind that such [draft] statements are to serve as the means of assessing the environmental impact of proposed agency actions, rather than as a justification for decisions already made.

SECTION IV

THERE ARE ALTERNATIVES TO PLUTONIUM POWERED PACEMAKERS

The CEQ guidelines for preparation of environmental impact statements require that the draft and final statements include a full discussion of alternatives to the proposed action, whether or not these alternatives are within the existing authority of the responsible agency. A high standard is specified for consideration of alternatives (CEQ guidelines, 1500.8 (a)(4)):

> A rigorous exploration and objective evaluation of the environmental impacts of all reasonable alternative actions, particularly those that might enhance environmental quality or avoid some or all of the adverse environmental effects [of the proposed action] is essential. (emphasis added).

Section 4.2.1 of the draft statement (pages 4-2 through 4-5) includes brief mention of "alternative pacemakers". There is no mention of other alternative actions. There is no mention of any environmental implications or impacts of any alternatives.

The CEQ guidelines are also quite specific in stating the various alternatives which must be considered. They include:

- -The alternative of taking no action or of postponing action pending further study
- -Alternatives requiring actions of a significantly different nature which would provide similar benefits with different environmental impacts
- -Alternatives related to different designs or details of the proposed action which would present different environmental impacts.

These requirements have been largely ignored in the draft statement.

The advantage claimed for the proposed plutonium powered cardiac pacemaker derives from its presumed longer operational life. Given the advanced age of the majority of pacemaker patients, longer lasting pacemakers than those presently available are of interest only for the younger class of potential pacemaker recipients. This is recognized in the draft statement: "The life expectancy of some patients is such that all patients do not need a pacemaker of improved longevity." (page 4-24).

There are several possible approaches that could lead to longer

lasting pacemaker systems: Improvements in apparatus and technique that would lead to fewer adverse pacemaker system/patient interactions necessitating surgical intervention (see e.g. ref. 8); Improvements in electrodes and pacemaker circuits that would permit lower energy per pulse (see e.g. refs. 26 & 27); and The development of longer lasting batteries. Only the latter approach was discussed in the draft statement.

There are three alternative methods being pursued toward the goal of longer lasting pacemaker power systems. The first is improvements in non-rechargeable chemical batteries. The second is the development of rechargeable chemical batteries. The third is the development of radioisotope powered power systems, one of which is the plutonium-238 powered pacemaker.

Improved nonrechargeable chemical batteries

Improved mercury batteries are discussed in the draft (page 4-2), and their operational life represented as: "...most of the pacemaker systems implanted have recommended pulse generator replacement times near the middle of the time range, or from 60 to 76 months." This statement appears to be the basis for the assumed life of alternatives to the plutonium pacemaker of 6 years.

There is no discussion of the environmental impact of the improved mercury battery alternative.

As is indicated in the draft statement, several alternative chemical batteries have been, or are being, developed. Foremost among these is the commercially available Lithium-Iodide battery pacemaker (ref. 28). Although the draft st[illegible] knowledges that it "is in clinical use in over 3,500 patients", has b[illegible]dergoing clinical tests "since 1972", and that this experie[illegible]ted operational life "out well beyond the six year objective[illegible] was not included in the benefit-risk analysis in the d[illegible]

[illegible]shed review of clinical experience with the Lith[illegible]e pacemaker (ref. 29) indicates that a ten year life is anticip[illegible] Its use[illegible]eral thousand patients is testimony to its acceptan[illegible]e medical community. The authors of the 1974 review (ref. 29) indicate

> This circuitry [that of the CPI pacemaker] combined with a lithium iodide power source, which has shown no failures in vitro or in vivo, gives close to an ideal pulse generator.

and

> ...even 5 years of in vivo life is the goal of most physicians treating patients with complete or intermittent [heart] block, since this is about the average life expectancy of the patient. By these statistics, if a CPI [Lithium-Iodide] pulse generator is used, the majority of patients requiring a pacemaker might never require a change of the unit.

These authors also have the reservation about unnecessarily exposing their patients to ionizing radiation which is characteristic of informed physicians:

> ...we do not know the long-term effects of the irradiation [which would be delivered to patients using nuclear-powered pulse generators], even though small, on bone marrow and lymph tissue, or on the gonads if implanted in the abdominal wall. This assessment cannot take place for 20 years or more if we are to judge from the remote effects of low-dose radiation elsewhere in the body, such as to the tonsils, thyroid, and thymus. These are potential problems of the future. More pertinent to the present are the high costs of these nuclear-powered units.

It should be noted that this last point, i.e. the high cost of the plutonium powered pacemakers, has not escaped notice elsewhere. The authors of a 1974 review of plutonium pacemakers take pains to note that (ref. 6):

> In our institutions, third-party insurance carriers have assumed their [the plutonium pacemaker's] cost.

There is no discussion in the draft statement of the environmental impact of the Lithium-Iodide battery powered pacemaker.

In conclusion, it has been established that conventional mercury batteries have a recognized operational life of at least six years and that the commercially available Lithium-Iodide battery powered pacemaker have a life "out well beyond the six year objective".

Rechargeable Chemical Batteries

At least two rechargeable chemical battery pacemaker systems are being used. One of these systems, the rechargeable Nickel-Cadmium battery developed by a Johns Hopkins University group, is briefly discussed in the

draft statement. A report on clinical experience with these pacemakers is now available in the medical literature, and it supports the anticipated advantages of this rechargeable system (ref. 30). At least 1,000 of these pacemakers are now in use (ref. 31). The draft statement discounts the rechargeable systems with the comment (page 4-4):

> ...some elderly patients cannot be relied on to recharge their pacemakers and ... physicians cannot, in many cases, burden such a patient with the responsibility of recharging his pacemaker.

While it cannot be denied that "some elderly patients" probably cannot themselves recharge their pacemakers, it is doubtful that such patients can care for their other needs either. This problem is not different from that imposed by chronic treatment with insulin, digitalis, or other drugs and presumably could be handled in the same manner. Also, as has been repeatedly noted in the draft statement, in the medical literature, and in these comments, the major use of any long-lasting pacemaker system will be in the younger patient group.

The AEC in the draft statement acknowledges that the operational life of the nickel-cadmium rechargeable pacemaker system will be 10 years. The draft contains no discussion of the environmental impact of rechargeable chemical battery pacemaker systems.

A new Mercury-Silver rechargeable pacemaker battery system has recently been developed and is now undergoing clinical testing. This system, which is not mentioned in the draft statement, is said to require recharging "only every 3-1/2 years," and have an "expected life span of more than 20 years". (ref. 31)

The commercially available Nickel-Cadmium rechargeable pacemaker is reported to have a cost of $2,200, including charger. This is about twice that of conventional, non-rechargeable, pacemakers, but less than half that of the proposed plutonium powered pacemaker.

Summary

Non-rechargeable, chemical battery pacemakers have recommended pulse generator replacement times ranging from 60 to 76 months. Commercially available, rechargeable Nickel-Cadmium pacemakers have an expected life of at least 10 years and are sold with a warranty of ten years for the pacer and three years for the charger (ref. 31). A new Mercury-Silver rechargeable pacemaker system is now undergoing clinical tests. This system is said to have "an expected life span of more than 20 years" and "may need a recharge only every 3-1/2 years".

The AEC draft impact statement on the plutonium powered pacemaker includes an inadequate discussion of these alternatives. In addition, it includes no discussion of the environmental impacts associated with these alternatives – because there are none!

The alternative of "taking no action" or of "postponing action pending further study"

As noted above, the CEQ guidelines, as well as common sense, requires that the alternative of not approving the plutonium powered pacemaker be considered. That this alternative is not discussed is not only a violation of CEQ guidelines, but also stands as mute testimony that this draft impact statement is intended as a justification for a decision already made by the AEC rather than as part of the assessment process of proposed agency actions.

It has been established: that longer lasting pacemakers would be desirable for at least some pacemaker patients; that the proposed nuclear powered pacemaker may have a longer battery life than some other commercially available pacemakers; that the proposed nuclear powered pacemaker carries with it significant environmental impact in the form of exposure to ionizing radiation; that alternative long lasting pacemakers are available; and that these alternatives not only avoid the adverse environmental impact of the plutonium pacemaker but also that they have no adverse environmental impacts at all.

CONCLUSION

The only reasonable conclusion that can be reached is that the AEC should "take no action". That is, that there be no approval for wide-spread use of the plutonium powered cardiac pacemaker.

SECTION V

OTHER SIGNIFICANT ERRORS OF COMMISSION AND OMISSION IN THE DRAFT STATEMENT

The purpose of the environmental impact statement, as stated by the Council on Environmental Quality Guidelines (CFR 40, Chapter V, Part 1500, section 1500.2) is:

> The purpose of this assessment and consultation process is to provide agencies and other decisionmakers as well as members of the public with an understanding of the potential environmental effects of proposed actions, to avoid or minimize adverse effects wherever possible, and to restore or enhance environmental quality to the fullest extent practicable. In particular, agencies should use the environmental impact statement process to explore alternative actions that will avoid or minimize adverse impacts and to evaluate both the long- and short-range implications of proposed actions to man, his physical and social surroundings, and to nature."

The balance of the CEQ guidelines, and the body of case law resulting from various National Environmental Policy Act (NEPA) cases, combine to impose upon the agencies stringent responsibilities for candor, completeness, and rigor in evaluating the implications of the proposed action and of alternatives to that proposed action.

This draft statement falls far short of this noble purpose. In preceding sections of these comments the inadequacy of the "benefit" analysis and of the consideration of alternatives was shown. In addition, there are throughout the draft statement a large number of errors, omissions, biased discussions, and technical shortcomings. A few of these are discussed below.

There is no discussion of the toxicity of plutonium

Nowhere in the report is there any discussion of the toxic nature of plutonium or of plutonium standards. This is a serious omission, particularly

as without such information, it is impossible to assess the significance of the various accidents which could result in releases of plutonium to the environment.

The "hazard evaluation for plutonium powered pacemakers" (p. 3-23 ff) discusses certain events that would, in the opinion of the authors of the draft impact statement, lead to an environmental release of plutonium from pacemakers. These include failure of the plutonium capsule during accidents of various kinds or during cremation of a body containing a plutonium pacemaker.

Without data regarding the toxicity and appropriate environmental standards for plutonium, having isotopic mixtures characteristic of those specified for the nuclear pacemaker (p. C-3), it is impossible to either understand the significance of these accident mode analyses or to evaluate the potential human exposures.

A single plutonium pacemaker contains between 0.15 and 0.5 grams of plutonium, depending on the model and manufacturer. The larger quantity represents a plutonium activity of about 8 curies (page 3-21). The significance of these quantities may be better appreciated when compared with appropriate standards.

* the maximum permissible concentration (MPC) for plutonium in air is 10^{-18} curies/ml (insoluble plutonium) (ref. 14)
* the maximum permissible lung burden is 5×10^{-10} curies for the general population (ref. 15)
* there are no generally recognized standards for ground contamination, but recently the State of Colorado adopted a maximum surface contamination level of 10^{-8} curie per square meter. (ref. 16)

Hence were there to be optimal dispersal of the plutonium in a single pacemaker, the result could be:

* contamination to the maximum permissible levels of —
  10,000 cubic kilometers of air
  or
  1,000 square kilometers of ground

* maximum permissible lung burdens to 20 billion people.

The magnitude of the risk of exposure can perhaps be better understood in the light of a statement by the Director of the National Cancer Institute in 1971 (ref. 20):

> There can be little doubt from experimental animal studies that inhaled plutonium-239 is one of the most potent respiratory carcinogens known. While epidemiological studies are in progress to assess pulmonary neoplasia in man resulting from occupational inhalation of plutonium, definitive results are not yet available. There is no reason at this time, however, to assume that plutonium-239 is less carcinogenic in man than in animals.

The "results" mentioned in the quote are still not available. But the significant point is that plutonium-238, the major component of pacemaker fuel, is 280 times more toxic than plutonium-239, the subject of the quote (ref. 15).

Nowhere in the impact statement are these implications discussed and without them the hazard evaluation is meaningless.

<u>There is no discussion of the effects of human exposure to ionizing radiation</u>

The draft acknowledges (see Section I above) that the risks associated with the proposed plutonium pacemaker are those of radiation exposures during normal operation of the pacemaker and resulting from various accidents that could lead to environmental releases of plutonium. It is mentioned that there are applicable standards which govern exposures to ionizing radiation. Yet, nowhere in the draft is there any discussion of: (1) The meaning and interpretation that must be given to those standards (a point that has been briefly mentioned in Section II above); (2) The nature of the effects of human exposure to ionizing radiation; or (3) The magnitude of the effects, genetic and somatic, or the relative significance to various individuals, for example that gonad exposures to ionizing radiation are more significant to a 20 year old woman than to a 60 year old woman.

Without this information, it is impossible to evaluate the significance of the radiation exposures which would result from wide-scale use of the plutonium powered cardiac pacemaker.

Human exposure to ionizing radiation may be much greater than that stated in the draft

The draft statement includes a rather long section dealing with radiation exposures to the individual pacemaker bearer (p. 3-1 ff). This entire discussion appears to be based on measurements with a single pacemaker containing 173.2 mg of plutonium of 90.14% by weight plutonium-238 and 0.26 ppm plutonium-236.

Although the draft is ambiguous on this point, it appears that the entire discussion of radiation exposures to the patient, the patient's family, and the general public is based on this single set of measurements. To base these determinations on measurements done in a single laboratory, with only one pacemaker, hardly inspires confidence in the statistical significance of the results.

Further, the reported results can not represent the probable radiation levels associated with pacemakers other than the one tested even were the measurements valid for that pacemaker. The specifications for medical grade pacemaker plutonium are included in Appendix C (p. C-2). This plutonium may contain various contaminants, isotopes other than plutonium-238, and also may contain up to 0.6 ppm plutonium-236. As the gamma dose resulting from a pacemaker is critically dependent on the plutonium-236 concentration, it is possible that a "real" pacemaker could emit (0.6 / 0.26) = 2.31 times the gamma dose as the sample tested.

The pacemaker tested is reported to contain 173 mg of plutonium. Other available pacemakers contain up to 500 mg. of plutonium (p. 2-5). Hence, due to the variation in plutonium content a "real" pacemaker could emit (500/173)= 2.89 times as much total radiation as the sample tested.

Were, then, a pacemaker to include the maximum permissible concentration of plutonium-236, and be of the 500 mg variety, the radiation doses that

would result could be (2.31 x 2.89) = 6.68 times those reported in Section 3 of the draft impact statement.

In addition, the neutron emissions arise primarily from spontaneous fission of the plutonium in the fuel and (alpha, n) reactions with light elements present either as contaminants in the plutonium or as other components of the pacemaker system (ref. 17). There is no indication in the draft impact statement as to the contribution to the total neutron doses from these two sources.

The discussion of radiation exposures to pacemaker recipients is inadequate. In the absence of further information, it must be assumed that radiation doses to the patient and the general public can be several times those represented in Section 3 of the draft impact statement.

Genetic effects of radiation exposure to pacemaker patients cannot be ignored

The draft statement dismisses genetic effects of radiation by noting (p. 4-18):

> With respect to the radiation exposure to the pacemaker patients, the effects, if any, would be predominantly somatic rather than genetic. Most pacemaker patients are unlikely to reproduce because the mean age of pacemaker patients is over 66 years and over 90% of patients are over 50 years of age. Therefore, the patient's subjective value of the radiation risk compared with is subjective value of the expected benefits, and the physician's medical judgment value of the risks versus benefits in his selecting a pacemaker for the patient, are more appropriate than a hypothetical value which might be placed on the radiation exposure received by a patient from his pacemaker.

The draft statement is in substantial agreement with the appropriate literature regarding the age distribution of pacemaker patients. That, however, is beside the point. The principal beneficiaries of nuclear pacemakers — or any other long-lived pacemaker system — are not likely to be the elderly, who comprise

the vast majority of pacemaker patients, but the relatively few young pacemaker patients.

The medical literature leaves no doubt whatsoever that physicians considering the nuclear pacemaker recognize this explicitly. Typical of the statements found are:

> For those patients with relatively short longevity expectations, improved chemical batteries will probably be used. The primary application of nuclear pacemakers is likely to be for the younger patients in whom they are most cost effective. (emphasis added) (ref. 6)

and

> ...There are certain other problems with the use of these power sources [nuclear pacemakers]. The radiation dose at the surface of the Medtronic 900U generator is stated by the manufacturer to be 3.7 millirem/hr at the beginning of life. The radiation level increases somewhat with time. This radiation dose in one year would give the patient's skin a dose approximately equal to that received during one diagnostic chest x-ray. However, the radiation dose to the skin is not really relevant. The radioactive energy absorbed by the bone (rib) and the bone marrow may be higher. If the generator is implanted in the abdominal wall, the dose to the gonad must also be considered. Comparisons with "allowable" doses of total body radiation are not valid. It may be argued that it is the younger patients who need a very long-life pacemaker. It can also be argued that it is the youngster who is most sensitive to the deleterious effects of radiation. It is precisely in the juvenile age group that one will have the longest possible time to develop potentially lethal alterations such as leukemia or genetic defects which may follow into later generations. Other

> problems that exist include the cost, which is not inconsiderable; the necessity for licensure to handle the generators; the difficulty of storage and transportation and the generally politically sensitive nature of radioactive substances. Although nuclear power gives great promise of being reliable, long-life pacemaker power source, their development may be associated with the development of new — and perhaps less desirable — problems. (emphasis added) (ref. 18)

The impact statement (tables 9 and 10, pp. 3-18 and 3-19) indicates ovary or uterus doses of about 0.25 rem for the tested pacemaker were it implanted above the left pectoral muscle and between 1.4 and 2.6 rem were it implanted in the left abdominal wall. As was demonstrated above, these doses appear to be based on a single series of measurements, in a single laboratory, and with a single pacemaker and hence must be regarded with suspicion. In addition, because the tested pacemaker is not necessarily a typical pacemaker (either in the total amount of plutonium present or the plutonium-236 contamination) the measured doses — even were the measurements accurate and representative of that type of pacemaker — could well be between six and seven times greater. Were this the case, then the ten-year dose to the ovaries and uterus might be as high as ten or fifteen rem. The doses to the testes are lower, but genetically significant.

Lederberg (ref. 19) has summarized the genetic implications of exposure to ionizing radiation as follows:

> The Atomic Energy Commission's standards of permissible exposure [the 170 millirem per year exposure limit to the general public]...would increase the natural rate of mutation by about 10 percent.

The gonad doses which would result from the plutonium pacemaker, were they to be received over the reproductive period, are significant. Pacemaker patients would be well advised not to become parents and the regulations regarding plutonium pacemakers should probably require that all male patients, and all pre-menopausal female patients, be sterilized upon receipt of a plutonium powered cardiac pacemaker.

It is difficult to assess the significance of the exposure to ionizing radiation by viduals other than the pacemaker bearer on the basis of the inform...on provided in the draft statement. The entire discussion of radiation exposures to other than the pacemaker bearer appears to derive from a single unpublished, draft report (cited as ref. 4 on page 3-20). The draft statement itself includes no discussion of the methodology, assumptions, assumed source terms, nor any other of the information that is necessary to evaluate the data presented under the heading "Radiation doses to critical groups from cardiac pacemakers" (Table 11, p. 3-21).

Further, it is not the average exposure to "critical groups" that must be assessed, but rather the exposure to individuals. Failure to include this information renders it impossible to assess the significance of these exposures. It is not improbable, however, that genetic doses to specific individuals, for example children living in the household of a pacemaker bearer, are important. In addition, it is quite possible that pacemaker bearers might be excluded from particular activities which could lead to exposure of critical population groups, for example employment as elementary or secondary school teachers.

<u>The discussion of the costs and implications of a plutonium spill is inadequate</u>

The draft impact statement includes (pages 3-44, 3-45) a brief discussion of the costs to clean up plutonium spills. The only reference for the value used for these clean-up costs is a "Conference at the University of Chicago" (p. 3-49, ref. 18), a reference that is rather difficult to check or evaluate.

A value for "probability of breach [of the pacemaker capsule] per year" is assumed, multiplied by the number of pacemakers considered and by $250,000. The value of $250,000 is taken as the "cost to clean up an industrial spill" of radium, not plutonium.

There have been instances of environmental contamination with plutonium, and these instances are well enough studied to permit discussion of the costs associated with a real environmental spill rather than some

hypothetical industrial spill which, in the first place, involves radium and not p nium and, in the second, is totally unrepresentative of the situati for a spill into the unrestricted environment.

To adequately describe environmental spills, these actual experiences must be evaluated. Some of the examples that should provide more realistic values would be:

* Costs to clean up the fraction of a millicurie said to have been involved in the contamination of the apartment of Ms. Karen Silkwood in Oklahoma in 1974 (ref. 21)
* Costs to clean up the few curies of plutonium released to the environment from the Rocky Flats plutonium plant in Colorado in 1971 (ref. 22)
* Costs to clean up the (probably) approximately 1000 curies of plutonium released in military accidents in Palamares, Spain in 1966 and Thule, Greenland in 1968. (Refs. 23 and 24)

An evaluation of the costs to clean up these real plutonium spills should establish a much more realistic cost estimate for the clean-up costs were a plutonium-powered pacemaker to breach and also would give some indication of the relationship between the quantity of plutonium spilled and the clean-up costs.

<u>There is insufficient discussion of the "reasonable and effective regulations" that would be necessary were there general licensing for the plutonium pacemaker</u>

The draft impact statement contains (pages 2-17 ff) a general discussion of "regulation of wide-scale use". It contains statements such as, "<u>A regulatory framework will be needed</u> for reasonable and effective regulatory control if such wide-scale use is authorized", and "...an equivalent [to the investigational program] level of control and recovery by means appropriate to wide-scale use of plutonium powered pacemakers <u>would be developed</u>." (emphasis added)

It is apparent that the general use of plutonium pacemakers would impose stringent requirements for licensing, record keeping, monitoring, on patients, hospitals, physicians, morticians, operators of crematoria, medical examiners, individuals and organizations (e.g., police, firemen, ambulance crews) commonly associated with dealing with accidents and emergencies, and other individuals and institutions.

In this regard the draft statement is totally inadequate in at least two respects: (1) its failure to include concise descriptions of these regulatory and other constraints sufficiently detailed so that the affected persons and institutions can meaningfully evaluate their impact; and (2) the failure of the AEC to actively inform these groups and individuals of the proposed action, to circulate the draft impact statement to them, and to solicit comments.

It is unrealistic to expect that the stringent requirements for patient registration, monitoring, and followup required by a plutonium pacemaker program would be met

The draft contains several sweeping statements about the extraordinary requirements for patient follow-up, recovery of devices, and record keeping that are inconsistent with clinical pacemaker experience to date. The experimental use of nuclear pacemakers has been carried out under constraints quite atypical of the usual pacemaker situation. Yet, "experience to date" (pages 2-4, 2-15) is presented as proof that the stringent controls necessarily associated with the general use of plutonium pacemakers will be met.

The situation which appears to be more typical of general pacemaker conditions is described, for example, by Goldman, et al in a 1974 review of pacemaker replacements (ref. 9):

> At present an estimated 100,000 people in the United States and Canada are living with implanted pacemakers. Almost 100 new patients per million population will receive pacemakers in the coming year, and an equal number will undergo replacement of exhausted units. As cardiac pacing assumes increasing importance in

> health care delivery, the logistical problems of patient volume, data management, and pulse generator replacement accumulate. In addition, there is a marked contrast between the casual attitude of the medical community in general to cardiac pacing and the intense interest exhibited by patients, hospital administrators, health insurance programs, the press, and the electronics industry. To compound these problems, follow-up on patients with pacemakers is often inadequate, sporadic, or at best unrealistic. (emphasis added)

With that situation existing for conventional pacemaker systems, what is the potential for realization of the incredibly more demanding "follow-up on patients" with plutonium pacemakers?

The assumed costs for inventory control, retrieval, disposal, and related monitoring costs are meaningless

As discussed immediately above, section 2 of the draft statement purports to discuss the regulatory framework and constraints that would be required were there general licensing of plutonium pacemakers. This discussion is vague and general but includes the establishment of various registries, identification programs, systems of periodic contact and monitoring, collection of used pacemakers, licensing of hospitals, and other regulatory programs. None of these programs are described in any but the most general manner.

Yet in section 3 of the draft statement we suddenly discover that the totality of these costs will amount to approximately $23.10 per pacemaker year. It is obvious that either: (1) these programs have been fully described, evaluated, and realistic budgets prepared which form the basis for the above mentioned cost estimates, or (2) the cost estimate is fiction. I suggest that alternative (2) is the more likely.

In addition, there is no discussion of licensing fees that might be required of hospitals, physicians, and other individuals or institutions

that would come into contact with plutonium pacemakers, no discussion of monitoring, no discussion of the regulatory obligations of the state and local health and safety authorities, or related matters.

These are grave omissions. Without these discussions it would be impossible for the various affected individuals and institutions to meaningfully evaluate the plutonium pacemaker program and make informed comments on the draft statement (even were they to be informed of its existence.)

The possibility of disruption of the pacemaker by gunshot is not discussed

The "interim safety performance tests for plutonium powered cardiac pacemakers" are presented on page 2-6 of the draft statement. The ability of the plutonium capsule to withstand the impact of the bullet from handguns or rifles, or other such missiles is not mentioned.

It is known that several persons per year in the U.S. are involved in gunshot incidents and it must be presumed that at least some of these might be bearers of pacemakers. In this regard it should be noted that among the first reports of clinical experience with nuclear pacemakers (ref. 25):

> One [of six patients in the control group] was shot to death as an innocent bystander in a service station holdup.

Failure to describe the effect of missiles such as bullets would have were they to impact the pacemaker and failure to discuss the resultant potential for environmental plutonium contamination must be regarded as a serious deficiency.

The draft statement overstates the complications resulting from pacemaker replacement

At several points in the draft statement comments are made regarding the alleged high incidence of non-fatal complications associated with pacemaker use and an attempt is made to imply that these complications would be eliminated were long-lived pacemaker power supplies available. The draft statement develops the argument as follows:

> Non-fatal medical/surgical complications occur following the implantation or reimplantation of a pacemaker with rates as high as 41% being reported in the literature. (page 4-11)

and

> The use of plutonium powered pacemakers would reduce the complications associated with replacement surgery. (page 4-11)

and

> Pain, suffering and anxiety are subjective and quantification of the value to the patient of reducing their occurrence is not attempted in this assessment but, to the patient, these benefits may be more significant that (sic) the reduction of surgical mortality and the reduction of complications. (page 4-11)

and

> If it is assumed that complications occur in 33% of reimplantations and that the average medical cost of treating a complication is $500, the saving for each reimplantation avoided by the use of a longer service life pacemaker would be $133.(emphasis added)(page 4-15/16)

While it is true that there is a high incidence of complications observed in patients who are pacemaker users, the literature does not substantiate the implication given above that a significant fraction of those complications is associated with pacemaker replacement. Rather, the complications are associated with the presence of a pacemaker system or the underlying disease.

The medical literature overwhelmingly supports the conclusion stated by Conklin et al (ref. 3) in a 1975 review of pacemaker implantation and reimplantation experience:

> ... the few complications [of pacemaker implantation and reimplantation] are easily corrected and appear to be largely avoidable with careful technique.

It has not been shown that there is monetary benefit to the patient

Section 4.3.2 (page 4-12 ff) purports to show that "There are monetary savings to be gained for patients who use a plutonium powered pacemaker for a period longer than the lifetime of two conventional pacemakers."

The analysis in Section 4.3.2 is faulty. In the first place, the draft statement acknowledges that the operational lifetime of conventional pacemakers is at least six years, compared to the postulated ten year lifetime for the plutonium pacemaker. Hence "the lifetime of two conventional pacemakers" exceeds that of the plutonium pacemaker and even were the analysis otherwise correct, which it is not, there would be no benefit to the patient.

Second, the cost data used in the analysis is unsupported. The only justification for the costs assumed in the draft is (page 4-12):

> Information on pacemaker and implantation costs were obtained from physicians' responses to inquiries.

This is hardly an adequate data gathering procedure.

Third, the analysis which purports to show, "Cumulative cost of pacemaker to patient" (Table 18, page 4-14) assumes a zero discount rate, the result being that future costs and benefits are directly equated with present costs and benefits. This form of analysis is totally without precedent.

The proposed method for plutonium pacemaker patient identification is inadequate

I share the opinion expressed by one of the other reviewers of this impact statement (comment of Prof. Karl Z. Morgan, dated February 26, 1975) that it is insufficient for the plutonium pacemaker bearer to "carry at all times an identification card" (page 2-11) and "to wear at all times a ... bracelet or other approved form of jewelry" (page 2-11). Prof. Morgan suggests that the bearer "should have tatooed on his body near the groin something like 'radioactive pacemaker — phone 202-408-6618'". The phone number being some office in the Nuclear Regulatory Commission that would be staffed 24 hours per day to provide instructions.

It might prove to be the case that the tatoo is also inadequate identification, but it would be more likely adequate than to "carry a card" or to "wear a bracelet".

SECTION VI

THE DRAFT STATEMENT DOES NOT SATISFY THE GUIDELINES OF THE COUNCIL ON ENVIRONMENTAL QUALITY AND HENCE IS INADEQUATE

The preparation of environmental impact statements and the procedural requirements on an agency preparing an environmental impact statement is governed by the guidelines established by the Council on Environmental Quality. These guidelines appear in the Code of Federal Regulations in Title 40, Chapter V, Part 1500. In addition there is a large body of applicable case law.

A very disturbing feature of this situation is that the draft statement has been prepared after the expenditure of several million dollars on the plutonium pacemaker by the AEC and after the agency has granted interim licensing for clinical testing. These activities, engaged in before the preparation of an impact statement, reveal contempt for the spirit of the National Environmental Policy Act and specifically violate the CEQ guidelines (Sec. 1500.7):

> In particular, agencies should keep in mind that such statements are to serve as the means of assessing the environmental impact of proposed agency actions, rather than as a justification for decisions already made. This means that draft statements on administrative actions should be prepared and circulated for comment prior to the first significant point of decision in the agency review process. (emphasis added)

The purpose of the environmental impact statement process, as stated by the CEQ guidelines (Sec. 1500.2) is:

> ... to provide agencies and other decisionmakers as well as members of the public with an understanding of the potential environmental effects of proposed actions, to avoid or minimize adverse effects wherever possible, and to restore or enhance environmental quality to the

> fullest extent practicable. In particular, agencies should use the environmental impact statement process to explore alternative actions that will avoid or minimize adverse impacts and to evaluate both the long- and short-range implications of proposed actions to man, his physical and social surroundings, and to nature. Agencies should consider the results of their environmental assessments along with their assessments of the net economic, technical and other benefits of proposed actions ...

As has been discussed in considerable detail above, this draft statement does not adequately identify environmental impacts, explore alternatives, or assess the economic, social, or health implications of the proposed action.

In several particular respects, this statement does not meet the other requirements as specified in the CEQ guidelines. Some examples follow.

Section 1500.6 (a) requires that the impact statement discuss, "... the overall, cumulative impact of the action proposed, related Federal actions and projects in the area, and further actions contemplated."

Nowhere does the impact statement include mention of the overall impact of the action proposed. Insofar as the plutonium pacemaker is concerned, the statement does not include environmental, occupational health and safety, or accident considerations during the preparation of the plutonium, the fabrication of the plutonium source, or the disposal of the plutonium. All of these are passed over with the note that:

> The production of plutonium and controlled disposal of any associated radioactive wastes are conducted as part of other licensed or AEC-contract operations ... this statement does not consider their environmental impact (draft p. 1-8)

The failure to include a complete and candid assessment of these phases of the production cycle is a serious deficiency.

Nowhere does the impact statement include mention of "related Federal actions and projects in the area" yet there are other programs involving the use of plutonium-238. One closely related is the proposed plutonium-powered artificial heart. Several others have been described in the literature. To not discuss these related actions and projects is a serious deficiency of the draft statement. The impact statement also fails to discuss the precedential significance of licensing the general use of plutonium-238. The proposed action, general licensing of plutonium-238 use for cardiac pacemakers, would be the first general approval for widespread utilization of plutonium-238. By not considering the precedential implications, the impact statement is deficient.

Related to the above comment, the draft statement does not discuss "further actions contemplated". As was mentioned, there are several other proposed uses of plutonium-238 which would require licensing of one sort or another. These other "contemplated" actions must be fully and completely disclosed and discussed. In this context, the existence of a research and development program involving these other uses of plutonium-238 must be taken as de facto evidence of "further actions contemplated".

Section 1500.6 (a) requires that "... agencies should bear in mind that the effect of many Federal decisions about a project or complex of projects can be individually limited but cumulatively considerable.... In all such cases, an environmental statement should be prepared if it is reasonable to anticipate a cumulatively significant impact on the environment from Federal action.

Hence, in this case it is not only necessary (as noted above) to describe and discuss individual cumulative total impact of the total fuel cycle as involves the artificial pacemaker, other related Federal actions and projects in the area, and further actions contemplated, but it is also mandated by the CEQ guidelines that the cumulative impact of this complex of activities be considered. The present draft statement does not even list the related activities, say nothing of attempting to assess their cumulative impact.

Section 1500.8 (a)(1) requires "A description of the proposed action, a statement of its purposes and a description of the environment affected, including information, summary technical data, and maps and diagrams where relevant, adequate to permit an assessment of potential environmental impact by commenting agencies and the public."

The draft statement, by not including a discussion of plutonium-238 toxicity, chemical and physical properties, the appropriate standards, and the current controversy surrounding the adequacy of those standards, does not satisfy this requirement.

The statement does not include a sufficiently detailed description of the regulatory actions, licensing requirements, and other procedural matters which are acknowledged to be necessitated were the proposed action undertaken.

The draft statement does not include any discussion of the deleterious effects of exposure to ionizing radiation. Yet, one of the environmental impacts considered in the draft statement is the exposure to ionizing radiation to the patient, his family, those he comes into contact with and the general public. Without a discussion of the applicable radiation standards, the guidance furnished by the responsible authorities regarding the need to minimize radiation exposure, and the effects resulting from the exposure to ionizing radiation, it is impossible to assess the significance of those acknowledged radiation exposures. The failure to include this "information ... adequate to permit an assessment of the potential environmental impact by commenting agencies and the public" must be regarded as a serious deficiency of the draft statement.

Section 1500.8 (a)(1) also notes, "...it is essential that the sources of data used to identify, quantify or evaluate any and all environmental consequences be expressly noted." Further, Section 1500.8 (b) requires, "In the case of documents not likely to be easily accessible (such as internal studies or reports), the agency should indicate how such information may be obtained."

There are numerous instances where reference is made to personal communication, and other source material that has not only been inadequately

identified, but is also "not likely to be easily accessible", and in no instance has it been indicated "how much information may be obtained." This is another failure to comply with CEQ guidelines.

Section 1500.8 (a)(3)(ii) requires that, "Secondary or indirect, as well as primary or direct, consequences for the environment should be included in the analysis."

This requirement also necessitates a discussion of the environmental impact associated with production, fabrication, and disposal of the plutonium power source. In addition, it requires that the interactions between the general management of high-level radioactive wastes from nuclear power reactors — from which the plutonium proposed for use in the nuclear pacemaker derives — and the nuclear pacemaker program be defined.

Other indirect consequences derive from the regulations, restrictions, and other measures which are acknowledged to derive from the plutonium pacemaker program were it to be implemented. These regulations, restrictions, and other measures are not (as is discussed more fully above) described in sufficient detail to permit their potential environmental consequences.

Section 1500.8 (a)(4) requires that "Alternatives to the proposed action, including, where relevant, those not within the existing authority of the responsible agency" be fully described, including: "A rigorous exploration and objective evaluation of the environmental impacts of all reasonable alternative actions, particularly those that might ... avoid some or all of the adverse environmental effects, is essential."

This requirement, only a portion of which is included above, is totally ignored in the present draft statement. The only mention of alternatives is a very short section that does little more than list alternatives. There is no discussion whatsoever of the environmental imoacts of alternative actions.

Without a full and candid evaluation of the environmental impacts of the alternatives to the proposed action this draft statement can only be regarded as a mockery of the entire environmental impact review process.

Section 1500.9 (a) requires the solicitation of review from "Federal and Federal-State agencies with jurisdiction by law or special expertise with respect to any environmental impact involved."

The AEC is currently involved in several proposed actions regarding plutonium in one or another of its forms. In particular, the AEC issued draft environmental impact statements on the liquid metal fast breeder reactor program (the LMFBR) and a proposed general licensing of plutonium recycle in light water reactors (the GESMO program). In both of these cases, there has been considerable attention given to the adequacy of the environmental impact statements, and the adequacy of Federal agency review. It has now been established and comments have been solicited by the AEC and by CEQ (see letters to agency heads by CEQ chairman Russell Peterson, dated Feb. 3, 1975) that a large number of Federal agencies have "jurisdiction by law or special expertise" with respect to the environmental impacts involved. These agencies include: the Justice Department, the State Department, the Arms Control and Disarmament Commission, the Central Intelligence Agency, the Department of Agriculture, to name but a few.

The environmental issues in the LMFBR program and the GESMO program include those associated with plutonium use in various power reactors. These potential environmental impacts derive from plutonium's special properties as: (1) a special nuclear material (SNM), and (2) as an exceedingly toxic radiological material.

Although the quantities of plutonium proposed for use in the plutonium powered cardiac pacemaker program are substantially smaller than those proposed for use in the above mentioned reactor programs, and the plutonium isotope mixtures are not the same, the issues are analogous. The cardiac pacemaker program presents the opportunity for: (1) diversion of special nuclear materials; (2) terrorist activities involving theft and possible dispersal of plutonium; (3) accidents that could lead to environmental releases of plutonium; (4) exposures to the general public and occupational exposures to plutonium.

The AEC did not circulate this impact statement to those agencies now being requested to comment on the LMFBR and GESMO impact statements. The

issues are analogous. Hence, the failure to solicit comments from agencies such as those listed above must be regarded as a serious deficiency.

Section 1500.9 (d) requires that, "Agencies should devise methods for publicizing the existence of draft statements, for example, by publication of notices in local newspapers or by maintaining a list of groups ... known to be interested in the agency's activities and directly notifying such groups of the existence of a draft statement,or sending them a copy, as soon as it has been prepared."

The AEC knew, or should have known, of a large number of environmental, public interest, medical, and other groups having interest in this proposed action. Yet, insofar as can be determined, no effort was made to inform those groups of the existence of the draft statement or to publicize the existence of the draft statement. In particular, the medical community appears to have been totally, and one must assume deliberately, excluded from any notice of this statement.

Section 1500.10 (a) requires that, "Agencies should make every effort to discover and discuss all major points of view on the environmental effects of the proposed action and its alternatives in the draft statement itself."

Although it is well known that there are sharply conflicting points of view on the environmental effects of the proposed plutonium pacemaker program, there is utterly no recognition of this in the draft statement. These conflicting points of view have been voiced not only in the discussions of other nuclear programs, but also are evident from even a superficial search of the medical literature.

Again, the AEC has not even attempted to satisfy this CEQ requirement for adequacy of a draft impact statement.

Conclusion

The draft statement on the plutonium powered cardiac pacemaker does not, in several fundamental respects, comply with the CEQ guidelines. Should the NRC (successor to the AEC) elect to persist in the promotion of this

program — with full recognition that, quite apart from the legal deficiencies of the draft environmental statement, it has been conclusively demonstrated that there is substantial risk associated with the program and no benefits — a totally new draft environmental impact statement must be issued. In the preparation of the new draft statement, one would hope that the CEQ guidelines would be consulted.

SECTION VII

REFERENCES AND FOOTNOTES

1) Federal Radiation Council, "Radiation protection guidance for Federal Agencies", Federal Register, 25, 97, 4402 (May 1960) and 26, 185, 9057 (Sept. 1961)

2) U.S. Public Health Service, "Drinking water standards, 1962", PHS Pub. No. 956, USGPO (1962)

3) E. Foster Conklin, et al, "Four hundred consecutive patients with permanent transvenous pacemakers", J. Thoracic and Cardiovascular Surg., 69 (1), 1-7 (Jan. 1975)

4) E. Sowton, et al, "Ten-year survey of treatment with implanted cardiac pacemaker", Brit. Med. J., 155-160 (20 July 1974)

5) D. Abrahamson and M. Trigg reviewed, during the preparation of these comments on the proposed plutonium powered pacemaker draft impact statement, all pacemaker implantations and reimplantations performed at the University of Minnesota Hospitals during 1972-1975. There were 150 surgical pacemaker reimplantations during that period (including a few cases when a pacemaker was moved to a new site or removed --- the surgical procedure in these cases being very similar to the placement of a new pacemaker unit) with no deaths and few complications. At time of this writing, five patient charts cannot be located. Further documentation regarding this pacemaker replacement series will be submitted later for inclusion with this comment.

6) Fred N. Huffman, et al, "Critical review: nuclear-fueled cardiac pacemakers", Chest, 65 (6), 667-672 (June 1974)

7) Wm. M. Chardack, "The current status of implantable pacemakers", J. Electrocardiology, 1 (2), 135-140 (1968)

8) G. D. Green, et al, "Progress in pacemaker technology", J. Electrocardiology, 7 (4), 375-378 (1974)

9) B. S. Goldman, et al, "Critical analysis of pulse generator replacement", Ann. Thoracic Surg., 18 (2), 156-163 (Aug. 1974)

10) A. S. Brenner, et al, "Transvenous, transmediastinal and transthoracic ventricular pacing", Circulation, 49, 407-414 (March 1974)

11) A. M. Imparato, et al, "Electrode complications in patients with permanent cardiac pacemakers", Arch. Surg., 105 705-710 (Nov. 1972)

12) J. W. Love, et al, "Experimental testing of a permanent rechargeable cardiac pacemaker", Ann. Thoracic Surg., 17, 152-156 (Feb. 1974)

13) Valborg Svendsen, et al, "Long-term survival of patients with permanent implanted cardiac pacemaker", Danish Med. Bull., 21 (4), 158-160 (June 1974)

14) Code of Federal Regulations, Title 10, Chapter 1, 1 Jan. 1970

15) G. P. Dix, et al, "Critical parameters in plutonium safety evaluations", Health Physics, 22, 569-574 (June 1972)

16) State of Colorado Rules and Regulations Pertaining to Radiation Control, Subpart RH 4.21.1, Adopted March 21, 1973

17) L. J. Mullins, et al, "Plutonium-238 for biomedical applications", paper presented at American Nuclear Society Meeting, June 9-13, 1968 [paper available from Los Alamos Scientific Laboratory, Los Alamos, New Mexico 87544]

18) David Friedberg, et al, "Progress in pacemaker longevity", J. Electrocardiology, 7 (1), 97-100 (1974)

19) Joshua Lederberg, "Government is most dangerous of genetic engineers", The Washington Post, July 19, 1970

20) Carl G. Baker, M.D., Director, National Cancer Institute, memorandum to Ass't Director for Collaborative Research, NIH, Dated July 1, 1971

21) see e.g., Atomic Energy Commission RO Investigation Report No. 74-09, Directorate of Regulatory Operations, Region III, "An employee and her residence were found to be contaminated with plutonium on November 7, 1974", available from U.S. Atomic Energy Commission, Washington, D.C.

22) see e.g., D. Shapley, "Rocky Flats: Credibility Gap Widens on Plutonium Plant Safety", Science, 569-571 (5 Nov. 1971)

23) W. H. Langham, "The problems of large-area plutonium contamination", Seminar paper No. 002, Bureau of Radiological Health, HEW

24) U.S. Air Force Nuclear Safety, Vol. 65, part 2, Special Edition, Project Crested Ice (AFRP-122-1, Jan/Feb/Mar/1970, No. 1)

25) Nicholas P.D. Smyth, et al, "Clinical experience with radioisotopic powered cardiac pacemakers", Henry Ford Hosp. Med. J., 22 (3), 113-116 (1974)

26) G.F.O. Tyers, et al, "Comparative studies of 'state of the art' and presently used clinical pacemaker electrodes", J. Thoracic and Cardiovascular Surg., 67 (6), 849-856 (June 1974)

27) Nicholas P. D. Smyth, et al, "Clinical evaluation of new pulse generator with narrow pulse width for conservation of battery energy", J. Thoracic and Cardiovascular Surg., 68 (3) 471-478 (Sept. 1974)

28) Cardiac Pacemakers Inc., 1140 Red Fox Rd., St. Paul, Mn. 55112

29) Richard C. Lillehei, et al, "A new solid-state, long-life, Lithium-powered pulse generator", Ann. Thoracic Surg., 18 (5), 473-489 (Nov. 1974)

30) K. B. Lewis, et al, "Early clinical experience with the rechargeable cardiac pacemaker", Ann. Thoracic Surg., 18 (5) 490-493 (Nov. 1974)

31) "New Pacemaker Goes On and On", Medical World News, 26-27 (10 Feb. 1975)

UNIVERSITY OF MINNESOTA
TWIN CITIES

Office of the Associate Dean

Medical School
1305 Mayo Memorial Building
Minneapolis, Minnesota 55455

March 31, 1975

Acting Deputy Director for Fuels and Materials
Directorate of Licensing-Regulation
U.S. Atomic Energy Commission
Washington, DC 20545

Dear Sir:

With the strongest possible means, I should like to protest the proposal to license for general use plutonium powered cardiac pacemakers.

Although the AEC should be aware of the inherent dangers of the use of plutonium which is probably the most toxic material known to man which might be considered for commercial utilization, somehow this factor seems to have been lost when it comes to the consideration of plutonium powered pacemakers. Admittedly, this is a technical feat demonstrating that a small quantity of plutonium can be harnessed to power a pacemaker.

On the other hand, the very slight potential advantage in having a plutonium powered cardiac pacemaker is more than offset by not only the actual but the theoretical dangers in the indiscriminate use of plutonium.

The present battery powered pacemakers are serving adequately and can be replaced without a high degree of difficulty. The risk that plutonium might escape or slight and the consequences of such plutonium release are too awesome to comprehend at the present time.

I would, therefore, strongly urge that no licensing of plutonium powered pacemakers be permitted at anytime now or in the foreseeable future.

Yours sincerely,

W. Albert Sullivan, Jr., M.D.
Associate Dean
and
Associate Professor of Surgery

WAS:mge

HEALTH SCIENCES

National Radiological Protection Board

Chairman: Sir Brian Windeyer Director: Dr A S McLean Secretary: L D G Richings

Harwell Didcot
Oxfordshire OX11 0RQ

Telephone Rowstock (023 583) 600

10 April 1975

To Mr Mason

Richard E. Cunningham
Assistant Director for
Fuel Cycle
Division of Materials and
Fuel Cycle Facility Licensing
United States Nuclear
Regulatory Commission
Washington DC 20555
USA

Dear Mr Cunningham,

Thank you for sending me the draft environmental statement on nuclear cardiac pacemakers. I hope you find the enclosed commentary useful.

Yours sincerely

L.D.G. Richings
Secretary

A-100

Draft Generic Environmental Statement on the Wide-Scale use of Plutonium Powered Cardiac Pacemakers

USAEC Fuels and Materials, Directorate of Licensing
January 1975

Comments by NRPB Staff

We feel that the Statement devotes too little attention to the major question of performance comparison between nuclear and conventional pacemakers and too much attention to the lesser problem of assessing the relative costs and benefits of nuclear pacemakers, particularly the directly dose-related costs.

As the Statement is presented the major benefit of nuclear pacemakers lies in their longer operating lifetime so that if a conventional battery with a similar lifetime and no off-setting detriments is developed there will be no benefit from the nuclear pacemaker to offset against the radiation-related costs. In view of this the dismissal of Lithium-Iodide Batteries, Sodium-Bromine Cells and Rechargeable Nickel-Cadmium Batteries in 21 lines on pages 4-4 to 4-5 seems arbitrary. The dismissal seems even more arbitrary when it is admitted that all three types have potential lifetimes of the order of 10 years.

It will certainly be pointed out in this respect by critics of the nuclear pacemaker that the nuclear batteries have yet to demonstrate a routine service lifetime of 10 years. It is hardly fair therefore to dismiss Lithium Iodide batteries out of hand when the clinical tests on these indicate an extrapolated life 'well beyond the six year objective' (para. 4.2.3.1).

In particular the statement in 4.3 'The plutonium powered cardiac pacemaker has a THEORETICAL (our capitals) battery lifetime of at least 10-20 years, an increase of several fold over units deriving their power chemically' is open to serious criticism. This statement forms the basis of the 'cost-benefit comparison' carried out later.

The conclusions stated in para 2 on page 4-24 do not seem to be supported by the detailed and more carefully qualified statements earlier in the text.

Conclusion 3) 'they (plutonium powered pacemakers) have a reliability (random failure rate) equal to or better than conventional pacemakers' seems to be based on the one failure in 2700 device months for Medtronic Model 9000 pacemakers. What this in fact demonstrates is 90% confidence that the device is as good as conventional pacemakers. The result for the ARCO NU-5 of no failures in 850 device months is insufficient to demonstrate even this.

Conclusion 2) 'Their life saving benefits would exceed the environmental and societal risks and costs associated with their use' is entirely dependent on the truth of Conclusion 4) 'they have a projected service life longer than the available conventional pacemakers'. This dependence should be clearly stated. As shown above there are grounds for doubting the unequivocal truth of Conclusion 4).

In view of these doubts of the basis for the 'cost-benefit comparison' the conclusions of the report seem too firm and the inclusion in these of precise monetary values not useful. The major omission from the conclusions is a caveat stating something like 'If a conventional pacemaker with a lifetime of 10-20 years is developed the conclusions of this study will need to be reviewed'.

We do not wish these comments to be interpreted as meaning that we are opposed to the use of nuclear powered cardiac pacemakers. We do, however, still consider that they are in a developmental and proving stage of their lives and further that improvements in conventional pacemakers may change the situation entirely in the next few years. In view of this we consider the Statement to be too definitive and final-sounding and that a more 'interim' attitude is appropriate at the present time.

NRPB
Harwell
Didcot
Oxon

10 April 1975

Natural Resources Defense Council, Inc.

917 15TH STREET, N.W.
WASHINGTON, D.C. 20005
202 737-5000

Western Office
664 HAMILTON AVENUE
PALO ALTO, CALIF. 94301
415 327-1080

New York Office
15 WEST 44TH STREET
NEW YORK, N.Y. 10036
212 869-0150

March 17, 1975

Mr. Howard Larson
Acting Deputy Director for Fuels
and Materials
Nuclear Regulatory Commission
7920 Norfolk Avenue
Bethesda, Maryland

Re: Draft Generic Environmental Statement
Plutonium Powered Cardiac Pacemakers

Dear Sir:

The Natural Resources Defense Council strongly protests your agency's proposed determination to permit the commercial use of plutonium powered cardiac pacemakers. Given the toxicity and persistence of plutonium, and the availability of preferable alternatives, we find it incredible that this proposed use of plutonium is still being seriously considered.

We have examined the draft impact statement and the comments of Dr. Dean E. Abrahamson on that draft and would like to adopt the comments of Dr. Abrahamson as those of NRDC. For the reasons stated by Dr. Abrahamson, we believe that the draft statement is fundamentally deficient in its discussion of both the environmental impacts and alternatives, that it fails to conform to the minimum standards set out for draft statements in NEPA Guidelines of the Council on Environmental Quality, and , accordingly, that the draft should be reissued in a form consistent with these standards. We urge that you take this action immediately.

Sincerely,

J.G. Speth

JGS/pa

621
85

DERMOT A. NEE
9015 LOGAN DRIVE
POTOMAC, MARYLAND 20854
TEL. 299-5173

May 13, 1975

Mr. Bernard Singer
Chief, Materials Branch
Directorate of Licensing
Nuclear Regulatory Commission
Atomic Energy Commission
Washington, D. C. 20555

Dear Sir:

Because of the complete and remarkable recovery which I have made, due to the nuclear pacemaker which was installed in me by Doctors Smyth and Bacos of Washington Hospital Center, I am prompted to write to you about it, and to express the gratitude I feel.

After a long period of deterioration, my heart beat had reached an average of less than forty beats per minute, and I knew that the end was not far away. Through a happy circumstance and Dr. Henry Ecker, I went to Doctors Bacos and Smyth, and after extensive tests, the nuclear pacemaker was implanted. My recovery was almost instantaneous, and even though this took place on December 5, 1975, I am feeling more normal every day, and once again I am a part of the community. My beat was set at a minimum of sixty-nine per minute, and every subsequent reading has shown it to be exactly at this rate.

My relief is so much greater because I don't expect to have battery troubles or a regular eighteen month change in batteries. The apprehension of a hospital visit during which the batteries are replaced grows as the patient finds it more and more difficult, painful and expensive to keep the battery pacemaker operative. I have a number of friends with battery pacemakers, and everyone is grateful for their pacemaker, but are always worried about their batteries. I have one friend who has had six such battery changes in the last four years. For many of these battery pacemaker patients, there is a constant fear that it will fail, and the dread of continuous hospitalization and surgery for the battery replacements every so often.

Since my own nuclear pacemaker was implanted, I have had no apprehension about my heart beat, nor have I had any worry about the need to replace this miraculous instrument. I do not even feel it. I don't even know it is there; in fact, I forget about it. This is not possible with the battery pacemaker. For myself, the relief, both mental and physical, which comes to me from my nuclear pacemaker is worth many times its cost.

A-102

I hope that the day comes, very soon, that all pacemakers will be nuclear-powered, thereby providing everyone with this wonderful advantage.

Sincerely yours,

Dermot A. Nee

DAN/lmj

Newark Beth Israel Medical Center
201 Lyons Avenue, Newark, New Jersey 07112 / at Osborne Terrace
Telephone (201) 926-

#39

APR 8 1975

April 7, 1975

Nuclear Regulatory Commission
Washington, D.C. 20545
Attn: Acting Deputy Director for
Fuels and Material
Directorate of Licensing - Regulation

Dear Sir:

I have reviewed the recent environmental impact statement of the Nuclear Regulatory Commission, and have heard that there have been adverse comments about the usefulness of plutonium powered pacemakers because there are now rechargeable pacemakers and chemical cells of great longevity and potential.

It is my personal opinion that there will remain, for the forseeable future, a real place for nuclear pacemakers, probably for 10 to 15% of all patients.

Rechargeable pacemakers are interesting, but require an action on the part of the patient at least once a week, and this takes the responsibility from the doctor to the patient. In a survey that I have conducted, very few patients given the choice of a programmable nuclear pacer, a ten year lithium pacer, or a rechargeable pacer, will choose the rechargeable unit. Therefore, such units can be recharged fully once every six months or once a year, and have a life expectancy that compares to other pacemakers, I do not see them as a threat to the position of nuclear pacemakers.

As for other long life cells, there is no doubt that they play a very substantial part in pacing, and obviously will become the standard pacemakers of the future. However, there is as yet no chemical cell that has potential life as great as the plutonium cells. The manufacturers speak of ten years life, but if the nuclear manufacturers were to exhibit the same degree of hopefullness, they would be speaking of 20 to 40 year life. (None of the manufacturers are taking into account deterioration of other components and wires.)

Pacemakers with nuclear cells are particularly well suited to young healthy adults who have otherwise normal long life expectancy. From the point of view of economic feasibility and reliability I cannot see how this area of usefulness will change in the near future.

Affiliate of College of Medicine and Dentistry of New Jersey
Member of Jewish Community Federation of Metropolitan New Jersey

A-103

621 186

Therefore, thermonuclear pacemakers have a real place in the field of pacing and their use continued should be encouraged for selected patients.

Sincerely yours,

Victor Parsonnet, M.D.
Director of Surgery

VP:wn
cc: Dr. Thomas Bustard

Newark Beth Israel Medical Center
201 Lyons Avenue, Newark, New Jersey 07112 / at Osborne Terrace
Telephone (201) 926-

April 16, 1975

Mr. Bernard Singer
Chief Materials Branch
Directorate of Licensing
Nuclear Regulatory Commission
United States Atomic Energy Commission
Washington, D.C. 20545

Dear Mr. Singer:

I have been sending periodic missives to you about the recent statement on the extension of licensing of nuclear pacemakers. As you know, I feel very strongly about it, and believe that at least for the present there is a real place for nuclear pacing.

I am in the process of preparing a review of this subject that will be presented at the Society for Vascular Surgery and the International Cardiovascular Society Meeting in Boston on June 20th. If you would like me to send you a preliminary copy of this manuscript, I will be glad to do so. I believe the facts will speak for themselves.

I am also concerned about the pressure put upon you by manufacturers of long life non-nuclear pacemakers. On the basis of past experience none of these companies can show that their pacemakers will be equal or superior to nuclear pacers, and until such time, we should proceed as planned with limited licensing of the nuclear units.

Thank you very much for your attention.

Sincerely yours,

Victor Parsonnet, M.D.
Director of Surgery

VP/na

Enclosure: Reprint of article that appeared in Newark Star Ledger, April 14, 1975.

cc: Dr. Nicholas Smyth, Dr. L. Gilbert, Dr. I. R. Zucker, Mr. A. Eickhoff, Dr. G. H. Myers.

The following enclosure was submitted with letter No. 43 and is available for examination in the Nuclear Regulatory Commission Public Document Room, 1717 H Street, Washington, D.C.:

1. J. Whitlow, "Atom-Powered Pacemaker Test Called Success," Newark Star Ledger, Newark, N.J., April 14, 1975.

621 188

Newark Beth Israel Medical Center
201 Lyons Avenue, Newark, New Jersey 07112 / at Osborne Terrace
Telephone (201) 926-7000

June 11, 1975

Mr. Bernard Singer
Materials Branch Section
Directorate of Licensure
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Singer:

I have prepared the following manuscript for presentation at the Society for Vascular Surgery on June 21st. Because this is in a way responsive to the "Draft on Generic Environmental Statement," I am sending it to you for that specific purpose.

If there is any other way that I can be of assistance in this matter, please let me know.

Sincerely yours,

Victor Parsonnet, M.D.
Director of Surgery

VP:cd

Enclosure: (Manuscript) Clinical Experience With Nuclear Pacemakers

*Signed in Dr. Parsonnet's absence.

A-105

The following enclosure was submitted with letter No. 60 and is available for examination in the Nuclear Regulatory Commission Public Document Room, 1717 H Street, Washington, D.C.:

1. V. Parsonnet, G. H. Myers, and others, "Clinical Experience with Nuclear Pacemakers" (processed), The Department of Surgery and the Pacemaker Center, Newark Beth Israel Medical Center, and the New Jersey Medical School, Newark, N.J., June 11, 1975.

621 189

Newark Beth Israel Medical Center
201 Lyons Avenue, Newark, New Jersey 07112 / at Osborne Terrace
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September 9, 1975

Bernard Singer, M.D., Chief
Materials Branch
Division of Materials and Fuel
Cycle Facility Licensing
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Dr. Singer

I have had the opportunity to review the comments on the Draft Environment Statement on Plutonium Pacemakers. Although I have already written two letters to you, and sent you a manuscript on the worldwide use of radio-isotope pacemakers to date, further amplification is indicated.

My confidence in the program has not been shaken by the adverse statements. A brief tabulation of my own of the statements received so far gives a definite nod to those against the nuclear pacemaker. Only a few of these comments have any serious impact. Most of the writers who are against the unit were either manufacturers or physicians associated with manufacturers who have a clear personal bias, often because they advocate use of other types of batteries that are competitive with the nuclear units. Favorable notes were often from satisfied patients, equally biased. Still other notes, which I must reject, are from semi-authorities whose comments were so sarcastic that one wonders about the objectivity of the author.

Also of considerable interest to me was the differing viewpoints of the clinicians and the engineers. This difference is similar to the proverbial problem that confronts medical school faculties where there is often a conflict between basic scientists and clinicians. Basic scientists and engineers tend to look at things in a statistical, if not cold blooded fashion that is quite distinct from the viewpoint of the clinician. The latter group tends to see the problem from the point of view of the patient. My associates and I, who for 15 years have experienced contact with patients who have been faced with the nuisance of repeated operations, can always see the huge advantage to any patient of one operation that requires no subsequent pacemaker maintenance.

The entire point, it seems to me, is that the pacemaker industry in combination with the physicians involved should have as an objective the development of a lifetime pacemaker system for every patient.

With regard to rechargeable cells, if a pacemaker could be recharged

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every six months to a year, my attitudes might change, although even then wouldn't you agree that it would be preferable to wear a pacemaker that would last the rest of a lifetime with no maintenance?

Proponents of rechargeable systems have repeatedly boasted of patient acceptability. All clinicians know that acceptance by a patient population cannot be in itself a proper criterion for widespread use. Patients will accept almost anything when persuaded by their doctors. For example, at one time patients were persuaded to wear an external radio-frequency power source, obviously a poor alternative, one that the proponents defended by saying that the patients liked it. They liked it despite the fact that they could not remove the external power source, to bathe, exercise, swim, travel, etc. On the other hand, we questioned a group of non-pacemaker wearers of all ages on their choice of pacemaker should they need one (see my recent manuscript). These choices included the nuclear and rechargeable pacemaker, and the lithium units, each described in as unprejudiced a fashion as possible. Not one of the respondents selected the present rechargeable pacemaker as his first choice.

There were a number of comments, by both clinicians and basic scientists- that the nuclear pacemaker offered only a very slight advantage over other alternatives. I can answer this by asking, very slight for whom? Certainly it may be very slight for the elderly person, but for the very young, the advantage may be quite palpable.

With regard to the wires, several respondents implied that there was no point in making long life pacemakers if the wires broke frequently, as if to ask why one should develop any long life pacemaker system, rechargeable, chemical, nuclear or other as long as the wires continued to break. Obviously, if wires break frequently with one system they will continue to break frequently with another - the power source is irrelevant. If one applied this type of logic to any development of mankind, there would be no progress at all. There is always a weak link in a chain.

Although wires remain a problem, it is an independent issue. In our hands, an understanding of how to handle the wires has eliminated fractures at the point of fixation of the wire to the tissues, at the so-called "butterfly" as described in my original article on the subject two years ago. Since using a newly designed butterfly there have been 1 to 5 fractures during the last 2 years. Other improvements, such as using absorbable ligatures around the wires, rather than non-absorbable ligatures, has eliminated another source of wire and insulation breaks. In actual fact, in the past 2 years, of 688 wires at risk, there were 17 fractures, or 1.2% a year, a clear improvement over past performance.

It is true that efforts must be made to improve the durability of the

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electrode wires, and I know that every manufacturer is working hard on this problem. Whether or not an improvement over the helical coil configuration, using wires of steel alloys or platinum-iridium will be found remains to be seen. Approximately 5% of re-operations each year are to correct wire fractures, but 70% are for battery failure. Where then is the problem? Obviously, the major task is to improve the battery.

Finally, were we to develop really superb alternative power sources, the nuclear pacemaker would pass by the wayside, having served its purpose as an interim development. For the moment, however, I am absolutely convinced that the plutonium pacemaker in its present form is absolutely safe, and objections to the contrary have been either emotional or scientifically unfounded.

Sincerely yours,

Victor Parsonnet, M.D.
Director of Surgery

VP:ri

CC: Mr. Mason

Affiliate of College of Medicine and Dentistry of New Jersey
Member of Jewish Community Federation of Metropolitan New Jersey

2389 Floral Hill Dr
Eugene Ore 97403
March 23 1975

Deputy Director for Fuels and Materials
Directorate of Licensing Regulations
USA EC Washington, D.C. 20545

Dear Sir:

Re: Plutonium Pacemakers

It seems that the few lives that would be extended by plutonium pacemakers would be more than offset by the excessive risk of illegal seizure and clandestine use of this most dangerous material.

I oppose the use of plutonium by individuals or almost any other use - except possibly some research.

Sincerely,
R Marriner-Drum

Pacemaker Foundation inc.

June 23, 1975

Mr. Bernard Singer
Materials Branch Section
Directorate of Licensure
U.S.Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Singer:

I am 63 years of age, a Compliance Officer, Compliance Staff, Meat and Poultry Inspection Service, APHIS, United States Department of Agriculture. In my position I am responsible for compliance with the Meat & Poultry Inspection Acts, by those in the meat and poultry industries. In my work, I cover the Greater New York/New Jersey Metropolitan area, often driving upwrds to 100 miles and interviewing upwards of 20 people or plants per day. I am active in religious and fraternal and charitable organizations, giving of my time and energy. These things in themselves are not remarkable, but were it not for my having a Pacemaker, I don't believe that I would be able to operate as effectively.

I am a Pacemaker since 1967, having had 3 standard pacemakers and, since April 11, 1973, I became the recipient of annuclear pacemaker made by Areo Nuclear Co., Leechburg, Pa.

Mr. Singer, could you have any idea of what a recipient of a battery energised pacemaker thinks of when theirunit becomes 20 or 22 months old? They are worried? Not in the least; they are actually scared, not knowing when the batteries will stop giving that little necessary life giving elctricity to keep their pacemakers going. I and many people I know have unfortunately shared that feeling, several times.

Now that I have a nuclear pacemaker, with the knowledge that medical knowhow and engineering believes it should last 10 perhaps 20 years, I sleep better, I do not worry about or looking forward that my batteries will conk out in about 2 years, that another pacemaker has to be implanted, resulting in time lost from my work and family, another surgical proceedure with the always attendant danger of infection, plus the additional high hospital costs.

I have a very close relationship with approximately 15 people who have nuclear pacemakers. I know and share with them the feeling of security they now have as opposed to the hundreds of people wearing battery pacemakers, that I have spoken to or answered their letters to me, regardless of age, all wanting to know with that unsure scared feeling that is never openly expressed "how long will their battery pacemakers last?".

Pacemaker Foundation inc.

Incorporated by:
Lawrence Gilbert, M.D.
Victor Parsonnet, M.D.
I. Richard Zucker, M.D.
Simon Arie
Albert J. Benninger
Max Bick
Nelson Cheatham
Frank Franzese
Harry Katz
Martin Meade
Catherine Piccione
Sam Piccione
Max Spieler
Carole Wilson

I have never before written to any policy making or licensing group trying to explain my feelings, but this time I am a case in point. I feel secure, therfore I am able to function as a normal being, without those little,annoying and sometimes scary doubts in the back of my mind as to "when will my pacemaker stop?", I, and others like me who are fortunate to have Nuclear pacemakers are happy. Ask Us!

If I can be of service to you to honestly answer any nonmedical or nontechinal questions, just the actions, thoughts and feelings of an individual feeling confidant in the life-giving energy of a nuclear pacemaker, feel free to call on me.

Respectfully submitted for your consideration

Max Spieler
15 Shepard Place
Nutley, New Jersey 07110

261 - 125

12740 San Fernando Road • Sylmar, California 91342 • U.S.A.• (213) 367-1911 • Cable: PACESETTER

PACESETTER SYSTEMS INC.

March 14, 1975

Atomic Energy Commission
Materials Branch
Fuels and Materials
Directorate of Licensing
Washington, D. C. 20545

Attention: Mr. Bernard Singer, Chief

Gentlemen:

I have just yesterday received a copy of your draft Environmental Statement on the Wide-Scale Use of Plutonium Powered Pacemakers. In spite of my education as a nuclear physicist and my experience in certain areas of such technology, I am not directing this letter specifically to the technical feasibility and safety of nuclear powered pacemakers. Instead, I intend to emphasize in this letter several aspects of the proposed use wherein I believe my background particularly qualifies me. Part of my reason for avoiding certain of the issues is that it must be recognized as President of Pacesetter Systems, Inc., manufacturer of the rechargeable pacemaker, my comments might be dismissed on the basis of partiality. On the contrary, although the nuclear pacemaker might command a small part of the market, such diversion would in my opinion not be significant.

I therefore write this letter as a responsible citizen and taxpayer who feels that continued expenditure of government funds in the subsidy of manufacture of plutonium for applications such as pacemakers is unwarranted and, further, that the substantially increased costs in use of such a product would add materially to the cost of our Medicare and Medicaid programs and to the price of independent medical insurance, which is borne by most of our citizens. Moreover, the BEIR Report (Report of the Advisory Committee on the Biological Effects of Ionizing Radiations) for the National Academy of Sciences and the National Research Council published by HEW and EPA in November, 1972, maintains that "No exposure to ionizing radiation should be permitted without the expectation of commensurate benefit." With several viable alternatives to nuclear powered pacemakers, the benefits from the ionizing units are hardly significant. Thus, the extensive distribution of devices containing the highly toxic plutonium cannot, in my opinion, be justified by any cogent argument.

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Aside from such technical and sociologic factors, my concern lies in the unscientific, self-serving approach used to promote the use of nuclear energy for pacemakers. Regardless of the technical and safety considerations or the justification of need for such devices, it is not so much the decision, whatever that may be, but the methodology employed that troubles me. Should not the government play a neutral, or in this case even a conservative role, with regard to making this decision?

There is certainly no doubt that the technical problems in designing a long-lived pacemaker powered by Plutonium 238 can and may already have been solved. I am not, however, persuaded that extended exposure to 5-15 millirems per hour of radiation at the pacer surface is safe and furthermore, such radiation exposure increases with time - typically by a factor of four in ten years. Even the lower initial level is above your own Atomic Energy Commission industrial safety standards. The BEIR Report, referenced above, recommends even lower standards. Although their main concern was with irradiation of the general population, they point out that the mutation doubling dosage for man from chronic radiation falls in the range of 20 to 200 rem and they suggest that exposure should be substantially lower than this level to minimize the incidence of genetic defects and cancer. If the doubling dose were 20 rem and if 20% of the ill health arises from mutations (estimated between 5% and 50%), then from a 5 rem per generation general exposure there would eventually be an increase of 5% in the ill health of our population. One can argue that 5% of the pacemaker patient population is not significant, and that these results do not apply since the radiation is localized, not general. On the other hand, for fuel with a four-fold increase in ionizing radiation in a device having an initial 15 mrem/hr. level, a 5 rem dose would be incurred in only 3½ days! Also, though localized, the radiation commonly affects critical tissue and bones. Thus, we must continue to question how the long term effects of such local radiation to critical body tissue and bones can be assessed without the passage of decades. The question becomes all the more important when it is considered that the primary market that might effectively use such a device consists of younger people, where the integrated dosage would be highest. One of the most significant objections must also be the proliferation of all the radioactive fuel and particularly the toxic plutonium throughout the world. The virtual certainty of failures and real dangers cannot be lightly dismissed.

The number of pacemakers to be used in 1975 worldwide will probably exceed 160,000 and this number continues to grow at a substantial rate. Of course many of these are replacements but nevertheless almost 100,000 new patients will receive their implants this year. Somewhat over half will be used in the United States. Neglecting the low market projections of only a 3% penetration for nuclear devices by the end of this decade as determined in a recent very extensive survey, it would seem that for the program to have any real significance then surely the objective must be to control of the

order of 10% of the total market as a minimum. Producing 16,000 such devices will present a significant challenge. Although your Commission has imposed very clearly defined standards and safeguards for manufacturing it should be recognized that these requirements are DESIGN SPECIFICATIONS AND NOT NECESSARILY PRODUCT SPECIFICATIONS. It is one thing to design and construct a small number of capsules that will survive almost any anticipated environment. It is yet another thing to build hundreds of these devices; and to build thousands without a significant number of failures is extraordinarily optimistic. To produce 10,000 or more per year without a significant statistical failure rate is in my opinion beyond any reasonable manufacturing competence. Even if all manufacturers of such devices were to match the enviable reliability record of Pacesetter Systems, there would still be a number of failures. Thus, in addition to the normalized effects of the irradiation, a full release of nuclear pacemaker manufacture and distribution undoubtedly will lead to a substantial number of cases in which highly toxic Plutonium 238 will be dispersed.

Pacemakers represent an interesting and virtually unique commercial device. The success of these products conjures up a special interest by the media so that a great deal of publicity accompanies any even moderately significant pacemaker news. Considering the anxiety of people about nuclear radiation, there is little doubt that even a modest number of nuclear pacemaker problems would receive extensive publication. I would anticipate that the dangers even though real would be substantially exaggerated to the extent of causing great social opposition and serious political impact on the entire Atomic Energy program. To me the risks attendant from such pressures, which include possible curtailment or even demise of worthwhile aspects of other applications for nuclear energy, would be far too great to justify wide spread use of nuclear pacemakers. I personally would find distressing any increase in opposition to nuclear power for the significant needs of our energy resources program because of problems associated with pacemakers, particularly when alternative techniques are available for meeting any need for such long term devices.

On the contrary, however, there appears to be a continuing effort to justify this questionable application. I see a repetition of my experience with proponents of atomic energy over the last two decades for another purpose. Prior to my association with Pacesetter Systems, I was the president of the two divisions of Textron, Inc. that were the primary suppliers of solar cells and arrays for spacecraft. In this capacity I became very familiar with the persuasive but usually inaccurate arguments used to promote nuclear power sources for spacecraft. Continually throughout that period over-optimistic projections and even blue sky fantasies were proposed relative to power-to-weight ratios and costs that would be achieved by expenditures of large sums of taxes for the development of such secondary power systems. To support these proposals, a reference standard for solar photovoltaic conversions systems was based on experience that was archaic history. Never was a moving target of solar power used as a comparison standard for the nuclear proposals. Thus two or three year old experience in solar power systems was compared with optimistic forecasts for nuclear power five years into the future so as to indicate that nuclear power might be competitive and even provide an advantage. As it turned out, the nuclear programs

never attained their goals, while great strides were being made in photovoltaic systems. With the substantially reduced system weights and costs, nuclear power never became a viable alternative except for a few isolated cases, gensrally for travel to planets in the far reaches of our solar system. Unfortunately I believe the arguments for funding of the nuclear programs were consciously made by both industry and government to further a cause which could not be justified by realistic objective evaluation.

What disturbs me at this time is that I see the same type of strategy employed again relative to cardiac pacemakers. In reviewing your draft statement, Paragraph 4.2.3.2, Rechargeable Nickel-Cadmium Battery, it reads, "A pacemaker is now being manufactured with batteries that can be recharged by the patient on a weekly basis. Results of bench tests, animal studies, and clinical investigation indicate that approximately 95% of the rechargeable pacemaker batteries may last 10 years. The use of this type of pacemaker, however, may be constrained by the recharging operation. It has been reported that some elderly patients cannot be relied on to recharge their pacemakers and that physicians cannot, in many cases, burden such a patient with the responsibility of recharging his pacemaker. Over 800 of these pacemakers are now in clinical use." The references for this information were listed as Pacesetter Systems, Michael C. Seremitis, M.D., and Richard E. Emmitt, Cyrus J. Lawrence and Sons. The reference of Pacesetter included a conversation and a letter 1½ and 1¾ years old, respectively. The two communications reflected early experience with only a few patients and our desire to maintain a conservative image. No recent efforts were made before publishing your draft to ascertain the later results of our experience in the approximately 1500 patients to date and thus to update the information. Moreover, the "quotation" appears to be incorrect and the conclusion false. The only information in the references to the 5% or 95% numbers was in our evaluation of patient suitability. We believe that about 5% of patients may not effectively or reliably carry out the recharging regimen. On the other hand, you quote that results of bench tests, animal studies and clinical investigation indicate approximately 95% of our batteries may last 10 years. That is just not true and we are at a loss to understand where you could have obtained such false information. Without benefit of our data how could you possibly make such a statement? We have every reason to believe based upon extensive accelerated and real-time testing, analysis and measurement, that our cells will last 40 to 50 years or more. In fact, the conservative design life of our entire pacemaker - not just the battery - is 30 years and we have yet to detect from extensive investigation any life limiting components even in such a time frame. No wear-out processes have been detected from such testing and analysis that would conflict with this projection. Reliability evaluations of our system indicate a considerably longer probable life. The most conservative study based on our experience to date, even incorporating infant mortality into our statistics projects that 91% of our pacemakers will last longer than 30 years. Separating random from process related problems, analysis of the data shows that 97% of our pacemakers should last longer than 20 years. Thus, not only is your statement an assumption made without benefit of our data, but it is also inaccurate.

You also quote an isolated doctor who is clearly negativ o our system and is not experienced with its use and a financial analyst ociated with a company involved with a competitor, both of whom are not competent to make a generalized judgment as stating that elderly patients cannot be relied on to recharge their systems. Unfortunately this argument, actively pursued by our competition, has been accepted by some physicians on face value and in other cases represents a convenient excuse for rejection of our long life device. As a matter of fact, extensive surveys of patients using the rechargeable pacemaker contradict this objection. There are a number of doctors using our system for the majority of their patients. In one such instance a doctor has employed our device in 60 out of a to al of 63 cases. Tw two patients (3%) he rejected the people as being unsuitable candidates because of mental deficiencies. When presented with the choice the third elected to have replacement with a conventional unit. Thus over 95% of his patients, ranging in age from 41 to 90 years, with a median age of 65 years, are satisfied with the Pacesetter rechargeable system and in not one single case has there ever been a problem with recharging nor has any patient ever complained about the regimen. In all cases these patients have expressed satisfaction with the system and approval of its use after their experience. This is not an isolated example, although this particular doctor has used our system in a higher proportion of his patients than have others. In a study being made of patients of a number of physicians we find virtually no negative reaction and a significant number who express a positive attitude about recharging. Thus your quote of a single prejudiced investigator and an analyst who both have negative attitudes based not on fact but on fiction is hardly unbiased. It would have been more appropriate to either make an independent analysis or to also inquire of users and of the manufacturer as to their experience and as to independent surveys. The approach that was employed would be expected from a salesman from a competitive company, not from a representative of our government, and brings to mind arguments raised in previous times about other applications of nuclear energy.

In challengin your presentation, I do not contradict the existence of the conviction large number of physicians that recharging is undesirable or unacceptа . There are a number of opinions underlying this feeling and it will be a matter of time, education and social and peer pressure and patient demand before this argument will be put into proper perspective and cease to be a factor. In the meantime one approach to eliminating the objection is the extension of time between charges and the reduction of the charging time. Significant progress is being made in both of these areas so that much of the opposition will ultimately be laid to rest. For example, in an extensive market survey of this subject some 75% of the physicians indicated that given a six-month recharging interval, they would consider the system suitable for their entire patient population. This result compares to only 25% of the physicians who would consider our system for the majority of their patient population with the present regimen of weekly or monthly recharging.

The Pacesetter system which will soon achieve 2,000 implants has clearly established a new standard in product reliability and is designed to last and will last beyond the lifetime of most if not all patients. Furthermore, the sole argument of patient dependence and involvement on recharging will vanish with product refinement so that this system will in fact meet the objectives of a reasonably receptive physician interested in the best medicine for his patient. For some conservative physicians and those with other interests, we believe that no long term pacemaker will gain acceptance for many years.

In addition to our rechargeable pacemaker and its evolutionary improvements there is the effort of Dr. O. F. Tyers of Pennsylvania State University using a rechargeable mercuric oxide-zinc-silver cell to achieve long charge intervals. Although their present experience is based upon a short interval regimen, they claim that they will ultimately be able to offer a 20-year life and be able to charge once every 3½ years. From inquiries and investigations on this program we would have to conclude that such claims might be premature, but there is certainly merit in pursuing the research. Other alternatives include the solid state lithium iodide, lithium bromide and sodium bromide batteries. At least five companies are already selling such cells and the first of these types is already in devices produced by several manufacturers. In fact Arco Nuclear, the successor company which was heavily subsidized by the Atomic Energy Commission for several years in development of a nuclear pacemaker is now pursuing a lithium iodide powered device which they overtly indicate to have more market appeal than their nuclear model. Thus even the most vocal commercial proponent of nuclear powered pacemakers is already pursuing alternative primary chemical cells as a better alternative. Although many claims of longevity are made for these newer chemical batteries, it is premature to really predict the ultimate truth. Suffice it to say that there is little question such pacemakers could certainly last over five years and in the next decade I predict that chemically powered primary cells may be able to power pacemakers for as long as 10 years or perhaps even more. I couch my projections carefully since it is difficult to accelerate tests of such primary cells so that the ultimate life of these pacemakers must be demonstrated by the passage of time.

To quote one of the physicians surveyed in the noted independent market study, "I think nuclear pacemakers are already obsolete and have no place. . . . ." While the need for research in this field may have been justified five to ten years ago, the consensus of the 339 physicians interviewed in the survey is that there are several viable alternatives that are more appropriate. I therefore see no real need for a nuclear powered pacer and with all the distribution and control problems inherent in such a product it would be foolhardy to expose our entire nuclear program to the social outrage which would result from any problems. In any case, regardless of your decision on licensing wide scale use of such device I do not believe it is in the public interest for any subsidy whatsoever to be provided to manufacturers,

who should bear the full and complete cost of manufacture of the plutonium fuel INCLUDING ALL COSTS OF ADMINISTRATION AND CONTROL. Even so, we as a nation will pay the high prices of such products since almost all pacemakers are reimbursed by Medicare, Medicaid or by insurance carriers who factor such costs into their premiums.

Sincerely,

ALFRED E. MANN
President

AEM/mh

Acting Deputy Director for Fuels and Materials
Directorate of Licensing - Regulation
U.S. Atomic Energy Commission
Washington, D.C.

February 17, 1975

Dear Sir:

I urge you to reject the idea of using radioactive materials for fuel in cardiac pacemakers. Though this is a most commendable medical advance and undoubtably a tremendous boon to the individual with heart irregularity, the potential spread of such highly toxic material through the activities of demented individuals, terrorist groups, or criminals for the purpose of political or financial extortion strongly indicates that this use of such material is definitely not justified.

It behooves the Nuclear Regulatory Commission to insure that a minimal or no amount of nuclear material that can be fashioned into crude weapons, or, as in this case, dispersed for extortion purposes, is made available, even with some difficulty, to terrorist or criminal elements.

to place dispersion-sized amounts of this material inside vulnerable human bodies is to negate the security which it demands.

Sincerely yours,

Stephen R. Parcher

Stephen R. Parcher, Doctor of Science
1603 Stockton Avenue
Bakersfield, California 93308

961 179

961 196

PEOPLE FOR PROOF

THE CALIFORNIA COMMITTEE FOR NUCLEAR SAFEGUARDS

2315 WESTWOOD BLVD., LOS ANGELES, CA. 90064 (213) 474-3320
405 SHRADER ST., SAN FRANCISCO, CA. 94117 (415) 386-0666

April 16, 19[illegible]

Mr. Bernard Singer, Chief
Materials Branch
Directorate of Licensing
U.S. Nuclear Regulatory Commission
Washington, D. C. 20555

Dear Mr. Singer:

People for Proof condemn the use of plutonium for the batteries of heart pacemakers, as contemplated in the "Draft Generic Environmental Statement on the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers," USAEC, January 1975.

Such uses of extremely dangerous radioisotopes appear to be proposed in an attitude profoundly insensitive to the social climate of our times. Any such widespread use of plutonium would offer irresistible opportunities to extortionists and other public enemies. In order to hold the center of a city for ransom, or to force its evacuation, ruthless criminals need only proceed as follows: "Find and kidnap James Seagren, a 52-year-old roofing contractor in St. Paul, Minnesota. Holding him incommunicado, claim that you have extracted his plutonium pacemaker and have dissolved it in acid. Threaten to blow up the acid solution in the center of town unless all your demands are met."

People for Proof have just qualified the enclosed initiative statute for the June 1976 California ballot, by gathering nearly 500,000 signatures statewide. Be assured that if the plutonium pacemaker program is not decisively terminated, we shall cite it in our election campaign as a prime example of the immaturity and recklessness which continues even under the new Nuclear Regulatory Commission.

Enclosure: Nuclear Initiative

Very truly yours,

Richard B. Spohn

Richard B. Spohn, Esq.
Chairperson

Copy: William A. Anders, Chairman, NRC

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The following enclosure was submitted with letter No. 44 and is available for examination in the Nuclear Regulatory Commission Public Document Room, 1717 H Street, Washington, D. C.:

1. "Land Use, Nuclear Power Liability and Safeguards Act," proposed Title 7.8, Government Code, State of California, initiative measure to be submitted directly to the electors, reproduced on petition circulated by People for Proof, Los Angeles, California.

3900 Cathedral Ave.
Washington, D. C.
June 19, 1975

Director of Licensing
Mr. Barners Singer, Chief
Materials Branch, Nuclear Regulatory Comm.
U. S. Atomic Energy Commission
Washington, D. C. 20555

Dear Mr. Singer:

I am a patient of Dr. Nicholas Smyth, and a nuclear pacemaker recipient.

I am not up to date re the criticism of the nuclear pacemakers versus the others , or the proposed legislation to control all. I am in favor certainly of protecting the individual. To my knowledge the percentage of nuclear pacemakers that have proved satisfactory is higher than that of the non-nuclear. I only wish the cost of the nuclear ones could be brought down so that more people would be able to afford them. I had three batteries between Jan. 1968 and June 1973 when my nuclear one was implanted. Now I have, hopefully, a 10-year period before needing a new one. The mental peace-of-mind that comes from not having to plan your life around entering the hospital to have a new battery every couple of years is tremendous. I have not detected any change in the operation or reliability of my new one and am looking forward to a long-lived unit with fewer operations. Here's to more and better nuclear pacemakers.

Sincerely yours,
Juliet Phillips

P.S. I would be interested to see any material re pacemakers vs. environmental impact?

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ROGER and CHARLOTTE POWERS
4411 38th Street
BRENTWOOD, MARYLAND 20722

JUNE 2, 1975

MEDTRONIC, LAURENS-ALCATEL MOD.9000
SERIAL # 3R00296

MR. BERNARD SINGER, CHIEF,
MATERIALS BRANCH,
NUCLEAR REGULATORY COMMISSION,
UNITED STATES ATOMIC ENERGY COMMISSION,
WASHINGTON, D. C., 20555.

DEAR MR. SINGER:

IN VIEW OF THE CURRENT CONTROVERSY CONCERNING PACE-MAKERS, I SHOULD LIKE TO EXPRESS MY CONFIDENCE IN THE NUCLEAR POWERED TYPES, ONE OF WHICH I RECEIVED IN FEBRUARY 1974. SINCE THAT TIME, I HAVE FELT MUCH MORE SECURE THAN I DID WITH THE CONVENTIONAL PACER WHICH I HAD PREVIOUSLY.

FROM WHAT I HAVE READ, I FEEL THAT MOST OF THE OBJECTIONS ARE DUE TO MONETARY CAUSES RATHER THAN PHYSICAL AND SCIENTIFIC.

RESPECTFULLY

Roger G. Powers

ROGER G. POWERS

CC:DR. N. P. D. SMYTH

Phone 301 927-9210

9211 629 1978

Public Citizen

March 10, 1975

Dr. Howard J. Larson
Acting Director
Office of Nuclear Material Safety and Safeguards
Nuclear Regulatory Commission
Washington, D.C. 20545

Dear Sir:

Enclosed are comments on the Draft Generic Environmental Statement on plutonium pacemakers. It is our conclusion that nuclear pacemakers are not needed. There are nonnuclear pacemakers under clinical investigation with lifetimes comparable to or greater than those of nuclear pacers. The claimed benefit of the plutonium pacer, reduction in operative mortality, is very small because the operative mortality in pacer replacement is very small. The potential risks of the plutonium pacer are, on the other hand, significant.

There is therefore no reason to permit commercial use of nuclear pacemakers. We strongly recommend that the NRC refrain from licensing nuclear pacers for commercial use and from supporting any further clinical evaluation of nuclear pacers.

Yours truly,

Sidney M. Wolfe, M.D.
Public Citizen Health Research Group

John Abbotts

John Abbotts
Public Interest Research Group

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HEALTH RESEARCH GROUP • 2000 P STREET, N.W., WASHINGTON, D.C. 20036 • (202) 872-0320

Comments on Draft Generic Environmental Statement On The Wide-Scale Use of Plutonium Powered Cardiac Pacemakers

Health Research Group
Public Interest Research Group
Washington, D.C.

Summary and Conclusions

As one of its last acts of nuclear power promotion to the detriment of regulation, the Atomic Energy Commission (AEC) recently announced its intention to allow widescale use of nuclear powered heart pacemakers.[1] This will commercialize a nuclear gadget which will provide little, if any, value. The Generic Environmental Statement (GES) which proposes wide-scale use of the plutonium pacemaker suffers from the following inadequacies:

1. The GES omits an evaluation of the effects of production and disposal of the pacer units, and does not adequately justify the omission.

2. The treatment and analysis by the GES of the dose to the patient carrying a plutonium pacer appears to underestimate the dose. The dose to younger more susceptible patients is not evaluated.

3. In its benefit-risk comparison, the GES ignores as alternatives two conventional pacers which have lifetimes comparable to the plutonium pacer. These conventional pacers have undergone clinical investigation more extensive than has the plutonium pacer.

Even if conventional pacers have lifetimes no greater than six years, electrodes and wires may become the limiting components for pacer lifetime. In this case there would be little advantage to the plutonium pacer.

4. The benefits of the plutonium pacer are overrated by the GES. A major justification for the nuclear pacer is reduction of operative mortality. Recent studies indicate operative mortality from pacer implantation may be negligible or, in some studies, nonexistent.

The case of the nuclear-powered artificial heart provides an instructive precedent for the nuclear pacemaker. The artificial heart, an implantable plutonium powered pump, was finally assessed for the National Heart and Lung Institute by an independent panel after it had been in development for several years. At the time of the panel review, there were no viable nonnuclear alternatives to the plutonium powered heart. Nevertheless, the panel recommended against the experimental use of the nuclear powered heart in humans[2], and recommended that "every effort" be spent in developing a nonnuclear alternative.[3]

There is experimental and observed evidence that plutonium concentrations in the lungs of animals as low as 0.2 micrograms produce cancer.[4] The plutonium pacemaker will carry up to 500 milligrams (mg) of plutonium. The GES believes the chances of plutonium dispersal from a nuclear pacer to the general population are small. Admittedly, the plutonium pacer will carry about one-hundredth of the 50 grams of plutonium in the artificial heart. Nonetheless, risks are still present.

A dangerous consequence of commercializing nuclear pacemakers is that it could establish a precedent for the proliferation of other nuclear "gadgets". The nuclear establishment has a host of such gadgets waiting to be developed. Metzger[5] describes the plans for nuclear-powered wrist watches, plutonium-heated diving suits, and plutonium powered coffee makers. Such gadgets have even less justification than the nuclear pacer. Their benefits are dubious and nonnuclear alternatives already exist.

The commercialization of these nuclear gadgets would develop a whole subindustry dependent upon the byproducts of nuclear reactors. Perhaps the justification for this subindustry is a partial "solution" to the waste problem by putting the byproducts to use. This scheme would hardly solve the waste problem. It would merely disperse the waste and increase the potential for each individual of being directly affected by nuclear reactor byproducts.

The inadequacies of the GES are discussed in greater detail below. This discussion will demonstrate that the benefits from the plutonium pacer are negligible or nonexistent. While there was no alternative to the artificial heart, there are alternative cardiac pacers which obviate the need for the plutonium pacer. There is therefore no reason to pursue widescale use of the plutonium pacer. Because of the additional risks imposed upon society by a nuclear pacemaker, it would be illogical to promote that gadget's commercialization.

The Nuclear Regulatory Commission (NRC) has the opportunity to rectify the dying-gasp mistake of the AEC. The NRC should not license the plutonium pacer, or any other nuclear cardiac pacemaker, for widescale use.

Discussion of the GES

1. Omissions

The GES does not investigate the effects of production and disposal of the plutonium pacer. The reason given for this is, "The production of plutonium and controlled disposal of any associated radioactive wastes are conducted as part of other licensed or AEC-contract operations", and the amounts generated "would be small compared to that which is produced for other purposes."[6]

But the plutonium pacer will introduce production and disposal effects that would not exist without the pacer. Widescale use of the plutonium pacer will cause occupational exposures, which otherwise would not have occurred, during production of plutonium and fabrication of the units. Eventual disposal of the plutonium will be complicated by the retrieval of pacers throughout the country. Disposal of nuclear waste from pacers will therefore be qualitatively different from disposal of plutonium waste from other existing sources.

If the cost-benefit analysis of the GES is to be comprehensive, it must include the occupational and environmental effects of plutonium production and disposal. If these effects are negligible, the GES must demonstrate they are negligible. It cannot minimize the potential effects by fiat.

2. Patient Exposures

The GES reports that pacemakers may contain as much as 500 mg of plutonium fuel.[7] The calculated dose to a patient from a nuclear pacer is based on a Battelle Northwest study with a unit containing 173.2 mg of plutonium.[8] There are no statements that the 500 mg pacer contains extra shielding to reduce its dose to that equivalent from the 173 mg pacer. Nor is there any indication that the calculated patient doses have been corrected for an expected number of 500 mg pacers. It must therefore be inferred that the 500 mg pacer has been ignored in the computation of patient dose.

If the 70 mrem/yr whole body dose calculated by the GES applies only to the 173 mg pacer, then the whole body dose for the 500 mg pacer would be 200 mrem/yr, all other things assumed equal.[9] This dose is greater than the recommended whole body dose to the "average" person of 170 mrem per year. The GES should therefore indicate if its

estimated patient doses reflect the commercialization of 500 mg pacers.

It is objectionable that the GES should evaluate the dose from the plutonium pacer by comparing the dose to background radiation. There are few known ways to eliminate background radiation, while man-made radiation can be reduced. The Artificial Heart Panel stated:[10]

> Potential public apprehension about the nuclear-powered artificial heart must be considered in the context of existing apprehension about the exposure to radiation from nuclear power plants, other atomic energy applications, and medical and dental x-rays. Indeed, the radiation effects from the artificial heart cannot be considered in isolation, since the effects on life are a function of cumulative exposure to radiation from all sources."

By the same token, the radiation from the plutonium pacer cannot be viewed in isolation, and it is not soothing that the dose from the pacer may be less than background. A more reasonable perspective for the pacer dose comes from comparing it with other man-made radiation sources. Similarly, the evaluation of the pacer dose should examine how its contribution, along with the contributions of medical x-rays and other sources, will move the patient toward the 500 mrem maximum non-occupational dose or the recommended 170 mrem dose for the "average"person.

As an additional matter, Drs. Friedberg and Lillehei have the following comments on dose to susceptible patients from the plutonium pacer:[11]

> "The radiation dose in one year would give the patient's skin a dose approximately equal to that received during one diagnostic chest x-ray. However, the radiation dose to the skin is not really relevant. The radioactive energy absorbed by the bone (rib) and the bone marrow may be higher."
> "Comparisons with 'allowable' doses of total body radiation are not valid. It may be argued that it is the younger patients who need a very long-life pacemaker. It can also be argued that it is the youngster who is most sensitive to the deleterious effects of radiation. It is precisely in the juvenile age group that one will have the longest possible time to develop potentially lethal alterations such as leukemia or genetic defects which may follow into later generations."

The GES does not address the apprehensions of Drs. Friedberg and Lillehei by evaluating pacer dose to younger, more susceptible patients.

3. Alternatives

The GES does not adequately address the nonnuclear alternatives. The GES acknowledges that conventional pacemakers under clinical investigation have potential lifetimes of 10 years or more. The clinical investigation of these alternatives has been more extensive than clinical investigation of the plutonium pacer. But in its benefit-risk analysis, the GES ignores the longer-lived alternatives and compares the plutonium with a hypothetical six-year conventional battery. If the comparison had been with the lithium-iodide or rechargeable batteries, the GES might have reached the scientifically supported conclusion that the plutonium pacer is unnecessary.

a. Lithium-iodide battery

The lithium-iodide pacemaker is an attractive alternative for several reasons.[12] The pacer has a salt crystal, not a corrosive liquid as its electrolyte. The reaction which generates electrical power does not generate any gas, which allows the unit to be hermetically sealed. The chemical capacity of the lithium pacer is roughly 4 times the capacity of a mercury battery. The lithium pacer's efficiency is also increased at body temperature.

The principal problem with the lithium pacer is a gradual buildup of internal resistance. Failure of the cell will therefore occur gradually, which could be viewed as yet another advantage over other cells which can fail catastrophically. At the extreme buildup that has been observed, elective replacement of the lithium cell will occur at 87.5 months (more than 7 years) for a demand pacer, and at 125 months (more than 10 years) for an asynchronous (fixed-rate) pacer.

The elective replacement point is based upon replacement at a battery voltage of 1.9v, which voltage would still allow the battery to operate effectively.

The extreme internal resistance buildup, on which the projected lifetimes above are based, is 400 ohms per month. The average in earlier cells is 150-250 ohms per month, and a more recently developed cell has a buildup of only 50-150 ohms month. It is therefore more than reasonable to expect that the lithium pacer could have a lifetime of ten years or more. At the time the GES was written, the lithium pacer was under clinical use with 3500 patients,[13] which represents a greater investigation than has been undertaken with the plutonium pacer.

Another alternative which would reduce the requirement for reimplantation operations would be a rechargeable pacemaker. As the GES[14] acknowledges, one rechargeable model is in clinical use in over 800 patients. The GES also acknowledges that 95% of the rechargeable units may last ten years. Another advantage of the rechargeable pacer is that its size and design allow an easier implantation operation. The rechargeable unit is small, and the connection between the lead and the pulse generator can be made with a 720-degree twist. The connection does not require tools, lubricant, or ties as do other units.[15]

The GES apparently dismisses the rechargeable pacer as an option because of the contention that elderly patients cannot be expected to recharge their units. While it is doubtless true that some patients might be so senile, to extend this to a generalization for all elderly patients would be nonsense. Elderly persons routinely administer digitalis and variable self-calculated doses of insulin to themselves. There is little reason that they could not be expected to recharge their

pacers.

According to persons involved with the rechargeable pacemaker, experience has not supported the GES contention on the inabilities of older patients to recharge their pacers. 1200 Pacesetter rechargeable units have been implanted thus far, and there supposedly has been "no known problem" with patients recharging their units on time.[16] Moreover, the Pacesetter unit actually contains 6-8 weeks of charge. Recharging is recommended weekly, at home, for a 90 minute period. It would take an extremely irresponsible person to neglect weekly charging for a time sufficient to endanger himself.

Even if experience showed that patients could not be expected to recharge their batteries, there are other measures that could be taken. There are presently pacemaker clinics in several locations around the country. These clinics were set up to check on the proper functioning of pacers. At a regular interval--typically 1 month to 4 months, depending on the age of the pacer, a patient reports to the clinic to have his pacers functions examined. This practice has reduced the number of operations for emergency reimplantation, and has allowed implantation operations to be delayed until the beginning of pacer malfunction are indicated.[17-19]

For patients in remote areas, a telephone pacemaker monitoring system has been used. The pacer discharge and pulse are monitored by a sound-sensing device connected to the telephone system. A periodic call allows the clinic to check the pacer operation over the phone.[20-22]

It should be expected that a telephone system could be used to meet the problem of forgetful patients. The clinic could by telephone remind the patient to recharge his pacer and then monitor

the pacer to insure it was operational. Alternatively, existing clinics could be expanded to require that the weekly recharging be performed at the clinic. Another measure could be to require the patient to recharge his pacer at the offices of his doctor or hospital.

c. Hardware

Another area that offers much potential for increased conventional unit life is the improvement of electrodes and leads. There are several references[23-26] which show how improvements in electrode design and placement can reduce the drain on the battery unit, therefore increasing battery life.

On the subject of hardware, it appears that with longer battery lives, the limiting factor in replacing pacemaker units could become failures of leads and electrodes. Although this problem does not appear to have been evaluated in detail, one reference[27] suggests that leads and wires may not last as long as ten years. Another reference[28] goes so far to state that leads and wires will not be durable enough for 5 and 10 year batteries.

If electrodes and wires will in fact become the limiting factor for batteries of greater than 5 years life, then there is no reason to use the nuclear powered pacer until there is a substancial improvement in the technology of this limiting hardware. The justification for the plutonium pacer, which is a reduction in implantation operations, will vanish. Limits in wires and electrodes will result in the same operation frequency for a plutonium pacer as for a conventional pacer of approximately six years life. While the patient with a plutonium pacer will not reduce his operation risk, he will subject himself to significantly greater radiation risk. Widescale use of the plutonium pacer in preference to the six

year conventional pacer would thus be foolish without an improvement in wire and electrode lives. The time necessary to bring about these improvements might also result in conventional batteries which would make the plutonium pacer even more obsolete by comparison.

The great strides recently made in the lifetimes of conventional pacers are striking. The lifetimes of older mercury batteries were generally in the range of 18-36 months. Only recently, mercury pacers with 5-6 year lives have been developed. The past few years have also brought the development of the rechargeable and lithium pacers, which have great promise of ten year lives. It is entirely conceivable in the next few years, the same time which will probably be necessary to develop more durable wires and electrodes, that another breakthrough in conventional pacer lifetime may occur.

In fact, the dramatic breakthrough in conventional pacer lifetime may have already occurred. Two patients have been implanted with a hermetically sealed, low-drain, rechargeable mercury-silver battery. Although recharging takes place every two weeks, the battery should last 3 years without recharging, and the projected life span of the unit is 20 years.[23,29,30]

In summary, the GES has not adequately considered the conventional cardiac pacemaker units available. Had the GES done so, it would have concluded that the plutonium pacer is unnecessary.

4. Cost

From the standpoint of cost, it makes more sense to use a nonnuclear pacer. The GES shows that initial implantation of the plutonium pacer costs $7250. Cumulative costs of conventional pacers are $5800 through the first replacement and $8150 through the second replacement.[31]

From the figures above, the conventional pacer costs do not surpass plutonium pacer costs until the second replacement. If the plutonium pacer had a 20-year lifetime, then a 10-year conventional pacer will always be cheaper. As is shown above, there are already conventional units which should have a 10-20 year lifetime. One rechargeable pacer, with a 10-year guarantee, costs $2200 for the pacer and its charging unit.[29] This is a thousand dollars greater than other conventional units, so this would raise the cumulative cost to $6800 after the first replacement. This is still less expensive than the costs for even a 20-year plutonium pacer. The average lifetime of a pacer patient, according to the GES, is 14 years. This is yet another reason for the individual to forego the plutonium pacer for a conventional pacer.

With regard to pacemaker prices in general, it should be pointed out that there is virtually no price-control mechanism. A Wall Street analysis of pacemakers has stated that since Medicare pays for most pacemakers, the patient is also not concerned with the price.[32] Thus, the demand for pacemakers is somewhat "inelastic" providing little, if any incentive for manufacturers to cut prices.

5. Benefit-risk analysis

The benefit-risk analysis is flawed because in addition to the aforementioned underplaying of risks, it overstates the benefits of the nuclear pacer. The alleged benefits of the plutonium powered pacemaker are that its long life will reduce mortalities from reimplantation operations. These benefits probably are negligible or nonexistent because of two factors. The first factor, mentioned above, is that with longer lived batteries, the limiting components in pacer life may be electrodes and wires. The plutonium pacer

will not reduce the number of reimplantation operations required to replace electrodes or wires.

The second factor is that the mortality rates assumed by the GES are unrealistically high. The GES assumed a 1% mortality rate for the reimplantation operation. This rate might have been valid for earlier circumstances when the majority of heart pacer implantations were done on very weak and sick patients, and when transthoracic operations were performed for the implantation.

The more recent literature, however, shows that the reimplantation and implantation operations can be performed easily with almost no risk:

1. One reference[33] reports 372 implantation and reimplantation operations with no mortality.

2. A second reference[34] reports a total of 726 implantation and reimplantation operations, with one postoperative death. The one death occurred during primary implantation. No mortalities occurred during replacement operations. The most serious complication, which was infection, was observed during one primary implant. The infection rate for primary implants was therefore 0.2% and on all pacer procedures was 0.13%.

3. In a third group of patients, the mortality rate for about 150 reimplantation operations was zero.[35]

It is clear that using the transvenous rather than the transthoracic operation, the mortality rate is extremely low. There are indications, moreover, that even the transthoracic technique could cause minimal risk when done properly. Tyers and associates[23] believe that with the selective use of a temporary transvenous lead during the transthoracic procedure, the operative mortality rates for both techniques would be comparable and the complication rates

with the transthoracic method would be lower.

In summary,an experienced surgical team using modern techniques can perform the pacemaker reimplantation operation with very low risk to the patient. The benefits of the plutonium pacemaker in reducing operation frequency are similarly very low. It can therefore be shown that the benefits of the plutonium pacer relative to other pacemakers with non-nuclear energy sources are practically zero. The risks- even those admitted by the GES-are significant. It thus makes no sense to permit commercial use of nuclear pacemakers

Footnotes

1. Draft Generic Environmental Statement On The Wide-Scale Use Of Plutonium Powered Cardiac Pacemakers, U.S. Atomic Energy Commission, Washington, January 1975. Referred to below as GES.

2. The Totally Implantable Artificial Heart, Artificial Heart Assessment Panel, National Heart and Lung Institute, DHEW Publication No. (NIH) 74-191, June 1973, p. 123. Referred to below as Heart Panel.

3. Ibid, p. 197

4. Radiation Standards For Hot Particles, A.B. Tamplin and T.B. Cochran, Natural Resources Defense Council, Washington, February 14, 1974, p. 5

5. The Atomic Establishment, H. Peter Metzger, Simon and Schuster, New York, 1972, p. 226-227

6. GES, p. 1-8

7. GES, p. 2-5

8. GES, p. 3-5

9. This is obtained by the approximation that the dose from a 500 mg pacer equals 70 mrem/yr x 500 mg/173 mg= 200 mrem/yr. This approximation treats the pacer as a point source and assumes that the shielding material and thickness for the 500 mg and 173 mg pacers are the same.

10. Heart Panel, p. 131

11. "Progress in Pacemaker Longevity",D. Friedberg and R.C. Lillehei, J. Electrocardiol. 7: 97-100 (Feb 1974)

12. The general information on the lithium iodide pacer comes from "A New Solid-State Long-Life, Lithium-Powered Pulse Generator", R.C. Lillehei et al, Ann. of Thor. Surg. 18: 479-489 (Nov 1974) and from the reference in footnote 11.

13. GES, p. 4-4

14. GES, p. 4-4

15. "Early Clinical Experience with the Rechargeable Cardiac Pacemaker", K.B. Lewis et al, Ann. Thor. Surg. 18: 490-493 (Nov 1974)

16. Communication with Dr. R.E. Fischell,The Johns Hopkins University Applied Physics Laboratory, Silver Spring, Maryland, March 3, 1975.

17. "Prediction of Impending Pacemaker Failure in a Pacemaker Clinic", V. Parsonnet et al, Amer. J. of Card. 25: 311-319 (March 1970)

18. "A Decade of Permanent Pacing of the Heart", V. Parsonnet, Cardiovascular Clinics: Arrythmias, Vol. 2, No. 2, F.A. Davis Co., Philadelphia, 1970, p. 181-199

19. " A Regional Network of Clinics for Analysis of Implanted Pacemakers", V. Parsonnet et al, Cardiac Arrhythmias, L.S. Dreifus and W. Likoff, eds, Grune & Stratton, New York and London, 1973, p. 635-649

References 20-22 describe the telephone monitoring systems:

20. " The Actual Lifespan of Pacemakers", D.P. Morse et al, Chest 64: 454-458 (October 1973)

21. " The Pacemaker Follow-up Clinic", S. Furman et al, Prog. in Cardiovas. Diseases, 14: 515-530 (March 1972)

22. "The Pacemaker Clinic", H. Mond et al, Cardiology 57: 262-276 (1972)

23. "The advantages of transthoracic placement of permanent cardiac pacemaker electrodes", G.F.O. Tyers et al, J. Thor. and Card. Surg 69: 8-14 (Jan 1975)

24. "Clinical evaluation of new pulse generator with narrow pulse width for conservation of battery energy", N.F.D. Smyth et al, J. Thor. and Card. Surg. 68: 471-478 (Sep 1974)

25. "Comparative studies of 'state of the art' and presently used clinical cardiac pacemaker electrodes", G.F.O. Tyers et al, J. Thor. and Card. Surg. 67: 849-856 (June 1974)

26. "The clinical application of low-output pacemakers", S. Center and P. Tarjian, J. Thor. and Card. Surg. 64: 935-940 (Dec 1972)

27. "The Ideal Permanent Pacemaker", D.J.W. Escher et al, Cardiac Arrhythmias, L.S. Dreifus and W. Likoff, eds, Grune & Stratton, New York and London, p. 607-617

28. "The natural history of pacemaker wires", V. Parsonnet et al, J. Thor. and Card. Surg. 65: 315-322 (Feb 1973)

29. "New pacemaker goes on and on", Medical World News, 16 No.3: 26-27 (Feb 10, 1975)

30. "Preclinical testing of a redundant, rechargeable cardiac pacemaker", G.F.O. Tyers et al, J. Thor. and Card. Surg. 62: 763-768 (Nov 1971)

31. GES, p. 4-14

32. See Testimony of Sidney M. Wolfe, M.D., Public Citizen Health Research Group, before Senate Health Subcommittee, September 14, 1973

33. "Ten-year Survey of Treatment with Implanted Cardiac Pacemaker", E.Sowton et al, Brit. Med. J. 3: 155-160 (July 20, 1974)

34. "Four hundred consecutive patients with permanent transvenous pacemakers", E.P. Conklin et al, J. Thor. and Card. Surg. 69: 1-7 (Jan 1975)

35. Prof. Dean Abrahamson, School of Public Affairs, University of Minnesota, Minneapolis, unpublished evaluation.

5 DALRYMPLE ST.
DOVER, N.J. 07801
21 AUGUST 1975

MR. LERNARD SINGER
CHIEF, MATERIALS BRANCH
DIVISION OF MATERIALS &
FUEL CYCLE FACILITY LICENSING
UNITED STATES NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

DEAR MR. SINGER;

HAVING HEARD OF SOME SORT OF A HASSLE CONCERNING A MR. NADER ON PLUTONIUM USED IN NUCLEAR CARDIAC PACE-MAKERS, I WOULD LIKE TO OFFER SOME INFORMATION THAT MAY CLEAR A POINT IN THE MATTER.

TO BEGIN WITH, I AM VERY HAPPY AND EXTREMELY PLEASED WITH MY NUCLEAR PACEMAKER WHICH IS NOW 28 MONTHS OLD WITH NO PROBLEMS. BEFORE THE NUCLEAR PACEMAKER IN A SPAN OF 14 YEARS I HAVE HAD 7 OPERATIONS RELATIVE TO THE REPLACEMENT OF THE CONVENTIONAL PACEMAKER AND ON SEVERAL OCCASIONS IT WAS NIP & TUCK AND VERY DISCOURAGING

621 207

I AM NOW 63 YEARS OLD AND IT IS A COMFORTING THOUGHT AND I AM VERY HAPPY TO THINK THAT I WILL NOT REQUIRE ANY MORE SURGERY FOR THE REST OF MY LIFE.

THEREFORE, MR. SINGER, IN VIEW OF THE ABOVE, I HOPE THAT THE NUCLEAR PACEMAKER WILL BE MADE AVAILABLE TO ALL WHO NEED IT.

SINCERELY YOURS,

Stanley J. Runsky

P.S IF ANY OTHER INFORMATION ON THIS SUBJECT IS REQUIRED, PLEASE, DO NOT HESITATE TO REQUEST IT.

A-124

SCIENTISTS' INSTITUTE FOR PUBLIC INFORMATION
30 EAST 68TH STREET
NEW YORK, NEW YORK 10021
TELEPHONE: 212 249-3200
CABLE: SIPINFO

March 7, 1975

Deputy Director for Fuels and Materials
Director of Licensing
United States Atomic Energy Commission
(Energy Resources Development Agency)
Washington, DC 20545

Gentlemen:

We urge you to extend the deadline for comments on your generic environmental statement on wide scale use of plutonium powered cardiac pacemakers invited in your communication of January 17, 1975, No. U-30, Contact: Clare Miles, on the following grounds:

1. We have received reliable information that comments were solicited almost exclusively from internal government bureaus, companies in the nuclear industry and the Association for the Advancement of Medical Instrumentation.

2. This will represent the first general licensing of plutonium.

3. The plutonium-238 to be used is estimated to be 280 times more active and hence more toxic on the basis of specific activity than plutonium-239 which is conceded to be among the most toxic substances known to man.

4. Specifically, the medical community has not been informed concerning this application and its ramifications.

5. Your environmental statement does not comment on plutonium toxicity in man.

6. Given the almost zero mortality rate associated with the skin-flap surgery required for reimplantation

of power sources, the dubious benefits of this power source, if any, are entirely outweighed by the following risks:

a. Each carrier patient whom you propose to identify by wrist band could become the target of terrorists or other reckless groups intent on procurement of the material.

b. The half gram of PU-238 with its nearly eight curies of radiation can be dispersed in a pulverized form by a cheap explosive device (e.g., dynamite) with a potential of threatening large numbers of people. For example, each pacemaker's plutonium could contaminate two square miles of urban land sufficient to require evacuation.

c. Furthermore, antisocial elements could easily impose carcinogenic levels on large populations by releasing the material through the ventilating systems of large institutions (New York Trade Center, Pentagon, etc.).

d. Since pacemaker installation often requires emergency delivery, rulings could follow which would permit air transport of these materials, thus enhancing the risk of airplane hijacking.

e. Given 100,000 cardiac pacemaker wearers in the United States and the government's intent to permit the implementation of 1,500 plutonium-238 pacemakers and in the context of the risks mentioned above, one must assess the terriorist-risk to each individual pacemaker carrier against conventional pacemakers currently in use which we believe to have a high degree of efficacy and long-lived power.

It should particularly be noted that pacemaker failure currently relates more to considerations exclusive of the power source such as electrodes breaking or falling out than it does to the power source.

For these reasons, we feel compelled to insist upon a broader discussion of these issues in the medical and scientific communities with full disclosure of all ramifications of this issue as required by the National Environmental Protection Act of 1970.

Sincerely yours,

Allen C. Nadler, M. D.
Executive Vice-Chairman

ACN:jg

NICHOLAS P. D. SMYTH, M.D., P.C.
108 IRVING STREET, NORTHWEST
WASHINGTON, D.C. 20010

THORACIC SURGERY
CARDIOVASCULAR SURGERY
PERIPHERAL VASCULAR SURGERY

TELEPHONE 723-5565

February 10, 1975

Bernard Singer, Chief
Materials Branch
Directorate of Licensing
U. S. ATOMIC ENERGY COMMISSION
Washington, D. C. 20545

Dear Mr. Singer:

Thank you for your letter of January 16th enclosing the copy of the AEC Environmental Statement on Plutonium powered cardiac pacemakers.

I apologize for the delay in answering your letter but I have been ill with the flu for the past ten days.

I read the statement from cover to cover with great interest. There are of course sections of the report that are outside my field of competance but I think you have provided an excellent assessment of the impact of the Plutonium powered cardiac pacemaker on the general life of people in this and other countries. I am glad to see that the Agency concludes that the Plutonium powered cardiac pacemaker should be released for general use subject to the reasonable requirements of accountability, recovery and disposal of the Plutonium and the appropriate follow-up of those units implanted during the investigational phase.

I agree with the statement in your report that the use of these units will undoubtedly increase significantly following general release. Their exact place in the field of pacemaking can only be established after longer clinical experience with the units. I think that most of us who are active in research in the pacemaking field believe that all types of pacemakers should continue to be used and developed to their utmost. My own guess is that the Mercury-Zinc battery has probably reached it's maximum development and we will have to look for longer life to alternative chemical battery such as the Lithium Iodide, Sodium Bromide, the re-chargeable battery, etc. One attractive thing about the Plutonium battery is that we have no doubts about it's longevity!

Again, thank you for sending me a copy of the Environmental Statement. It is a monumental work and I congratulate you and all of you staff on the work done to produce such a comprehensive and excellent document.

Kindest regards.

Yours sincerely,

NPDS:jp

Nicholas P. D. Smyth, M.D.

A-126

621 209

Director of Licensing
Mr Bernard Singer
Chief, Materials Branch
Nuclear Regulatory Commission
U S Atomic Energy Commission
Washington, D. C. 20555

9 June 1975

SUBJECT: Plutonium Powered Cardiac Pacemaker

After much advice and consultations with Dr. Nicholas P. D. Smyth (my Physician) I was operated on the third of October 1974 for the implanting of a nuclear pacemaker. Prior to the operation I researched literature, talked with other persons who had heart pacers, and came to the conclusion that the nuclear pacemaker was far superior to the conventional demand type.

Subsequent to reading the report prepared by the Health Research Group, and discussions with my doctor I find there is a move on by some people who are opposed to the nuclear pacemakers and who feel that the nuclear pacemakers are a potential hazard and should not be marketed commercially. In all probability the majority of the persons commenting on both the impact to the environment and the patient have little concern for or a vested interest in the potential recipient. They are just commenting because someone has indicated that there is a potential danger because the pacemaker is powered by plutonium. They also feel there is a slight chance for rupture and there maybe some potential adverse impact on the environment or to the recipient. I am confident that there is no chance of any rupture and thus no impact on either the environment or the recipient.

With the conventional demand pacemakers I was always light headed, not able to work at my job regurarly, and unable to perform even the lightest household chores without fully utilizing all of my energy. My heart beat was irregular, blood pressure low. I had three (3) demand type pacemakers implanted over a period of two years and one month. The conventional pacemakers never worked properly, thus I was unable to get around and feel free to perform normal routine duties, I constantly worried and was under extreme mental strain. Each scheduled operation was nerve wrecking, and required a period of up to three (3) weeks for convalenscence in intensive care units.

The nuclear pacemaker operation was less arduous, and I was able to be out of bed and walking the same day. The fifth day I was able to go home and drove to church the following week-end. Just knowing that the nuclear pacemaker will last approximately twenty (20) years and that you will not have to endure another operation improves one's mental attitude, thus causing less strain on the heart. Even though the initial total cost for the nuclear pacemaker is more than the conventional one, I feel there is a savings over the long run by not having several operations within the twenty (20) years life expectancy of the nuclear pacemaker. The total cost for the three (3) previous pacemakers had cost approximately $20,000 whereas the cost of the nuclear one was approximately $10,000.

In relation to the conventional pacemaker the nuclear pacemaker is much lighter, and I hardly realize that I am carrying it around. I am convinced that there is no potential danger from radioactive discharge. In my opinion there is no risk imposed upon society by the nuclear pacemaker, and I would recommend the nuclear pacemaker over the conventional type to any potential recipient. Disposal creates no problem, since after the demise of the recipient the device is removed and returned to control of the AEC. This is accomplished by a written agreement between the recipient and the AEC.

I fully realize that great strides have been made and are continuing to be made in the Research and Development to improve the lifetime expectancy of the conventional pacemakers. If and when they develop a non-nuclear pacemaker whose life span is equivalent to at least twenty (20) years of the nuclear one, then one could make a realistic decision in choosing between the two pacemakers. Also, I am aware that there is a mortality risk in the number of repetitive operations which must occur in the implanting of the conventional pacemakers, and further there is still Research and Development to be accomplished with regards to the nuclear pacemakers. From personal experience, all in all, I am convinced that the nuclear pacemaker is <u>far superior</u> to the conventional types, and I would wholeheartidly recommend it to any potential recipient.

LOYETTA C. WHEELBARGER
4410 Oglethorpe Street
Hyattsville, Md. 20781

WILSON GREATBATCH LTD 4690 SHISLER RD., CLARENCE, N.Y. 14031 U.S.A. TEL: 716/759-6901

WG

06 March 1975

Mr. Melvin W. Schupe
Materials Division
U.S. Atomic Energy Commission
Washington, D.C. 20545

Dear Mr. Schupe:

Thank you for the opportunity to study and comment on yourrecently released draft "Generic Environmental Statement on the Wide-Scale use of Plutonium Powered Cardiac Pacemakers."

This draft is an exceptionally detailed and lucid statement of the pros and cons of nuclear pacemakers. I am in agreement with your conclusions and also with the reasoning which led you to those conclusions.

I have made some comments, most of which concern typographical errors in the draft (such as the spelling of my name, sic!) and the updating of information on various chemical batteries. None of these comments have any significant impact on your conclusions. They are as follows:

p (ix) under g. and h. I find it hard to believe you can track a patient through a data bank for a year for $10 and then recover and dispose of his pacemaker for $80. I know we couldn't do it for twice that, but you have experience to draw on and we do not.

p(xix) H3 WGL'd. does not manufacture pacemakers, only pacemaker power sources.

p1-2 H8 sp. "Greatbatch"

p1-3 H1 This sentence implies that RM1 group 2 mercury cells have twice the chemical capacity of RM1 group 1 cells. I suggest the following wording "Improved mercury batteries with the same chemcial capacity but claimed to have about double the previous lifetime..."

p2-5 H7 suggest "... and under any credible accident.. "

p2-19 H20 sp. "followed"

p4-3 H17 The term "directly excite" leads to confusion with direct charge collection systems currently being discussed for tritium batteries. I suggest the following wording "...promethium 147 impact on a semiconductor..."

p4-4 H3 suggest deletion of word "well". We currently do not make any statistical claims beyond six years.

p4-4 H8 Suggest "... investigation , as reported by the manufacturer, indicate....". I am not aware of any independent clinical reports that suggest this.

p4-4 last line change to "1200 of these pacemakers are now in use with only two failures reported to date".

p4-5 sec 4.2.3.3. I think the sodium-bromine battery could safely be deleted from your environmental statement. We hear nothing more of this cell and a recent paper: Powers, R. and Mitoff,S. An analysis of the impedance of polycrystalline beta alumina. J. Electrochem. Soc. 122,2:226 (1975) suggested the discovery of some fundamental problems involving cracking of the substrate by sodium penetration.

Your environmental statement should probably confine itself to systems which have at least seen some clinical use. By this criteria however, you may wish to say something about the GE zinc mercury battery which is in clinical use, although GE is quite secretive about reporting clinical results, to date.

p3-33 under 3.7 I agree that cremation represents the most likely release incident.
It is encouraging to see the change from plutonium-scandium alloy to the oxide. Perhaps it might be well to note that there are still about 1000 older plutonium-scandium units in world-wide use. My feeling is that these units probably should not be reimplanted but should be replaced with oxide fueled units anytime the clinical opportunity presents itself. Similarly it would probably be worthwhile to spend three or four times the effort and funds to agressively follow these units through the patient's lifetime to insure eventual recovery. The risk of dispersions is slight in either case, but greater in the case of the alloy.

Similarly, the study should include the risk to the downwind population from cremation of a mercury-powered unit. My feeling is that this is a very serious matter that has received no attention whatsoever in the literature.

p3-5 A common objection to nuclear pacemakers is the remote possibility of long-term genetic effect from the low-level radiation. Actually a telling argument is available to you here. Jet crews and Colorado residents get more radiation then do pacemaker patients. To my knowledge, no adverse genetic effects have ever been reported for either group and long-term data is certainly available for the latter. This represents positive evidence that long-term genetic effects are not present.

p4-12 It might be more convincing to actually calculate and show the confidence levels of the Medtronic nuclear test. Using my own binomial expansion version of Rosenbaum's criteria:

$$P \leq 1 - \sum \frac{(pn)^r}{r!} (1-p)^{(n-r)}$$

For 272 pacemakers accumulating 2700 pacemaker-months with one failure:

$$P = 1 - \sum_{r=0,1} \frac{(.0015(2700))^r}{1} (1-.0015)^{(2700-r)} = 1-(.0174+.0674) = 91.3\%$$

For 642 pacemakers accumulating 4488 pacemaker-months with one failure:

$$P = 1 - \sum_{r=0,1} \frac{(.0015(4488))^r}{1} (1-.0015)^{(4488-r)} = 1-(.001+.008) = 99.1\%$$

Thank you for the opportunity for reading this report and commenting on it. It is a good report that clearly and openly presents all the risks and benefits that I know of. I can find no serious fault with it.

Respectfully,

WILSON GREATBATCH LTD.

Wilson Greatbatch

Wilson Greatbatch
President

WG/mfl
encl.

The following enclosures were submitted with letter No. 19 and are available for examination in the Nuclear Regulatory Commission Public Document Room, 1717 H Street, Washington, D.C.:

1. R. W. Powers and S. P. Mitoff, "An Analysis of the Impedance of Polycrystalline Beta-Alumina," J. Electrochem. Soc., 122: 226-231 (1975).

2. Linear Random Failure Analysis, "Reliability Considerations," (no other reference given).

ZERO POPULATION GROWTH

January 31, 1975

Acting Deputy Director for Fuels and Materials
Directorate of Licensing - Regulation
U. S. Atomic Energy Commission
Washington, D. C. 20545

Dear Sir:

Please add this letter to the file of public comments on the "Draft Generic Environmental Statement on the Wide-Scale Use of Plutonium Powered Cardiac Pacemakers," dated January 1975 (deadline for public comments March 10, 1975).

The half-gram of 90% plutonium-238 dioxide proposed for each pacemaker represents 6.82 curies of alpha activity, the equivalent of about 110 grams of plutonium-239. This quantity is more than enough, if deliberately dispersed in the air conditioning system of a large skyscraper, to give a certain lung-cancer dose to all occupants within an hour. It is, moreover, enough to bring 2.1 square miles of a city to levels requiring some evacuation and cleanup. These conclusions are straightforward deductions from Table 2-2 of Nuclear Theft: Risks and Safeguards by Mason Willrich and Theodore B. Taylor (Ballinger, 1974, p. 25).

The draft environmental statement proposes that 1500 or more pacemaker recipients go about their daily affairs wearing a required identification bracelet, notifying observant criminals that they bear such a "radioactive pacemaker" in their chests. This is equivalent to sending engraved invitations to underworld figures, inviting them to deeds which are not the least bit impossible for their being unspeakable. The encapsulation of the ceramic Pu-238 in tantalum and titanium would matter only slightly to murderous criminals or terrorists, who following extraction could readily grind up the plutonium battery core for dispersal, utilizing an improvised glovebox.

The draft environmental statement is devoid of any safeguards discussion for this "fiendishly toxic" isotope, despite recognition therein that it is too hazardous even to permit its burial with a deceased pacemaker patient. This wholesale avoidance of the safeguards question represents a contemptible and intolerable violation of public trust and responsibility--though not the greatest such violation among nuclear promoters. It is my devout hope that reckless atomic gadgeteers, whose visionary proposed uses for ultratoxic nuclides are accompanied by near-total blindness for their criminal uses, shall be decisively stopped prior to large-scale societal tragedy. To this end, total rejection of the proposed plutonium-238 pacemaker program is absolutely mandatory. The draft environmental statement concedes that an accidental spill involving one pacemaker could cost $250,000 to clean up (pages 3-44 and 3-45). How many millions of dollars would a deliberate dispersal cost??

Enclosures

L. Douglas DeNike

L. Douglas DeNike, Ph.D.
Vice-President

Los Angeles Chapter: 2315 Westwood Boulevard / Suite 2 / Los Angeles, California 90064
Telephone 213/474-2154

621 213

The following enclosures were submitted with letter No. 1 and are available for examination in the Nuclear Regulatory Commission Public Document Room, 1717 H Street, Washington, D.C.:

1. L. D. DeNike, "Radioactive Malevolence," reprinted from Science and Public Affairs, 1974.

2. L. D. DeNike, Public Interest Report: Nuclear Terrorism, Environmental Alert Group, Los Angeles, California.

ZERO POPULATION GROWTH

March 19, 1975

Honorable William A. Anders
Chairman
United States Nuclear Regulatory Commission
Washington, D. C. 20555

Dear Colonel Anders:

Enclosed is my conception as to how a nuclear-powered cardiac pacemaker battery could be fairly simply transformed into a radiological terrorism weapon more powerful than any employed to date. I do not ask for comment as to its technical accuracy, nor can your agency derive much comfort if it indeed has specific flaws. It illustrates a general truth which the underworld is certain to seize upon. Were this not obvious, I would not have written it.

But such possibilities must be raised now, before the pacemaker program has proceeded any further. We sometimes forget the intellectual resources sometimes reflected in illegal deeds. Witness the mass manufacture of heroin and other sophisticated dangerous drugs. Witness the successful passage in Munich, Germany of three false 1000-mark notes, forged entirely by hand, using only a pen and ink (Los Angeles Times, February 21, 1975). And witness the second enclosure, containing news reports of six actual thefts of radioactive material.

If the Nuclear Regulatory Commission is to rise from the level of profound public distrust it inherited from its predecessor agency, it must decisively terminate the plutonium-238 heart pacemaker program, and all other such trivial applications. It must launch a broad review of other uses involving large quantities of long-lived radioactive material (such as industrial gauges, radiotherapeutic gamma sources, and food irradiators), to end their vulnerability both to theft and to terrorist dispersal in situ with explosives.

As crime levels mount, I would hope that your agency would see the handwriting on the wall. There is precious little enjoyment to me in circulating formulations such as the enclosed "terrorism recipie." It has been financially burdensome for me to set my career aside in order to combat the idolatrous nuclear religion. But our national safety, and your agency's survival, both depend upon a much tighter rein being held on the uses of long-lived radiotoxic materials. So I have no choice but to continue to publicize vulnerabilities as I encounter them, and you have no choice but to act swiftly and decisively in the public interest by eliminating these vulnerabilities.

Very truly yours,

L. Douglas DeNike

L. Douglas DeNike, Ph.D.

Enclosures
Copies: Commissioners

Los Angeles Chapter: 2315 Westwood Boulevard / Suite 2 / Los Angeles, California 90064
Telephone 213/474-2154

The following enclosures were submitted with the DeNike letter (dated Mar. 19, 1975) and are available for examination in the Nuclear Regulatory Commission Public Document Room, 1717 H Street, Washington, D.C.:

1. "Cesium Sources Stolen, Found: Damage Reported," Nuclear News, February, 1975.
2. L. D. DeNike, "How to Convert a Plutonium-Powered Heart Pacemaker into a Terrorism Weapon Capable of Making up to Two Square Miles of Any City Uninhabitable," Zero Population Growth, Los Angeles, California.
3. Excerpt from article (no title given) beginning "A nuclear power plant technician...," Los Angeles Times, January 23, 1975.
4. "FBI Fears Rise of A-Threats," Los Angeles Times, January 4, 1975.
5. "Much Uranium Missing from Plants, Paper Says," Los Angeles Times, December 30, 1974.
6. "Nuclear Device Threatens Thief," AP dispatch, June 8, 1974.
7. Public notices, San Francisco Examiner, August 14, 1974.
8. "Radioactive Needle Sought after Theft Suspect Is Arrested," Los Angeles Times, November 28, 1974.
9. "Radioactive Plates Stolen from Lab," Los Angeles Times, October 3, 1974.
10. "Smuggles Uranium...," Environment, December 1974.
11. WTOP News Release, WTOP News Radio, Washington, D.C., October 25, 1974.
12. (There were three entries dealing with theft of nuclear materials — all three were untitled and references were not given.)

ZERO POPULATION GROWTH

April 16, 1975

Mr. Howard J. Larson, Director
Division of Materials and
Fuel Cycle Facility Licensing
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555

Dear Mr. Larson:

Thank you for your letter of April 8, stating that the possibility of misuse of nuclear material in the proposed plutonium-powered cardiac pacemaker "will be dealt with definitively in the final (environmental) statement."

Surely a definitive discussion of this topic would include assessment of the health effects and countermeasures for a release of 8 curies of respirable $^{238}PuO_2$ particles on a workday noon in the downtown area of a major metropolis. Surely a definitive treatment would also discuss the problem of a similar contaminative release within an office building or factory, together with the dislocation, expense, time loss, manpower, and equipment required for decontamination to the extent decontamination is possible, which should also be stated. Surely a definitive discussion will involve declassification of the government's secret studies on the effects of plutonium contamination in urban areas.

A definitive treatment will no doubt suggest an "informed consent" form for the prospective pacemaker recipient along these lines: "No responsibility is assumed in the event that the patient is kidnapped and/or killed in connection with the blackmail/terrorism/illicit sale value of the plutonium in this device. The U.S. government certifies the honesty and security measures of all radioactive pacemaker manufacturers, transporters, hospitals, mortuaries, and waste disposal sites which may be involved in the fuel cycle for this pacemaker. The recipient guarantees to wear the required identification bracelet at all times, despite its cueing potential for possible malefactors, or else the device will be removed as a penalty (what other penalty is proposed?)."

I am not simply being facetious. Precedent for frank inclusion of these matters, implicit under the provisions of NEPA, includes Vol. 4, p. V-48 and 49 of GESMO (WASH-1327, August 1974), and Vol. IV, p. 7.4-19 of the proposed final WASH-1535 (December 1974). "If the purpose is to force evacuation of the building or costly decontamination with minimal injury to personnel, 1 g (of plutonium, isotopic composition unspecified) uniformly scattered on the 20,000 to 100,000 m² of floor area would be sufficient."

L Douglas DeNike

cc: Asher J. Finkel, AMA

L. Douglas DeNike, Vice-President

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The following enclosures were submitted with letter No. 42 and are available for examination in the Nuclear Regulatory Commission Public Document Room, 1717 H Street, Washington, D.C.:

1. C. E. Gleit, excerpt from letter to W. Morris re: DeNike's "How to Convert...," March 26, 1975.
2. "Nuclear Energy: It Costs Too Much," (no reference given).
3. "Dispersion of Plutonium," Generic Environmental Statement on Mixed Oxide Fuel, August 1974 (with annotations).

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Appendix B

INTERIM SAFETY GUIDE FOR THE DESIGN AND TESTING OF NUCLEAR-POWERED CARDIAC PACEMAKERS

B.1 GENERAL GUIDELINES

This interim guide* for the safety design and testing of nuclear-powered cardiac pacemakers supersedes the interim guide dated July 1972 and incorporates changes based on experience and information obtained since that time and on the Nuclear Energy Agency's (NEA) August 23, 1974 draft interim standard for nuclear-powered pacemakers.

This guide is intended to assist manufacturers and distributors of nuclear-powered pacemakers and nuclear power sources for pacemakers to be implanted in humans for investigational purposes. A separate guide entitled "Guide for Licensing the Investigational Use of Nuclear Powered Cardiac Pacemakers" describes the clinical information that should be contained in a proposal for investigational use in man.

These standards are subject to review and amendment as additional experience and information is obtained in the United States and other countries.

B.1.1 Information to be submitted (12 copies)

The pacemaker:

1. Model number or other specific designation used to identify the pacemaker.

2. A complete description of the pacemaker including (a) annotated drawings or sketches that describe all materials of construction, dimensions, methods of fabrication, and means of mounting the fuel capsule in the device; and (b) a detailed description of all design features that protect the fuel capsule from abuse and minimize radiation levels associated with the device.

Battery and battery housing:

1. Model number or other specific designation used to identify the battery.

2. A description of the battery and battery housing including annotated drawings or sketches that describe all materials of construction, dimensions, methods of fabrication, and sealing of the battery housing.

Fuel capsule:

1. Model number or other specific designation used to identify the fuel capsule.

2. Description of the nuclear fuel, including all stable and radioactive isotopes that will influence the type and intensity of radiation, the maximum activity per capsule, the chemical and physical form of the nuclear fuel, and the method of depositing fuel in the capsule.

3. A description of the capsule including annotated drawings or sketches that describe all materials of construction, dimensions, and methods of fabrication and sealing of the capsule.

In order to increase safety, the physical and chemical form of the fuel should be as nondispersible (in the environment) and nontransportable (in the body) as is practicable.

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*Prepared by the Radioisotopes Licensing Branch, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, March 26, 1974 (Revised January 1976).

Labeling:

A description of the fuel capsule, battery, and pacemaker labeling:

1. The fuel capsule (or battery housing in the case where the fuel capsule is permanently sealed within the battery housing) shall be conspicuously and legibly marked by means resistant to fire and corrosion (it shall be ensured that the markings do not compromise the reliability of the safe containment system) as follows:

   a. The radiation symbol;

   b. The words "Radioactive Pacemaker" or substantially similar wording;

   c. The words "Notify Health Authorities for Disposal" or substantially similar wording;

   d. Identity and activity of the principal radioisotope and year of sealing of the fuel capsule;

   e. The name of the manufacturer and serial number of the battery (or fuel capsule).

2. The pacemaker housing shall be conspicuously and legibly marked by means resistant to fire* and corrosion with the following:

   a. The radiation symbol;

   b. The words "Radioactive Pacemaker" or substantially similar wording;

   c. Identification (name of element and mass number) and activity of the contained radioactive fuel and the date of sealing of the pacemaker;

   d. The name of the manufacturer and serial number of the pacemaker;

   e. The words "Notify Health Authorities for Disposal" or substantially similar wording.

Radiation characteristics:

A description and analysis of radiation dose equivalents delivered to the pacemaker bearers (whole body, tissues, and organs) and to members of the general population, supported by:

1. Radiation level and tissue dose-equivalent rates at the pacemaker surface, at critical organs, and at a distance of 50 cm from the pacemaker surface, and the basis for determining these values. Sufficient data should be included to give a complete three-dimensional profile of radiation levels and dose-equivalent rates at the pacemaker surface.

2. Values of tissue dose-equivalent rates as they vary with time over a period at least equal to the useful life of the pacemaker, and the basis for the values.

3. Time-integrated tissue dose-equivalent values over a period at least equal to the useful life of the pacemaker, and the basis for these quantities.

4. All quality factors utilized in determining dose equivalents, the basis for selection of each quality factor (including a spectral analysis of all emitted radiation), formulas, constants, conversion factors, calculational methods, measurement methods, and a description of equipment and instruments used.

All measurements and calculations should be based on the maximum amount of radioactive material to be used in the pacemaker and shall take into account isotopic content, radioactive decay, and buildup of radioactive materials that may contribute to tissue dose.

Safety performance:

A detailed description and analysis of tests and test results that establish the integrity of the fuel capsule construction and seal under the conditions specified in Sect. B.2. This information should be submitted in the form of a concise report including:

*Where a pacemaker housing is essentially composed of epoxy resin, it shall bear a label fulfilling all the requirements except resistance to fire. Following exposure to fire, which will consume the epoxy resin and the protective covering, the markings on the battery housing will become visible.

1. All test results. Satisfactory test performance must be based on all tests performed (not on selected tests) and their results.

2. A detailed description of test equipment, instruments, and conditions.

3. Identification of the group that performed each test, including name, location, and responsible personnel.

4. Sufficient information to assure that the tests were performed in accordance with the test conditions specified in Sect. B.2.

The safety tests on prototype pacemakers and components are designed to specify severe conditions of impact, dynamic stress (crush), fire temperature, cremation temperature, and corrosion. Based on current information, it is unlikely that accidents more severe than these safety tests would occur to pacemakers in use. Therefore, the testing of pacemakers and components to these specifications provides a high degree of assurance that the nuclear fuel will be contained during normal use, disposal, and in case of accident.

Quality assurance:

A description of a quality control program (Sect. B.3) shall be provided and implemented to insure that each production unit will be essentially a replica of units that have successfully passed the required safety tests and conform to specifications furnished the Commission.

Additional tests:

Additional safety tests of prototype samples may be required if any modifications are made to pacemakers or their component parts that might produce different testing results than the results of previous tests.

Independent testing and evaluation:

Manufacturers or distributors of pacemakers who wish to distribute pacemakers for use in investigations in humans may be required to furnish prototypes to the Commission for testing purposes.

B.2 SAFETY TESTING

B.2.1 General information

All pacemakers and components to be safety tested shall be typical and representative of production-grade quality.

The leak-tightness of the fuel containment system (or any individual envelope thereof) of quality control samples and fuel capsules to be used in safety tests shall be established by a series of tests and examinations (such as bubble tests, microscopic examination, and radiographic, immersion, lithium chloride leach, and helium leak tests) capable of detecting any breach of containment down to an ultimate limit of sensitivity equivalent to 10^{-8} cm^3/sec of helium at STP. Prepressurization of the specimen at 60 psi for at least 4 hr in helium is required as a part of a helium leak test unless helium generation by the fuel is shown to be adequate for test purposes. In addition, it shall be determined that each fuel capsule is free of removable contamination by wiping the entire outer surface of the fuel capsule and determining that the wipe is free of contamination, using instrumentation capable of detecting 10^{-5} μCi or less of alpha particle activity and 10^{-4} μCi or less of beta particle activity.

Following each of the safety tests, the ability of the fuel containment system and the nondispersibility of the fuel to prevent leakage of the radioactive fuel shall be established by an analysis of a series of examinations and tests (such as microscopic and metallographic examinations, and immersion, lithium chloride leach, bubble, helium leak, and radioactive contamination tests). The engineering and technical bases for the selection of tests and examinations to demonstrate the ability of the fuel containment system and the non-dispersibility of the fuel to prevent leakage shall be explained. The criteria for passing or failing the tests and examinations selected shall be specified.

B.2.2 Mechanical tests

For purposes of the mechanical tests, the internal capsule pressure shall be at the level that corresponds to the end of the useful life (the useful life shall be explicitly stated), and the tests shall be performed within 50°C of the normal operating temperature.

B.2.2.1 Impact

Tests shall be performed by projecting the fuel capsule (or battery, where the fuel capsule is an intergral part of the battery) with an impact velocity of 50 m/sec onto a flat, essentially unyielding surface (e.g., granite, steel, or concrete). The impact target shall have a minimum mass 50 times that of the test specimen. If concrete is used, it shall have a minimum compressional strength of 250 kg/cm^2. The surface shall be normal to the trajectory of the capsule. The capsule shall be oriented in the position at which it will sustain maximum damage upon impact.

B.2.2.2 Static stress

Tests shall be performed by placing the fuel capsule (or battery, where the fuel capsule is an integral part of the battery) between roughened steel jaws having a Rockwell hardness of greater than or equal to C58. The jaws of the press shall have a surface area that is large compared with the cross-sectional area of the capsule. The jaws shall be of sufficient hardness and thickness so as to impart a force of 1000 kg on the capsule without deformation or yielding of the jaws. Tests shall be carried out by applying a load at 1000 kg to the capsule, which shall be oriented such that it will sustain maximum damage. The choice of capsule orientation should be supported by an engineering analysis.

B.2.3 Thermal tests

B.2.3.1 Temperature test (fire)

It shall be demonstrated by a series of thermal, metallurgical, engineering, leak, compatibility, pressure at high temperature, and other appropriate tests, that the pacemaker can, at any time during the useful life of the battery, withstand exposure to 800°C in an oxidizing atmosphere (free air) for 30 min followed by quenching in a large volume of water at room temperature and a static stress test (of the fuel capsule that has been removed from the tested pacemaker) in accordance with Sect. B.2.2.2.

Where tests are performed in a furnace, the pacemaker position and orientation inside the furnace should be that at which maximum damage will be experienced by the fuel capsule. The choice of pacemaker orientation shall be supported by an engineering analysis. Where the pacemaker housing is vented for laboratory safety reasons in the performance of the tests, an engineering analysis shall be provided that demonstrates that venting the pacemaker housing has not compromised the outcome of the temperature test. The total time/temperature thermal profile and the methods used to calibrate temperature-measuring instruments, to measure the temperature of the furnace and to determine the temperature of the pacemaker, shall be described.

B.2.3.2 Temperature test (cremation)

It shall be demonstrated by a series of thermal, metallurgical, engineering, leak, compatibility, pressure at high temperature, and other appropriate tests that the pacemaker can, at any time during the useful life of the battery, withstand exposure to a cremation cycle of 2 hr at a minimum temperature of 800°C in which there shall be a sustained temperature of 1300°C for at least 90 min in an oxidizing atmosphere representative of air-rich conditions found in crematoriums. The cremation test shall be carried out in such a manner that the pacemaker position and orientation inside the furnace is such that maximum damage will be experienced by the fuel capsule. The choice of pacemaker orientation shall be supported by an engineering analysis. Where the pacemaker housing is vented, an engineering analysis shall be provided that demonstrates that venting the pacemaker housing has not compromised the outcome of the test.

B.2.4 Corrosion tests

It shall be demonstrated by a series of tests and analyses that, when corrosion is extrapolated to a time corresponding to 10 half-lives of the radioisotopic fuel, sufficient encapsulating material will remain to ensure containment of the fuel for 10 half-lives in seawater including consideration of possible pressure buildup inside the fuel capsule.

The linear rate of corrosion for the fuel capsule and each fuel containment envelope shall be determined by a series of engineering analyses, corrosion tests (described below), accelerated tests, microscopic examinations, measurement of variation of mass, and measurement of wall thickness.

Before implantations can be authorized, a program plan for corrosion tests of each fuel containment envelope (including possible galvanic reactions), as appropriate, shall be submitted and evaluated. If tests on complete pacemakers are omitted from the plan, a justification for such omission shall be included. As a minimum, the test plan should include tests in synthetic seawater (standard ASTM-1141-53 ref. ASTM standard 1964, par. 23, p. 196) at room temperature for a period of one year (accelerated tests may be used provided it is established that they will have an equivalent effect on the fuel containment system) to determine the maximum rate of corrosion as follows:

a. Immersion of one set of test specimens (the number and type as justified by the program plan) in oxygenated (aerobic) seawater;

b. Immersion of another set of test specimens (the number and type as justified by the program plan) in deoxygenated (anaerobic) seawater.

The test specimens shall be immersed in a volume of seawater equivalent to not less than 0.1 liter per square centimeter of specimen surface area.

Until such time as results of testing have been evaluated (in no event beyond the period of investigational use) theoretical analyses that draw on generally accepted and documented knowledge may be used to calculate a maximum linear corrosion rate for each containment envelope. These rates (including possible galvanic reactions) should be used to determine the maximum linear corrosion (weighted for each envelope) in seawater.

B.3 QUALITY CONTROL PROGRAM

B.3.1 Basic requirements

Information concerning quality control shall include, as a minimum, a description of the following:

a. The organization responsible for quality assurance, the authority of this organization, and the unambiguous and independent relationship of this organization with manufacturing.

b. Provisions that ensure conformance with quality requirements and standards; and prevention, detection, and timely correction of discrepancies. Evidence of quality assurance, including a plan for shelf-life testing of pacemakers shall be provided.

c. Provisions to ensure that the radioisotopic containment is leak tight, free of removable contamination in compliance with the design specifications. This shall include a 100% visual inspection, leak test in accordance with Sect. B.2.1 for each of those envelopes (where appropriate) intended to provide fuel containment, and a final test for removable contamination.

d. Means of identifying materials, parts and components, whether they are in the course of manufacture or in storage, and of ensuring that materials which have lost their identity or are otherwise not properly identifiable with the specifications will not be used.

e. Means of identifying and separating material which has been rejected or which has not been released for further production and the procedure, if any, for subsequently releasing this material for production, based on evaluation of subsequent study or an accumulation of additional information which was previously lacking.

f. Means as may be appropriate to ensure that materials, components, and services supplied by other manufacturers or subcontractors meet the specifications.

B.3.2 Record keeping

Confirmation that a complete record of all tests, audits, and actions relating to quality control will be maintained by the manufacturers or importers of nuclear-powered pacemakers or component parts and will be available to any customer, the Commission, or any Agreement State for a period of 25 years from the date of manufacture.

Appendix C

GUIDE FOR LICENSING THE INVESTIGATIONAL USE OF NUCLEAR-POWERED CARDIAC PACEMAKERS

C.1 INTRODUCTION

This guide* is intended to assist manufacturers of nuclear-powered pacemakers and medical organizations proposing to implant nuclear-powered pacemakers in humans for investigational purposes.

Programs to implant radioisotope-powered pacemakers in man for purposes of investigating the safety, longevity, and reliability of the devices are licensed under the provisions of 10 CFR Part 70 (for devices containing special nuclear material) or 10 CFR Part 30 (for devices containing by-product material).

A standard research protocol should be prepared by the manufacturer or importer of the pacemaker as sponsor of the investigation. The standard protocol should describe those aspects of the clinical implantation and follow-up program that are to be followed by all of the participating investigators. This protocol, when accepted for licensing by the Commission and the Agreement States, can be furnished to all of the participating medical institutions and incorporated by them into their applications for licenses. The study team of an applicant medical institution may propose modifications they wish to make in the standard protocol, but, in the interest of a uniform and effective overall evaluation of a pacemaker, numerous and widely varying modifications are not encouraged.

C.2 CONTENTS OF A STANDARD PROTOCOL

The standard research protocol developed by the manufacturer or importer of nuclear-powered cardiac pacemakers should contain the following:

†1. Title and purpose of the investigational program.

†2. Description of the pacemaker and radionuclide.

3. Patient selection for nuclear pacemakers. In addition to the medical considerations for which a cardiac pacemaker is prescribed, patients selected for implantation of nuclear pacemakers during the investigational phase of use should have an upper age limit such that the life expectancy is in excess of ten years and should not have any coexistent diseases that would probably limit their life expectancy to less than ten years. Patients should also be selected who are reliable subjects and who have a record of stable residence in the community such that they are willing to cooperate in, and are likely to remain available for, the long-term follow-up required in this study.

†4. Time period over which pacemakers will be implanted for the study.

5. The follow-up and reporting of pacemakers implanted during the investigation should continue during the life of the patient or until the pacemaker is removed from the patient.

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*Prepared by the Radioisotopes Licensing Branch, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, August 1974 (Revised January 1976).

†These items are repetitious of information furnished by the sponsor to the NRC in the investigational plan and in the description of the design and prototype testing of the pacemaker. Their repetition in the standard protocol serves to inform the clinical participants, and, since the protocol is included by reference in the participant's application for license, it is the mechanism for obtaining the applicant's commitment to these statements.

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6. Control group. A series of comparable control patients with conventional pacemakers of the same type (i.e., demand or fixed rate, bipolar or unipolar) should be followed. The control patients should be treated and followed using the same procedures for patient selection, medical procedures, follow-up, and reporting.

7. Implantation procedures and lead systems to be used. Since this is an investigational program, not routine clinical use, it is preferable that a limited number of lead systems be used in order to limit the number of variables in the total pacing system and thus to develop more meaningful data on longevity and reliability of the pacemaker systems. Compatible lead systems or adapters should be specified if lead systems from previously implanted conventional pacemakers are to be used.

8. Specification of stimulation threshold measurements. The testing should be by battery-operated pulse generator with an adjustable current amplitude calibrated to an accuracy of ±10% and a pulse duration within ±15% of that of the pacemaker to be implanted. For newly implanted electrodes, only those electrodes may be used that have a threshold no greater than one-fourth the milliampere output of the nuclear pacemaker against a 500-ohm load. If the electrodes have been chronically implanted, the threshold may not be greater than one-third the output of the nuclear pacemaker against a 500-ohm load.

9. Registration and implant data and reports. Promptly after each implantation, registration and implant data shall be reported to the sponsor including the name and contact information of the patient and at least two responsible persons to be contacted if the patient cannot be located; name and address of the hospital and responsible physician(s); clinical data relevant to the pacemaker and its implantation; pacemaker identification by model and serial numbers, date of implantation, surgical procedure, and site of implantation; identification of leads, whether newly implanted or preexisting, by make, type, model, and serial number; date of implantation; vein used and location of electrode(s); threshold measurements, including current pulse-width equipment used; stimulation rate of the pacemaker (if demand type, rate should be measured with and without magnet); and history of previous implants and removals of pacemakers and leads, and reasons for such removals. A copy of the form to be used for collecting and reporting this data should be included in the protocol.

10. Follow-up data and reports. Prior to release from the hospital, and at intervals of not less than six months thereafter, each patient shall receive a follow-up examination, and data thereon shall be reported to the sponsor including identification of patient; pacemaker; hospital; physician; date of implantation; date of follow-up examination; performance of pacemaker, including stimulation rate with and without magnet; any malfunction of pacemaker or lead system; any modification or replacement of pacemaker or lead system; any adverse reaction or problem associated with pacemaker or lead system; physician's opinion and comments on pacemaker system, including being satisfactory or unsatisfactory; summary of medical examination relevant to; whether patient is carrying identification card; whether patient is wearing a bracelet or its equivalent; and whether contact with patient has been maintained since the last follow-up examination. A copy of the form to be used for collecting and reporting this data should be included in the protocol.

11. Data and report of replacement or removal. Any pacemaker or lead that is replaced or removed for any reason shall be reported within five days to the sponsor. The report shall include details of the elements removed or replaced, reasons for removal or replacement, date of removal or replacement, date of implantation of the elements removed or replaced, tests performed on removed or replaced elements, and results thereof. In case of death of the patient, autopsy findings related to the pacemaker shall be reported, and, if possible, the function of the pacemaker and lead system shall be determined at autopsy. The pacemaker and, if possible, the intact lead system shall be removed at autopsy and returned to the sponsor for evaluation and approved disposal of the nuclear source.

12. Notification by the licensee to the Radioisotopes Licensing Branch, Directorate of Licensing, U.S. Nuclear Regulatory Commission shall be made, within 24 hours of occurrence, of the death of any nuclear pacemaker patient and any adverse reaction and/or malfunction involving a pacemaker system, including the leads. A written report giving details of the adverse reaction and/or malfunction shall be submitted within 30 days.

13. The licensee shall notify the Radioisotopes Licensing Branch, within 10 days, of loss of contact with a nuclear pacemaker patient.

14. The patient, or his representative, shall be informed of and shall agree in writing to the following:

a. Radionuclide-powered pacemakers are under investigation; there are alternative treatments; and the patient must be willing to participate in the investigation.

b. Because of the radiation risk associated with burial, cremation, or loss of a radionuclide source to the environment, the pacemaker shall be removed from the body upon the death of the patient, and the pacemaker, when removed at death or for any reason prior to death, shall be returned to the sponsor for disposal.

c. The patient must carry at all times an identification card containing the patient's name; the word "Radioactive;" the trefoil radiation symbol; identification of the patient as a bearer of a radionuclide-powered cardiac pacemaker; identification of the pacemaker by manufacturer's name and model number, amount and type of contained radionuclide; the words "In case of emergency, hospitalization, or death, call collect (name and telephone number of the participating institution);" and information pertaining to the patient's consent to remove the pacemaker in case of death of the patient.

d. The patient must wear at all times a durable, fireproof bracelet, or other approved form of jewelry, engraved with the patient's name, the words "Radioactive Pacemaker," the trefoil radiation symbol, identification of the radionuclide, and the words "In case of emergency, hospitalization, or death, call collect (telephone number)."

e. Long-term follow-up examinations are necessary, and they will be scheduled by the participating medical institution.

f. The hospital must be informed of any change in the patient's address or telephone number or if there is a change in regard to the persons to be contacted in case the patient cannot be located.

g. The patient must notify, through the hospital and sponsor, the appropriate licensing authority prior to any travel outside of the United States.

Copies of the forms and identification cards and a sample or replica of the bracelet shall be furnished as part of each application or may be included in the standard protocol and thereby incorporated by reference in applications.

15. All hospital records concerning nuclear pacemakers, implantations, and follow-ups, or copies thereof, shall be maintained separately from routine hospital records.

C.3 LICENSING OF PARTICIPATING INSTITUTIONS

During the investigational phase of nuclear pacemaker use, licenses are being issued only to medical institutions that can assure continuity of follow-up of patients with implanted pacemakers, rather than to individual physicians. A license issued to a medical institution authorizes a specified possession limit of special nuclear material (plutonium fuel) or by-product material (promethium) contained in pacemakers and requires the licensed institution to be responsible for the follow-up and recovery of the nuclear pacemakers implanted in patients under the license. The physicians designated as the responsible investigators by the medical institution should have substantial experience with pacemakers in the specialities of cardiology and thoracic surgery. The medical institution is expected to have an established program and appropriate facilities for the implantation and follow-up of cardiac pacemakers.

Each application from a medical institution should include the following:

1. Identification of the institution as the applicant.

2. Incorporation of the standard protocol by reference, and a commitment to follow it.

3. For each physician on the study team, name, specialty and board certification, previous experience in the implanation and follow-up of pacemakers, including specific information on the duration and number of pacemakers implanted and/or followed, and the position of the physician with the applicant.

4. A description of the applicant's present pacemaker implantation and follow-up program including size, duration, and types of implanation.

5. A description of the physical facilities and equipment available for implanation and follow-up, including specific test equipment required to carry out the tests discussed in the protocol.

6. A description of the applicant's procedures for accountability and security against loss of theft of pacemakers before implantation and after removal from patients.

7. A description of the applicant's procedures to assure notification of appropriate individuals within the licensed medical institution upon receipt of a report or inquiry concerning a pacemaker patient, including written instructions given to telephone operators.

8. A procedure for periodically reviewing all implantation and follow-up records on nuclear pacemaker patients and follow-up as necessary to verify that loss of contact with the patient has not occurred.

9. An acknowledgment from the institution administration of their long-term commitment to and responsibility for the follow-up and recovery of nuclear pacemakers.

The instructions furnished to licensees by the sponsor shall include details on packaging, labeling, and shipping nuclear pacemakers for return to the sponsor. Include a copy with investigational plan.

C.4 REPORTS

The sponsor shall tabulate the data and observations received from the investigators into a report to his licensing agency at least every six months during the licensed investigation. The reports shall include information needed to correlate the duration of satisfactory performance or the time of service before malfunction, and the nature of malfunction, with the type of implantation for both pacemakers and each type of lead used with pacemakers.

Appendix D

PROPERTIES OF PLUTONIUM-238 AND FABRICATION OF PLUTONIUM SOURCES

D.1 INTRODUCTION

Plutonium power sources used in cardiac pacemaker applications are designed to conform with safety performance requirements identified in Sections 1 and 2 of the Nuclear Energy Agency standards, as well as NRC standards and criteria, so that the safe containment of fuel and minimal external radiation levels are assured.

D.2 CHARACTERISTICS OF PLUTONIUM-238 PACEMAKER FUEL

Plutonium-238 is a man-made radioactive element that is useful as a heat source because of the conversion of energy from radioactive decay to heat by self-adsorption of the alpha particles within the plutonium source. Alpha particles of up to 5.5 MeV energy[1] are emitted at a rate of 600 billion per second per gram by plutonium-238 in its radioactive decay (half-life: 87.8 years)[2] to uranium-234 (240,000-year half-life), which in turn decays by alpha-particle emission to thorium-230. The specific thermal power and specific activity for plutonium-238 are 0.56 W/g and 17.2 Ci/g respectively.[3]

Kilogram quantities of plutonium-238 are routinely produced by neutron irradiation of neptunium target material that has previously been separated from fission products. The nuclear reaction for production of plutonium-238 is as follows:

$$^{237}Np + n \rightarrow {}^{238}NP \xrightarrow{\beta} {}^{238}Pu$$

The irradiation of neptunium also produces other isotopes of plutonium. The specifications for the high-purity plutonium-238 used for pacemaker sources are: (1) not less than 89% plutonium-238 and (2) not more than 0.6 part plutonium-236 per million.

Plutonium-236 is the principal contaminant in plutonium-238 because of its contribution of up to half of the gamma radiation from pacemaker sources. The abundance of plutonium-236 in the product varies with the conditions of irradiation of the neptunium target material.

Plutonium-236 (half-life: 2.8 years) decays to uranium-232, an alpha emitter with a 72-year half-life. Decay of uranium-232 produces a chain of daughters. One of the daughter products is thallium-208, a 2.6-MeV gamma emitter, which grows in such a rate that its maximum abundance is achieved 18 years after production of the plutonium fuel. Calculations show that, after 10 years, the total radiation dose from a pacemaker would increase by 32 to 41% from the initial rate, due to buildup of plutonium-236 daughter isotopes, and after 18 years a maximum increase of 35 to 60% could be expected.

The following is a typical isotope composition of plutonium used for pacemaker power sources.

Pu isotope	Abundance, wt %
238	90.4
239	9.0
240	0.6
241	0.03
242	<0.01
236	$<6 \times 10^{-5}$[a]

[a]Less than 0.6 ppm.

Because of the low specific activity of plutonium-239 as compared with plutonium-238 (1/280 as much), it is not feasible to use plutonium-239 for a heat source. Therefore, plutonium produced in irradiated fuel of nuclear reactors is not suitable for heat sources for pacemakers.

D.3 RADIATION FROM PLUTONIUM-238 FUEL

Penetrating radiations from plutonium-238 fuels (of the above isotopic composition) are derived primarily from the following sources:[1]

1. neutrons produced by spontaneous fission,
2. neutrons produced by (α,n) reactions in impurities of low atomic number (14 and below),
3. fast neutrons produced by fission,
4. photons from plutonium isotopes and their daughters,
5. photons that result from alpha-particle reactions with impurity elements of low atomic number.

Neutron emission rates are associated with the spontaneous fission of plutonium-238 and -240 and are 2785 neutrons sec^{-1} g^{-1} and 1020 neutrons sec^{-1} g^{-1} respectively. Therefore, the neutron dose rate will essentially decrease exponentially with time as the plutonium-238 decays.

Neutrons resulting from (α,n) reactions depend on the other elements present and their concentrations. The important elements in this respect are lithium, beryllium, boron, carbon, oxygen, fluorine, sodium, magnesium, aluminum, and silicon. The (α,n) contribution in present production-grade plutonium-238 dioxide, containing ordinary oxygen, is approximately 12,000 neutrons sec^{-1} g^{-1}. These neutrons are nearly eliminated by exchanging the oxygen-17 and -18 atoms with enriched oxygen-16, using established chemical techniques.

Gamma rays accompany the alpha decay of plutonium-238 and account for most of the gamma radiation observed from isotopically pure plutonium-238. This gamma activity is intense (6.7×10^{10} photons g^{-1} sec^{-1}) but, because of its generally low energy (0.017 MeV), is easily shielded.

As indicated above, the principal gamma radiation from plutonium heat sources is from the daughter products of the plutonium-236 contaminant.

D.4 RADIATION FROM A PACEMAKER

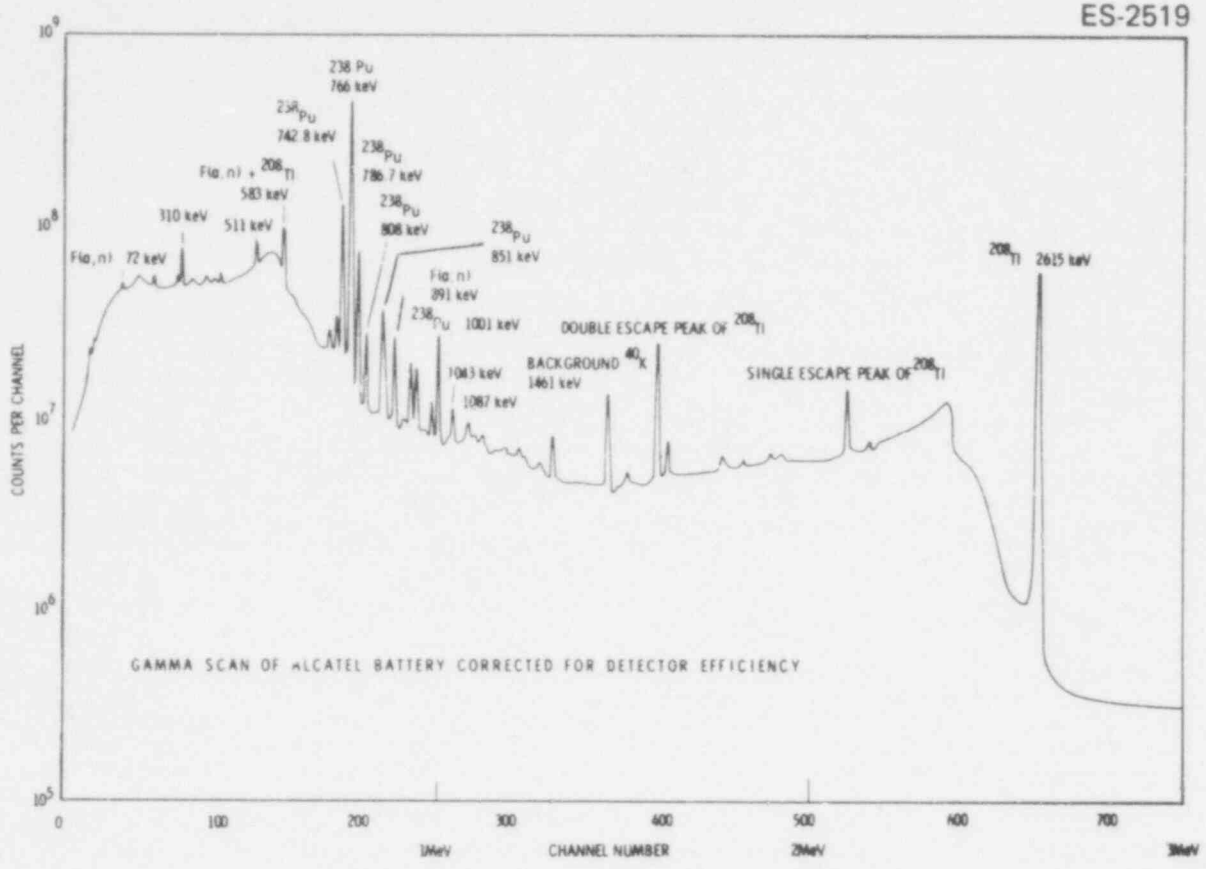
The photon energy spectrum measurements of a nuclear-powered pacemaker[4] were made with a lithium-drifted germanium [Ge(Li)] semiconductor detector. The 20-cm^3 detector was large enough to have moderate efficiency in the MeV energy range and had a thin beryllium window so that fluorescent x rays from shielding material could be detected. For the spectrum measurements, the battery and pulse generator were placed on a plastic tower (for low scattering) 2 in. above the face of the detector. The Ge(Li) detector had been previously calibrated using several sets of standard gamma-ray sources provided by the International Atomic Energy Agency (IAEA), so that the absolute photon intensity could be measured for sources at various positions on the plastic tower. A 1024-channel analyzer was used to collect data over a range of 0 to 4 MeV, and a computer program was written to correct for detector efficiency and to plot the spectra.

The two gamma spectra presented in Fig. D.1 show the gamma spectrum through the side of a pacemaker battery and the flat side of the pulse generator containing the same battery. The gamma-ray spectrum results from the decay of plutonium-238, the daughters of plutonium-236, and other impurities in pacemaker sources. The tantalum and platinum-iridium capsules effectively remove all of the lower energy photons below about 150 keV. The highest energy observed was the 2.615-MeV photopeak from thallium-208, a decay product of plutonium-236. This photopeak contributes more to the dose than any other single photopeak (approximately one-third of the total dose). These spectra have been corrected for detector efficiency, and the area under the photopeak is proportional to the photon intensity. Photopeaks observed at 72, 583, and 891 keV may arise from $F(\alpha,n)$ reactions and suggest the presence of low atomic number impurities. The photopeaks observed at 300 and 312 keV arise from proactinium-238, the daughter of neptunium-237 (the target material for the production of plutonium-238).

Most of the neutrons arise from the spontaneous fission of plutonium-238. These neutrons have a Maxwellian distribution in energy: a modal energy of about 0.8 to 0.9 MeV, an average energy of about 2.0 to 2.1 MeV, and a long "tail" up to about 15 MeV. Neutrons arising from (α,n) reactions from low atomic number impurities also have energies in this range; for example, the $F(\alpha,n)$ reaction has an energy of 1.4 MeV. Since the plutonium-238 sources are very small and have a low neutron yield, direct measurements are tedious and subject to error.

621 227

ES-2519



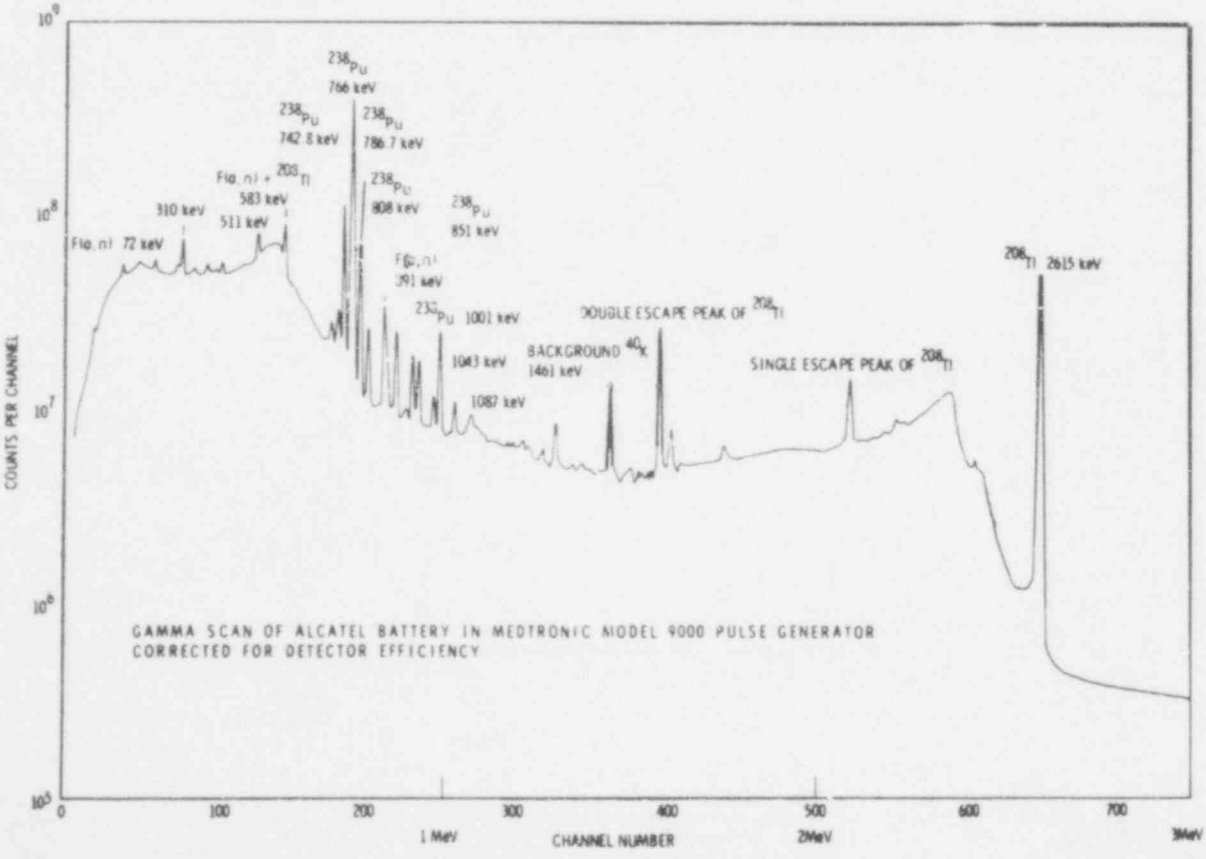


Fig. D.1. Gamma scan of a pulse generator.

The largest reduction of neutron intensity was in the directions of the most hydrogenous plastic (epoxy) shielding. A nearly isotropic neutron emission is suggested. The neutron emission rate calculated for the nuclear-powered pacemaker was 716 neutrons/sec. The battery contained 160 mg of plutonium-238, giving a specific neutron yield of 4590 neutrons sec^{-1} g^{-1}, which is about 75% higher than the yield from pure plutonium-238, as calculated from the rate of spontaneous fission. Because of the uncertainties of the measuring method, the measured value is estimated to be accurate within 10 to 20%.

An in-depth discussion of the patient radiation doses from plutonium-powered pacemakers can be found in Appendix F.

D.5 PLUTONIUM DIOXIDE FUEL FORM

The fuel form used in plutonium-powered pacemakers is plutonium dioxide, which has been well characterized[1-3,5-9] for use as a heat source. Plutonium dioxide is chemically and metabolically inert and only 1 x 10^{-6} of an ingested quantity is absorbed into the body. Its high melting point (2365 ± 30°C), high chemical stability (heat of formation, 935 ± 10 cal/g at 25°C), and low vapor pressure (heat of vaporization, 493 ± 10 cal/g), together with its hardness (approximately 850 DPH) and strength (approximately 14,000 psi tensile strength[10] and 48,000 psi compressive strength[11]), make the use of plutonium dioxide intrinsically consistent with good safety design practices.[12] A compact of the plutonium-238 dioxide is used since the power density is low for powder (about 1 W/cm^3) and high for pellets (about 4.2 W/cm^3).

D.6 SOURCE FABRICATION

Using well-established technology, plutonium heat sources are fabricated by commercial vendors using cold pressing and sintering techniques (to approximately 1500°C) to form a tough ceramic pellet that is highly resistant to abrasion. Most pellets are cylindrical with dimensions approximately 1/4 by 1/4 in. This pellet is encapsulated in a refractory metal, generally tantalum or a tantalum-base alloy. A void space is provided in the capsule to accommodate the helium that is generated from the decay of the plutonium. The capsule material is chosen on the basis of its strength, shielding characteristics, and compatibility[13] with the fuel. A second and possibly a third encapsulation of the fuel are accomplished with materials selected to provide resistance to corrosion and oxidation. All envelopes are sealed by welding techniques such as tungsten inert gas or electronic beam.

Thermoelectric power generators (nuclear batteries) operate on the principle that an electric current will be generated by a thermocouple or thermopile if there is a temperature difference between two junctions. Heat for the hot junction is provided by the fuel pellet. Nuclear-powered pacemaker batteries typically use dissimilar semiconductive materials, $Bi_2Te_3$80:$Bi_2Se_3$20 (negative "n") and $Bi_2Te_3$30: $Sb_2Te_3$70 (positive "p"), which provide electrical energy through the Seebeck effect. The "n" and "p" thermoelectric interconnects consist of small metallic strips, which are firmly attached across electrical insulators that physically separate the elements. One bimetallic thermocouple system that is used consists of Cupron (Ni-Cu alloy) and Trophel (Ni-Cr alloy) fabricated into thermocouples in a series with parallel configuration. A temperature difference of approximately 60°C is maintained between the hot and cold junctions.

Highly efficient thermal insulation surrounds the thermoelement and channels the flow of heat across the two junctions. The output of the nuclear battery is in the range of 250 to 600 μW. The battery generally is contained in a titanium housing and is sealed by welding. Since the heat loss from the battery to the body is low, there is no significant difference between the surface temperature of the pacemaker housing and the temperature of the body.

REFERENCES FOR APPENDIX D

1. G. M. Matlack and C. F. Metz, *Radiation Characteristics of Plutonium-238*, Report LA-3696, Los Alamos Scientific Laboratory, 1967.

2. T. K. Keenan, R. A. Kent, R. N. Mulford, and M. W. Shupe, *Data Sheets for PPO Radioisotopic Fuel*, Report LA-5160 MS, Los Alamos Scientific Laboratory, 1973.

3. W. H. Smith et al., *Plutonium-238 Isotopic Fuel Form Data Sheets*, Report MLM-1961, Monsanto Research Corporation, October 1969.

4. L. W. Brackenbush, G. W. R. Endres, and B. I. Griffin, *Radiation Doses from the Medtronic Laurens-Alcatel Model 9000 Pulse Generator*, Report 2311201653, Amendment 2, Pacific Northwest Laboratories, October 1973.

5. R. N. R. Mulford and B. A. Mueller, *Measurement of Helium Release from Materials Containing $^{238}PuO_2$*, Report LA-5215, Los Alamos Scientific Laboratory, 1973.

6. L. J. Mullins, *Preparation and Evaluation of Medical-Grade Plutonium-238 Fuel*, Report LA-5506 PR, Los Alamos Scientific Laboratory , 1974.

7. W. J. Lindsey, P. L. Roggenkamp, and W. K. Woods, "Production of ^{238}Pu with Minimum ^{236}Pu Contamination," *Trans. Am. Nucl. Soc.*, 11: 496 (1970).

8. *ARCO Nuclear Technical Document*, Report 032974, ARCO Nuclear Company, April 15, 1974.

9. W. N. Miner, Ed., "Plutonium 1970 and Other Activities," *Nuclear Metallurgy*, Vol. 17, parts I and II (1970).

10. R. F. Cannon, J. T. A. Roberts, and R. J. Beals, "The Mechanical Properties of Uranium Dioxide," *J. Am. Cer. Soc.*, Vol. 54, p. 105 (February 1971).

11. Letter to Materials Branch from S. S. Hecker, Los Alamos Scientific Laboratory, dated August 26, 1974.

12. G. A. Graves, "Nuclear Safety in Nuclear Power Propulsion Devices for Space," *Astronautica Acta*, Vol. 18, pp. 99-111, Pergamon Press (1974).

13. J. E. Selle, J. J. English, P. E. Teaney, and J. R. McDougal, *The Compatibility of $^{238}PuO_2$ with Various Refractory Metals and Alloys*, Report MLM-1706, Mound Laboratory, October 23, 1973.

Appendix E

STATISTICAL EVALUATION OF THE PERFORMANCE OF NUCLEAR-POWERED CARDIAC PACEMAKERS

E.1 INTRODUCTION

Procedures have been developed for evaluating the reliability of nuclear-powered pacemakers using information on clinical experience obtained from the investigational programs. These evaluation procedures, based on statistical techniques, provide a systematic means to determine the acceptability or nonacceptability of nuclear pacemakers as rapidly as possible. Suitable criteria are met when it is established, with a high degree of confidence, that the failure rate of nuclear units is less than or equal to an acceptable standard.

For the investigational program, a limitation is imposed on the monthly implantation rate, which is aimed at controlling the number of units in circulation until routine use is authorized. Also, constraints are placed on the number of pacemaker-patient-months that are allotted to any one manufacturer for the evaluation of the performance of his units.

Computer programs were developed for the Commission (by Drs D. Kleitman and A. Barnett, of the Massachusetts Institute of Technology; D. Rosenbaum of Mitre Corporation; and B. Singer, of Columbia University) to evaluate pacemaker performance. These programs require as input the following predetermined parameters: The maximum acceptable failure standard, R; the confidence level on the maximum acceptable failure standard, P; the total accumulated number of pacemaker-patient-months in which a decision must be reached, T; a desired confidence level to terminate a unit's evaluation due to an excessive number of pacemaker failure's, C, and a parameter concerned with determining whether pacemakers are failing at a constant rate, α. The output from these programs provides the information necessary to determine whether one of the following circumstances exists:

(1) There is a high degree of confidence (P) that the unit's failure rate is less than the acceptable standard (R), and the test can be discontinued because acceptability is demonstrated.

(2) The number of device failures has become so large that, with a high degree of confidence (C), pacemaker acceptability cannot be demonstrated, even if the investigation is run to conclusion. In this case, the test should be discontinued and this pacemaker model removed from further implanting.

(3) Not enough data has been collected to establish one of the above conditions and the experiment should continue.

For purposes of this evaluation, a pacemaker is considered to fail if, for any reason, the pacemaker needs to be removed and/or replaced because of failure to provide satisfactory pacing to the patient.

E.2 PLAN FOR STATISTICAL TESTING

Acceptability of pacemaker performance is based on the failure pattern of the devices undergoing clinical tests. If pacemaker failures occur at random intervals (from the date of implantation), a constant failure rate model can be used to set the acceptable failure standard. It is also important to know whether there is evidence for any increase with time in the failure rate for any one pacemaker model. A statistical test for significant deviations from a constant failure rate is given in Sect. E.3.

The "confidence interval criterion" is used to determine pacemaker acceptability. Success is determined at time T if it can be deduced from the data, with confidence level P, that the failure rate of the unit is less than or equal to R. If the evaluation of the other data should reveal an excessive failure rate for the unit, implantation of the devices is to be halted. This does not imply that implanted devices should be removed.

E.2.1 Computer program for test analysis and stop test criteria

This computer program for pacemaker test analysis and stop test criteria, requires, as inputs, the maximum number of trials (pacemaker-months) allowed in the test; the maximum allowed failure

rate of the pacemaker being tested (in failures per pacemaker-month); the minimum allowed probability that the pacemaker has a failure rate less than or equal to the maximum failure rate allowed; and, the smallest P(T,S,:Q,F) allowed (note: $P(T,S:Q,F) \leq 1 - C$).

An example of input and output data for this program are given in Tables E.1, E.2, and E.3.

Table E.1. Sample input data

Maximum allowed failure rate (pacemaker failures per month)	0.00150
Minimum allowed probability that pacemaker has failure rate less than or equal to maximum allowed	0.90000
Smallest P(T,S:Q,F) allowed	0.05000
Maximum pacemaker months of test	25,000

Table E.2. Sample output data

Probability that the failure rate is less than or equal to the maximum allowed rate	Number of failures in 25,000 pacemaker-maker-months
1.00000	0
1.00000	1
1.00000	2
1.00000	3
1.00000	4
1.00000	5
1.00000	6
1.00000	7
1.00000	8
1.00000	9
1.00000	10
1.00000	11
1.00000	12
1.00000	13
0.99999	14
0.99997	15
0.99993	16
0.99985	17
0.99967	18
0.99932	19
0.99868	20
0.99753	21
0.99557	22
0.99239	23
0.98743	24
0.97998	25
0.96923	26
0.95430	27
0.93429	28
0.90839	29
0.87599	30

The program prints out, ordered by numbers of failures, a table (Table E.3.) that tells at each reporting period whether to stop the test because the pacemaker has passed or failed or whether to continue. The printout should be used as follows. At the end of each reporting period, which might be monthly for example, one looks along the row beginning with the total number of failures up to that point. If the number of pacemaker-months up to that point is less than the number listed in the column entitled "minimum pacemaker-months justifying continuance," then the test is judged a failure and should be stopped. If the number of pacemaker-months up to that point is at least as large as the number listed in the column entitled "minimum pacemaker-months justifying success," then the test is judged a success and should be stopped. If the number of

pacemaker-months up to that point lies between the two minimum numbers, then not enough data has been collected to come to a decision, and the test should be continued. The other two columns give the actual values of the relevant parameters.

Table E.3. Sample output from program for pacemaker test analyses and stop test criteria

Actual number of failures	Minimum pacemaker months justifying continuance	Calculated P(T,S:Q,F)	Minimum pacemaker months justifying success	Probability that failure rate is less than or equal to maximum allowed for minimum pacemaker months justifying success
0	0	1.00000	1534	0.90001
1	45	0.05093	2592	0.90004
2	311	0.05024	3547	0.90005
3	721	0.05009	4453	0.90009
4	1214	0.05002	5328	0.90008
5	1764	0.05006	6181	0.90000
6	2356	0.05008	7020	0.90007
7	2981	0.05003	7845	0.90001
8	3635	0.05003	8661	0.90002
9	4314	0.05005	9469	0.90006
10	5015	0.05005	10269	0.90004
11	5736	0.05004	11063	0.90002
12	6476	0.05003	11852	0.90003
13	7234	0.05001	12636	0.90002
14	8010	0.05003	13416	0.90002
15	8803	0.05004	14192	0.90001
16	9612	0.05000	14965	0.90003
17	10439	0.05001	15735	0.90005
18	11284	0.05004	16501	0.90001
19	12146	0.05002	17265	0.90000
20	13027	0.05000	18027	0.90002
21	13929	0.05001	18786	0.90000
22	14854	0.05004	19544	0.90004
23	15803	0.05003	20299	0.90002
24	16781	0.05003	21052	0.90000
25	17793	0.05001	21804	0.90002
26	18849	0.05003	22554	0.90001
27	19963	0.05001	23303	0.90003
28	21167	0.05001	24050	0.90003
29	22548	0.05002	24795	0.90000

E.2.2 Stopping tests prior to completion

This Section discusses the problem of when to stop the test if the device is obviously failing. Let T be the total number of device-months in the total test schedule and S the maximum allowable number of failures that the pacemaker could sustain in T device-months. Then, one crude test would be to stop the test whenever the (S+1)st failure occurs. However, if S pacemakers were implanted the first month, and all failed immediately, the criterion would still indicate that the test should continue. Therefore, a more sensitive criterion is clearly required.

Consider the situation in which F pacemakers have failed in the first Q pacemaker-months. Assume that there are exactly S failures in the total T pacemaker-months. Then, the probability [P(T,S:Q,F)] that there could be F or more failures in the first Q pacemaker-months purely at random can be expressed as follows:

$$P(T,S:Q,F) = \left(1/\binom{T}{S}\right) \sum_{j=F}^{L(S,Q)} \binom{Q}{j}\binom{T-Q}{S-j}, \qquad (E.1)$$

where L(S,Q) is the smaller of S and Q. If this probability is low enough, less than 5% for example, the test will be considered to be unsuccessfully concluded. The lowest acceptable value of P(T,S:Q,F) must be supplied to the computer program.

E.2.3 Determining the confidence that the failure rate does not exceed R

Let Q be the total number of pacemaker-months. Then, if F is the number of failures in this period, it can be said, with confidence C, that the failure rate is no greater than R if

$$\sum_{j=0}^{F} \binom{Q}{j} (1 - R)^{Q-j} R^{j} \leq 1-C \quad . \tag{E.2}$$

The sample output data given in Table E.3 also shows the confidence level in the last column.

E.3 TESTING THE STATISTICAL ASSUMPTION

This entire analysis of pacemaker test data is based upon the assumption of a constant failure rate. The resultant decisions on passing or failing the test are sensitive to this assumption. It is, therefore, important to monitor the data to determine whether there is any significant evidence of deviation from a constant failure rate, particularly if the evidence indicates an increasing failure rate.

Suppose r pacemakers fail up to some point in time T at ages a_1, ... a_r, with $a_j \leq a_{j+1}$. Each of the pacemakers used has been in service a certain unit of time. For each pacemaker, one can calculate a set of numbers X_1, .., X_r, where X_j is the total number of months the pacemaker was in service between its ages a_{j-1} and a_j, (a_0=0). This number will be 0 if the device did not attain an age over a_{j-1} during the experiment, $a_j - a_{j-1}$ if it survived up to a_j, and $w-a_{j-1}$ if it was w units old at the point of testing (T) of the test, with $a_{j-1} < w < a_j$. Summing over all devices, one may compute r numbers, S_1, S_2, .. S_r as the total number of pacemaker months of service in each age class.

Since it is assumed that the failure rate of the pacemakers does not change with age, the numbers S_1, S_2, ..S_r should be neither systematically increasing nor decreasing. This does not mean, however, that these should be identical, since the Poisson assumption itself allows for the random ages at which individual pacemakers fail. Correlation between the values of S_j and j must be identified, and whether such a correlation is too great to be caused by normal fluctuations in Poisson distributions must be determined.

If S_j tends to decrease as j increases (with increasing service life), failures are getting closer together and the devices have an increasing failure rate. Such an effect can be tested by examining the behavior of G(r) as follows:

$$G(r) = \frac{\sum_{j=1}^{r} S_j(r-j)}{\sum_{j=1}^{r} S_j} \tag{E.3}$$

G(r) is a weighted average of the S_j's with S_1 multiplied by (r-1), S_2 by (r-2), $S_{(r-1)}$ by 1, etc. Note that the S_j's for lower j are weighted more heavily in this average.

If the Poisson hypothesis is correct, the average of this ratio is expected to be r-1/2. If S_j is decreasing for rising j, since the weighted average counts the earlier S_j's more heavily, the first S_j's furnish a disproportionate part of the sum and G(r) will increase above its expected values r-1/2. If G(r) is found to be well above its expected value, it suggests a systematic tendency toward more frequent failures among older pacemakers.

When the likelihood is sufficiently great, the assumption of a constant failure rate should be examined to determine whether some other assumption might be more compatible with the data.

A standard method of testing for deviations from a Poisson distribution is as follows:

The mean value u, of G(r), is given by u = (r-1)/2;

The variance of G(r), σ^2, is given by

$$\sigma^2 = \frac{(r-1)}{12} \tag{E.4}$$

The parameter (α) represents the point at which one rejects the hypothesis of constant failure rate. Typically the hypothesis might be rejected if the observed value of G(r) exceeded its mean by 2 standard deviations (2σ) or more; this would correspond to α near 0.05.

The constant failure rate is rejected when

$$\text{erfc}[(G(r)-\mu)/\sigma] \geq 1-\alpha \quad ,$$

where

$$\text{erfc}\ (x) \equiv (2\pi)^{-1/2} \int_{-\infty}^{x} e^{-y^2/2} dy \quad .$$

E.3.1 Computer program for testing the assumption of a constant failure rate

This section discusses a computer program for testing the assumption of a constant failure rate. The program requires, as input, the probability (α) that the hypothesis of constant failure rate will be rejected when it is, in fact, valid; the date of implantation for each pacemaker; the dates of failure (for those pacemakers that have failed); the date of removal from the patient (for those pacemakers that have been removed without failing); and the date (T) of evaluation of data. A sample input is shown in Table E.4.

Table E.4. Example of input parameters

Statistical Analysis for Constancy of Failure Rate as of 74-5-11

Pacemaker serial no.	Date implanted	Date removed, failed, or present date	Days of service
1	73-1-11	74- 4- 1	000446
2	73-1-20	74- 2-15	000390
3	73-2-10	74- 5-11	000457
4	73-3-17	74- 4- 8	000386
5	73-4- 8	74- 5-11	000398
6	73-7- 5	73-10- 1	000087
7	74-1-13	74- 2- 1	000018
8	74-2-10	74- 5-11	000092
9	74-1-20	74- 3- 1	000041
10	74-3- 1	74- 5-11	000070

10 devices in file

Failures

Pacemaker serial no.	Date implanted	Date failed	Days of service
7	74-1-13	74- 2- 1	000018
9	74-1-20	74- 3- 1	000041
4	73-3-17	74- 4- 8	000386
2	73-1-20	74- 2-15	000390
1	73-1-11	74- 4- 1	000446

Removals

Pacemaker serial no.	Date implanted	Date removed	Days of service
6	73-7- 5	73-10- 1	000087

For each pacemaker, the program gives the following output (ordered by device serial number): the date installed; the date removed or failed; and the total days of service as of the date of data evaluation. It also lists separately the same data (ordered by days of service) for those pacemakers that have failed and those that have been removed without failing. Finally, the program lists the pacemaker-days in each interval class (S_j) and the value of $\text{erfc}[(G(r)-\mu)/\sigma]$. Unless this value is less than $1-\alpha$ the hypothesis of constant failure is rejected. The following is an example of the computer output, using the input data listed in Table E.4:

5 = R = Failures before test end
1 = Removals before test end
2.0000 = (R-1)/2
2.1310 = G(R)
0.3333 = Variance of G(R)
0.590 = ERFC

Pacemaker days in interval classes:

180.0 207.0 1851.0 16.0 120.0

Alpha is the probability of rejecting the hypothesis of constant failure rate when it is in fact valid. Alpha is an input that would typically be 0.05 so that, in this case, one would not reject the constant failure hypothesis.

E.4 SAMPLE PRINTOUT OF THE MAIN COMPUTER PROGRAM

```
//B1211567 JOB (1211,5672),'M.W.SHUPE      X7463U',MSGLEVEL=1,CLASS=F
//              EXEC FORTHCLG,PARM.FORT='BCD,OPT=2',REGION=240K,TIME=10
//FORT.SYSIN    DD *
C  PACEMAKER EXPERIMENTAL TEST ANALYSIS AND STOP TEST CRITERIA
C PROGRAM TO MONITOR  NT TRIALS FOR SUFFICIENT FAILURES TO JUSTIFY STOPPPING EXP
C OR SUFFICIENT LACK OF FAILURES TO CONCLUDE  EXPERIMENT IS SUCCESSFUL
      IMPLICIT REAL*8(A-H,O-Z)
      COMMON DFACT(25001)
      DATA NBLK/' '/
      DATA NST/'*'/
      CALL ERRSET(209,256,-1,1)
      CALL ERRSET(208,256,-1,1)
      CALL ERRSET(207,256,-1,1)
      DFACT(1)=0.0D+00
      DO 10 I=2,25001
      AI=I
   10 DFACT(I)=DFACT(I-1)+DLOG(AI)
  505 CONTINUE
      READ(5,100,END=900)   RSPEC,CONF,PSUCC,NTEE
  100 FORMAT(3F10.0,I10)
      PRINT 101,RSPEC,CONF,PSUCC,NTEE
      IF(NTEE.GT.25000) STOP
  101 FORMAT(1H1,10X,'INPUT DATA',// ,1H ,'MAXIMUM ALLOWED FAILURE RATE'
     1    ,T53,F13.5,/,1H ,'MINIMUM ALLOWED PROBABILITY THAT DEVICE HAS F
     2AILURE',/,1H ,'RATE LESS THAN OR = MAX ALLOWED',T53,F13.5,
     3              /,1H ,'SMALLEST P(T S Q F) ALLOWED',T53,F13.5,
     C/,1H ,'MAXIMUM TRIALS OF TEST',T53,I13)
      PRINT 510,NTEE
  510 FORMAT(/,1H0,'PROBABILITY THAT THE FAILURE RATE IS',T45,'IF THE NU
     1MBER OF',/,1H ,'LESS THAN OR EQUAL TO THE MAXIMUM',T45,'FAILURES I
     2N',/,1H ,'ALLOWED RATE IS',T45,I5,'  TRIALS IS')
      NS=0
  103 CALL ROSE1(RSPEC,CALCON,NS,NTEE)
      PRINT 110,CALCON,NS
  110 FORMAT(1H ,10X,F9.5,T50,I7)
      IF(CALCON.LE.CONF)  GO TO 102
      NOLD=NS
      OLD=CALCON
      NS=NS+1
      IF(NS.GT.NTEE*RSPEC)  GO TO 104
      GO TO 103
  104 PRINT 105
  105 FORMAT(1H ,'FAILURE IN ROSE1')
      GO TO 505
  102 CONTINUE
      CALCON=OLD
      NS=NOLD
      NNS=NS+1
      PRINT 108
  108 FORMAT(1H1,@ACTUAL@,T15,@MINIMUM@,T30, @CALCULATED@,T47,@MINIMUM@,
     1T61,'PROBABILITY',/,1H ,'NUMBER',T15,'TRIALS'      ,T30,'P(T S Q F)
     2',T47,'TRIALS',T61,'FAILURE RATE',/,1H ,'OF',T15,'JUSTIFYING',T30,
     3'AFTER TRIALS',T47,'JUSTIFYING',T61,'LESS OR =MAX',/,1H ,'FAILURES
     4',T15,'CONTINUANCE',T30,'IN PREV COL',T47,'SUCCESS',T61,'ALLOWED F
     5OR',/,1H ,T61,'MINIMUM TRIALS',/,1H ,T61,'JUSTIFYING',/,1H ,T61,'S
     6UCCESS')
      DO 206 I=1,NNS
      NF=I-1
      IF(NF.NE.0)  GO TO 405
      NQ=0
      CALSUC=1.0
```

621 237

```
      GO TO 704
405   CONTINUE
      ITER=0
      NFIN1=NBLK
      NUPPER=NTEE
      NLOWER=0
404   NQ =(NUPPER+NLOWER)/2
208   CALL ROSF2(CALSUC,NF,NQ,NS,NTEF)
      IF(NUPPER-NLOWER.LT.4)  GO TO 207
      IF(DABS(CALSUC-PSUCC).LT..001)  GO TO 207
      IF(ITER.GT.50)  GO TO 704
      ITER=ITER+1
      IF(CALSUC.GT.PSUCC)  GO TO 401
      NLOWER=NQ
      GO TO 404
401   NUPPER=NQ
      GO TO 404
704   NFIN1=NST
1001  FORMAT(1H ,3I8,3D18.8)
207   CONTINUE
      IF(NFIN1.NE.NBLK)  GO TO 550
      ISET=1
      IF(CALSUC.GT.PSUCC)  ISET=-1
      DELT=CALSUC-PSUCC
      DO 506 II=1,NTEE
      IF(NQ.LE.NF.OR.NQ.GE.NTEE)  GO TO 550
      NQ=NQ+ISET
      CALL ROSF2(CALSUC,NF,NQ,NS,NTEF)
      IF((CALSUC-PSUCC)/DELT.GE.0.000)  GO TO 506
      GO TO 507
506   CONTINUE
507   CONTINUE
      IF(ISET.EQ.-1) NQ=NQ+1
      CALL ROSF2(CALSUC,NF,NQ,NS,NTEF)
550   CONTINUE
      NFIN2=NBLK
601   ITER=0
      NUPPER=NTEE
      NLOWER=0
703   NNQ=(NUPPER+NLOWER)/2
210   CALL ROSF1(RSPEC,CALCON,NF,NNQ)
      IF(NUPPER-NLOWER.LT.4)  GO TO 209
      IF(DABS(CALCON-CONF).LT..001)  GO TO 209
      IF(ITER.GT.50)  GO TO 701
      ITER=ITER+1
      IF(CALCON.GT.CONF )  GO TO 702
      NLOWER=NNQ
      GO TO 703
702   NUPPER=NNQ
      GO TO 703
701   NFIN2=NST
209   CONTINUE
      IF(NFIN2.NE.NBLK)  GO TO 551
      ISET=1
      IF(CALCON.GT.CONF)  ISET=-1
      DELT=CALCON-CONF
      DO 508 II=1,NTEE
      IF(NNQ.LE.NF.OR.NNQ.GE.NTEF)  GO TO 551
      NNQ=NNQ+ISET
      CALL ROSF1(RSPEC,CALCON,NF,NNQ)
      IF((CALCON-CONF)/DELT.GE.0.000)  GO TO 508
```

```
      GO TO 509
  508 CONTINUE
  509 CONTINUE
      IF(ISET.EQ.-1)  NNQ=NNQ+1
      CALL ROSE1(RSPEC,CALCON,NF,NNQ)
  551 CONTINUE
      PRINT 211,NF,NQ,CALSUC,NFIN1,NNQ,CALCON,NFIN2
  211 FORMAT(1H ,I4,5X,I8,4X,F10.5,A1,4X,I8,7X,F10.5,A1,4X,218)
  206 CONTINUE
      GO TO 505
  900 STOP
      END
      SUBROUTINE ROSE2%P,NF,NQ,MS,NT<
      IMPLICIT REAL*8(A-H,O-Z)
      COMMON DFACT(25001)
      DIMENSION NS%1<
      I=1
      NS%1<=MS
      P=0.0D+00
      MIN=NS(I)
      IF(NQ.LT.MIN) MIN=NQ
      IF(NT-NQ.LT.NS(I)-NF) GO TO 40
      IF(NF.GT.MIN) GO TO 40
      MIX=NF+1
      MAX=MIN+1
      DO 50 JJ=MIX,MAX
      J=JJ-1
      P=P+DEXP(FACT(NS(I))+FACT(NT-NS(I))-FACT(NT)-FACT(J)-FACT(NQ-J)
     X+FACT(NQ)-FACT(NS(I)-J)-FACT(NT-NQ-NS(I)+J)+FACT(NT-NQ))
   50 CONTINUE
   51 FORMAT(1H ,3I9,2D18.10)
   40 CONTINUE
      IF(P.LT.0.0) P=0.0
      RETURN
      END
      FUNCTION FACT(II)
      IMPLICIT REAL*8(A-H,O-Z)
      COMMON DFACT(25001)
      FACT    =0.0
      IF(II.LE.1) RETURN
      FACT    =DFACT(II)
      RETURN
      END
      SUBROUTINE ROSF1%X,PR,NF,NQ<
      IMPLICIT REAL*8(A-H,O-Z)
      ERF(D)=DERF(D)
      PR=0.0
      CON=2.0/9.0
      A=NF+1
      B=NQ-NF+1
      IF(NQ.LT.15)  GO TO 400
      DISC=(A+B-1.0)*(1.0-X)
      IF(DISC.GT..8) GO TO 201
      CHISQ=DISC*(3.0-X)-(1.0-X)*(B-1.0)
      ANU=2.0*B
      IF(ANU.LT.50.0) GO TO 200
      X=((CHISQ/ANU)**(1.0/3.0)-(1.0-CON/ANU))
     C/DSQRT(CON/ANU*2.0)
      PR=.5-DERF(X )*.5
      GO TO 202
  201 CONTINUE
```

```
      EG1=(B*X)**(1.0/3.0)
      EG2=(A*(1.0-X))**(1.0/3.0)
      Y=1.5*(EG1*(1.0-1.0/9.0/B)-EG2*(1.0-1.0/9.0/A))/
     C(EG1*EG1/B+EG2*EG2/A)**.5
      Y=Y*DSQRT(2.0D+00)
      PR=.5*(1.0+ERF(Y))
  202 CONTINUE
  200 CONTINUE
      IF(PR.LT.0.0)  PR=0.0
      RETURN
  400 CALL ROSE4(X,PR,NF,NQ)
      RETURN
      END
      SUBROUTINE ROSE4(X,PR,NF,NQ)
      IMPLICIT REAL*8(A-H,O-Z)
  100 FORMAT(8F10.0)
      PR=0.0D0
      NNF=NF
      MAX=NQ-NNF
      IF(MAX.LT.0)  GO TO 101
      PR=X**(NNF+1)/     (NNF+1)/DEXP(FACT(NQ-NNF))
      IF(MAX.LT.1) GO TO 200
      PHASE=1.0
      DO 103  N=1,MAX
      PHASE=PHASE*(-1.0)
  103 PR=PR+PHASE*X**(NNF+N+1)/ (NNF+1+N)/DEXP(FACT(N)+FACT(NQ-NNF-N))
  200 PR=PR*DEXP(FACT(NQ+1)-FACT(NNF))
      IF(PR.LT.1.0D-05)  GO TO 101
  101 CONTINUE
  300 FORMAT(1H ,D13.5,2I5,D13.5)
      RETURN
      END
/*
//GO.SYSIN DD *
/*
```

E.5 SAMPLE PRINTOUT OF THE COMPUTER PROGRAM FOR TESTING THE ASSUMPTION OF A CONSTANT FAILURE RATE

```
//R1211567 JOB (1211,5572),'M.W.SHOPE      X7465J',MSGLEVEL=1,CLASS=F
//             EXEC FORTGCLG,PARM.FORT='BCD',REGION=170K
//FORT.SYSIN   DD *
      IMPLICIT REAL*8(A-H,O-Z)
      DIMENSION NSER(2000)
      INTEGER*2 NAGE,IPOS,NCODE(2000),NTEMP1(2000,3),NTEMP2(2000,3),
     *IPR(10),NDAYS(2000)
      DIMENSION  NAGE(2000,6),IPOS(2000),SUM(1000) ,NDATE(3)
      DATA IPR/'0','1','2','3','4','5','6','7','8','9'/
      IN=5
      NOUT=6
      DO 101 I=1,1000
  101 SUM(I)=0.0
  100 FORMAT(I6,6I2,2X,I1)
      N=0
      READ 104, NDATE
  104 FORMAT(3I2)
      PRINT 206,NDATE
  206 FORMAT(1H1,     'STATISTICAL ANALYSIS FOR CONSTANCY OF FAILURE RATE
     1 AS OF',3(1X,I2),
     1/,1H0,'DEVICE',T15,'DATE',T30,'DATE REMOVED,',T50,
     *'DAYS OF SERVICE'
     2,/,1H ,'SERIAL NO.',T15,'INSTALLED',T30,'FAILED, OR',
     */,1H ,T30,'PRESENT DATE')
  609 N=N+1
      READ(IN,100,END=900) NSER(N),(NTEMP1(N,J),J=1,3),
     * (NTEMP2(N,J),J=1,3),NCODE(N)
      IPOS(N)=N
      IF(NTEMP2(N,1).NE.0) GO TO 200
      NTEMP2(N,1)=NDATE(1)
      NTEMP2(N,2)=NDATE(2)
      NTEMP2(N,3)=NDATE(3)
  200 NDAYS(N)= 365*(NTEMP2(N,1)-NTEMP1(N,1)) +30.4*(NTEMP2(N,2)-
     *  NTEMP1(N,2))+NTEMP2(N,3)-NTEMP1(N,3)
      NDAYS=NDAYS(N)
  300 DO 103 I=1,6
      M=NDAYS/(10.0**(6-I))
      NDAYS=NDAYS-10**(6-I)*M
      NAGE(N,I)=IPR(M+1)
  103 CONTINUE
      PRINT 208, NSER(N),(NTEMP1(N,J),J=1,3),(NTEMP2(N,J),J=1,3),
     * (NAGE(N,J),J=1,6)
  208 FORMAT(1H0,I8,7X,3(I2,1X), 6X,   3(I2,1X),15X,6A1)
      GO TO 609
  900 N=N-1
      PRINT 207,N
  207 FORMAT(1H0,I8,' DEVICES IN FILE')
      L=6
      KTYP=43
      CALL ASORT(NAGE,IPOS,N,L,KTYP)
      PRINT 601
  601 FORMAT(1H1,///,'  FAILURES',/,
     1 1H0,'DEVICE',T15,'DATE',T30,'DATE FAILED',T51,'DAYS OF SERVICE'
     2,/1H ,'SERIAL NO.',T15,'INSTALLED')
      DO 602 I=1,N
      IF(NCODE(IPOS(I)).NE.1) GO TO 602
      PRINT 208, NSER(IPOS(I)),(NTEMP1(IPOS(I),J),J=1,3),
     * (NTEMP2(IPOS(I),J),J=1,3),(NAGE(IPOS(I),J),J=1,6)
  602 CONTINUE
      NF=0
      PRINT 701
```

```
  701 FORMAT(1H1,///,'  REMOVALS',/,
     11H0,'DEVICE',T15,'DATE',T30,'DATE REMOVED',T51,'DAYS OF SERVICE'
     2,/1H ,'SERIAL NO.',T15,'INSTALLED')
      DO 702 I=1,N
      IF(NCODE(IPOS(I)).NE.2) GO TO 702
      NF=NF+1
      PRINT 208, NSER(IPOS(I)),(NTEMP1(IPOS(I),J),J=1,3),
     * (NTEMP2(IPOS(I),J),J=1,3),(NAGE(IPOS(I),J),J=1,6)
  702 CONTINUE
      NLAST=0
      I=0
      NR=0
  401 I=I+1
      IF(I.GT.N)  GO TO 402
      IF(NCODE(IPOS(I)).NE.1)  GO TO 401
C NCODE =1 MEANS DEVICE FAILED ,0MEANS NEVER FAILED
      NDELT=NDAYS(IPOS(I))-NLAST
      NR=NR+1
      L=NDELT
      DO 303  K=1,N
      L=NDAYS(IPOS(K))-NLAST
      IF(NDELT.LE.L)  L=NDELT
      IF(L.LE.0)  GO TO 303
      SUM(NR)=SUM(NR)+L
  303 CONTINUE
      NLAST=NDAYS(IPOS(I))
      GO TO 401
  400 CONTINUE
  402 CONTINUE
      G=0.0
      ADEN=0.0
      DO 500  J=1,NR
      G=G+SUM(J)*(NR-J)
  500 ADEN=ADEN+SUM(J)
      G=G/ADEN
      AR=NR
      U=((AR-1)/2.0)
C     SIGSQ=U*U*(((AR+1)*8.0*(2*AR-1.0)/AR/(AR-1.0))-1.0)          OLD VERS
C     ZILCH=(G-U)/SIGSQ/DSQRT(2.0D0)                               OLD VERS
      SIGSQ=U/6.0
      ZILCH=(G-U)/DSQRT(SIGSQ*2.0)
      BANS= .5*DERFC(-ZILCH)
      PRINT 403,NR,NF,U,G,SIGSQ,BANS
  403 FORMAT(1H1,///21X,I8,' =R=FAILURES BEFORE TEST END',/,1H ,20X,
     *I8,' =  REMOVALS BEFORE TEST END',/,1H ,20X,F8.4,' =  (R-1)/2',/,
     *1H ,20X,F8.4,' =  G(R)',/,1H ,20X,F8.4,' =  VARIANCE OF G(R)',/,
     *1H ,20X,F8.4,' =  ERFC')
      PRINT 409
  409 FORMAT(1H1,'DEVICE DAYS IN INTERVAL CLASSES')
      PRINT 406,(SUM(I),I=1,NR)
  406 FORMAT(1H ,5F13.1)
      BANS=1.-BANS
      PRINT 410,BANS
  410 FORMAT(///,1H0,      'ALPHA SHOULD BE LESS THAN',F8.4,' OR THE',/,
     *1H ,'HYPOTHESIS OF CONSTANT FAILURE IS REJECTED.',///,
     *1H0,'ALPHA IS THE PROBABILITY THAT YOU WILL REJECT THE HYPOTHESIS'
     *,/,1H ,
     *'OF CONSTANT FAILURE RATE WHEN IT IS IN FACT VALID.'/1H ,'ALPHA IS
     * AN INPUT.')
  407  FORMAT(1H ,10I8)
       STOP
```

```
      END
      SUBROUTINE ASORT(NAM,IPOS,N,L,KTYP)
      INTEGER*2 NAM,INPREC,IALPR,NFLAG,IPR,IPOS
      DIMENSION IPOS(1500)
     C          ,NFLAG(1500),NAM(2000,06),INPREC(11),IPR(43),IALPR(32)
      DATA IPR  /' ','A','B','C','D','E','F','G','H','I','J','K','L',
     1'M','N','O','P','Q','R','S','T','U','V','W','X','Y','Z','-','(',')'/
     2',','.','=', '?','0','1','2','3','4','5','6','7','8','9'/
      KTYP=43
      DO 100 I=1,N
      NFLAG(I)=0
  100 IPOS(I)=I
      DO 200  J=1,L
      NSUB=1
  300 K=0
  301 K=K+1
      NSWIT=0
      I=NSUB
      GO TO 302
  303 I=I+1
      IF(I.LE.N)  GO TO 306
      IF(K.LT.KTYP) GO TO 301
      GO TO 200
  306 IF(NFLAG(I).EQ.0)  GO TO 302
      IF(NSUB.EQ.I)  GO TO 300
      IF(K.LT.KTYP)  GO TO 301
      NSUB=I
      GO TO 300
  302 M=IPOS(I)
  305 IF(NAM(M,J).NE.IPR(K))  GO TO 303
      IPOS(I)=IPOS(NSUB)
      IPOS(NSUB)=M
      IF(NSWIT.EQ.1) GO TO 304
      NSWIT=1
      NFLAG(NSUB)=1
  304 NSUB=NSUB+1
      IF(NSUB.LE.N)  GO TO 303
  200 CONTINUE
      RETURN
      END
/*
//GO.SYSIN DD *
/*
```

REFERENCES FOR APPENDIX E

1. E. Mosteller, J. W. Tukey, "Data Analysis, Including Statistics," *Handbook of Social Psychology*, Vol. II, A. Lindzey, Ed., Addison, Wesley Publisher, pp. 160-161 (1968).

Appendix F

PATIENT RADIATION DOSES FROM IMPLANTED PLUTONIUM-POWERED PACEMAKERS

The radiation doses from a Medtronic model 9000 pulse generator containing 173.2 mg of plutonium, of 90.14% by weight plutonium-238 (156.1 mg) and 0.26 ppm plutonium-236, were determined by Battelle Pacific Northwest Laboratories.[1]

Gamma doses to various organs in a patient were measured using thermoluminescent dosimeters (TLDs) in a Rando phantom (Fig. F.1), with the pulse generator located above the left pectoral muscle and at the left side of the abdomen. The Rando phantom is a natural human skeletal phantom that is surrounded by molded tissue-equivalent plastic in order to simulate the human body without the head and lower legs. The phantom was made according to the dimensions of an average woman. The phantom is assembled in 1-in.-thick slabs and has small holes drilled at locations representative of body organs to permit placement of dosimeters in or near these organs and other points (e.g., along the spine). The measurement locations were close to the center of the specified organ except for the liver, where top, middle, and lower positions were used.

The TLD locations are shown in Fig. F.2 for the pulse generator located above the left pectoral muscle and in Fig. F.3 for the pulse generator located on the left side of the abdomen. Exposures were made for approximately one week (145.16 hr) with the pulse generator above the pectoral muscle and 166.5 hr with the pulse generator on the abdomen.

Gamma doses and dose rates in the phantom, at various organ, spine, and depth locations, and the distances of these locations from the plutonium source are shown in Tables F.1 through F.5.

Neutron dose equivalents were determined using tissue-equivalent proportional counters (TEPCs) in a phantom that consisted of various slabs of a polymer gel having the same neutron dose attenuation as tissue-equivalent solutions. The TEPC neutron dosimeter measures the dose to tissue-like materials in the cavity of a proportional counter. Neutron dose equivalents were determined at distances equal to the distances at which the gamma doses were measured in the Rando phantom. At distances shorter than about 7 cm of tissue, the neutron dose equivalent predominates; at greater distances, the gamma dose predominates, since tissue attenuates the emitted neutrons more effectively than gamma emissions.

Neutron dose rates decrease exponentially with time as the plutonium-238 decays. Table F.6 contains factors that relate the initial neutron dose rates to the average neutron dose rates over 0-5, 0-10, 0-15, and 0-20 year periods. The gamma dose rate variation with time is more complex and depends on the decay of plutonium-238 and the buildup of daughter products of plutonium-236, which, in turn, depend on the amount of plutonium-236 contaminant present in the plutonium-238. Table F.7 contains factors that relate the initial gamma dose rates from a source containing 0.26 ppm plutonium-236 to the average gamma dose rates over 0-5, 0-10, 0-15, and 0-20 year periods.

The "average" dose to small organs was determined by adding the gamma dose measured near the center of the organ in the Rando phantom and the neutron dose equivalent measured in the polymer gel phantom at a source-detector distance equal to the source-organ distance in the Rando phantom. For larger organs, it was necessary to divide the organ into several sections, to determine the "average" dose to each section, and to find the arithmetic mean. The whole-body dose equivalent was determined by dividing the body into 2-in. slabs and calculating the dose equivalent to each slab. The dose equivalent of each slab was multiplied by the fraction of the total body weight (58 kg) represented by the slab, and the products were summed to obtain the whole-body dose equivalent.

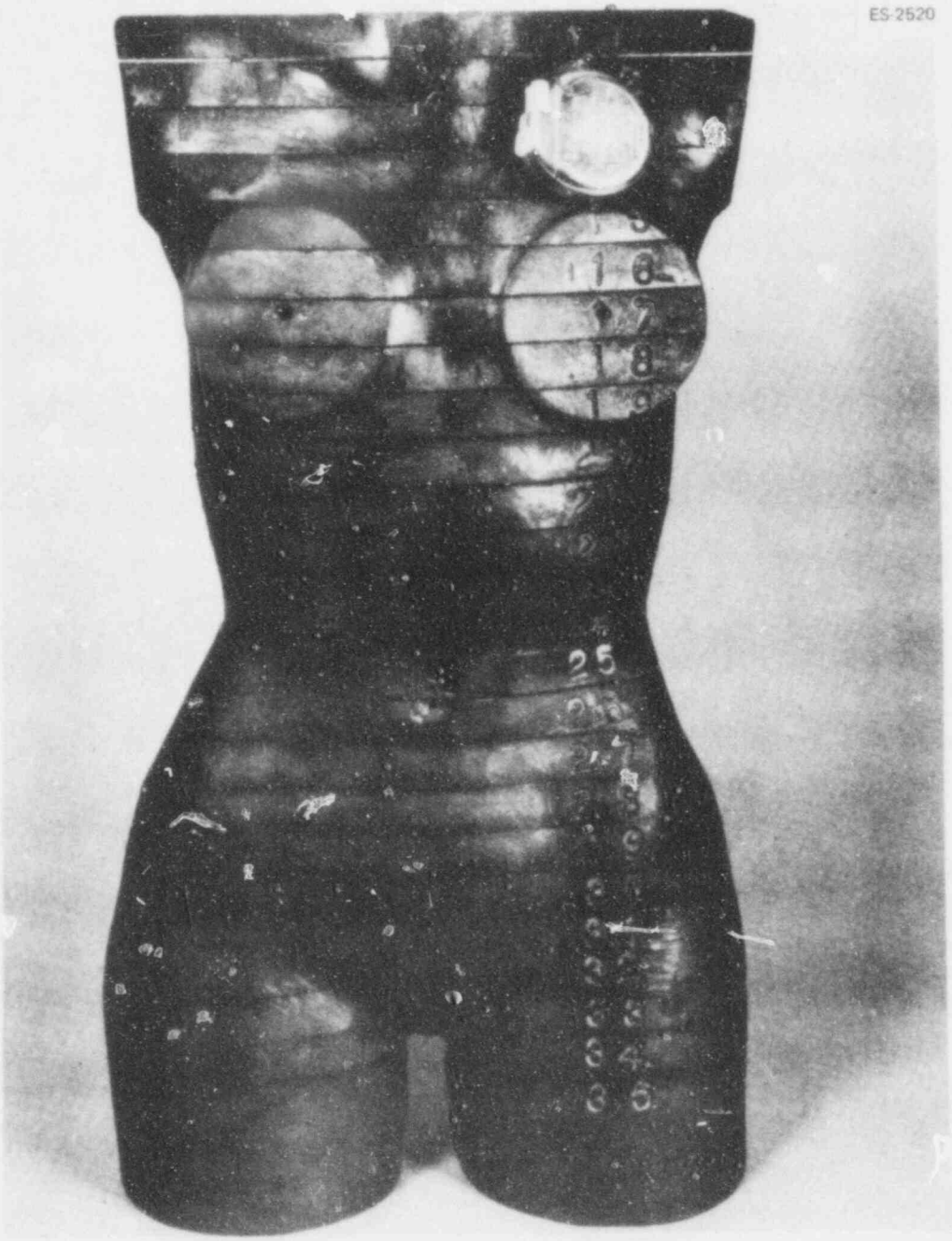


Fig. F.1. Phantom used for gamma dose measurements. Source: L. W. Brackenbush, G. W. R. Endres, and B. I. Griffin, *Radiation Doses from the Medtronic Laurens-Alcatel Model 9000 Pulse Generator*, Report 2311201653, Amendment 2, Pacific Northwest Laboratories, October 1973.

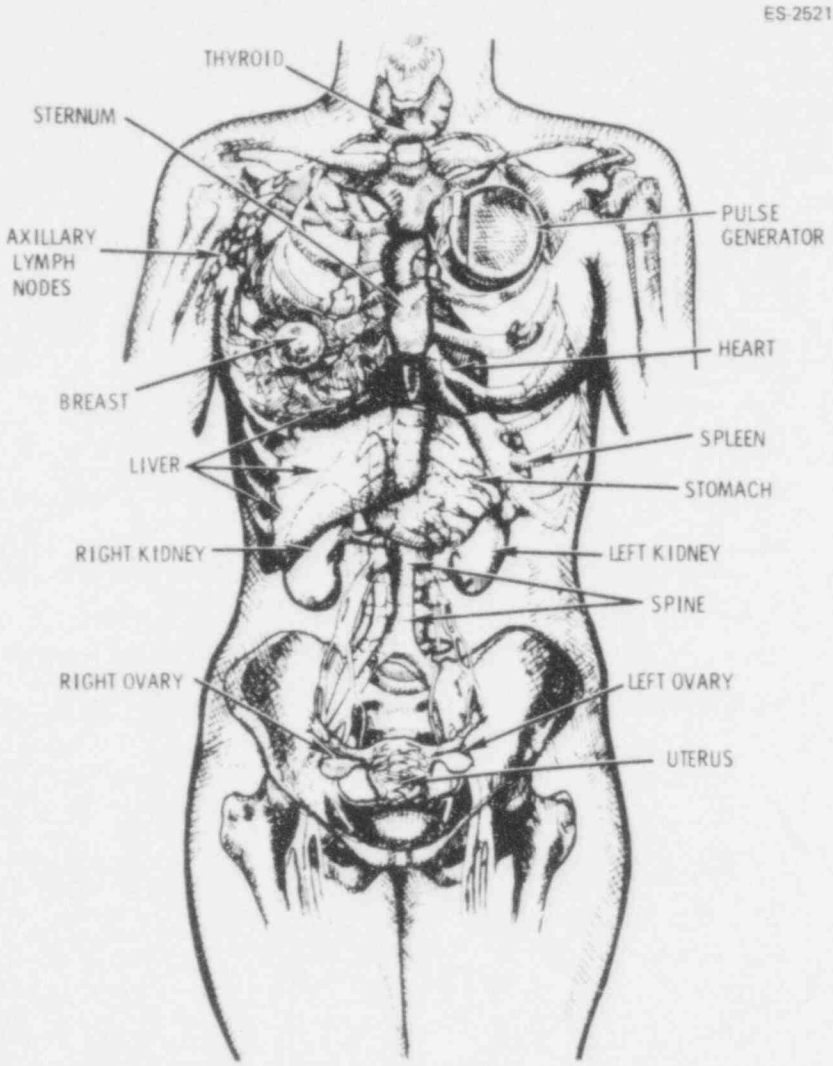


Fig. F.2. Location for normal implantation of a pacemaker above left (or right) pectoral muscle. Source: L. W. Brackenbush, G. W. R. Endres, and B. I. Griffin, *Radiation Doses from the Medtronic Laurens-Alcatel Model 9000 Pulse Generator*, Report 2311201653, Amendment 2. Pacific Northwest Laboratories, October 1973.

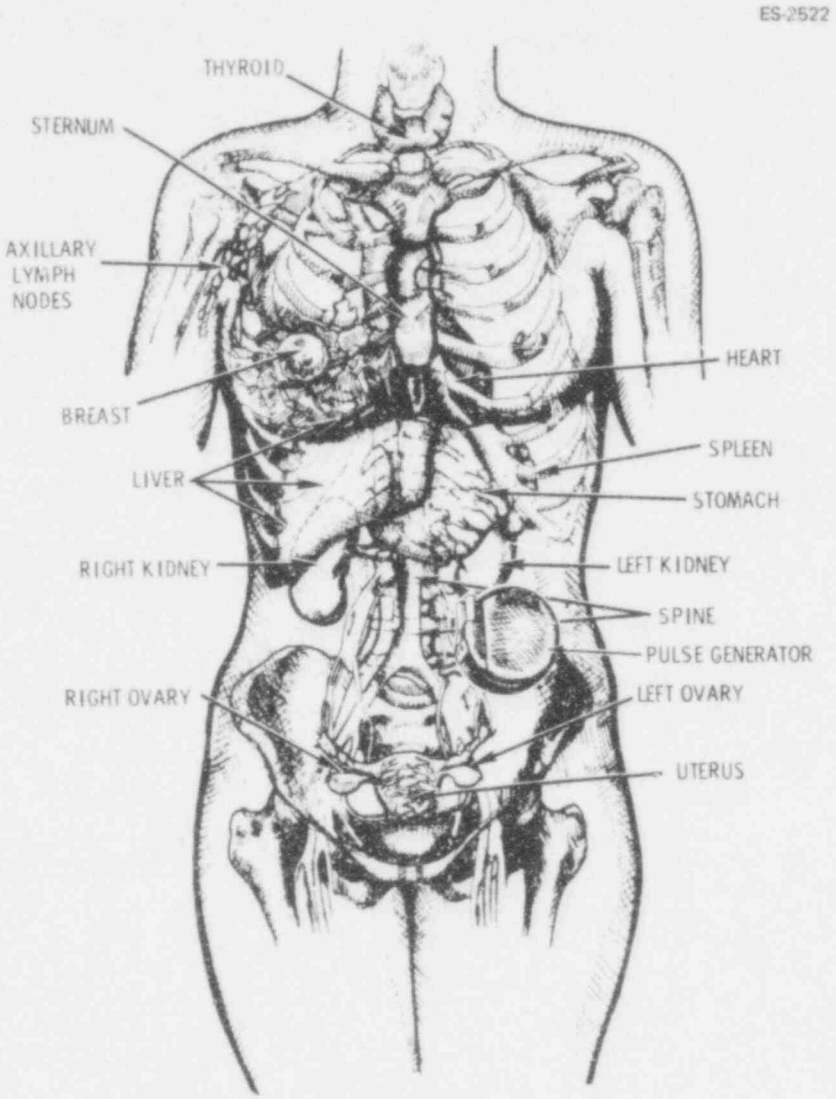


Fig. F.3. Alternate location for implantation of a pacemaker in the left side of the abdomen. Source: L. W. Brackenbush, G. W. R. Endres, and B. I. Griffin, *Radiation Doses from the Medtronic Laurens-Alcatel Model 9000 Pulse Generator*, Report 2311201653, Amendment 2, Pacific Northwest Laboratories, October 1973.

Table F.1. Gamma doses and dose rates from a pulse generator that contains 173 mg of PuO_2 in the phantom at various organ locations, measured with TLD-200 dosimeters (Pulse generator on surface above left pectoral muscle)

Location	Distance from ^{238}Pu source, cm	Gamma dose, mrads	Gamma dose rate or dose-equivalent rate, mrads/hr or mrems/hr[b]
Thyroid	9.1	6.7	0.046 ± 0.011
Sternum	9.5	6.4	0.044 ± 0.012
Heart	15.5	3.6	0.025 ± 0.008
Liver			
Top	18.7	3.0[c]	0.021 ± 0.010[c]
Middle	26.3	2.7[c]	0.019 ± 0.010[c]
Bottom	29.3	4.3[c]	0.030 ± 0.014[c]
Spleen	17.9	2.6	0.018 ± 0.004
Stomach	23.2	3.0	0.021 ± 0.006
Kidney			
Left	29.4	2.1	0.014 ± 0.013
Right	30.7	2.1	0.014 ± 0.009
Ovary			
Left	45.9	1.9	0.013 ± 0.009
Right	47.1	2.5	0.017 ± 0.013
Uterus	48.9	2.7	0.019 ± 0.009

[a] 145.16-hr exposure.

[b] One standard deviation estimated from range statistics. (C. A. Bennett and N. L. Franklin, *Statistical Analysis of Chemistry and the Chemical Industry*, John Wiley & Sons, New York, p. 165, 1954.)

[c] Gamma dose measurements were determined from small differences between two large numbers. In view of the low dose rates measured (in most cases the measured value was less than dosimeter background) and the overlap of rate ± errors, the apparent inconsistencies of dose vs distance from source for the top, middle, and bottom sections of the liver are not unreasonable.

Table F.2. Gamma doses and dose rates from a pulse generator that contains 173 mg of PuO_2 in the phantom along the spine, measured with TLD-200 dosimeters (Pulse generator on surface above left pectoral muscle)

Distance from pacemaker, cm	Gamma dose, mrads[b]	Gamma dose rate or dose-equivalent rate, mrads/hr or mrems/hr[c]
10.6	4.2	0.029 ± 0.013
11.9	3.1	0.021 ± 0.011
12.2	5.3	0.036 ± 0.012
18.5	2.2	0.015 ± 0.012
22.6	1.9	0.013 ± 0.012
27.4	*d*	*d*
30.8	0.3	0.002 ± 0.005
36.6	1.2	0.008 ± 0.008
41.8	1.0	0.007 0.016

[a] 145.16-hr exposure.

[b] Gamma dose measurements were determined from small differences between two large numbers. In view of the low dose rates measured (in most cases the measured value was less than dosimeter background), the apparent inconsistencies of dose vs distance from source are not unreasonable.

[c] One standard deviation estimated from range statistics. (C. A. Bennett and N. L. Franklin, *Statistical Analysis of Chemistry and the Chemical Industry*, John Wiley & Sons, New York, p. 165, 1954.)

[d] Not measured.

Table F.3. Gamma depth-dose distribution from a pulse generator that contains 173 mg of PuO_2 in section 13 of phantom, measured with TLD-200 dosimeters (Pulse generator on surface above left pectoral muscle)

Distance, cm	Gamma dose, mrads	Gamma dose rate or dose-equivalent rate, mrads/hr or mrems/hr[b]
1	46.4	0.32 ± 0.02
2	23.4	0.10 ± 0.02
3	15.6	0.11 ± 0.02
4	11.8	0.08 ± 0.02
5	8.1	0.06 ± 0.01
6	8.5	0.06 ± 0.01
8	6.3	0.04 ± 0.02
10	3.2	0.02 ± 0.01
12	2.3	0.02 ± 0.01

[a]145.16-hr exposure.

[b]One standard deviation estimated from range statistics. (C. A. Bennett and N. L. Franklin, *Statistical Analysis of Chemistry and the Chemical Industry*, John Wiley & Sons, New York, p. 165, 1954.)

Table F.4. Gamma doses and dose rates from a pulse generator that contains 173 mg of PuO_2 in the phantom at various organ locations, measured with TLD-200 dosimeters (Pulse generator on surface at left side of abdomen)

Location	Distance from pacemaker, cm	Dose, mrads	Gamma dose rate or dose equivalent rate, mrads/hr or mrems/hr[b]
Thyroid	44.8	[c]	[c]
Axillary lymph nodes			
Left	30.1	0.4	0.003 ± 0.019 148 hr
Right		0.8	0.005 ± 0.011 148 hr
Sternum	28.2	0.8	0.005 ± 0.015
Pectoral muscle (base of breasts)			
Left	31.3	1.5	0.009 ± 0.019
Right	[c]	[c]	[c]
Heart	20.6	[c]	[c]
Liver			
Top	19.1	2.2	0.01 ± 0.02
Midpoint	17.9	2.9	0.02 ± 0.01
Bottom	15.5	4.7	0.03 ± 0.02
Spleen	18.2	2.7	0.02 ± 0.01
Stomach	13.0	3.6	0.02 ± 0.02
Kidney			
Left	14.0	5.6	0.03 ± 0.02
Right	15.7	4.3	0.03 ± 0.02
Ovary			
Left	12.6	2.7	0.02 ± 0.02
Right	14.9	2.8	0.02 ± 0.01
Uterus	17.4	0.9	0.005 ± 0.025
Male gonads[d]	23.2	4.3	0.03 ± 0.03 148 hr

[a] 166.5-hr exposure.

[b] One standard deviation estimated from range statistics. (C. A. Bennett and N. L. Franklin, *Statistical Analysis of Chemistry and the Chemical Industry*, John Wiley & Sons, New York, p. 165, 1954.)

[c] Not measured.

[d] At simulated position of testes on female phantom.

Table F.5. Gamma doses and dose rates from a pulse generator that contains 173 mg of PuO_2 in the phantom along the spine, measured with TLD-200 dosimeters (Pulse generator on surface at left side of abdomen)

Distance from ^{238}Pu source, cm	Dose mrads	Gamma dose rate or dose-equivalent rate, mrads/hr or mrems/hr[b]
37.7	c	c
33.0	c	c
28.2	c	c
23.7	c	c
15.8	c	c
15.1	5.2	0.03 ± 0.03
9.3	4.1	0.03 ± 0.02
9.3	5.6	0.03 ± 0.01
12.5	2.7	0.02 ± 0.01
19.3	2.4	0.01 ± 0.01

[a] 166.5-hr exposure.

[b] One standard deviation estimated from range statistics. (C. A. Bennett and N. L. Franklin, *Statistical Analysis of Chemistry and the Chemical Industry*, John Wiley & Sons, New York, p. 165, 1954.)

[c] Below background.

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Table F.6. Factors to determine average neutron dose-equivalent rate from a pulse generator containing a plutonium-238 heat source

Time period (years)	Factor to multiply by to obtain average dose rate
0-5	0.980
0-10	0.961
0-15	0.943
0-20	0.925

Table F.7. Factors to determine average gamma dose rate from pulse generator containing a heat source with 0.26 ppm plutonium-236

Time period (years)	Factor to multiply by to obtain average dose rate
0-5	1.18
0-10	1.41
0-15	1.53
0-20	1.60

The total annual dose equivalent as a function of distance from the plutonium-238 source was obtained by adding the neutron and gamma dose equivalents as shown in Fig. F.4. This figure gives the annual dose equivalents (millirems/year) for a 2-year-old source containing 0.26 ppm plutonium-236. The total annual dose equivalent was plotted as a function of distance in this figure to enable a comparison with annual rates from natural radiation sources. However, the integrated dose equivalents over 0-5 years, 0-10 years, etc., cannot be determined directly from this graph. The values must be corrected for the radioactive decay of plutonium-238 and the growth of daughter radiations from plutonium-236.

The photon dose rate variation is a complex function of the plutonium isotopic composition and the time since chemical separation of the plutonium. Battelle Northwest Laboratory has developed a computer program called PUSHLD that accounts for these variables for plutonium. Figure F.5 shows the variation in photon dose rate with time at the surface of a pulse generator, adjacent to the plutonium-238 source, as a function of plutonium-236 content. For these calculations a 156-mg plutonium-238 source was used that had an isotopic content of 90.14% plutonium-238 and 0.414% plutonium-241. In 18 years only 1 ppm of plutonium-236 can increase the dose rate by a factor of 4.6. However, the dose rate from the daughters of plutonium-236 reaches a maximum at 18 years.

The gamma dose rates and neutron dose-equivalent rates were multiplied by the factors in Tables F.6 and F.7. Dose equivalents are given in Tables F.8 and F.9 for the pulse generator above the left pectoral muscle and on the left side of the abdomen respectively. Approximate iso-dose-equivalent curves are shown in Figs. F.6 and F.7 for a plane passing through the pulse generator. The organs do not necessarily lie in this plane, and, therefore, the organ dose equivalents may not agree with those indicated in the figures.

All of the organ dose equivalents are below the 0.5 rem per year, which is the maximum permissible dose equivalent for nonoccupational exposures to the whole body and critical organs, including blood-forming organs, of individual members of the population. As a basis of comparison, Fig. F.8 contains the annual dose equivalents to individuals from natural radiation backgrounds and diagnostic medical x rays estimated for 1970 by the U.S. Environmental Protection Agency.[2] The figure also contains the doses to various organs and the whole body of the pacemaker patient with the pulse generator located above the left pectoral muscle. The annual dose equivalent at 8 cm from the source is the same as that received by a jet airline crew member flying 80 hours per month. The annual dose equivalent to the ovaries and testes from the pulse generator located above the left pectoral muscle is below natural background levels. (The highest gonad dose-equivalent rate was about 210 millirems/year to the left ovary from the pulse generator located in the left side of the abdomen.) The annual dose equivalent to the whole body is about 70 millirems/year for the pulse generator located in the left side of the abdomen.

REFERENCES FOR APPENDIX F

1. L. W. Brackenbush, G. W. R. Endres, and B. I. Griffin, *Radiation Doses From the Medtronic Laurens-Alcatel Model 9000 Pulse Generator*, Report No. 2211201653, Amendment 2, Battelle Pacific Northwest Laboratories, October 1973.

2. A. W. Klement, Jr., C. R. Miller, R. P. Minx, and B. Shleier, *Estimates of Ionizing Radiation Doses in the United States 1960-2000*, Report ORP/CSB 72-1, U.S. Environmental Protection Agency, 1972.

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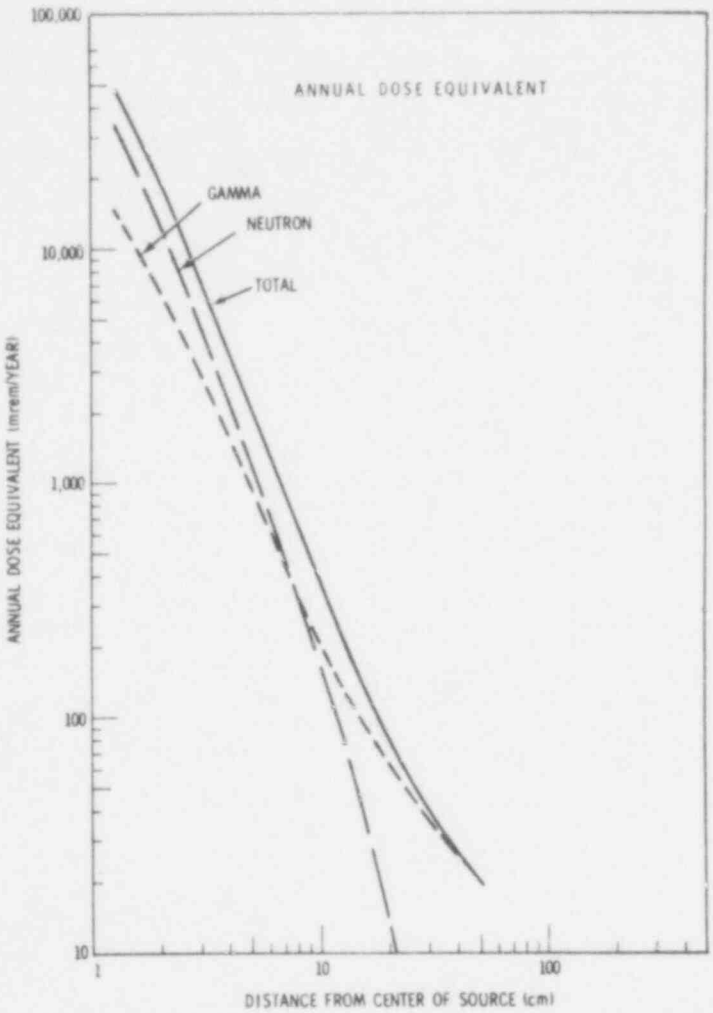

Fig. F.4. Annual dose equivalent as a function of distance in tissue from a pulse generator containing 0.26 ppm plutonium-236 at two years after chemical separation. Source: L. W. Brackenbush, G. W. R. Endres, and B. I. Griffin, *Radiation Doses from the Medtronic Laurens-Alcatel Model 9000 Pulse Generator*, Report 2311201653, Amendment 2, Pacific Northwest Laboratories, October 1973.

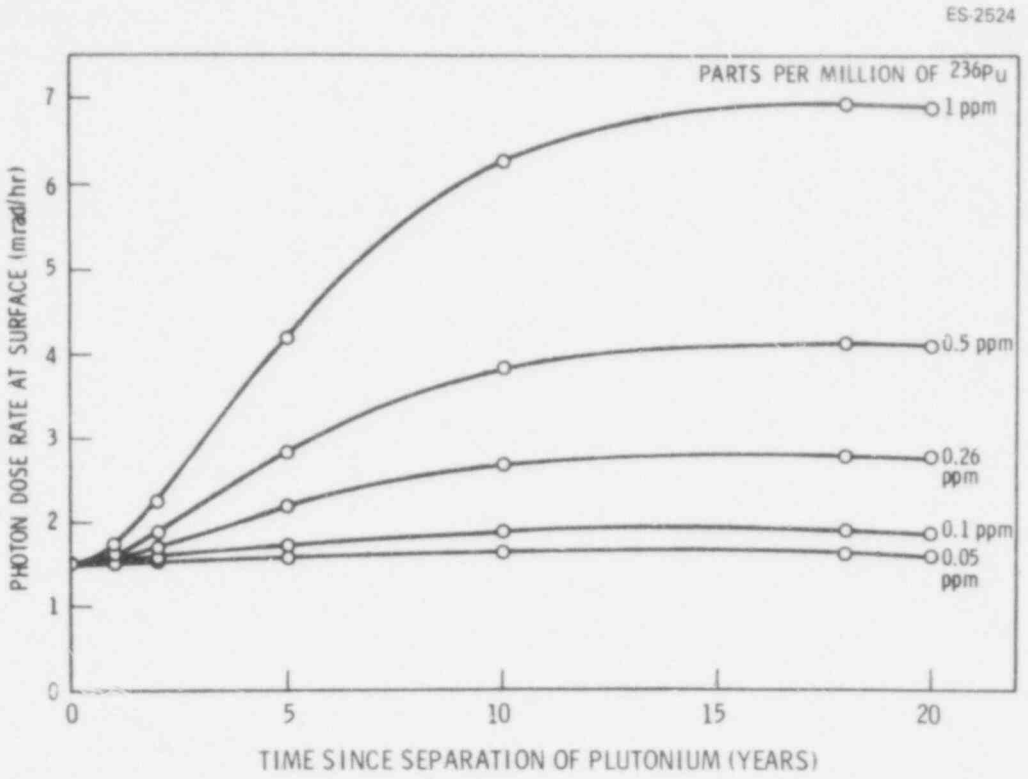

Fig. F.5. Gamma dose rate variation with time at the surface of a pulse generator. Source: L. W. Brackenbush, G. W. R. Endres, and B. I. Griffin, *Radiation Doses from the Medtronic Laurene-Alcatel Model 9000 Pulse Generator*, Report 2311201653, Amendment 2, Pacific Northwest Laboratories, October 1973.

Table F.8. Dose equivalents to organs for 5-, 10-, 15-, and 20-year periods from a pulse generator that contains 173 mg of PuO_2 and is located above the left pectoral muscle

Location	Integrated dose equivalent, neutron and gamma			
	5 years, rems	10 years, rems	15 years, rems	20 years, rems
Thyroid	2.7	5.5	8.9	12
Left axillary lymph nodes	2.4	5.1	8.1	11
Right axillary lymph nodes	0.33	0.88	1.2	1.7
Sternum	2.3	4.7	7.8	10
Left pectoral muscle (base of breast)	0.76	1.8	2.7	3.6
Right pectoral muscle (base of breast)	0.31	0.82	1.2	1.7
Heart	0.70	1.7	2.5	3.2
Liver	0.23	0.64	0.97	1.4
Spleen	0.30	1.3	1.9	2.4
Stomach	0.29	0.80	1.2	1.6
Left kidney	0.20	0.52	0.81	1.2
Right kidney	0.19	0.48	0.75	1.1
Left ovary	0.11	0.25	0.41	0.60
Right ovary	0.11	0.24	0.40	0.58
Uterus	0.10	0.23	0.38	0.54
Testes	0.09	0.20	0.32	0.43
Spine (average)	0.70	1.6	2.4	3.3
Torso (average)	0.70	1.7	2.5	3.3
Whole body (average)	0.36	0.95	1.3	1.8

Table F.9. Dose equivalents to organs for 5-, 10-, 15-, and 20-year periods from a pulse generator that contains 173 mg of PuO_2 and is located on the left side of the abdomen

Location	Integrated dose equivalent, neutron and gamma			
	5 years, rems	10 years, rems	15 years, rems	20 years, rems
Thyroid	0.11	0.26	0.43	0.62
Left axillary lymph nodes	0.19	0.50	0.79	1.1
Right axillary lymph nodes	0.16	0.38	0.63	0.90
Sternum	0.20	0.56	0.87	1.2
Left pectoral muscle (base of breast)	0.18	0.47	0.74	1.0
Right pectoral muscle (base of breast)	0.17	0.42	0.68	0.98
Heart	[illegible]8	0.98	1.4	1.9
Liver	[illegible]0	1.3	1.9	2.4
Spleen	0.49	1.2	1.8	2.5
Stomach	1.1	2.4	3.7	5.0
Left kidney	0.90	2.1	3.2	4.2
Right kidney	0.59	1.65	2.5	3.2
Left ovary	1.1	2.6	4.0	5.3
Right ovary	0.76	1.8	2.7	3.6
Uterus	0.53	1.4	2.0	2.6
Testes	0.29	0.80	1.15	1.6
Spine (average)	0.89	2.1	3.4	4.3
Torso (average)	0.87	2.1	3.2	4.3
Whole body (average)	0.53	1.3	2.0	2.6

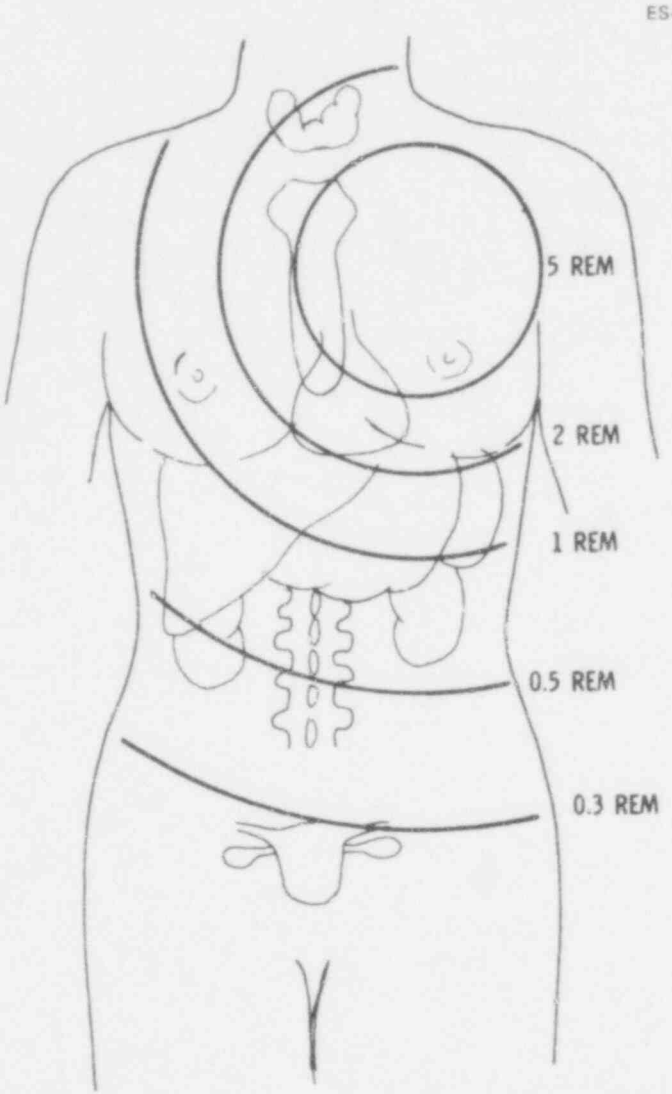

Fig. F.6. Iso-dose-equivalent curves for pulse generator placed above left pectoral muscle for a 10-year period. (The curves shown are for a 173-mg plutonium-238 source. For a 250-mg source, the dose equivalent should be multiplied by a factor of 1.45.) Source: L. W. Brackenbush, G. W. R. Endres, and B. I. Griffin, *Radiation Doses from the Medtronic Laurens-Alcatel Model 9000 Pulse Generator*, Report 2311201653, Amendment 2, Pacific Northwest Laboratories, October 1973.

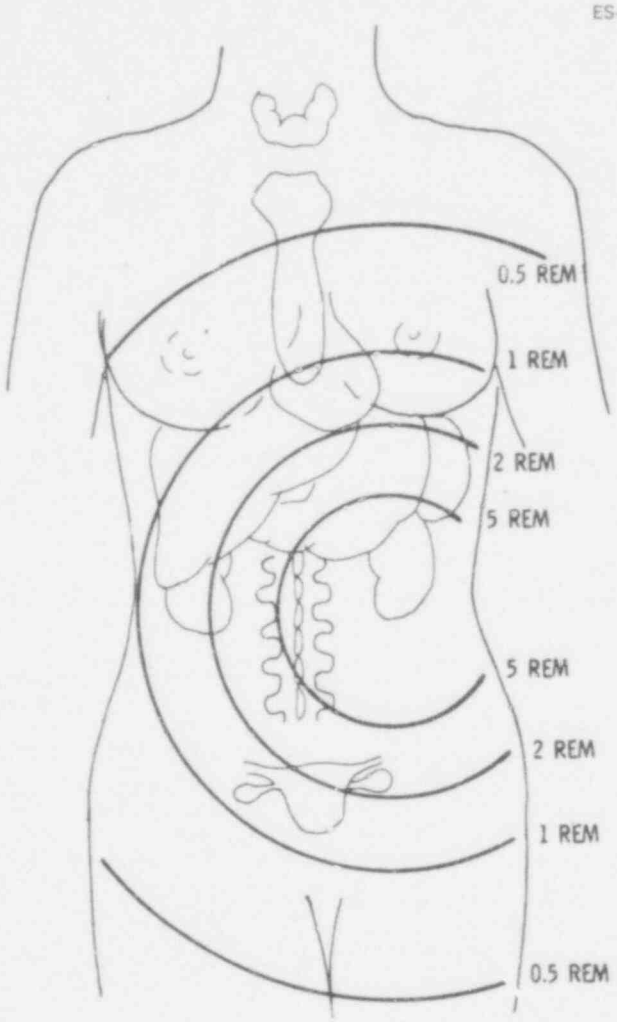

Fig. F.7. Iso-dose-equivalent curves for pulse generator placed on abdomen for a 10-year period. (The curves shown are for a 173-mg plutonium-238 source. For a 250-mg source, the dose equivalent should be multiplied by a factor of 1.45.) Source: L. W. Brackenbush, G. W. R. Endres, and B. I. Griffin, *Radiation Doses from the Medtronic Laurens-Alcatel Model 9000 Pulse Generator*, Report 2311201653, Amendment 2, Pacific Northwest Laboratories, October 1973.

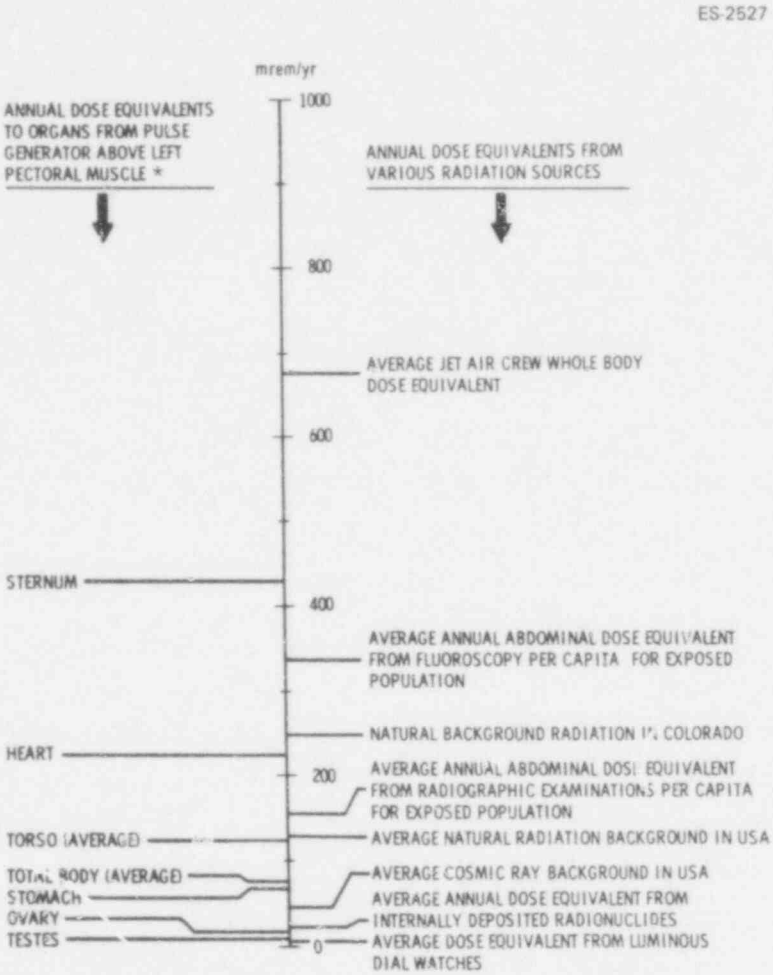

Fig. F.8. Annual dose equivalents from various radiation sources compared with annual dose equivalents from a pulse generator. (*From a 2-year-old source containing 0.26 ppm plutonium-236.) Source: L. W. Brackenbush, G. W. R. Endres, and B. I. Griffin, *Radiation Doses from the Medtronic Laurens-Alcatel Model 9000 Pulse Generator*, Report 2311201653. Amendment 2, Pacific Northwest Laboratories, October 1973.

Appendix G

SUMMARY OF RESPONSES TO THE PHYSICIAN'S QUESTIONNAIRE

In January 1975 the Atomic Energy Commission (now the Nuclear Regulatory Commission) issued the *Draft Generic Environmental Statement on the Wide-Scale Use of Plutonium-Powered Cardiac Pacemakers* for comment by other government agencies and the public. A number of the comments received stated that a more complete discussion of the alternatives available and of the need for nuclear-powered pacemakers should be included in the Final Environmental Statement. Some of the comments expressed the opinion that, in view of the availability of nonnuclear pacemakers with long useful service lives, the use of nuclear pacemakers is not necessary or justified.

The Commission, in order to prepare an analysis of the need for nuclear pacemakers in light of the availability of nonnuclear alternatives, requested information from physicians who have had broad experience with pacemakers in their practice. A questionnaire was distributed to pacemaker manufacturers and medical institutions licensed to participate in the clinical investigation program (discussed in Sect. 2) with a request that it be completed by one or more of their physicians. In addition, pacemaker manufacturers were invited to send the questionnaires to physicians who are not using nuclear pacemakers under an NRC or Agreement State license.

One hundred thirty-three responses to the questionnaires were received by December 1975. These responses were summarized according to question number. Responses have been grouped into broad categories to simplify the presentation of the results. There are many instances where several physicians have not responded to some of the questions, citing lack of experience necessary to answer the particular question. There are also several questions for which several responses are given and these multiple responses are grouped accordingly. Situations in which there were only one or two responses in a category were omitted from this summary. Responses in which the physician gives extensive narrative in order to more clearly explain his position are abstracted and included as part of the discussion for the particular question. There are many cases where several physicians expressed similar or differing opinions or a new viewpoint, and, for each of these cases, the most representative and comprehensive comment was chosen.

Questionnaire to Physicians Regarding the Need for,
and Choice of, Long-Lived Cardiac Pacemakers
(Approved by GAO; B-180225 (575033); Expires 9-30-75.)

1. *For what types of cases are long-lived pacemakers most desirable?*

Responses	Total
Younger patients	55
10-20 year life expectancy	38
All patients	11
Patients in good health	12
Patients under 50 years of age	8
Patients under 65 years of age	11
Patients under 80 years of age	4
Children	1

1.1 It should be noted that "younger patients" usually refers to patients under 65 years of age; the average age of a pacemaker patient is approximately 68. There is little indication of pacemaker use in persons under 30 years of age.

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2. *In your own practice, how many (approxin ely) of your last 100 pacemaker patients were of these types?*

Response	Total
0 %	7
1-10	63
11-20	17
21-30	11
31-40	2
41-50	5
51-60	2
61-70	2
71-80	4
81-90	0
91-100	6

3. *What percentage (approximately) of your patients have required one or more replacements of their pacemakers?*

Response	Total
0 %	0
1-10	4
11-20	5
21-30	12
31-40	7
41-50	17
51-60	12
61-70	15
71-80	26
81-90	17
91-100	8

4. *List the unique advantages of:*

a. *mercury battery powered pacemakers,*

Response	Total
None	13
Low price	34
Proven experience and reliability	63
Availability	5
Long life	3
Smaller size	3

b. *lithium battery powered pacemakers,*

Response	Total
None	6
Low price	4
Longer life	79
Smaller size	7
Hermetic seal	5

c. *rechargeable nickel-cadmium battery powered pacemakers,*

Response	Total
None	20
Long life	43
Smaller size	12
No need to replace	15

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d. *nuclear (plutonium and/or promethium) battery powered pacemakers.*

Response	Total
None	2
Long life	104
Smaller size and weight	7
No need to replace	4
No need to recharge	3
Reliability	4

4.1 Physician's comment (42):

"I assume that there are no technologic advantages to nuclear or nonnuclear pacers other than longevity for the nuclear unit. It must be remembered that no units have been in use long enough to demonstrate the accuracy of the longevity projections. Many such projections in the past have been inaccurate.

"(a) mercury - at present these are lowest in cost.

"(b) lithium - cost is about 30 to almost 100% more than non-nuclear units of comparable capability. Major advantages are: (2) easy hermetic sealing of the unit with presumed reduction in electronic failure, (2) projected longevity.

"(c) Ni-Cd rechargeable - projected longevity is greater than that for the mercury-zinc cell.

"(d) The unique longevity is the major advantage. One nuclear unit is the smallest pacemaker now available."

4.2 Physician's comment (104):

"(a) About the only advantage of the mercury battery powered pacemaker is the fact that we know more about it than any other kind.

"(b) ...the unique advantage of the lithium battery powered pacemaker is the fact that it promises longer life than is possible with the mercury pacemaker without the complexity, cost, and small risk associated with the nuclear fueled device.

"(c) The unique advantage of the rechargeable nickel-cadmium battery powered pacemaker is its promise of long life again at a lower cost than a nuclear fueled device.

"(d) The unique advantage of the nuclear battery powered pacemaker is its promise of much greater longevity than is possible with any other system...The longevity that is possible with the plutonium-powered pacemaker is of the order of 20 to 40 years and could easily be much longer. These devices offer a truly unique advantage of a lifetime pacemaker for almost any patient."

4.3 Physician's comment (105):

"(d) Nuclear battery powered pacemakers longevity would be the primary advantage. This is offset to some extent by the increased cost and we currently wonder whether the circuitry itself will last as long as the nuclear power source. However, we currently seem to have available an excellent and highly miniaturized nuclear unit which appears very attractive..."

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4.4 Physician's comment (121):

"As far as the Mercury and the Lithium batteries are concerned the only advantage will be which chemical will allow for longer life. At the moment, Lithium supporters say that their batteries will last six or seven years whereas the Mercury supporters say that their battery will go 5-6 years. In my own experience the Mercury battery produced by Medtronic has been the most reliable up to this time. In regard to the rechargeable nickel-cadmium battery powered pacemakers, unless there is a particularly long life expectancy to this type of pacemaker I am completely against it because I cannot see allowing the patient to take the responsibility or make a cardiac cripple out of the patient by making him aware that every week he must recharge his pacemaker. When the pacemaker will require recharging only once a year, it may be a different story. The clinically

available rechargeable pacemaker at this time requires recharging once a week making the patient aware of this. I am totally against this concept. As far as the nuclear battery is concerned, in my hands they have thus far been quite satisfactory. We have inserted 10 nuclear powered pacemakers supplied by the Medtronic Corporation under the appropriate grant. These pacemakers have been inserted in those of our group who are 65 or younger. They have thus far worked quite well...I believe that the concept of inserting an artificial device into a patient and then being able to tell him to forget all about it is most important for the patient and will save money in the long run since every time it is necessary to tamper with the battery, there is always the possibility of problems and we have certainly had occasional infection in our series during battery changes which required extensive surgery thereafter."

5. *List the unique disadvantages of:*

a. *mercury battery powered pacemakers,*

Response	Total
None	3
Short life and frequent replacement	96
Large size	8
Unreliable battery	14

b. *lithium battery powered pacemakers,*

Response	Total
None	13
Relatively short life	9
Large size and weight	13
Limited use, unproven reliability	44
Higher cost	7

c. *rechargeable nickel-cadmium battery powered pacemakers,*

Response	Total
Unproven	15
Recharging unacceptable	76

d. *nuclear (plutonium and/or promethium battery powered pacemakers).*

Response	Total
None	6
Large size	11
Unproven	9
High cost	61
Radiation risk	27
Paperwork and "red tape"	20
Unavailable	9

5.1 Physician's comment (105):

"(a) Mercury battery powered pacemakers - The only disadvantage is that of relatively short life expectancy of pacemaker which we hope has now been circumvented so that these pacemakers will, indeed, last 5-8 years, the average life expectancy of our average pacemaker patients.

"(b) Lithium battery powered pacemakers - Disadvantage is that of the Lithium source itself which has created some difficulty. The increased cost and the possible susceptibility of the circuitry to failure prior to the Lithium power source.

"(c) Rechargeable nickel-cadmium battery powered pacemakers - No advantage. This places an unfair and ill advised responsibility on our patients, many of whom are older individuals and unable to cope with technical problems of this kind...I fail to see any particular advantage in this kind of unit and would hesitate to delegate to our patients the responsibility for either recharging these themselves or reporting to us for recharging on any rigid schedule.

"(d) Nuclear (plutonium and/or promethium) battery powered pacemakers - These pacemakers are potentially dangerous not only to the individual but also possibly to the community at large from the standpoint of radioactive material. They are also disadvantageous in that these individuals must be closely followed for many years, actually for their life expectancy, by the responsible operating surgeon, which would not generally be feasible."

5.2 Physician's comments (104):

"The unique disadvantage of the mercury battery powered pacemaker is the fact that until recently at least the batteries have been unreliable and most of the pulse generator failures have been due to premature battery failure due to internal shorting or some other mechanism. While this has been greatly improved the mercury battery has been developed to the peak of refinement and it is not likely that any further longevity can be achieved with the mercury battery powered pacemaker. Since longevity is the major problem facing the pacemaker industry today it is clear that we cannot expect a solution from the mercury battery powered pacemaker.

"The unique disadvantage of the lithium battery powered pacemaker is the fact that it is a bulky unit and of course its behavior over a long period of time is still an unknown factor. It will take time to establish whether lithium-iodide or lithium-silver chromate or some other configuration of the battery will prove to be more advantageous. Another disadvantage of the lithium unit is the fact that it is really a medium longevity device and while better than the mercury powered pacemaker does not approach a lifetime pacemaker except for some very elderly patients.

"The unique disadvantage of the rechargeable nickel-cadmium battery powered pacemaker is undoubtedly the clumsiness of the recharging mechanism. While the device is an interesting engineering break-through the necessity for frequent recharging renders it unacceptable for many physicians and many patients. In my personal practice most of my patients are elderly and do not wish to be reminded of their handicap. Necessity for frequent use of a recharging device is a burden that many of them simply could not handle and would not want to. It also is a constant reminder of the patient's handicap and while some patients treasure their ailments and adjust to them well most patients would rather forget them and the rechargeable device makes this impossible. In my opinion this is not a good solution to the problem of longevity in permanent pacemakers.

"The unique disadvantage of the nuclear battery powered pacemaker is the fact that at least in it's most promising form the fuel is plutonium oxide. This is a toxic substance and does pose some theoretical risks at least. The actual risk may be considered under two headings. One is the risk of contamination due to release of the plutonium fuel into the atmosphere. The possibility of this seems remote in view of the very careful testing program developed by the Atomic Energy Commission and very stringent requirements in the manufacture of these devices. The second threat is that of possible radiation damage over a period of years. This potential threat has led some people to the belief that these devices should not be used in small children but we have no real evidence that such a danger exists. However, it must be realized that some people would consider it a danger and would prefer not to use these devices."

5.3 Physician's comment (42):

"(a) It is the largest - in present day configurations - usually the heaviest and <u>perhaps</u> the shortest lived of the units.

"(b) These are temperature sensitive. Some of the cells are large so that there is little saving in size over the Hg-Zn pacer. The temperature sensitivity is such that pacer rate can vary with body temperature during a febrile course.

"(c) This pacer has the major disadvantage that its function is in the direct control of the patient. This is a great vulnerability. In my series of patients, numbering about 1500 implants, 90% of those patients I deemed competent to use a rechareable unit rejected it as being an unnecessary bother when offered it, along with a mercury, lithium, and where appropriate a nuclear pacer along with a full explanation of the virtues and liabilities of each.

"Also, at least 10% of my entire living patient group are hospitalized each year for non-pacer related causes some not at the institution at which I work. Twenty-five percent of all my patients live in a chronic care facility. Frankly, I wonder whether such patients will be adequately recharged as they are widely dispersed among institutions. My impression of the general level of comprehension of pacer technology in the general medical and nursing public does not inspire confidence that these patients will receive adequate care.

"(d) The nuclear pacemakers are in restricted use. Many patients and physicians have persistent questions concerning the safety of these units both for the individual and those about him. As one of my patients (who eventually accepted a nuclear pacemaker) indicated, the pacer is designed to resist all credible accidents, but the world is becoming more incredible daily. The question of free international travel for those with nuclear pacemakers seems to remain unresolved but may be a hindrance to use of nuclear units."

5.4 Physician's comment (75):

"...if I needed a pacer I would be willing to accept the possibility that the new nuclear unit at least offered me the opportunity of never needing another replacement, and accept this rather than a unit which I knew had to be replaced within a given period of time. From the personal experience we have had with patients, very few had been willing in our area to accept the rechargeable concept. I think most people do not want to be constrained by the fact that they have to have the unit recharged and become psychological cripples as the result of this. Their experience with rechargeable flashlights, etc. has certainly not stood the test of time, and I doubt if a pacemaker will be any different."

6. *Do any of the disadvantages you listed in Question 4 make the pacemakers unacceptable for your use, at least in some patients?*

a. *Hg*

Yes	17
No	63

b. *Li*

Yes	22
No	52

c. *Ni-Cd*

Yes	68
No	28

d. *Nuclear*

Yes	52
No	45

6.1 Physician's comment (48):

"(a) Hg; No, not unacceptable but undesirable.

"(b) Li; Yes; lithium pacemaker is too large to permit use in patients with minimal subcutaneous tissue.

"(c) Ni-Cd; Yes; this pacemaker can best be used in patients who are intelligent, highly motivated to live, and who live in a stable residence where a single type of electrical current is employed (i.e. presently unsuitable for foreign travelers)

"(d) Nuclear; Yes, unsuitable for patients who are unwilling to have the device removed following its failure or their death; the beta cell pacemaker is probably inappropriate for use in younger patients due to the unknown hazards of its higher radiation levels."

6.2 Physician's comment (65):

"(b) We have not used the lithium powered unit to date because it is relatively new but I believe it will replace the mercury units in our practice in the near future.

"(c) We have not used the nickel-cadmium unit because of rumored unpredictable performance and the fact that the weekly sessions with recharging add to the psychological burden of life hinging on a pacemaker.

"(d) Nuclear unit would be unacceptable for elderly patients with questionable longevity and obviously for those unable to meet the cost of the unit."

6.3 Physician's comment (50):

"I have come to feel that due to the excessive cost and the stringent regulations placed upon the patient receiving a nuclear powered pacemaker, that these have now become unacceptable for my use. I feel with the marked improvement and longevity of alternative pacemakers that alternatives are now available for use."

7. *Are there patients for which the nuclear powered pacemaker is the most viable alternative amongst the types previously mentioned?*

Yes	97
No	3
For younger patients	20
For older patients	1

7.1 Physician's comment (121):

"...any patient who has a lifetime expectancy of longer than 10 years or more, should certainly have a nuclear powered pacemaker offered to him."

7.2 Physician's comment (104):

"I believe that a substantial percentage of patients would be suitable for nuclear powered pacemakers assuming that widespread use of these devices is permitted. I suspect that in time the mercury powered pacemaker will be phased out and the choice will be between nuclear powered pacemakers and lithium powered pacemakers. It may well be that the nuclear powered pacemaker will be the pacemaker of choice for all but the extremely young and the extremely old and those who fear the potential dangers of the nuclear device. Many surgeons estimate that 10 to 20% of their patients might require a nuclear powered pacemaker. My own feeling is that the percentage will be well over 50 once the unit becomes generally available. I have detected no fear of the device amongst my patients and most of the referring doctors."

7.3 Physician's comment (42):

"For the patients who are young adults or up to the age of 60 or 70 years and remain basically healthy except for the cardiac arrhythmia, the nuclear pacer remains a satisfactory alternative. The group of patients who fall into the young and healthy category seems not to exceed 15% of the total.

"A question has been raised concerning the use of a nuclear pacemaker and its recovery and reuse in the event of a patient's death. The Montefiore Hospital and Medical Center series is carefully followed, at great effort and cost, yet the yield of pacemaker recovery after death, including those who die and are buried before we are notified, lead me to believe that the recovery rate for nuclear pacers, were they to be widely used would be too low to make the prospect of consistent reuse feasible. An effort to increase the recovery rate would be too expensive and perhaps intrusive in persons' privacy to be a viable alternative."

8. *Do you believe life expectancy should be a consideration in the prescribing of nuclear pacemakers? If so, what would be the minimum life expectancy for which a nuclear implant is considered?*

Yes	120
No	7

Minimum life expectancy	Total
less than 5 years	2
5-9 years	18
10 years	33
more than 10 years	33

8.1 Physician's comment (104):

"Life expectancy should not be a consideration in the prescribing of nuclear pacemakers except for the extremely aged patient perhaps in his nineties for whom life expectancy would hardly justify a 20 to 40 year pacemaker. I think the patient should have a life expectancy of at least five or six years before a nuclear powered pacemaker would be considered, anything less than this would be an indication for a lithium powered device or possibly a mercury powered pacemaker. The prevailing feeling that nuclear powered pacemakers should be reserved for young patients and not prescribed for old patients I believe is mistaken. I think in advocating this view we are looking through the wrong end of the telescope. Insurance statistics have shown that patients that reach the age of 70 which is the most common age for insertion of a permanent pacemaker have an 80% expectancy of living another ten years. Many of them have a 15 to 20 year life expectancy at the age of 70. We cannot make second class citizens of the largest group of patients for whom pacemakers are required and I believe that people at this age around 65 to 70 will be those for whom the nuclear powered pacemakers should be first considered. In this connection it should be pointed out that a patient who gets into difficulties in his thirties or forties and requires a pacemaker very likely will not live very long. Furthermore there are some people who feel that extremely young age may be a contra-indication for the use of the nuclear pacemaker because of the possible long term effects of the minimal radiation. We are left then with the reverse picture of that commonly presented, namely that the older patient and these of course are the ones most frequently requiring a pacemaker."

9. *If your patients had a choice of pacemaker type, what percent do you believe would choose nuclear powered pacemakers versus alternative ones when the performance characteristics, relative risks, and any other pertinent factors are disclosed to them?*

Response	Total
0 %	5
less than 5	15
5-10	19
11-20	6
21-50	16
more than 50	49
more than 90	15
few (≤50%)	66
most (>50%)	58

9.1 Physician's comment(75):

"No patient that I offered a nuclear unit to date has refused it."

9.2 Physician's comment (40):

"I do not believe my patient should have the choice of pacemaker type. I feel this is, strictly speaking, a medical decision and the patient should not participate in it."

9.3 Physician's comment (102):

"In my own practice, I limit the patient input as to choice of pacemaker to some extent since I do not believe most patients have the medical background to accurately evaluate the proper unit for their own use."

9.4 Physician's comment(48):

"By in large, the patient accepts whatever pacemaker system is recommended to them by their responsible physician and does not possess sufficient technical knowledge to make a valid judgment himself."

10. *In your opinion, should any limitations be imposed on patient selection for nuclear pacemakers? If so, specifically what do you recommend? (e.g., maximum age, minimum age, expected survival time, coexistent conditions, emotional suitability)*

Yes 96
No 24

Age limitations

Maximum	Total	Minimum	Total
70 or more years	8	less than 18 years	9
65 years	11	more than 18 years	7
60 years	6		
less than 60 years	12		

10.1 Physician's comment (102):

"I believe the final decision as to the use of such units should rest with the implanting physician."

10.2 Physician's comment (42):

Yes. The limitations should be:

"(a) No growing children until local radiation effects - whatever they are or are not - have passed the test of greater time.

"(b) Maximum age of 65 - 70 years.

"(c) Life expectancy about 15 years.

"(d) Obviously no life threatening coexistant conditions should exist. For a neoplasm such as breast carcinoma I would want a ten year survival free of tumor before considering a nuclear pacer.

"(e) Emotional stability is important for the patient's peace of mind."

10.3 Physician's comment (24):

"At the present time it is my opinion based on current available technology that nuclear pacemakers should be limited to clinical evaluation. The availability of long life lithium battery powered pacemaker units do not justify the inherent risks in fabrication, materials handling and use of nuclear pacemakers."

10.4 Physician's comment (108):

"Age range of recipients is currently estimated at 15-65 and should be matched with an estimated patient survival time. Any coexistent condition which might be the basis for seriously questioning patients longevity would constitute a relative contraindication for use of a nuclear device. Because of the restrictions on patient mobility, the necessity for recovery of the radioactive material postmortem and the follow-up relationship even in the absence of any pending pacemaker failure or the necessity for replacement is such that an emotionally unstable patient should probably be disqualified as an appropriate recipient of a nuclear device."

11. *If you recommended any limitations in the preceding question, should they be imposed by:*

a. *conditions of licensing nuclear pacemakers?*

Yes	50
No	36

b. *insurers (Medicare, Blue Cross, etc.)?*

Yes	12
No	60

c. *peer review?*

Yes	58
No	29

12. *What is the mortality rate for elective replacement of still functioning pacemakers? What is the rate and seriousness of complications in these replacements?*

Mortality rates	Total
0 %	77
less than 0.5	7
more than .5 but less than 1	14
1-5	15
Minimal	10

Morbidity rates	Total
0 %	5
less than 1	6
1-5	35
5-9	7
10-20	2
more than 20	1

Source of complication	Total
Infection	37
Lead related	4
Other	15

12.1 Physician's comment (48):

"In this institution there has never been a death related to elective replacement of a pacemaker device in approximately 3500 procedures. Complications from these replacements increase with each succeeding replacement as tissue vascularity becomes further compromised by repeated incisions."

12.2 Physician's comment (21):

"Negligible in our hands. I do not remember a death in the past ten years. The principal complication is infection, which requires repacement of the system but is not life endangering."

12.3 Physician's comment (75):

"The mortality rate for elective replacement of functioning pacers is essentially zero for transvenous units. Mortality is not the problem but the morbidity associated with these repeated surgical procedures, namely at least an overall 20% to 30% complication rate when one includes extrusion of the pacer, infection, damaging electrodes, displacing electrodes and the pain and suffering of the repeated operations, particularly when it is the third or fourth procedure. Also, the older patients are generally not able to cooperate under local anesthesia and require a general anesthetic."

13. *What is the mortality rate for replacement of pacemakers that have gone to battery depletion? What is the rate and seriousness of complications in these replacements?*

Mortality rate due to battery depletion, %	Total
0	42
less than 1	6
1-2	9
3-5	13
6-10	4
11-20	4
more than 20	1

13.1 Physician's comment (48):

"There has been no mortality whatsoever in this institution relative to any type of permanent pacemaker procedure regardless of whether the battery had gone to depletion or not. However, it may well be that certain patients who have died outside of the hospital had done so due to undetected battery depletion. In our own group of patients we have never documented this despite careful followup of all patients who have died."

13.2 Physician's comment (75):

"The mortality rate for replacements of pacers that have gone to battery depletion again is probably unknown since a good percentage of those people would die suddenly and not reach the hospital, particularly if they were pacer dependent. If they were not totally pacer dependent, the major complication is syncopal episodes which can lead to multiple episodes of cerebral ischemia each of which would cause some degree of brain damage. As these patients come in with battery depletion, they become emergency cases which require monitoring beds in intensive care or coronary care units. Secondly, they usually require immediate placement of a temporary pacemaker through subclavian vein puncture. This procedure in itself can be quite serious, particularly since it can lead to a pneumothorax that is a collapsed lung or perforation of the subclavian artery with hemothorax as a complication. If one is in the 60 to 70 age bracket, this is indeed a serious complication. In addition to that, of course, if one is on anticoagulants such as a patient needing a prosthetic valve replacement, serious hematoma can form within the wound and secondary infection is a very real problem. Of course, the major concern in older debilitated thin patients is extrusion of a pacer through the skin when repeated surgery is required."

14. *What is the value to the patient to avoid, or to extend the interval between, pacemaker replacements? Be as specific or quantify your answer as much as possible.*

Values to patients	Total
Pain and discomfort	33
Anxiety	22
Surgery/hospitalization	27
Cost/expenses	76
Inconvenience/time	29
Complications	12
Mortality and morbidity	55
Risk	13
Hardware/battery failure	22

14.1 Physician's comment (90):

"No one desires repeated replacements..."

14.2 Physician's comment (25):

"There is a significant emotional benefit to a patient who does not have to return, often precipitously for an elective or semiemergency replacement. If one tries to extend the interval by frequent observations, clinic visits, etc., there is an additional emotional stress. The patient will often request that the replacement be done electively as a 'lesser evil.'"

14.3 Physician's comment (20):

"Basically, one wishes to avoid repeated surgical intervention in a pacemaker pocket where one could possibly damage the catheter that may function for many years and also avoid introduction of infection into a pacemaker site. At the present time the longevity of pacemakers will depend on the catheter itself as power sources such as nuclear pacing or nickel-cadmium batteries would appear to have enough longevity to cover the vast majority of patients."

14.4 Physician's comment (54):

"(a) Painful, frightening experience. Older people tolerate stress and hospitalization very poorly.

"(b) Cost for hospitalization.

"(c) Constant concern of patient that pacer is running down."

14.5 Physician's comment (42):

"The value lies in avoidance of the possibility of complications during replacement and avoidance of the followup procedures which by their nature are somewhat restrictive. I have patients who are vigorous and travel internationally. As they approach the two year period after implant they feel a weight on their maneuverability because of the relatively sudden nature of battery depletion with the mercury-zinc pacer. For these people a prolonged extension of longevity would be very useful."

14.6 Physician's comment (21):

"Additional comments: At the present time the longevity of power sources is still under evaluation. Improved mercury cells have been documented to go for five years; expectancy with their use in conjunction with programmable pulse generators may reach 8-10 years. Lithium cells may reach a longevity of 10-15 years but documentation covers only three years. Nuclear powered pulse generators have been documented for a little over five years. Their theoretical life certainly extends to 20 years or more. It is most important that all power sources receive more exposure. Estimation of future potential life for nuclear units rests on more solid grounds and this is a strong argument for their retention in armamentarium until equal performance of other systems is proven out."

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123. V. L. Willman, M.D.
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124. David Winsor, M.D.
St. Vincent Medical Center
2131 West Third Street
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125. Zak Vera
Sacramento Medical Center
Stockton Blvd.
Sacramento, Calif.

126. Lawrence E. Ver Husen, M.D., Inc.
St. Bernardine's Hospital
2101 North Waterman Avenue
San Bernardino, Calif. 92404

127. W. G. Yalett, M.D.
Lee Memorial Hospital
Fort Myers, Fla. 33901

128. Yale H. Zimberg
St. Mary's Hospital
Richmond, Va.

129. Walter Zuckerman, M.D.
Mt. Auburn Hospital
300 Mt. Auburn Street
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130. Bayfront Medical Center, Inc.
701 Sixth Street, South
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(No physician given)

131. University of Mississippi Medical Center
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(Envelope address)

132-133. No name given

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