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COMMENTS ON SAFETY AND LICENSING ASPECTS OF A RADIOISOTOPE FUELED CIRCULATORY SUPPORT SYSTEM, PHASES I, II AND III

Phase I (Initial Study Phase) and Phase II (Growth Phase) are concerned primarily with regulatory and licensing aspects of isotope power sources and do not need commenting.

Phase III (General Applications) is concerned mainly with an evaluation of the public hazard from isotope power sources from accidents or from random exposure to radiation from implanted power sources.

The number used in all risk estimates is the equilibrium number, i.e., the number of 200,000 implanted devices at a given time. This figure is calculated by using, among others, the introduction rate of devices, an age specific mortality rate of the recipients and device failure rate.

For the introduction rate, a value of 10,000 implants per year was assumed. As I understand it, this number is an estimate made by the National Heart Institute (originally a figure of 100,000 was suggested). I do not know what this number is based on, but it is conceivable that the logistics involved in implanting (large numbers of) devices could possibly limit the implantation rate to less than 10,000 per year. Also, it is not clear whether this number refers to the implantation of devices in new patients or includes replacement of devices that have failed (approximately 6% of total number of devices).

It is felt that several of the assumptions made in estimating the number of implants are unacceptable from the medical point of view, and result in an unrealistically large number of devices implanted. As an example, in calculating mortality data, it is assumed that recipients live and die as normal individuals, their age specific mortality will not change with time and that all death to natural heart disease will be prevented.

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It would seem to me that in view of the many pathological changes such as arterio sclerotic changes that frequently accompany or cause cardiac abnormalities this assumption is incorrect and unrealistically increases the life span of recipients. This leads to an increase in the total number of devices at equilibrium. Furthermore, implantation of an assist device does not prevent death from heart disease and, in fact, could be an important cause of death in recipients of assist devices.

In view of this it would seem reasonable that use of corrected assumptions could significantly reduce the projected number of implanted devices at equilibrium and thus decrease the radiation exposure to the population at large.

Another important assumption in estimating the radiation exposure to the general population depends on the return to normal activities or life-pattern of all recipients of assist devices. This assumption is tenuous in view of available information on clinical follow-up of cardiac patients. Therefore, it would be of importance to calculate the exposure of the general public in the case that only 75% or 50% of the heart recipients are able to return to normal life.

In general it would seem that the conclusions are based on assumptions that favor unrealistically large numbers of devices, long life-spans of patients and devices and extreme effectiveness of the therapeutic measure. Applying available medical knowledge and expertise in a reevaluation of assumptions used by the originators of the report is recommended with the expectance that this might conceivably result in significant lower estimates of radiation dose to the public.

In final analysis, it is necessary to realize that perhaps the main problem in connection with implanted isotope power sources is the involuntary exposure of the general public without an evident direct benefit attached. If one conservatively assumes a linear dose-effect relationship for radiation induced malignancies, this problem of involuntary exposure becomes an absolute one, even if the actual radiation exposure is found to be only a fraction of the one estimated in the report. In view of the potential uncertainties in the conclusions, I feel that we cannot comment at this time on the anticipated risks to the general public from isotope power sources.

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