QUARTERLY PROGRESS REPORT

BIOMEDICAL ENGINEERING SUPPORT

Contract AT(11-1)-2155-12

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Third Quarterly Report

for

February 16 to May 15, 1974

Institute for Biomedical Engineering and

Division of Artificial Organs

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SUMMARY

During the quarter covered by this progress report (February 16 to May 14) a fit trial experiment was conducted to determine and evaluate the accommodation in a calf of the proposed Westinghouse blood pump drive train and electric motor configuration. The proposed system would permit exchange of the electric motor with the plutonium loaded thermal converter sometime after total heart replacement had occurred and the calf was convalescing. Modifications were made and a tentative drive train system was established which would permit successful interchange of the electric motor and thermal converter.

Tentative surgical protocol and procedures were developed for future total heart implantation experiments, including the protocol for thermal converter exchange and implantation.

The application for a Special Nuclear Materials License (as Ammendment Number 6 to the University of Utah's SNM663) has been prepared and submitted to the AEC Division of Material Licensing. It is anticipated that no serious obstacles will arise in acquiring permission from the AEC to receive and utilize the encapsulated Pu-sources.

Modifications to the electric motor controller unit were made to provide higher maximum output torques and permit electrical monitoring of certain operating variables. The electric motor housing was modified to accommodate a tubular wound cooling system which could remove heat generated by the electrical motor and maintain local surrounding tissue at acceptable temperatures.

An AEC Artificial Heart Program Planning Meeting composed of AEC, WANL, Philips, University of Utah and other personnel, was held at the

Institute for Biomedical Engineering at the University of Utah, from April 29 to May 1, 1974. The fit trial experiments were conducted and tentative protocols were established in addition to discussion and planning related to the program's goals.

A formal paper on the "Development of the Implantation of a Total Nuclear-Powered Artificial Heart System" was prepared and presented at the annual American Society of Artificial Internal Organs meeting in Chicago, Illinois, April 3 to April 5, 1974.

Mr. Lee Smith has devoted 80% of his time to this project during the reporting period. Furthermore, Dr. Gary Sandquist has devoted 33% of his time to the project during the quarter and Dr. Donald Olsen has devoted 25% of his time to the project during the quarter. Contract requirements are thus being fulfilled.

I. AEC FIT TRIAL EXPERIMENTS

As the procedure of choice, the long term evaluation of the AEC blood pump and thermal convertor will begin with a small electric motor power supply eventually to be replaced with the thermal convertor. One justification for this is to minimize the unnecessary handling and exposure of personnel and recipients to the AEC thermal convertor. Initially an electric motor will be installed to power the AEC blood pump. After a sufficient period of time has elapsed and it appears the recipient has stabilized and is doing satisfactorily with the blood pump mechanism, then and only then will the electric motor power supply be replaced with the nuclear powered thermal convertor. During the April 29 meeting in Salt Lake City, a 105 kg calf was sacrificed for use in a fit trial experiment. This consisted of initially suturing quick connect and great vessel grafts and installation of the AEC blood pump. The flexible drive shaft was installed and attached to the blood pump. In the abdomen of the cadaver calf was implanted a mockup of the electric motor we plan to use in future experiments. Finally several techniques of replacing the electric motor with a mockup of the thermal convertor were examined. Items looked at carefully were speed, difficulty in making and breaking drive and circulating fluid connections to gear boxes and proper anatomical fit of the thermal convertor in the animal's abdomen. As seen in the accompanying photographs, there is sufficient space in the abdomen for both the electric motor and thermal convertor. Ideally the electric motor would be removed from the calf's abdomen while still connected to a right angle gear box and drive shaft (Fig. 1). Then the AEC thermal convertor would be connected in parallel to the side of the gear boss (Fig. 2). This would necessitate stopping the electric motor and blood pump only while the thermal convertor connection

Figure 1: Fit trial using the cadavor calf to demonstrate the simultaneous positioning of the electric motor next to the thermoconvertor in the calf's abdominal incision.

Figure 2: Fit trial to illustrate the AEC thermoconvertor with right angle gear box after removal of electric motor prior to inserting these components into the calf's abdomen.

Figure 3: Mockup models of AEC blood pump, flexible drive shaft, right angle gear box, thermal converter and electric motor, to illustrate relative sizes. (Blood pump mockup does not include ventricle outflow and inflow ports.)

is being made. This would use approximately 5-10 seconds for the spline of the thermal convertor to engage the spline hole in the gear boss. Once engaged the electric motor would again be started to run the blood pump while also serving to start the thermal convertor. Final twisting of connector threads on the thermal convertor could be completed after the electric motor was restarted. Should the thermal convertor fail to start there would be no loss in power to the blood pump. After the thermal convertor is started and when it is determined to be operating correctly, the electric motor would be removed. The final step is to insert the thermal convertor back into the calf's abdomen into the same space taken previously by the electric motor (Fig. 2). This sequence offers several advantages: One, just a few seconds of actual heart stoppage; two, the electric motor remains connected to the blood pump at all times in case the thermal convertor should fail to start or operate correctly; three, only the abdomen of the calf is surgically opened, there is no need to reopen the calf's thorax; and four, minimal handling of the thermal convertor by personnel and minimal radiation exposure to the recipient until satisfactory results are obtained. with the electric motor power supply. See Figure 3 for relative sizes of electric motor and AEC thermoconvertor.

Further details to be worked out are the oil coolant lines running from the thermal convertor to the blood pump. Cooperation between our staff and other AEC contractors will continue as design modifications require. Design of the total prototype system requires intensive investigation into design changes that may effect the conversion from an electric motor drive to the nuclear powered thermal convertor. At this time we find no reason why this conversion cannot be made quickly, carefully and effectively.

II. PROTOCOL FOR TOTAL HEART REPLACEMENT AND THERMAL CONVERTER INTERCHANGE

During the April 29 meeting at Salt Lake City, University of Utah, WANL and AEC personnel drafted the following two protocols. First, a protocol for the changeover from an implanted electric motor to the nuclear powered thermal convertor. This is only the first draft of such a protocol and it is subject to change as design changes demand. The second protocol deals with the handling of the nuclear powered thermal convertor. Again, this protocol is subject to modification as experience and design changes dictate.

Since representatives of Philips of North America, subcontractors for construction of the thermal convertor, were in attendance at the April meeting, we were able to benefit from their input in drafting the following two protocols.

PROTOCOL FOR TOTAL HEART REPLACEMENT

May 1, 1974

Preoperative:

1. Hematologic workup on calf.
2. Confine calf to cage for 8-10 hours and train on the treadmill.
3. Keep calf NPO 24 hours, except for water 12 hours.
4. Neomycin 2000 mg orally 6 hours preop.
5. Lab packs.
6. Drive shaft is attached to the pump and is primed with coolant in the circulation tubes with shunt and oil in the shaft. The nose cone is in place. The coolant and oil is sterile as well as the exterior of all the components.

Operation:

1. Induce with Brevane and 2 mg Atropine and place calf on its back.
2. Intubate and connect calf to respirator.
3. Insert urinary catheter if female.
4. Prep and drape to insert pressure lines in left leg.
5. Expose the right jugular vein and carotid artery.
6. Make incision through the right paramedian abdominal muscle to the peritoneum to receive the electric motor.
7. Midsternal split incision and dissect mediastinum.
8. Dissect SVC and IVC and place tourniquets.
9. Open pericardium, dissect aorta, pulmonary artery, place tourniquets and preclot grafts.
10. Heparinize with standard dose, 5 mg/kg.
11. Place bypass lines (arterial line in carotid artery).
12. Start partial bypass very slowly, not more than 0.5 L/min. Stay on partial bypass for at least 5 min. to get adequate mixture of blood and priming solution.
13. Total bypass. Ligate hemiazygos vein and excise ventricles.
14. Suture both atrial cuffs.
15. Suture P.A. graft.
16. Suture Ao. graft and check for leaks.
17. Pass shaft through the diaphragm and place the blood pump into the thorax.
18. Flush ventricles with CO₂.
19. Connect electric motor with gear box to the drive shaft.
20. Recharge lubricating oil.
21. Tunnel and pass power and coolant lines through the skin and hand to power control operator.
22. Connect atrial and aortic and PA quick connects.
23. Prime ventricles and start pumping.
24. Stop bypass and place chest drains.
25. Check for leaks, remove bypass lines and start protamine sulfate, 1.5 x H dose. Add 600 mEq KCl I.V.
26. Close chest, carotid artery and ligate jugular vein.
27. Place calf in cage.
28. Initiate vacuum on chest drains.
29. Initiate recovery procedure, normothermia and lung ventilation as indicated by blood gases.
30. Intensive postoperative care.

PROTOCOL FOR THERMAL CONVERTOR

May 1, 1974

Criteria for Implantation:

Stable preparation using available physiological parameters. The animal is eating and drinking with no O_2 support and standing, a minimum of 48 hours post-implantation.

Procedure:

Preoperative:

1. Thermal convertor has been sterilized and is running on auxiliary cooling and speed control load.
2. Anesthetize, intubate and surgically prep the animal.

Operative:

1. Incise through former abdominal incision and expose the gear box and electric motor.
2. Prepare site for thermal convertor using dummy for space requirements.
3. Heparinize.
4. Remove running thermal convertor with auxiliary cooling lines from its sterile chamber.
5. Place thermal convertor in proximity to gear box.
6. Remove nut cover from gear box.
7. Stop thermal convertor (10 minutes maximum). (Can restart with external power source.) Coolants are circulating.
8. Stop electric motor, start timer, at 60 seconds restart electric motor.
9. Effect the mating, including sperm oil charge.
10. Restart electric motor.
11. Connect the internal cooling system.
12. Monitor blood pressures and temperatures.
13. Remove electric motor and cap motor connector.
14. With oil filled syringe engage bleeding port on gear box and charge with sperm oil and remove any air-creating mild vacuum. Cap self-sealing bleeding port.

PATHOLOGICAL REPORT: FIBRIN DEPOSITION ON AEC BLOOD PUMP VENTRICLES

To properly demonstrate the rate at which a fibrin neointima develops on the inside of a fibrilized silastic ventricle, the following observation was made.

AEC Experiment #7 (TH73 C46 B43 AEC7) began on December 11, 1973 and lasted only 25 hours. After removal of the blood pump ventricles from the mechanical blood pump assembly, a sample of the neointima was peeled away from the inside of the ventricles and sent to a histopathology laboratory.

Examination of several sections of the prosthetic neointima reveals that it consists almost entirely of fibrin with scattered inflammatory cells including lymphocytes, neutrophils, macrophages and possibly occasional fibroblasts. However, the fibroblasts have not yet begun to produce collagen. Scattered within the neointima layer are occasional Dacron fibrils.

This neointima layer just described is a fairly common observation with silastic rubber fibrilized ventricles. One important point illustrated by this observation is the speed at which this layer can develop. In the case in point the neointima layer formed was 12 mils thick. Fibrin deposition at this rate would completely fill the ventricle's pump volume in approximately 75 days if it continued. In fact, with air driven silastic fibrilized ventricles used in other calves, a heavy, thick fibrin layer, of approximately 2 cm thick, was found after only 36 days when bacterial infection was present.

The use of silastic rubber fibrilized surfaces, however, are very suitable for medium-term testing of blood pump ventricles up to approximately 40 days.

At present we are looking into the feasibility of using other material for the blood pump ventricles to circumvent the fibrin deposition problem.

Material such as Lycra and Avcothane, both polyurethane, seem to hold great promise. At the present time we have a calf surviving in our laboratory using a Lycra air driven Jarvik heart that has been pumping 53 days with no signs of reduced stroke volume due to fibrin deposition.

Another problem encountered with fibrilized surfaces and born out by our pathological study of the neointima is the loosening of Dacron fibrils from the ventricular surface. These fibrils can eventually work their way free of the neointima and lodge in the brain or other vital organs. Again, the use of smooth polyurethane or hydrogel surfaces offers a long term solution and alternative to this problem. We will continue to use the rough fibrilized silastic surfaces for our next studies. However, past experience has demonstrated that in spite of their many inherent problems they still can afford a suitable blood pump ventricle for medium-term evaluation.

III. APPLICATION FOR SPECIAL NUCLEAR MATERIALS LICENCE

In order for the Institute of Biomedical Engineering at the University of Utah to receive, store and utilize Pu-238 encapsulated sources used as power supplies for the thermal converter, an application for a Special Nuclear Materials License (as Ammendment Number 6 to the University of Utah SNM663) was prepared and submitted to the Division of Material Licensing (DML) of the U.S. AEC. The application provides detailed information and data on the insitute and the AEC Artificial Heart Program, as indicated below:

1. General information on the Institute.
2. Duration requested for SNM license.
3. Special nuclear materials inventory.
4. Activity proposed under the SNM license and site description.
5. Administration and technical qualifications.
6. Health physics equipment facilities.
7. Nuclear criticality evaluation.
8. Hazard assessment and maximum credible accident evaluation.
9. Shipment of SNM.
10. Detailed description and usage of SNM in the artificial heart system.
11. Record maintenance.

Since licensing from DML for the same Pu-sources has been previously obtained by Westinghouse and the proposed procedures for receiving, storing, transporting and utilizing the Pu-sources are conservative and safe, it is deemed that possession by the Institute of the SNM will not result in undue risk to the Institute personnel or to the public or its welfare and that the license will be granted by DML. A complete copy of the SNM Licence Application (Ammendment Number 6 to SNM663) is appended to this progress report.

IV. COOLANT SYSTEM FOR ELECTRIC MOTOR DRIVE

Evidenced in earlier experiments was the need for proper cooling of the small electric motor used to test and evaluate the AEC blood pump.

Heat flux measurements indicated that as much as 9-10 watts of excess heat was given off by the electric motor while undergoing full pumping capacity of the blood pump. The first attempt using the electric motor completely implanted in the calf's abdomen showed severe tissue damage resulting from thermal hot spots on the electric motor casing.

One method to reduce this problem is to increase the surface area that dissipates heat. However, with 10 watts of heat to dissipate this alternative is not realistic.

Our solution was to wrap a copper cooling coil completely around the electric motor and flow water through the coil to maintain the electric motor at or near the calf's body temperature. The cooling coil was insulated from the body tissue with a silastic rubber coating (see Fig. 4) over which was placed a Dacron velour layer to allow for tissue ingrowth. Water coolant lines carry approximately 600 ml/minute and were bundled together with electric motor power lines, vacuum line and transducer leads. This bundle was sealed with silicone RTV, medical grade rubber and covered with Dacron velour and exited the calf's side near the abdomen, eliminating leads through the chest wall.

Initial experiments utilizing the cooling coil with a similar external heat exchanging coil demonstrated that less than 1/2 watt of heat is dissipated from the electric motor. This, coupled with a surface area of the electric motor and coil of approximately 400 cm^2 , yield a heat flux of less than 0.001 watt/cm^2 . Heat dissipation can be reduced to zero or even to the point where the motor temperature is cooler than the calf's body temperature.

However, we have found it satisfactory to maintain the electric motor to within $\pm 1^{\circ}\text{C}$ of the calf's body temperature. This can be done easily and requires the external cooling coil heat exchanger to radiate its heat to the ambient air. Cooling water flow rates of 400-600 ml/min. is more than sufficient.

This cooling technique allows for efficient cooling of the electric motor and also allows the surface area of the motor package to be kept at a minimum. A thermistor is permanently attached to the electric motor to continuously maintain the electric motor temperature as part of the experimental evaluation of the AEC blood pump.

Figure 4: Variable electric motor prior to implantation. Motor has a tightly wound copper cooling coil covered with silastic rubber insulation and wrapped with an outer layer of Dacron velour. Power and vacuum lines also are bundled and wrapped with Dacron velour.

Figure 5 provides a photographic view of the tissue cavity produced by the presence of the electrical motor in the abdomen of the calf. A pathological examination at autopsy revealed hyperemia and increased vascularity resulting from surgical trauma of the implantation of the electrical motor contiguous to the peritoneal wall.

Figure 5: Photograph taken from left side looking through evicerated abdomen to right peritoneal wall lining. Outlined shape is electric motor which at autopsy evidenced hyperemia and increased vascularity, resulting from surgical trauma and pressure of electric motor against the peritoneal wall.

V. AEC ARTIFICIAL HEART PROGRAM PLANNING MEETING

During the period April 29 to May 1, 1974 a planning meeting for participants in the AEC Artificial Heart program was held at the Institute for Biomedical Engineering, University of Utah, Salt Lake City, Utah. A list of the participants and their affiliation is listed in the following table.

TABLE

<u>PARTICIPANTS</u>	<u>INSTITUTION</u>
Dr. William E. Mott	AEC
Mr. Donald Cole	AEC
Dr. Ron Persing	AEC
Mr. Don R. Roberts	WANL
Mr. Dave Pouchoť	WANL
Mr. Nat Bifano	WANL
Mr. Alex Daniels	Philips Corp.
Dr. Frank Donovan, Jr.	Mississippi, Universities Center
Dr. Murt Billis	Pacific University, Battelle
Dr. Al Hoffman	Washington University, Seattle
Dr. F.A. Kallfelz	Cornell University
Dr. W.J. Kolff	University of Utah
Dr. Gary Sandquist	University of Utah
Mr. Lee M. Smith	University of Utah
Dr. Donald B. Olsen	University of Utah
Mr. Dick Luntz	University of Utah
Dr. Joseph Andrade	University of Utah
Dr. David Lentz	University of Utah
Mr. Karl Schatten	University of Utah

TABLE (Continued)

<u>PARTICIPANTS</u>	<u>INSTITUTION</u>
Mr. Jerrold Foote	University of Utah
Dr. Hartmut Oster	University of Utah
Dr. John Lawson	University of Utah
Mr. Tom Kessler	University of Utah
Mr. Dennis Coleman	University of Utah

Most of the out of town participants arrived Monday evening, April 29, 1974. On Tuesday, April 30, Dr. Kolff welcomed the participants and Dr. William Mott and Mr. Donald Cole (AEC) presented a review of the program status. At 9:00 am a review of the proposed procedure for the total heart replacement, which utilizes initially an electric motor implanted in the calf's abdomen, was discussed. The electric motor is replaced by the Pu-powered thermal convertor at a later time, ostensibly after the calf has stabilized and the prognosis for the calf is good. Westinghouse personnel presented a plan and design option with dummy models proposed to permit successful interchange of the electric motor and thermal convertor, post replacement of the heart.

From 10:00 am to 12:30 pm actual fit trial experiments were performed in a cadaver calf. At 1:30 pm, after lunch, the group reconvened and observations made during the fit trial experiments were discussed and evaluated. A tentative drive train configuration was established for construction and testing by Westinghouse. Later, tentative surgical protocols and handling procedures were developed for future total heart experiments, which provided for the interchange of the electric motor and thermal convertor post heart replacement.

That evening after dinner (April 30) discussion of major program decisions and problem areas were discussed, including the following:

1. Fixation of blood pump and engine/converter.
2. Options for stopping blood pump.
3. Engine/convertoir interchange techniques.
4. Heat dissipation options.
5. Heart-lung bypass procedure.
6. Flexible drive shaft problems.

On Wednesday morning Dr. Gillis from Pacific University discussed their experimental program for determining heat dissipation tolerance in swine from heat sources. Application to the AEC thermal converter with its anticipated heat dissipation requirements were discussed. Later the renewal proposal prepared by the Institute for Biomedical Engineering at the University of Utah, submitted to the AEC, was presented and discussed. Proposed activities under the Institute proposal were discussed and evaluated.

After lunch the planning meeting was adjourned and participants returned to their institutions. The agenda for the Planning Meeting and minutes of certain portions of the meeting are appended to this report.

VI. PAPER PRESENTED AT THE AMERICAN SOCIETY OF ARTIFICIAL
INTERNAL ORGANS ON APRIL 5, 1974 AT CHICAGO, ILLINOIS

In order to better acquaint the medical and scientific community of the current progress relating to developments in the AEC Artificial Heart Program, the following manuscript was submitted and presented at the American Society of Artificial Internal Organs (ASAI0) meeting in Chicago, Illinois on April 5, 1974.

DEVELOPMENT ON THE IMPLANTATION OF A TOTAL NUCLEAR-POWERED
ARTIFICIAL HEART SYSTEM

L. Smith, K. Backman, G. Sandquist, W. J. Kolff,
K. Schatten and T. Kessler*

In 1971 the United States Atomic Energy Commission^(1,2) initiated the development of a totally implantable nuclear-powered artificial heart. Early in 1972 a bench model was designed, constructed and tested. Design criteria and specifications were directed at the widest possible spectrum of the adult U.S. population. Work performed by Dr. Frank Donovan⁽³⁾ at the Universities Center in Jackson, Mississippi has shown that approximately 99% of the present adult population could be maintained providing no anemia with such a total artificial heart.

The implantable nuclear-powered heart consists of two main sub-systems: the thermal converter, built by Philips of North America, which serves as a power supply and the blood pump mechanism (see Figure 1), mechanical portions of which were built by Westinghouse Astronuclear Laboratory with blood handling portions built at the University of Utah. Rotational mechanical power is transmitted from the thermal converter to the blood pump via a flexible drive shaft.

The thermal converter⁽²⁾ is a gas driven Sterling cycle engine which uses a 33 watt, 60 Gm Plutonium 238 heat source. Assuming a cost of approximately \$1,000 per Gm this low inventory of Plutonium represents a savings of about \$20-30,000 over other current nuclear powered assist devices. For a 10-year life expectancy the Sterling cycle engine offers the advantage of increased reliability--most of the seals with critical dimensions and tolerances are maintained in the cooler regions of the

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engine, where longevity of these components is increased because of reduced wear and fatigue. Plutonium 238 was chosen because of its long half life of 88 years and because the major decay products are high energy alpha and low energy gamma rays, which are readily shielded from the recipients.

Power transmitted to the blood pump is converted into linear reciprocating motion by a scotch yoke mechanism. Two pusher cups attached to this mechanism pump the blood alternately. Ventricle diaphragms are attached and sealed to the pusher cups with a roll-sock connection which reduces fatigue by minimizing flexing in the diaphragm. All load bearing points in the pump are supported by lubricated ball bearings.

5.6 watts of power are transmitted to the blood pump by the flexible drive shaft at approximately 97% efficiency (see Table I). The scotch yoke and planetary gear system deliver 4.8 watts of power to the ventricles at 85% efficiency. The alternating pumping ventricles deliver 3.4 watts of power to the blood at an efficiency of 70%. These figures are representative of the bench model only. Future prototype modifications could increase the efficiencies, further reducing the isotope inventory and cost.

Table II lists some of the physical characteristics of the bench model blood pump. The weight is 1,523 Gm with a displacement of 980 cc, including stainless steel quick connects. Stroke volume of the ventricles is 111 ml; at a pumping rate of 120 beats per minute they provide a cardiac output of 12 L/min at 100 mm Hg average outflow pressure and low venous inflow pressure. Hemolysis tests⁽⁴⁾ have demonstrated that with this particular ventricle design and alternating pumping mode there is less blood damage than with air driven hearts. For a smooth surface heart

the Hemolysis Index was .008 Gm hemoglobin produced per 100 L of blood pumped, compared with .04 Gm for air driven hearts of various configurations.

The soft shell⁽⁵⁾ construction of the ventricles allows the heart to respond to Starling's Law. Dacron reinforced Silastic rubber is used in the ventricle construction (see Figure 2) and all blood contacting surfaces are coated with Dacron fibrils. Stainless steel quick connects facilitate atria and great vessel connections to the blood pump.

Implantation protocol and ventricle design began with an exhaustive series of fit trial experiments on calves of appropriate size. Inert models of the AEC thermal converter (see Figure 3) have been implanted in 8 calves--5 normal calves with an average weight of 100 Kg and 3 dwarf calves averaging 130 Kg. The object of these experiments was to determine tolerance of the chronic effects of the weight and size of such an implant in the abdominal region over extended periods of time.

The most desirable implantation site was found to be the abdomen, immediately between the peritoneum and muscle wall. Implantation was to the left of the umbilicus near the costal arch anteriorly. Attempts to implant the inert models subcutaneously and intermuscularly were less successful. Experiments using normal calves were more successful than those using dwarfs. All but one of the inert models were constructed of Dow Corning Silastic RTV "D" mold making rubber. The one exception was highly polished aluminum. All models were encapsulated with Dacron reinforced Silastic rubber. The animal with the aluminum model was terminated after 15 months and there was no apparent contamination of body fluids through the Silastic casing. The aluminum surface was still highly polished and the capsule formed around the model showed dense fibrous connective tissue with no indication of foreign body reaction or infection.

Fit trial experiments using inert models of the blood pump and flexible drive shaft were also conducted on cadaver calves. The anatomical fit of atria and great vessel connections were determined as well as the bend radii of the flexible drive shafts. Clay models were then constructed and reexamined for proper fit. Dental stone models (see Figure 4) were cast and additional fit trial examinations performed. Aluminum molds were machined and Dacron reinforced Silastic rubber was layered over the molds and cured into the finished ventricle. The complete pump assembly with quick connects was again positioned in the animal's chest for proper anatomical fit.

A main objective was to test the bench model blood pump and for the sake of simplicity, the thermal converter was substituted with a small electric motor as the power source.

The first scheme was to externally place the electric motor and transmit power to the pump via a 36-inch flexible drive shaft. The motor was stabilized and fixed to the calf's hip with the drive shaft entering the thoracic cavity through the chest wall between the ribs. A sternal split surgical procedure was followed with the animal on heart-lung bypass for 2 hours.

The first successful experiment using an externally placed electric motor resulted in the animal standing at 9 hours postoperative. The second attempt found the calf stabilized and standing at 25 hours postoperative. This calf survived 69 hours and was terminated because of severe sepsis. A third experiment ended at 25 hours, when early and rapid fatigue of the flexible drive shaft caused it to be determined.

It became apparent that the flexible shaft protruding through the chest wall to an external electric motor provided a pathway for infection and placed great stress on the drive shaft itself.

This knowledge prompted the use of a smaller, totally encapsulated electric motor and shorter 8-inch drive shaft which could be totally implanted. The electric motor was inserted beneath the peritoneum in the abdomen to the right of the umbilicus. The drive shaft was tunneled under the skin and diaphragm into the chest cavity. After removing the animal's heart the atria and great vessel grafts were sutured with their quick connect assemblies and the blood pump was inserted.

At 25 hours postoperative the animal was standing and at 30 hours he was extubated. Aortic pressures were 150/90 with a venous filling pressure of only 7 mm Hg. Blood gases were normal and chest drainage had stopped. The animal was very active, which unfortunately resulted in his falling and damaging the internally placed drive shaft. Twenty minutes later, at approximately 36 hours postoperative, the flexible shaft seized up, terminating the experiment.

Inert models of the AEC nuclear powered thermal converter can be tolerated in the abdominal region of the calves for up to 15 months with no side effects. The mechanical blood pump can provide cardiac output which is more than adequate to sustain experimental calves with an average weight of 110 Kg. The alternating pumping action in combination with this ventricle design is compatible with the animal's blood and maintains excellent outflow pressures with low inflow pressures. An electric motor totally implanted in the abdomen is well tolerated and this internal placement method is recommended over the use of an external power source for testing and evaluating AEC mechanical blood pump.

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TABLE I

THERMAL CONVERTER & BLOOD PUMP--POWER CHARACTERISTICS

	<u>INITIALLY</u>	<u>AFTER 10 YEARS</u>
THERMAL INPUT (watts)	33	31
CONVERTER Eff.(%)	17	17
OUTPUT (watts)	5.6	5.2
PUMP DRIVE Eff.(%)	85	85
POWER INTO VENTRICLES (watts)	4.8	4.4
VENTRICULAR Eff.(%)	70	70
POWER TO BLOOD (watts)	3.4	3.1

TABLE II

PHYSICAL CHARACTERISTICS OF BLOOD PUMP

WEIGHT	1,523 gm.
DISPLACEMENT	980 cc.
DENSITY	1.55 gm/cc.
STROKE VOLUME	111 ml.
PUMPING RATE	120 beats/min.
CARDIAC OUTPUT	12 L/min.
HEMOLYSIS INDEX	.008 (g/100L pumped)
PUMPING	Alternating

TABLE III

SUMMARY

1. Inert Model Implants Tolerated
2. Sufficient Cardiac Output
3. Alternating Pumping Tolerated
4. Implanted Electric Motor Tolerated
5. Complete System-- Blood Pump and
Internal Electric Motor Tolerated

AGENDA

AEC ARTIFICIAL HEART PROGRAM PLANNING MEETING
DIVISION OF ARTIFICIAL ORGANS
BUILDING 518
UNIVERSITY OF UTAH
APRIL 29 to May 1, 1974

Sunday, April 28, 1974

6:00 p.m. Arrival of Dr. Frank Donovan (accommodations - Little America)

Monday, April 29, 1974

3:10 p.m. Arrival of Drs. W. Mott and R. Persing of AEC (accommodations - Hotel Utah).

Mr. Lee Smith will pick them up at Salt Lake Airport and take them to their hotel.

6:00 p.m. Mr. Donald Cole of AEC, Mr. Don Roberts, Mr. Dave Pouchot, Mr. Nat Bifano of WANL and Mr. Alex Daniels of Philips Corporation of North America (arrival late Monday evening). Accommodations - Hotel Utah/Motel Utah - to be arranged by group.

Late p.m. Arrival of Dr. Murt Gillis (Pacific Universities - Battelle), and Dr. Kallfelz (Cornell University), accommodations to be arranged.

Tuesday, April 30, 1974

8:00 a.m. Morning Conference - Building 518. Dr. Haapanen - 10 minutes, and Dr. Gillis speaking on Thermal Dumping - 10 minutes.

8:30 a.m. Coffee and Rolls

8:45 a.m. Welcoming - Dr. Kolff
Introduction - Mr. Donald Cole/Dr. Bill Mott

9:00 a.m. Review of Fit-Trial experiment (John Lawson recording)
a.) Anatomical Review - Dr. Don Olsen
b.) Proposed Plan and Design Options - WANL Personnel
c.) Design Improvements on Drive Shaft - WANL Personnel (Mr. Dave Pouchot)

10:15 a.m. Travel to St. Mark's Hospital

10:30 a.m. Experiment - fit trial with cadaver calf.
Convene - 4th floor, surgery department.
Conversion from electric motor to thermal convertor.

12:30 p.m. Reconvene for lunch - Conference Room, 1st floor (Lawson to prepare)

1:30 p.m. Open discussion of experiment - Dr. Kolff presiding

Agenda
AEC Artificial Heart Program Planning Meeting
Page Two

- 2:00 p.m. Short presentation about potential problems - Dr. Andrade, Dr. Olsen, Mr. L. Smith, Dr. Frank Donovan - 10 minutes each.
- 2:30 p.m. Coffee
- 2:45 p.m. Open discussion - all participants (J. Lawson recording)
- a.) Fixation of pump and engine
 - b.) Stopping pump
 - c.) Conversion technique
 - d.) Heat dissipation problems
 - e.) Off-heart-lung bypass procedure
 - f.) Drive shaft problems
- 3:30 p.m. Sequestering of three people to write implantation procedure - Dr. Olsen, Mr. Roberts and Dr. Donovan
- 3:30 p.m. Discussion of AEC proposal renewal - Dr. Kolff, Mr. Cole, Dr. Mott, Dr. Sandquist and Mr. Smith - Library at St. Marks
- Other visitors free
- 6:15 p.m. Dinner at Andy's Smorgasbord, 3350 Highland Dr. Discussion of presentation by Dr. Andrade, Dr. Olsen and Mr. Smith. Open discussion by participants (J. Lawson recording).

Wednesday, May 1, 1974

- 8:00 a.m. Morning Conference - Dr. Gary Sandquist - Bldg. 518
- 8:30 a.m. Coffee
- 8:45 a.m. Dr. Gillis - Discussion on Thermal Dumping
- 9:30 a.m. Presentation of proposal with discussion - Lee Smith, Gary Sandquist and Frank Donovan
- 10:00 a.m. Coffee
- 10:15 a.m. Open Discussion
- 11:30 a.m. Recess for lunch - Panorama Room, Union Building, University of Utah - all participants
- Recess before 1:00 p.m.

APPLICATION FOR
AMENDMENT NUMBER 6 TO
SPECIAL NUCLEAR MATERIALS LICENSE-663

Prepared by
The Division of Artificial Organs
University of Utah
Salt Lake City, Utah

T A B L E O F C O N T E N T S

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1.) General Information on Applicant

The University of Utah hereby applies for an amendment to Special Nuclear Materials License SNM 663 from the U.S. Atomic Energy Commission to receive, possess, use and transfer special nuclear materials at the Division of Artificial Organs of the University of Utah in Salt Lake City, Utah.

Applicant: Division of Artificial Organs
Building 518
University of Utah
Salt Lake City, UT 84112

Complete information appertaining to 10CFR70.22(a)(1) has been previously provided to the AEC under SNM 663 and Broad Form License 43-01884-01 (C78).

The University of Utah is a non-profit, state supported public institution of higher education as provided for under laws of the State of Utah. The University of Utah also has a Broad Form License 43-01884-01 (C78) granted by the AEC for the utilization of prescribed radioisotopes. An existing Radiological Health Committee and a Radiation Safety Officer service the University community in radiological health and safety matters.

An SNM License pertaining to identical or similar encapsulated plutonium-238 sources has been previously issued by the Atomic Energy Commission to Westinghouse Electric Corporation (SNM-951). Thus many of the aspects of this license application have been previously reviewed by the Materials Branch of the Atomic Energy Commission.

2.) Duration Requested for SNM License

The University of Utah requests that this amendment to the SNM License become effective October 1, 1974 and serve for a duration of five years to expire October 31, 1978.

for

3.) Special Nuclear Materials Inventory

The maximum quantity of special nuclear material which will be possessed under this license at the location specified in Section 1 will not exceed the following amount:

Plutonium	150 grams	as 2 encapsulated sources only, specifically Pu-238 (as PuO ₂) encapsulated as heat sources for artificial heart devices
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The material will be utilized in accordance with contractual program requirements. Transfer of material will be arranged as needed, either with AEC licensed facilities or in accordance with AEC contractual arrangements. No production, consumption, or significant loss of special nuclear material is anticipated. Intrinsic encapsulation design and stringent nuclear materials management procedures will preserve the encapsulation of the special nuclear material.

The actual isotopic inventory of the plutonium used in the encapsulated sources is well represented by the following table (Table 3.1) which gives the gamma-spectroscopy analysis by Mound Laboratory (using a 20 cc Ge(Li) crystal on a 2.7 gr sample of Pu-238 used in a 1.5 watt SNAP-15A source.

TABLE 3.1
COMPOSITION OF REACTOR PRODUCED Pu-238

Element	Atomic %	Microscopic Cross Section (barns) (for thermal neutrons)	
		absorption	fission
Pu-238	76.9	557	17
Pu-239	16.4	1013	742
Pu-240	2.5	280	<0.08
Pu-241	0.64	~462	~100
Pu-242	0.1	20	<0.2
Pu-236	<0.3 ppm	~150	~150
Th 232	few ppm (est.)	7.4	41x10 ⁻⁶
U-234	2.6	94	<5 x10 ⁻³
Np-237	0.1	169	0.018
Am-241	0.16	710	3

Note: For isotopes given above, the ratio of the fission to absorption reaction rate at thermal neutron energy is:

$$\frac{\Sigma(\text{fission})}{\Sigma(\text{absorption})} = .222$$

4.) Activity Under SNM License and Site Description

Specific application of the encapsulated plutonium (Pu) sources will be directed towards testing, evaluating and developing a total artificial heart system which employs Pu-238 as a heat source to power a Stirling cycle engine which in turn provides mechanical rotary power to a blood pump. This artificial heart system will be subjected to mock circulation studies and will be implanted into experimental animals (non human) for study, evaluation and further development.

The Division of Artificial Organs at the University of Utah has extensive experience and competence in this area of medical research and has been selected by the Division of Applied Technology of the AEC to perform such medical research, including utilization of plutonium-238 as heat energy sources under contract, AT (11-1) 2155.

The University of Utah is located on the foothills of the Wasatch Mountains and forms part of the extreme eastern boundary of the Salt Lake Valley. The campus of the University occupies about 1100 acres and has a faculty numbering 2566 and a student population of about 21,000 (see Figs. 4.1 and 4.2 for a map of the University of Utah and Environs). The University supports a fully accredited College of Medicine and a College of Engineering, both of which serve as the basis for the Division of Artificial Organs.

The Division of Artificial Organs is housed in several buildings (Fig. 4.3). Building 518 on campus is the administrative headquarters for the Division, while an engineering group is located in the Merrill Engineering Building. All experiments requiring surgical procedures are conducted in the former Saint Mark's Hospital Building (now occupied only by the Division) at 809 North 3rd West, Salt Lake City, Utah. It will be in

the Saint Mark's Hospital where the Pu sources will be received, utilized and stored. It is anticipated that all Pu sources will remain at Saint Mark's during the tenure of employment by the Division of Artificial Organs. It is felt that frequent transport of the sources on public roads is an undue and unnecessary risk. If occasional utilization at one of the other locations of the Division of Artificial Organs is necessary, detailed procedures and facilities will be developed to ensure the safe and competent movement and storage of the sources. If the sources are to be stored or used at a location other than Saint Mark's Hospital for over 48 hours, similar storage, monitoring and emergency facilities which exist at St. Mark's will be established at the proposed location of the sources. To ensure compliance with these provisions, movement of any of the sources from St. Mark's Hospital (other than approved shipment under DOT and AEC approval) will require prior approval of the Chairman or Assistant Chairman of the Division of Artificial Organs and the University's Radiation Safety Officer.

Figure 4.4 shows the location of the Pu storage room selected for storing the Pu sources. This below ground room was previously used for radioisotope storage when Saint Marks was utilized as a functioning hospital. The Pu storage room's interior dimensions are 10 feet wide, 10 feet high, 12 feet deep. Walls and ceiling are nominally one foot thick reinforced concrete. Radiation levels at the outside surface of the Pu storage room walls arising from two Pu sources is estimated at less than 0.05 mrem/hr which is only about twice background level for this location. Except for small plumbing pipes entering the room, the only opening is the single locked door which connects to a short hallway. At the end of this hallway is another locked door which employs a combination lock. Furthermore all entrances to the storage area are locked, so that a minimum of three separate locked security

barriers exist between the Pu storage room and outside or generally accessible areas.

The storage room will contain an alarm system, operated by D.C. batteries, which is capable of triggering an alarm upon the following conditions:

a.) Forced Entry

If entry is attempted by forcing of the door to the room, a magnetic switch at the door cell triggers the alarm. Deactivation of the magnetic switch requires that an inconspicuous key-operated switch be operated.

b.) High Temperature

If the temperature in the Pu-storage room exceeds a preset value (approximately 120⁰ F) the alarm is triggered.

c.) High Radiation

If the radiation level in the room exceeds a preset level (approximately 1 mrem/hr) the alarm is triggered.

Figures 4.5 - 4.9 show the floor plan for those areas of the Saint Mark's Hospital Building now utilized by the Division of Artificial Organs. Surgical procedures are performed on the third floor (Figure 4.9) and in vivo animal experiments utilizing the Pu sources would be conducted on this floor in one of the surgical operating rooms. Movement of the Pu sources between the Pu storage room and the surgical floor will always employ at least two Division staff members. A plutonium source locator board placed at the central surgical station will indicate the status and location of all the Pu sources.

Graduate School Meeting Operations (Bldg. 402), L. 14
 Graduate School of Science Bldg. 1, M. 4
 Graduate School of Science Bldg. 1, M. 4
 Graduate School of Science & Technology Engineering Bldg. 1, M. 4
 Graduate School Library 1, L. 12
 Graduate School (310 Park Building), L. 4
 Graduate School of Social Work, M. 5

Graduate School 1310 Park Building, 1-4
Graduate School of Social Work, M 5

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RESEARCH CENTER

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100-443887-100

A schematic diagram of the experimental setup. A subject is seated at a table, viewing a video screen. A camera is positioned above the screen. A target is placed on the table. A light source is positioned to the right of the target. A scale bar is shown below the target.

100-443887-100

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A schematic diagram of a neural network model. It consists of three layers of nodes. The bottom layer has four square nodes. The middle layer has four circular nodes. The top layer has four square nodes. Connections are shown between the bottom and middle layers, and between the middle and top layers. Some connections are labeled with 'A' and 'U'.

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Graduate School Meeting Operations (Bldg. 402), L. 14
 Graduate School of Science Bldg. 1, M. 4
 Graduate School of Science Bldg. 1, M. 4
 Graduate School of Science & Technology Engineering Bldg. 1, M. 4
 Graduate School Library 1, L. 12
 Graduate School (310 Park Building), L. 4
 Graduate School of Social Work, M. 5

[illegible]

Human Resources 33
Humanities College of 205 Oregon Avenue Hall K 7
Medicals Laboratory E 5
Industrial Services Division 33
Information Center 38 112
International Registrar's Office 428 E 1
International House 428 112 E 16
Korean American Center 428 112 17

Kennedy: Religion Center Gd
Kingsdale H2
KUFN: 31st Hapt H1
KUFN (Kingsdale Hapt): H2
Lam L1
LDS Institute of Religion East G10
LDS Institute of Religion (Lam): H1

LDC Chemistry First Stage Center L 14
 Local Chemistry Physics Sciences Building H 3
 Library Materials L 6
 Life Sciences H 3
 Making Bureaus R to S 13 E 14
 Material Library L 6
 Materials Engineering Lab G 4
 Mathematics L 6

[illegible]

Mrs. Benjamin H. Education: 19
 Mrs. P. H. G. 1
 Mrs. C. H. H. 1
 Mrs. S. H. H. 1
 Mrs. P. H. H. 1
 Mrs. M. H. H. 1
 Mrs. P. H. H. 1

Metastasis to E 15
 Breast Cancer to 3
 Metastasis to E 15
 Metastasis to 3
 Metastasis to E 15
 Breast Cancer to E 15
 Breast Cancer to E 15
 Breast Cancer to E 15

[illegible][illegible]

Psychology Research 16 Jg 404 D 17
 Public Safety - Brg 4221 72 10
 Purchasing Department - Brg 401 H 4
 Red Cross P 17
 Restaurant - 100 Park St (Rm 122) D 15
 Registrar - 100 Park St 12
 Relations - General - Meeting Room 401 H 4
 Secretary - 100 Park St 12

FIGURE 4.2

FIGURE 4.3

DIVISION OF ARTIFICIAL ORGANS FACILITIES

OLD ST. MARK'S HOSPITAL

COLLEGE OF ENGINEERING

MEDICAL CENTER

MICROCIRCUIT LABORATORY
University of Utah - (off campus)
19 East Oakland

Modern microcircuit production facility including ion implantation, visual and auditory prosthesis laboratory.

BUILDING 518 (HERCIK BUILDING)
(3,825 sq. feet)

Large conference room, offices, machine shop, woodworking shop, dark room, and operating room.

BUILDING 403

Additional dialysis facility, classrooms, offices, laboratory.

FIGURE 4.4

Basement Floor Plan - 2,800 ft²
Old St. Mark's Hospital

Basement Floor Plan - 3,680 ft²

OLD ST. MARK'S HOSPITAL

FIGURE 4.5

Ground Floor Plan - 3,680 ft²

OLD ST. MARK'S HOSPITAL

FIGURE 4.6

First Floor Plan - 3,680 ft²

OLD ST. MARK'S HOSPITAL

FIGURE 4.7

Second Floor Plan - 3,680 ft²

OLD ST. MARK'S HOSPITAL

FIGURE 4.8

Third Floor Plan - 3,680 ft²

OLD ST. MARK'S HOSPITAL

FIGURE 4.9

5.) Administration and Technical Qualifications

5.1) Administration

The Division of Artificial Organs at the University of Utah is a formally organized division within the university organization (Fig. 5.1) under the College of Medicine and the College of Engineering and the Research Division. The Division of Artificial Organs has approximately 111 technical personnel representing multidisciplines such as Medicine (surgery, cardiology, nephrology, etc.), Engineering (Electrical, Mechanical, Chemical, Nuclear) and Science (Physics, Chemistry, Materials, Biology, Computer Science, etc).

Dr. W. J. Kolff (M.D. and Ph.D.) is the Chairman of the Division and the Principal Investigator for the Division's contract with the AEC to develop the Pu power source artificial heart system.

Although most of the personnel in the Division will have some interaction with the specific program of R&D on the Pu powered artificial heart, those charged with specific responsibilities in the AEC sponsored program who are directly involved in this license application are given as follows:

- (1) W. J. Kolff, M.D., Ph.D.
Chairman of the Division of Artificial Organs and
Principal Investigator
- (2) Don B. Olsen, D.V.M.
Assistant Chairman of the Division of Artificial Organs
- (3) Gary M. Sandquist, Ph.D.
Radioactive Materials Supervisor
- (4) Robert Pendleton, Ph.D.
Radiation Safety Officer for the University

There are other numerous physicians, engineers, technicians, and health physicists involved in the program but their activities which are pertinent to this

FIGURE 5.1) ORGANIZATIONAL CHART

license application are directly under the control of the above named personnel. Dr. Kolff with his assistant, Dr. Olsen, are ultimately responsible to the University and the AEC for the safe and competent utilization of the SNM employed in this program. Dr. Sandquist will be responsible to the Division Chairman for all radiological aspects associated with the Pu sources and will have chief responsibility for ensuring that no undue risk or hazard results to Division personnel or the public as a consequence of the possession and utilization of these sources.

Dr. Pendleton, the Radiation Safety Officer, is charged by the University for ensuring radiological health and safety and full compliance by users of radioactive materials with pertinent University and government regulations.

5.2 Technical Qualifications

Complete vitae on each of the personnel given in section 5.1 are contained in Enclosure 2. Dr. Sandquist, who will be most actively involved with the sources is also Chief Reactor Supervisor for the University AGN-201 Nuclear Reactor (License R-25) and a TRIGA Nuclear Reactor which is under construction (CPPR-119). He also administers the SNM license for the TRIGA reactor's fuel (SNM 1263) and a By-Products Material License (43-01884-15) for 15 mg of Californium-252. Dr. Pendleton administers the University's Broad Form Material License 43-01884-01 (C78) and Special Materials License (SNM-663), maintains the University's detection and radiation dosimetry equipment, and provides personnel radiation monitoring. Both Drs. Pendleton and Sandquist serve on the University's Radiological Health Committee which is responsible for ensuring health and safety in all radiological matters under University cognizance.

6.) Health Physics Equipment and Facilities and Emergency Procedures

6.1) Health Physics Manual

The radiation protection procedures described in the University of Utah Radiological Health Manual will be used. Currently, the latest revision of this manual is dated 1973. A copy of this manual has been previously submitted to the DML.

6.2) Radiation Detection Instruments

A list of the various types of radiation detection instruments available to the Division of Artificial Organs is given in Figure 6.1. The following instrument calibration methods and frequency have been established by the Radiation Safety Officer of the University of Utah.

Counting Room Instruments

Scintillation and proportional counters will be calibrated semiannually using standardized radioisotope counting sources.

Portable Survey Meters

Beta-gamma survey meters will be calibrated semiannually and/or following repair by exposure to a standard source on a response/distance relationship. Meter response will be verified before use by exposure to laboratory check sources. Alpha survey meters will be calibrated semiannually and/or following repair using a standard source. Alpha meters will be checked before use with an alpha check source.

NUCLEAR DETECTION AND DOSIMETRY EQUIPMENT

TYPE OF INSTRUMENTS (Include make and model number of each)	SERIAL NUMBER	RAD. DETECTED	SENS. RANGE (mr/hr)	WINDOW THICK. ² (Mg/cm ²)	DETECTOR TYPE	USE (Monitor, Survey, Measure)
<u>PORTABLE SURVEY INSTRUMENTS</u>						
Eberline Model E-510	429	BG	0-200	14	GM	SURVEY
"	273	"	"	"	"	"
"	105	"	"	"	"	"
"	409	"	"	"	"	"
"	107	"	"	1.4	"	"
Atomic Accessories SX-136	136-24	"	0-10 ⁵ CPM	"	"	"
Eberline Model Pac-3G	1568	"	"	0.7	Gas Prop.	"
"	1712	"	"	"	"	"
Victoreen Scintillac 645	354	A	"	-	Scint.	"
Eberline Model PAC-15A	764	"	0-20KCPM	-	"	"
" PAC-2S	102	"	"	-	"	"
Precision Scintillator 111-B	211	G	0-5	-	"	"
Victoreen Model 440	384	BGX	0-300	0.7	ION Cham.	MONITORING SURVEY
"	1014	"	"	"	"	"
" 666	198	"	0-5000R	Air Equiv.	"	"
Baird-Atomic Model 414	362	BG	0-3000	1.4	"	"
Tracerlab Model SU-1H	1792	"	0-1500	"	"	"
Nuclear-Chicago Model 2586	1036	"	0-2500	0.7	"	"
"	970	"	"	"	"	"
" 2588	2379N	"	0-250R	"	"	"
Eberline Model FN-4	119	N	0-1000	"	Hurst Cham.	"
" PNC-1	220	"	0-10 ⁵ CPM	-	BF	"
Texas Nuclear Memo 9140	112	"	0-10 ⁴ MREM	-	Bonner Sphere	"
Victoreen Minometer II 6876	502	X	0-10	Air Equiv.	ION Cham.	"
" Condenser R-Meter 570	611	GX	0-250R	"	"	"
" Roentgen Rate Meter	33338	"	0-3000R	"	ION Cham.	"
<u>PERSONNEL DOSIMETERS</u>						
Landsverk Dosimeter Charger L-24K	4800	-	-	-	-	PERSONNEL DOSIMETRY
"	4471	-	-	-	-	"
Landsverk Direct-Reading Dosimeters	16 ea.	G	0-200	40	ION Cham.	"

FIGURE 6.1

TYPE OF INSTRUMENTS (Include make and model number of each)	SERIAL NUMBER	RAD. DETECTED	SENS. RANGE (mr/hr)	WINDOW THICK (Mg/cm ²)	DETECTOR TYPE	USE (Monitor, Survey, Measure)
Landsverk Direct-Reading Dosi- meters	8 ea.	G	0-200	40	ION Cham.	PERSONNEL DOSIMETRY
Eberline TLD Reader TLR-5	246	-	0-10 ⁶ R	-	-	"
"	247	-	"	-	-	"
Harshaw Lif Dosimeters TLD-100	2000 ea.	BG	0-5000R	-	TLD	"
<u>AREA MONITORS</u>						
Eberline Model RM-2	180	G	0-20	-	ION Cham.	AREA MONITOR & ALARM
" R1-5	186	"	0-100	-	GM	"
" HILEM	193	"	0-1000R	-	ION Cham.	"
<u>LAB. COUNTING SYSTEMS</u>						
Nuclear-Chicago Scaler 186 with Internal Proportional Detector	37	ABG	0-10 ⁶ CPM	-	GAS Prop.	SAMPLE ANALYSIS, LEAK TEST
Eberline Model SAC-2	164	A	"	-	SCINT.	
RIDL 400-Channel Analyser with 4" x 8" NaI(TL) Detector	-	G	"	-	"	
<u>AIR SAMPLERS</u>						
Eberline Model AIM-3	186	A	0-1000CPM	-	SCINT.	AIRBORNE ACTIVITY MONITORING
"	276	BG	0-10 ⁴ CPM	-	"	"
" LAS-1	128	-	-	-	-	HIGH VOLUME AIR SAMPLING
"	110	-	-	-	-	"
"	113	-	-	-	-	"
<u>GAMMA SPECTROSCOPY EQUIPMENT</u>						
Harshaw 5" NaI Scintillation Detector	-	G	-	-	SCINT.	SPECTROSCOPY
Cannberra 30 cc Ge(Li) Detector	-	G	-	-	SOLID ST.	"
TMC 1024 Multichannel Analyzer	-	G	-	-	-	"

6.3) Emergency Procedures

General instructions for emergency procedures are given in the University of Utah's Radiological Health Manual. However, it is deemed desirable that specific instructions and emergency procedures be established relating to the storage and utilization of Pu sources at Saint Mark's Hospital.

6.3.1) Fire

a. Immediately notify Salt Lake City Fire Department by telephone or alarm box. Telephone number: 363-4401. Location of alarm boxes: on each floor near elevator.

b. Evacuate the threatened areas of all personnel except those necessary for imperative duties.

c. Ascertain the specific location and extent of the fire and if possible employ immediately available fire fighting equipment to extinguish the fire.

d. Notify Gary Sandquist at 581-7372 (home: 486-8521), Robert Pendleton, Radiation Safety Officer at 581-6141 (home: 466-2705), W. J. Kolff at 581-6296 (home: 582-3056) or Don Olsen at 581-6296 (home: 272-0160).

e. Determine the actual location of all Pu sources by examining the Pu locator board. If all Pu sources are in the storage room, inform the Fire Department of their location upon their arrival. If it appears that an extreme fire threat exists in the Pu source storage area, request that the Fire Department flood the storage room through the existing plumbing conduit.

f. If any Pu source is not in storage and may be threatened by the fire, it should be removed from the building if possible and placed in custody of Gary Sandquist or Robert Pendleton for safe keeping.

g. If the Pu source is implanted in an experimental animal, the experiment should be immediately terminated and either the animal removed from the building or the Pu source surgically removed from the animal and then taken from the building.

6.3.2) Bomb Threat or Riot

In the event of a bomb threat or other violent threat directed at Saint Mark's Hospital or its personnel, the following actions should be taken:

a. Immediately notify the Salt Lake City Police Department by telephone at 328-7111. If this is not possible, use a fire alarm box in the building or (unobtrusively if under immediate personal threat) trip outside alarm.

b. Determine (unobtrusively if necessary) the actual location of all Pu sources by examining the Pu locator board. If possible return Pu sources to secure storage.

c. Do not indicate the existence or location of the Pu sources to intruders unless under immediate personal threat.

d. If under immediate personal threat, comply with the demands of the intruders, but carefully observe each intruder so that an accurate description of each intruder can be supplied later to the police and FBI.

6.3.3) Earthquake, Flooding and other Natural Disasters.

Such disasters pose no immediate threat to the Pu sources and primary emphasis is upon minimizing personnel injury from the natural disaster. Operations for recovery of the Pu sources will be under the direction of Gary Sandquist and Robert Pendleton.

7.) Nuclear Criticality

The actual composition by isotopes of the reactor produced Pu-238 employed in the encapsulated heat sources is given in Table 3.1. The quantity of SNM material requested in this application is 150 grams of Pu; however, the actual total quantity of SNM isotopes in the two encapsulated sources with fission cross sections greater than 0.1 barn at thermal energy is as follows:

<u>Isotope</u>	<u>Total Grams</u>	<u>Fission Cross Section (barns)</u>
Pu-238	106.6	17
Pu-239	22.7	741
Pu-241	.89	100
Pu-242	.14	0.2
Pu-236	4.1×10^{-6}	150
Am-241	.23	3

It is apparent from these quantities that nuclear criticality is not possible under any conceivable condition of moderation or intimate inter-mixing. From Table 3.1 the value of the ratio $\Sigma(\text{fission})/\Sigma(\text{absorption}) = 0.222$ and conservatively using a maximum value of the neutron yield per fission (ν) = 3.0 then the infinite multiplication factor for the Pu-238 heat sources is $K_{\infty} \leq \nu \frac{\Sigma f}{\Sigma a} = .667$. It is apparent that this isotopic plutonium composition cannot become critical regardless of the mass considered even if parasitic neutron capture in non-fissionable materials and leakage is ignored.

Since the quantity of SNM material (Pu) requested is less than 300 grams the requirements of 10CFR70.24 do not apply. It is further anticipated that the two encapsulated sources will not be stored or used in intimate contact with each other.

8.) Hazard Assessment and Maximum Credible Accident Evaluation

After considering in detail the possible credible accidents involving the Pu sources which might pose some hazard or risk to personnel, property, or the general public, it is believed that fire in the building providing housing for the sources poses the greatest, most credible risk. The reasoning behind this conclusion and the assessment of other risks and hazards considered is as follows.

8.1) Maximum Radiation Exposures

Radiation levels at 10 cm from a single Pu source are as follows:

19.1 mrem/hr - neutrons

9.2 mrem/hr - gammas

28.3 mrem/hr - total

These levels represent a maximum continuous annual exposure of 248 rem. Although this is a high dose it is not lethal and the likelihood of a single person being exposed to such a value unknowingly is very small. Even willful exposure by an individual would be limited and controlled by personnel radiation monitoring devices, surveys by health physics technicians and periodic unannounced inspections by the University Radiation Officer. Annual maximum operational radiation exposures to personnel most heavily involved with handling and utilization of the Pu sources is estimated conservatively as follows.

Activity

Surgical Implantation
Procedures

5 hrs/implant x 20 implants
x 28.3 mrem/hr = 2.8 rem

Long-Term In Vivo Animal
Experiments

40 hrs/wk x 50 wks x 3 mrem/hr
= .6 rem

All personnel working in near proximity of a Pu source will be required to wear appropriate personnel dosimetry devices as currently specified by the Radiological Health Committee. Present devices are TLD for gamma and X-rays and film badges for neutrons.

8.2) Theft or Sabotage

Since the isotopic composition of the plutonium in these heat sources is such that the sources do not constitute useful fissile material and the sources have such specialized and limited application, their value to illicit organizations or criminals is believed to be small. Nevertheless, because of the great value and importance of these sources both for the AEC and the Division of Artificial Organs, an extensive security program will be initiated to minimize the potential for theft or sabotage. A strict accounting procedure for the storage and movement will be implemented. No source may be removed from storage without approval of the Chairman or Assistant Chairman of the Division.

Saint Mark's Hospital and its facilities are manned twenty-four hours per day either by members of the Artificial Organs Staff (regular hours are from 8:00 a.m. to 6:00 p.m.) or the evening security guard (6:00 p.m. to 8:00 a.m.). When animal experiments are underway (essentially the only time when the Pu sources would not be in the locked storage area), there is twenty-four hour coverage by Division staff members who will be fully instructed in all emergency procedures related to the Pu sources and will be capable of implementing these procedures. Both University and Salt Lake City police are available and have been appraised of the emergency procedures for handling the Pu sources.

8.3) Maximum Credible Accident

Probably the most credible and hazardous event that could threaten the integrity of the Pu sources is major fire in Saint Mark's Hospital which involves the sources. The buildings constituting Saint Mark's Hospital are of brick, concrete and masonry construction and considered fire resistant. The areas of the building presently used by the Division of Artificial Organs are quasi-fire proof and primary fire threat would arise primarily from localized electrical or chemical fires that would probably not threaten the building structure itself. The encapsulation of the Pu sources is designed to survive exposure to temperatures of 2500⁰ F for two hours without failure. The melting temperature of PuO₂ is about 5000⁰ F. Temperatures of 2000⁰ F or more are not attainable from the limited quantity of flammable materials in the building and the presence of high temperature generators (e.g. high voltage electrical lines, flammable gases, oxygen tanks, explosive materials) near the Pu sources will be prohibited except for limited exposure such as the presence of an oxygen supply tank necessary for respiration assistance of an animal experiment employing the Pu source.

The consequences of a fire in or near the storage room would pose no credible threat to the Pu sources. No electrical (except for the low voltage radiation alarm system) or combustible materials exist or will be placed in or near the storage room. Walls, ceiling and floor of the storage room are heavy reinforced concrete and provision exists for flooding the room with water if necessary. Part of the total alarm system in the Pu storage room will include a high temperature sensing device which will trigger the alarm system if a set temperature (approximately 120⁰ F) is exceeded.

A fire involving a Pu source implanted in an experimental animal would probably pose the greatest threat to the source. In this case, even if no attempt was made to remove the source (emergency procedures require this action if possible) from the vicinity of the fire, it appears highly improbable that any release of radioactive material would occur. This conclusion is based upon the fact that the animal's body represents a thermal heat sink of about 220,000 BTU and that temperatures of over 2000⁰ F for many hours are not credible in the environment considered.

9.) Shipment of SNM Materials

Shipments of SNM will be made in appropriate DOT Specification packagings. For those shipments which will involve only intrastate movements, the transportation will be in accordance with the requirements of the State of Utah. Transfers and receipts of SNM will be accounted for by completion and distribution of Nuclear Material Transfer Reports (Form AEC-741) as specified in 10CFR70.54.

10.) Description and Usage of SNM in Artificial Heart Systems

10.1) Purpose

Under USAEC Contract, the University of Utah is to experimentally evaluate function and performance of an implantable model of a total nuclear powered (plutonium heat source) artificial heart system. A vented $^{238}\text{PuO}_2$ radioisotope capsule used as the power source for thermal converter supplied by the USAEC is an integral component of the system to be evaluated. Figure 10.1 shows the IVBM thermal converter with the Pu-heat source installed. To carry out this USAEC Program, permission to receive and use these plutonium radioisotope capsules at the Division of Artificial Organs of the University of Utah in experimental tests is required.

10.2) Capsule Description

The cutaway view of the radioisotope capsules to be used is shown in Figure 10.2. Also included is information on the overall size and thermal power. In the thermal converter the design surface temperature of the capsule is 1565°F . The atmosphere surrounding the capsule will be at 10^{-4} torr or lower vacuum when in place in the thermal converter.

The capsule is a three layer, flat-ended heat source consisting of a platinum-rhodium alloy (Pt-20 Rh) liner, a non-selective PRD, a T-111 strength member, and a Pt-20 Rh outer clad. One end cap contains a cavity for the capillary tube. The capillary is 4 inches long and has an ID of 0.005 inch. It is welded to the liner/PRD, penetrates the strength member, and is then welded to the clad. The T-111 strength member is thus sealed and impervious to any contaminants from either the fuel or the external atmosphere. In addition, the capillary reduces the level of Radon-220 emitted by the fuel to acceptable levels; and it minimizes the contaminants entering the interior of the capsule.

THERMAL CONVERTER

613713 ICA

Figure 10.1 IVBM Thermal Converter

Figure 10.2 ARTIFICIAL HEART HEAT SOURCE

The Pt-20Rh liner is 0.020 inch thick. Each end cap has a 0.010 inch step to facilitate positioning during welding operation. One cap accomodates the PRD-capillary assembly. The PRD, a shortened and simplified version of the Transit PRD, extends into a recess in the fuel and is welded flush with the liner cap. The fuel is medical grade Pu-238. The T-111 strength member is 0.095 inch thick. Each end cap includes a 0.040 inch step for positioning during welding operation. The Pt-20Rh clad consists of a cylinder having a 0.010 inch thick. The end caps are thicker to enable a 0.010 inch step to be incorporated for ease of assembly and welding.

The capsule will be fueled, assembled, and closure welded at Mound Laboratory. E. B. and TIG welds will be used as appropriate. Quality control will be in accordance with Mound Laboratory procedure. Quality assurance by USAEC inspectors at Mound Laboratory will be in accordance with AEC-AL Quality Control Policy QC-1, (not provided). Other capsule parameters are as follows:

Fuel Pellet Weight (g)	77.2
Weight Pu (g)	61.6
Typical Composition	11.2 WT% O ₂ , 88.2 WT% Pu
Fuel Form	
Chemical	Plutonium Dioxide
Physical	Pressed and Sintered
Specific Activity (Curies/g)	13.3
Neutron Emission Rate (n/sec/g)	3300
Dose Rates at 10 cm	
Neutron (mR/hr/g)	0.31
Gamma (mR/hr/g)	0.15

The design of the radioisotope capsule is such as to meet the following safety and accident conditions:

Impact:	216 ft/sec against solid granite
Fragmentation:	30-06 caliber rifle bullet at 2000 ft-lb
Crushing:	5000 lb static load on concrete
Cremation or Fire:	2500 ⁰ F for two hours
Post Accident	1300 ⁰ F Indefinitely (Simulates 6" soil burial)

The vent is essentially the same as that used on the Pioneer and Transit heat sources.

10.3) On Site Handling

10.3.1) General Safety and Handling Conditions

The Pu sources described above are scheduled to be used at the University of Utah for a period commencing on or about Oct. 1, 1974. It is expected that at any one time a maximum of two capsules will be on hand, and possibly implanted in experimental animals.

The radioisotope capsules will be shipped to the University of Utah in containers currently licensed under DOT Special Permit No. 5791. The shipping container is a drum-type birdcage of the following characteristics:

Model No.:	131 (AL-M6)
Capacity (Gallons)	55
Maximum Thermal Decay Energy	
Output of Contents (Watt):	65
Inner Container Max.	6.5 ID.,
Dimensions (inches)	16 Height

The container is further described Monsanto Research Corporation's Sketch No. 4 (Model AL-M6). The shipping container (s) will be retained at Saint Mark's Hospital in the Pu-storage room as the storage container (s) for the radioisotope capsules. Specific procedures for handling the Pu sources are discussed below.

10.3.2) Storage

The University of Utah Radiation Safety Officer will be notified when the Pu sources arrive at the shipping/receiving area. A health physics technician will make preliminary surveys for both neutron and gamma radiation to verify the levels specified on the shipping papers. Following the initial radiation survey, a wipe test will be made of the shipping container at the nearest surface to the capsule accessible for smear testing to determine that leakage is less than 0.005 microcuries of removable alpha contamination. If the alpha contamination is acceptable, the capsules in the container will be moved to the storage room. If the smear test indicates removable alpha contamination, the capsules and container will be moved to the storage room to await return to the sender.

10.3.3 Installation in Thermal Converter

When the time comes to place a plutonium source capsule into the artificial heart thermal converter the storage container will be moved to a location near the bench on which the thermal converter is located. Using tongs to protect against heat and to minimize neutron/gamma radiation hand exposure, the one capsule will be transferred from the storage container to the isolated glove box. Sufficient test runs will be performed as training with unfueled capsules to assure a smooth transfer and minimize the chance of dropping a capsule. The source is designed however, such that no damage will occur if a capsule should drop to the floor.

The radioisotope heat source capsule is inserted into the hot side assembly of the Stirling Engine. The engine is mounted such that the cylindrical axis of the radioisotope capsule is vertical. The hot side assembly is shown in Figure 10.3. The engine crank case which is to the bottom of the figure is not shown nor are the internal details of the hot finger. The radioisotope capsule is positioned with a nickel conduction sleeve at the top of the hot finger. The hot side assembly is designed to provide ready access to the radioisotope capsule while reducing heat losses through the insulation package to a minimum and maintain the insulation package in a permanent static vacuum.

The vacuum foil insulation package is a set of concentric cup and annular baffles contained in a permanently evacuated space between the engine hot finger and an outer can welded to the hot finger at the cold end the of the hot finger just above the heat exchanger. The hot side assembly including the heat exchanger will be removable from the engine crankcase by a flange to be placed at the bottom of the crankcase. The displacer shown in Figure B-1 is attached to the rhombic drive mechanism in the crankcase by a rod. When the flange at the heat exchanger is broken, the displacer stays with the crankcase. This opens a cylindrical path inside the hot finger for insertion and removal of the Pu-238 heat source.

The insertion sequence of the Pu-238 heat source is as follows:

1. The engine hot side assembly is removed by breaking a flange at the bottom of the heat exchanger.
2. The snap ring indicated in Figure B-1 between the Pu-238 heat source and displacer is removed.
3. The assembly is inverted and the heat source lowered into the hot finger by a metal suction cup attached to a small suction pump.

Figure 10.3. Hot Side Assembly

4. After the heat source bottoms against the blind end of the hot finger, the vacuum is turned off. The suction probe is removed and the snap ring replaced to hold the heat source in place.
5. The hot finger is then inverted and reattached to the crankcase at the flange.

10.3.4) Implantable Model Usage

It is anticipated that the implantable artificial heart system will be tested throughout the license period. During this period when Pu sources are inserted in the thermal converter, the capsule will remain at a nearly constant equilibrium temperature as the heat rate demanded by the engine is constant. Variations in engine output are obtained by throttling the engine at constant heat input. The radioisotope capsule will be in a constant temperature, argon environment.

The only forces present are those from engine vibration. These forces are estimated to be a maximum of 0.01 g at 10 cycles/sec. It is inconceivable that vibrations of this level will damage the well secured radioisotope capsule. Because the heat source is in the working gas environment its surface temperature will not be much different than the hot finger wall temperature or 1000 K (1340 F). Pressure levels in the working gas vary from approximately 11.5 atmospheres to 17.5 atmospheres 10 times a second. The vented capsule exhaust capillary was designed with this pressure fluctuation in mind.

A detailed step-by-step procedure for installation of the Pu-238 heat source in the thermal converter preparatory to surgical implantation of the thermal converter in the experiment replacing the implanted electrical motor is given as follows. Also a tentative surgical protocol for thermal converter implantation is presented. These activities will

initially be proctored by Westinghouse Astronuclear Laboratory personnel who have previous experience in handling and assembling the thermal converter system under SNM-951.

Thermal Converter Startup and Shutdown Procedure

Pu-238 Heat Source

Startup

1. Assemble equipment as per Figure 10.4. Thermal converter should be assembled but without Pu-238 heat source installed.
2. Mount thermal converter and thermal converter cooling water connections, auxiliary oil system, argon supply, and instrumentation.
3. Purge thermal converter leaving argon supply attached.
4. Remove Pu-238 heat source from shortage. Place in glove box.
5. Purge glove box. After purge, maintain slight (2" H₂O) argon pressure inside.
6. Remove hot finger assembly from thermal converter.
7. Insert Pu-238 heat source in hot finger assembly. Start thermal converter cooling water.
8. Install fueled hot finger assembly on thermal converter.
9. Start auxiliary oil system and pressurize thermal converter with argon using the following procedure. Start auxiliary oil pump and gradually increase the argon gas pressure per established procedures until equilibrium is reached at 200 psig. The oil pressure should then read 135 psig. The difference between average gas pressure and oil pressure should be 50 to 65 psig through this process.
10. Connect flex shafts. Use starter motor or hand crank to turn over engine. After engine starts, control speed by starter motor or dynamometer. If starter is used, remove starter motor and place cap over shaft end.
11. Control speed by dynamometer until thermal converter conditions stabilize. When stable, adjust engine speed control to hold speed under varying load.
12. Isolate or disconnect thermal converter from auxiliary oil system.

Figure 10.7 System Start-up Schematic

10.7

Shutdown

1. Activate or connect and activate auxiliary oil system.
2. Block engine speed control in full throttle position.
3. Overspeed engine by 10% by reducing dynamometer load. Allow heat source to cool approximately 100⁰C.
4. Stall engine and depressurize (quickly).
5. Remove hot finger assembly from thermal converter.
6. Remove Pu-238 heat source from hot finger assembly. Allow to cool.
7. Replace hot finger assembly on thermal converter.
8. Inactivate test setup in same manner as for electrically heated thermal converter.

WARNING: During any of these procedures, the hot finger temperatures should be continuously monitored. If any temperature exceeds 1800⁰F, destroy thermal insulation vacuum by cutting vacuum pinch-off.

Surgical Protocol for Thermal Converter Implantation

Criteria for Implantation

Stable preparation using available physiological parameters. The animal is eating and drinking with no O₂ support and standing a minimum of 48 hours.

Procedure

Pre-Op

1. Thermal converter has been sterilized and is running on auxiliary cooling.
2. Anesthetize and intubate and surgically prep the animal.
3. Incise through former abdominal incision and expose the gear box and electric motor.
4. Prepare site for thermal converter using dummy for space requirements.
5. Heparinize.
6. Remove running thermal converter with auxiliary cooler lines from its sterile chamber.
7. Place thermal converter in proximity to gear box.
8. Remove nut cover from gear box.
9. Stop thermal converter (10 minutes maximum). (Can be restarted with external power source.) Coolants are circulating.
10. Stop electric motor; start timer at 60 seconds, restart electric motor.
11. Effect the mating, including sperm oil charge.
12. Restart electric motor.
13. Connect cooling system.
14. Monitor blood pressures and temperatures.

15. Remove electric motor and cap motor connector.
16. With oil filled syringe, engage bleeding port on gear box and charge with sperm oil and remove and create air creating mild vacuum. Cap self sealing bleeding port.

10.3.5) Accidents

The only internal failure of real concern would be an inadvertent stall of the thermal converter after operating conditions are reached. Under these conditions it is expected that the temperature of the capsule could reach temperatures as high as 2350⁰F in as little as one hour if the vacuum in the insulation space were maintained and the capsule were not removed from the hot finger. The three thermocouples that measure the hot finger temperature in the heat source location will be continuously monitored either by personnel or by an alarm.

In the event that alarm monitoring is being used, thermal insulation will be installed with auxiliaries that will break the insulation vacuum seal and backflood the insulation with helium and ruin its insulation capability. Based on bench model experience using a similar system, capsule temperatures after backflooding quickly reduce to less than 300⁰ F.

In the event that the system is being monitored by personnel when an engine stall accident occurred, the procedure would be somewhat different. First an attempt to restart would be made. Second, if restart failed, an attempt to remove the hot finger and then remove the capsule would be made. Third, if the second procedure failed also, the vacuum seal on the thermal insulation would be broken manually and the insulation allowed to fill with the argon in the glove box in which the nuclear thermal converter or nuclear system tests will be carried out.

In the event that the alarm system failed to function properly or that personnel did not respond to the accident condition at 2350⁰ F the Udimet material of the structural portion of the hot finger would melt. This would flood the insulation with the engine working fluid which is argon. This also would relieve the overtemperature condition. In the event

that the engine stall had been caused by a loss of working fluid, the pressure in the engine would still be at least as great as the local ambient, or about one atmosphere, and it takes less than 1/10 of an atmosphere gas pressure to totally ruin the insulation's effectiveness. Rather obviously this latter "safety procedure" would destroy the engine and test program. However, the integrity of the radioisotope capsule would not be threatened because of the 2500⁰ F, two hour fire capability of the capsule.

In view of the building characteristics it is considered incredible that any building fire could generate enough heat to violate the capsule integrity. With respect to external failures, what we have said concerning forces and temperatures for the thermal converter is also true for the capsule in storage.

11.) Record Maintenance

The Division of Artificial Organs will create and maintain records showing the receipt, inventory, location and transfer of all special nuclear material under its control. The Radiation Safety Officer as part of his assigned duties will periodically review these records for accuracy and completeness. The applicant will promptly notify the AEC of any loss of special nuclear material.