CONTINUOUS RADIONUCLIDE GENERATION. I. PRODUCTION AND EVALUATION OF A ^{81m}Kr MINIGENERATOR

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An improved generator has been devised as a prototype for clinical use which will provide continuous production of ^{81m}Kr. Delivery of ^{81m}Kr can be in liquid or gaseous state. Preparation of parent radionuclide and design of the generator and delivery system emphasizes a decreased contamination with the parent radionuclide and severe miniaturization of the generator and delivery system. Elution is by an injectable isotonic solution.

Rubidium-81, the parent radionuclide which has a half-life of 4.7 hr, is produced on the Argonne 60-in. cyclotron by alpha-irradiation of cuprous bromide on a copper target mounted over an aluminum base. Following activation, the copper and bromide ions are removed. The purified residual ^{81}Rb is dissolved in distilled water and transferred to the generator. The generating column is housed inside the cylindrical hub of a stainless steel connector in a space measuring 2.5 mm in diameter and 22 mm in height. The generator is shielded by 4 in. of lead. Fifty to 100 mCi of ^{81}Rb are routinely produced and trapped on Dowex 50 resin which is sandwiched between two layers of inert filtering material. The ^{81m}Kr may be eluted by distilled water, 5% dextrose in distilled water, or by air.

The ^{81m}Kr has a half-life of 13 sec. It emits a monoenergetic 190-keV gamma ray produced by isomeric transition. Similar levels of ^{81m}Kr activity are delivered by gaseous or liquid elution by a constant-volume infusion pump. The ^{81m}Kr may be continuously delivered for many hours through a polyethylene catheter.

Generators for the production of ^{81m}Kr from the parent radionuclide ^{81m}Rb have been previously described by Jones and Clark (*1,2*) and by Yano, McRae, and Anger (*3,4*). Krypton-81m is a radionuclide of a noble gas which has a 13-sec half-life. It decays to the ground state of ^{81}Kr by isomeric transition, emitting a monoenergetic gamma ray of 0.190 MeV, 65% abundant and 35% internally converted. Krypton-81m decays with a 2×10^5 year half-life to stable ^{81}Br. The parent radionuclide, ^{81}Rb, has a half-life of 4.7 hr. It has previously been produced by alpha irradiation, in the cyclotron, of natural bromine as NaBr (*4,5*). This method, however, has several drawbacks. One drawback is the presence of large quantities of Na^+ ions, which as mentioned below, interferes with the generator operation. Another drawback stems from the fact that bromide salts are very unstable to radiation and thermal decomposition, which severely limits the beam densities needed to obtain high specific activities. After testing bromine compounds of all the alkali metals, alkaline earths, rare earths, lead, silver, iron, and many others, we have found that cuprous bromide, Cu_2Br_2, mounted on a metallic copper backing, appears to be the most stable under our conditions and provides a simple chemical system for the preparation of carrier-free ^{81}Rb.

Several advantages of ^{81m}Kr for scintigraphic applications have been discussed by previous investigators (*2*). The authors generally agree with these advantages and, in addition, have proposed the intra-arterial administration of ^{81m}Kr solution to determine the kinetics of capillary exchange (*6*). The generators described by previous workers have specific disadvantages which are indicated below, which,

Received Dec. 10, 1973; revision accepted May 9, 1974.

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if corrected, would facilitate significantly the clinical use of ^{81m}Kr.

1. The presence of sodium, introduced as NaBr in other generators, presents a problem as it displaces ^{81}Rb from the cation-exchange resins at concentrations greater than 1.5×10^{-4} *M* (Fig. 1).
2. The dimensions of the generators previously reported, as well as tubing and connections, require excessive shielding and excessively large volumes of air or solution to deliver the ^{81m}Kr. Thus, optimal delivery of activity in minimal volume is not possible.
3. The elution by distilled water and subsequent mixing with hypertonic sodium chloride solutions in other generators to provide isotonicity increases delivery time and intersystem volume. This contributes to the complexity of the generator and problems of sterility and pyrogenicity are increased.
4. The continuous elution and constant delivery of ^{81m}Kr in gas or liquid form and in minimal volume by the same generator were not adequately provided.
5. The provision of adequate catheters for intravenous and intra-arterial delivery were not provided.

METHODS AND MATERIALS

We have devised the following procedure to prepare ^{81}Rb uncomplicated by the presence of NaBr (*2*). Other details have been reported (*7*).

The target. The target was constructed of $\frac{1}{8} \times 1 \times$ 6-in. sheet copper with eight grooves, each $\frac{1}{16} \times \frac{1}{16} \times 4$ in. The target was directly water cooled. When charged with target material, the target was covered with a 0.001-in. foil of anodized aluminum supported on a Teflon spacer ring.

The target material. The Cu_2Br_2 target material was prepared by dissolving reagent grade Cu_2O in HBr, forming the $Cu_2Br_3^-$ complex; Cu_2Br_2 was precipitated by diluting this solution with deaerated and demineralized distilled water. This dissolution and precipitation step was repeated three or four times to insure against contaminating ions such as Na^+ or Ca^{2+}. The purified Cu_2Br_2 precipitate was stored under deaerated water until placed on the target to preclude oxidation to $CuBr_2$.

Filling the target. The target was charged as shortly before the bombardment as feasible with approximately 1 gm of wet Cu_2Br_2. The material was packed into the target grooves and dried with a stream of nitrogen gas heated to 100°C. The salt in the grooves should be white; any yellow tinge indicates oxidation. The prepared target was placed in a storage unit filled with nitrogen gas until loaded into the target holder.

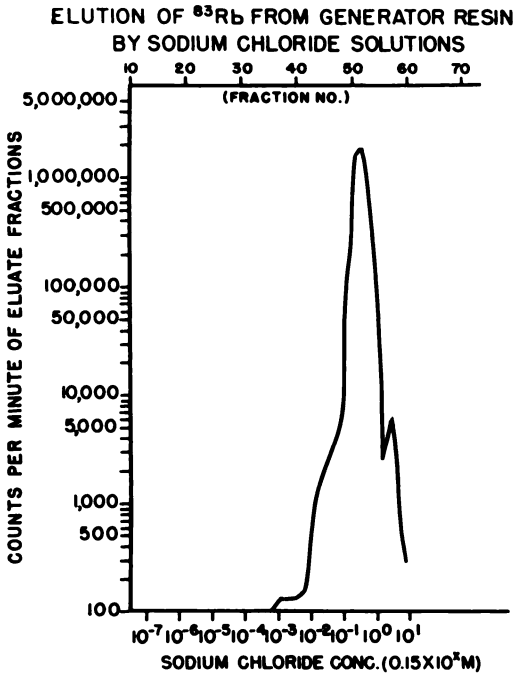

FIG. 1. Replacement of ^{83}Rb chelated to Dowex 50-X8 cation-exchange resin by NaCl.

Target bombardment. The target was bombarded in the 60-in. Argonne Cyclotron with alpha particles having an energy of 46.5 MeV attenuated to 28–30 MeV before reaching the target material. The $^{79}_{35}Br$ $(^{4}_{2}He,2n)^{81}_{37}Rb$ reaction produced a yield of approximately 2 mCi of $^{81}Rb/\mu$A-hr. The total yield was in the 50 mCi range at 25 or greater μA-hr.

Extracting and purifying the target material. The irradiated target was transferred in a plastic bag to a hot cell and degassed. It was then placed in a bath of 80 ml of 9 *N* HCl in an appropriately shaped tube at 70°C. Adhering salts were scraped off for dissolution with a copper wire. The resultant solution was decanted and evaporated in a beaker at 100°C in a stream of nitrogen gas to reduce oxidation until nearly dry. Meticulous care should be exercised in removing all aluminum foil as the aluminum ions will interfere with the binding of ^{81}Rb by the Dowex 50-X8 resin. The cooled residue was redissolved in the least possible volume of 9 *N* HCl, usually about 20 ml. Copper and bromine salt complexes were extracted from this solution by passage through a Dowex 1-X8 resin (100–200 mesh) anion-exchange column 2×15 cm in size. The effluent containing the purified Rb was evaporated in a small beaker at 100°C in a current of nitrogen gas until dry. The

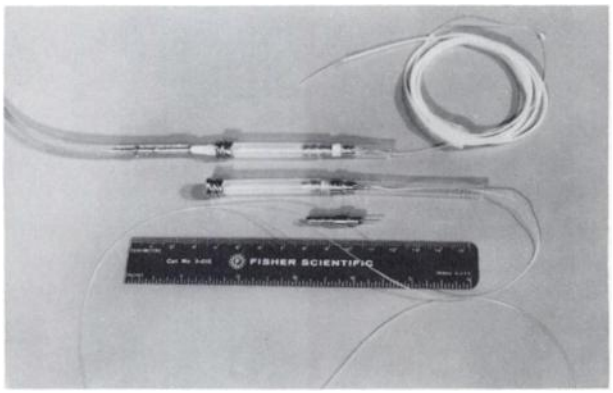

FIG. 2. The ^{81}Rb-^{81m}Kr minigenerator with accessory connectors and catheters.

small amount of residue was redissolved in 2–5 ml of distilled water and passed through the column of the generator which trapped the Rb on Dowex 50-X8 resin. The generator was then washed several times with distilled water to remove residual acid and other impurities. An x-ray spectrum taken with a 17 cm^3 coaxial Ge-Li detector showed that at the end of the separation, 29% of the observed total gamma activity was the result of ^{81m}Kr; the remainder was ^{81}Rb, ^{82}Rb, ^{83}Rb, and ^{84}Rb (*7,8*). The only other radioactive Kr isotope eluted is ^{83}Kr ($t_{1/2}$ = 1.9 hr), which decays by the emission of an almost undetectable 9-keV x-ray and is not comparable in activity to the ^{81m}Kr, being present in a 6×10^{-4}-to-one ratio. The Rb isotopes are all firmly bound to the cation-exchange resin and are not detectable in any significant amount in the generator effluent.

The generator. The generator column was located within a stainless steel elution tube tip, Fig. 2 (ER Squibb and Sons, Inc.). The internal dimensions of this tip were 2.5-mm i.d. and 22 mm long; the volume of this space was 108 mm^3. The space was filled with a layer of Amicon polypropylene inert porous filter support at the outlet, followed by 0.08 ml of Dowex 50-X8 (200–400 mesh) resin and stoppered at the inlet by a small plug of glass wool (Corning 3950). The outlet was tapered to a 22-gage needle, ⅜ in. long. Attached to the outside of the column at the inlet was the lower two-thirds of a plastic disposable tuberculin syringe (Monoject®) to which a luer-lok was added.

Delivery system—the catheter. A 5-in. length of PE 50 INTRAMEDIC® polyethylene tubing (Clay-Adams), 0.58 mm i.d., was heat-fused to the needle. The tip of a 58-in. length of PE 10 INTRAMEDIC® polyethylene tubing, 0.28-mm i.d., was inserted into the lumen of the tip of the PE 50 tubing and heat-fused to be leakproof. The PE 10 tubing is then sheathed in a stiff polypropylene tubing, i.d. 0.8 mm and o.d. 1.2 mm, and held in place by a drop of epoxy resin.

The pump. The generator was connected to the infusion pump by thick-wall tygon tubing. The junction with the generator was made through a 1.5-in., 18-gage needle in the lumen of the thick-walled tubing and a luer-lok connection to a modified tuberculin syringe barrel which was fitted over the stainless steel jacket of the generator. The pump was a Motomatic® motor generator infusion pump (Electrocraft Corp., Model E650-048), obtained from Cole-Parmer Instrument Co. The flow rate was regulated by a variable controller of motor rpm (Cole-Parmer Constant Speed Control Unit). The motor and the pump were connected through a 100-to-1 reduction gear box.

Shielding. The charged generator, connected to pump and catheter, was placed in a groove in an 8 × 4 × 2-in. lead brick. The cave is constructed of a double thickness of bricks of this dimension to provide 4 in. of shielding in all directions. The entire assembly was placed on a heavy-duty, stainless steel cart. The activity on the surface of the shielding was several milliroentgens per hour. The assembly may be placed within 12 to 18 in. lateral to the scintillation detector without significant interference in imaging ^{81m}Kr.

RESULTS AND DISCUSSION

Various measurements were made to evaluate the system described. These determinations deal with the content of the eluate, its delivery through the catheter, its decay and detection in transit and at the delivery site at the catheter tip.

Elution of the generator. The generator may be eluted with distilled water with a yield of approximately 80% of the generated ^{81m}Kr. This was tested by setting a loaded generator in front of a Ge-Li detector and observing the counting rate of the ^{81m}Kr, 190-keV gamma ray while eluting with distilled water at various flow rates. It was found that the residual ^{81m}Kr activity remaining in the generator decreased with increasing flow and asymptotically approached 15% at a flow of 7 λ/sec; therefore the required flow rate of water for optimal elution of ^{81m}Kr is 0.5 ml/min or more. The eluted activity is virtually free of ^{81}Rb activity. Several hours of elution will yield less than 0.01 μCi of ^{81}Rb as determined by counting the eluate in a whole-body counter with an 8 × 4-in. NaI(Tl) crystal and employing a Nuclear-Data 512 channel analyzer. This level may be considered insignificant when compared with the multimillicurie quantities of ^{81m}Kr constantly being produced. For practical purposes the generator may be tested for significant ^{81}Rb contamination by elut-

ing into a closed container of water, discontinuing the delivery of eluate, and monitoring the activity for several minutes. In the absence of significant Rb contamination, the activity decayed to room background within ten half-lives of ^{81m}Kr (130 sec). The elution of the generator with a 5% dextrose-in-water solution, being nonionic, is identical to the elution with water. This solution has the advantage of isotonicity and may be used in intravascular infusion (*6–8*).

The pump is able to deliver equivalent volumes of liquid or gas. When the generator is eluted with air, no detectable ^{81}Rb contamination occurs.

Displacement of ^{81}Rb from the Dowex 50 resin will result when eluted with sodium chloride solutions. This was evaluated by substituting ^{83}Rb for ^{81}Rb and eluting with aliquots of successively increasing concentrations of NaCl. The concentrations ranged from 0.15×10^{-7} *M* to 1.5 *M*. The lowest concentration producing detectable Rb elution was 1.5×10^{-4} *M*. Physiological saline use will result in total elution of the resin-bound Rb (Fig. 1).

Delivery of ^{81m}Kr activity. The pump will deliver ^{81m}Kr activity at constant rates at motor rpm levels of 3000 or less. The volume of solution delivered, the time in transit, and the percentage decay in transit between 100 and 3000 rpm may be seen in Table 1. Some variability in delivery time to the catheter tip is observed when comparing individual generators. This variability is more apparent at higher rates of delivery and is probably attributable to variations in resistance within the generator columns. The reproducibility of delivery for 1-sec intervals at high rpm is within ±1%.

When a resting generator was eluted into a long catheter monitored by the scintillation camera, the activity was observed to increase very rapidly, overshoot the equilibrium level, and then return to and maintain this level. The overshoot represents elution of ^{81m}Kr at equilibrium in the generator. When the pump is stopped, the activity in the catheter decays (Fig. 3). These data accumulations were made over 100 2-sec intervals.

Observations of 100 20-sec interval counts reveal the delivery decreasing at a constant rate, reflecting the decay of ^{81}Rb, the parent radionuclide.

Equilibration of ^{81m}Kr activity in a closed compartment. A plastic container (9.1 cm high × 4.3 cm wide × 2.3 cm deep) with a hole at the top was placed on the face of the scintillation camera detector. The catheter tip was placed into this container and ^{81m}Kr activity was delivered into the container by liquid or gaseous elution. The activity was observed at 1-sec intervals for various pump rates between 500 and maximum rpm. These equilibration

TABLE 1. CHARACTERISTICS OF DELIVERY OF WATER THROUGH A GENERATOR AND CATHETER (5 IN. OF PE 50 AND 58 IN. OF PE 10 TUBING)

Setting (rpm)	Vol delivered (ml/min)	Time in transit in catheter (sec)	% decay in transit
3000	1.41	5.1	24.0
2000	1.12	6.4	29.0
1000	0.60	12.0	47.0
500	0.28	25.8	75.0
300	0.20	30.0	80.0
100	0.07	102.6	99.6

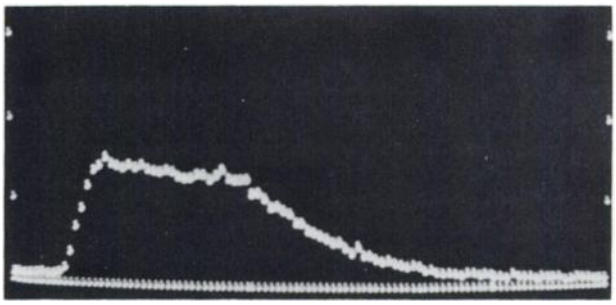

FIG. 3. Count profile of ^{81m}Kr activity in long catheter viewed by scintillation camera. Each point represents 2-sec interval. From left to right may be seen delay time in transit; arrival, increase, overshoot, and equilibration of activity. Delivery of ^{81m}Kr was stopped by switching off pump motor, with subsequent decay of activity in catheter.

kinetics for liquid and gaseous delivery of ^{81m}Kr may be seen in Fig. 4(A–E). The comparative activity at equilibrium for liquid and gaseous elution and delivery from the same generator were 5550 cps for liquid elution and 6900 for gaseous elution. This 24% increase may be attributed to the lesser viscosity of the gas, permitting greater velocity in transit through the 0.28-mm i.d. catheter. The possibility of more efficient elution by air as compared with water must be considered. The counts measured are significantly influenced by geometry, efficiency, and deadtime.

The generator described is produced from ^{81}Rb uncontaminated with sodium ions. The generator and catheter system are severely miniaturized, allowing rapid delivery in low volume of liquid solution or gaseous ^{81m}Kr. Elution with 5% dextrose-and-water provides an isotopic solution for intravascular administration. The pump and catheter provide precision delivery of gas or liquid at a constant rate. The catheter is compatible with delivery for inhalation, intravenous, and intra-arterial administration. The problem of producing a sterile, pyrogen-free generator and the problem of radiolysis of the ion-exchange resin in the generator by the recoil of radioactive decay remain to be evaluated. A practical,

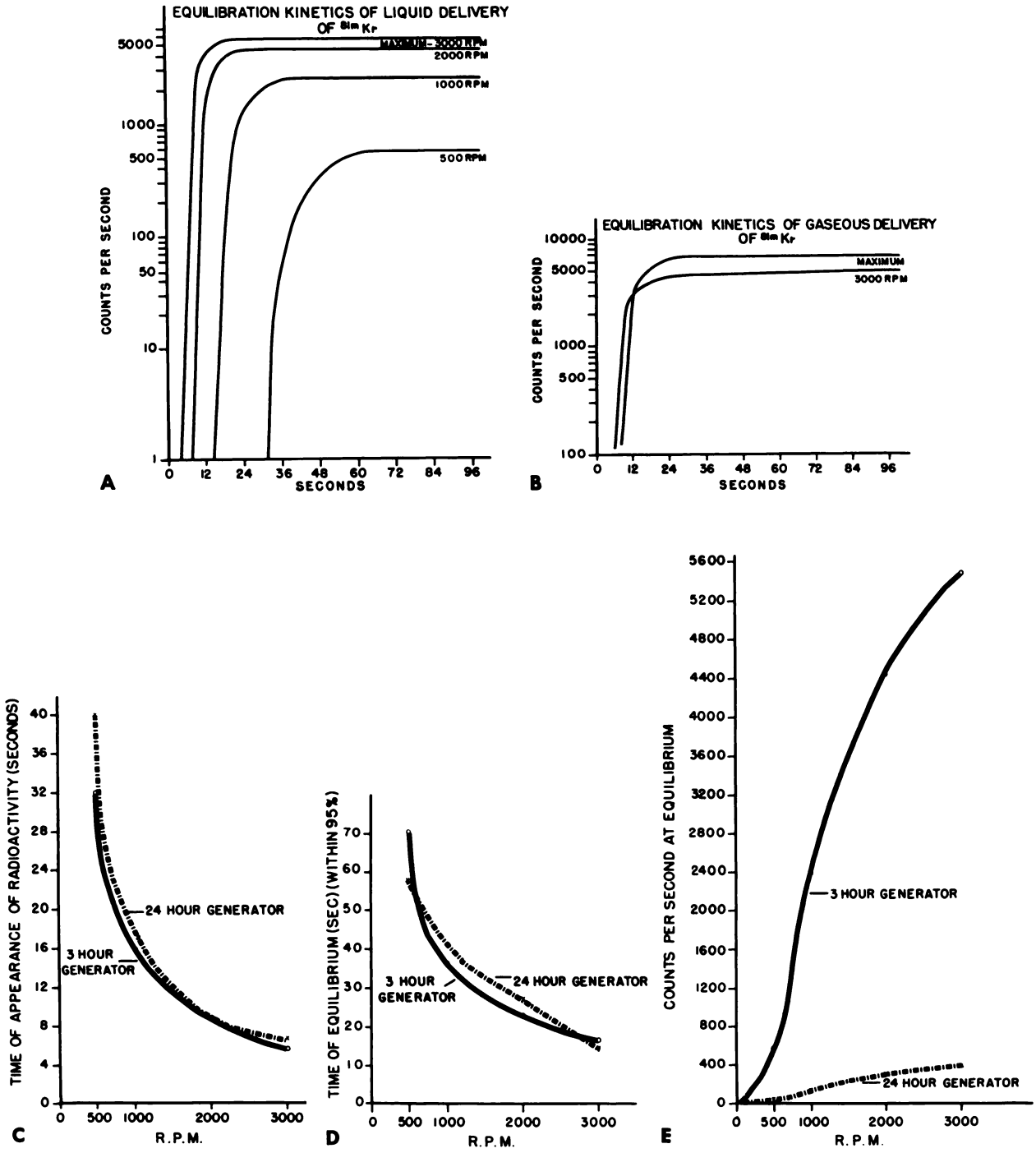

FIG. 4. (A) Equilibration kinetics of liquid delivery of ^{81m}Kr as determined by activity in closed container. (B) Equilibration kinetics of gaseous delivery of ^{81m}Kr as determined by activity in closed container. (C) Correlation of time of activity appearing at 1.5-meter catheter tip in liquid delivery of ^{81m}Kr to pump rate. (D) Correlation of time of 95% equilibration of activity appearing at catheter tip in liquid delivery of ^{81m}Kr to pump rate. (E) Correlation of counts per second at equilibrium in closed container at catheter tip in liquid delivery of ^{81m}Kr to pump rate.

clinical generator for parenteral human infusion appears likely from the described prototype.

The generator has been employed by the authors for in vivo testing in the dog with successful production of scintigraphic images during constant rate delivery of ^{81m}Kr. Administration of the gas to human subjects by inhalation has also been accomplished with ample scintigraphic image production. These studies have been separately reported (*6*).

ACKNOWLEDGMENT

This work was supported in part by the United States Atomic Energy Commission.

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