Form AEC-313
(8-64)
10 CFR 30

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

Form approved.
Budget Bureau No. 38-R0027

INSTRUCTIONS.—Complete Items 1 through 16 if this is an initial application or an application for renewal of a license. Information contained in previous applications filed with the Commission with respect to Items 8 through 15 may be incorporated by reference provided references are clear and specific. Use supplemental sheets where necessary. Item 16 must be completed on all applications. Mail two copies to: U.S. Atomic Energy Commission, Washington, D.C., 20545, Attention: Isotopes Branch, Division of Materials Licensing. Upon approval of this application, the applicant will receive an AEC Byproduct Material License. An AEC Byproduct Material License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Part 20.

1. (a) NAME AND STREET ADDRESS OF APPLICANT. *(Institution, firm, hospital person, etc. Include ZIP Code.)*

Department of the Army, Fitzsimons
General Hospital and U.S. Army Medical
Research and Nutrition Laboratory
Denver, Colorado 80240

(b) STREET ADDRESS(ES) AT WHICH BYPRODUCT MATERIAL WILL BE USED. *(If different from 1(a). Include ZIP Code.)*

Same as 1 (a)

2. DEPARTMENT TO USE BYPRODUCT MATERIAL

Nuclear Medicine Service

3. PREVIOUS LICENSE NUMBER(S). *(If this is an application for renewal of a license, please indicate and give number.)*

Amendment to license No. 05-00046-13

4. INDIVIDUAL USER(S). *(Name and title of individual(s) who will use or directly supervise use of byproduct material. Give training and experience in Items 8 and 9.)*

As specified and approved by the
Radioisotope Committee
Fitzsimons General Hospital

5. RADIATION PROTECTION OFFICER. *(Name of person designated as radiation protection officer if other than individual user. Attach resume of his training and experience as in Items 8 and 9.)*

Same as No. 4

6. (a) BYPRODUCT MATERIAL. *(Elements and mass number of each.)*

Technetium 99m

(b) CHEMICAL AND/OR PHYSICAL FORM AND MAXIMUM NUMBER OF MILLICURIES OF EACH CHEMICAL AND/OR PHYSICAL FORM THAT YOU WILL POSSESS AT ANY ONE TIME. *(If sealed source(s), also state name of manufacturer, model number, number of sources and maximum activity per source.)*

Technetium 99m labeled albumin microspheres (human) using Technetium Pertechnetate generated by the E.R. Squibb and Sons Model No. 08871 Generator authorized under present license 05-0046-13; labeling of microsphere to be done using 37. Albumin Microsphere Tc 99m Labeling Kit.
100 millicuries.

7. DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED. *(If byproduct material is for "human use," supplement A (Form AEC-313a) must be completed in lieu of this item. If byproduct material is in the form of a sealed source, include the make and model number of the storage container and/or device in which the source will be stored and/or used.)*

See Form AEC-313a

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TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEM 4 (Use supplemental sheets if necessary)

8. TYPE OF TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COURSE (Circle answer)
a. Principles and practices of radiation protection	See present license #05-00046-13		Yes No	Yes No
b. Radioactivity measurement standardization and monitoring techniques and instruments			Yes No	Yes No
c. Mathematics and calculations basic to the use and measurement of radioactivity			Yes No	Yes No
d. Biological effects of radiation			Yes No	Yes No

9. EXPERIENCE WITH RADIATION. (Actual use of radioisotopes or equivalent experience.)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
		See present license #05-00046-13		

10. RADIATION DETECTION INSTRUMENTS. (Use supplemental sheets if necessary.)

TYPE OF INSTRUMENT (Include make and model number)	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE (mr/hr)	WINDOW THICKNESS (mg/cm²)	USE (Monitoring, surveying, measuring)
See present license #05-00046-13					

11. METHOD, FREQUENCY, AND STANDARDS USED IN CALIBRATING INSTRUMENTS LISTED ABOVE.

See present license #05-00046-13

12. FILM BADGES, DOSIMETERS, AND BIO-ASSAY PROCEDURES USED. (For film badges, specify method of calibrating and processing, or name of supplier.)

See present license #05-00046-13

INFORMATION TO BE SUBMITTED ON ADDITIONAL SHEETS IN DUPLICATE

13. FACILITIES AND EQUIPMENT. Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. Explanatory sketch of facility is attached. (Circle answer) Yes No See present license #05-00046-13

14. RADIATION PROTECTION PROGRAM. Describe the radiation protection program including control measures. If application covers sealed sources, submit leak testing procedures where applicable, name, training, and experience of person to perform leak tests, and arrangements for performing initial radiation survey, servicing, maintenance and repair of the source.

See present license #05-00046-13

15. WASTE DISPOSAL. If a commercial waste disposal service is employed, specify name of company. Otherwise, submit detailed description of methods which will be used for disposing of radioactive wastes and estimates of the type and amount of activity involved. See present license #05-00046-13

CERTIFICATE (This item must be completed by applicant)

16. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PART 30, AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.

Date 22 June 72

RECEIVED 1972 JUL 17 AM 6 15

Dept. of the Army, FGH & US Army Med Rsch & Nutr Lab, Denver, Colo. 80240
Applicant named in item 1

By: Herbert F. Cowgill

H. F. COWGILL, COL, MC
Chairman, Radioisotope Committee
Title of certifying official

WARNING.—18 U. S. C., Section 1001; Act of June 25, 1948, 62 Stat. 749; makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

* U.S. GOVERNMENT PRINTING OFFICE : 1968 O—322-213

Form AEC-313a
(11-63)
10 CFR 30
PAGE 1

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A—HUMAN USE

Form approved.
Budget Bureau No. 38-R0080

If byproduct material is for "human use" (internal administration of byproduct material, or the radiation therefrom to human beings), complete this supplement and attach to the application for byproduct material license.

1. (a) USING PHYSICIAN'S NAME

Department of the Army
Fitzsimons General Hospital
Denver, Colorado 80240

(b) NAME AND ADDRESS OF APPLICANT (If different from 1(a). Include ZIP Code.)

and U.S.Army Medical Research and Nutrition Laboratory

2. THE USING PHYSICIAN INDICATED ABOVE IS LICENSED TO DISPENSE DRUGS IN THE PRACTICE OF MEDICINE BY A STATE OR TERRITORY OF THE UNITED STATES, THE DISTRICT OF COLUMBIA, OR THE COMMONWEALTH OF PUERTO RICO.
CIRCLE ANSWER — (YES) NO

3. A STATEMENT OF USING PHYSICIAN'S CLINICAL RADIOISOTOPE EXPERIENCE (PAGE 3 OF THIS SUPPLEMENT) IS SUBMITTED IN SUPPORT OF THIS APPLICATION. IF ANSWER IS NO, USE PAGE 2 OF THIS SUPPLEMENT TO EXPLAIN OR REFER TO OTHER APPLICATION OR RELATED DOCUMENTS ON WHICH THIS INFORMATION APPEARS.
CIRCLE ANSWER — YES (NO)

PROPOSED DIAGNOSIS OR TREATMENT

4. (a) DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED INCLUDING SPECIFIC CONDITIONS OR DISEASES TO BE DIAGNOSED OR TREATED (Use page 2 if necessary):

For lung imaging.

(b) CHEMICAL FORM ADMINISTERED:

Technetium 99m labeled.
Albumin microspheres (human) - To be prepared by using the 37 Albunin Microsphere $99^{m}Tc$ Labeling Kits.

(c) DESCRIBE PROCEDURES WHICH WILL BE OBSERVED TO MINIMIZE HAZARD FROM HANDLING, STORAGE, AND DISPOSAL OF THE BYPRODUCT MATERIAL:

See present license #05-00046-13

(d) DESCRIPTION AND SKETCHES OF SPECIAL DEVICES TO BE USED FOR ADMINISTERING BYPRODUCT MATERIAL TO HUMAN BEINGS ARE
(1) ATTACHED (LITERATURE REFERENCES WILL SUFFICE) — CIRCLE ANSWER — YES (NO)
(2) ON FILE WITH THE ISOTOPES BRANCH
REFER TO APPLICATION NO 05-00046-13 — CIRCLE ANSWER — (YES) NO

5. PROPOSED DOSAGE SCHEDULE
(a) In millicuries for internally administered byproduct material other than discrete fixed sources; and in roentgens or rads, as appropriate, for internal or external irradiation from discrete fixed sources (gold seeds, cobalt needles, etc.) state separately for each condition or disease (use page 2 if necessary):

1-4 millicuries, with usual adult dose of 2 millicuries

(b) INVESTIGATIVE PROPOSAL FOR EXPERIMENTAL, NEW OR UNUSUAL HUMAN USES IS ATTACHED. (Attachment should include outline of conditions to be evaluated, including data from animal studies and/or abstract of literature reference if any, number and type of patients (i. e. age group, moribund, etc.)) — CIRCLE ANSWER — YES (NO)

6. IF BYPRODUCT MATERIAL WILL NOT BE OBTAINED IN PRECALIBRATED FORM FOR ORAL ADMINISTRATION OR IN PRECALIBRATED AND STERILIZED FORM FOR PARENTERAL ADMINISTRATION, DESCRIBE IDENTIFICATION, PROCESSING, AND STANDARDIZATION PROCEDURES:

Will be prepared using sterile eluate ($99^{m}Tc$) of Mo 99 generator and 37 albumin microsphere $99^{m}Tc$ Labeling Kits. See attached inclosure 1-6

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7. THE PROPOSED USE OF BYPRODUCT MATERIAL HAS BEEN, OR WILL BE, APPROVED BY THE MEDICAL ISOTOPE COMMITTEE. — CIRCLE ANSWER — (YES) NO

HOSPITAL FACILITIES FOR INDIVIDUAL PRACTICE USE ONLY

8. (a) THE APPLICANT HAS COMPLETED ARRANGEMENTS FOR A HOSPITAL TO ADMIT RADIOACTIVE PATIENTS WHENEVER ADVISABLE. — CIRCLE ANSWER — YES NO
(b) A COPY OF INSTRUCTIONS TO BE FURNISHED TO THE HOSPITAL AS TO RADIOLOGICAL SAFETY PRECAUTIONS TO BE TAKEN AND AVAILABLE RADIATION INSTRUMENTATION IS ATTACHED. — CIRCLE ANSWER — YES NO

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A—HUMAN USE

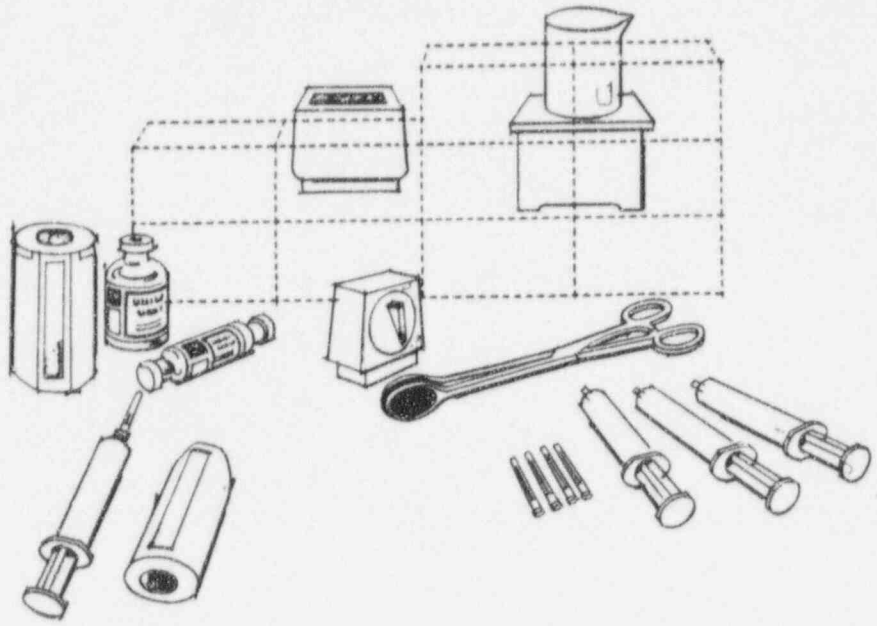
This page may be usad for providing additional information. Please cross reference to specific items.

* U.S. GOVERNMENT PRINTING OFFICE : 1966 O—322-213

LABELING INSTRUCTIONS

3M BRAND ALBUMIN MICROSPHERE
^{99m}Tc LABELING KIT

PREPARATION FOR LABELING



1. *ASSEMBLE SUPPLIES*

   LABELING VIAL
   RINSING AND SUSPENDING SOLUTION VIAL
   ULTRASONIC BATH
   BOILING WATER BATH
   HOLDING FORCEPS
   SYRINGES -- 4-20 cc SYRINGES
   HYPODERMIC NEEDLES
   - 4-20 g Needles
   - 1-25 g Needle (provided)

   TIMER OR WATCH
   SHIELDING
   - Work Area Shielding
   - Labeling Vial Shield
   - Syringe Shield (20 cc)

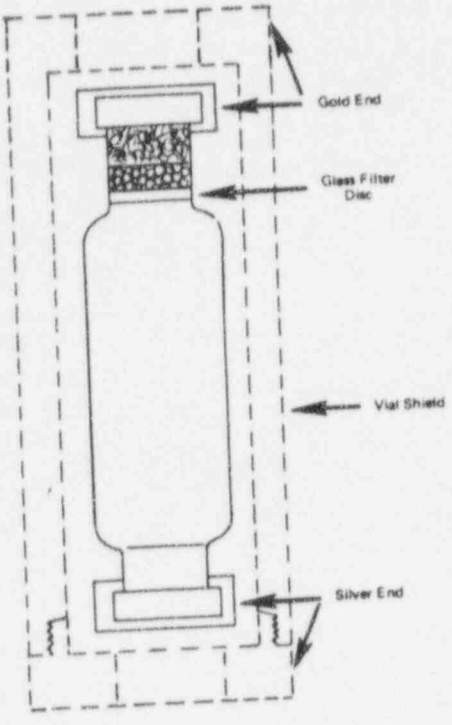
2. *USE ASEPTIC TECHNIQUES THROUGHOUT.*
3. *PLACE THE LABELING VIAL IN THE LABELING VIAL SHIELD* - Gold End First. The color code on the Labeling Vial will then match the color code on the Vial Shield.
4. *OBTAIN SODIUM ^{99m}Tc PERTECHNETATE* of desired concentration (recommended 40 mCi in 10 cc) in sterile saline solution.
5. *ADMIT 10 cc OF PERTECHNETATE* solution and 2 cc of *AIR* into a shielded 20 cc syringe.

LABELING PROCEDURE

ALBUMIN MICROSPERES (HUMAN)

PERFORM ALL STEPS ON THIS PAGE *WITHOUT INTERRUPTION*

LABELING VIAL POSITION: FILTER (GOLD) END UP – IN SHIELD



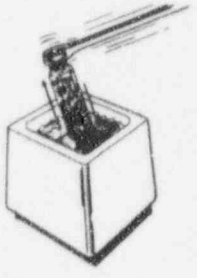
1 ADD PERTECHNETATE solution (10 cc + 2 cc of air) from a shielded syringe using the 25 g, 3/8" needle to the *GOLD* end. If the pertechnetate has not been completely drawn into the labeling vial within 90 seconds, discard the vial.

2. REMOVE SYRINGE AND NEEDLE from the Labeling Vial.

3. Remove the Labeling Vial from its shielding by *GRIPPING THE SILVER END WITH THE FORCEPS.*

LABELING VIAL POSITION: SILVER END UP – MINUS SHIELD

4. Agitate the Labeling Vial, filter (GOLD) end down, in the ULTRASONIC BATH for *2 minutes.* Vigorously shake the Labeling Vial during this time.



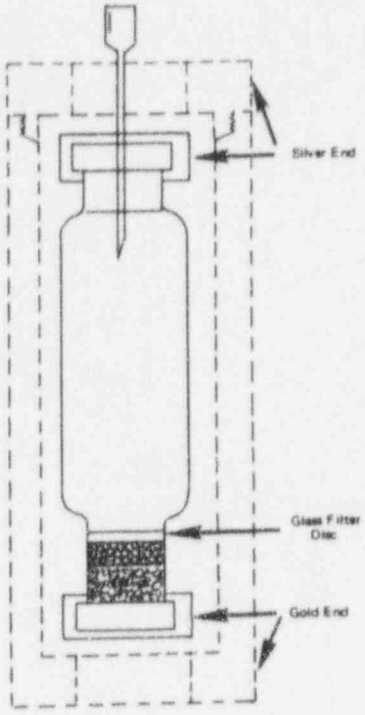
5. Agitate the Labeling Vial in the *BOILING WATER BATH* for *6 minutes.*

THE MICROSPHERES ARE NOW LABELED

6. COOL THE LABELING VIAL prior to rinsing the Microspheres.

RINSING PROCEDURE

LABELING VIAL POSITION FOR RINSING: SILVER END UP – IN SHIELD



1. VENT the Labeling Vial (SILVER END) with a 20 g needle.

2. WITHDRAW ALL LIQUID from the Labeling Vial through the filter (GOLD) end using a shielded syringe.

3. RINSE THE microspheres:
   a. Add 10 cc of RINSING AND SUSPENDING SOLUTION to the *SILVER END* of the Labeling Vial leaving the venting needle in place.
   b. Subject the Labeling Vial (minus shield) to ultrasonic agitation for 1 minute (GOLD END DOWN).
   c. Return the Labeling Vial to the shield and withdraw liquid from the filter (GOLD) end of the Labeling Vial.

4. After the rinse, ADD 10 cc of RINSING AND SUSPENDING SOLUTION (SILVER END) to be used as the injection vehicle.

5. REMOVE venting needle and affix the Radioactivity Warning Label.

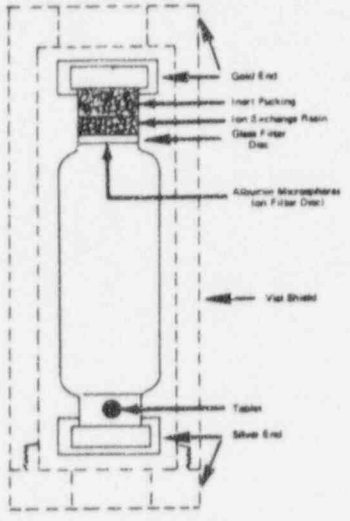
6. Before withdrawing the Albumin Microspheres (SILVER END) from the Labeling Vial *(WITH A PLASTIC SYRINGE)*, shake the Labeling Vial well or ultrasonically agitate for 1 minute and inspect for aggregation. Repeat if necessary.

NOTE: It is recommended that the Microspheres be rerinsed once if they have stood for more than three hours after labeling. This rinse step should be performed just prior to injection to minimize the free ^{99m}Tc. Withdraw the supernatant solution through the filter (GOLD) end of the Labeling Vial and replace with fresh Rinsing and Suspending Solution. Then follow the instructions in Step 6. The Microspheres need not be rinsed again if they are used within the recommended time limit of eight hours from the time of labeling.

DETAILED OBSERVATIONS

PREPARATION FOR LABELING

1. Assemble Supplies
   a. A *Labeling Unit* consists of:
      1 – Labeling Vial
      1 – Rinsing and Suspending Solution Vial
      1 – 25 g, 3/8" Needle
      1 – Radioactive Warning Label
   b. The recommended accessories are:
      1 – 20 cc Syringe Shield - 3/32" lead wall (must provide access to both ends of the Labeling Vial)
      1 – Labeling Vial Shield - 1/4" lead wall
      1 – Tongs - 10" length (must be capable of gripping the Labeling Vial securely)
      1 – Water bath (a 250 cc beaker on a hot plate is adequate)
      1 – Ultrasonic Generator
      Tank Size: 3.5"x3.5"x2.6"
      Overall Size: 5"x5"x5"
      Power Output: 25 watts
      Disposable Syringes (a plastic syringe is recommended for the injection step)
   c. The Labeling Vial components are:



   d. Pertechnetate Supply
      a) The volume of activity added to the Labeling Vial should be 10 cc.
      b) Any dilution must be made with Sodium Chloride Injection, U.S.P.
      c) The labeling reaction depends on maintaining reducing conditions. Therefore, any oxidant present in the pertechnetate supply may adversely affect the labeling reaction.
      d) Technetium-99 content of >0.01 mg may discolor the Microspheres. This should not occur with Generator-produced technetium.

5. Syringe Preparation
   Use a shielded, disposable syringe.

LABELING PROCEDURE

1. Add Pertechnetate
   a. Use the *25 g needle* provided to obtain the correct flow rate through the ion-exchange resin bed. This is important so that the sodium ions in the saline can release the acid from the ion-exchange resin. About 45 seconds is normal.
   b. Allow the *vacuum* in the Labeling Vial to draw the pertechnetate through the resin; DO NOT INJECT. The 2 cc of air will purge the ^{99m}Tc solution from about the resin.
   c. IF VACUUM HAS BEEN LOST THE VIAL SHOULD BE DISCARDED.

4. Ultrasonic Treatment
   a. The *Microspheres* are contained primarily on the *glass filter disc*. The ultrasonic and manual agitation thoroughly remove the Microspheres from the filter disc and *separate* them one from another for labeling.
   b. The tablet, containing *Sodium Thiosulfate*, need *not be* totally dissolved in this step.
   c. Foaming of the liquid may be expected.

5. Heating Step
   a. The reaction between the acid, sodium thiosulfate, pertechnetate and microspheres produces the ^{99m}Tc-labeling Albumin Microspheres.
   b. It is important that vigorous shaking of the Labeling Vial be continued for the entire 6 minute period for optimal labeling of the Microspheres.

6. Cooling the Labeling Vial – A convenient technique is simply putting the Labeling Vial in the ultrasonic unit with the switch *OFF* for 1 minute. The Labeling Vials are Pyrex and are heat resistant.

RINSING PROCEDURE

1. Venting facilitates addition and removal of liquid from the Labeling Vial.

2. Withdrew Liquid
   a. Withdrawing liquid through the Gold end causes the Microspheres to be filtered and retained in the Labeling Vial by the porous glass disc.
   b. Removal of the liquid causes most of the "free" technetium to be removed.

3. Rinsing several times brings the free technetium to a very low value. Experience has shown that a single rinse is sufficient if care is taken to follow the instructions provided.

Approved

Nuclear Products 3M COMPANY
3M CENTER · ST. PAUL, MINNESOTA 55101

A. Clinic Area and Hospital Area

1. Film badges and any other special monitoring devices, directed by the health physicists, will be worn in the nuclear medicine clinic at all times.

2. Clothing that can be stored for decay which might be contaminated with radiomaterials, will be worn at all times in the clinic or while working with radiomaterials.

B. Hot Lab Area

1. Disposable gloves will be worn any time a technologist is handling liquid isotopes, and if any cuts or sores are present on the hands.

2. There will be no eating, drinking, smoking, or application of cosmetics in the laboratory area.

3. Acids, alkaies, organic solvents, radioactive materials, and body fluids which are disposed of in the hot sink will be flushed with large volumes of water.

4. All personnel will wear gloves while handling, administering, of radiomaterials.

5. All personnel will wear disposable gloves and laboratory jackets when reaching with their hand, remote handling devices inside the shielded area of the laboratory where radiomaterials are stored.

6. All gloves, protective clothing, instruments, and glassware will be checked for radiocontamination with appropriate monitoring devices after use, and, if contaminated, will be placed in the appropriate receptacle to await decontamination and/or decay.

7. All radiomaterials will be stored, handled, and administered in designated areas of the clinic.

8. Glass shipping containers of radiomaterials will be stored inside lead containers, inside the shielded area of the laboratory.

9. No radiomaterials will be pipetted by mouth.

10. Tracer or theraputic doses of radiomaterials and samples for counting will be stored in the shielded area in the laboratory until their use.

11. There will be no items for human use stored in the laboratory refrigerator.

12. No water for drinking purpose will be obtained from the laboratory.

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Appendix 2

CALCULATIONS

ACTIVITY:

Decay all counts to the time of assay.

(Decay Factor)(Original Activity)=Activity/ml

(Activity/ml)(10ml)=Initial Activity

FINAL ACTIVITY:

$$\frac{\text{(3M-Vial Full B)-(3M-Vial Empty)}}{\text{(3M-Vial Full A)}} \times \text{(Initial Activity)}$$

ACTIVITY/ml

$$\frac{\text{Final Activity}}{\text{Volume}}$$

% TAG:

$$\frac{\text{(3M-Vial Full B) (100)}}{\text{3M-Vial Full A}}$$

SPECIFIC ACTIVITY

$$\frac{\text{\% Tag X Initial Activity}}{\text{5 ugm}}$$

% Free $^{99m}TcO_4$:

$$\frac{\text{(Syringe Fourth Wash) (100)}}{\text{3M-Vial Pre-Fourth Wash}}$$

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Appendix 3

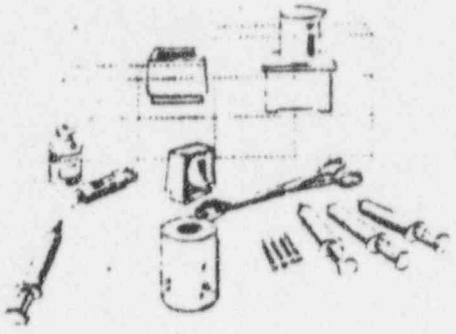
Labeling 3-M Albumin Microspheres with ^{99m}Tc

1. Reaction vial - Gold end up.
2. Add 20-25 mCi ^{99m}Tc in 10 cc saline and 2 cc air thru 3/8" 25 Ga needle.
   Add slowly, vacuum in vial.
3. Remove syringe, shake vial vigorously (15 sec.)
4. Shake in ultra-sonic bath, gold end of vial down (1 min.)
5. Place vial in boiling water bath, 6 min. with constant shaking.
6. Place vial in ultra-sonic bath (switch off) cool, 1 mi.
7. Vent silver end - 22 Ga needle. Remove supernatant through Gold end.
   Assay $^{99m}TcO_4$ in mediac.
8. Add 10 cc of suspending solution, through silver end.
9. Place in ultra-sonic bath, switch on (1 min.)
   Repeat steps 7 and 8 (2 times).*
10. Remove vent needle, shake in ultra-sonic bath - 1 mCi.
11. Before sampling, shake vigorously.
    Remove through silver end.
12. Assay - paper chromatogram, particle by microscope.

* Extra wash advised by Donner Lab.

Figure I

A RECOMMENDED SETUP FOR PERFORMING THE REQUIRED LABELING PROCEDURE



LABELING

PERFORM LABELING WITH NO DELAY BETWEEN CONSECUTIVE STEPS

7. ADMIT THE 10cc OF PERTECHNETATE SOLUTION AND THE 2cc OF AIR INTO THE EVACUATED LABELING VIAL THROUGH THE GOLD END. (45 sec

   a) Use the special 25 ga. needle.

   b) Do not attempt to force the solution into the vial. (Light tapping on the plunger may be used to overcome friction between plunger and syringe barrel.)

   c) If the vial has lost its vacuum, remove the pertechnetate syringe and needle. Restore vacuum by making 3 successive draws through the silver end with a 20cc syringe, and begin Step 7 again.

8. IMMEDIATELY, REMOVE PERTECHNETATE SYRINGE AND NEEDLE: REMOVE LABELING VIAL FROM ITS SHIELD.

9. IMMEDIATELY SHAKE THE VIAL VIGOROUSLY, TO SUSPEND THE MICROSPHERES. (15 sec

10. IMMEDIATELY, SHAKE LABELING VIAL IN ULTRASONIC BATH (switch "ON") GOLD END DOWN. (1 min

    a) Shake hard enough to keep the contents splashing.

    b) Complete dissolving of the tablet is not essential at this time.

11. QUICKLY IMMERSE THE LABELING VIAL IN THE BOILING WATER BATH AND CONTINUE SHAKING FOR THE ENTIRE 6 MINUTE PERIOD. (6 min

3M BRAND ALBUMIN MICROSPHERES ^{99m}Tc LABELING KIT INSTRUCTIONS

PREPARATION

1. READ THE ENTIRE SET OF INSTRUCTIONS THOROUGHLY

2. ASSEMBLE SUPPLIES

   a) 3M Brand Albumin Microspheres ^{99m}Tc Labeling Kit consisting of:
      - Labeling Vial
      - 3/8" 25 ga. needle
      - Vial of Suspending Solution pH 4.5

   b) Ultrasonic Bath - containing tap water

   c) Boiling Water Bath - for example, a 250 cc beaker on a hot plate

   d) Forceps - for gripping the labeling vial securely by the end while handling and shaking

   e) Syringes and Needles - Three 20 cc syringes with 20 ga. needles
      One 20 cc syringe with special 3/8" 25 ga. needle (supplied)
      One spare 20 ga. needle for venting vial (Step 13)

   f) Timer or Watch

   g) Shielding - General shielding for water bath and ultrasonic unit. (eg. lead bricks or L-block)
      - Labeling Vial shield, providing access to both septa. (eg. lead pig with a 1/2" hole drilled through the bottom.)

3. SHIELD BOILING WATER BATH AND ULTRASONIC BATH

4. EXPOSE BOTH SEPTA OF LABELING VIAL AND PLACE VIAL IN SHIELD GOLD END UP.

5. OBTAIN OR PREPARE SODIUM ^{99m}Tc PERTECHNETATE OF DESIRED CONCENTRATION IN STERILE PHYSIOLOGICAL SALINE SOLUTION.

   a) Have the desired number of millicuries in 10 cc of solution.

   b) Any dilution must be made with Sodium Chloride Injection USP.

   c) Minimal oxidant concentration is desirable. (eg. hydrogen peroxide, etc.)

6. PREPARE 10 cc OF PERTECHNETATE AND 2 cc OF AIR IN THE SINGLE SYRINGE WITH THE SPECIAL 3/8" 25 GA. NEEDLE ATTACHED.

12. PLACE LABELING VIAL IN THE ULTRASONIC BATH (Switch "OFF") (1 min.)
TO COOL.

FIGURE II ADDING THE PERTECHNETATE (Step 7)

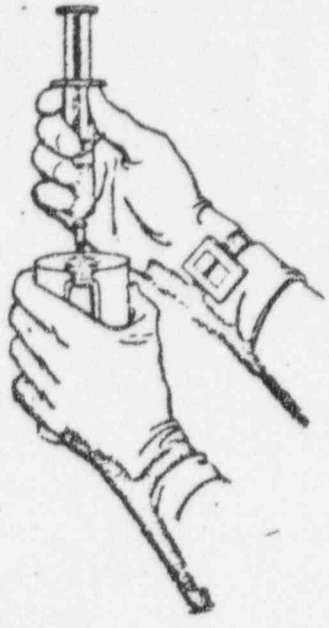
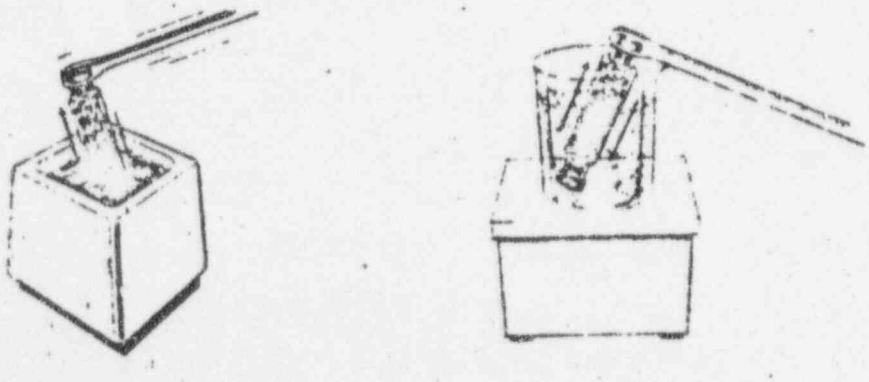


FIGURE III SHAKING VIAL IN BATH (Steps 9 & 10)



RINSING AND SUSPENDING

13. Vent silver end with 20 ga. needle and place labeling vial in vial shield, gold end down.

14. Remove free technetium by withdrawing all liquid through gold end of labeling vial.

15. Add 10 cc suspending solution through silver end of the labeling vial.

16. Place labeling vial in ultrasonic bath (switch "ON") for one minute.

17. Repeat Steps 14 and 15.

18. Remove Vent Needle and shake in ultrasonic bath for one minute. Keep contents splashing.

19. Assay labeled Microsphere suspension.

FIGURE IV THE RINSING PROCESS

(Steps 13-16)

USE

20. Shake vigorously for 3-4 seconds.

21. Withdraw dose from silver end. (Avoid leaving residual positive pressure in vial.)

SQUIBB TECHNETOPE II (TECHNETIUM 99m)STERILE GENERATOR

DIRECTIONS FOR ELUTING ^{99m}Tc

Carefully follow each step in the order described.

1. Insert the needle end of the elution tube into the horizontal slot in the generator stand so that the needle points upwards; insert the other end of the elution tube in the vertical slot on the side of the stand.

2. Remove the bottom lead plug in the generator shield and swab the rubber closure with a suitable germicide using a sterile cotton-tipped applicator. Do not remove top of lead shield. Do not take the column out of lead shield.

3. Remove the protective sleeve covering the elution tube needle and firmly place the generator on the exposed needle. Do not remove the internal sleeve.

4. Place the shielding sleeve over the generator.

5. Remove the top lead plug and swab the closure with germicide.

6. Insert the eluent needle adapter, spike end up, into the top closure of the generator column. Remove the plastic protective sleeve, holding the hub of the adapter firmly so as not to dislodge it.

7. Swab the eluent bottle rubber closure with germicide. Invert the eluent bottle and place it firmly on the plastic spike. Attach tube to eluent bottle as shown in diagram. No additional support is required for the eluent bottle.

8. Place the sterile evacuated collecting vial into the lead container and cover with the lead top provided. Swab the rubber closure with germicide.

9. Swab the rubber closure of the elution tube with germicide.

10. Insert one of the two milking tube needles into the closure of the elution tube. Quickly insert the free milking tube needle into the evacuated collecting vial.

11. Eluted ^{99m}Tc solution will flow rapidly into the collecting vial. Should the eluent not flow freely, replace the evacuated collecting vial.

12. When the elution is complete clamp the milking tube with a hemostat; remove the end connected to the gererator first, then the end inserted in the vial. Discard the milking tube using appropriate radiation safety precautions.

13. The eluent bottle, the eluent needle adapter, and the elution tube should not be removed during the life of the generator.

Appendix 6