613 J9B

Form AEC-313 (5-58)

ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

Form approved. Budget Bureau No. 38-R027.4.

INSTRUCTIONS.–Complete Items 1 through 16 if this is an initial application. If application is for renewal of a license, complete only Items 1 through 7 and indicate new information or changes in the program as requested in Items 8 through 15. Use supplemental sheets where necessary. Item 16 must be completed on all applications. Mail three copies to: U. S. Atomic Energy Commission, Washington 25, D. C. Attention: Isotopes Branch, Division of Licensing and Regulation. 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.)*

Department of the Army
Fitzsimons General Hospital
US Army Medical Research & Nutritional Lab
Denver, Colorado 80240

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

Same as Para. 1 (a) and Summit of Pikes Peak, Colorado

2. DEPARTMENT TO USE BYPRODUCT MATERIAL

Physiology Division
US Army Medical Research & Nutrition Lab

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

Present application is for amendment to License No. 5-46-13 and Condition No. 11

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 FGH and USAMRNL

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 Para. 4

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

^{51}Chromium
^{85}Strontium
^{141}Cerium
^{169}Ytterbium
^{125}Iodine

(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.)*

C.H.O. Microspheres		2 Millicuries
"	"	2 Millicuries
"	"	2 Millicuries
"	"	2 Millicuries
"	"	2 Millicuries

Chemical and/or Physical Forms
See Appendix -1, 3M Tracer Microspheres, Nuclear Products, 3M Company, 3M Center, St. Paul, Minn. 55101

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.)*

Non-human use, protocols approved by local Radioisotope Committee.

SENT TO COMPLIANCE

15848

(Continued on reverse side)

9703040353 970220
PDR FOIA
GLADE96-395 PDR

Form AEC-313 (5-58) Page Two

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	Individuals will have appropriate Training and Experience prior to their approval by the Radioisotope Committee, Fitzsimons General Hospital and U.S. Army Medical Research and Nutrition Lab.		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

RECEIVED
1970 MAY 4 PM 1 43
U.S. ATOMIC ENERGY COMM.
REGULATORY
MAIL SECTION

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
		Same as #8		

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

TYPE OF INSTRUMENTS (Include make and model number of each)	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE (mr/hr)	WINDOW THICKNESS (mg/cm²)	USE (Monitoring, surveying, measuring)
As described in Application for Renewal of Byproduct Material License No. 5-46-13 dated June 25, 1968.					

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

Same as para. 10

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

Same as para. 10

INFORMATION TO BE SUBMITTED ON ADDITIONAL SHEETS

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 Same as para. 10

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.

Same as para. 10

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. Same as para. 10

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.

Dept. of the Army, Fitzsimons Gen. Hosp. of USAMRNL, Denver, Colo. 80240
Applicant named in item 1

Date 11 Apr. 1970

By Paul C. Siebert

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 : 1961 OF—615965

I. Introduction

3M Brand Tracer Microspheres are small, spherical particles (Fig. 1 capable of being labelled with a variety of isotopes and available in a range of standard sizes from 1 to 1000 microns. They provide the medical and biomedical researchers a new tool for studying a variety of physiological processes. The primary purpose of this status report is to summarize the many studies involving Microspheres described in the medical literature. A secondary purpose is to briefly review the pertinent properties of the Microspheres of interest to the medical profession.

II. Physical and Chemical Properties of Tracer Microspheres

The 3M Tracer Microspheres, sometimes referred to as "carbonized microspheres", are black in appearance and consist of carbon, hydrogen, oxygen and a trace amount of the nuclide of interest. The nuclide is incorporated in the Microsphere and is not merely a coating on the surface. The Microspheres have an absolute density of approximately 1.3 gram/cc. They resist temperatures up to 400°C above which they begin to disintegrate.

The Microspheres themselves are quite insoluble in all common organic or inorganic solvents at room temperature but can be dissolved by boiling in concentrated acids or bases. The "leachability" of the tracer nuclide from the Microsphere depends on both the nuclide and the solvent. However, in the solvents of interest in most studies (Dextran, saline, water, blood and body fluids), no significant leaching is observed even over prolonged periods.

Microspheres labelled with four different nuclides are routinely available (^{169}Yb, ^{51}Cr, ^{85}Sr and ^{141}Ce). The usual specific activity range is from 1-10 mc/gm. Microspheres labelled with other nuclides are available on request. The available size ranges and the approximate number of Microspheres per mg for each size are shown below:

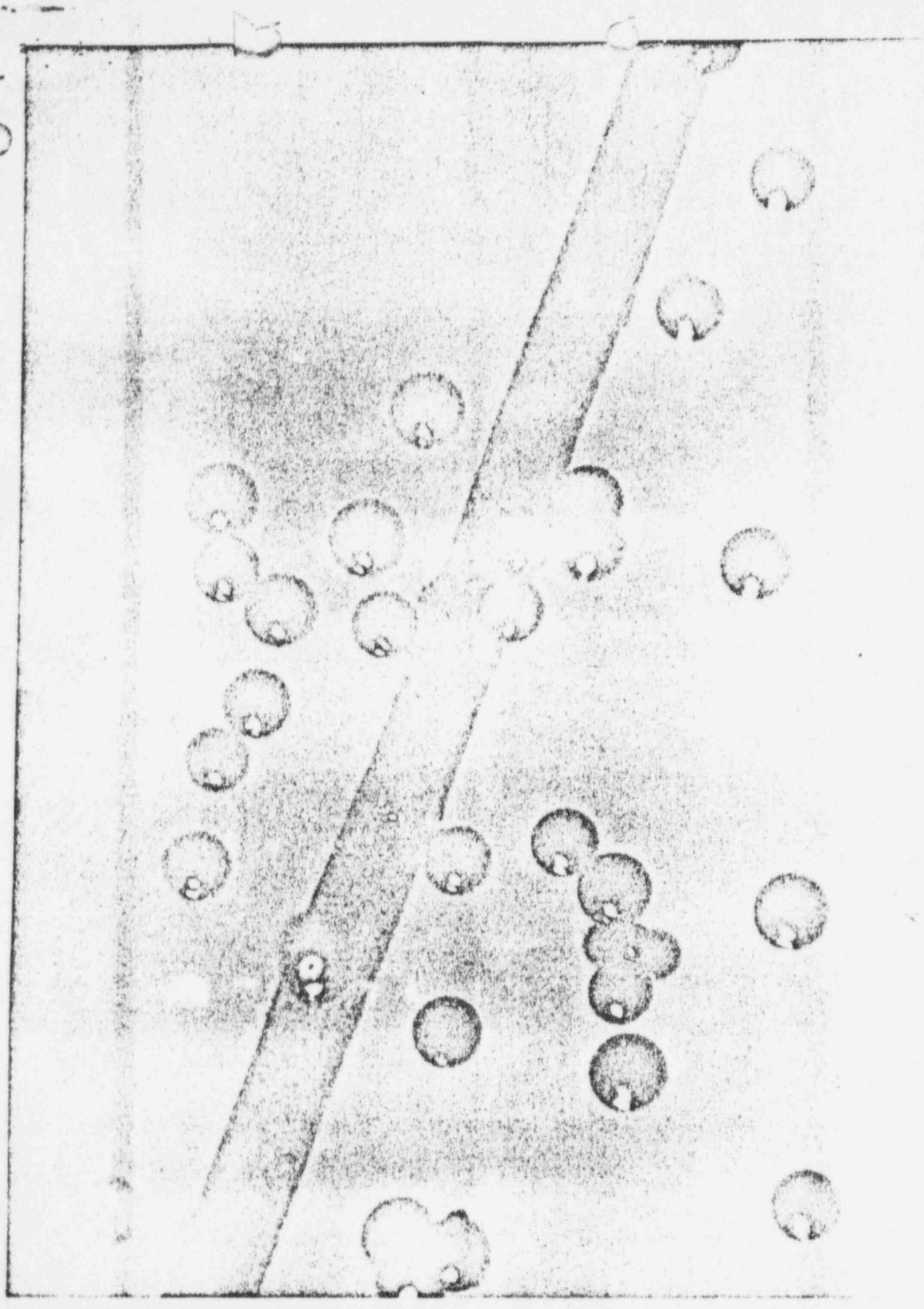
Standard Size (μ)	Number of Microspheres per mg (approximate)
0.5-10	-
15±5	440,000
25±5	85,000
35±5	35,000
50±10	12,000
80±20	3,000

The pertinent properties of the four nuclides are listed below:

Nuclide	Half-Life	Radiations
^{169}Yb	31 d	EC; γ 0.008-0.310
^{51}Cr	27.8 d	EC; γ 0.320
^{85}Sr	65 d	EC; γ 0.514 (others)
^{141}Ce	32.5 d	γ 0.145
		β 0.440 & 0.580

III. How Furnished

Microspheres are packaged either in the dry form or as an autoclaved suspension in 20% Dextran or isotonic saline solution. The Microspheres have a tendency to aggregate, thereby forming clumps. In order to avoid this, and to provide a homogeneous dispersion, one drop of Tween-80 (polyoxyethylene sorbitan mono-oleate) is injected into each ampule. Should the Microspheres be obtained in the dry form for later suspension, it is recommended that either a drop of Tween-80 be added, or the suspension be subjected to ultrasonic treatment, which also dispels any aggregates.



PHOTOMICROGRAPH
COMPARISON OF HUMAN HAIR
AND 3M BRAND MICROSPHERES