

UNITED STATES ATOMIC ENERGY COMMISSION
APPLICATION FOR BYPRODUCT MATERIAL LICENSE

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 Army Medical Center and U. S. Army Medical Laboratory Denver, Colorado 80240		(b) STREET ADDRESS(ES) AT WHICH BYPRODUCT MATERIAL WILL BE USED (If different from 1 (a) Include ZIP Code.) Department of the Army Fitzsimons Army Medical Center and U. S. Army Medical Laboratory Denver, Colorado 80240	
2. DEPARTMENT TO USE BYPRODUCT MATERIAL Department of Radiology 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 Existing License No. 05-00046-13 (30 April 1974)	
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.) See application dated 12 March 1973. (Control No. 35871)		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.) See application dated 12 March 1973 (Control No. 35871)	
6. (a) BYPRODUCT MATERIAL (Elements and mass number of each) See para 6 cc, Amendment 28 (24 Apr 73) to existing license 05-00046-13		(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.) See para 7 cc and 8 cc, amendment 28 (24 Apr 73) to existing license 05-00046-13.	
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.) Human Use: See para 9 cc of amendment 28 (24 Apr 73) to existing license 05-00046-13. <u>Change para 9cc to read: Bone Imaging.</u> (The amendment is requested to relieve Fitzsimons Army Medical Center from the 100 additional patient restriction placed on the use of Technetium-99 labeled polyphosphates in bone imaging in Amendment 27 to License No. 05-00046-13.) 39779 9703050209			

(Continued on reverse side)

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

B. 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 application dated 12 March 1973 (Control No. 35871) and application dated 25 June 1968.		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 application dated 12 March 1973 (control No. 35871) and application dated 25 June 1968.				

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/cm ²)	USE (Monitoring, surveying, measuring)
See application dated 12 March 1973 (control No. 35871) and application dated 25 June 1968.					

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

See application dated 12 March 1973 (control No. 35871) and application dated 25 June 1968.

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

See application dated 12 March 1973 (control No. 35871) and application dated 25 June 1968.

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. (Include make and model number of each). (Circle answer) Yes No	See application dated 12 March 1973 (control No. 35871) and application dated 25 June 1968.
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 application dated 12 March 1973 (Control No. 35871) and application dated 25 June 1968.
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 to dispose of waste and estimate of the type and amount of activity involved.	See application dated 12 March 1973 (control No. 35871) and application dated 25 June 1968.

CERTIFICATE (This form 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.

Fitzsimons Army Medical Center
Denver, Colorado 80240

Date 23 July 1973

By: H. F. Cowgill, J.D.
Colonel, MC
Chief, Department of Radiology
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.

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
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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	(b) NAME AND ADDRESS OF APPLICANT (If different from 1(a). Include ZIP Code.) Department of the Army, Fitzsimons Army Medical Center and U. S. Army Medical Laboratory, Denver, Colorado 80240
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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. See application dated 12 March 1973 (control No. 35871)	YES	NO
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CIRCLE ANSWER

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 <u>NO</u> , USE PAGE 2 OF THIS SUPPLEMENT TO EXPLAIN OR REFER TO OTHER APPLICATION OR RELATED DOCUMENTS ON WHICH THIS INFORMATION APPEARS. See application dated 12 Mar 73	YES	NO
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CIRCLE ANSWER

Control No. 35871

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): See application dated 16 November 1972 and Letter MEDEO-X, Hqs, FAMC, Subject: Information Pertaining to Tc-99m Labeled Polyphosphates Amendment 27 to USAEC (b) CHEMICAL FORM ADMINISTERED: License 05-00046-13, dated 11 May 1973.		
(c) DESCRIBE PROCEDURES WHICH WILL BE OBSERVED TO MINIMIZE HAZARD FROM HANDLING, STORAGE, AND DISPOSAL OF THE BYPRODUCT MATERIAL:		
(d) DESCRIPTION AND SKETCHES OF SPECIAL DEVICES TO BE USED FOR ADMINISTERING BYPRODUCT MATERIAL TO HUMAN BEINGS ARE (1) ATTACHED (LITERATURE REFERENCES WILL SUFFICE) (2) ON FILE WITH THE ISOTOPES BRANCH REFER TO APPLICATION NO _____	YES	NO
	CIRCLE ANSWER	
	CIRCLE ANSWER	

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): See application dated 16 November 1972 and Letter MEDEO-X, Hqs, FAMC, Subject: Information Pertaining to Tc-99m Labeled Polyphosphates Amendment 27 to USAEC License 05-00046-13, dated 11 May 1973.		
(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.))	YES	NO
	CIRCLE ANSWER	

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:

See application dated 16 November 1972 and Letter MEDEO-X, Hqs, FAMC, Subject: Information Pertaining to Tc-99m Labeled Polyphosphates Amendment 27 to USAEC License 05-00046-13, dated 11 May 1973.		
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7. THE PROPOSED USE OF BYPRODUCT MATERIAL HAS BEEN, OR WILL BE, APPROVED BY THE MEDICAL ISOTOPE COMMITTEE.	YES	NO
	CIRCLE ANSWER	

HOSPITAL FACILITIES FOR INDIVIDUAL PRACTICE USE ONLY

8. (a) THE APPLICANT HAS COMPLETED ARRANGEMENTS FOR A HOSPITAL TO ADMIT RADIOACTIVE PATIENTS WHENEVER ADVISABLE.	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	
	CIRCLE ANSWER	

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL
SUPPLEMENT A—HUMAN USE

PAGE 2

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

U.S. ATOMIC ENERGY COMM.
REGULATORY
MAIL SECTION

1973 AUG 2 AM 10 45

RECEIVED

^{99m}Tc-STANNOUS POLYPHOSPHATE FORFitzsimons General Hospital

New England Nuclear Corp.

BONE IMAGING

Denver, Colorado

Date	Patient No.	Sex	Age Yrs.	Wt. Lbs.	Lot No.	Dose in mCi	Volume Injected	Interval Between Dose and Imaging	Indications for Imaging	Post Image Diagnosis	Any Adverse Effect	Was Image Clinically Useful		Confirmation of Diagnosis by Other Methods	
												Yes	No	Concur	Do not Concur
23 Jan 73	1	M	54	152	4003	9.6	1 ml.	3 hrs.	Pain	Metastatic CA	No	X		Clinical	
23 Jan 73	2	M	67	170	4003	8.22	1 ml.	3 hrs.	Pain	Post trauma	No	X		X-ray	
30 Jan 73	3	F	39	138	4003	10	.9 ml.	3 hrs.	Pain	Metastatic CA	No	X		Clinical	
31 Jan 73	4	M	19	145	4003	10	1.41	3 hrs.	Staging disease	No bone Metastases	No	X		Clinical X-ray	
31 Jan 73	5	F	35	130	4003	10	1.62	3 hrs.	Followup X-ray Rx	Response to X-ray Rx	No	X		Clinical X-ray	
14 Feb 73	6	F	47	175	4003	10	.79	3 hrs.	Pain	Metastatic CA	No	X		Clinical	

*Describe as positive (+) or negative (-).

If positive (+), on a separate sheet, include brief clinical history and describe the reaction as well as your interpretation of the nature and cause of the reaction.

**Indicate Means

Summary Report Form No. 2

Hospital:

^{99m}Tc-STANNOUS POLYPHOSPHATE FORFitzsimons General Hospital

New England Nuclear Corp.

BONE IMAGING

Denver, Colorado

Date	Patient No.	Sex	Age Yrs.	Wt. Lbs.	Lot No.	Dose in mCi	Volume Injected	Interval Between Dose and Imaging	Indications for Imaging	Post Image Diagnosis	Any Adverse Effect	Was Image Clinically Useful		Confirmation of Diag. by Other Method		
												Yes	No	Concur **	Do not Concur **	P
4 Feb 73	7	F	25	108	4003	10	.81 ml.	3 hr.	Pain Wt. loss	Rib Fractures	No	X		X-ray		
4 Feb 73	8	M	53	210	4003	10	1.1	3 hrs.	Followup disease	Possible Metastases	No	X		Clinical		
5 Feb 73	9	F	41	134	4003	10	1	3 hrs.	Pain Fx-rib	Metastatic CA	No	X		Clinical X-ray		
12 Feb 73	10	F	35	122	4003	10	3.6	3 hrs	Staging of disease	No Metastases	No	X		Surgery Clinical X-ray		
12 Feb 73	11	M	63	205	4003	10	3.8	3 hrs.	Pain	Metastatic CA	No	X		Clinical X-ray		
23 Feb 73	12	F	51	170	4003	10	2.1	3 hrs.	Pain	Arthritis	No	X		Clinical X-ray		

*Describe as positive (+) or negative (-).

If positive (+), on a separate sheet, include brief clinical history and describe the reaction as well as your interpretation of the nature and cause of the reaction.

**Indicate Means

Summary Report Form No. 3

Hospital:

^{99m}Tc-STANNOUS POLYPHOSPHATE FOR

Fitzsimons General Hospital

New England Nuclear Corp.

BONE IMAGING

Denver, Colorado

Date	Patient No.	Sex	Age Yrs.	Wt. Lbs.	Lot No.	Dose in mCi	Volume Injected	Interval Between Dose and Imaging	Indications for Imaging	Post Image Diagnosis	Any Adverse Effect	Was Image Clinically Useful		Confirmation of Diagnosis by Other Methods		
												Yes	No	Concur **	Do not Concur **	Per
27 Feb 73	13	F	37	175	4003	10	.6 ml.	3 hrs.	Pain	Metastatic CA	No	X		Clinical		
27 Feb 73	14	F	44	135	4003	10	.77	3 hrs.	Anemia Poss. Bone Marrow Met.	Hypoplastic Anemia--- No Metastases	No	X		Clinical X-ray		
1 Mar 73	15	M	58	200	4003	10	1.2	3 hrs.	Staging of disease	No Bone Metastases	No	X		Surgery Clinical X-ray		
5 Mar 73	16	F	46	95	4003	10	.42	3 hrs.	Pain	Normal	No	X		Clinical X-ray		
9 Mar 73	17	M	69	195	4003	10	1.1	3 hrs.	Pain	Multiple involvement with myeloma	No	X		Clinical X-ray		
12 Mar 73	18	F	50	155	4003	10.4	.35	3 hrs.	Pain	Prob. Arthritis	No	X		Clinical X-ray		

*Describe as positive (+) or negative (-).

If positive (+), on a separate sheet, include brief clinical history and describe the reaction as well as your interpretation of the nature and cause of the reaction.

**Indicate Means

Summary Report Form No. 4

Hospital:

^{99m}Tc-STANNOUS POLYPHOSPHATE FOR

New England Nuclear Corp.

BONE IMAGING

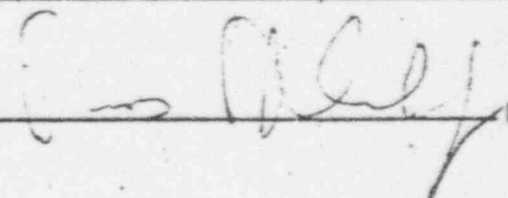
Fitzsimons General HospitalDenver, Colorado

Date	Patient No.	Sex	Age Yrs.	Wt. Lbs.	Lot No.	Dose in mCi	Volume Injected	Interval Between Dose and Imaging	Indications for Imaging	Post Image Diagnosis	Any Adverse Effect	Was Image Clinically Useful		Confirmation of Diagn by Other Methods		
												Yes	No	Concur **	Do not Concur **	Per
2 Mar 73	19	F	46	160	4003	10.6	.4 ml	3 hrs.	Pain-hip Normal X-ray	Metastatic CA	No	X		Clinical		
12 Mar 73	20	M	21	107	4003	10.6	.45	3 hrs.	Pain	Multiple Met. (Ewing's Sarcoma)	No	X		Clinical X-ray		
13 Mar 73	21	M	55	122	4003	10	.51	3 hrs.	Pain	No Metastases	No	X		Clinical X-ray		
14 Mar 73	22	M	68	175	4003	10	.9	3 hrs.	Staging of disease	No Metastases	No	X		Clinical X-ray		
1 Mar 73	23	F	69	150	4003	10	.8	3 hrs.	Staging of disease	Metastatic CA	No	X		Clinical X-ray		
1 Apr 73	24	F	55	145	4003	10	1	3 hrs.	Staging of disease Pain	Benign lesions Amalgam filling Metastatic CA	No	X		Clinical		

*Describe as positive (+) or negative (-).

If positive (+), on a separate sheet, include brief clinical history and describe the reaction as well as your interpretation of the nature and cause of the reaction.

**Indicate Means



^{99m}Tc-STANNOUS POLYPHOSPHATE FOR
BONE IMAGINGFitzsimons General Hospital
Denver, Colorado

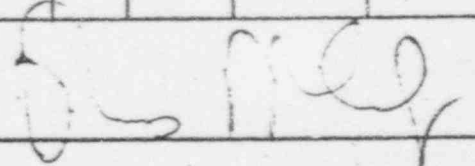
New England Nuclear Corp.

Date	Patient No.	Sex	Age Yrs.	Wt. Lbs.	Lot No.	Dose in mCi	Volume Injected	Interval Between Dose and Imaging	Indications for Imaging	Post Image Diagnosis	Any Adverse Effect	Was Image Clinically Useful		Confirmation of Diagnosis by Other Methods		
												Yes	No	** Concur	Do not ** Concur	Pe
5 Apr 73	25	F	40	130	4003	8	.89	3 hrs.	Pain	Degenerative Arthritis	No	X		Clinical X-ray		
9 Apr 73	26	M	25	160	4003	7.9	.33	3 hrs.	Staging of Disease	No metastases	No	X		Clinical X-ray		
10 Apr 73	27	M	40	165	4003	8	.62	3 hrs.	Fracture	Viable Fracture Site	No	X		Clinical X-ray		
12 Apr 73	28	F	23	110	4003	10	1.2	3 hrs.	Fracture	Viable Fracture Site	No	X		Clinical X-ray		
13 Apr 73	29	M	25	155	4003	10	1.4	3 hrs.	Staging of Disease	No metastases	No	X		Clinical X-ray		
16 Apr 73	30	M	50	160	4003	10	2.3	3 hrs.	Fracture	Viable Fracture Site	No	X		Clinical X-ray		

*Describe as positive (+) or negative (-).

If positive (+), on a separate sheet, include brief clinical history and describe the reaction as well as your interpretation of the nature and cause of the reaction.

**Indicate Means



Summary Report Form No. 6

Hospital:

^{99m}Tc-STANNOUS POLYPHOSPHATE FOR
BONE IMAGINGFitzsimons General Hospital
Denver, Colorado

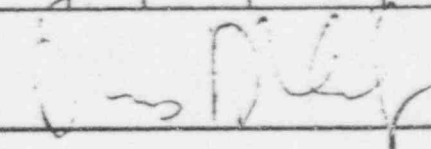
New England Nuclear Corp.

Date	Patient No.	Sex	Age Yrs.	Wt. Lbs.	Lot No.	Dose in mCi	Volume Injected	Interval Between Dose and Imaging	Indications for Imaging	Post Image Diagnosis	Any Adverse Effect	Was Image Clinically Useful		Confirmation of Diagnosis by Other Methods		
												Yes	No	Concur	Do not Concur	Per
16 Apr 73	31	M	49	185	4003	9.9	2.6	3 hrs.	Fracture	Viable Fracture Site	No	X		Clinical X-ray		
6 Apr 73	32	M	50	175	4003	9.6	3	3 hrs.	Staging of Disease	No metastases	No	X		Clinical X-ray		
0 Apr 73	33	F	30	140	4003	7.8	1	3 hrs.	Pain	No metastases	No	X		Clinical X-ray		
20 Apr 73	34	F	26	98	4003	10	1.4	3 hrs.	Fracture	Viable Fracture Site	No	X		Clinical X-ray		
3 Apr 73	35	M	55	180	4003	10	2.6	3 hrs.	Staging of Disease	No Metastases	No	X		Clinical X-ray		
3 Apr 73	36	F	38	130	4003	10	2.6	3 hrs.	Staging of Disease (Hodgkins)	No Metastases	No	X		Clinical X-ray		

*Describe as positive (+) or negative (-).

If positive (+), on a separate sheet, include brief clinical history and describe the reaction as well as your interpretation of the nature and cause of the reaction.

**Indicate Means



^{99m}Tc-STANNOUS POLYPHOSPHATE FOR
BONE IMAGINGFitzsimons General Hospital
Denver, Colorado

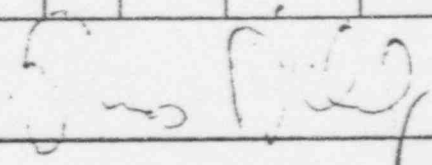
New England Nuclear Corp.

Date	Patient No.	Sex	Age Yrs.	Wt. Lbs.	Lot No.	Dose in mCi	Volume Injected	Interval Between Dose and Imaging	Indications for Imaging	Post Image Diagnosis	Any Adverse Effect	Was Image Clinically Useful		Confirmation of Diagnosis by Other Methods		
												Yes	No	** Concur	Do not ** Concur	Pe
5 Apr 73	37	M	16	140	4003	10	.75	3 hrs.	Fracture	Viable Fracture Site	No	X		Clinical X-ray		
5 Apr 73	38	F	27	98	4003	10	1.1	3 hrs.	Fracture	Viable Fracture Site	No	X		Clinical X-ray		
5 Apr 73	39	M	36	165	4003	10	1.0	3 hrs.	Fracture	Viable fracture Site	No	X		Clinical X-ray		
0 Apr 73	40	M	22	180	4003	9.92	1.6	3 hrs.	Fractures 10 mos. post	Viable Fracture Site	No	X		Clinical X-ray		
27 Apr 73	41	M	39	125	4003	10	3.1	3 hrs.	Fracture	Viable Fracture Site	No	X		Clinical X-ray		
6 Apr 73	42	F	30	140	4003	10.2	1.45	3 hrs.	Staging of Disease	Metastatic CA	No	X		Clinical		

*Describe as positive (+) or negative (-).

If positive (+), on a separate sheet, include brief clinical history and describe the reaction as well as your interpretation of the nature and cause of the reaction.

**Indicate Means



^{99m}Tc-STANNOUS POLYPHOSPHATE FOR
BONE IMAGINGFitzsimons General Hospital
Denver, Colorado

New England Nuclear Corp.

Date	Patient No.	Sex	Age Yrs.	Wt. Lbs.	Lot No.	Dose in mCi	Volume Injected	Interval Between Dose and Imaging	Indications for Imaging	Post Image Diagnosis	Any Adverse Effect	Was Image Clinically Useful		Confirmation of Diag. by Other Method		
												Yes	No	Concur **	Do not Concur **	Pt
27 Apr 73	43	M	45	155	4003	10.2	1.45	3 hrs.	Staging of Disease (lymphoma)	No Metastatic CA	No	X		Clinical		
30 Apr 73	44	M	20	100	4003	9.9	.65	3 hrs.	Staging of Disease (osteosarcoma)	No extension of disease	No	X		Clinical X-ray		
30 Apr 73	45	M	25	190	4003	10.1	.55	3 hrs.	Fracture	Viable Fracture Site	No	X		Clinical X-ray		
2 May 73	46	M	20	100	4005	10	1.2	3 hrs.	Staging of Disease (Osteosarcoma)	No extension of Disease	No	X		Clinical X-ray		
3 May 73	47	F	43	110	4005	10	.96	3 hrs.	Pain	No metastases	No	X		Clinical X-ray		
3 May 73	48	F	58	110	4005	10.1	1.4	3 hrs.	Pain	Metastatic CA	No	X		Clinical		

*Describe as positive (+) or negative (-).

If positive (+), on a separate sheet, include brief clinical history and describe the reaction as well as your interpretation of the nature and cause of the reaction.

**Indicate Means



Summary Report Form No. 9

Hospital:

^{99m}Tc-STANNOUS POLYPHOSPHATE FOR
BONE IMAGINGFitzsimons General Hospital
Denver, Colorado

New England Nuclear Corp.

Date	Patient No.	Sex	Age Yrs.	Wt. Lbs.	Lot No.	Dose in mCi	Volume Injected	Interval Between Dose and Imaging	Indications for Imaging	Post Image Diagnosis	Any Adverse Effect	Was Image Clinically Useful		Confirmation of Diagn by Other Methods		
												Yes	No	** Concur	Do not ** Concur	Per
4 May 73	49	M	68	182	4005	10.3	1.8	3 hrs.	Staging of Disease	No metastases	no	X		Clinical X-ray		
May 73	50	M	21	165	4005	10.2	1.9	3 hrs.	Fracture 10 mos. post	Viable Fracture Site	No	X		Clinical X-ray		
May 73	51	F	82	130	4005	10.3	2.5	3 hrs.	Pain-back	Fracture No Metastases Lumbar comp.	No	X		Clinical X-ray		
May 73	52	M	19	160	4005	10.6	.5	3 hrs.	Fracture	Viable Fracture Site	No	X		Clinical X-ray		
May 73	53	M	23	155	4005	10.1	.6	3 hrs.	Pain-back	TB of Spine	No	X		Clinical X-ray		
3 May 73	54	M	30	135	4005	10.8	.8	3 hrs.	Fracture	Viable Fracture Site	No	X		Clinical X-ray		

*Describe as positive (+) or negative (-).

If positive (+), on a separate sheet, include brief clinical history and describe the reaction as well as your interpretation of the nature and cause of the reaction.

**Indicate Means

Summary Report Form No. _____

10

^{99m}Tc-STANNOUS POLYPHOSPHATE FOR

Hospital:

Fitzsimons General Hospital

New England Nuclear Corp.

BONE IMAGING

Denver, Colorado

Date	Patient No.	Sex	Age Yrs.	Wt. Lbs.	Lot No.	Dose in mCi	Volume Injected	Interval Between Dose and Imaging	Indications for Imaging	Post Image Diagnosis	Any Adverse Effect	Was Image Clinically Useful		Confirmation of Diagn. by Other Methods		
												Yes	No	Concur **	Do not Concur **	Per
May 73	55	M	28	165	4005	10.6	.9	3 hrs.	Fractures multiple	Viable Fractures Sites	No	X		Clinical X-ray		
May 73	56	M	15	103	4005	7.7	.8	3 hrs.	Fracture 6 wks. post (myositis ossificans)	Viable Fracture Site	No	X		Clinical X-ray		
May 73	57	M	65	106	4005	10.1	1.1	3 hrs.	Staging of disease	Metastases--multiple	No	X		Clinical X-ray		
May 73	58	M	23	160	4005	10.3	1.3	3 hrs.	Fracture	Viable Fracture Site	No	X		Clinical X-ray		
10 May 73	59	M	28	213	4005	10.5	1.4	3 hrs.	Staging of Disease	Metastatic CA	No	X		Clinical		
11 May 73	60	F	62	130	4005	9.9	1.5	3 hrs.	Staging of Disease	Degenerative Arthritis No Metastases	No	X		Clinical X-ray		

*Describe as positive (+) or negative (-).

If positive (+), on a separate sheet, include brief clinical history and describe the reaction as well as your interpretation of the nature and cause of the reaction.

**Indicate Means

Summary Report Form No. 11

Hospital:

^{99m}Tc-STANNOUS POLYPHOSPHATE FOR

New England Nuclear Corp.

BONE IMAGING

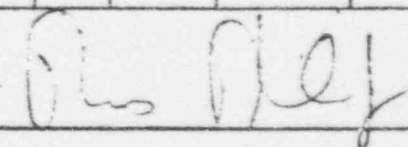
~~Fitzsimons General Hospital~~
Denver, Colorado

Date	Patient No.	Sex	Age Yrs.	Wt. Lbs.	Lot No.	Dose in mCi	Volume Injected	Interval Between Dose and Imaging	Indications for Imaging	Post Image Diagnosis	Any Adverse Effect	Was Image Clinically Useful		Confirmation of Diagnosis by Other Methods		
												Yes	No	Concur	Do not Concur	P
14 May 73	61	M	17	132	4005	10.1	.42	3 hrs.	Fractures 4 mos. post	Viable Fracture Sites	No	X		Clinical X-ray		
14 May 73	62	M	31	201	4005	10.1	.47	3 hrs.	Staging of disease	Normal	No	X		Clinical X-ray		
15 May 73	63	M	37	180	4005	10.3	1	3 hrs.	Staging of disease	Metastatic Ca--multiple	No	X		Clinical		
16 May 73	64	M	58	174	4005	10	.73	3 hrs.	Fracture	Viable Fracture Site	No	X		Clinical X-ray		
16 May 73	65	M	22	180	4005	10	.82	3 hrs.	Fractures 6 mos. post	Viable Fracture Sites	No	X		Clinical X-ray		
16 May 73	66	F	56	98	4005	10.1	1.1	3 hrs.	Staging of disease	No metastases	No	X		Clinical X-ray		

*Describe as positive (+) or negative (-).

If positive (+), on a separate sheet, include brief clinical history and describe the reaction as well as your interpretation of the nature and cause of the reaction.

**Indicate Means



^{99m}Tc-STANNOUS POLYPHOSPHATE FORFitzsimons General Hospital
Denver, Colorado

New England Nuclear Corp.

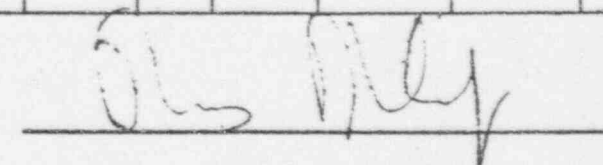
BONE IMAGING

Date	Patient No.	Sex	Age Yrs.	Wt. Lbs.	Lot No.	Dose in mCi	Volume Injected	Interval Between Dose and Imaging	Indications for Imaging	Post Image Diagnosis	Any Adverse Effect	Was Image Clinically Useful		Confirmation of Diag by Other Method		
												Yes	No	** Concur	Do not ** Concur	P
17 May 73	67	M	17	170	4005	10	1.9	3 hrs.	Fracture	Viable Fracture Site	No	X		Clinical X-ray		
18 May 73	68	M	44	165	4005	10.3	1.9	3 hrs.	Femoral head Deformities	Heterotopic ossification Viable	No	X		Clinical X-ray		
21 May 73	69	F	62	122	4005	10	.43	3 hrs.	Poss. bone tumor (chondrosarcoma)	Prob. bone tumor	No	X		Clinical X-ray		
22 May 73	70	M	57	195	4005	10.1	.8	3 hrs.	Staging of disease	Normal	No	X		Clinical X-ray		
23 May 73	71	M	64	153	4005	9.9	.9	3 hrs.	Staging of disease	Degenerative Arthritis	No	X		Clinical X-ray		
23 May 73	72	F	18	90	4005	10.6	1.2	3 hrs.	Poss bone tumor	No evidence of bone tumor	No	X		Clinical X-ray		

*Describe as positive (+) or negative (-).

If positive (+), on a separate sheet, include brief clinical history and describe the reaction as well as your interpretation of the nature and cause of the reaction.

**Indicate Means



^{99m}Tc-STANNOUS POLYPHOSPHATE FOR

Fitzsimons General Hospital

New England Nuclear Corp.

BONE IMAGING

Denver, Colorado

Date	Patient No.	Sex	Age Yrs.	Wt. Lbs.	Lot No.	Dose in mCi	Volume Injected	Interval Between Dose and Imaging	Indications for Imaging	Post Image Diagnosis	Any Adverse Effect	Was Image Clinically Useful		Confirmation of Diag by Other Method		
												Yes	No	Concur **	Do not Concur **	Pc
24 May 73	73	F	37	155	4005	10.8	1	3 hrs.	Staging of disease	Normal	No	X		Clinical X-ray		
24 May 73	74	F	53	155	4005	10.3	1.2	3 hrs.	Staging of disease	Normal	No	X		Clinical X-ray		
25 May 73	75	M	57	168	4005	10.8	2	3 hrs.	Staging of disease	Metastases---multiple	No	X		Clinical		
25 May 73	76	F	44	105	4005	9.6	2	3 hrs.	Staging of disease	Metastases---extensive	No	X		Clinical X-ray		
30 May 73	77	M	70	100	4005	10	.7	3 hrs.	Staging of disease	Metastases---multiple	No	X		Clinical X-ray		
30 May 73	78	M	42	180	4005	10	1.1	3 hrs.	Staging of disease	No Metastases	No	X		Clinical X-ray		

*Describe as positive (+) or negative (-).

If positive (+), on a separate sheet, include brief clinical history and describe the reaction as well as your interpretation of the nature and cause of the reaction.

**Indicate Means

Summary Report Form No. 114

Hospital:

^{99m}Tc-STANNOUS POLYPHOSPHATE FOR
BONE IMAGINGFitzsimons General Hospital
Denver, Colorado

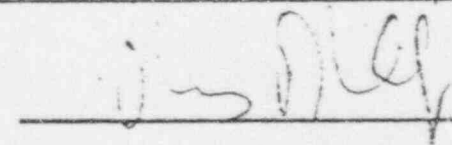
New England Nuclear Corp.

Date	Patient No.	Sex	Age Yrs.	Wt. Lbs.	Lot No.	Dose in mCi	Volume Injected	Interval Between Dose and Imaging	Indications for Imaging	Post Image Diagnosis	Any Adverse Effect	Was Image Clinically Useful		Confirmation of Diagnosis by Other Methods		
												Yes	No	Concur	Do not Concur	F
31 May 73	79	M	12	80	4005	5	.7	3 hrs.	Chronic osteomyelitis	Chronic osteomyelitis	No	X		Clinical X-ray		
1 Jun 73	80	F	46	170	4005	10	1	3 hrs.	Pain-hip	Metastases---multiple	No	X		Clinical		
1 Jun 73	81	F	57	160	4005	10	1.2	3 hrs.	Staging of disease	No Metastases	No	X		Clinical X-ray		
4 Jun 73	82	F	48	149	4005	10	.43	3 hrs.	Staging of disease	No Metastases	No	X		Clinical X-ray		
6 Jun 73	83	M	60	165	4005	10	.71	3 hrs.	Fracture	Avascular area	No	X		Clinical		
6 Jun 73	84	F	27	137	4005	10	1	3 hrs.	Primary bone tumor (chondrosarcoma)	No Metastases	No	X		Clinical X-ray		

*Describe as positive (+) or negative (-).

If positive (+), on a separate sheet, include brief clinical history and describe the reaction as well as your interpretation of the nature and cause of the reaction.

**Indicate Means



^{99m}Tc-STANNOUS POLYPHOSPHATE FOR
BONE IMAGING

Fitzsimons General Hospital
Denver, Colorado

New England Nuclear Corp.

Date	Patient No.	Sex	Age Yrs.	Wt. Lbs.	Lot No.	Dose in mCi	Volume Injected	Interval Between Dose and Imaging	Indications for Imaging	Post Image Diagnosis	Any Adverse Effect	Was Image Clinically Useful		Confirmation of Dia by Other Metho	
												Yes	No	** Concur	** Do not Concur
7 Jun 73		F	76	100	4005	10	1.2	3 hrs.	Staging of disease	No Metastases	No	X		Clinical X-ray	
7 Jun 73	86	F	36	138	4005	10	1.4	3 hrs.	Staging of disease	No Metastases	No	X		Clinical X-ray	
8 Jun 73	87	M	70	186	4005	10.6	1.8	3 hrs.	Staging of disease Pain-back	Degenerative Arthritis	No	X		Clinical X-ray	
11 Jun 73	88	M	15	85	4005	7.1	1.7	3 hrs.	Primary bone tumor	No evidence of bone tumor	No	X		Clinical X-ray	
11 Jun 73	89	M	51	150	4005	10	.8	3 hrs.	Staging of disease	Metastases---multiple	No	X		Clinical X-ray	
11 Jun 73	90	M	17	130	4005	10	.85	3 hrs.	Staging of disease	No metastases	No	X		Clinical X-ray	

*Describe as positive (+) or negative (-).

If positive (+), on a separate sheet, include brief clinical history and describe the reaction as well as your interpretation of the nature and cause of the reaction.

*Indicate Means

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^{99m}Tc-STANNOUS POLYPHOSPHATE FOR

BONE IMAGING

Fitzsimons General Hospital
Denver, Colorado

New England Nuclear Corp.

Date	Patient No.	Sex	Age Yrs.	Wt. Lbs.	Lot No.	Dose in mCi	Volume Injected	Interval Between Dose and Imaging	Indications for Imaging	Post Image Diagnosis	Any Adverse Effect	Was Image Clinically Useful		Confirmation of Dis by Other Metho	
												Yes	No	** Concur	Do not ** Concur
12 Jun 73	91	M	70	186	4005	10	.52	3 hrs.	Staging of disease Pain-back	Degenerative Arthritis	No	X		Clinical X-ray	
12 Jun 73	92	F	48	120	4005	10	.7	3 hrs.	Staging of disease	Normal	No	X		Clinical X-ray	
13 Jun 73	93	M	39	180	4005	10	1.1	3 hrs.	Staging of disease	Normal	No	X		Clinical X-ray	
14 Jun 73	94	F	57	160	4006	10	.9	3 hrs.	Staging of disease	No Metastases	No	X		Clinical X-ray	
14 Jun 73	95	M	27	174	4006	10.2	1.3	3 hrs.	Staging of disease	Normal	No	X		Clinical X-ray	
15 Jun 73	96	F	52	120	4006	10	1.5	3 hrs.	Possible bone tumor	No evidence of bone tumor	No	X		Clinical X-ray	

*Describe as positive (+) or negative (-).

If positive (+), on a separate sheet, include brief clinical history and describe the reaction as well as your interpretation of the nature and cause of the reaction.

**Indicate Means



^{99m}Tc-STANNOUS POLYPHOSPHATE FOR
BONE IMAGING

New England Nuclear Corp.

Fitzsimons General Hospital
Denver, Colorado

Date	Patient No.	Sex	Age Yrs.	Wt. Lbs.	Lot No.	Dose in mCi	Volume Injected	Interval Between Dose and imaging	Indications for Imaging	Post Image Diagnosis	Any Adverse Effect	Was Image Clinically Useful		Confirmation of Diag by Other Method		
												Yes	No	Concur **	Do not Concur **	P
18 Jun 73	97	M	78	140	4006	10	.5	3 hrs.	Staging of disease	Normal	No	X		Clinical X-ray		
19 Jun 73	98	M	58	175	4006	10	.6	3 hrs.	Staging of disease	Metastases---multiple	No	X		Clinical X-ray		
20 Jun 73	99	F	50	165	4006	10	.75	3 hrs.	Staging of disease	Metastases---multiple	No	X		Clinical X-ray		
20 Jun 73	100	M	30	160	4006	10	1	3 hrs.	Arthritis	Consistent with arthritis	No	X		Clinical X-ray		
21 Jun 73	101	M	78	150	4006	10	1	3 hrs.	Staging of disease	Degenerative Arthritis	No	X		Clinical X-ray		
21 Jun 73	102	M	44	160	4006	10	1.2	3 hrs.	Staging of disease	No Metastases	No	X		Clinical X-ray		

*Describe as positive (+) or negative (-).

If positive (+), on a separate sheet, include brief clinical history and describe the reaction as well as your interpretation of the nature and cause of the reaction.

**Indicate Means

Summary Report Form No. 18

Hospital:

^{99m}Tc-STANNOUS POLYPHOSPHATE FOR
BONE IMAGINGFitzsimons General Hospital
Denver, Colorado

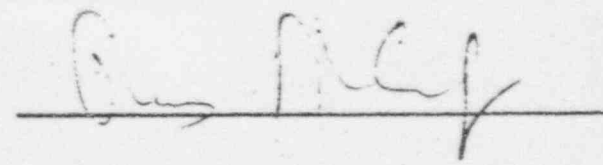
New England Nuclear Corp.

Date	Patient No.	Sex	Age Yrs.	Wt. Lbs.	Lot No.	Dose in mCi	Volume Injected	Interval Between Dose and Imaging	Indications for Imaging	Post Image Diagnosis	Any Adverse Effect	Was Image Clinically Useful		Confirmation of Diag by Other Method		
												Yes	No	** Concur	Do not ** Concur	Pc
25 Jun 73	103	F	49	120	4006	10	.42	3 hrs.	Staging of disease	Normal	No	X		Clinical X-ray		
25 Jun 73	104	F	67	135	4006	10	.63	3 hrs.	Staging of disease	Metastases---solitary	No	X		Clinical X-ray		
26 Jun 73	105	M	18	140	4006	10	.6	3 hrs.	Gunshot wound	Viable wound site	No	X		Clinical		
28 Jun 73	106	M	37	150	4006	10	1.1	3 hrs.	Staging of disease	Normal	No	X		Clinical X-ray		
28 Jun 73	107	F	78	130	4006	10	1.3	3 hrs.	Staging of disease	Degenerative Arthritis	No	X		Clinical X-ray		
29 Jun 73	108	F	58	145	4006	10	1.5	3 hrs.	Pain	Metastatic CA	No	X		Clinical		

*Describe as positive (+) or negative (-).

If positive (+), on a separate sheet, include brief clinical history and describe the reaction as well as your interpretation of the nature and cause of the reaction.

**Indicate Means



^{99m}Tc-STANNOUS POLYPHOSPHATE FORFitzsimons General Hospital
Denver, Colorado

New England Nuclear Corp.

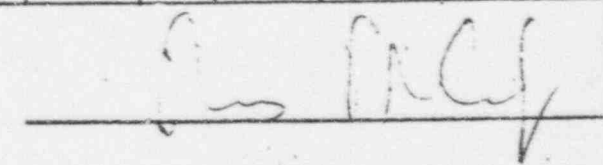
BONE IMAGING

Date	Patient No.	Sex	Age Yrs.	Wt. Lbs.	Lot No.	Dose in mCi	Volume Injected	Interval Between Dose and Imaging	Indications for Imaging	Post Image Diagnosis	Any Adverse Effect	Was Image Clinically Useful		Confirmation of Dia by Other Metho	
												Yes	No	** Concur	** Do not Concur
2 Jul 73	109	F	37	125	4006	10	.5	3 hrs.	Pain	Metastatic CA	No	X		Clinical	
2 Jul 73	110	M	52	155	4006	10	.54	3hrs.	Staging of disease	Normal	No	X		Clinical X-ray	
3 Jul 73	111	F	62	120	4006	10	.92	3 hrs.	Staging of disease	Normal	No	X		Clinical X-ray	
5 Jul 73	112	M	55	195	4006	10	1.1	3 hrs.	Staging of disease	Normal	No	X		X-ray Clinical	
5 Jul 73	113	F	36	130	4006	10	1.4	3 hrs.	Staging of disease	No metastases	No	X		Clinical X-ray	
6 Jul 73	114	F	55	148	4006	10	1.6	3 hrs.	Staging of disease	Normal	No	X		Clinical X-ray	

*Describe as positive (+) or negative (-).

If positive (+), on a separate sheet, include brief clinical history and describe the reaction as well as your interpretation of the nature and cause of the reaction.

**Indicate Means



^{99m}Tc-STANNOUS POLYPHOSPHATE FOR
BONE IMAGINGFitzsimons General Hospital
Denver, Colorado

New England Nuclear Corp.

Date	Patient No.	Sex	Age Yrs.	Wt. Lbs.	Lot No.	Dose in mCi	Volume Injected	Interval Between Dose and Imaging	Indications for Imaging	Post Image Diagnosis	Any Adverse Effect	Was Image Clinically Useful		Confirmation of Diag by Other Method		
												Yes	No	** Concur	Do not ** Concur	P.
6 Jul 73	115	F	40	163	4006	10	1.8	3 hrs.	Staging of disease	Normal	No	X		Clinical X-ray		
9 Jul 73	116	F	51	130	4006	10	.65	3 hrs.	Staging of disease	Metastatic CA	No	X		Clinical X-ray		
10 Jul 73	117	F	18	200	4006	10	.8	3 hrs.	Staging of disease	Metastatic CA	No	X		X-ray Clinical		
10 Jul 73	118	M	51	145	4006	10	.65	3 hrs.	Pain	Normal	No	X		Clinical X-ray		
10 Jul 73	119	M	42	160	4006	10	.93	3 hrs.	Fracture	Viable fracture site	No	X		Clinical X-ray		
11 Jul 73	120	M	58	142	4006	10	1.1	3 hrs.	Staging of disease	Metastases---multiple	No	X		X-ray Clinical		

*Describe as positive (+) or negative (-).

If positive (+), on a separate sheet, include brief clinical history and describe the reaction as well as your interpretation of the nature and cause of the reaction.

**Indicate Means



Summary Report Form No. 21

Hospital:

^{99m}Tc-STANNOUS POLYPHOSPHATE FORFitzsimons General Hospital

BONE IMAGING

Denver, Colorado

New England Nuclear Corp.

Date	Patient No.	Sex	Age Yrs.	Wt. Lbs.	Lot No.	Dose in mCi	Volume Injected	Interval Between Dose and Imaging	Indications for Imaging	Post Image Diagnosis	Any Adverse Effect	Was Image Clinically Useful		Confirmation by Other Means	
												Yes	No	Concur	Do not Concur
11 JUL 73	121	F	50	109	4006	10	1.2	93 hrs.	Staging of disease	Metastases---solitary	No	X		Clinical X-ray	

*Describe as positive (+) or negative (-).

If positive (+), on a separate sheet, include brief clinical history and describe the reaction as well as your interpretation of the nature and cause of the reaction.

**Indicate Means