TO: License Fee and Accounts Receivable Branch

FROM: Region IV - WCFO

SUBJECT: **VOIDED APPLICATION**

Applicant: Hilo Medical Center

Control Number: 572391

License No.: 53-03506-01

Docket No.: 030-03542

Date Voided: 11/01/96

Reason for Void:

This notification will be combined with Control No. 572423 amendment.

James J. Montgomery 10/31/96
Signature Date

Attachment:
Official Record Copy of
Voided Action

FOR LFARB USE ONLY

Final Review of VOID completed:

___ Refund Authorized and processed

___ No Refund Due

___ Fee Exempt or Fee Not Required

ML40 0/1

Comments: 060013

Log completed _____
Processed by: _____

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02120
STATUS CODE: 0
FEE CATEGORY: 7C
EXP. DATE: 20050228
FEE COMMENTS: CODE 12
DECOM FIN ASSUR REQD: N

RE
RIV
96 AUG -8

LICENSE FEE TRANSMITTAL

A. REGION ~~V~~

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: HILO MEDICAL CENTER
RECEIVED DATE: 960726
DOCKET NO: 3003542
CONTROL NO.: 572391
LICENSE NO.: 53-03506-01
ACTION TYPE: NOTIFICATIONS

2. FEE ATTACHED
AMOUNT:
CHECK NO.: none

3. COMMENTS

SIGNED Joan Starck
DATE 7-24-96

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED)

1. FEE CATEGORY AND AMOUNT: 7C FEE NOT REQUIRED

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR: Notification
AMENDMENT ✓
RENEWAL
LICENSE

3. OTHER

SIGNED Rita Messer
DATE 8/6/96

1996 AUG -1 PM 3:25

RECEIVED BY LFMS
Date 8/1/96
Log Cat C IV
By Kent
Date Completed 8/6/96

Notification

BENJAMIN J. CAYETANO
GOVERNOR

LAWRENCE MIIKE
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
HILO MEDICAL CENTER
1190 WAIANUENUE AVENUE
HILO, HAWAII 96720

July 20, 1996

Mr. James Montgomery
U.S. Nuclear Regulatory Commission
Walnut Creek Field Office
1450 Maria Lane, Ste. #210
Walnut Creek, CA 94596

Ref: Part 35.14 Notifications

Refer: NRC License No. 53-03506-01
Docket No. 030-03542

Dear Mr. Montgomery,

The below listed enclosures are submitted in accordance with the reference listed below as a notification that we have granted Dr. Lee E. Miyasato, M.D. and Dr. Peter A. Remedios, M.D. privileges as authorized users in categories of 35.100, 35.200, 35.300 and 35.500.

Also, in my letter dated January 29, 1996 granting Dr. David Camacho, Jr., M.D., I had added him to our license for a period of six months. I would like this extended for an indefinite period at this time.

If I can provide any additional or more specific information, please do not hesitate to call me at (808)969-4416.

Sincerely,

C.N.M.T.

Daniel W. Rickenbacher, C.N.M.T.
Radiation Safety Officer

DWR/kg

572391

ENCL:

1. Letter dated June 20, 1996 granting hospital privileges to Dr. Lee E. Miyasato, M.D., at Hilo Medical Center

2. Certification of License for Dr. Lee E. Miyasato, M.D.

3. Perceptor Statement for Dr. Lee E. Miyasato, M.D.

4. Letter dated June 20, 1996 granting hospital privileges to Dr. Peter A. Remedios, M.D., at Hilo Medical Center

5. Certification of License for Dr. Peter A. Remedios, M.D.

6. Perceptor Statement for Dr. Peter A. Remedios, M.D.

7. Copy of California Materials License #3192-40 with Dr. Peter Remedios, M.D. listed

8. Copy of California Materials License #5592-70 with Dr. Peter Remedios, M.D. listed

9. Radiation Safety Committee Meeting dated June 24, 1996 approving Dr. Lee E. Miyasato, M.D. and Dr. Peter A. Remedios, M.D. as authorized users at Hilo Medical Center

BENJAMIN J. CAYETANO
GOVERNOR

LAWRENCE MIIKE
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
HILO MEDICAL CENTER
1190 WAIANUENUE AVENUE
HILO, HAWAII 96720

June 20, 1996

TO WHOM IT MAY CONCERN

Re: **Lee E. Miyasato, M.D.**

On June 6, 1996 Dr. Lee E. Miyasato was approved by the Medical Executive Committee of Hilo Medical Center for active staff membership with privileges in Radiology.

Sincerely,

William Carnett, D.O.
Medical Director

STATE OF HAWAII
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
PROFESSIONAL AND VOCATIONAL LICENSING DIVISION
1010 RICHARDS STREET
P.O. BOX 3469
HONOLULU, HAWAII 96801

05/02/96

STATE OF HAWAII
HILO MEDICAL CENTER
MEDICAL STAFF OFFICE
1190 WAIANUENUE AVENUE
HILO HI 96720

RE: VERIFICATION OF LICENSE/EXAM SCORES DATED 05/02/96 FOR
E MIYASATO

BOARD/COMMISSION:	BOARD OF MEDICAL EXAMINERS
LICENSE TYPE:	PHYSICIAN
LICENSE IDENTIFICATION:	MD 9407
METHOD OF LICENSURE:	ENDORSEMENT-THROUGH NATIONAL EXAM
DATE LICENSED:	02/21/96
LICENSE STATUS:	CURRENT, VALID & IN GOOD STANDING
LICENSE EXPIRATION DATE:	01/31/98
DISCIPLINARY ACTION:	NONE

CERTIFIED BY:

Constance Cabral-Makanani

CONSTANCE CABRAL-MAKANANI
EXECUTIVE OFFICER

ACCORDING TO OUR COMPLAINT RECORDS WHICH DATE BACK TO 1985:

☑ NO DEROGATORY INFORMATION IS ON FILE.

☐ THE ATTACHED INFORMATION IS ON FILE CONCERNING THIS LICENSEE.

NRC FORM 313M SUPPLEMENT A
(9-81)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Lee E. Miyasato, M.D.	HI

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Radiology	Diplomate	June 1995

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES *(Hours)* C	SUPERVISED LABORATORY EXPERIENCE *(Hours)* D
a. RADIATION PHYSICS AND INSTRUMENTATION	July 1, 1991-June 30, 1995 University of Virginia Charlottesville, VA	100	50
b. RADIATION PROTECTION	See above	30	20
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	See above	20	5
d. RADIATION BIOLOGY	See above	20	
e. RADIOPHARMACEUTICAL CHEMISTRY	See above	30	10

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Tc-99m	30 mCi	UVa Hospital, Chville	1040 hrs in all	Clinical
Mo-99	3000 mCi	"	"	"
I-131	200 mCi	"	"	"
Yb-169	500 uCi	"	"	"
In-111	5 mCi	"	"	"
Ga-67	10 mCi	"	"	"
Tl-201	4 mCi	"	"	"
I-125	50 uCi	"	"	"

NRC FORM 313M SUPPLEMENT B (9-81) U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME: Lee E. Miyasato, M.D.

STREET ADDRESS: 117 Tintern Court

CITY: Charlottesville | STATE: VA | ZIP CODE: 22901

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION	2	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME	8	
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
OTHER	Tc-99m gastric Emptying	90	
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING	3	
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	215	
OTHER	In-111 DTPA cisternography	2	
Tc-99m	BRAIN IMAGING	4	
	CARDIAC IMAGING	136	
	THYROID IMAGING	36	
	SALIVARY GLAND IMAGING	1	
	BLOOD POOL IMAGING	24	
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING	12	
	LUNG IMAGING	235	
	BONE IMAGING	535	
OTHER	T1-201 myocardial imaging	56	

RECEPTOR STATEMENT *(Continued.*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA	5	
	TREATMENT OF HYPERTHYROIDISM	42	
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR	15	
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS	30	
Other			
Ga-67	Gallium imaging	42	
Tc-99m	Hepatobiliary imaging	35	
Tc-99m	Renal Imaging	150	
Tc-99m	GI Bleeding imaging	10	
Tc-99m	Parathyroid imaging	11	
I-131	Adrenal Imaging	7	

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

July 1, 1992-June 30, 1995 1040 hours

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
Charles D. Teates, M.D.

b. NAME OF INSTITUTION
University of VA Medical Center

c. MAILING ADDRESS
Box 486, Dept. of Radiology

d. CITY
Charlottesville

5. MATERIALS LICENSE NUMBER(S)
45 000 34-26

6. PRECEPTOR'S SIGNATURE
Charles D Teates

7. PRECEPTOR'S NAME *(Please type or print)*
Charles D. Teates, M.D.

8. DATE
1/16/96

NRC FORM 313M SUPPLEMENT B
(9-81)

GPO 890-913

BENJAMIN J. CAYETANO
GOVERNOR

LAWRENCE MIIKE
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
HILO MEDICAL CENTER
1190 WAIANUENUE AVENUE
HILO, HAWAII 96720

June 20, 1996

TO WHOM IT MAY CONCERN

Re: **Peter A. Remedios, M.D.**

Dr. Peter A. Remedios has been a member of the consulting staff staff at Hilo Medical Center since March 4, 1996 with privileges in Radiology. He previously had temporary membership from October 30, 1995 to March 4.

Sincerely,

William Carnett, D.O.
Medical Director

STATE OF HAWAII
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
PROFESSIONAL AND VOCATIONAL LICENSING DIVISION
1010 RICHARDS STREET
P.O. BOX 3469
HONOLULU, HAWAII 96801

10/16/95

STATE OF HAWAII
DEPARTMENT OF HEALTH
HILO MEDICAL CENTER
1190 WAIANUENUE AVENUE
HILO HI 96720

RE: 'RIFICATION OF LICENSE/EXAM SCORES DATED 10/16/95 FOR
'ER A REMEDIOS

BOARD/COMMISSION:	BOARD OF MEDICAL EXAMINERS
LICENSE TYPE:	PHYSICIAN
LICENSE IDENTIFICATION:	MD 9285
METHOD OF LICENSURE:	ENDORSEMENT-THROUGH NATIONAL EXAM
DATE LICENSED:	09/25/95
LICENSE STATUS:	CURRENT, VALID & IN GOOD STANDING
LICENSE EXPIRATION DATE:	01/31/96
DISCIPLINARY ACTION:	NONE

CERTIFIED BY:

Constance Cabral-Makanani

CONSTANCE CABRAL-MAKANANI
EXECUTIVE OFFICER

ACCORDING TO OUR COMPLAINT RECORDS
WHICH DATE BACK TO 1985:

☑ NO DEROGATORY INFORMATION IS ON FILE.

☐ THE ATTACHED INFORMATION IS ON FILE CONCERNING THIS LICENSEE.

DIAGNOSTIC RADIOLOGY RESIDENT
1983-1987
1987-1988 Fellowship Body Imaging & Interventional

EXHIBIT 2

TRAINING AND EXPERIENCE—MEDICAL AUTHORIZED USER OR RADIATION SAFETY OFFICER

This form is to accompany an application form (RH 2000) or a letter referencing your Califor Radioactive Materials License Number.

1. Name of Proposed Authorized User or Radiation Safety Officer: PETER ANTHONY REMEDIOS, M.D

2. California Physician s and Surgeon s Certificate Number, if Applicable: G 51796

3. Certification

Specialty Board	Category	Month and Year Certifie
DIAGNOSTIC RADIOLOGY, AMERICAN BOARD OF RADIOLOGY	DIAGNOSTIC RADIOLOGY (included section on NUCLEAR MEDICINE)	6-86

4. Training Received in Basic Radioisotope Handling Techniques

Field of Training A	Location and Date(s) of Training B	Type and Length of Training Lecture/ Laboratory Courses (hours) C	Type and Length of Training Supervised Laboratory Experience (hou D
a Radiation Physics and Instrumentation	LAC+USC Medical Center Division of Nuclear Med. 1200 N. State St. Rm. 5250 Los Angeles, CA 90033	45	45
b Radiation Protection		25	none
c Mathematics Pertaining to the Use and Measurement of Radioactivity	Dates of Training: 9-1-84 - 9-30-84 11-1-85 - 12-31-85	20	20
d Radiation Biology	2-3-86 - 2-28-86 5-1-86 - 5-30-86	20	none
e Radiopharmaceutical Chemistry	9-1-86 - 9-30-86 A total of 6 months	40	40

5. Experience with Radiation (actual use of radioisotopes or equivalent experience)

Isotope	Maximum Amount	Where Experience Was Gained	Duration of Experience	Type of Use
Tc-99m	500 mCi	As under 4B	6 months clinical rotation during residency in Diagnostic Radiology	Diagnostic and therapeutic
Ga-67	20 mCi			
In-111	10 mCi			
Cr-51	100 mCi			
Iodine-123	10 mCi			
I-131	100 mCi			
Xe-133	50 mCi			
Tl-201	10 mCi			

PRECEPTOR STATEMENT

This part must be completed by the applicant physician's preceptor. If more than one preceptor is necess document experience, obtain a separate statement from each.

1. Applicant Physician's Name and Address

Full Name: Peter Anthony Remedios, M.D.

Street Address: 2265 22nd Street

City: Santa Monica, CA State: CA ZIP Code: 90405

2. Clinical Training and Experience of Above Named Physician

Key to Column C

Personal participation should consist of:

1. Supervised examination of patients to determine the suitability for radionuclide diagnosis and/or treatment and recommendation for prescribed dosage.
2. Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements, and plotting of data.
3. Supervised interpretation of results of diagnostic studies.
4. Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

Isotope A	Conditions Diagnosed or Treated B	Number of Cases Involving Personal Participation C	Comments (Additional information or comments may be submitted in duplicate on separate sheets) D
I-131	Diagnosis of thyroid function	120	
or	Determination of blood and blood plasma volume	6	
I-125	Liver function studies	-	
	Kidney function studies	100	
	In vitro studies	-	
OTHER	B-12, I-123, etc.	30	

2. Clinical Training and Experience of Above Named Physician (continued)

Isotope A	Conditions Diagnosed or Treated B	Number of Cases Involving Personal Participation C	Comments (Additional information or comments may submitted in duplicate on separate sheets D
Cr-51	Detection of thrombosis	30	
I-123 I-131	Thyroid imaging	80	
P-32	Eye tumor localization	-	
Se-75	Pancreas imaging	-	
In-111 DTPA Yb-169	Cisternography	25	
Xe-133	Blood flow studies and pulmonary function studies	135	
OTHER			
	Brain imaging	85	
	Cardiac imaging	150	
	Thyroid imaging	45	
	Salivary gland imaging	6	
	Blood pool imaging	115	
	Liver and spleen imaging	350	
	Lung imaging	250	
	Bone imaging	400	
OTHER			
P-32 (soluble)	Treatment of polycythemia vera, leukemia, and bone metastases	8	
P-32 (colloidal)	Intracavitary treatment	2	
I-131	Treatment of thyroid carcinoma	15	
	Treatment of hyperthyroidism	25	

2. Clinical Training and Experience of Above Named Physician (continued)

Isotope A	Conditions Diagnosed or Treated B	Number of Cases Involving Personal Participation C	Comments (Additional information or comments may submitted in duplicate on separate sheet) D
Ra-226 or	Interstitial treatment	-	
Cs-137	Intracavitary treatment	-	
I-125 or Ir-192	Interstitial treatment	-	
Co-60 or Cs-137	Teletherapy treatment	-	
Sr-90	Treatment of eye disease	-	
	Radiopharmaceutical preparation	-	
Mo-99/ Tc-99m	Generator	35	
Tc-99M	Reagent kits	50	
OTHER			

3. Dates and Total Number of Hours Received in Clinical Radioisotope Training: 9-1-84 - 9-30-84, 5-1-85 - 5-30-86
11-1-85 - 12-31-85, 2-3-86 - 2-28-86, 9-1-86 - 9-30-86 (A total of 6 months).

4. The Training and Experience Indicated Above Was Obtained Under the Supervision of:
   a. Name of Supervisor: Michael E. Siegel, M.D., Director, Nuclear Medicine
   b. Name of Institution: LAC/USC Medical Center
   c. Mailing Address: 1200 N. State Street Rm. #5250
   d. City, State, and ZIP Code: Los Angeles, CA 90033

5. Materials License Number(s): 0134-70

6. Preceptor's Signature: [signature]

7. Preceptor's Name (Please type/print.): Michael E. Siegel, M.D., Professor of Radiology

8. Date: May 14, 1993

RADIOACTIVE MATERIAL LICENSE

License Number: 3192-40

Supplementary Sheet

Amendment Number: 13

Twin Cities Community Hospital
1100 Las Tablas Road
Templeton, CA 93465

Attention: Michael P. Curran, M.D.
Radiation Safety Officer

In response to the letters with attachments dated August 18, 1993, and July 29, 1993, signed by Michael P. Curran, M.D., Radiation Safety Officer, and John B. Richards, M.D., Director, Department of Nuclear Medicine respectively, License Number 3192-40 is hereby amended in part as follows:

To DELETE:

Subitems 12. (b), 12. (c), and 12. (d) are hereby deleted in their entirety.

To add:

12. The individuals named below are authorized the specific uses of radioactive material described in Items 6, 7, 8 and 9 of this license as follows:

(b)	Harold R. Griffith, M.D.	Groups 1, 2, 3, and 9
(c)	Donna Winningham, M.D.	Groups 1, 2, 3, 4 (Iodine 131 only), and 9
(d)	Peter A. Remedios, M.D.	Groups 1, 2, 3, 4, 5, and 9

13. (h) The letter dated August 18, 1993, signed by Michael P. Curran, M.D., Radiation Safety Officer, regarding the use of Technetium 99m DTPA aerosol.

For the State Department of Health Services

Date: November 16, 1993 By: [signature] 3

Radiologic Health Branch
P.O. Box 942732
Sacramento, CA 94234-7320

(Int.) (1/91)

RADIOACTIVE MATERIAL LICENSE

Pursuant to the California Administrative Code, Title 17, Chapter 5, Subchapter 4, Group 2, Licensing of Radioactive Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, use, possess, transfer, or dispose of radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders of the Department of Health Services now or hereafter in effect and to any conditions specified in this license.

1. *Licensee*	Twin Cities Community Hospital	3. *License No.*	3192-40 · *Amendment No.* 15
2. *Address*	1100 Las Tablas Road Templeton, CA 93465	4. *Expiration date*	June 9, 2001
Attention:	Michael P. Curran, M.D. Radiation Safety Officer	5. *Inspection agency*	Radiologic Health Branch Berkeley

License Number 3192-40 is hereby renewed in its entirety:

In accordance with California Radiation Control Regulations, Title 17, Subchapter 4, Article 4, Section 30195, the Medical Use Groups specified below grant the use of radioactive material, as approved by the United States Food and Drug Administration, the California State Board of Medical Quality Assurance and/or the California State Board of Pharmacy, for diagnosis and treatment of patients, when prescribed and as directed by an appropriately authorized physician listed on this license.

GROUPS AUTHORIZED UNDER THIS LICENSE

Group 1 - Diagnostic studies involving measurement of uptake, dilution, or excretion but not involving imaging.

Group 2 - Diagnostic Studies involving imaging including the use of Xenon 127 and/or Xenon 133 gas.

Group 3 - Use of reagent kits including Mo/Tc 99m and Rb/Kr 81m generators for preparation of radiopharmaceuticals listed in Group 2.

Group 4 - Internal therapy not usually requiring hospitalization.

Group 5 - Internal therapy usually requiring hospitalization for purposes of radiation safety.

For the State Department of Health Services

Date June 20, 1994 by 3

Radiologic Health Section
744 P Street, Sacramento, CA 95814

RADIOACTIVE MATERIAL LICENSE

License Number: 3192-40

Amendment Number: 15

Supplementary Sheet

Group 9 - Nonhuman uses using sources identified in Items 6, 7, and 8 below.

6. Nuclides	7. Forms	8. Authorized Use
A. Any radionuclide with Atomic numbers 3-83 inclusive except: (1) Strontium 90 and (2) Lead 210	A. Sealed sources, manufactured, labeled packaged, and distibuted in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or Agreement State, not to exceed 10 mCi each.	A. Marker sources and calibration.

Group 11 - Manufacturer-sponsored clinical investigations

6. Nuclide	7. Form	8. Authorized Use
A. Any radiopharmaceutical or Biologic not prohibited by U.S. Food and Drug Administration.	A. Any radiopharmaceutical in an IND which has been accepted in writing by the U.S. Food and Drug Administration.	A. To be used for diagnostic or therapeutic studies conducted in strict accordance with Physician-sponsored or Manufacturer-sponsored IND(s) which have been accepted and approved by the State of California Food and Drug Administration or the U.S. Food and Drug Administration.

9. Possession Limits

Combined possession limit for Group 1, Group 2, Group 3, Group 4, Group 5, Group Group 9, and Group 11 -- A total not to exceed 1.0 Curie

10. Radioactive material shall be used only at the following locations:

(a) 1100 Las Tablas Road, Templeton, CA.

For the State Department of Health Services

Date: June 20, 1994 By:

Radiologic Health Branch
P.O. Box 942732
Sacramento, CA 94234-7320

RADIOACTIVE MATERIAL LICENSE

License Number: 3192-40

Amendment Number: 15

Supplementary Sheet

11. This license is subject to an annual fee for sources of radioactive material authorized to be possessed at any one time as specified in Item 8 of this license. The annual fee for this license is required by and computed in accordance with Sections 30230-30232 of the California Radiation Control Regulations and is also subject to an annual cost-of-living adjustment pursuant to Section 113 of the California Health and Safety Code.

12. The individuals named below are authorized the specific uses of radioactive material authorized in Use Groups and Items 6, 7, 8 and 9 as described in this license:

(a)	Michael P. Curran,	Group(s) 1, 2, 3, 4, 5, 9, and 11
(b)	Harold R. Griffith, M.D.	Group(s) 1, 2, 3, and 9
(c)	Donna Winningham, M.D.	Group(s) 1, 2, 3, 4, (I-131 only), and 9
(d)	Peter A. Remedios, M.D.	Group(s) 1, 2, 3, 4, 5, and 9

13. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in the documents listed below. The Department's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    (a) The letter dated April 22, 1991 and application with attachments dated April 22, 1991 signed by Michael P. Curran, M.D., Radiation Safety Officer, all related to the renewal of license.

    (b) The letter dated August 18, 1993, signed by Michael P. Curran, M.D., Radiation Safety Officer, regarding the use of Technetium 99m DTPA aerosol.

14. (a) The Radiation Safety Officer in this program shall be Michael P. Curran, M.D..

    (b) The Chairperson of the Radiation Safety Committee shall be Michael P. Curran, M.D..

    (c) The Custodian of sealed sources shall be Barbara Benson, CNMT

15. Analytical tests for leakage and/or contamination of sealed sources shall be performed only by persons specifically authorized to perform that service.

(2/8.

For the State Department of Health Services

Date: June 20, 1994 By:

Radiologic Health Branch
P.O. Box 942732
Sacramento, CA 94234-7320

RADIOACTIVE MATERIAL LICENSE

Supplementary Sheet

License Number: 3192-40

Amendment Number: 15

16. The following individuals are authorized to collect wipe test samples of sealed sources possessed under this license using leak test kits acceptable to the California Department of Health Services.

    (a) The Radiation Safety Officer
    (b) Qualified individuals designated by the Radiation Safety Officer

17. Records of leak test results shall be kept in units of microcuries and maintained for inspection. Records may be disposed of following Department inspection. Any leak test revealing the presence of 0.005 microcuries or more of removable radioactive material shall be reported to the Department of Health Services, Radiologic Health Branch, P. O. Box 942732, Sacramento, CA 94234-7320, within five days of the test. This report shall include a description of the defective source or device, the results of the test, and the corrective action taken.

18. The licensee is authorized to hold radioactive materials with a physical half-life of less than 90 days for decay-in-storage before disposal in ordinary trash provided:

    (a) Radioactive waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.

    (b) Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

    (c) Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

19. Except as otherwise specifically provided by this license, radiopharmaceuticals to be administered to humans shall be procured in prepackaged, precalibrated form, from a supplier who is registered with the U. S. Food and Drug Administration, or prepared and compounded from a prescription, in accordance with the regulations of the California Board of Pharmacy.

20. Except as otherwise specifically provided by this license, radioactive biologicals (including human serum albumin) to be administered to humans shall be procured in prepackaged, precalibrated form, from a supplier licensed for the preparation and distribution of such products by the Division of Biologics Standards of the National Institutes of Health, or U. S. Food and Drug Administration; or prepared in accordance with the regulations of the California Board of Pharmacy.

For the State Department of Health Services

e: June 20, 1994 By: 3

Radiologic Health Branch
P.O. Box 942732
Sacramento, CA 94234-7320

RADIOACTIVE MATERIAL LICENSE

License Number: 3192-40

Supplementary Sheet

Amendment Number: 15

21. Radioactive materials prepared, processed, or modified by the licensee shall not be administered to humans except as specifically authorized by this license.

22. Technetium 99m generators approved by the Department may be used as sources of Technetium 99m for use in preparations to be administered to humans, provided the generators are used in strict accordance with the manufacturer's instructions, or with the regulations of the California Board of Pharmacy.

23. The licensee shall elute generators and process radioactive material with reagent kits in accordance with instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit.

24. Technetium 99m labelled pharmaceuticals prepared by the licensee by aseptic addition of pertechnetate to sterile, pyrogen-free reagents may be administered to humans provided the radioassay of the final product is determined with an overall error not exceeding ten percent. When the pharaceutical is prepared from reagents procured in the form of approved kits, the licensee must strictly follow all instructions and recommendations contained in the package inser information; otherwise the pharmaceutical must be prepared and compounded from a prescription in accordance with the regulations of the California Board of Pharmacy.

25. Where users or their assistants are engaged in elution of pertechnetate 99m from generators, the exposure to the fingers or hands shall be monitored as required by Title 10, Code of Federal Regulations, Part 20, Section 20.1502(a).

26. Mo-99 break through may not exceed 0.15 uCi per mCi of Tc-99m, and less than 2.5 uCi Mo-99 per administered dose.

27. Equipment for radiometric assay of pharmaceuticals, body fluids, excreta, or in vitro assay samples shall be calibrated to ensure the reliability of data obtained. The stability of the equipment shall be checked at least once on each day of use, using appropriate standards.

28. Nuclear medicine technology procedures shall be performed by nuclear medicine technologists pursuant to the California Code of Regulations, Title 17, Subchapter 4.6. Such procedures shall be performed under the supervision of individuals listed as authorized users on this license who meet the criteria specified in Section 30510. Certificates or special permits issued pursuant to Subchapter 4.6 shall be prominently displayed at the facility(ies) authorized on this license.

For the State Department of Health Services

Date: June 20, 1994 By: 3

Radiologic Health Branch
P.O. Box 942732
Sacramento, CA 94234-7320

RADIOACTIVE MATERIAL LICENSE

License Number: 3192-40

Supplementary Sheet

Amendment Number: 15

29. Treatment and management of patients receiving therapeutic quantities of unsealed radioactive materials shall be in accordance with guidance contained in Chapter 4, "Release from Hospital of Patients Containing Radioactive Materials", National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides" (NCRP Publications, P.O. Box 30175, Washington, D.C. 20014).

30. Radioactive materials shall be used by occupational workers in such a manner that the dose limits specified in Title 10, Code of Federal Regulations, Part 20, Subpart C (Sections 20.1201 through 20.1208) are not exceeded.

31. The licensee shall monitor occupational exposures to radiation and shall supply and require the use of individual monitoring devices by personnel as required by Title 10, code of Federal Regualtions, Part 20, Section 20.1502 (a).

32. The licensee shall monitor occupational intakes of radioactive material by, and assess the committed effective dose equivalent to, individuals who may have exceeded or are likely to exceed, the limits specified in Title 10, Code of Federal Regulations (CFR), Part 20, Section 20.1502(b). Suitable and timely measurements used for determination of such internal exposures shall be performed as specified by 10CFR 20.1204.

33. This license does not authorize distribution to persons licensed pursuant to Section 30195 (a) and (b) of the California Radiation Control Regulations or equivalent provisions of the Nuclear Regulatory Commission or Agreement States.

34. A copy of this license and a copy of all records and documents pertaining to this license shall be maintained available for inspection at 1100 Las Tables Road, Templeton, CA.

For the State Department of Health Services

Date: June 20, 1994 By: [signature]

Radiologic Health Branch
P.O. Box 942732
Sacramento, CA 94234-7320

RADIOACTIVE MATERIAL LICENSE

Pursuant to the California Code of Regulations, Division 1, Title 17, Chapter 5, Subchapter 4, Group 2, Licensing of Radioactive Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, use, possess, transfer, or dispose of radioactive material listed below, and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders of the Department of Health Services now or hereafter in effect and to any standard or specific condition specified in this license.

1. *Licensee*	USC University Hospital	3. *License No.* 5592-70	*Amendment No.* 17
2. *Address*	1500 San Pablo Street Los Angeles, CA 90033	4. *Expiration date* June 3, 1998	(3)
Attention	James R. Bading, Ph.D. Radiation Safety Officer	5. *Inspection agency*	Los Angeles County Department of Health Services

License Number 5592-70 is hereby amended as follows:

6. Nuclide	7. Form	8. Possession Limit
A. Group 1 as specified in Item 9. Any radionuclide with atomic number 3-83.	A. Any	A.- C. Combined possession limit of Groups 1, 2, and 3 not to exceed 600 mCi.
B. Group 2 as specified in Item 9. Any radionuclide with atomic number 3-83.	B. Any	
C. Group 3 as specified in Item 9. Any radionuclide with atomic number 3-83.	C. Any Excluding Generators	
D. Group 4 as specified in Item 9. 1. Phosphorous 32 2. Iodine 131	D. 1. Any 2. Any	D. Total not to exceed 60 mCi.
E. Group 5 as specified in Item 9. 1. Phosphorous 32 2. Iodine 131	E. 1. Any 2. Any	E. Total not to exceed 300 mCi.
F. Group 8 as specified in Item 9. Cobalt 60	F. Sealed or solid sources Sealed sources (General Electric Company AB Elekta Model No. 43047)	F. Total 6600 Ci in 201 sources, no single source to exceed 36 Ci each.

RADIOACTIVE MATERIAL LICENSE

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6. Nuclide	7. Form	8. Possession Limit
G. Group 9 as specified in Item 9. 1. Any radionuclide with atomic number 3-83 inclusive, except: Strontium 90 and Lead 210.	G. 1. Sealed or solid sources manufactured in accordance with a specific license issued by the United States Nuclear Regulatory Commission or an Agreement State.	G. 1. Total not to exceed 30 mCi. Each radionuclide not to exceed 20 mCi.
2. Gadolinium 153	2. Sealed sources (Model 3601)	2. Total 800 mCi, in sources, no single source to exceed 250 mCi.
H. Group 10 as specified in Item 9. Any radionuclide with atomic number 3-83.	H. Any	H.-I. Total 10 mCi.
I. Group 11 as specified in Item 9. Any radionuclide with atomic number 3-83.	I. Any	

RADIOACTIVE MATERIAL LICENSE

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9. Authorized Use

A. Group 1 Diagnostic studies involving measurement of uptake, dilution, or excretion but not involving imaging.

B. Group 2 Diagnostic studies involving imaging including the use of Xenon 127 and/or Xenon 133 gas.

C. Group 3 Reagent kits utilizing bulk technetium prepared by a radiopharmacy for preparation of radiopharmaceuticals listed in Group 2.

D. Group 4 Internal therapy not usually requiring hospitalization and palliative treatment.

E. Group 5 Internal therapy and palliative treatment requiring hospitalization for purposes of radiation safety .

F. Group 8 Teletherapy of cancer and Teleradiosurgery.

G. Group 9 Nonhuman use: Marker and calibration sources.

H. Group 10 Physician-Sponsored nonroutine medical uses of radioactive materials (Physician-Sponsored IND).

I. Group 11 Manufacturer-Sponsored nonroutine medical uses of radioactive material (Manufacturer-Sponsored IND).

LICENSE CONDITIONS

10. Radioactive material shall be used only at the following locations:

A. 1500 San Pablo Street, Los Angeles, CA

11. This license is subject to an annual fee for sources of radioactive material authorized to be possessed at any one time as specified in Item 8 of this license. The annual fee for this license is required by and computed in accordance with Sections 30230-30232 of the California Radiation Control Regulations and is also subject to an annual cost-of-living adjustment pursuant to Section 113 of the California Health and Safety Code.

RADIOACTIVE MATERIAL LICENSE

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12. The individuals named below are authorized the specific uses of radioactive material described in Items 6, 7, 8 and 9 of this license as follows:

(a) James Huprich, M.D.	Groups 1, 2, 3 and 9
(b) Patrick Cilletti, M.D.	Groups 1, 2, 3, 4 ,5 and 9
(c) Aziz N. Ansari, M.D.	Groups 1, 2, 3, 4, 5 and 9
(d) Peter S. Conti, M.D., Ph.D.	Groups 1, 2, 3, 4, 5 and 9
(e) Scott T. Grafton, M.D.	Groups 1, 2, 3 and 9
(f) James R. Bading, Ph.D.	Group 9 (Physical measurements only)
(g) Nelson Arnstein, M.D.	Groups 1, 2, 3, 4, 5 and 9
(h) Azizullah N. Ansari, M.D.	Groups 1, 2, 3, 4, 5, 9, 10 and 11
(i) David C.P. Chen, M.D.	Groups 1, 2, 3, 4, 5 and 9
(j) Michael E. Siegel, M.D.	Groups 1, 2, 3, 4, 5 and 9
(k) Zbigniew Petrovich, M.D.	Group 8
(l) Gary Luxton, Ph.D.	Group 9 (Physical measurements only)
(m) Gheng Yu, Ph.D.	Group 9 (Physical measurements only)
(n) Robert W. Henderson, M.D.	Groups 1, 2, 3, 4, 5 and 9
(o) Peter A. Remedios, M.D.	Groups 1, 2, 3, 4, 5 and 9
(p) Deirdre M. Cohen, M.D.	Group 8
(q) Kousha Zarnegar, M.D.	Groups 1, 2, 3, 4, 5 and 9
(r) Gabor Jozsef, Ph.D.	Group 9 (Physical measurements only)

13. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 7, 8 and 9 of this license in accordance with statements, representations, and procedures contained in the documents listed below. The Department's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

(a) The license application with attachments dated February 26, 1991, signed by Gerald G. Bosworth, CEO, as modified by the letter with attachments dated May 1, 1991, signed by Donald K. Wadsworth, and the letter with attachments dated May 22, 1991, signed by Kai H. Lee, Ph.D.

(b) The letter with attachments (regarding quality assurance) dated July 15, 1991, signed by Kai H. Lee, Ph.D.

(c) The letters with attachments dated June 19, 1992, signed by James Huprich, M.D. and James Bading, Ph.D., as modified by the letter with attachments dated July 30, 1992, signed by James Bading, Ph.D.

(d) The letters with attachments dated February 10, 1993 and April 26, 1993, both signed by James Bading, Ph.D., regarding the use of fludeoxyglucose.

RADIOACTIVE MATERIAL LICENSE

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13. (Continued)

(e) The letter with attachments dated November 10, 1993, signed by Gerald G. Bosworth, Chief Executive Officer, regarding the possession and installation of a Cobalt 60 Stereotactic Leksell Gamma Unit. The licensee is authorized to use the unit for physical measurements only, not for patient therapy. After physical measurements and calibration have been done successfully, licensee should submit a request along with the calibration results to the Department for final approval.

(f) The letter dated May 2, 1994, signed by James Bading, Ph.D., regarding the authorization of Group 11.

(g) The letter with attachments dated July 13, 1994, signed by James Bading, Ph.D., Radiation Safety Officer, as amended by the letter dated July 22, 1994, signed by Gary Luxton, Ph.D. and David Symonds, regarding the operation of the Gamma Knife Unit and associated Radiation Field measurements.

(h) The letter with attachments dated September 13, 1994, signed by James R. Bading, regarding the authorization for a Gamma Camera and Pinhole Collimator, in addition, to the existing Scintillation Probe for Thyroid uptake measurements.

(i) The letter dated October 14, 1994, signed by James Bading, Ph.D., regarding uses of the Gamma Knife Unit.

(j) The letter dated November 23, 1994, signed by James Bading, Ph.D., regarding changes in Gamma Knife Unit emergency procedures and calibration procedures for the new cameras.

(k) The letters, both dated June 5, 1995, signed by James Bading, Ph.D., Radiation Safety Officer, regarding the purchase of a system employed to improve nuclear medicine images, the method for taking and measuring package wipe tests, and the method employed for leak testing of the Cobalt 60 sources in the Gamma knife teletherapy unit. The Gamma knife quality control procedures are excluded from this authorization.

14. (a) The Radiation Safety Officer in this program shall be James R. Bading, Ph.D.

(b) The Chairperson of the Radiation Safety Committee shall be James R. Bading, Ph.D.

15. Sealed sources possessed under this license shall be tested for leakage and/or contamination as required by Section 30275 (c) of the California Radiation Control Regulations.

16. Quantitative analytical assays for the purpose of tests for leakage and/or contamination of sealed sources shall be performed only by persons specifically authorized to perform that service.

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17. The following individuals are authorized to collect wipe test samples of sealed sources possessed under this license using leak test kits acceptable to the California Department of Health Services:

(a) the Radiation Safety Officer
(b) qualified individuals designated in writing by the Radiation Safety Officer

18. Records of leak test results shall be kept in units of microcuries and maintained for inspection. Records may be disposed of following Department inspection. Any leak test revealing the presence of 0.005 microcuries or more of removable radioactive material shall be reported to the Department of Health Services, Radiologic Health Branch, 601 N. 7th Street P.O. Box 942732, Sacramento, CA 94234-7320, within five days of the test. This report shall include a description of the defective source or device, the results of the test, and the corrective action taken.

19. The licensee shall conduct a physical inventory every six months to account for all sealed sources and/or devices received and possessed under the license. Records of the inventories shall be maintained for inspection, and may be disposed of following Department inspection.

20. Except as otherwise specifically provided by this license, radiopharmaceuticals to be administered to humans shall be procured in prepackaged, precalibrated form from a supplier who is registered with the U. S. Food and Drug Administration, or prepared and compounded, from a prescription, in accordance with the regulations of the California Board of Pharmacy.

21. Except as otherwise specifically provided by this license, radioactive biologicals (including human serum albumin) to be administered to humans shall be procured in prepackaged, precalibrated form from a supplier who is licensed for the preparation and distribution of such products by the Division of Biologics Standards of the National Institutes of Health, or U. S. Food and Drug Administration, or prepared in accordance with the regulations of the California Board of Pharmacy.

22. Radioactive materials prepared, processed, or modified by the licensee shall not be administered to humans except as specifically authorized by this license.

23. The licensee shall elute generators and process radioactive material with reagent kits in accordance with instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit.

24. Technetium 99m labelled pharmaceuticals prepared by the licensee by aseptic addition of pertechnetate to sterile, pyrogen free reagents may be administered to humans provided the radioassay of the final product is determined with an overall error not exceeding ten percent. When the pharmaceutical is prepared from reagents procured in the form of approved kits, the licensee must strictly follow all instructions and recommendations contained in the package insert information; otherwise the pharmaceutical must be prepared and compounded from a prescription in accordance with the regulations of the California Board of Pharmacy.

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25. Equipment for radiometric assay of pharmaceuticals, body fluids, excreta, or in-vitro assay samples shall be calibrated to ensure reliability of data obtained. The stability of the equipment shall be checked at least once each day of use, using appropriate standards.

26. The licensee may use any commercially available device, acceptable to the Nuclear Regulatory Commission or any Agreement State, for doing linearity tests of its dose calibrator provided the procedures, described by the manufacturer of the linearity device are followed.

27. Nuclear medicine technology procedures shall be performed by nuclear medicine technologists pursuant to the California Code of Regulations, Title 17, Subchapter 4.6. Such procedures shall be performed under the supervision of individuals listed as authorized users on this license who meet the criteria specified in Section 30510. Certificates or special permits issued pursuant to Subchapter 4.6 shall be prominently displayed at the facility(ies) authorized on this license.

28. Treatment and management of patients receiving therapeutic quantities of unsealed radioactive materials shall be in accordance with guidance contained in Chapter 4, "Release from Hospital of Patients Containing Radioactive Material" National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides" (NCRP Publications, P. O. Box 30175, Washington, D. C., 20014).

29. Teletherapy facilities shall be so constructed as to permit continuous observation of patients from outside the treatment room.

30. Tests for leakage and/or contamination of teletherapy sealed sources shall be performed in accordance with Section 30275 (c) of the California Radiation Control Regulations, except that Cobalt-60 sources may be tested at intervals not exceeding two years, provided that the tests performed at the time of installation of the source, and six months thereafter, do not reveal leakage and/or contamination in excess of the specified limit.

31. Leakage/contamination test samples shall be taken from the inner surface of the beam port, or other surface communicating with the source capsule, and shall be taken with the source in the "off" position.

32. The licensee shall post operator instructions at the console as follows:

(a) To assure that only the patient is in the treatment room at the start of the radiation treatment.

(b) To assure that emergency procedures are followed if unable to turn off the primary beam or if any other abnormal operation occurs.

(c) To assure that the appropriate personnel be notified by posting the names and telephone numbers of authorized users and the Radiation Safety Officer.

33. Electrical interlocks on entrance doors to the teletherapy room shall be tested for proper operation at least once every six months. Records of test results shall be maintained available for inspection.

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34. At least 30 days prior to the initiation of any of the actions listed below, the licensee shall submit an application to the Department for a license amendment authorizing the proposed action. The application shall include a completed form RH 2000D, with such drawings and other information as may be necessary for evaluation of radiation safety. Such actions requiring amendment are:

(a) Installation, removal, or replacement of a radioactive source.
(b) Installation, removal, or replacement of a partially shielded container, such as a drawer, containing a radioactive source.
(c) Installation or replacement of a complete teletherapy unit or of a teletherapy unit head which provides complete shielding of the radioactive source.
(d) Relocation or reorientation of a teletherapy unit for use within a shielded room.
(e) Any other change in the teletherapy unit, treatment room, or shielding, or in the manner of use of the unit, or in the occupancy or use of any adjacent area, which could produce radiation levels or exposures of individuals in excess of those indicated in previous applications or radiation survey reports.

35. At least 30 days prior to the initiation of any of the actions listed below, the licensee shall notify the Department in writing:

(a) Removal from a shielded room of a complete teletherapy unit which is not to be replaced.
(b) Removal from a shielded room of a complete teletherapy unit head which is not to be replaced.

36. Pursuant to California Radiation Control Regulations, the licensee is authorized to possess the natural or depleted uranium used for purposes of shielding or collimation in teletherapy and/or accelerator units.

37. Each teletherapy unit shall be fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism. This inspection and servicing shall be performed by persons specifically licensed to do so by the U. S. Nuclear Regulatory Commission or an Agreement State. The licensee shall maintain available for inspection, a report of each inspection and servicing. The report shall be that received by the licensee from the person who performed the inspection and servicing.

38. Special Requirements for Teletherapy Calibration and Spot-Checks:

(a) Requirement to perform full calibration measurements of teletherapy units.

(1) Full calibration of the output of each teletherapy unit shall be performed before the unit is first used for treatment of patients, and thereafter:

a. whenever spot-check measurements indicate that the output value differs by more than five percent from the value obtained at the last full calibration corrected mathematically for physical decay,
b. following replacement of the radiation source,

38. (Continued)

c. following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly, and

d. at intervals not exceeding one year.

(2) Full calibration measurements required by this condition shall include determination of:

a. the exposure rate or dose rate to an accuracy within three percent for the range of field sizes and for the range of distances (or for the axis distance) used in radiation therapy,

b. the congruence between the radiation field and the field indicated by the light beam localizing device,

c. the uniformity of the radiation field and its dependence upon the orientation of the useful beams,

d. timer accuracy, and

e. the accuracy of all distance measuring devices used for treatment of patients.

(b) Requirement to perform periodic spot-check measurements of teletherapy units.

(1) Spot-check measurements shall be performed on each teletherapy unit used for treating humans at intervals not exceeding one month.

(2) Spot-check measurements required by this condition shall include determination of:

a. timer accuracy,

b. the congruence between the radiation field and the field indicated by the light beam localizing device,

c. the accuracy of all distance measuring devices used for treatment of patients,

d. the exposure rate, dose rate, or a quantity related in a known manner to these rates for one typical set of operating conditions.

38. (Continued)

(c) Calibration and spot-check procedures.

(1) Full calibration and spot-check measurements shall be made in accordance with either of the procedures recommended by the American Association of Physicists in Medicine; Physics in Medicine and Biology, Vol. 16, No. 3, pp. 379, 1971 or Medical Physics 10, No. 6, pp. 741, 1985.

(2) Calibration and spot-check measurements shall be performed with radiation measuring instrumentation which has been calibrated within the proceeding two years directly, or through no more than one exchange, at the National Bureau of Standards, or facility determined acceptable by the Department.

(3) Full calibration measurements shall be performed by or under the direct supervision of a physicist who has been determined by the Department to have adequate training, experience and knowledge in radiation therapy physics, and who shall be present at the facility during such calibration.

(4) Spot-check measurements shall be performed in accordance with procedures established by a physicist qualified per paragraph (c) (3) of this condition. (A physicist need not actually perform the spot-check measurements). If a physicist does not perform the spot-check measurements, the results of the spot-check measurement shall be reviewed by the qualified expert within 15 days.

(a) Removal from a shielded room of a complete teletherapy unit which is not to be replaced.

(b) Removal from a shielded room of a complete teletherapy unit head which is not to be replaced.

39. Special Requirements for Teletherapy Room Monitoring

(a) Requirement for installation of a teletherapy room radiation monitor.

(1) Each teletherapy room shall be equipped with a radiation monitoring device which continuously monitors the teletherapy beam condition. This device shall energize a visible signal to make the operator continuously aware of teletherapy beam condition in order that appropriate emergency procedures may be instituted to prevent unnecessary radiation exposure.

(2) The monitoring device required in paragraph (1) shall be equipped with a back up power supply for emergency operation.

(3) Operating procedures shall require daily operational testing of the installed radiation monitor.

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39. (Continued)

(4) The radiation monitor must be checked daily with a dedicated radiation check source.

(5) The licensee shall promptly repair or replace the radiation monitor if it is inoperable.

(b) Requirement for use of a portable radiation survey meter.

(1) Any person entering the teletherapy room following irradiation shall enter with an operable, calibrated radiation survey meter and shall determine the beam condition whenever the room monitor is not operational.

40. No individual shall be allowed to act as an assistant during any teletherapy equipment operation authorized by this license until that individual has been instructed in, and has demonstrated understanding of, the procedures required for the operation, as well as the fundamentals of radiation safety as set forth in Section 30335 (a) of the California Radiation Control Regulations.

41. No teletherapy equipment operation authorized by this license shall be initiated unless the licensee has in his possession detailed written instructions specific for the make and model of teletherapy equipment and for the type of operation involved.

42. The licensee shall notify the Radiologic Health Branch of the California Department of Health Services by telephone and confirm should any malfunction occur, unsafe conditions be discovered, or difficulty arise which might lead to the radiation exposure of any individual above the limits specified in Title 10 Code of Federal Regulations, Part 20, Sections 20.1201 and 20.1301.

43. Teletherapy sources shall be transported only in DOT-approved shipping containers.

44. The licensee shall not transfer or install any radioactive source, or device containing a radioactive source, except in accordance with the transferee's radioactive material license as to kind and amount of radioactive material, manufacturer and model number of the radioactive source, and manufacturer and model number of the teletherapy unit.

45. This license does not authorize commercial distribution of radioactive material.

46. Production or processing of radiopharmaceuticals for the purpose of distribution to other licensees is not authorized by this license.

47. Radioactive materials shall be used by occupational workers in such a manner that the dose limits specified in Title 10, Code of Federal Regulations, Part 20, Subpart C (Sections 20.1201 through 20.1208) are not exceeded.

48. The licensee shall monitor occupational exposures to radiation and shall supply and require the use of individual monitoring devices by personnel as required by Title 10, Code of Federal Regulations, Part 20, Section 20.1502 (a).

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49. The licensee shall monitor occupational intakes of radioactive material by, and assess the committed effective dose equivalent to, individuals who may have exceeded or are likely to exceed, the limits specified in Title 10, Code of Federal Regulations (CFR), Part 20, Section 20.1502 (b). Suitable and timely measurements used for determination of such internal exposures shall be performed as specified by 10CFR 20.1204.

50. This license does not authorize distribution to persons licensed pursuant to Section 30195 (a) and (b) of the California Radiation Control Regulations or equivalent provisions of the NRC or Agreement States.

51. For a period not to exceed 60 days in any calendar year, a visiting physician is authorized to use licensed materials for human use under the terms of this license, provided the visiting physician:

    (a) Has the prior written permission of the hospital's Administrator and its Radiation Safety Committee.

    (b) Is specifically named as a user on an Nuclear Regulatory Commission (NRC) or Agreement State license authorizing human use.

    (c) Performs only those procedures for which the physician is specifically authorized by the Nuclear Regulatory Commission (NRC) or Agreement State license.

    The licensee shall maintain for inspection copies of the written permission specified in (a) above and the license(s) specified in (b) and (c) above. These records shall be maintained for five years from the time the licensee grants its permission under (a) above.

52 A copy of this license and a copy of all records and documents pertaining to this license shall be maintained available for inspection at 1500 San Pablo Street, Los Angeles, CA

e July 18, 1995

For the State Department of Health Services

By: [signature]

Radiologic Health Branch
P.O. Box 942732, Sacramento, CA 94234-7320

HILO MEDICAL CENTER
HILO, HAWAII

RADIATION SAFETY COMMITTEE MEETING
Monday, June 24, 1996

Present: Dr. James Lambeth, Radiation Safety Committee Vice-Chairman
Phoebe Lambeth, Administration
Susan Hultberg, Nursing Office
Josepha DeSilva, Radiology Department
Scott Dube, Physicist from Queen's Medical Center
Daniel Rickenbacher, Radiation Safety Officer

CALL TO ORDER

Meeting called to order at 11:50 a.m. by Daniel Rickenbacher, Radiation Safety Officer.

MINUTES

Minutes of March 29, 1996 were approved as circulated.

NEW BUSINESS

Meeting was turned over to Scott Dube who is here today doing his quarterly audit. According to S. Dube, there are fewer deficiencies being found lately due to excellent monitoring by the present RSO.

The following items were reported on by S. Dube:

- **Film badge records for the first quarter of 1996.** Of the three nuclear medicine technologists, none of them exceeded 10% of the quarterly allowable limit, which is consistent with the past so that is good.

- **Quality Management Program review.** It was a very busy first quarter in 1996.

1. All of the strontium 90 cases, P32, strontium 89, and iodine over 30 microcuries were reviewed. In the 4th quarter of 1995 we did 4 patients, and in the first quarter of 1996 we did 19 patients. All of the records were reviewed and found to have proper documentation as required.

2. The quality management program forms have been revised so that it gives the ordering physician, the authorized user, a chance to write the ordered dose and the dose that actually arrived and intended for the patient.

3. In looking at the dose calibrator record, the calibrator was tested and testing was done on it. All the tests were performed on schedule as usual. It was recommended we order a new 5 millicurie cobalt 57 source next year.

4. In talking to J. DeSilva, there were some issues that came out of the JCAHO review. One was on inspection of lead apron. It was recommended that the service department check it and have a written policy on how to check the lead aprons every year. It is best that the technologists who use the aprons check it themselves like they do at Queen's. S. Dube will obtain a copy of Queen's written policy and criteria on lead aprons inspection.

NEW BUSINESS:

1. R. Rickenbacher announced that a letter has been received from NRC that extended our license by five years. So now, our license does not expire until February 28, 2005. Also we received a bill from NRC which was handed over to J. DeSilva for payment of $4300 which is our annual fee for the hospital.

2. The committee reviewed the professorship of two radiologists to be named on our nuclear medicine license. Following review of the records, motion made and seconded (Dr. Lambeth/P. Lambeth) for the promotion of Peter A. Remedios, M.D. to be added to our license in Part 100, 200, 300 and 500 as listed on a previous license that he was on. All voting members approved by show of hands to allow Dr. Remedios to have privileges on our license.

3. The next person is Dr. Lee E. Miyasato. We also have him applying for part 100, 200 and 300. He would like to have privileges on our license and those in 500. Motion made and seconded (P. Lambeth/Dr. Lambeth) that Dr. Miyasato have privileges as requested. All voting members present signified approval by ayes.

ADJOURNMENT:

Meeting adjourned at 12:01p.m.

Daniel Rickenbacher
Radiation Safety Officer

DR:lu

NRC Form 374
(3-83)

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 62

ORC

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Hilo Medical Center	In accordance with letter dated July 20, 1996,
2. 1190 Waianuenue Avenue Hilo, HI 96720	3. License number 53-03506-01 is amended in its entirety to read as follows:
	4. Expiration date February 28, 2005
	5. Docket or Reference No. 030-03542

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200	B. As needed
C. Any byproduct material in 10 CFR 35.300	C. Any radiopharmaceutical identified in 10 CFR 35.300	C. 3.3 curies (no single container to exceed 200 millicuries)
D. Strontium-90	D. Sealed source in an applicator	D. 50 millicuries

9. Authorized Use

A. Medical use described in 10 CFR 35.100.
B. Medical use described in 10 CFR 35.200.
C. Medical use described in 10 CFR 35.300.
D. Treatment of superficial eye conditions.

ML40

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 1190 Waianuenue Avenue, Hilo, Hawaii.

11. The Radiation Safety Officer for this license is Daniel W. Rickenbacher.

12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users	Material and Use
James Lambeth	10 CFR 35.100, 35.200, 35.300 and Strontium 90
Rodney Matsubara, M.D.	10 CFR 35.100 and 35.200
Michael J. T. Seu, M.D.	10 CFR 35.100, 35.200 and 35.300
Clarence Funaki, M.D.	10 CFR 35.100, 35.200, 35.300 and Strontium 90
Harvey T. Nakamura, M.D.	10 CFR 35.100, 35.200, 35.300 and Strontium 90
George R. Ainge, M.D.	10 CFR 35.100, 35.200, 35.300 and Strontium 90
Scott Dube	Calibration and reference sources as authorized in 10 CFR 35.57 for instrument calibration
Scott R. Grosskreutz, M.D.	10 CFR 35.100, 35.200 and 35.300
Lee E. Miyasato, M.D.	10 CFR 35.100, 35.200 and 35.300
Peter A. Remedios, M.D.	10 CFR 35.100, 35.200 and 35.300
David Camacho, Jr., M.D.	10 CFR 35.100, 35.200, 35.300 and Strontium 90

13. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

14. The licensee shall maintain records of information related to decommissioning at 1190 Waianuenue Avenue, Hilo, Hawaii per the provision of 10 CFR 30.35(g) until this license is terminated by the Commission.

15. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
53-03506-01

Docket or Reference Number
030-03542

Amendment No. 62

16. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated August 1, 1994
B. Facsimile dated February 1, 1995
C. Letter dated January 29, 1996
D. Letter dated July 20, 1996
E. Letter dated October 1, 1996
F. Facsimile dated November 6, 1996

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date NOV - 7 1996

By James L. Montgomery
Materials Branch
Region IV, WCFO
Walnut Creek, California 94596

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02120
Status Code: 0
Fee Category: 7C
Exp. Date: 20050228
Fee Comments: CODE 12
Decom Fin Assur Reqd: N

1996 NOV -7 AM 10:29

96 NOV 12 PM 12:43

LICENSE FEE TRANSMITTAL

A. REGION V

1. APPLICATION ATTACHED
   Applicant/Licensee: HILO MEDICAL CENTER
   Received Date: 961029
   Docket No: 3003542
   Control No.: 572423
   License No.: 53-03506-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: $ 440.00
   Check No.: 000045

3. COMMENTS

Signed Jean Garcia
Date 10-30-96

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered) V

1. Fee Category and Amount: 7C $440

2. Correct Fee Paid. Application may be processed for:
   Amendment ✓
   Renewal
   License

3. OTHER

Signed Rita Mascari
Date 11/7/96

Log Nov 1 V
Remitter
Check No. 000477 $440
Amount
Fee Category 7C
Type of Fee Amd
Date Check Rec'd. 11/7/96
Date Completed
By: Rita

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV

Walnut Creek Field Office
1450 Maria Lane
Walnut Creek, California 94596-5368

NOV - 7 1996

Hilo Medical Center
ATTN: Daniel W. Rickenbacher
Radiation Safety Officer
1190 Waianuenue Avenue
Hilo, Hawaii 96720

SUBJECT: LICENSE AMENDMENT

Please find enclosed Amendment 62 to License No. 53-03506-01. You should review this license carefully and be sure that you understand all conditions. If you have any questions, you may contact the reviewer who signed your license at 510-975-02[illegible]9.

NRC expects licensees to conduct their progr[illegible]s with meticulous attention to detail and a high standard of compliance. Because of the serious consequences to employees and the public which can result from failure to comply with NRC requirements, you must conduct your program involving radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Possess radioactive material only in the quantity and form indicated in your license.

3. Use radioactive material only for the purpose(s) indicated in your license.

4. Notify NRC in writing of any change in mailing address (no fee required if the location of radioactive material remains the same).

5. Request and obtain written NRC consent before transferring your license or any right thereunder, either voluntarily or involuntarily, directly or indirectly, through transfer of control of your license to any person or entity. A transfer of control of your license includes not only a total change of ownership, but also a change in the controlling interest in your company whether it is a corporation, partnership, or other entity. In addition, appropriate license amendments must be requested and obtained for any other planned changes in your facility or program that are contrary to your license or contrary to representations made in your license application, as well as supplemental correspondence thereto, which are incorporated into your license. A license fee may be charged for the amendments if you are not in a fee-exempt category.

6. Maintain in a single document decommissioning records that have been certified for completeness and accuracy listing all the following items applicable to the license:

   - Onsite areas designated or formerly designated as restricted areas as defined in 10 CFR 20.3(a)(14) or 20.1003.

   - Onsite areas, other than restricted areas, where radioactive materials in quantities greater than amounts listed in Appendix C to 10 CFR 20.1001-20.2401 have been used, possessed, or stored.

   - Onsite areas, other than restricted areas, where spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site have occurred that required reporting pursuant to 10 CFR 30.50(b)(1) or (b)(4), including areas where subsequent cleanup procedures have removed the contamination.

   - Specific locations and radionuclide contents of previous and current burial areas within the site, excluding radioactive material with half-lives of 10 days or less, depleted uranium used only for shielding or as penetrators in unused munitions, or sealed sources authorized for use at temporary job sites.

   - Location and description of all contaminated equipment involved in licensed operations that is to remain onsite after license termination.

7. Submit a complete renewal application with proper fee, or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.

8. Request termination of your license if you plan to permanently discontinue activities involving radioactive material.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation; imposition of a civil

penalty; or an order suspending, modifying, or revoking your license as specified in the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 60 FR 34381, June 30, 1995.

Thank you for your cooperation.

Sincerely,

James L. Montgomery
Senior Health Physicist
Materials Branch

Docket: 030-03542
License: 53-03506-01
Control: 572423

Enclosures: As stated

bcc:

Docket File
WCFO Inspection File
LFDCB, T-9 E10
State of Hawaii (License Only)

DOCUMENT NAME: G:\572423

To receive copy of document, indicate in box: "C" = Copy without enclosures "E" = Copy with enclosures "N" = No copy

RIV:MB											
JLMontgomery											
11/7/96											

OFFICIAL RECORD COPY

BENJAMIN J. CAYETANO
GOVERNOR

LAWRENCE MIIKE
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
HILO MEDICAL CENTER
1190 WAIANUENUE AVENUE
HILO, HAWAII 96720

FAX TRANSMITTAL COVER SHEET

DATE: 11/6/96 TIME: 13:39 NO. OF PAGES: 2 (including cover sheet)

RECEIVER INFORMATION

TO: James Montgomery
(Authorized receiver's name)
TELEPHONE: _____ FAX: 510-975-0351

SENDER INFORMATION

FROM: Rick - rm - H/H.
TELEPHONE: _____ FAX: 935-1889

REMARKS:

WARNING:
This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged or confidential and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient, or the employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by telephone, and return the original to us at the above address via the U.S. postal service. Thank you.

INSTRUCTIONS TO AUTHORIZED RECEIVER:

Upon receipt or for retransmittal, please call _____ at _____.

VERIFICATION RECEIVED

_____ at _____.
Receiver's Name Date/Time

Revised 2/96

Attachment A

Attachment A

BENJAMIN J. CAYETANO
GOVERNOR

LAWRENCE MIIKE
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
HILO MEDICAL CENTER
1190 WAIANUENUE AVENUE
HILO, HAWAII 96720

November 6, 1996

Mr. James Montgomery
U.S. Nuclear Regulatory Commission
Walnut Creek Field Office
1450 Maria Lane, Ste. #210
Walnut Creek, CA 94596

REFER: NRC License No. 53-03506-01

SUBJECT: Training In Basic Radioisotope Handling Techniques For:
Harvey T. Nakamura, M.D.
George R. Ainge, M.D.
David W. Camacho, Jr., M.D.

Dear Mr. Montgomery:

This letter confirms that Dr. Harvey Nakamura, Dr. George Ainge, and Dr. David Camacho have each received 24 hours of classroom and laboratory training in basic radioisotope handling techniques applicable to the use of Strontium-90 for ophthalmic radiotherapy. Portions of this training occurred in their respective residency and fellowship programs and portions occurred under my direct supervision at Hilo Medical Center.

Sincerely,

James T. Lambeth, M.D.

Amendment

BENJAMIN J. CAYETANO
GOVERNOR

LAWRENCE MIIKE
DIRECTOR OF HEALTH

RECEIVED
96 OCT 02 PM 12:38

STATE OF HAWAII
DEPARTMENT OF HEALTH
HILO MEDICAL CENTER
1190 WAIANUENUE AVENUE
HILO, HAWAII 96720

October 1, 1996

Mr. James Montgomery
U.S. Nuclear Regulatory Commission
Walnut Creek Field Office
1450 Maria Lane, Ste. #210
Walnut Creek, CA 94596

REFER: NRC License No. 53-03506-01
Docket No. 030-03542

ENCL: Preceptor Statements For;
David W. Camacho, Jr., M.D.
George R. Ainge, M.D.
Harvey T. Nakamura, M.D.
Check for $440.00 to cover amendment fees.

Dear Mr. Montgomery:

Enclosed I have included the preceptor statements for 3 (three)of our authorized users to be given privileges to use the SR-90 Eye Applicator. Also, there is a check in the amount of $440.00 to cover the fee for this amendment.

If I can provide any additional or more specific information, please do not hesitate to call me at (808) 969-4416.

Sincerely,

Daniel W. Rickenbacher, C.N.M.T.
Radiation Safety Officer

572423

EXHIBIT 3 (Continued)

PROPOSED PHYSICIAN USER

HARVEY T NAKAMURA, M.D.

PRECEPTOR STATEMENT (Continued)

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued)

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
P-32 (Soluble)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 (Colloidal)	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE	9 (nine)	
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

LOCATION	DATES	CLOCK HOURS OF EXPERIENCE

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR: JAMES T. LAMBETH, M.D.

b. NAME OF INSTITUTION: HILO MEDICAL CENTER

c. MAILING ADDRESS: 1190 Waianuenue Ave.

d. CITY: Hilo, Hawaii 96720

5. MATERIALS LICENSE NUMBER(S): 53-03506-01

6. PRECEPTOR'S SIGNATURE: James T. Lambeth

7. PRECEPTOR'S NAME (Please type or print): JAMES T. LAMBETH, M.D.

8. DATE: Oct. 1, 1996

EXHIBIT 3 (Continued)

PROPOSED PHYSICIAN USER

GEORGE R. AINGE, M.D.

PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE	6 (six)	
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

LOCATION	DATES	CLOCK HOURS OF EXPERIENCE

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR

JAMES T. LAMBETH, M.D.

b. NAME OF INSTITUTION

HILO MEDICAL CENTER

c. MAILING ADDRESS

1190 Waianuenue Ave.

d. CITY

Hilo, Hawaii 96720

5. MATERIALS LICENSE NUMBER(S)

53-03506-01

6. PRECEPTOR'S SIGNATURE

James T Lambeth

7. PRECEPTOR'S NAME *(Please type or print)*

JAMES T. LAMBETH, M.D.

8. DATE

Oct 1, 1996

EXHIBIT 3 (Continued)

PROPOSED PHYSICIAN USER

DAVID W. CAMACHO JR. M.D.

PRECEPTOR STATEMENT (Continued)

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued)

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
P-32 (Soluble)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 (Colloidal)	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION	5 (five)	
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

LOCATION	DATES	CLOCK HOURS OF EXPERIENCE

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR

JAMES T. LAMBETH, M.D.

b. NAME OF INSTITUTION

HILO MEDICEAL CENTER

c. MAILING ADDRESS

1190 Waianuenue Ave.

d. CITY

Hilo, Hawaii 96720

e. MATERIALS LICENSE NUMBER(S)

53-03506-01

5. PRECEPTOR'S SIGNATURE

James T Lambeth

7. PRECEPTOR'S NAME (Please type or print)

JAMES T. LAMBETH M.D.

8. DATE

Oct. 1, 1996

Notification
Amendment

BENJAMIN J. CAYETANO
GOVERNOR

LAWRENCE MIIKE
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
HILO MEDICAL CENTER
1190 WAIANUENUE AVENUE
HILO, HAWAII 96720

July 20, 1996

Mr. James Montgomery
U.S. Nuclear Regulatory Commission
Walnut Creek Field Office
1450 Maria Lane, Ste. #210
Walnut Creek, CA 94596

Ref: Part 35.14 Notifications

Refer: NRC License No. 53-03506-01
Docket No. 030-03542

Dear Mr. Montgomery,

The below listed enclosures are submitted in accordance with the reference listed below as a notification that we have granted Dr. Lee E. Miyasato, M.D. and Dr. Peter A. Remedios, M.D. privileges as authorized users in categories of 35.100, 35.200, 35.300 and 35.500.

Also, in my letter dated January 29, 1996 granting Dr. David Camacho, Jr., M.D., I had added him to our license for a period of six months. I would like this extended for an indefinite period at this time.

If I can provide any additional or more specific information, please do not hesitate to call me at (808)969-4416.

Sincerely,

C.N.M.T.

Daniel W. Rickenbacher, C.N.M.T.
Radiation Safety Officer

DWR/kg

572423

ENCL:

1. Letter dated June 20, 1996 granting hospital privileges to Dr. Lee E. Miyasato, M.D., at Hilo Medical Center

2. Certification of License for Dr. Lee E. Miyasato, M.D.

3. Perceptor Statement for Dr. Lee E. Miyasato, M.D.

4. Letter dated June 20, 1996 granting hospital privileges to Dr. Peter A. Remedios, M.D., at Hilo Medical Center

5. Certification of License for Dr. Peter A. Remedios, M.D.

6. Perceptor Statement for Dr. Peter A. Remedios, M.D.

7. Copy of California Materials License #3192-40 with Dr. Peter Remedios, M.D. listed

8. Copy of California Materials License #5592-70 with Dr. Peter Remedios, M.D. listed

9. Radiation Safety Committee Meeting dated June 24, 1996 approving Dr. Lee E. Miyasato, M.D. and Dr. Peter A. Remedios, M.D. as authorized users at Hilo Medical Center

BENJAMIN J. CAYETANO
GOVERNOR

LAWRENCE MIIKE
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
HILO MEDICAL CENTER
1190 WAIANUENUE AVENUE
HILO, HAWAII 96720

June 20, 1996

TO WHOM IT MAY CONCERN

Re: **Lee E. Miyasato, M.D.**

On June 6, 1996 Dr. Lee E. Miyasato was approved by the Medical Executive Committee of Hilo Medical Center for active staff membership with privileges in Radiology.

Sincerely,

William Carnett, D.O.
Medical Director

STATE OF HAWAII
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
PROFESSIONAL AND VOCATIONAL LICENSING DIVISION
1010 RICHARDS STREET
P.O. BOX 3469
HONOLULU, HAWAII 96801

05/02/96

STATE OF HAWAII
HILO MEDICAL CENTER
MEDICAL STAFF OFFICE
1190 WAIANUENUE AVENUE
HILO HI 96720

RE: ~RIFICATION OF LICENSE/EXAM SCORES DATED 05/02/96 FOR
E MIYASATO

BOARD/COMMISSION:	BOARD OF MEDICAL EXAMINERS
LICENSE TYPE:	PHYSICIAN
LICENSE IDENTIFICATION:	MD 9407
METHOD OF LICENSURE:	ENDORSEMENT-THROUGH NATIONAL EXAM
DATE LICENSED:	02/21/96
LICENSE STATUS:	CURRENT, VALID & IN GOOD STANDING
LICENSE EXPIRATION DATE:	01/31/98
DISCIPLINARY ACTION:	NONE

CERTIFIED BY:
Constance Cabral-Makanani

CONSTANCE CABRAL-MAKANANI
EXECUTIVE OFFICER

ACCORDING TO OUR COMPLAINT RECORDS
WHICH DATE BACK TO 1985:

☑ NO DEROGATORY INFORMATION IS ON FILE.

☐ THE ATTACHED INFORMATION IS ON FILE CONCERNING THIS LICENSEE.

NRC FORM 313M SUPPLEMENT A
(9-81)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Lee E. Miyasato, M.D.	HI

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Radiology	Diplomate	June 1995

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES *(Hours)* C	SUPERVISED LABORATORY EXPERIENCE *(Hours)* D
a. RADIATION PHYSICS AND INSTRUMENTATION	July 1, 1991-June 30, 1995 University of Virginia Charlottesville, VA	100	50
b. RADIATION PROTECTION	See above	30	20
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	See above	20	5
d. RADIATION BIOLOGY	See above	20	
e. RADIOPHARMACEUTICAL CHEMISTRY	See above	30	10

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Tc-99m	30 mCi	UVa Hospital, Chville	1040 hrs in all	Clinical
Mo-99	3000 mCi	"	"	"
I-131	200 mCi	"	"	"
Yb-169	500 uCi	"	"	"
In-111	5 mCi	"	"	"
Ga-67	10 mCi	"	"	"
Tl-201	4 mCi	"	"	"
I-125	50 uCi	"	"	"

NRC FORM 313M SUPPLEMENT B
(9-81)

U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME: Lee E. Miyasato, M.D.

STREET ADDRESS: 117 Tintern Court

CITY: Charlottesville | STATE: VA | ZIP CODE: 22901

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION	2	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME	8	
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
OTHER	Tc-99m gastric Emptying	90	
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING	3	
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	215	
OTHER	In-111 DTPA cisternography	2	
Tc-99m	BRAIN IMAGING	4	
	CARDIAC IMAGING	136	
	THYROID IMAGING	36	
	SALIVARY GLAND IMAGING	1	
	BLOOD POOL IMAGING	24	
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING	12	
	LUNG IMAGING	235	
	BONE IMAGING	535	
OTHER	Tl-201 myocardial imaging	56	

RECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA	5	
	TREATMENT OF HYPERTHYROIDISM	42	
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR	15	
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS	30	
Other			
Ga-67	Gallium imaging	42	
Tc-99m	Hepatobiliary imaging	35	
Tc-99m	Renal Imaging	150	
Tc-99m	GI Bleeding imaging	10	
Tc-99m	Parathyroid imaging	11	
I-131	Adrenal Imaging	7	

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

July 1, 1992-June 30, 1995 1040 hours

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
Charles D. Teates, M.D.

b. NAME OF INSTITUTION
University of VA Medical Center

c. MAILING ADDRESS
Box 486, Dept. of Radiology

d. CITY
Charlottesville

5. MATERIALS LICENSE NUMBER(S)
45 000 34-26

6. PRECEPTOR'S SIGNATURE
Charles D Teates

7. PRECEPTOR'S NAME *(Please type or print)*
Charles D. Teates, M.D.

8. DATE
1/16/96

NRC FORM 313M SUPPLEMENT B
(9-81)

GPO 890-913

BENJAMIN J. CAYETANO
GOVERNOR

LAWRENCE MIIKE
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
HILO MEDICAL CENTER
1190 WAIANUENUE AVENUE
HILO, HAWAII 96720

June 20, 1996

TO WHOM IT MAY CONCERN

Re: **Peter A. Remedios, M.D.**

Dr. Peter A. Remedios has been a member of the consulting staff staff at Hilo Medical Center since March 4, 1996 with privileges in Radiology. He previously had temporary membership from October 30, 1995 to March 4.

Sincerely,

William Carnett, D.O.
Medical Director

STATE OF HAWAII
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
PROFESSIONAL AND VOCATIONAL LICENSING DIVISION
1010 RICHARDS STREET
P.O. BOX 3469
HONOLULU, HAWAII 96801

10/16/95

STATE OF HAWAII
DEPARTMENT OF HEALTH
HILO MEDICAL CENTER
1190 WAIANUENUE AVENUE
HILO HI 96720

RE: 'RIFICATION OF LICENSE/EXAM SCORES DATED 10/16/95 FOR
'ER A REMEDIOS

BOARD/COMMISSION:	BOARD OF MEDICAL EXAMINERS
LICENSE TYPE:	PHYSICIAN
LICENSE IDENTIFICATION:	MD 9285
METHOD OF LICENSURE:	ENDORSEMENT-THROUGH NATIONAL EXAM
DATE LICENSED:	09/25/95
LICENSE STATUS:	CURRENT, VALID & IN GOOD STANDING
LICENSE EXPIRATION DATE:	01/31/96
DISCIPLINARY ACTION:	NONE

CERTIFIED BY:

Constance Cabral-Makanani

CONSTANCE CABRAL-MAKANANI
EXECUTIVE OFFICER

ACCORDING TO OUR COMPLAINT RECORDS
WHICH DATE BACK TO 1985:

☑ NO DEROGATORY INFORMATION IS ON FILE.

☐ THE ATTACHED INFORMATION IS ON FILE CONCERNING THIS LICENSEE.

2nd USC
DIAGNOSTIC RADIOLOGY RESIDENT
1983-1987
1987-1988 Fellowship Body Imaging & Interventional

EXHIBIT 2

TRAINING AND EXPERIENCE—MEDICAL AUTHORIZED USER OR RADIATION SAFETY OFFICER

This form is to accompany an application form (RH 2000) or a letter referencing your Califor Radioactive Materials License Number.

1. Name of Proposed Authorized User or Radiation Safety Officer: PETER ANTHONY REMEDIOS, M.D

2. California Physician s and Surgeon s Certificate Number, if Applicable: G 51796

3. Certification

Specialty Board	Category	Month and Year Certifie
DIAGNOSTIC RADIOLOGY, AMERICAN BOARD OF RADIOLOGY	DIAGNOSTIC RADIOLOGY (included lectures on NUCLEAR MEDICINE)	6-86

4. Training Received in Basic Radioisotope Handling Techniques

Field of Training A	Location and Date(s) of Training B	Type and Length of Training: Lecture/ Laboratory Courses (hours) C	Type and Length of Training: Supervised Laboratory Experience (hou D
a Radiation Physics and Instrumentation	LAC+USC Medical Center Division of Nuclear Med. 1200 N. State St. Rm. 5250 Los Angeles, CA 90033	45	45
b Radiation Protection		25	none
c Mathematics Pertaining to the Use and Measurement of Radioactivity	Dates of Training: 9-1-84 - 9-30-84 11-1-85 - 12-31-85	20	20
d Radiation Biology	2-3-86 - 2-28-86 5-~~1~~86 - 5-30-86	20	none
e Radiopharmaceutical Chemistry	9-1-86 - 9-30-86 A total of 6 months	40	40

5. Experience with Radiation (actual use of radioisotopes or equivalent experience)

Isotope	Maximum Amount	Where Experience Was Gained	Duration of Experience	Type of Use
Tc-99m	500 mCi	As under 4B	6 months clinical rotation during residency in Diagnostic Radiology	Diagnostic and therapeutic
Ga-67	20 mCi			
In-111	10 mCi			
Cr-51	100 mCi			
Iodine-123	10 mCi			
I-131	100 mCi			
Xe-133	50 mCi			
Tl-201	10 mCi			

PRECEPTOR STATEMENT

This part must be completed by the applicant physician's preceptor. If more than one preceptor is necess document experience, obtain a separate statement from each.

1. Applicant Physician's Name and Address

Full Name: Peter Anthony Remedios, M.D.

Street Address: 2265 22nd Street

City: Santa Monica, CA State: CA ZIP Code: 90405

2. Clinical Training and Experience of Above Named Physician

Key to Column C

Personal participation should consist of:

1. Supervised examination of patients to determine the suitability for radionuclide diagnosis and/or treatment and recommendation for prescribed dosage.
2. Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements, and plotting of data.
3. Supervised interpretation of results of diagnostic studies.
4. Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

Isotope A	Conditions Diagnosed or Treated B	Number of Cases Involving Personal Participation C	Comments (Additional information or comments may submitted in duplicate on separate sheets D
I-131	Diagnosis of thyroid function	120	
or	Determination of blood and blood plasma volume	6	
I-125	Liver function studies	-	
	Kidney function studies	100	
	In vitro studies	-	
OTHER	B-12, I-123, etc.	30	

2. Clinical Training and Experience of Above Named Physician (continued)

Isotope A	Conditions Diagnosed or Treated B	Number of Cases Involving Personal Participation C	Comments (Additional information or comments may be submitted in duplicate on separate sheets) D
I-125	Detection of thrombosis	30	
I-123 I-131	Thyroid imaging	80	
P-32	Eye tumor localization	-	
Se-75	Pancreas imaging	-	
In-111 DTPA Yb-169	Cisternography	25	
Xe-133	Blood flow studies and pulmonary function studies	135	
OTHER			
	Brain imaging	85	
	Cardiac imaging	150	
	Thyroid imaging	45	
	Salivary gland imaging	6	
	Blood pool imaging	115	
	Liver and spleen imaging	350	
	Lung imaging	250	
	Bone imaging	400	
OTHER			
P-32 (soluble)	Treatment of polycythemia vera, leukemia, and bone metastases	8	
P-32 (colloidal)	Intracavitary treatment	2	
I-131	Treatment of thyroid carcinoma	15	
	Treatment of hyperthyroidism	25	

2. Clinical Training and Experience of Above Named Physician (continued)

Isotope A	Conditions Diagnosed or Treated B	Number of Cases Involving Personal Participation C	Comments (Additional information or comments may submitted in duplicate on separate sheet) D
Ra-226 or	Interstitial treatment	-	
Cs-137	Intracavitary treatment	-	
I-125 or Ir-192	Interstitial treatment	-	
Co-60 or Cs-137	Teletherapy treatment	-	
Sr-90	Treatment of eye disease	-	
	Radiopharmaceutical preparation	-	
Mo-99/ Tc-99m	Generator	35	
Tc-99M	Reagent kits	50	
OTHER			

3. Dates and Total Number of Hours Received in Clinical Radioisotope Training: 9-1-84 - 9-30-84, 11-1-85 - 12-31-85, 2-3-86 - 2-28-86, 5-1-86 - 5-30-86, 9-1-86 - 9-30-86 (A total of 6 months).

4. The Training and Experience Indicated Above Was Obtained Under the Supervision of:
   a. Name of Supervisor: Michael E. Siegel, M.D., Director, Nuclear Medicine
   b. Name of Institution: LAC/USC Medical Center
   c. Mailing Address: 1200 N. State Street Rm. #5250
   d. City, State, and ZIP Code: Los Angeles, CA 90033

5. Materials License Number(s): 0134-70

6. Preceptor's Signature: [signature]

7. Preceptor's Name (Please type/print.): Michael E. Siegel, M.D., Professor of Radiology

8. Date: May 14, 1993

RADIOACTIVE MATERIAL LICENSE

License Number: 3192-40

Supplementary Sheet

Amendment Number: 13

Twin Cities Community Hospital
1100 Las Tablas Road
Templeton, CA 93465

Attention: Michael P. Curran, M.D.
Radiation Safety Officer

In response to the letters with attachments dated August 18, 1993, and July 29, 1993, signed by Michael P. Curran, M.D., Radiation Safety Officer, and John B. Richards, M.D., Director, Department of Nuclear Medicine respectively, License Number 3192-40 is hereby amended in part as follows:

To DELETE:

Subitems 12. (b), 12. (c), and 12. (d) are hereby deleted in their entirety.

To add:

12. The individuals named below are authorized the specific uses of radioactive material described in Items 6, 7, 8 and 9 of this license as follows:

(b)	Harold R. Griffith, M.D.	Groups	1, 2, 3, and 9
(c)	Donna Winningham, M.D.	Groups	1, 2, 3, 4 (Iodine 131 only), and 9
(d)	Peter A. Remedios, M.D.	Groups	1, 2, 3, 4, 5, and 9

13. (h) The letter dated August 18, 1993, signed by Michael P. Curran, M.D., Radiation Safety Officer, regarding the use of Technetium 99m DTPA aerosol.

For the State Department of Health Services

Date: November 16, 1993 By: [signature] 3

Radiologic Health Branch
P.O. Box 942732
Sacramento, CA 94234-7320

RADIOACTIVE MATERIAL LICENSE

Pursuant to the California Administrative Code, Title 17, Chapter 5, Subchapter 4, Group 2, Licensing of Radioactive Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, use, possess, transfer, or dispose of radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders of the Department of Health Services now or hereafter in effect and to any conditions specified in this license.

1. Licensee	Twin Cities Community Hospital	3. License No.	3192-40 Amendment No. 15
2. Address	1100 Las Tablas Road Templeton, CA 93465	4. Expiration date	June 9, 2001
Attention:	Michael P. Curran, M.D. Radiation Safety Officer	5. Inspection agency	Radiologic Health Branch Berkeley

License Number 3192-40 is hereby renewed in its entirety:

In accordance with California Radiation Control Regulations, Title 17, Subchapter 4, Article 4, Section 30195, the Medical Use Groups specified below grant the use of radioactive material, as approved by the United States Food and Drug Administration, the California State Board of Medical Quality Assurance and/or the California State Board of Pharmacy, for diagnosis and treatment of patients, when prescribed and as directed by an appropriately authorized physician listed on this license.

GROUPS AUTHORIZED UNDER THIS LICENSE

Group 1 - Diagnostic studies involving measurement of uptake, dilution, or excretion but not involving imaging.

Group 2 - Diagnostic Studies involving imaging including the use of Xenon 127 and/or Xenon 133 gas.

Group 3 - Use of reagent kits including Mo/Tc 99m and Rb/Kr 81m generators for preparation of radiopharmaceuticals listed in Group 2.

Group 4 - Internal therapy not usually requiring hospitalization.

Group 5 - Internal therapy usually requiring hospitalization for purposes of radiation safety.

For the State Department of Health Services

Date June 20, 1994 by 3

Radiologic Health Section
744 P Street, Sacramento, CA 95814

RADIOACTIVE MATERIAL LICENSE

License Number: 3192-40

Amendment Number: 15

Supplementary Sheet

Group 9 - Nonhuman uses using sources identified in Items 6, 7, and 8 below.

6. Nuclides	7. Forms	8. Authorized Use
A. Any radionuclide with Atomic numbers 3-83 inclusive except: (1) Strontium 90 and (2) Lead 210	A. Sealed sources, manufactured, labeled packaged, and distibuted in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or Agreement State, not to exceed 10 mCi each.	A. Marker sources and calibration.

Group 11 - Manufacturer-sponsored clinical investigations

6. Nuclide	7. Form	8. Authorized Use
A. Any radiopharmaceutical or Biologic not prohibited by U.S. Food and Drug Administration.	A. Any radiopharmaceutical in an IND which has been accepted in writing by the U.S. Food and Drug Administration.	A. To be used for diagnostic or therapeutic studies conducted in strict accordance with Physician-sponsored or Manufacturer-sponsored IND(s) which have been accepted and approved by the State of California Food and Drug Administration or the U.S. Food and Drug Administration.

9. Possession Limits

Combined possession limit for Group 1, Group 2, Group 3, Group 4, Group 5, Group Group 9, and Group 11 -- A total not to exceed 1.0 Curie

10. Radioactive material shall be used only at the following locations:

(a) 1100 Las Tablas Road, Templeton, CA.

For the State Department of Health Services

Date: June 20, 1994

By:

Radiologic Health Branch
P.O. Box 942732
Sacramento, CA 94234-7320

RADIOACTIVE MATERIAL LICENSE

License Number: 3192-40

Supplementary Sheet

Amendment Number: 15

11. This license is subject to an annual fee for sources of radioactive material authorized to be possessed at any one time as specified in Item 8 of this license. The annual fee for this license is required by and computed in accordance with Sections 30230-30232 of the California Radiation Control Regulations and is also subject to an annual cost-of-living adjustment pursuant to Section 113 of the California Health and Safety Code.

12. The individuals named below are authorized the specific uses of radioactive material authorized in Use Groups and Items 6, 7, 8 and 9 as described in this license:

(a)	Michael P. Curran,	Group(s) 1, 2, 3, 4, 5, 9, and 11
(b)	Harold R. Griffith, M.D.	Group(s) 1, 2, 3, and 9
(c)	Donna Winningham, M.D.	Group(s) 1, 2, 3, 4, (I-131 only), and 9
(d)	Peter A. Remedios, M.D.	Group(s) 1, 2, 3, 4, 5, and 9

13. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in the documents listed below. The Department's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    (a) The letter dated April 22, 1991 and application with attachments dated April 22, 1991 signed by Michael P. Curran, M.D., Radiation Safety Officer, all related to the renewal of license.

    (b) The letter dated August 18, 1993, signed by Michael P. Curran, M.D., Radiation Safety Officer, regarding the use of Technetium 99m DTPA aerosol.

14. (a) The Radiation Safety Officer in this program shall be Michael P. Curran, M.D..

    (b) The Chairperson of the Radiation Safety Committee shall be Michael P. Curran, M.D..

    (c) The Custodian of sealed sources shall be Barbara Benson, CNMT

15. Analytical tests for leakage and/or contamination of sealed sources shall be performed only by persons specifically authorized to perform that service.

(2/8.

For the State Department of Health Services

Date: June 20, 1994 By:

Radiologic Health Branch
P.O. Box 942732
Sacramento, CA 94234-7320

RADIOACTIVE MATERIAL LICENSE

License Number: 3192-40

Supplementary Sheet

Amendment Number: 15

16. The following individuals are authorized to collect wipe test samples of sealed sources possessed under this license using leak test kits acceptable to the California Department of Health Services.

    (a) The Radiation Safety Officer
    (b) Qualified individuals designated by the Radiation Safety Officer

17. Records of leak test results shall be kept in units of microcuries and maintained for inspection. Records may be disposed of following Department inspection. Any leak test revealing the presence of 0.005 microcuries or more of removable radioactive material shall be reported to the Department of Health Services, Radiologic Health Branch, P. O. Box 942732, Sacramento, CA 94234-7320, within five days of the test. This report shall include a description of the defective source or device, the results of the test, and the corrective action taken.

18. The licensee is authorized to hold radioactive materials with a physical half-life of less than 90 days for decay-in-storage before disposal in ordinary trash provided:

    (a) Radioactive waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.

    (b) Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

    (c) Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

19. Except as otherwise specifically provided by this license, radiopharmaceuticals to be administered to humans shall be procured in prepackaged, precalibrated form, from a supplier who is registered with the U. S. Food and Drug Administration, or prepared and compounded from a prescription, in accordance with the regulations of the California Board of Pharmacy.

20. Except as otherwise specifically provided by this license, radioactive biologicals (including human serum albumin) to be administered to humans shall be procured in prepackaged, precalibrated form, from a supplier licensed for the preparation and distribution of such products by the Division of Biologics Standards of the National Institutes of Health, or U. S. Food and Drug Administration; or prepared in accordance with the regulations of the California Board of Pharmacy.

For the State Department of Health Services

Date: June 20, 1994

By: 3

Radiologic Health Branch
P.O. Box 942732
Sacramento, CA 94234-7320

RADIOACTIVE MATERIAL LICENSE

License Number: 3192-40

Supplementary Sheet

Amendment Number: 15

21. Radioactive materials prepared, processed, or modified by the licensee shall not be administered to humans except as specifically authorized by this license.

22. Technetium 99m generators approved by the Department may be used as sources of Technetium 99m for use in preparations to be administered to humans, provided the generators are used in strict accordance with the manufacturer's instructions, or with the regulations of the California Board of Pharmacy.

23. The licensee shall elute generators and process radioactive material with reagent kits in accordance with instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit.

24. Technetium 99m labelled pharmaceuticals prepared by the licensee by aseptic addition of pertechnetate to sterile, pyrogen-free reagents may be administered to humans provided the radioassay of the final product is determined with an overall error not exceeding ten percent. When the pharaceutical is prepared from reagents procured in the form of approved kits, the licensee must strictly follow all instructions and recommendations contained in the package inser information; otherwise the pharmaceutical must be prepared and compounded from a prescription in accordance with the regulations of the California Board of Pharmacy.

25. Where users or their assistants are engaged in elution of pertechnetate 99m from generators, the exposure to the fingers or hands shall be monitored as required by Title 10, Code of Federal Regulations, Part 20, Section 20.1502(a).

26. Mo-99 break through may not exceed 0.15 uCi per mCi of Tc-99m, and less than 2.5 uCi Mo-99 per administered dose.

27. Equipment for radiometric assay of pharmaceuticals, body fluids, excreta, or in vitro assay samples shall be calibrated to ensure the reliability of data obtained. The stability of the equipment shall be checked at least once on each day of use, using appropriate standards.

28. Nuclear medicine technology procedures shall be performed by nuclear medicine technologists pursuant to the California Code of Regulations, Title 17, Subchapter 4.6. Such procedures shall be performed under the supervision of individuals listed as authorized users on this license who meet the criteria specified in Section 30510. Certificates or special permits issued pursuant to Subchapter 4.6 shall be prominently displayed at the facility(ies) authorized on this license.

For the State Department of Health Services

Date: June 20, 1994 By: 3

Radiologic Health Branch
P.O. Box 942732
Sacramento, CA 94234-7320

RADIOACTIVE MATERIAL LICENSE

License Number: 3192-40

Amendment Number: 15

Supplementary Sheet

29. Treatment and management of patients receiving therapeutic quantities of unsealed radioactive materials shall be in accordance with guidance contained in Chapter 4, "Release from Hospital of Patients Containing Radioactive Materials", National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides" (NCRP Publications, P.O. Box 30175, Washington, D.C. 20014).

30. Radioactive materials shall be used by occupational workers in such a manner that the dose limits specified in Title 10, Code of Federal Regulations, Part 20, Subpart C (Sections 20.1201 through 20.1208) are not exceeded.

31. The licensee shall monitor occupational exposures to radiation and shall supply and require the use of individual monitoring devices by personnel as required by Title 10, code of Federal Regualtions, Part 20, Section 20.1502 (a).

32. The licensee shall monitor occupational intakes of radioactive material by, and assess the committed effective dose equivalent to, individuals who may have exceeded or are likely to exceed, the limits specified in Title 10, Code of Federal Regulations (CFR), Part 20, Section 20.1502(b). Suitable and timely measurements used for determination of such internal exposures shall be performed as specified by 10CFR 20.1204.

33. This license does not authorize distribution to persons licensed pursuant to Section 30195 (a) and (b) of the California Radiation Control Regulations or equivalent provisions of the Nuclear Regulatory Commission or Agreement States.

34. A copy of this license and a copy of all records and documents pertaining to this license shall be maintained available for inspection at 1100 Las Tables Road, Templeton, CA.

For the State Department of Health Services

Date: June 20, 1994 By: [signature]

Radiologic Health Branch
P.O. Box 942732
Sacramento, CA 94234-7320

RADIOACTIVE MATERIAL LICENSE

Pursuant to the California Code of Regulations, Division 1, Title 17, Chapter 5, Subchapter 4, Group 2, Licensing of Radioactive Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, use, possess, transfer, or dispose of radioactive material listed below, and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders of the Department of Health Services now or hereinafter in effect and to any standard or specific condition specified in this license.

1. *Licensee*	USC University Hospital	3. *License No.* 5592-70	*Amendment No.* 17
2. *Address*	1500 San Pablo Street Los Angeles, CA 90033	4. *Expiration date* June 3, 1998	(3)
Attention	James R. Bading, Ph.D. Radiation Safety Officer	5. *Inspection agency*	Los Angeles County Department of Health Services

License Number 5592-70 is hereby amended as follows:

6. Nuclide	7. Form	8. Possession Limit
A. Group 1 as specified in Item 9. Any radionuclide with atomic number 3-83.	A. Any	A.- C. Combined possession limit of Groups 1, 2, and 3 not to exceed 600 mCi.
B. Group 2 as specified in Item 9. Any radionuclide with atomic number 3-83.	B. Any	
C. Group 3 as specified in Item 9. Any radionuclide with atomic number 3-83.	C. Any Excluding Generators	
D. Group 4 as specified in Item 9. 1. Phosphorous 32 2. Iodine 131	D. 1. Any 2. Any	D. Total not to exceed 60 mCi.
E. Group 5 as specified in Item 9. 1. Phosphorous 32 2. Iodine 131	E. 1. Any 2. Any	E. Total not to exceed 300 mCi.
F. Group 8 as specified in Item 9. Cobalt 60	F. Sealed or solid sources Sealed sources (General Electric Company AB Elekta Model No. 43047)	F. Total 6600 Ci in 201 sources, no single source to exceed 36 Ci each.

RADIOACTIVE MATERIAL LICENSE

License Number: 5592-70

Supplementary Sheet

Amendment Number: 17

6. Nuclide	7. Form	8. Possession Limit
G. Group 9 as specified in Item 9. 1. Any radionuclide with atomic number 3-83 inclusive, except: Strontium 90 and Lead 210.	G. 1. Sealed or solid sources manufactured in accordance with a specific license issued by the United States Nuclear Regulatory Commission or an Agreement State.	G. 1. Total not to exceed 30 mCi. Each radionuclide not to exceed 20 mCi.
2. Gadolinium 153	**2. Sealed sources (Model 3601)**	**2. Total 800 mCi, in sources, no single source to exceed 250 mCi.**
H. **Group 10 as specified in Item 9.** Any radionuclide with atomic number 3-83.	H. Any	H.-I. Total 10 mCi.
I. **Group 11 as specified in Item 9.** **Any radionuclide with atomic number 3-83.**	I. Any	

RADIOACTIVE MATERIAL LICENSE

License Number: 5592-70

Supplementary Sheet

Amendment Number: 17

9. Authorized Use

A. Group 1 Diagnostic studies involving measurement of uptake, dilution, or excretion but not involving imaging.

B. Group 2 Diagnostic studies involving imaging including the use of Xenon 127 and/or Xenon 133 gas.

C. Group 3 Reagent kits utilizing bulk technetium prepared by a radiopharmacy for preparation of radiopharmaceuticals listed in Group 2.

D. Group 4 Internal therapy not usually requiring hospitalization and palliative treatment.

E. Group 5 Internal therapy and palliative treatment requiring hospitalization for purposes of radiation safety .

F. Group 8 Teletherapy of cancer and Teleradiosurgery.

G. Group 9 Nonhuman use: Marker and calibration sources.

H. Group 10 Physician-Sponsored nonroutine medical uses of radioactive materials (Physician-Sponsored IND).

I. Group 11 Manufacturer-Sponsored nonroutine medical uses of radioactive material (Manufacturer-Sponsored IND).

LICENSE CONDITIONS

10. Radioactive material shall be used only at the following locations:

A. 1500 San Pablo Street, Los Angeles, CA

11. This license is subject to an annual fee for sources of radioactive material authorized to be possessed at any one time as specified in Item 8 of this license. The annual fee for this license is required by and computed in accordance with Sections 30230-30232 of the California Radiation Control Regulations and is also subject to an annual cost-of-living adjustment pursuant to Section 113 of the California Health and Safety Code.

RADIOACTIVE MATERIAL LICENSE

License Number: 5592-70

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12. The individuals named below are authorized the specific uses of radioactive material described in Items 6, 7, 8 and 9 of this license as follows:

(a)	James Huprich, M.D.	Groups 1, 2, 3 and 9
(b)	Patrick Cilletti, M.D.	Groups 1, 2, 3, 4 ,5 and 9
(c)	Aziz N. Ansari, M.D.	Groups 1, 2, 3, 4, 5 and 9
(d)	Peter S. Conti, M.D., Ph.D.	Groups 1, 2, 3, 4, 5 and 9
(e)	Scott T. Grafton, M.D.	Groups 1, 2, 3 and 9
(f)	James R. Bading, Ph.D.	Group 9 (Physical measurements only)
(g)	Nelson Arnstein, M.D.	Groups 1, 2, 3, 4, 5 and 9
(h)	Azizullah N. Ansari, M.D.	Groups 1, 2, 3, 4, 5, 9, 10 and 11
(i)	David C.P. Chen, M.D.	Groups 1, 2, 3, 4, 5 and 9
(j)	Michael E. Siegel, M.D.	Groups 1, 2, 3, 4, 5 and 9
(k)	Zbigniew Petrovich, M.D.	Group 8
(l)	Gary Luxton, Ph.D.	Group 9 (Physical measurements only)
(m)	Gheng Yu, Ph.D.	Group 9 (Physical measurements only)
(n)	Robert W. Henderson, M.D.	Groups 1, 2, 3, 4, 5 and 9
(o)	Peter A. Remedios, M.D.	Groups 1, 2, 3, 4, 5 and 9
(p)	Deirdre M. Cohen, M.D.	Group 8
(q)	Kousha Zarnegar, M.D.	Groups 1, 2, 3, 4, 5 and 9
(r)	**Gabor Jozsef, Ph.D.**	**Group 9 (Physical measurements only)**

13. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 7, 8 and 9 of this license in accordance with statements, representations, and procedures contained in the documents listed below. The Department's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

(a) The license application with attachments dated February 26, 1991, signed by Gerald G. Bosworth, CEO, as modified by the letter with attachments dated May 1, 1991, signed by Donald K. Wadsworth, and the letter with attachments dated May 22, 1991, signed by Kai H. Lee, Ph.D.

(b) The letter with attachments (regarding quality assurance) dated July 15, 1991, signed by Kai H. Lee, Ph.D.

(c) The letters with attachments dated June 19, 1992, signed by James Huprich, M.D. and James Bading, Ph.D., as modified by the letter with attachments dated July 30, 1992, signed by James Bading, Ph.D.

(d) The letters with attachments dated February 10, 1993 and April 26, 1993, both signed by James Bading, Ph.D., regarding the use of fludeoxyglucose.

RADIOACTIVE MATERIAL LICENSE

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13. (Continued)

(e) The letter with attachments dated November 10, 1993, signed by Gerald G. Bosworth, Chief Executive Officer, regarding the possession and installation of a Cobalt 60 Stereotactic Leksell Gamma Unit. The licensee is authorized to use the unit for physical measurements only, not for patient therapy. After physical measurements and calibration have been done successfully, licensee should submit a request along with the calibration results to the Department for final approval.

(f) The letter dated May 2, 1994, signed by James Bading, Ph.D., regarding the authorization of Group 11.

(g) The letter with attachments dated July 13, 1994, signed by James Bading, Ph.D., Radiation Safety Officer, as amended by the letter dated July 22, 1994, signed by Gary Luxton, Ph.D. and David Symonds, regarding the operation of the Gamma Knife Unit and associated Radiation Field measurements.

(h) The letter with attachments dated September 13, 1994, signed by James R. Bading, regarding the authorization for a Gamma Camera and Pinhole Collimator; in addition, to the existing Scintillation Probe for Thyroid uptake measurements.

(i) The letter dated October 14, 1994, signed by James Bading, Ph.D., regarding uses of the Gamma Knife Unit.

(j) The letter dated November 23, 1994, signed by James Bading, Ph.D., regarding changes in Gamma Knife Unit emergency procedures and calibration procedures for the new cameras.

(k) The letters, both dated June 5, 1995, signed by James Bading, Ph.D., Radiation Safety Officer, regarding the purchase of a system employed to improve nuclear medicine images, the method for taking and measuring package wipe tests, and the method employed for leak testing of the Cobalt 60 sources in the Gamma knife teletherapy unit. The Gamma knife quality control procedures are excluded from this authorization.

14. (a) The Radiation Safety Officer in this program shall be James R. Bading, Ph.D.

(b) The Chairperson of the Radiation Safety Committee shall be James R. Bading, Ph.D.

15. Sealed sources possessed under this license shall be tested for leakage and/or contamination as required by Section 30275 (c) of the California Radiation Control Regulations.

16. Quantitative analytical assays for the purpose of tests for leakage and/or contamination of sealed sources shall be performed only by persons specifically authorized to perform that service.

RADIOACTIVE MATERIAL LICENSE

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17. The following individuals are authorized to collect wipe test samples of sealed sources possessed under this license using leak test kits acceptable to the California Department of Health Services:

(a) the Radiation Safety Officer
(b) qualified individuals designated in writing by the Radiation Safety Officer

18. Records of leak test results shall be kept in units of microcuries and maintained for inspection. Records may be disposed of following Department inspection. Any leak test revealing the presence of 0.005 microcuries or more of removable radioactive material shall be reported to the Department of Health Services, Radiologic Health Branch, 601 N. 7th Street P.O. Box 942732, Sacramento, CA 94234-7320, within five days of the test. This report shall include a description of the defective source or device, the results of the test, and the corrective action taken.

19. The licensee shall conduct a physical inventory every six months to account for all sealed sources and/or devices received and possessed under the license. Records of the inventories shall be maintained for inspection, and may be disposed of following Department inspection.

20. Except as otherwise specifically provided by this license, radiopharmaceuticals to be administered to humans shall be procured in prepackaged, precalibrated form from a supplier who is registered with the U. S. Food and Drug Administration, or prepared and compounded, from a prescription, in accordance with the regulations of the California Board of Pharmacy.

21. Except as otherwise specifically provided by this license, radioactive biologicals (including human serum albumin) to be administered to humans shall be procured in prepackaged, precalibrated form from a supplier who is licensed for the preparation and distribution of such products by the Division of Biologics Standards of the National Institutes of Health, or U. S. Food and Drug Administration, or prepared in accordance with the regulations of the California Board of Pharmacy.

22. Radioactive materials prepared, processed, or modified by the licensee shall not be administered to humans except as specifically authorized by this license.

23. The licensee shall elute generators and process radioactive material with reagent kits in accordance with instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit.

24. Technetium 99m labelled pharmaceuticals prepared by the licensee by aseptic addition of pertechnetate to sterile, pyrogen free reagents may be administered to humans provided the radioassay of the final product is determined with an overall error not exceeding ten percent. When the pharmaceutical is prepared from reagents procured in the form of approved kits, the licensee must strictly follow all instructions and recommendations contained in the package insert information; otherwise the pharmaceutical must be prepared and compounded from a prescription in accordance with the regulations of the California Board of Pharmacy.

RADIOACTIVE MATERIAL LICENSE

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25. Equipment for radiometric assay of pharmaceuticals, body fluids, excreta, or in-vitro assay samples shall be calibrated to ensure reliability of data obtained. The stability of the equipment shall be checked at least once each day of use, using appropriate standards.

26. The licensee may use any commercially available device, acceptable to the Nuclear Regulatory Commission or any Agreement State, for doing linearity tests of its dose calibrator provided the procedures, described by the manufacturer of the linearity device are followed.

27. Nuclear medicine technology procedures shall be performed by nuclear medicine technologists pursuant to the California Code of Regulations, Title 17, Subchapter 4.6. Such procedures shall be performed under the supervision of individuals listed as authorized users on this license who meet the criteria specified in Section 30510. Certificates or special permits issued pursuant to Subchapter 4.6 shall be prominently displayed at the facility(ies) authorized on this license.

28. Treatment and management of patients receiving therapeutic quantities of unsealed radioactive materials shall be in accordance with guidance contained in Chapter 4, "Release from Hospital of Patients Containing Radioactive Material" National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides" (NCRP Publications, P. O. Box 30175, Washington, D. C., 20014).

29. Teletherapy facilities shall be so constructed as to permit continuous observation of patients from outside the treatment room.

30. Tests for leakage and/or contamination of teletherapy sealed sources shall be performed in accordance with Section 30275 (c) of the California Radiation Control Regulations, except that Cobalt-60 sources may be tested at intervals not exceeding two years, provided that the tests performed at the time of installation of the source, and six months thereafter, do not reveal leakage and/or contamination in excess of the specified limit.

31. Leakage/contamination test samples shall be taken from the inner surface of the beam port, or other surface communicating with the source capsule, and shall be taken with the source in the "off" position.

32. The licensee shall post operator instructions at the console as follows:

(a) To assure that only the patient is in the treatment room at the start of the radiation treatment.

(b) To assure that emergency procedures are followed if unable to turn off the primary beam or if any other abnormal operation occurs.

(c) To assure that the appropriate personnel be notified by posting the names and telephone numbers of authorized users and the Radiation Safety Officer.

33. Electrical interlocks on entrance doors to the teletherapy room shall be tested for proper operation at least once every six months. Records of test results shall be maintained available for inspection.

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34. At least 30 days prior to the initiation of any of the actions listed below, the licensee shall submit an application to the Department for a license amendment authorizing the proposed action. The application shall include a completed form RH 2000D, with such drawings and other information as may be necessary for evaluation of radiation safety. Such actions requiring amendment are:

(a) Installation, removal, or replacement of a radioactive source.
(b) Installation, removal, or replacement of a partially shielded container, such as a drawer, containing a radioactive source.
(c) Installation or replacement of a complete teletherapy unit or of a teletherapy unit head which provides complete shielding of the radioactive source.
(d) Relocation or reorientation of a teletherapy unit for use within a shielded room.
(e) Any other change in the teletherapy unit, treatment room, or shielding, or in the manner of use of the unit, or in the occupancy or use of any adjacent area, which could produce radiation levels or exposures of individuals in excess of those indicated in previous applications or radiation survey reports.

35. At least 30 days prior to the initiation of any of the actions listed below, the licensee shall notify the Department in writing:

(a) Removal from a shielded room of a complete teletherapy unit which is not to be replaced.
(b) Removal from a shielded room of a complete teletherapy unit head which is not to be replaced.

36. Pursuant to California Radiation Control Regulations, the licensee is authorized to possess the natural or depleted uranium used for purposes of shielding or collimation in teletherapy and/or accelerator units.

37. Each teletherapy unit shall be fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism. This inspection and servicing shall be performed by persons specifically licensed to do so by the U. S. Nuclear Regulatory Commission or an Agreement State. The licensee shall maintain available for inspection, a report of each inspection and servicing. The report shall be that received by the licensee from the person who performed the inspection and servicing.

38. Special Requirements for Teletherapy Calibration and Spot-Checks:

(a) Requirement to perform full calibration measurements of teletherapy units.

(1) Full calibration of the output of each teletherapy unit shall be performed before the unit is first used for treatment of patients, and thereafter:

a. whenever spot-check measurements indicate that the output value differs by more than five percent from the value obtained at the last full calibration corrected mathematically for physical decay,
b. following replacement of the radiation source,

38. (Continued)

c. following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly, and

d. at intervals not exceeding one year.

(2) Full calibration measurements required by this condition shall include determination of:

a. the exposure rate or dose rate to an accuracy within three percent for the range of field sizes and for the range of distances (or for the axis distance) used in radiation therapy,

b. the congruence between the radiation field and the field indicated by the light beam localizing device,

c. the uniformity of the radiation field and its dependence upon the orientation of the useful beams,

d. timer accuracy, and

e. the accuracy of all distance measuring devices used for treatment of patients.

(b) Requirement to perform periodic spot-check measurements of teletherapy units.

(1) Spot-check measurements shall be performed on each teletherapy unit used for treating humans at intervals not exceeding one month.

(2) Spot-check measurements required by this condition shall include determination of:

a. timer accuracy,

b. the congruence between the radiation field and the field indicated by the light beam localizing device,

c. the accuracy of all distance measuring devices used for treatment of patients,

d. the exposure rate, dose rate, or a quantity related in a known manner to these rates for one typical set of operating conditions.

38. (Continued)

(c) Calibration and spot-check procedures.

(1) Full calibration and spot-check measurements shall be made in accordance with either of the procedures recommended by the American Association of Physicists in Medicine; Physics in Medicine and Biology, Vol. 16, No. 3, pp. 379, 1971 or Medical Physics 10, No. 6, pp. 741, 1985.

(2) Calibration and spot-check measurements shall be performed with radiation measuring instrumentation which has been calibrated within the proceeding two years directly, or through no more than one exchange, at the National Bureau of Standards, or facility determined acceptable by the Department.

(3) Full calibration measurements shall be performed by or under the direct supervision of a physicist who has been determined by the Department to have adequate training, experience and knowledge in radiation therapy physics, and who shall be present at the facility during such calibration.

(4) Spot-check measurements shall be performed in accordance with procedures established by a physicist qualified per paragraph (c) (3) of this condition. (A physicist need not actually perform the spot-check measurements). If a physicist does not perform the spot-check measurements, the results of the spot-check measurement shall be reviewed by the qualified expert within 15 days.

(a) Removal from a shielded room of a complete teletherapy unit which is not to be replaced.

(b) Removal from a shielded room of a complete teletherapy unit head which is not to be replaced.

39. Special Requirements for Teletherapy Room Monitoring

(a) Requirement for installation of a teletherapy room radiation monitor.

(1) Each teletherapy room shall be equipped with a radiation monitoring device which continuously monitors the teletherapy beam condition. This device shall energize a visible signal to make the operator continuously aware of teletherapy beam condition in order that appropriate emergency procedures may be instituted to prevent unnecessary radiation exposure.

(2) The monitoring device required in paragraph (1) shall be equipped with a back up power supply for emergency operation.

(3) Operating procedures shall require daily operational testing of the installed radiation monitor.

RADIOACTIVE MATERIAL LICENSE

Supplementary Sheet

39. (Continued)

(4) The radiation monitor must be checked daily with a dedicated radiation check source.

(5) The licensee shall promptly repair or replace the radiation monitor if it is inoperable.

(b) Requirement for use of a portable radiation survey meter.

(1) Any person entering the teletherapy room following irradiation shall enter with an operable, calibrated radiation survey meter and shall determine the beam condition whenever the room monitor is not operational.

40. No individual shall be allowed to act as an assistant during any teletherapy equipment operation authorized by this license until that individual has been instructed in, and has demonstrated understanding of, the procedures required for the operation, as well as the fundamentals of radiation safety as set forth in Section 30335 (a) of the California Radiation Control Regulations.

41. No teletherapy equipment operation authorized by this license shall be initiated unless the licensee has in his possession detailed written instructions specific for the make and model of teletherapy equipment and for the type of operation involved.

42. The licensee shall notify the Radiologic Health Branch of the California Department of Health Services by telephone and confirm should any malfunction occur, unsafe conditions be discovered, or difficulty arise which might lead to the radiation exposure of any individual above the limits specified in Title 10 Code of Federal Regulations, Part 20, Sections 20.1201 and 20.1301.

43. Teletherapy sources shall be transported only in DOT-approved shipping containers.

44. The licensee shall not transfer or install any radioactive source, or device containing a radioactive source, except in accordance with the transferee's radioactive material license as to kind and amount of radioactive material, manufacturer and model number of the radioactive source, and manufacturer and model number of the teletherapy unit.

45. This license does not authorize commercial distribution of radioactive material.

46. Production or processing of radiopharmaceuticals for the purpose of distribution to other licensees is not authorized by this license.

47. Radioactive materials shall be used by occupational workers in such a manner that the dose limits specified in Title 10, Code of Federal Regulations, Part 20, Subpart C (Sections 20.1201 through 20.1208) are not exceeded.

48. The licensee shall monitor occupational exposures to radiation and shall supply and require the use of individual monitoring devices by personnel as required by Title 10, Code of Federal Regulations, Part 20, Section 20.1502 (a).

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49. The licensee shall monitor occupational intakes of radioactive material by, and assess the committed effective dose equivalent to, individuals who may have exceeded or are likely to exceed, the limits specified in Title 10, Code of Federal Regulations (CFR), Part 20, Section 20.1502 (b). Suitable and timely measurements used for determination of such internal exposures shall be performed as specified by 10CFR 20.1204.

50. This license does not authorize distribution to persons licensed pursuant to Section 30195 (a) and (b) of the California Radiation Control Regulations or equivalent provisions of the NRC or Agreement States.

51. For a period not to exceed 60 days in any calendar year, a visiting physician is authorized to use licensed materials for human use under the terms of this license, provided the visiting physician:

(a) Has the prior written permission of the hospital's Administrator and its Radiation Safety Committee.

(b) Is specifically named as a user on an Nuclear Regulatory Commission (NRC) or Agreement State license authorizing human use.

(c) Performs only those procedures for which the physician is specifically authorized by the Nuclear Regulatory Commission (NRC) or Agreement State license.

The licensee shall maintain for inspection copies of the written permission specified in (a) above and the license(s) specified in (b) and (c) above. These records shall be maintained for five years from the time the licensee grants its permission under (a) above.

52 A copy of this license and a copy of all records and documents pertaining to this license shall be maintained available for inspection at 1500 San Pablo Street, Los Angeles, CA.

For the State Department of Health Services

Date July 18, 1995

By: [signature]

Radiologic Health Branch
P.O. Box 942732, Sacramento, CA 94234-7320

HILO MEDICAL CENTER
HILO, HAWAII

RADIATION SAFETY COMMITTEE MEETING
Monday, June 24, 1996

Present: Dr. James Lambeth, Radiation Safety Committee Vice-Chairman
Phoebe Lambeth, Administration
Susan Hultberg, Nursing Office
Josepha DeSilva, Radiology Department
Scott Dube, Physicist from Queen's Medical Center
Daniel Rickenbacher, Radiation Safety Officer

CALL TO ORDER

Meeting called to order at 11:50 a.m. by Daniel Rickenbacher, Radiation Safety Officer.

MINUTES

Minutes of March 29, 1996 were approved as circulated.

NEW BUSINESS

Meeting was turned over to Scott Dube who is here today doing his quarterly audit. According to S. Dube, there are fewer deficiencies being found lately due to excellent monitoring by the present RSO.

The following items were reported on by S. Dube:

- **Film badge records for the first quarter of 1996.** Of the three nuclear medicine technologists, none of them exceeded 10% of the quarterly allowable limit, which is consistent with the past so that is good.

- **Quality Management Program review.** It was a very busy first quarter in 1996.

1. All of the strontium 90 cases, P32, strontium 89, and iodine over 30 microcuries were reviewed. In the 4th quarter of 1995 we did 4 patients, and in the first quarter of 1996 we did 19 patients. All of the records were reviewed and found to have proper documentation as required.

2. The quality management program forms have been revised so that it gives the ordering physician, the authorized user, a chance to write the ordered dose and the dose that actually arrived and intended for the patient.

3. In looking at the dose calibrator record, the calibrator was tested and testing was done on it. All the tests were performed on schedule as usual. It was recommended we order a new 5 millicurie cobalt 57 source next year.

4. In talking to J. DeSilva, there were some issues that came out of the JCAHO review. One was on inspection of lead apron. It was recommended that the service department check it and have a written policy on how to check the lead aprons every year. It is best that the technologists who use the aprons check it themselves like they do at Queen's. S. Dube will obtain a copy of Queen's written policy and criteria on lead aprons inspection.

NEW BUSINESS:

1. R. Rickenbacher announced that a letter has been received from NRC that extended our license by five years. So now, our license does not expire until February 28, 2005. Also we received a bill from NRC which was handed over to J. DeSilva for payment of $4300 which is our annual fee for the hospital.

2. The committee reviewed the professorship of two radiologists to be named on our nuclear medicine license. Following review of the records, motion made and seconded (Dr. Lambeth/P. Lambeth) for the promotion of Peter A. Remedios, M.D. to be added to our license in Part 100, 200, 300 and 500 as listed on a previous license that he was on. All voting members approved by show of hands to allow Dr. Remedios to have privileges on our license.

3. The next person is Dr. Lee E. Miyasato. We also have him applying for part 100, 200 and 300. He would like to have privileges on our license and those in 500. Motion made and seconded (P. Lambeth/Dr. Lambeth) that Dr. Miyasato have privileges as requested. All voting members present signified approval by ayes.

ADJOURNMENT:

Meeting adjourned at 12:01p.m.

Daniel Rickenbacher
Radiation Safety Officer

DR:lu

Notification

January 29, 1996

STATE OF HAWAII
DEPARTMENT OF HEALTH
HILO MEDICAL CENTER
1190 WAIANUENUE AVENUE
HILO, HAWAII 96720

Mr. James Montgomery
Health Physicist
Materials Radiation Protection
Inspection and Licensing Section
U.S. Nuclear Regulatory Commission
Walnut Creek Field Office
1450 Maria Lane, Ste. #210
Walnut Creek, CA 94596

Encl: 1) Letter dated January 22, 1996 granting hospital privileges to Dr. David Camacho, at Hilo Medical Center
2) Radiation Safety Meeting Minutes dated January 22, 1996 approving Dr. David Camacho as an authorized user at Hilo Medical Center
3) Letter dated December 18, 1995 certifying Dr. David Camacho Jr. in the broad field of Nuclear Medicine by the American Board of Nuclear Medicine

Ref: Part 35.14 Notifications

Refer: NRC License No. 53-03506-01
Docket No. 030-03542

Dear Mr. Montgomery:

The above listed enclosures are submitted in accordance with the reference listed above as a notification that we have granted Dr. David Camacho Jr. privileges as an authorized user in the categories of 35.100, 35.200, 35.300, and 35.500 for approximately the next six (6) months, starting January 22, 1996.

If I can provide any additional or more specific information, please do not hesitate to call me at (808) 969-4416.

Sincerely,

CNMT

Daniel W. Rickenbacher, C.N.M.T.
Radiation Safety Officer

DWR:kmg

572291

1/23/96

BENJAMIN J. CAYETANO
GOVERNOR

LAWRENCE MIIKE
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
HILO MEDICAL CENTER
1190 WAIANUENUE AVENUE
HILO, HAWAII 96720

January 22, 1996

#478

David Camacho, M.D.
Radiology Department
Hilo Medical Center
Hilo, HI 96720

Dear Dr. Camacho:

This is to notify you that you have been approved for temporary membership with privileges in Radiology. Your temporary membership will be in effect until your application has been approved by the Governing Body for provisional active staff membership.

Welcome to the Hilo Medical Center Medical Staff. If you have any questions, or if I can be of any service to you, please don't hesitate to call me.

Sincerely,

John H Westerman

John H. Westerman
Chief Executive Officer

cc: Nursing
Emergency Room
Admissions/Switchboard
Lab
X-Ray
Medical Records
Business Office
Pharmacy
URNC

HILO MEDICAL CENTER

RADIATION SAFETY COMMITTEE Radiology Department

Date: January 22, 1996

Place: Hilo Medical Center
Time Started: 9:00A.M.
Time Ended: 9:30A.M.

Attendance: D. Lambeth, D. Nakamura, Mrs. P. Lambeth, Mr. Rickenbacher, Mrs. Pat Thompson-Spencer, Mrs. J. DeSilva

TOPIC	DISCUSSION	ACTION
CALL TO ORDER	The meeting was expressly called to order for the purpose of reviewing Dr. David William Camacho's certification from the American Board of Nuclear Medicine showing him to be now recognized as a certified specialist in Nuclear Medicine, also his approval for temporary membership with privileges in Radiology were reviewed. After a careful review of the above documentation followed by a discussion by the members of this committee, a vote was taken to make Dr. David William Camacho, Jr. an authorized user on our NRC license. The vote was taken with all present (6) voting to allow Dr. David Camacho Jr. the privileges of an authorized user.	
ADJOURNMENT	With no further business, the meeting was adjourned.	

Daniel W. Rickenbacher
Radiation Safety Officer

Adm. 10/81

The American Board of Nuclear Medicine
A MEMBER BOARD OF THE AMERICAN BOARD OF MEDICAL SPECIALTIES

900 Veteran Avenue Los Angeles, California, 90024-1786 Telephone (310)825-6787
Fax (310)825-9433

December 18, 1995

David William Camacho, Jr.
136 Mendiola Dr.
Agana Heights, Guam 96919

Dear Doctor :

With great pleasure, the American Board of Nuclear Medicine informs you that you have passed its September 9 , 1995 Certifying Examination in the broad field of nuclear medicine and are now recognized as a certified specialist in nuclear medicine. A certificate indicating this recognition will be sent to you in the near future. The American Board of Nuclear Medicine congratulates you upon your achievement and this recognition!

The scores below indicate your performance in the several content areas of the examination. Please consult the enclosed interpretive note for future explanation. The Board hopes this information will be helpful.

Content Area	Percent You Answered Correctly	Comparison Group Mean % Correct
Bas. Sci - Rad. Hlth-NMR	72	73
Cardiovascular	72	76
Endocrine	86	80
Gastrointestinal	80	76
Hematology/Oncology	77	71
Neurology	66	74
Pulmonary	71	75
Renal	73	75
Musculo-skeletal	82	75

Sincerely yours,

James W. Fletcher, M.D.
Chairman

02802

U.S. NUCLEAR REGULATORY COMMISSION
REGION V

TELEPHONE OR VERBAL CONVERSATION RECORD

DATE ~~00/00/00~~ 2/26/96

TIME ~~00:00~~ (am)/pm

[ ] INCOMING CALL [X] OUTGOING CALL [ ] VISIT

PERSON CALLING:	OFFICE/ADDRESS:	PHONE NUMBER:

PERSON CALLED:	OFFICE/ADDRESS:	PHONE NUMBER:
Dan Rickenbacker	Hilo Hospital	(808)969-4416

CONVERSATION

SUBJECT - Control No. 572291

SUMMARY -

The notification information for Dr. David Camacho Jr. looks fine.

At the time of the next amendment, the reviewer will ask whether Dr. Camacho should be added to the license.

- B. Prange

REFERRED TO: NEXT REVIEWER

[ ] ADVISE ME ON ACTION TAKEN

ACTION REQUESTED:

INITIALS:

DATE:

ACTION TAKEN:

INITIALS:

DATE:

NRC FORM 218 REV-0 8/93 [WP/Ldc-R1V]

STATE OF HAWAII
DEPARTMENT OF HEALTH
HILO MEDICAL CENTER
1190 WAIANUENUE AVENUE
HILO, HAWAII 96720

RADIOLOGY DEPT.

TELEPHONE: (808) 969-4411 FAX: (808) 935-1889

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TO: Beth Prange

FROM: Dan Rickenbacker

REMARKS:

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TO

NAME	TELEPHONE
Dan Rickenbacher	(808) 969-4416

NAME AND LOCATION OF COMPANY (If other than NRC)

Hilo Medical Center

TELECOPY NUMBER	VERIFICATION NUMBER
(808) 935-1889	

FROM

NAME	TELEPHONE	MAIL STOP
Beth Prange FAX: (510) 975-0381	(510) 975-0250	RIV; WCFO

TELECOPY DATA

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PRIORITY

- [ ] IMMEDIATE
- [ ] OTHER (Specify)

SPECIAL INSTRUCTIONS

Regarding your letter of 1/29/96 — Please fax me a copy of Dr. Camacho's license to practice medicine.

Thanks,

Beth

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STATE OF HAWAII DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
BOARD OF MEDICAL EXAMINERS

PHYSICIAN

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(SIGNATURE OF LICENSEE) DHCamacho Jr.

§ 35.645 Reports of teletherapy surveys, checks, tests, and measurements.

A licensee shall mail a copy of the records required in §§ 35.636, 35.641, 35.643, and the output from the teletherapy source expressed as roentgens or rads per hour at one meter from the source and determined during the full calibration required in § 35.632, to the appropriate Commission Regional Office listed in § 30.6 of this chapter within thirty days following completion of the action that initiated the record requirement.

§ 35.647 Five-year inspection.

(a) A licensee shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Commission or an Agreement State.

(c) A licensee shall keep a record of the inspection and servicing for the duration of the license. The record must contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

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Subpart J—Training and Experience Requirements

§ 35.900 Radiation Safety Officer.

Except as provided in § 35.901, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.32 to be an individual who:

(a) Is certified by:

(1) American Board of Health Physics in Comprehensive Health Physics;

(2) American Board of Radiology;

(3) American Board of Nuclear Medicine;

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≫(4) American Board of Science in Nuclear Medicine;

(5) Board of Pharmaceutical Specialties in Nuclear Pharmacy;

(6) American Board of Medical Physics in radiation oncology physics;

(7) Royal College of Physicians and Surgeons of Canada in nuclear medicine;

(8) American Osteopathic Board of Radiology; or

(9) American Osteopathic Board of Nuclear Medicine; or

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(b) Has had classroom and laboratory training and experience as follows:

(1) 200 hours of classroom and laboratory training that includes:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Radiation biology; and

(v) Radiopharmaceutical chemistry; and

(2) One year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes the medical use of byproduct material; or

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(c) Be an authorized user identified on the licensee's license.

§ 35.901 Training for experienced Radiation Safety Officer.

An individual identified as a Radiation Safety Officer on a Commission or Agreement State license before October 1, 1986 need not comply with the training requirements of § 35.900.

§ 35.910 Training for uptake, dilution, and excretion studies.

Except as provided in §§ 35.970 and 35.971, the licensee shall require the authorized user of a radiopharmaceutical in § 35.100(a) to be a physician who:

(a) Is certified in:

(1) Nuclear medicine by the American Board of Nuclear Medicine; OR 1995

(2) Diagnostic radiology by the American Board of Radiology; or

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≫(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(5) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and supervised clinical experience as follows:

(1) 40 hours of classroom and laboratory training that includes:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Radiation biology; and

(v) Radiopharmaceutical chemistry; and

(2) 20 hours of supervised clinical experience under the supervision of an authorized user and that includes:

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≫(i) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

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(ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

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ABNM cert. Sept. 9, 1995
OR for 35.100, 200, 300, 500.

59 FR 61767 ≫(iii) Administering dosages to patients or human research subjects and using syringe radiation shields;

51 FR 36932 (iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and

59 FR 61767 ≫(v) Patient or human research subject followup; or

51 FR 36932 (c) Has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

§ 35.920 Training for imaging and localization studies.

Except as provided in § 35.970 or 35.971, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit in § 35.200(a) to be a physician who:

(a) Is certified in:

(1) Nuclear medicine by the American Board of Nuclear Medicine;

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59 FR 61767 ≫(2) Diagnostic radiology by the American Board of Radiology;

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology;

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(5) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

51 FR 36932 (b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows:

(1) 200 hours of classroom and laboratory training that includes:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Radiopharmaceutical chemistry; and

(v) Radiation biology; and

(2) 500 hours of supervised work experience under the supervision of an authorized user that includes:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

59 FR 61767 ≫(iii) Calculating and safely preparing patient or human research subject dosages;

51 FR 36932 (iv) Using administrative controls to prevent the misadministration of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Eluting technetium-99m from generator systems, measuring and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

(3) 500 hours of supervised clinical experience under the supervision of an authorized user that includes:

59 FR 61767 ≫(i) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;

51 FR 36932 (ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

59 FR 61767 ≫(iii) Administering dosages to patients or human research subjects and using syringe radiation shields;

51 FR 36932 (iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and

59 FR 61767 ≫(v) Patient or human research subject followup; or

51 FR 36932 (c) Has successfully completed a six-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

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§ 35.930 Training for therapeutic use of unsealed byproduct material.

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Except as provided in § 35.970, the licensee shall require the authorized user of radiopharmaceuticals in § 35.300 to be a physician who:

(a) Is certified by:

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(1) The American Board of Nuclear Medicine;

(2) The American Board of Radiology in radiology, therapeutic radiology, or radiation oncology;

(3) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(4) The American Osteopathic Board of Radiology after 1984; or

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(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and supervised clinical experience as follows:

(1) 80 hours of classroom and laboratory training that includes:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

(2) Supervised clinical experience under the supervision of an authorized user at a medical institution that includes:

(i) Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals; and

(ii) Use of iodine-131 for treatment of thyroid carcinoma in 3 individuals.

§ 35.932 Training for treatment of hyperthyroidism.

Except as provided in § 35.970, the licensee shall require the authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows:

(a) 80 hours of classroom and laboratory training that includes:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

(b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for diagnosis of thyroid function, and the treatment of hyperthyroidism in 10 individuals.

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§ 35.934 Training for treatment of thyroid carcinoma.

Except as provided in § 35.970, the licensee shall require the authorized user of only iodine-131 for the treatment of thyroid carcinoma to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating thyroid carcinoma, and supervised clinical experience as follows:

(a) 80 hours of classroom and laboratory training that includes:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology; and

(b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for the treatment of thyroid carcinoma in 3 individuals.

§ 35.940 Training for use of brachytherapy sources.

Except as provided in § 35.970, the licensee shall require the authorized user of a brachytherapy source listed in § 35.400 for therapy to be a physician who:

(a) Is certified in:

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(1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

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(2) Radiation oncology by the American Osteopathic Board of Radiology;

(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(b) Is in the active practice of therapeutic radiology, has had classroom and laboratory training in radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources, supervised work experience, and supervised clinical experience as follows:

(1) 200 hours of classroom and laboratory training that includes:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology;

(2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Checking survey meters for proper operation;

(iii) Preparing, implanting, and removing sealed sources;

(iv) Maintaining running inventories of material on hand;

(v) Using administrative controls to prevent the misadministration of byproduct material; and

(vi) Using emergency procedures to control byproduct material; and

(3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

(i) Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

(ii) Selecting the proper brachytherapy sources and dose and method of administration;

(iii) Calculating the dose; and

(iv) Post-administration followup and review of case histories in collaboration with the authorized user.

§ 35.941 Training for ophthalmic use of strontium-90.

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Except as provided in § 35.970, the licensee shall require the authorized user of only strontium-90 for ophthalmic radiotherapy to be a physician who is in the active practice of therapeutic radiology or ophthalmology, and has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy as follows:

(a) 24 hours of classroom and laboratory training that includes:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology;

(b) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals that includes:

(1) Examination of each individual to be treated;

(2) Calculation of the dose to be administered;

(3) Administration of the dose; and

(4) Followup and review of each individual's case history.

§ 35.950 Training for use of sealed sources for diagnosis.

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Except as provided in § 35.970, the licensee shall require the authorized user of a sealed source in a device listed in § 35.500 to be a physician, dentist, or podiatrist who:

(a) Is certified in:

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(1) Radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(2) Nuclear medicine by the American Board of Nuclear Medicine;

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(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

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(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

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(b) Has had 8 hours of classroom and laboratory training in basic radioisotope handling techniques specifically applicable to the use of the device that includes:

(1) Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

(2) Radiation biology;

(3) Radiation protection; and

(4) Training in the use of the device for the uses requested.

§ 35.960 Training for teletherapy.

Except as provided in § 35.970, the licensee shall require the authorized user of a sealed source listed in § 35.600 in a teletherapy unit to be a physician who:

(a) Is certified in:

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(1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(2) Radiation oncology by the American Osteopathic Board of Radiology;

(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(b) Is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a teletherapy unit, supervised work experience, and supervised clinical experience as follows:

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(1) 200 hours of classroom and laboratory training that includes:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology;

(2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:

(i) Review of the full calibration measurements and periodic spot checks;

(ii) Preparing treatment plans and calculating treatment times;

(iii) Using administrative controls to prevent misadministrations;

(iv) Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and

(v) Checking and using survey meters; and

(3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology