

VOID SHEET

RECEIVED

TO: License Fee Management 900917 26 A8:58

FROM: Region IV

SUBJECT: VOIDED APPLICATION LIC. FEE MGMT. BRANCH

Control Number: 463290

Applicant: Med. Ctr. of Oklahoma

Date Voided: 9/17/90

Reason for Void: Licenses decided to withdraw request since they will no longer perform therapy.

Billie Gruzynski 9/17/90
Signature Date

Attachment:
Official Record Copy of
Voided Action

FOR LFMB USE ONLY

Final Review of VOID Completed:

- Refund Authorized and processed
- No Refund Due
- Fee Exempt or Fee Not Required

ML40

Comments: _____

Log completed
Processed by: W. M... 9/27/90

901120074 900917
REG4 LIC30
MATLSLICENSING PDR

CONVERSATION RECORD

TIME

DATE

11:00a

9/11/90

TYPE

 VISIT CONFERENCE TELEPHONE INCOMING OUTGOING

ROUTING

NAME/SYMBOL INT

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU

ORGANIZATION (Office, dept., bureau, etc.)

TELEPHONE NO.

Dr. Thomas Kimball

Med. Ctr. of SEPK

(415)
924-3058

SUBJECT

Request for further training & experience info on 9/25/90

SUMMARY

I reminded Dr. Kimball of his conversation w/ V. Campbell. He said they had decided to withdraw the request due to the requirements Ms. Campbell spoke of. He said they would drop the therapy. We thought someone had given us a call to tell us this.

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Billie Brzezynski 9/11/90

ACTION TAKEN

SIGNATURE

TITLE

DATE

CONVERSATION RECORD

TIME 8:35a

DATE 7/25/90

TYPE

VISIT

CONFERENCE

TELEPHONE

INCOMING

OUTGOING

ROUTING

NAME/SYMBOL INT

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU

ORGANIZATION (Office, dept., bureau, etc.) TELEPHONE NO.

Thomas Kimball, M.D. Med. Ctr. of SEOK. (405) 924-3088

SUBJECT

SUMMARY

Training + experience criteria for using 35.300 material

Discussed requirements: 1) Recency of training 35.972
2) Clinical experience 35.930
3) Treated 10 individuals - hyperthyroid.

Dr. Kimball: preceptor not complete

Dr. Huddle: preceptor shows only 4 patients for hyper treats. needs additional training

ACTION REQUIRED

M/S 15

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Vivian Campbell

Vivian A. Campbell

7/25/90

ACTION TAKEN

SIGNATURE

TITLE

DATE

Medical Center Of
SOUTHEASTERN
OKLAHOMA

1800 University Blvd., Durant, Oklahoma 74701
(405) 924-3080

MS 16 T3

JUL 15 1990

July 10, 1990

Vivian H. Campbell
Nuclear Regulatory Commissio.
Region IV
611 Ryan Plaza Drive
Suite 1000
Arlington, Texas 76011

Dear Ms. Campbell:

In response to your letter, Control No. 463090 dated June 11, 1990, we have enclosed Dr. John P. Huddle's record of therapy education which should allow him to administer Thyroid Therapy doses.

If there are any questions, please call 405/924-3080.

Thank you for your assistance in this matter.

Sincerely,


J. David McCormack
Executive Director

JDM/al

030-13028

463090

463090

UNITED STATES ATOMIC ENERGY COMMISSION
APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL
SUPPLEMENT A—PRECEPTOR STATEMENT

This page is to be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each. Page 2 may be used for comments and additional information.

10. NAME AND ADDRESS OF APPLICANT PHYSICIAN (Include ZIP Code.)
John P. Huddle, D.O., Aultman Hospital
2600 Sixth Street S.W., Canton, Ohio 44710

11. CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN NAMED IN ITEM 10 ABOVE

(A) ISOTOPE	(B) CONDITIONS DIAGNOSED OR TREATED	(C) No. Cases Observed (See 1 in key below)	(D) No. Cases Involving Person Participation (See 2 in key below)
I-131 or I-125	Diagnosis of thyroid function	127	256
	Determination of blood and blood plasma volume	1	3
	Liver function studies	1	1
	Fat absorption studies	1	1
	Kidney function studies		
	In vitro studies		
Cr-51	Gastrointestinal protein loss studies		
	Determination of red blood cell volume and studies of red blood cell survival	1	1
Fe-59	Iron turn over studies		
Co-58or Co-60	Intestinal absorption studies (Co-57)	5	10
K-42	Potassium space determinations		
I-131	Thyroid imaging	33	126
	Brain tumor localization and cardiac imaging		
	Cisternography (Ytterbium-169 DTPA)	2	4
	Lung imaging		
	Liver imaging (Rose Bengal)	1	2
	Kidney imaging	1	2
	Placenta localization		
Cr-51	Placenta localization		
	Spleen imaging	1	1
Au-198	Liver imaging		
Hg-197	Brain imaging		
	Kidney imaging	1	2
Hg-203	Brain imaging		
Sr-85	Bone imaging		
Tc-99m	Brain imaging	162	324
	Thyroid imaging	10	24
	Salivary gland imaging		
	Blood pool imaging		

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

(A) ISOTOPE	(B) CONDITIONS DIAGNOSED OR TREATED	(C) No. Cases Observed (See 1 in key below)	(D) No. Cases Involving Personal Participation (See 2 in key below)
Tc-99m	Placenta localization		
	Liver and spleen imaging	75	150
	Lung imaging	40	80
	Bone imaging	28	56
Xe-133	Blood flow studies and pulmonary function studies	8	16
Se-75	Pancreas imaging	10	21
P-32	Treatment of polycythemia, leukemia, and Bone metastases		
	Intracavitary treatment		
I-131	Treatment of thyroid carcinoma		
	Treatment of hyperthyroidism and cardiac condition	2	4
Au-198	Intracavitary treatment		
Co-60 or CO-137	Interstitial treatment		
	Intracavitary treatment		
Ir-192	Interstitial treatment		
Co-60 CO-137	Teletherapy treatment		
Sr-90	Treatment of eye disease		

Key to Column (C) and (D) above

1. Observation should consist of observing radioisotope administration techniques and discussion with preceptor the case histories to establish most appropriate diagnostic and/or therapeutic procedure, limitation, contraindications, etc.
2. Personal participation should consist of (a) supervised examination of patients to determine the suitability of radioisotope diagnosis and/or treatment and recommendation on dosage to be prescribed; (b) collaboration in calibration of the dose and the actual administration of the dose to the patient including calculation of the radiation dose, related measurements, and plotting of data; and (c) adequate period of training to enable the physician to manage radioactive patients and to follow patients through diagnosis and/or the course of treatment.

12. DATES AND TOTAL NUMBER OF HOURS OF CLINICAL RADIOISOTOPE TRAINING October 1, 1975-December 31, 1975: 520 h

13. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF Robert N. Di Simone, M.D.

AT Aultman Hospital, Canton, Ohio #34-01312-01
(Institution) Name and Address (Byproduct Material License Number)

Robert N. Di Simone
(Signature of Preceptor)

...necessary to document experience, obtain

148710

AS ABOVE

DISEASES DIAGNOSED OR TREATED	(C) No. Cases Observed (See 1 in key below)	(D) No. Cases Involving Participation (See 2 in key)
...tion	127	256
... of blood and blood plasma volume	1	3
... ion studies	1	1
Poi absorption studies	1	1
Kidney function studies		
In vitro studies		
Gastrointestinal protein loss studies		
Determination of red blood cell volume and studies of red blood cell survival	1	1
Iron turn over studies		
Intestinal absorption studies (Co-57)	5	10
Potassium space determinations		
Thyroid imaging	33	126
Brain tumor localization and cardiac imaging		
Cisternography (Ytterbium-169 DTPA)	2	4
Lung imaging		
Liver imaging (Rose Bengal)	1	2
Kidney imaging	1	2
Placenta localization		
Placenta localization		
Spleen imaging	1	1
Liver imaging		
Brain imaging		
Kidney imaging	1	2
Brain imaging		
Brain imaging		
Thyroid imaging	162	324
Salivary gland imaging	10	24
Blood pool imaging		

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

(A) ISOTOPE	(B) CONDITIONS DIAGNOSED OR TREATED	(C) No. Cases Observed (See 1 in key below)	(D) No. Cases Involving P Participation (See 2 in ke
Tc-99m	Placenta localization		
	Liver and spleen imaging	75	150
	Lung imaging	40	80
	Bone imaging	28	56
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Se-75	Pancreas imaging	10	21
P-32	Treatment of polycythemia, leukemia, and Bone metastases		
	Intracavitary treatment		
I-131	Treatment of thyroid carcinoma		
	Treatment of hyperthyroidism and cardiac condition	2	4
Au-198	Intracavitary treatment		
Co-60 or CO-137	Interstitial treatment		
	Intracavitary treatment		
Ir-192	Interstitial treatment		
Co-60 CO-137	Teletherapy treatment		
Sr-90	Treatment of eye disease		

Key to Column (C) and (D) above

1. Observation should consist of observing radioisotope administration techniques and discussion with preceptor the case histories to establish appropriate diagnostic and/or therapeutic procedure, limitation, contraindications, etc.
2. Personal participation should consist of (a) supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation on dosage to be prescribed; (b) collaboration in calibration of the dose and the actual administration of the dose to the patient including calculation of the radiation dose, related measurements, and plotting of data; and (c) adequate period of training to enable the physician to manage radioactive patients and to follow patients through diagnosis and/or the course of treatment.

12. DATES AND TOTAL NUMBER OF HOURS OF CLINICAL RADIOISOTOPE TRAINING October 1, 1975-December 31, 1975; 56

13. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF Robert N. Di Simone, M.D.

at Aultman Hospital, Canton, Ohio

(Institution) Name and Address

#34-01312-01

(Byproduct Material License Number)

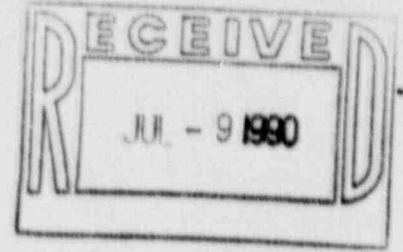
Robert N. Di Simone, M.D.
(Signature of Preceptor)

463090

Medical Center Of
SOUTHEASTERN
OKLAHOMA

1800 University Blvd., Durant, Oklahoma 74701
(405) 924-3080

M/S #16



July 5, 1990

Vivian H. Campbell
Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive
Suite 1000
Arlington, Texas 76011

Dear Ms. Campbell:

In response to your letter, Control No. 463090 dated June 11, 1990, we have enclosed Dr. Tom Kimball's record of therapy education which should allow him to administer Thyroid Therapy doses.

At the present time Dr. Huddle's records are unavailable. When we receive his records we will submit them to you and amend our license again at that time.

If there are any questions, please call 405/924-3080.

Thank you for your assistance in this matter.

Sincerely,

A handwritten signature in cursive script that reads "J. David McCormack".

J. David McCormack
Executive Director

JDM/al

463090

**TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER**

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER

Tom Kimball, M.D.

2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Hawaii

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Radiology	Radiology	June, 1980

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	Univ. of Oklahoma HSC Radiology Residency 7/1/76 to 6/30/80	30	80
b. RADIATION PROTECTION	"	5	35
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	"	10	15
d. RADIATION BIOLOGY	"	15	30
e. RADIOPHARMACEUTICAL CHEMISTRY	"	10	25

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	Univ. of Oklahoma HSC	11/78 to 1/79	diagnostic
Mo-99	500 mCi	Univ. of Oklahoma HSC	11/78 to 1/79	generator
I-131	200 mCi	Univ. of Oklahoma HSC	11/78 to 1/79	diagnostic-therapeutic
Ga-67	5 mCi	Univ. of Oklahoma HSC	11/78 to 1/79	diagnostic
Cr-51	300 μ Ci	Univ. of Oklahoma HSC	11/78 to 1/79	diagnostic
I-125	200 μ Ci	Univ. of Oklahoma HSC	11/78 to 1/79	diagnostic (in vivo)
Ig 111	500 μ Ci	Univ. of Oklahoma HSC	11/78 to 1/79	diagnostic (in vitro)

463090

JUN 11 1990

NMLS:VHC
Control No. 463090

Medical Center of Southeastern Oklahoma
ATTN: J. David McCormack
Executive Director
1800 University Boulevard
Durant, Oklahoma 74701

Gentlemen:

We have reviewed your letter dated May 22, 1990, requesting an amendment to your byproduct material license for use in nuclear medicine. However, before further action can be taken, we will require the following additional information.

Although you indicated that both Dr. Huddle and Dr. Kimball were board certified, we are unable to verify the required certification as specified in 10 CFR 35.930. You should carefully review the training and experience requirements specified in §35.930 and supply the information requested.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter. Please reply in duplicate and refer to Control No. 463090.

Sincerely,

Original Signed By
Vivian H. Campbell

Vivian H. Campbell
Health Physicist
Nuclear Materials Licensing Section

Enclosure:
Regulatory Guide 10.8, Revision 2,
"Guide for the Preparation of
Applications for Medical Use
Programs," August 1987

RIV:NMLS
VHCampbell
6/8/90

(FOR LFMS USE)
INFORMATION FROM LTS

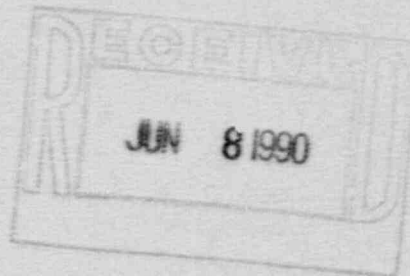
BETWEEN:
LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

PROGRAM CODE: 02120
STATUS CODE: 0
FEE CATEGORY: 7C
EXP. DATE: 19920930
FEE COMMENTS: NOT EX EFF. 9/25/87

LICENSE FEE TRANSMITTAL

A. REGION ✓

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: MED. CTR. OF SOUTHEASTERN OK.
RECEIVED DATE: 900530
DOCKET NO: 3013028
CONTROL NO.: 463090
LICENSE NO.: 35-17598-01
ACTION TYPE: AMENDMENT



2. FEE ATTACHED
AMOUNT:
CHECK NO.: 4

3. COMMENTS

See note on letter SIGNED Billig Gussowski
DATE 5/30/90

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

1. FEE CATEGORY AND AMOUNT: 7C (\$120)

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

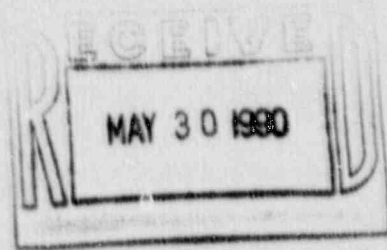
3. OTHER _____

SIGNED Mr. Gussowski
DATE 6/1/90

MEDICAL CENTER

of Southeastern Oklahoma Durant, Oklahoma 74701

1800 University Blvd., Durant, Oklahoma 74701
(405) 924-3080



May 22, 1990

Vivian Campbell
United States Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive
Suite 1000
Arlington, Texas 76011

RECEIVED
90 JAN -1 P2:02
U.S. NUCLEAR REGULATORY COMMISSION
FEE RECEIVED

RE: Amendment to NRC License 35-17598-01 for up to 30 mCi of ¹³¹I for therapy for Hyperthyroidism.

Dear Ms. Campbell:

First I wish to inform the NRC that I have been appointed Hospital Administrator of the Medical Center of Southeastern Oklahoma.

Our hospital is continuing to develop and we now wish to add the capability of ¹³¹I therapy for hyperthyroidism with a possession limit of 30 mCi of ¹³¹I. We plan to treat these patients as out patients and will only use the radionuclide in capsule form for therapy purposes. Both Dr. Huddle and Dr. Kimball are Board Certified and thus qualify for use of these materials.

Enclosed please find a check in the amount of \$120 for the amendment fee. Should you require additional information, please contact us.

Ms. Campbell, should you need additional information, we shall be pleased to respond.

Sincerely,

J. David McCormack
J. David McCormack
Executive Director

*Yes - 1-12
Durant HMA Inc.
001832
\$120
7C
And
6/5/90
6/5/90
messier*

JDM/al

463090

5/30/90 - I informed Mr. McCormack this date that no check was enclosed. He is to send check directly to Mr. Messier. By