



U. S. Department of Justice

Federal Bureau of Prisons

*Federal Correctional Complex*

Br. 1

Federal Medical Center  
P. O. Box 1500  
Butner, NC 27509

June 28, 2006

US Nuclear Regulatory Commission  
Region 1  
475 Allendale Road  
King of Prussia, PA 19406

32-25613-01  
03036175

Dear Mr. Lee,

In response to the voidance of the last action, Control Number 138627, we are resubmitting our amendment request. I have included additional information for completion of our license amendment.

1. We have attached a copy of NRC Form 313A for your review. Please add Dr. Coughlin as an Authorized User (AU).
2. We have attached a letter from the current Radiation Safety Officer (RSO), Dr. Lester. Dr. Lester has attested that Dr. Coughlin has the required experience to serve as the new RSO.
3. We wish to add 35.300 authorization to our NRC license. Total activities for I-131 = 150 mCi, Sr-90 = 6 mCi, Sm-153 = 150 mCi. The byproduct material will be stored in the Hot Lab, XR-29. It has a shielded hood, as well as a shielded lock storage cabinet. Portable shields will be used as needed.
4. Dr. Coughlin should be the only AU for 35.300. Samuel N Bone, and Samuel Nicholas Bone, III, MD are the same individual.

Please let me know if you have any questions.

Respectfully,

A.F. Beeler, Warden  
FCC, Butner (Medical)

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REGION 1  
2006 JUL 13 PM 1:41

(Ref 138627)

139117  
NMSS/RGNI MATERIALS-C02



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

June 15, 2006

Docket No. 03036175  
Control No. 138627

License No. 32-25613-01

Jim Reed  
Health Services Administrator  
Federal Medical Center  
Bureau of Prisons  
P. O. Box 1500  
Butner, NC 28540

SUBJECT: FEDERAL MEDICAL CENTER, VOIDANCE OF APPLICATION FOR LICENSE  
AMENDMENT, CONTROL NO. 138627

Dear Mr. Reed:

This concerns the subject application for an Amendment to your material license. Based on telephone conversations with your Health Physics Consultant, Gary Parker, you informed us that you will not be able to supply the additional information required to complete the requested action for some time, we have voided your application. This action is taken without prejudice to the resubmission of your request.

Sincerely,

Willie J. Lee  
Health Physicist  
Medical Branch  
Division of Nuclear Materials Safety

cc:  
James W. Lester, Jr., M.D., Radiation Safety Officer

**From:** "Willie Lee" <WJL1@nrc.gov>  
**To:** <j1reed@bop.gov>  
**Date:** 5/24/2006 5:01:19 PM  
**Subject:** Information Request, Federal Medical Center, Control No. 138627

REQUEST FOR ADDITIONAL INFORMATION

LICENSEE: Federal Medical Center, Bureau of Prisons  
LICENSE NUMBER: 32-25613-01  
DOCKET NUMBER: 030-36175  
CONTROL NUMBER: 138627  
DATE: May 24, 2006

ATTN: Jim Reed, Health Services Administrator

Additional information is needed for completion of your license amendment, as follows:

1. As followup to your amendment request contained in the application dated March 7, 2006 and signed by Christopher T. Coughlin, M.D., please submit a letter requesting that Dr. Coughlin be named as an Authorized User (AU) on your NRC license. Your request must include a previous license number (if issued by the NRC) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by a Commission master materials licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee on which Dr. Coughlin is specifically named as an AU for the uses requested.
2. Please confirm in the letter that Dr. Coughlin has been delegated as the Radiation Safety Officer (RSO) and should be named as such on your NRC license. Your request must include a previous license number (if issued by the NRC) or a copy of the license (if issued by an Agreement State) or a copy of a permit issued by a Commission master materials licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee on which Dr. Coughlin is specifically named as an RSO for the uses requested. If Dr. Coughlin has not been previously listed as an RSO, you can include a separate statement signed by your current RSO (Dr. Lester) providing written attestation that Dr. Coughlin has the required training and experience in the radiation safety, regulatory issues, and emergency procedures for the types of use authorized by your NRC license and can function independently as an RSO.
3. Please confirm your request to add 35.300 authorization to your NRC license. Also specify the total amount (in millicuries) requested. For types of use permitted by 35.300, please provide the locations where byproduct material will be stored. Describe the rooms where patients will be housed if they cannot be released under 10 CFR 35.75. The discussion should include a description of shielding, if applicable.
4. Your application included a number of American Board of Radiology (ABR) certificates for physicians who are to be listed on your license as Authorized Users. Please provide a list of those individuals, to include their proposed authorized use (e.g. 35.100, 35.200 and/or 35.300). The majority of the physicians are currently listed on your NRC license for 35.100, 35.200, and Iodine-131 for imaging and localization studies. If you wish to add 35.300 authorization for the currently listed physicians, you will need to provide documentation for those individuals similar to that requested for Dr. Coughlin in Item 1. Certificates were included for Samuel N. Bone, M.D. and Samuel Nicholas Bone, III, M.D. Please verify that these are two individuals if both names are included in your list of Authorized Users.

Please note that you may not reply to this request by return e-mail. Your prompt reply must be in writing by letter, signed by a member of Senior Management, which can be sent by facsimile to (610) 337-5269. Please reference the Control Number. Contact me if there are any questions regarding this request.

Willie J. Lee, Health Physicist  
US Nuclear Regulatory Commission  
Region 1  
475 Allendale Road  
King of Prussia, PA 19406  
(610) 337-5090 (Phone)  
(610) 337-5269 (FAX)



State of New Hampshire  
Department of Health and Human Services  
Office of Community & Public Health  
Bureau of Radiological Health

Page 1 of 2 pagesLicense No. 130R  
Amendment No. 68**Radioactive Material License****Supplementary Sheet**

Mary Hitchcock Memorial Hospital  
One Medical Center Drive  
Lebanon, New Hampshire 03756

In accordance with letter dated December 17, 1999 and February 24, 2000, signed by Paul B. Gardent, Executive Vice President, and David Gladstone, Sc.D., New Hampshire Radioactive Material License No. 130R is hereby amended as follows:

Condition 11 changed to read:

11. Radioactive material may be used only by the physicians listed below for the uses specified:

- |    |  |  |
|----|--|--|
| A. | Bruce J. Friedman, M.D.<br>Robert D. Harris, M.D.<br>Thomas J. Sullivan, M.D.<br>Helene M. Nagy, M.D.<br>Robert Dallas, M.D. | - all diagnostic uses authorized by the license  |
| B. | Harte C. Crow, M.D.<br>Robert Jeffery, M.D.<br>Steven K. Sargent, M.D.<br>Peter Spiegel, M.D.<br>Petra Jane Lewis, M.D.      | - all diagnostic uses authorized by the license; therapy with P-32; treatment of hyperthyroidism and cardiac dysfunction with I-131                    |
| C. | Alan Siegel, M.D.  | - all diagnostic uses authorized by the license; therapy with P-32; treatment of hyperthyroidism, cardiac dysfunction and thyroid carcinoma with I-131 |
| D. | Christopher T. Coughlin, M.D.<br>Richard S. Wagman, MD   | - all therapeutic uses authorized by the license   |

(Cont'd on next page)



State of New Hampshire  
Department of Health and Human Services  
Office of Community & Public Health  
Bureau of Radiological Health

Page 2 of 2 pagesLicense No. 130R  
Amendment No. 68**Radioactive Material License****Supplementary Sheet**

## Condition 11. (cont'd)

E. James P. Aubuchon, M.D.

- in-vitro studies with Cr-51, Tc-99m and In-111 as U.S. Food and Drug Administration (FDA) approved radiopharmaceuticals to be administered for human studies in dose ranges, routes of administration and in physical and chemical forms specified in the package inserts and listed in the New Drug Applications (NDA) for each product

Such studies shall be authorized, when conducted for purposes not listed in the NDA, only subsequent to approval by an appropriately constituted and FDA-listed Institutional Review Board, the approval of the licensee's human use and experimentation committee if separately constituted, and only when the licensee has obtained informed consent from the subjects prior to the studies.

F. Edward Catherwood, M.D.

- diagnostic uses of Tc-99m and Tl-201 for cardiac imaging only

G. Edward H. Abraham, M.D.

- therapy with Sr-89 and Sm-153 for bone metastases

H. John F. Marshall, M.D.

- brachytherapy; treatment of hyperthyroidism with I-131; therapy with Sr-89 and Sm-153 for bone metastases

I. The blood irradiator shall be used by or under the supervision of David J. Gladstone, Sc.D.

Operators of the unit under the supervision of this individual shall have successfully completed training as specified by application dated April 30, 1991 and letter dated August 27, 1991, and shall be so listed in the licensee's records.

J. Radioactive material for non-human applications, including in-house survey meter calibration, may also be used by, or under the supervision of, David J. Gladstone, Sc.D.

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For the Department of Health and Human Services  
Office of Community & Public Health

*Original signed by Diane E. Tefft*

Date: May 17, 2000

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Diane E. Tefft, Administrator  
Bureau of Radiological Health



**U. S. Department of Justice**

Federal Bureau of Prisons

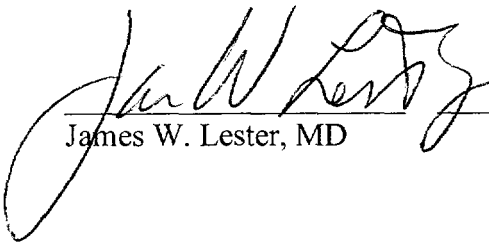
*Federal Correctional Complex*

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*Butner, North Carolina 27509*

- ☐ *Federal Medical Center  
P.O. Box 1500*
- ☐ *Federal Correctional Institution  
P.O. Box 1000*
- ☐ *Low Security Correctional Institution  
P.O. Box 999*

I have reviewed Dr. Coughlins education and training as required in part 35.300. I attest that he has the required training and experience in Radiation Safety, Regulatory issues and Emergency procedures to function independently as the Radiation Safety Officer at the Butner Federal Complex.

 6-12-06  
James W. Lester, MD                      Date

**MEDICAL USE TRAINING AND EXPERIENCE  
AND PRECEPTOR ATTESTATION**

APPROVED BY OMB: NO. 3150-0120  
EXPIRES: 10/31/2008

**PART I -- TRAINING AND EXPERIENCE**

**Note:** Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulation (10 CFR Part 35)

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)

Christopher T. Coughlin, MD Radiation Safety Officer 10CFR35.300

2. For Physicians, Podiatrists, Dentists, Pharmacists -- State or Territory Where Licensed

North Carolina

**3. CERTIFICATION**

- Provide a copy of the board certification. (Stop here if applying under 10 CFR Part 35, Subpart J or 35.590(a); continue if applying under other subparts.)
- Provide documentation in appropriate items 4 through 10 of training or clinical case work required by 35.50(e); 35.51(c); 35.290(c)(1)(ii)(G) for AU seeking 35.200 authorization; 35.390(b)(1)(ii)(G); 35.396(d)(1) and 35.396(d)(2); 35.590(c); or 35.690(c).
- Provide completed Part II Preceptor Attestation, Items 11a through 11d.  
Stop here after completing items 3a, 3b, and 3c when using board certification to meet 10 CFR Part 35 training and experience requirements.

**4. INDIVIDUALS IDENTIFIED ON A LICENSE OR PERMIT AS RADIATION SAFETY OFFICERS (RSO),  
AUTHORIZED USERS (AU), AUTHORIZED MEDICAL PHYSICISTS (AMP), OR  
AUTHORIZED NUCLEAR PHARMACISTS (ANP) SEEKING ADDITIONAL AUTHORIZATIONS**

- Provide a copy of the license or broadscope permit listing the current authorization **and** (b) or (c)
- Complete items 6c (and 10 when training is provided by an RSO, AMP, ANP, or AU) and preceptor items 11b through 11d to meet requirements for: RSO in 35.50(c)(2) or 35.50(e); or AU in 35.290(c)(1)(ii)(G) or 35.390(b)(1)(ii)(G) or 35.590(c) or 35.690(c); or AMP under 35.51(c).
- Complete items 5, 6a, 6b, 10, and Preceptor items 11a through 11d to meet AU requirements in 35.396(a).

**5. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)**

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation	Montefiore Hospital Bronx, NY	240 hours	1978-79
Radiation Protection	Montefiore Hospital Bronx, NY	240 hours	1978-79
Mathematics Pertaining to the Use and Measurement of Radioactivity	Montefiore Hospital Bronx, NY	240 hours	1978-79
Radiation Biology	Bronx Veterans Administration Bronx, NY	50 hours	1978
Chemistry of Byproduct Material for Medical Use	Montefiore Hospital Bronx, NY	240 hours	1978-79
OTHER			




## MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

## 6a. WORK OR PRACTICAL EXPERIENCE WITH RADIATION

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
Administration of I-131, P-32, Sr-90, Sm-153	Dr. Frank Lane	Dartmouth-Hitchcock Medical Center Lebanon, NH	1980-86
Administration of I-131, P-32, Sr-90, Sm-153	Dr. Dick Piontek	Dartmouth- Hitchcock Medical Center Lebanon , NH	1982-2000

## 6b. SUPERVISED CLINICAL CASE EXPERIENCE (describe experience elements in 6a)

Radionuclide	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
I-131(150 mCi)	Thyroid Cancer	2400	Dr. Frank Lane	Dartmouth-Hitchcock	1980-2000
Sr-90 (6mCi)	Prostate Cancer	150	Dr. Dick Piontek	Dartmouth-Hitchcock	1982-2000
Sm-153(150mCi  )	Prostate,Breast Cancer	30	Dr. Dick Piontek	Dartmouth-Hitchcock	1982-2000

## MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

## 6c. TRAINING FOR SECTIONS 35.50(e), 35.51(c), 35.590(c), or 35.690(c)

Training Element	Type of Training *	Location and Dates
Hematology	Fellowship	Montefiore Hospital Bronx, NY 1976-79
Medical Oncology	Fellowship	Montefiore Hospital Bronx, NY 1976-79

\* Types of training may include supervised (complete item 10 for 35.50(e), 35.51(c), and 35.690(c)), didactic, or vendor training.

## 7. FORMAL TRAINING Physicians (for uses under 35.400 and 35.600) and Medical Physicists

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Number	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)
Hematology/ Medical Oncology Radiation Therapy	Montefiore Hospital Bronx, NY	1976-80	Montefiore Hospital Bronx, NY

## 8. RADIATION SAFETY OFFICER (RSO) -- ONE-YEAR FULL-TIME EXPERIENCE

- ☐ YES Completed 1 year of full-time radiation safety experience (in areas identified in item 6a) under supervision.
- ☒ N/A of \_\_\_\_\_ the RSO for License No. \_\_\_\_\_

## 9. MEDICAL PHYSICIST -- ONE-YEAR FULL-TIME TRAINING/WORK EXPERIENCE

- ☐ YES Completed 1 year of full-time training (for areas identified in item 6a) in therapeutic radiological physics (35.961) or medical physics (35.51) under the supervision of \_\_\_\_\_
- ☐ N/A who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51);

and

- ☐ YES Completed 1 year of full-time work experience (at location providing radiation therapy services described and for topics identified in item 6a) for (specify use or device) \_\_\_\_\_
- ☐ N/A under the supervision of \_\_\_\_\_ who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51) (specify use or device) \_\_\_\_\_

**MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

**10. SUPERVISING INDIVIDUAL -- IDENTIFICATION AND QUALIFICATIONS**

The training and experience indicated above was obtained under the supervision of (if more than one supervising individual is needed to meet requirements in 10 CFR Part 35, provide the following information for each) :

A. Name of Supervisor

Dr. Charles Bolstein (Program Dir.)

B. Supervisor is:

☐

Authorized User

☐

Authorized Medical Physicist

☒

Radiation Safety Officer

☐

Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s)

for medical uses in Part 35, Section(s)

D. Address

Montefiore Hospital  
Bronx, NY

E. Materials License Number

**PART II -- PRECEPTOR ATTESTATION**

**Note:** This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet training requirements in 35.590 or Part 35, Subpart J (except 35.980).

I attest the individual named in Item 1:

11a.

☐

has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s)

as documented in section(s) of this form.

11b. Select one

☐

meets the requirements in ☐ 35.50(e) ☐ 35.51(c) ☐ 35.390(b)(1)(ii)(G) ☐ 35.690(c) for

☒

N/A

types of use, as documented in section(s) of this form.

11c.

☐

has achieved a level of competency sufficient to independently operate a nuclear pharmacy (for 35.980); **or**

☐

has achieved a level of competency sufficient to function independently as an authorized  
for uses (or units); **or**

☐

has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee ; **or**

☒

N/A

11d.

☐

I am an Authorized Nuclear Pharmacist; **or**

☐

I am a Radiation Safety Officer; **or**

☐

I meet the requirements of section(s) of 10 CFR Part 35

or equivalent Agreement State requirements to be a preceptor

☐

AU

or

☐

AMP

for the following byproduct material uses (or units):

A. Address

B. Materials License Number

C. NAME OF PRECEPTOR (print clearly)

D. SIGNATURE -- PRECEPTOR

E. DATE

This is to acknowledge the receipt of your letter/application dated

6/28/2006, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amendment 32-25613-01 There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number 139117.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.