



Danbury Hospital

March 10, 2006

Shirley Xu
Nuclear Materials Safety Branch
United States Nuclear Regulatory Commission, Region 1
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Q-8

Re: NRC License No. 06-08544-01
Control # 138427

03001274

Dear Ms. Xu:

In response to your inquiry from 3/8/06 regarding our NRC license amendment proposal of 2/2/06:

1. The area adjacent to the hot lab at the proposed Southbury, CT cardiology site is an exam room/ECHO room that is part of the cardiology facility. Routine area surveys will be performed in this area as per our usual protocols.
2. I am forwarding a copy of Dr. Mani's official ASNC certificate (she had received a copy since we sent the original proposal) along with preceptorship statements from Dr. Jonathan Alexander & myself who are both licensed users here at Danbury Hospital.
3. I have corrected the information (10 CFR 35 numbers) on Dr. Savino's paperwork to correspond with your current system.

Please inform me if you require any further information.

Sincerely,

William D. Johns, MD
Radiation Safety Officer
Danbury Hospital
24 Hospital Avenue
Danbury, CT 06810

Tel: 203-797-7222
Fax: 203-739-6473

WDJ:wj
3/10/06

138427

NMSS/RONI MATERIALS-002



Danbury Hospital

February 2, 2006 (corrections February 8, 2006- WJ)

Licensing Assistant Section
Nuclear Materials Safety Branch
U. S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

RE: NRC License No. 06-08544-01 (Danbury Hospital)
Amendment Request

To Whom It May Concern:

Enclosed you will find an application and supporting information for an amendment to the Danbury Hospital material license. We recently completed our 10-year renewal process. Included in this proposed amendment will be:

1. Addition of a satellite facility (owned and operated by Danbury Hospital) for nuclear cardiology diagnostic imaging located in Southbury, Connecticut. The address of the facility will be:
Cardiovascular Diagnostic Center (Danbury Hospital)
22 Old Waterbury Road, Suite 106
Southbury, CT 06488
Tel: 203-262-4270

The facility will be staffed by Danbury Hospital employees and will include 1 gamma camera and other equipment required for operation. Tc-99m and Tl-201 will be used for diagnostic imaging and other sealed sources will be required for instrument calibration, etc. We will have a hot lab and on-site radioactive waste storage. No therapeutic modalities using isotopes will be performed at this site. Diagrams of the planned facility and hot lab are enclosed.

The facility will be under the supervision of the Radiation Safety Officer (Dr. William Johns) and our medical physics staff at Danbury Hospital, with activities being overseen by the Radiation Safety Committee at Danbury Hospital. All hospital policies and procedures will be followed at the satellite facility for compliance with NRC and State of Connecticut regulations.

2. We would like to add 2 physicians to our NRC license:
 - a. Robert Savino, OD: Dr. Savino is Chief of Endocrinology at Danbury Hospital. He is board certified in Endocrinology and has completed an 80-hour course in radiation physics/nuclear

endocrinology (certificate enclosed). He has been supervised here at Danbury Hospital in the administration of I-131 therapies to 10 patients with hyperthyroidism and 3 patients with thyroid cancer. He is applying for privileges under 10 CFR **35.392** (treatment of hyperthyroidism) and **35.394** (treatment of thyroid cancer). Preceptorship statements are also attached.

- b. Susan Mani, MD: Dr. Mani is a staff Cardiologist here at Danbury Hospital. She is board certified in Cardiology and Nuclear Cardiology. Her certifications are enclosed. She is applying for privileges for Nuclear Cardiology diagnostic imaging under 10 CFR 35.100 and 35.200.

Please inform us if you require any further information. Inquiries may be directed to the Radiation Safety Officer (Dr. William Johns).

Sincerely,



Patricia O'Connor
Senior Vice President, Operations
Danbury Hospital
24 Hospital Avenue
Danbury, CT 06810

WDJ:wj
2/2/06



Danbury Hospital

January 19, 2006 (amended March 8, 2006- WJ)

Nuclear Materials Safety Branch
United States Nuclear Regulatory Commission, Region 1
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Re: NRC License No. 06-08544-01

Subject: Addition of Robert Savino, D.O. to Hospital License

To Whom It May Concern:

We request the addition of Dr. Robert Savino to the Danbury Hospital NRC license as an authorized user for treatment of hyperthyroidism (35.392) and thyroid carcinoma (35.394). Dr. Savino is currently the Chief of Endocrinology here at the hospital. He completed his fellowship training in endocrinology in 1994 and coursework in radiological physics in 2003 (certificate attached).

He has completed 80 hours of classroom and laboratory training that includes radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, and radiation biology. Dr. Joseph Belsky who is currently a licensed user has supervised him in treatment of hyperthyroidism in 10 individuals here at Danbury Hospital. Drs. Gupta and Johns who are currently licensed users have also supervised him in treatment of thyroid cancer in 3 individuals here at Danbury Hospital. We certify that he has successfully completed training and is competent in the use of I-131 to treat both hyperthyroidism and thyroid cancer.

Sincerely,

Shiv Gupta, MD (Preceptor)
Chief of Nuclear Medicine
Chairman, Radiation Safety Committee, Danbury Hospital

William Johns, MD (Preceptor)
Nuclear Medicine
Radiation Safety Officer, Danbury Hospital

Joseph Belsky, MD (Preceptor)
Endocrinology, Danbury Hospital

NRC FORM 313A (10-2005) U.S. NUCLEAR REGULATORY COMMISSION 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: William Johns, MD
B. Supervisor is: [X] Authorized User, [X] Radiation Safety Officer, [] Authorized Medical Physicist, [] Authorized Nuclear Pharmacist
C. Supervisor meets requirements of Part 35, Section(s) 35.394 (Cancer Therapy)
D. Address: Danbury Hospital, 24 Hospital Avenue, Danbury, CT 06810
E. Materials License Number: 06-08544-01

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 35.690 or Part 35, Subpart J (except 35.980).

I attest the individual named in Item 1: Robert Saino DO

11a. [X] has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) 35. as documented in section(e) C 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(e) of this form.

11c. [] has achieved a level of competency sufficient to independently operate a nuclear pharmacy (for 35.980); OF
[X] has achieved a level of competency sufficient to function independently as an authorized user (or units); OF
LIC for I131 cancer therapy
[] has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use license; OF
[] N/A

11d. [] I am an Authorized Nuclear Pharmacist; OF [X] I am a Radiation Safety Officer; OF
[X] I meet the requirements of 35.394 section(s) of 10 CFR Part 35
or equivalent Agreement State requirements to be a preceptor [X] AU or [] AMP
for the following byproduct material uses (or units): I131 Therapy (Cancer)

A. Address: Danbury Hospital, 24 Hospital Avenue, Danbury, CT 06810
B. Materials License Number: 06-08544-01

C. NAME OF PRECEPTOR (print clearly): William D. Johns, MD
D. SIGNATURE - PRECEPTOR: William Johns, MD
E. DATE: 1/19/06

NRC FORM 313A
(10-2004)

U.S. NUCLEAR REGULATORY COMMISSION

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

Shiv Gupta, MD

B. Supervisor is:

Authorized User

Authorized Medical Physicist

Radiation Safety Officer

Authorized Nuclear Pharmacist

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

35.394 (Laser Therapy)

for medical uses in Part 35, Section(s)

D. Address

Danbury Hospital
24 Hospital Avenue
Danbury, CT 06810

E. Materials License Number

06-08544-01

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: Robert Savoia DO

11a.

has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) 35 as documented in section(s) C 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); **OF**

has achieved a level of competency sufficient to function independently as an authorized user for I-131 cancer therapy uses (or units); **OF**

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

N/A

11d.

I am an Authorized Nuclear Pharmacist; **OF** I am a Radiation Safety Officer; **OF**

I meet the requirements of 35.394 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): I-131 Therapy (cancer)

A. Address

Danbury Hospital
24 Hospital Avenue
Danbury, CT 06810

B. Materials License Number

06-08544-01

C. NAME OF PRECEPTOR (print clearly)

Shiv Gupta, MD

D. SIGNATURE - PRECEPTOR

[Signature]

E. DATE -

1/19/2006

NRC FORM 313A
(10-2005)

U.S. NUCLEAR REGULATORY COMMISSION

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

Joseph Belsky, MD

B. Supervisor is:

Authorized User

Authorized Medical Physicist

Radiation Safety Officer

Authorized Nuclear Pharmacist

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

35.392 (Hypothyroid)

for medical uses in Part 35, Section(s)

D. Address

Danbury Hospital
24 Hospital Avenue
Danbury, CT 06810

E. Materials License Number

06-08544-01

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: Robert Savino, DO

11a.

has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) 35.1 as documented in section(s) C 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 types of use, as documented in section(s) of this form.

N/A

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 USCR for I-131 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 35.392 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): I-131 (Hypothyroid Rx)

A. Address

Danbury Hospital
24 Hospital Avenue
Danbury, CT 06810

B. Materials License Number

06-08544-01

C. NAME OF PRECEPTOR (print clearly)

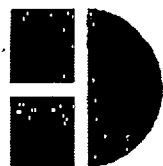
Joseph Belsky, MD

D. SIGNATURE - PRECEPTOR

X Joseph L. Belsky, MD

E. DATE

1/19/06



Danbury Hospital

March 9, 2006

Nuclear Materials Safety Branch
United States Nuclear Regulatory Commission, Region 1
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Re: NRC License No. 06-08544-01
Control #: 138427

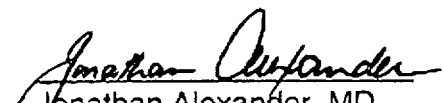
Subject: Addition of Susan Mani, MD to Hospital License

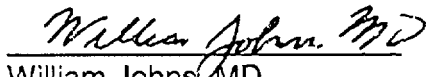
To Whom It May Concern:

We request the addition of Dr. Susan Mani to the Danbury Hospital NRC license as an authorized user for diagnostic Nuclear Cardiology (35.100, 35.200). She completed her training in Nuclear Cardiology and is board certified by the American Society of Nuclear Cardiology.

She has been employed at Danbury Hospital since June 2005 and has been precepted here by Dr. Jonathan Alexander and Dr. William Johns. She is familiar with all procedures using isotopes in Nuclear Cardiology, as well as having demonstrated good knowledge regarding radiation safety procedures and isotope handling. We certify that she is competent to be placed on our license.

Sincerely,


Jonathan Alexander, MD
Director of Nuclear Cardiology


William Johns, MD
Nuclear Medicine/Radiation Safety Officer

WDJ:wj
3/9/06

THE CERTIFICATION BOARD OF NUCLEAR CARDIOLOGY

Incorporated 1996

CERTIFIES THAT

Susan Mani, M.D.

HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS BOARD FOR PHYSICIANS RESIDING
IN THE UNITED STATES AND HAVING SATISFACTORILY PASSED THE REQUIRED EXAMINATION,
IS HEREBY DESIGNATED

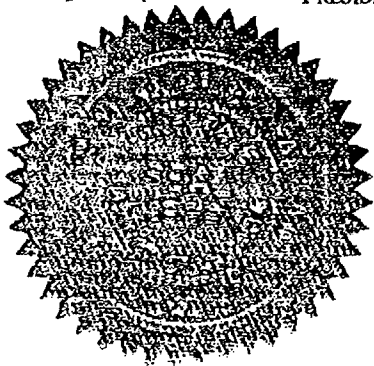
A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF

NUCLEAR CARDIOLOGY

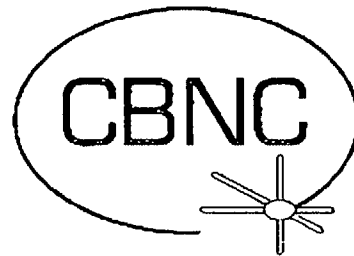
FOR THE PERIOD 2005 THROUGH 2015

Manuel D. Cervera
PRESIDENT

Joe A. Amighi
SECRETARY



CERTIFICATE # 4061



OCTOBER 23, 2005

NRC FORM 313A (10-2005)	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2008
MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION		

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)
Susan Masi, MD - Authorized User Nuclear Cardiology

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

3. CERTIFICATION

- a. 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.)
- b. 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).
- 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

- a. Provide a copy of the license or broadscope permit listing the current authorization and (b) or (c)
- b. 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).
- 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	<i>Board Certified -</i>		
Radiation Protection	<i>American Society of</i>		
Mathematics Pertaining to the Use and Measurement of Radioactivity	<i>Nuclear Cardiology</i>		
Radiation Biology	<i>Fellowship Training Done</i>		
Chemistry of Byproduct Material for Medical Use			
OTHER			

Sybil Marie, MD

NRC FORM 313A (10-2005) U.S. NUCLEAR REGULATORY COMMISSION

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
Nuclear Cardiology Training / Fellowship		New York Presbyterian Hospital - NY, NY	met requirements for Nuc Card Board 6/01 - 6/05
Clinical Training over 500 clinical cases & radiation safety instructions / supervisor	Jonathan Alexander, MD William John, MD	Danbury Hospital 06-08549-01	6/05 - 3/06

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
Tc-99m	diagnostic imaging	>500	Jonathan Alexander, MD		
SEPTA MIBI	1)		William John, MD	Danbury Hospital	6/05 - 3/06
Tl-201	1)			24 Hospital Bldg Danbury, CT	
Thallium, Cl	1)			06-08549-01	
Tc-99m RBC					

Susan Mari, MD

NRC FORM 313A
(10-2005)

U.S. NUCLEAR REGULATORY COMMISSION

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

Jonathan Alexander

B. Supervisor is:

Authorized User

Authorized Medical Physicist

Radiation Safety Officer

Authorized Nuclear Pharmacist

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

35.100, 35.200

for medical uses in Part 35, Section(s)

35.290

D. Address

Danbury Hospital
24 Hospital Avenue
Danbury, CT 06810

E. Materials License Number

06-085-44-01

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) 11c of this form.

35.100
35.200

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 W/C for 35.200, 35.100 uses (or units); OR

over 500 cases

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

Medical certificates

N/A

11d.

I am an Authorized Nuclear Pharmacist; OR I am a Radiation Safety Officer; OR

I meet the requirements of 35.100 35.200 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): Nuclear Cardiology - all isotopes

A. Address

Danbury Hospital
24 Hospital Avenue
Danbury, CT 06810

B. Materials License Number

06-085-44-01

C. NAME OF PRECEPTOR (print clearly)

Jonathan Alexander

D. SIGNATURE - PRECEPTOR

Jonathan Alexander

E. DATE

3/10/06

Susan Mari MD

MRC FORM 313A (10-2005)

U.S. NUCLEAR REGULATORY COMMISSION

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

William John

B. Supervisor is:

Authorized User

Authorized Medical Physicist

Radiation Safety Officer

Authorized Nuclear Pharmacist

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

35.100, 35.200

for medical uses in Part 35, Section(s)

35.290

D. Address

Danbury Hospital
24 Hospital Avenue
Danbury, CT 06810

E. Materials License Number

06-02544-01

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) 35.100, 35.200 as documented in section(s) 11c 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 _____ types of use, as documented in section(s) _____ of this form.

N/A

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 USER for 35.100, 35.200 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 35.100, 35.200 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): Nuclear Cardiology - all nuclear use,

A. Address

Danbury Hospital
24 Hospital Avenue
Danbury, CT 06810

B. Materials License Number

06-02544-01

C. NAME OF PRECEPTOR (print clearly)

William D. John, MD

D. SIGNATURE - PRECEPTOR

William D. John MD

E. DATE

3/10/06