Q-5
MS-16

Thomas I. Knox, M.D., F.A.C.C.
106 Gillett Street
Hartford, CT 06105
Phone: 860-547-1489 Fax: 860-548-9105
www.hartford.cardiology@yahoo.com

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CT/NRC

To comply with your request, with respect to NUREG 1556, Vol.9, Rev 2:

Item 9: Facility Diagram:

See original application for facility diagram, including location and room numbers and principal use of each room or area where byproduct material is prepared, used and/or stored; treatment rooms, including adjacent areas, and shielding information.

Item 9: Radiation Monitoring Instruments

Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibration. We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61. A description of the instrumentation that will be used is provided in the original license application. We reserve the right to upgrade our survey instruments as needed as long as they are adequate to measure the type and level of the radiation for which they are used.

Item 9: Dose Calibrator and Other Dosage Measuring Equipment

Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions.

Item 10: Area Surveys

We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements

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NMSS/RGN1 MATERIALS-002

of 10 CFR 20.1501 and 10 CFR 35.70.

Item 10: Occupational Dose

Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20, or we will provide dosimetry that meets the requirements listed under "Criteria" in NUREG-1556, Vol.9, Rev.2, "Consolidated Guidance About Materials Licenses" Program-Specific Guidance About Medical Use Licensees."

Item 10: Safe Use of Unsealed Licensed Material

We have developed and will implement and maintain procedures for the safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

Item 10: Spill Procedures

We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101.

Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources.

NC Systems Inc. will install and service our equipment, and will train our NMT. See full license application previously provided.

Item 11: Waste Management

We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of Subpart K to 10 CFR Part 20 and 10 CFR 35.92.

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

b. Supervised Radiation Safety Experience (continued)

(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervising Individual	License/Permit Number listing supervising individual as a Radiation Safety Officer

This license authorizes the following medical uses:

- ☐ 35.100
- ☒ 35.200
- ☐ 35.300
- ☐ 35.400
- ☐ 35.500
- ☐ 35.600 (remote afterloader)
- ☐ 35.600 (teletherapy)
- ☐ 35.600 (gamma stereotactic radiosurgery)
- ☐ 35.1000 (_____)

c. Describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.

Description of Training	Training Provided By	Dates of Training*
Radiation safety, regulatory issues, and emergency procedures for 35.100, 35.200, and 35.500 uses	Institute for Nuclear medical education Boulder, Co	2/02 & 6/02
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses	" "	2/02 & 6/02
Radiation safety, regulatory issues, and emergency procedures for 35.400 uses	" "	2/02 & 6/02
Radiation safety, regulatory issues, and emergency procedures for 35.600 - teletherapy uses	" "	2/02 & 6/02
Radiation safety, regulatory issues, and emergency procedures for 35.600 - remote afterloader uses	" "	2/02 & 6/02
Radiation safety, regulatory issues, and emergency procedures for 35.600 - gamma stereotactic radiosurgery uses	" "	2/02 & 6/02
Radiation safety, regulatory issues, and emergency procedures for 35.1000, specify use(s):	" "	2/02 & 6/02

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

AND

Third Section
Complete for ALL

☑ I attest that Thomas Knox, MD has achieved a level of radiation safety knowledge
Name of Proposed Radiation Safety Officer

sufficient to function independently as a Radiation Safety Officer for a medical use licensee.

Fourth Section
Complete the following for Preceptor Attestation and signature

I am the Radiation Safety Officer for _____
Name of Facility

License/Permit Number: _____

Name of Preceptor	Signature	Telephone Number	Date
	Thomas D Knox MD	860-547-1489	7/10/08

NRC FORM 313A (RSO) (2-2007) | U.S. NUCLEAR REGULATORY COMMISSION

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.50]

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

Name of Proposed Radiation Safety Officer

Requested Authorization(s) *The license authorizes the following medical uses (check all that apply)*:

☐ 35.100 ☒ 35.200 ☐ 35.300 ☐ 35.400 ☐ 35.500 ☐ 35.600 (remote afterloader)
☐ 35.600 (teletherapy) ☐ 35.600 (gamma stereotactic radiosurgery) ☐ 35.1000 ( )

PART I -- TRAINING AND EXPERIENCE
(Select one of the four methods below)

*Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

☐ **1. Board Certification**

a. Provide a copy of the board certification.

b. Use Table 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.

c. Skip to and complete Part II Preceptor Attestation.

OR

☐ **2. Current Radiation Safety Officer Seeking Authorization to Be Recognized as a Radiation Safety Officer for the Additional Medical Uses Checked Above**

a. Use the table in section 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for the additional types of medical use for which recognition as RSO is sought.

b. Skip to and complete Part II Preceptor Attestation.

OR

☒ **3. Structured Educational Program for Proposed Radiation Safety Officer**

a. Classroom and Laboratory Training

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	Institute for Nuclear medical education Boulder, CO	100	2/02 6/02
Radiation protection	" "	30	2/02 6/02
Mathematics pertaining to the use and measurement of radioactivity	" "	20	2/02 6/02
Radiation biology	" "	20	2/02 6/02
Radiation dosimetry	" "	30	2/02 6/02
Total Hours of Training:	200		

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

b. Supervised Radiation Safety Experience
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Training/ License or Permit Number of Facility	Dates of Training*
Shipping, receiving, and performing related radiation surveys		
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides		
Securing and controlling byproduct material		
Using administrative controls to avoid mistakes in administration of byproduct material		
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures		
Using emergency procedures to control byproduct material		
Disposing of byproduct material		
Licensed Material Used (e.g., 35.100, 35.200, etc.)+ _____ _____ _____ _____		

+ Choose all applicable sections of 10 CFR Part 35 to describe radioisotopes and quantities used: 35.100, 35.200, 35.300, 35.400, 35.500, 35.600 remote afterloader units, 35.600 teletherapy units, 35.600 gamma stereotactic radiosurgery units, emerging technologies (provide list of devices).

THE CERTIFICATION BOARD OF NUCLEAR CARDIOLOGY

Incorporated 1996

CERTIFIES THAT

Thomas I. Knox, MD

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 2002 THROUGH 2012

Mark D. Carqueville
PRESIDENT

SECRETARY

CERTIFICATE # 2433

CBNC

OCTOBER 20, 2002

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

c. Training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license (continued)

Supervising Individual *If training was provided by supervising RSO, AU, AMP, or ANP. (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)*	License/Permit Number listing supervising individual

License/Permit lists supervising individual as:

☐ Radiation Safety Officer ☐ Authorized User ☐ Authorized Nuclear Pharmacist

☐ Authorized Medical Physicist

Authorized as RSO, AU, ANP, or AMP for the following medical uses:

☐ 35.100 ☒ 35.200 ☐ 35.300 ☐ 35.400

☐ 35.500 ☒ 35.600 (remote afterloader) ☐ 35.600 (teletherapy)

☐ 35.600 (gamma stereotactic radiosurgery) ☐ 35.1000 (_____)

d. Skip to and complete Part II Preceptor Attestation.

OR

☒ **4. Authorized User, Authorized Medical Physicist, or Authorized Nuclear Pharmacist identified on the licensee's license**

a. Provide license number.

b. Use the table in section 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.

c. Skip to and complete Part II Preceptor Attestation.

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

First Section
Check one of the following:

☐ **1. Board Certification**

☐ I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Radiation Safety Officer

10 CFR 35.50(a)(1)(i) and (a)(1)(ii); or 35.50 (a)(2)(i) and (a)(2)(ii); or 35.50(c)(1).

OR

☐ **2. Structured Educational Program for Proposed Radiation Safety Officers**

☐ I attest that _____ has satisfactorily completed a structural educational
Name of Proposed Radiation Safety Officer

program consisting of both 200 hours of classroom and laboratory training and one year of full-time radiation safety experience as required by 10 CFR 35.50(b)(1).

OR

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
	For an individual qualifying under 10 CFR 35.50(b):	
	Description of the training and experience specified in 10 CFR 35.50(b) demonstrating that the proposed RSO is qualified by training and experience as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.	☒
	AND	
	Description of the training and experience specified in 10 CFR 35.50(e) demonstrating that the proposed RSO is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.	☒
	AND	
	Written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed the required training and experience specified in 10 CFR 35.50(b), as well as the training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval, and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.	☒
	AND	
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☒
	For an individual qualifying under 10 CFR 35.50(c)(1):	
	Copy of the certification(s) as a medical physicist by a board whose certification process has been recognized[11] by the NRC or an Agreement State under 10 CFR 35.51(a) and description of the experience specified in 10 CFR 35.50(c)(1) demonstrating that the proposed RSO is qualified by experience as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.	☐
	AND	
	Description of the training and experience specified in 10 CFR 35.50(e) demonstrating that the proposed RSO is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO.	☐
	AND	

[11]The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Web site http://www.nrc.gov/materials/miau/med-use-toolkit.html.

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
	Written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed the required training and experience specified for certification, as well as training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval, and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO. **AND**	☐
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐
	For an individual qualifying under 10 CFR 35.50(c)(2):	
	Copy of the licensee's license indicating that the individual is an AU, AMP, or ANP identified on the licensee's license and has experience with radiation safety aspects of similar types of use of byproduct material for which the applicant seeks approval of an individual to serve as RSO. **AND**	☐
	Description of the training and experience specified in 10 CFR 35.50(e) demonstrating that the proposed RSO is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of an individual to serve as RSO. **AND**	☐
	Written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed the requirements in 10 CFR 35.50(c)(2), as well as training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval, and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO. **AND**	☐
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 9: Facility Diagram	A diagram is enclosed that describes the facilities and identifies activities conducted in all contiguous areas surrounding the area(s) of use. The following information is included:	☒
	• Drawings should be to scale, and indicate the scale used.	☒
	• Location, room numbers, and principal use of each room or area where byproduct material is prepared, used or stored, as provided above under the heading "Discussion";	☒
	• Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms; indicate whether the room is a restricted or unrestricted area as defined in 10 CFR 20.1003; and	☒
	• Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, including a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy including the dimensions of any portable shield, if one is used; source storage safe, etc.).	☒
	In addition to the above, for teletherapy and GSR facilities, applicants should provide the directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation.	☐
Item 9: Radiation Monitoring Instruments	A statement that: "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations." **AND/OR**	☒
	A statement that: "We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61." **AND**	☐
	A description of the instrumentation (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys. **AND**	☒
	A statement that: "We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used."	☒

ON OU floor plan

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal
(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 9: Dose Calibrator and Other Dosage Measuring Equipment	A statement that: "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."	☒
Item 9: Therapy Unit - Calibration and Use	We are providing the procedures required by 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645, if applicable to the license application.	☐ NO
Item 9: Other Equipment and Facilities	Attached is a description identified as Attachment 9.4, of additional facilities and equipment.	☐
	For manual brachytherapy facilities, we are providing a description of the emergency response equipment.	☐ NO
	For teletherapy, GSR, and remote afterloader facilities, we are providing a description of the following:	
	• Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room;	☐
	• Area radiation monitoring equipment;	☐
	• Viewing and intercom systems (except for LDR units);	☐
	• Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) are in the treatment room;	☐
	• Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons; and	☐
	• Emergency response equipment.	☐
Item 10. Safety Procedures and Instructions	Attached procedures required by 10 CFR 35.610	☐
Item 10: Occupational Dose	A statement that: "Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under "Criteria" in NUREG-1556, Vol. 9, Rev. 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees." **OR**	☒
	A description of an alternative method for demonstrating compliance with the referenced regulations.	☐

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal
(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 10: Area Surveys	A statement that: "We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70."	☒
Item 10: Safe Use of Unsealed Licensed Material	A statement that: "We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301."	☒
Item 10: Spill Procedures	A statement that: "We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101."	☒
Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources	Name of the proposed employee and types of activities requested: NC Systems, Inc. **AND**	☒
	Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested. **AND**	☐
	Copy of the manufacturer's training certification and an outline of the training in procedures to be followed.	☐
Item 10: Minimization of Contamination	A response is not required under the following condition: the NRC will consider that the above criteria have been met if the information provided in applicant's responses satisfy the criteria in Sections 8.14, 8.15, 8.20, 8.24, 8.26, and 8.28, on the topics: Facility and Equipment; Facility Diagram; Radiation Protection Program; Safety Program; and Waste Management.	N/A
Item 11: Waste Management	A statement that: "We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of Subpart K to 10 CFR Part 20 and 10 CFR 35.92."	☒