College Fields MRI and Medical Imaging
Terry D. Shaffer, MD and Associates
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MS-16

Materials Licensing Branch
U.S. NRC, Region I
Attention: Tara Weigner
475 Allendale Road
King of Prussia, PA 19406-1415

37-31198-01
03037360

November 16, 2006

RE: Control # 139607

Dear Ms. Weigner:

I understand that you had a telephone conversation with Mr. Charles Anthony Giomuso, MS, our Medical Physicist the other day regarding our license application. The following paragraphs will help to address any other issues that you might have.

1. Enclosed please find the checklist that has been completed which indicates the possession limits for radioactive materials that we plan on utilizing.

2. The old file room that is indicated on a more complete diagram of our office is the hot lab. It does have a lockable door to avoid any inadvertent entry by the general public.

3. Mr. Charles Anthony Giomuso, MS has been given the authority to act as the Radiation Safety Officer of our nuclear laboratory. As such, he or his associates will visit our department on a quarterly basis to review the entire radiation safety program. Any problems or issues that are uncovered will be addressed and corrected by management of College Fields MRI and Medical Imaging. There will be a written report of all findings that will follow each visit to the department and available for the NRC to review.

All of the appropriate equipment has been or will be purchased for routine use in the department prior to opening. In the event that any additional funds are needed to maintain the program ALARA will be discussed and decided among the management and RSO to determine if funds need to be released.

139607
NMSS/RGN1 MATERIALS-002

Mr. Giomuso does serve as Radiation Safety Officer at other locations in Pennsylvania and near the Ohio border. This is a full time business of which he is President and as such, can direct any of the associates to assist with items of radiological concern should they arise.

College Fields MRI and Medical Imaging will utilize the qualified Nuclear Medicine Technologist to act as the in house point of contact person to communicate any problems or issues directly to the RSO.

Charles Anthony Giomuso, MS is available via telephone (216-272-4669) 24 hours a day and can be reached via voice mail as well (888-934-1871). Fax (440-256-0056) and e-mail cag7ampr@adelphia.net are also available to us within the department. Mr. Giomuso's office is approximately 45 – 60 minutes away from our location, so in the event of an emergency, he can reasonably be on site within 2 hours.

I trust that this information will assist you in completing the review of our application. Should you have any questions regarding this letter, please feel free to contact Mr. Giomuso at the above indicated cell number.

Sincerely,

Terry D. Shaffer, M.D.

enclosures

Table C.2 outlines the detailed responses that may be made to Items 5 and 6 on Form 313 for type of radioactive material requested and purposes for which it will be used. For example, if the applicant is seeking a license for unsealed byproduct material under 10 CFR 35.100 or 35.200, then the applicant should check the "yes" column next to 10 CFR 35.100 and 35.200 in Table C.2. The table then indicates appropriate responses for that type of use. An applicant may copy the checklist and include it in the license application.

Table C.2 Items 5 and 6 on NRC Form 313: Radioactive Material And Use

(If using this checklist, check applicable rows and fill in details, and attach copy of checklist to the application.)

Yes	Radionuclide	Form of Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
✓	Any byproduct material permitted by 10 CFR 35.100	Any	As needed	Any uptake, dilution, and excretion study permitted by 10 CFR 35.100.
✓	Any byproduct permitted by 10 CFR 35.200	Any	As needed	Any imaging and localization study permitted by 10 CFR 35.200
✓	Any byproduct material permitted by 10 CFR 35.300	Any	50 millicuries	Any radiopharmaceutical therapy procedure permitted by 10 CFR 35.300.
	Iodine-131	Any	___ millicuries	Administration of I-131 sodium iodide.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide ________)	Sealed source or device (Manufacturer ____________, Model No.______)	___ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide ________)	Sealed source or device (Manufacturer ____________, Model No.______)	___ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide ________)	Sealed source or device (Manufacturer ____________, Model No.______)	___ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide ________)	Sealed source or device (Manufacturer ____________, Model No.______)	___ millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Strontium-90	Sealed source or device (Manufacturer ____________, Model No.______)	___ millicuries	Treatment of superficial eye conditions using an applicator distributed pursuant to 10 CFR 32.74 and permitted by 10 CFR 35.400.

Table C.2 (continued)

Yes?	Radionuclide	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
	Byproduct material permitted by 10 CFR 35.500 Check all that apply: ☐ Gd-153; ☐ I-125; ☐ Other, describe	Sealed source or device (Manufacturer _____, Model No.____)	___ curies per source and ___ curies total	Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g)
	Iridium-192	Sealed source or device (Manufacturer _____, Model No.____)	___ curies per source and ___ curies total	One source for medical use permitted by 10 CFR 35.600, in a Manufacturer _____ Model No. _____ remote afterloading brachytherapy device. One source in its shipping container as necessary for replacement of the source in the remote afterloader device.
	Cobalt-60	Sealed source or device (Manufacturer _____, Model No.____)	___ curies per source and ___ curies total	One source for medical use permitted by 10 CFR 35.600, in a Manufacturer _____ Model No. _____ teletherapy unit. One source in its shipping container as necessary for replacement of the source in the teletherapy unit.
	Cobalt-60	Sealed source or device (Manufacturer _____, Model No.____)	___ curies per source and ___ curies total	For medical use permitted by 10 CFR 35.600, in a Manufacturer _____ Model No. _____ stereotactic radiosurgery device. Sources in the shipping container as necessary for replacement of the sources in the stereotactic radiosurgery device.
	Any byproduct material under 10 CFR 31.11	Prepackaged kits	___ millicuries	*In vitro* studies.
	Depleted uranium	Metal	___ kilograms	Shielding in a teletherapy unit.

Table C.2 (continued)

Yes	Radionuclide	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
	Depleted uranium	Metal	___ kilograms	Shielding in a linear accelerator.
	Any radionuclide in excess of 30 millicuries for use in calibration, transmission, and reference sources. (List radionuclide: _____)	Sealed source or device (Manufacturer _____, Model No._____)	___ millicuries	For use in a Manufacturer _____Model No._____ for calibration and checking of licensee's survey instruments.
	Americium-241	Sealed source or device (Manufacturer _____, Model No._____)	___ millicuries per source and ___ millicuries total	Use as an anatomical marker.
	Plutonium (principal radionuclide Pu-238)	Sealed sources	___ millicuries per source and ___ grams total	As a component of Manufacturer _____Model No._____, nuclear-powered cardiac pacemakers for clinical evaluation in accordance with manufacturer's protocol dated _____. This authorization includes: follow-up, explantation, recovery, disposal, and implantation.
	Other	Form or Manufacturer/ Model No.	___ millicuries	Purpose of use

Table C.3 is a checklist that may be used to identify the attached documents that the applicant is supplying for items for which a response is required. For example, an applicant may fill in the name(s) of Radiation Safety Officer in Table C.3 and then check the boxes indicating which documents pertaining to the RSO are being included in the license application. An applicant may copy the checklist and include it in the license application.

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 7: Radiation Safety Officer Name: Charles Anthony Giordano Medical Physicist	Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) that authorized the uses requested and on which the individual was specifically named as the RSO.	☑
	OR	
	Copy of the certification(s) for the board(s) recognized by NRC and as applicable to the types of use for which he or she has RSO responsibilities.	☐
	OR	
	Description of the training and experience specified in 10 CFR 35.900(b).	☐
	OR	
	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 he or she has RSO responsibilities.	☐
	AND	
	Written certification, signed by a preceptor RSO, that the above training and experience has been satisfactorily completed and that a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use licensee has been achieved.	☐
	AND	
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐

Table C.3 (continued)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 7: Authorized Users Names and Requested Uses for Each Individual Kerry D. Shapper, MD Gerald Stanley, MD	Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the physician was specifically named as an AU for the uses requested.	X
	OR	
	Copy of the certification(s) for the board(s) recognized by NRC under 10 CFR Part 35, Subparts D, E, F, G, H, and as applicable to the use requested.	☐
	OR	
	Description of the training and experience identified in 10 CFR Part 35 Subpart J demonstrating that the proposed AU is qualified by training and experience for the use requested.	☐
	OR	
	A description of the training and experience identified in 10 CFR Part 35 Subparts D, E, F, G, and H demonstrating that the proposed AU is qualified by training and experience for the use requested;	☐
	AND	
	Written certification, signed by a preceptor physician AU, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an AU for the medical uses authorized has been achieved.	☐
	AND	
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐
Item 7: Authorized Nuclear Pharmacists Names: _____	Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the individual was specifically named ANP.	☐
	OR	
	Copy of the certification(s) for the radiopharmacy board(s) recognized by NRC under 10 CFR 35.55(a) or 10 CFR 35.980(a).	☐
	OR	
	Description of the training and experience demonstrating that the proposed ANP is qualified by training and experience.	☐
	AND	
	Written certification, signed by a preceptor ANP, that the above training and experience has been satisfactorily completed and that a level of competency • sufficient to function independently as an ANP has been achieved (10 CFR 35.55), or • sufficient to independently operate a nuclear pharmacy (10 CFR 35.980).	☐
	AND	
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐

Table C.3 (continued)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 7: Authorized Medical Physicists Names: _____	Previous license number (if issued by NRC) or a copy of the license (if issued by an Agreement State) on which the individual was specifically named as an AMP for the units requested. **OR**	☐
	Copy of the certification(s) for the board(s) recognized by NRC in 10 CFR 35.51(a) or 10 CFR 35.961(a) or (b). **OR**	☐
	Description of the training and experience demonstrating that the proposed AMP is qualified by training and experience identified in 10 CFR 35.961(c) for the units requested. **OR**	
	Description of the training and experience demonstrating that the proposed AMP is qualified by training and experience identified in 10 CFR 35.51(b) for the units requested. **AND**	☐
	Written certification, signed by a preceptor AMP, that the above training and experience has been satisfactorily completed and that a level of competency sufficient to function independently as an AMP has been achieved. **AND**	☐
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐
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:	☒ Previously Submitted
	• 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.	☐

Table C.3 (continued)

Item Number and Title	Suggested Response	Check box to indicate material included in application
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."	☒
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.	☒
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.	☐
	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.	☒

Table C.3 (continued)

Item Number and Title	Suggested Response	Check box to indicate material included in application
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, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees," dated October 2002." **OR** A description of an alternative method for demonstrating compliance with the referenced regulations.	X ☐
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."	X
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."	X
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."	X
Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of *Therapy Devices Containing* Sealed Sources	Name of the proposed employee and types of activities requested: _____ **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."	X