Regional Radiology P.A.
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X-Ray • CT Scan • Fluoroscopy • Mammography • Open MRI • Bone Densitometer • Nuclear Medicine • Ultrasound • Color Doppler

MS16
K-8

February 28, 2005

Sandra Gabriel, Ph.D.
Senior Health Physicist
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

03036724

Re: NRC License No. 29-30983-01
Control No. 136191

Dear Dr. Gabriel:

I have enclosed a description of our byproduct materials program as you requested. Our authorized use will be restricted to radiopharmaceuticals specified in 10 CFR 35.200 exclusive of generators and gas.

If you need additional information please contact me at your earliest convenience.

Sincerely,

Satish P. Shah, M.D.
Administrator

136191

NMSS/RGN1 MATERIALS-002

New Albany Professional Center • 2800 Route 130 North • Suite 202 • Cinnaminson, New Jersey 08077
Phone (856) 786-7044 • Fax (856) 786-7079

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NRC LICENSE NO. 29-30983-01

BYPRODUCT MATERIALS PROGRAM – FEBRUARY 2005

Authorized byproduct material/radiopharmaceutical: **Any identified in 35.200 except generators and gas.**

Maximum possession limit: **As needed.**

Authorized use: **Any imaging and localization procedure approved in 10 CFR 35.200.**

Authorized Users: **Ashokkumar Baharia, M.D.** (presently on license 29-30289-01)
Satish P. Shah, M.D. (presently on license 29-30289-01)

Radiation Safety Officer: **Ashokkumar Baharia, M.D.**

Equipment: Dose Calibrator – **CRC-15R**

Survey Meter – **Bicron 2000**

Well Counter – **Caprac**

Facilities diagram is attached.

Radiation Safety Program is described in the attached Table C.3.

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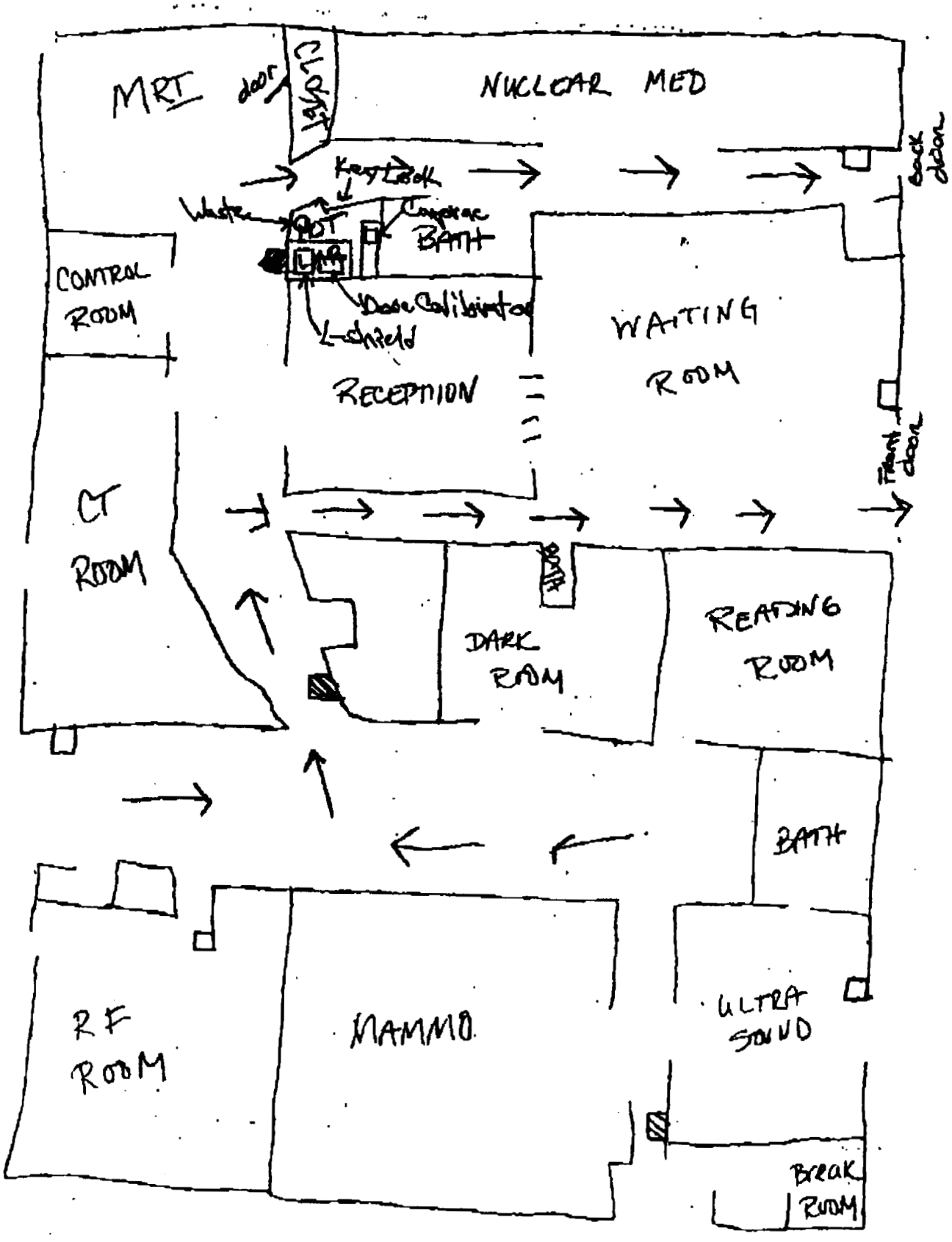

Table C.3 is a checklist that may be used to identify the attached documents that the applicant is supplying for items for which a response is required. For example, an applicant may fill in the name(s) of Radiation Safety Officer in Table C.3 and then check the boxes indicating which documents pertaining 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: [illegible] Babaian, M.D.	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.	☐

APPENDIX C

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 [illegible] Balseiro, M.D.	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.	☒
	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: N.A.	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: N.A.	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: • 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.	☒ ☐ ☐ ☐ ☐ ☐

APPENDIX C

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 N.A.	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 N.A.	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.	☒ ☐
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 N.A.	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."	☒