Culpeper
Regional Hospital
Promoting health. Preserving community.

Q-8
MS-16

May 16, 2005

U.S. Nuclear Regulatory Commission
Region 1
License Assistance Team
475 Allendale Road
King of Prussia, PA 19406-1415

Attention: Ms. Shirley Xu
Control # 136721

03020205

Re: Renewal of NRC License **45-23040-01**
Culpeper Regional Hospital, Culpeper, Virginia

Dear Ms. Xu,

Pursuant to a conversation between your office and our consulting physicist, (P. Norman Fenton, Ph. D.), I offer the following with respect to the hospital renewal application. Enclosed, please find a shortened application version of Nureg 1556. If necessary, we will submit (in the future) an amendment request for sealed sources referenced in 35.500 for camera attenuation. In addition, please find the corrected authorized user list.

Finally, please use the street address (501 Sunset Lane) as the correct hospital reference.

Sincerely,

Ms. Patricia Mullins, RN, MSN, CFNP
Senior Vice President Hospital Operations

501 Sunset Lane
P.O. Box 592
Culpeper, Virginia 22701
Phone (540) 829-4100
www.culpeperhospital.com

136721
NMSS/RGN1 MATERIALS-002

Table C.2 - Request for License - *Culpeper Regional Hospital*

Yes	Radionuclide	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
X	Any byproduct material permitted by 10 CFR 35.100	Any	As needed	Any uptake, dilution, and excretion study permitted by 10 CFR 35.100.
X	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		Any radiopharmaceutical therapy procedure permitted by 10 CFR 35.300.
	Iodine-131	Any	millicuries	Administration of I-131 sodium iodide.
	Byproduct material under 10 CFR 35.400 (Radionuclide)	Sealed source or device (Manufacturer , Model No.)	millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material under 10 CFR 35.400 ( )	Sealed source or device (Manufacturer, Model)	millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material under 10 CFR 35.400 (Radionuclide)	Sealed source or device (Manufacturer , Model No.)	millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material under 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.

Yes	Radionuclide	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
	Byproduct material under 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.
X	Any byproduct material under 10 CFR 31.11	Prepackaged kits	**5.0 millicuries**	*In vitro* studies.
	Depleted uranium	Metal	kilograms	Shielding in a teletherapy unit.

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 - Renewal of License 45-19273-01 - ***Community Memorial Hospital***

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 7: Radiation Safety Officer Name: **David R. Weber, M.D.** currently listed as authorized user under NRC license # 45-23040-01	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.	X
	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.	___

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 **See attached list**	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.	X ___ ___ ___ ___
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.	___ ___ ___ ___

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: • 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.	X X X X ____ ____

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."	X ___ ___ ___
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."	X
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; and • Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons. • Emergency response equipment.	___ ___ ___ ___ ___ ___ ___ ___
Item 10. Safety Procedures and Instructions	Attached procedures required by 10 CFR 35.610	___

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

Facilities and Equipment

Nuclear medicine/cardiology is located on the second floor of a medical building. Nuclear medicine is made up of a camera room, stress lab and a hot lab (see diagrams below). Lead bricks and small pigs are used to shield specific sources in the hot lab. Shielded trash cans and pigs are used for short-term decay for disposal. The hot lab is equipped with a leaded L-shield and a lead cave for bench top storage.

FACILITY DIAGRAM FOR CULPEPER REGIONAL HOSPITAL

PREVIOUSLY SUBMITTED

AUTHORIZED USER / RADIATION SAFETY OFFICER

Radioactive materials will be used by or under the supervision of the following:

ATT 7.1.1 David R. Weber, M.D.	(*)License No.: 45-23040-01 10 CFR 35.100; 35.200; 31.11; 35.500
7.1.2 Toby Louis Brown, M.D.	License No.: 45-23040-01 10 CFR 35.100; 35.200; 31.11; 35.500
7.1.3 Linda H. Daniel, M.D.	License No.: 45-23040-01 10 CFR 35.100; 35.200; 31.11; 35.500
7.1.4 Keith Hellems, M.D.	License No.: 45-23040-01 10 CFR 35.100; 35.200; 31.11; 35.500
7.1.5 Todd H. Hillman, M.D.	License No.: 45-23040-01 10 CFR 35.100; 35.200; 31.11; 35.500
7.1.6 Philip N. Massey, M.D.	License No.: 45-23040-01 10 CFR 35.100; 35.200; 31.11; 35.500
7.1.7 Stephen L. Miller, M.D.	License No.: 45-23040-01 10 CFR 35.100; 35.200; 31.11; 35.500
7.1.8 James Koepke, M.D.	License No.: 45-23040-01 10 CFR 35.100; 35.200; 31.11; 35.500
7.1.9 Patrick F. Zazzaro, M.D.	License No.: 45-23040-01 10 CFR 35.100; 35.200; 31.11; 35.500
7.1.10 Margaret M. Sanders, M.D.	License No.: 45-23040-01 10 CFR 35.100; 35.200; 31.11; 35.500
7.1.11 Douglas J. Markert, M.D.	License No.: 45-23040-01 10 CFR 35.100; 35.200; 31.11; 35.500
7.1.12 Ravi M. Giyanahi, M.D.	License No.: 45-23040-01 10 CFR 35.100; 35.200; 31.11; 35.500
7.1.13 Duyanh T. Vu, M.D.	License No.: 45-23040-01 10 CFR 35.100; 35.200; 31.11; 35.500
7.1.14 Jennifer T. Wargo, M.D.	License No.: 45-23040-01 10 CFR 35.100; 35.200; 31.11; 35.500
7.1.15 David Perlmutter, M.D.	License No.: 45-23040-01 10 CFR 35.100; 35.200; 31.11; 35.500
7.1.16 Maria E. Pace, M.D.	License No.: 45-23040-01 10 CFR 35.100; 35.200; 31.11; 35.500
7.1.17 Pamela Philips, M.D.	License No.: 45-23040-01 10 CFR 35.100; 35.200; 31.11; 35.500
7.1.18 John P. Schreiber, M.D.	License No.: 45-23040-01 10 CFR 35.100; 35.200; 31.11; 35.500
7.1.19 Michael B. Robins, M.D.	License No.: 45-23040-01 10 CFR 35.100; 35.200; 31.11; 35.500
7.1.20 Craig C. Jonas, M.D.	License No.: 45-23040-01 10 CFR 35.100; 35.200; 31.11; 35.500
7.1.21 Stephanie Mendlow, M.D.	License No.: 45-23040-01 10 CFR 35.100; 35.200; 31.11; 35.500
7.1.22 Edwin H. Kim, M.D.	License No.: 45-23040-01 10 CFR 35.100; 35.200; 31.11; 35.500

(*) Radiation Safety Officer

Training and experience documentation is already on file under this license.