



June 21, 2007



UNITED STATES NUCLEAR REGULATORY COMMISSION
Region III, Materials Licensing Section
2443 Warrenville Road
Suite 210
Lisle, IL 60532-4352

Re: Amendment for license No. 21-03194-01, E.L. Bixby Medical Center

1. Please amend our license to add Faheem Ahmad, M.D., Rajender K. Ahuja, M.D., Wayne S. Court, M.D., John Feldmeier, M.D., Harold A. Johnson, M.D., Gerald W. Marsa, M.D. William K Mueller, M.D. Steven J. Rubin, M.D. and Steven R. Zeidner, M.D. to our license for 35.300. They are currently listed as an authorized user on the Ohio Department of Health License for Radioactive Material license number 02120490004 for 3701:1-58-37 Use of unsealed radioactive material for which a written directive is required. . A copy of this license is enclosed for your review. They are already approved on our license for 35.400.

Thank you for your cooperation.

Sincerely,

A handwritten signature in cursive script, appearing to read "Carol Boyce".

Administration
E.L. Bixby Medical Center

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OHIO DEPARTMENT OF HEALTH

LICENSE FOR RADIOACTIVE MATERIAL

Pursuant to Chapter 3748 of the Ohio Revised Code, and in reliance on statements and representations made by the licensee, a license is hereby issued authorizing the licensee named herein to receive, acquire, possess, and transfer radioactive material as designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the applications of Chapter 3748 of the Ohio Revised Code and all applicable rules promulgated thereunder. This license is subject to all applicable rules, regulations and orders of the Ohio Department of Health now or hereinafter in effect and to any conditions specified below.

LICENSEE		LICENSE NUMBER
1. Flower Hospital		3. 02120490004
		EXPIRATION DATE
2. 5200 Harroun Road Sylvania, Ohio 43560-2196		4. August 1, 2008
		BUREAU DOCKET NUMBER
		5. AC51-12-97

6. RADIOACTIVE MATERIAL	7. CHEMICAL AND/OR PHYSICAL FORM	8. MAXIMUM QUANTITY THAT LICENSEE MAY POSSESS AT ANY ONE TIME UNDER THIS LICENSE
A. Any radioactive material permitted by rule 3701:1-58-32 of the Ohio Administrative Code	A. Any radiopharmaceutical	A. As needed. Not to exceed 3.7 GBq (100 mCi) Cobalt-57
B. Any radioactive material permitted by rule 3701:1-58-34 of the Ohio Administrative Code	B. Any radiopharmaceutical	B. As needed
C. Any radioactive material permitted by rule 3701:1-58-37 of the Ohio Administrative Code	C. Any radiopharmaceutical	C. As needed
D. Any radioactive material permitted by rule 3701:1-58-43 of the Ohio Administrative Code	D. Any brachytherapy sources	D. As needed
E. Any radioactive material permitted by rule 3701:1-46-11 of the Ohio Administrative Code	E. Prepackaged Kits	E. As needed
F. Yttrium-90	F. Any form	F. 4.1 GBq (110 mCi)
G. Uranium depleted in Uranium-235	G. Cadmium plated metal	G. As needed
H. Iridium-192 permitted by rule 3701:1-58-43 of the Ohio Administrative Code	H. Brachytherapy Source Wire (Amersham Model ICW.100)	H. Not to exceed 7.4 GBq (200 millicuries) per source wire. Total possession not to exceed 11.1 GBq (300 millicuries)

9. Authorized Use

- Any uptake, dilution and excretion study permitted by rule 3701:1-58-32 of the Ohio Administrative Code.
- Any imaging and localization study as permitted by rule 3701:1-58-34 of the Ohio Administrative Code.
- Any medical use permitted by rule 3701:1-58-37 of the Ohio Administrative Code.
- Any brachytherapy sources for therapeutic medical use permitted by rule 3701:1-58-43 of the Ohio Administrative Code.
- In vitro studies permitted by rule 3701:1-46-11 of the Ohio Administrative Code.

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9. Authorized Use

- F. Calibration and reference source for Yttrium-90 Zevalin use.
- G. Shielding in a linear accelerator.
- H. Therapeutic medical use as permitted by rule 3701:1-58-43 of the Ohio Administrative Code.

 CONDITIONS

10. Licensed material may only be used at the licensee's facilities located at:

Flower Hospital
 5200 Harroun Road
 Sylvania, Ohio 45360-2196

Lake Park Continuing Care Facility
 5100 Harroun Road
 Sylvania, Ohio 45360-2196

(diagnostic/therapeutic administration of
 radiopharmaceuticals only)

11. Radiation Safety Officer for this licensee is:

James C. Burns, M.S.

12. Licensed material is only authorized for use by, or under the supervision of:

1. Individuals permitted to work as an authorized user, authorized nuclear pharmacist, and / or authorized medical physicist in accordance with rule 3701:1-58-08 and 3701:1-58-09 of the Ohio Administrative Code.
2. The following individuals are authorized users for the material and medical uses indicated:

Authorized User	Material and Uses
A. Dohra S. Achinger, M.D.	A. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 of the Ohio Administrative Code.
B. Faheem Ahmad, M.D.	B. Uses permitted by rules 3701:1-58-37 and 3701:1-58-43 of the Ohio Administrative Code.
C. Rajender K. Ahuja, M.D.	C. Uses permitted by rules 3701:1-58-37 and 3701:1-58-43 of the Ohio Administrative Code.
D. Wayne S. Court, M.D.	D. Uses permitted by rules 3701:1-58-37 and 3701:1-58-43 of the Ohio Administrative Code.
E. Amy Culler, M.D.	E. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 of the Ohio Administrative Code.
F. Robert S. Disalle, M.D.	F. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-46-11 of the Ohio Administrative Code.
G. Malcom T. Doyle, M.D.	G. Uses permitted by rules 3701:1-58-32, 3701:1-58-34, 3701:1-58-37 and 3701:1-46-11 of the Ohio Administrative Code.
H. John Feldmeier, M.D.	H. Uses permitted by rules 3701:1-58-37 and 3701:1-58-43 of the Ohio Administrative Code.
I. James A. Fugazzi, M.D.	I. Uses permitted by rules 3701:1-58-37 and 3701:1-58-43 of the Ohio Administrative Code.
J. Murray A. Howe, M.D.	J. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-46-11 of the Ohio Administrative Code.
K. Harold A. Johnson, M.D.	K. Uses permitted by rules 3701:1-58-37 and 3701:1-58-43 of the Ohio Administrative Code.

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L. Allan S. Kaufman, M.D.	L. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-46-11 of the Ohio Administrative Code.
M. Blaine A. Keigley, M.D.	M. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-46-11 of the Ohio Administrative Code.
N. Vincent J. Keiser, M.D.	N. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-46-11 of the Ohio Administrative Code.
O. Steven Kumar-Jindal, M.D.	O. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 of the Ohio Administrative Code.
P. Chun Ji Mah, M.D.	P. Uses permitted by rules 3701:1-58-37 and 3701:1-58-43 of the Ohio Administrative Code.
Q. Gerald W. Marsa, M.D.	Q. Uses permitted by rules 3701:1-58-37 and 3701:1-58-43 of the Ohio Administrative Code.
R. Tamara S. Martin, M.D.	R. Uses permitted by rules 3701:1-58-32, 3701:1-58-34, 3701:1-58-37 and 3701:1-46-11 of the Ohio Administrative Code.
S. William K. Mueller, M.D.	S. Uses permitted by rules 3701:1-58-37 and 3701:1-58-43 of the Ohio Administrative Code.
T. William G. Novak, M.D.	T. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-46-11 of the Ohio Administrative Code.
U. Dhaval Kirit Parikh, M.D.	U. Uses permitted by rules 3701:1-58-37 and 3701:1-58-43 of the Ohio Administrative Code.
V. Parag U. Parikh, M.D.	V. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-46-11 of the Ohio Administrative Code.
W. David A. Parker, M.D.	W. Uses permitted by rules 3701:1-58-32, 3701:1-58-34, 3701:1-58-37 and 3701:1-46-11 of the Ohio Administrative Code.
X. Charles I. Price, M.D.	X. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-46-11 of the Ohio Administrative Code.
Y. Timothy J. Quinn, M.D.	Y. Uses permitted by rules 3701:1-58-32, 3701:1-58-34, 3701:1-58-37 and 3701:1-46-11 of the Ohio Administrative Code.
Z. Steven J. Rubin, M.D.	Z. Uses permitted by rules 3701:1-58-37 and 3701:1-58-43 of the Ohio Administrative Code.
AA. Robin B. Shorris, M.D.	AA. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-46-11 of the Ohio Administrative Code.
BB. Daniel Singer, M.D.	BB. Uses permitted by rules 3701:1-58-32, 3701:1-58-34, 3701:1-58-37 and 3701:1-46-11 of the Ohio Administrative Code.
CC. Ibrahim Naveed Syed, M.D.	CC. Uses permitted by rules 3701:1-58-32, 3701:1-58-34, 3701:1-58-37 (limited to the treatment of hyperthyroidism) and 3701:1-46-11 of the Ohio Administrative Code.
DD. Stephen F. Stoll, M.D.	DD. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and oral administration of sodium iodide Iodine-131 as permitted in rule 3701:1-58-37 of the Ohio Administrative Code.
EE. Keith D. Wilson, M.D.	EE. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-46-11 of the Ohio Administrative Code.

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Authorized User	Material and Uses
FF. Jonathan J. Yobbagy, M.D.	FF. Uses permitted by rules 3701:1-58-32, 3701 1-58-34 and 3701:1-46-11 of the Ohio Administrative Code.
GG. Steven R. Zeldner, M.D.	GG. Uses permitted by rules 3701:1-58-37 and 3701:1-58-43 of the Ohio Administrative Code.
<p>13. All persons performing activities meeting the definition of "Nuclear Medicine Technologists" as specified in R.C. 4773.01 shall be licensed and in good standing with the State of Ohio.</p> <p>14. All sealed sources that are used or obtained shall have been evaluated and approved under the provisions of rule 3701:1-46-49 of the Ohio Administrative Code or by equivalent NRC, Agreement State, or NARM licensing state regulation.</p> <p>The licensee shall establish and implement a bioassay program for all individuals involved with preparation and administration of Iodine-131 therapy doses in excess of 30 millicuries. The program shall be equivalent to that outlined in Appendix P of Regulatory Guide 10.8 Revision 2.</p> <p>The licensee shall maintain records of information related to decommissioning at the location listed in Item 2 of this license as specified in rule 3701:1-40-17(I) of the Ohio Administrative Code until this license is terminated by the Commission.</p> <p>15. In addition to the requirements in rule 3701:1-58-30 of the Ohio Administrative Code, any patient administered gamma emitting radiopharmaceuticals or permanent brachytherapy sources shall be provided a patient release card to include:</p> <ol style="list-style-type: none"> (1) The patient's name. (2) The radionuclide administered and its activity. (3) The facility name which administered the radionuclide. (4) The date of the administration of the radionuclide. (5) The expiration date of the card. <p>The card is not applicable to those patients who are institutionalized (Hospitals, Nursing Homes, Correctional Institutions, etc.) or whose radiation levels do not exceed 0.1 mR/hr at one meter.</p> <p>16. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of sealed source licensed material to quantities below the minimum limit specified in rule 3701:1-40-17(C) of the Ohio Administrative Code for establishing decommissioning financial assurance.</p> <p>17. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Ohio Department of Health's statutes, rules, and orders shall govern unless statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.</p>	
A. Application dated May 20, 2003.	
B. Facsimile letters dated June 16, 2003 August 5, 2003, August 12, 2003 and August 27, 2003.	
C. Amendment #13 of license 02120490004; renews license in its entirety.	
D. Letter dated October 20, 2004.	
E. Amendment to convert to rule 58 of the Ohio Administrative Code (Amendment # 15)	
F. Facsimile dated November 3, 2005 (Amendment #16)	
G. Director's Order dated April 21, 2006. (Amendment #17)	
H. Letter dated July 17, 2006 (Amendment # 18)	

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For the Ohio Department of Health

DATE:

9/7/06

BY:


Director, Ohio Department of Health

3701:1-58-37 Use of unsealed radioactive material for which a written directive is required.

A licensee may use any unsealed radioactive material prepared for medical use and for which a written directive is required that is:

- (A) Obtained from a manufacturer or preparer licensed under rule 3701:1-16-43 of the Administrative Code or equivalent United States nuclear regulatory commission, agreement state, or NARM licensing state for NARM requirements;
- (B) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in rules 3701:1-58-36 or 3701:1-58-40 of the Administrative Code, or an individual under the supervision of either as specified in rule 3701:1-58-14 of the Administrative Code;
- (C) Obtained from and prepared by an United States nuclear regulatory commission, agreement state, or NARM licensing state for NARM licensee for use in research in accordance with an investigational new drug protocol accepted by United States food and drug administration; or
- (D) Prepared by the licensee for use in research in accordance with an investigational new drug protocol accepted by United States food and drug administration.

Effective: 08/15/2005

R.C. 119.032 review dates: 08/15/2010

CERTIFIED ELECTRONICALLY

Certification

08/05/2005

Date

Promulgated Under: 119.03
Statutory Authority: 3748.02, 3748.04
Rule Amplifies: 3748.04