



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

JUL 23 1996

REGIONAL TECHNICAL ASSISTANCE REQUEST FORM

96-54
Assign to IMAS
Due 10/15/96
RM

Date: July 19, 1996

To: Don Cool, Director, Division of Industrial and Medical Nuclear Safety, NMSS

From: John Madera, Chief, Nuclear Materials Safety and Safeguards Branch, RIII

Licensee: Borgess Medical Center

License No. 21-12275-02

☐ Control No.: 301576 (enclosed)

☐ Letters dated: July 5, 1996 (enclosed)

☐ Problem/Issue: This limited scope medical licensee is requesting authorization to use phosphorus-32 for intravascular use as a cardiac stent. Therefore, an exemption from the provisions of 10 CFR35.400 appears to be needed to allow this activity.

☐ Action Required: Please review the information submitted and determine if RIII can issue the exemption with the current information provided or describe what additional information is needed.

☐ Recommended Action: RIII recommends an exemption be granted for the use of phosphorus-32 for intravascular use by physicians who meet the training and experience criteria of 10 CFR 35.940 for brachytherapy procedures.

☐ Remarks: The potential medical benefits from this new procedure provides a justification for the exemption and the licensee's radiation safety procedures appear adequate.

Headquarters Reviewer: _____

Regional Reviewer: EVELYN MATSON

Reviewer Code: R9

Reviewer Phone No.: (708)829-9822 EMAIL: ERM

Request Needed by: 8/31/96

Form TAR-10
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MATERIALS LICENSE

Amendment No. 71

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 20, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below, to use such material for the purposes and at the places designated below, to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

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Licensee		In accordance with letter dated December 11, 1995	
1. Borgess Medical Center		3. License Number 21-12275-02 is amended in its entirety to read as follows:	
2. 1521 Gull Road Kalamazoo, MI 49001		4. Expiration Date July 31, 1995	
		5. Docket or Reference No. 030-02115	
6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License	
A. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed	
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200	B. As needed	
C. Any byproduct material identified in 10 CFR 35.300	C. Any radiopharmaceutical identified in 10 CFR 35.300	C. As needed	
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy sources identified in 10 CFR 35.400	D. As needed	
E. Any byproduct material identified in 10 CFR 31.11	E. Prepackaged Kits	E. As needed	

9. Authorized Use:

- A. Medical use described in 10 CFR 35.100.
- B. Medical use described in 10 CFR 35.200.
- C. Medical use described in 10 CFR 35.300.

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- D. Medical use described in 10 CFR 35.400
- E. In vitro studies.

CONDITIONS

10. Location of use: 1521 Gull Road, Kalamazoo, Michigan.
11. Radiation Safety Officer: Tim TenCate
12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized UsersMaterial and Use

- | | |
|---------------------------------|---|
| A. Gary L. Bowman, M.D. | 10 CFR 35.100, 35.200 and 31.11. |
| B. John W. Copenhaver, M.D. | 10 CFR 35.100, 35.200, 35.500 and 31.11. |
| C. J. Alex Gardner, M.D. | 10 CFR 35.100, 35.200, 35.500 and 31.11. |
| D. Leonard A. Brunette, M.D. | 10 CFR 35.100, 35.200, 35.500 and 31.11. |
| E. Arthur Gregory Laurell, M.D. | 10 CFR 35.100, 35.200, 35.500 and 31.11. |
| F. James R. Dolan, M.D. | 10 CFR 35.100, 35.200, 35.300, 35.400 and 35.500. |
| G. Geoffrey A. Wardwell, M.D. | 10 CFR 35.100 and 35.200. |
| H. N. Warn Courtney, M.D. | 10 CFR 35.100, 35.200, 35.300 and 31.11. |
| I. Richard R. McConnell, M.D. | 10 CFR 35.100, 35.200, 35.300 (excluding iodine-131 for thyroid carcinoma), 35.500 and 31.11. |
| J. Edwardo R. Crotte, M.D. | 10 CFR 35.100, 35.200 and 31.11. |
| K. David Tague, M.D. | 10 CFR 35.100, 35.200 and 31.11. |
| L. L. Enrique Leguizamon, M.D. | 10 CFR 35.200 (limited to cardiovascular clinical procedures). |
| M. Thomas McCormick, M.D. | 10 CFR 35.100, 35.200, 35.500 and 31.11. |

COPY

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Authorized UsersMaterial and Use

N. John E. Francis, M.D.	10 CFR 35.200 (limited to cardiovascular clinical procedures).
O. Kenzo Kawamura, M.D.	10 CFR 35.200 (limited to cardiovascular clinical procedures).
P. Dennis P. Burke, M.D.	10 CFR 35.100, 35.200 and 31.11.
Q. William B. Campbell, M.D.	10 CFR 35.200 (limited to cardiovascular clinical procedures).
R. Umakant S. Doctor, M.D.	10 CFR 35.200 (limited to cardiovascular clinical procedures).
S. Yoo Sup Hwang, M.D.	10 CFR 35.400.
T. Khlid Altaf Mian, M.D.	10 CFR 35.200 (limited to cardiovascular clinical procedures).
U. Evalt Ayerdi, M.D.	10 CFR 35.200 (limited to cardiovascular clinical procedures).
V. Stephen L. Peck, M.D.	10 CFR 35.200 (limited to cardiovascular clinical procedures).
W. Robert J. LaPenna, M.D.	10 CFR 35.200 (limited to cardiovascular clinical procedures).
X. Benjamin A. Perry, M.D.	10 CFR 35.200 (limited to cardiovascular clinical procedures).
Y. Robert H. Jongeward, M.D.	10 CFR 35.100, 35.200, 35.500 and 31.11.
Z. George J. Balogh, M.D.	10 CFR 35.100, 35.200, 35.500 and 31.11.
AA. Robert B. Davis, M.D.	10 CFR 35.100, 35.200 and 35.300.
BB. Katherine Gadwood, M.D.	10 CFR 35.100, 35.200 (excluding generators) and 31.11.
CC. Charles Gregory Hodgman, M.D.	10 CFR 35.100, 35.200, 35.500 and 31.11.

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Authorized UsersMaterial and Use

DD. Janos Gellert, M.D.	10 CFR 35.200 (limited to cardiovascular clinical procedures).
EE. John A. Azevedo, M.D.	10 CFR 35.200 (limited to cardiovascular clinical procedures).
FF. Sharma Saith, M.D.	10 CFR 35.200 (limited to cardiovascular clinical procedures).
GG. Steven P. Soper, M.D.	10 CFR 31.11.
HH. Bruce D. Goethe, M.D.	10 CFR 35.100, 35.200 and 31.11.
II. Patrick A. Sorek, M.D.	10 CFR 35.100, 35.200 and 31.11.
JJ. Susan J. Phelps, M.D.	10 CFR 35.100, 35.200 and 31.11.
KK. David Lynn Keedy, M.D.	10 CFR 35.200 (limited to cardiovascular clinical procedures).
LL. Douglas J. Wunderly, M.D.	10 CFR 35.200 (limited to cardiovascular clinical procedures).
MM. Jonathan Levi, M.D.	10 CFR 35.200 (limited to cardiovascular clinical procedures).
NN. Jim Chul Kim, M.D.	10 CFR 35.300 and 35.400.
OO. Heung (Henry) Shik Shin, M.D.	10 CFR 35.300 and 35.400.
PP. David G. Brachman, M.D.	10 CFR 35.300 and 35.400.
QQ. Marc Bernstein M.D.	10 CFR 35.200 (limited to cardiovascular clinical procedures).
RR. Anthony King, M.D.	10 CFR 35.200 (limited to cardiovascular clinical procedures).
SS. Alicia Williams, M.D.	10 CFR 35.200 (limited to cardiovascular clinical procedures).
TT. Antonio P. Carrillo, M.D.	10 CFR 35.100 and 35.200 (limited to cardiovascular clinical procedures).

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Authorized Users

UU. Ramon Raneses, M.D.

Material and Use

10 CFR 35.200 (limited to cardiovascular clinical procedures).

13. The licensee will establish and implement model procedure for radiation safety during implant therapy that was published in Appendix Q to Regulatory Guide 10.8, Revision 2.
14. The licensee shall maintain records of information important to safe and effective decommissioning at the address in Condition 10. per provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.
15. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.
16. 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, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
 - A. Application dated March 20, 1990; and
 - B. Letters dated May 25, 1990 (with attachments), July 3, 1990 (with enclosures), October 17, 1990 (with attachments), and December 11, 1995.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date 1/3/96

By James Mullins
Nuclear Materials Licensing Branch, Region III

CCBY