

HACKETTSTOWN CANCER CENTER

651 Willow Grave Street
Hackettstown, New Jersey 07840-1798

Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, Pa. 19406-1415
ATTN: Ms. Sandra Gabriel

Br 1

29-16585-01

03011347

2009 APR 8 AM 10:08

R EOEI VED
STION M1

March 25, 2009

Ref: Hackettstown Cancer Center

Dear Ms Gabriel:

Per telephone conversation today with Rosemary Gallagher, Medical Physicist, attached please find documentation to **support** request for amendment to Hackettstown Regional Medical Center's License **#29-16585-01** to allow for the use of Zevalin by the following authorized users:

- 1) Michael Joseph Pereira, M.D.
- 2) Thomas M. Herskovic, M.S.

Both physicians have previously been authorized for 35.300 on NRC license **#29-10191-02**, copy attached. We are requesting authorization for **Y90** only with the maximum possession limit of **200mCi** as a reference standard and **110 mCi** for patient treatment.

Enclosed please find a facility diagram along with a commitment statement.

We are respectfully requesting that you expedite action on this request as the department **currently** has patients in need of this treatment.

I am the physicist working on this amendment. Please do not hesitate to contact me with any **further** questions. I can be reached at (917) 572-8414. Also, my fax number is: 718-720-7174 and my mailing address is:

Rosemary T. Gallagher
Compliance Consulting Services
47 Bertha Place
Staten Island, New York 10301

Thank you for your prompt response.

Sincerely,

Michael Maninaos, M.D.
Radiation Safety Officer

[Signature]
Enc.

[Signature]

Judith Wiegand
Executive Director,
Business Development and Facility Planning

143630

HACKETTSTOWN REGIONAL MEDICAL CENTER
Diagnostic Imaging Policy and Procedure

Section: Nuclear Medicine

Number: 7650.365

Number of Pages: 1 of 1

Issue Date: March 2009

Reviewed/Revised: March 2009

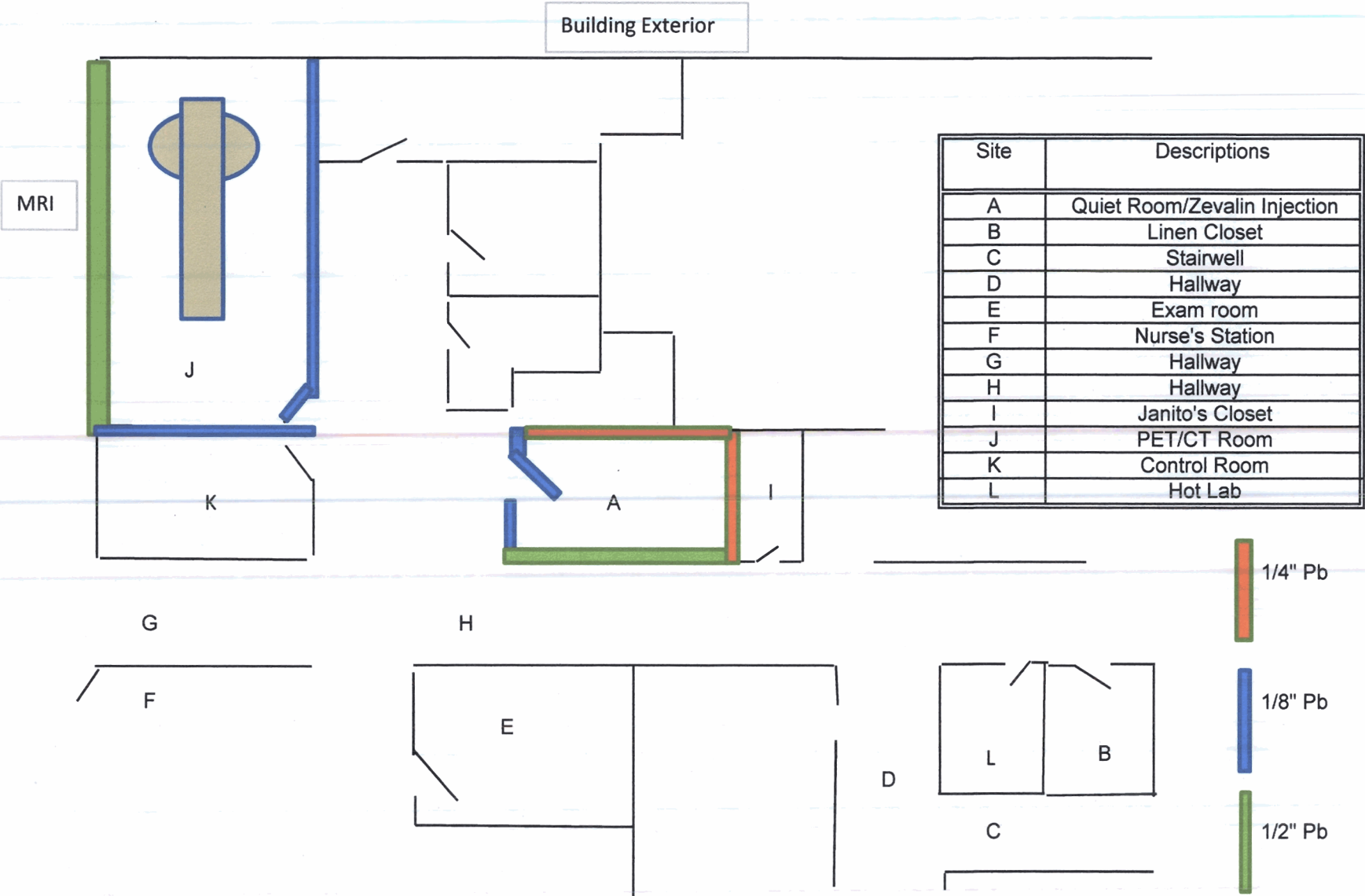
Title: Release of individuals containing unsealed byproduct material (Y-90 - Zevalin)

The following policy shall be implemented to ensure compliance with requirements in 10 CFR 35.75 for release of individuals containing unsealed byproduct material.

Patients who have been administered **Zevalin** may be released **from** the medical facility if the following has been complied with:

- 1) The total effective dose equivalent to any other person from exposure to the released individual is not likely to exceed 0.5 rem.
- 2) The patient has been provided with recommendations, including ~~written~~ instructions on how to keep doses to other individuals **as low as** reasonably achievable.
- 3) If the total effective dose equivalent to a nursing infant or child could exceed 0.1 rem, the instructions must include guidance on the interruption or stoppage of breast-feeding and information on the potential consequences of not following the guidance.
- 4) Records of the basis used to release the patient shall be kept as per 10 **CFR 35.2075**
- 5) Records shall be maintained of instructions provided to a breast-feeding female in accordance with 10CFR 35.2075(b).

HACKETTSTOWN PET/CT
Facility Diagram
(Basement Level)



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**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
29-10191-02

Docket or Reference Number
030-02526
29-10191-03

Amendment No. 88

- E. Strontium-90 for ophthalmic radiotherapy permitted by 10 CFR 35.400.
- F. One source for medical use permitted by 10 CFR 35.600, in a Nucletron Engineering B.V. Model 105.999 remote afterloader unit. The source activity may not exceed 10 curies at the time of use. One source in its shipping container as necessary for replacement of the source in the remote afterloader unit.
- G. Shielding in a linear accelerator.

CONDITIONS

- 10. A. Licensed material may be used or stored at the licensee's facilities located at 703 Main Street, Paterson, New Jersey.
- B. Licensed material listed in Item 8.D. may be used or stored at the licensee's facilities located at Surgicare Surgical Associates, P.A., 15-01 Broadway, Route 4 West, Suite 4, Fair Lawn, New Jersey.
- C. Licensed material listed in Items 8.A., 8.B., and 8.C., for which the patient can be released under the provisions of 10 CFR 35.75, may be used or stored at the licensee's facilities located at St Joseph's Specialty Centers in Clifton, 1135 Broad Street, Clifton, New Jersey.
- 11. The Radiation Safety Officer for this license is J a m T. Plomo, M.S., DABR.
- 12. Licensed material is only authorized for use by, a under the supervision of:
 - A. Individuals permitted to work as an authorized user and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.
 - B. The following individuals are authorized users for medical use as indicated:

Authorized Users

Material and Use

Vidor Bernstein, M.D.

35.100; 35.200; 35.300

John Capitenelli, M.D.

35.200

David E. Cohen, M.D.

35.200

Frederick N. Cushmore, M.D.

35.100; 35.200; 35.300

Dhirendra Nath Das, M.D.

35.100; 36.200.

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Authorized Users

Material and Use

Ajay Kumar Gupta, M.D.

35.200

Thomas M. Herskovic, M.D.

35.300; 35.400: Iridium 192 for uses in a High Dose Rate Remote Afterloader Unit; Depleted Uranium

Michael E. Kelly, M.D.

35.200

Michael Joseph Pereira, M.D.

35.300; 35.400; Iridium 192 for uses in a High Dose Rate Remote Afterloader Unit; Depleted Uranium

Ijaz R. Vohra, M.D.

35.200

Roger Steinfield, M.D.

35.200

Lawrence Weinstein, M.D.

35.200

Frank Yuppa, M.D.

35.100; 35.200

Mahendra R. Modl, M.D.

35.100; 35.200; 35.300

Donna Konlian, M.D.

35.200

Daniel K. Ng, M.D.

35.200

Stewart Berkowitz, M.D.

Iodine 125 for procedures permitted by 35.400

Perry Williams, M.D.

Iodine 125 for procedures permitted by 35.400

Patrick Conte, M.D.

35.100; 35.200; 35.300

Robert T. Fallace, M.D.

35.100; 35.200

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C. The following individuals are authorized medical physicists as indicated:

Authorized Medical PhysicistsMaterial and Use

James T. Pierno, M.S.

Iridium-192 in a High Dose Rate Remote Afterloader Unit for calibrations, spot-checks, and training; Strontium-90 ophthalmic sources for physical decay calculations and calibrations

Robert Buchanan, M.S.

Iridium-192 in a High Dose Rate Remote Afterloader Unit for calibrations, spot-checks, and training; Strontium-90 ophthalmic sources for physical decay calculations and calibrations

Shymala Kanumalla, M.S.

Iridium-192 in a High Dose Rate Remote Afterloader Unit for calibrations, spot-checks, and training; Strontium-90 ophthalmic sources for physical decay calculations and calibrations

13. In addition to the possession limit; 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) and 40.36(b) for establishing decommissioning financial assurance.
14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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15. 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. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. 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. Facsimile dated April 7, 1994, pages 16, 17, and 18
- B. Letter dated July 6, 2004, except attachments A and B [ML042020446]
- C. Letter dated July 12, 2005, except HDR facility drawings and shielding calculations [ML052010428]
- D. Facsimile dated September 27, 2005 [ML052730619]

For the U.S. Nuclear Regulatory Commission

Date July 25, 2008

By



Penny Lanzisera

Medical Branch

Division of Nuclear Materials Safety

Region I

King of Prussia, Pennsylvania 19406

Friday, July 25, 2008 12:05:04

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This is to acknowledge the receipt of your lettered application dated

3/25/2009, and to inform you that the initial processing which includes an administrative review has been performed.

☒ AMEND. 29-16565-01 There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 143630.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.