## 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

Br1

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 he sitate 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 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 -

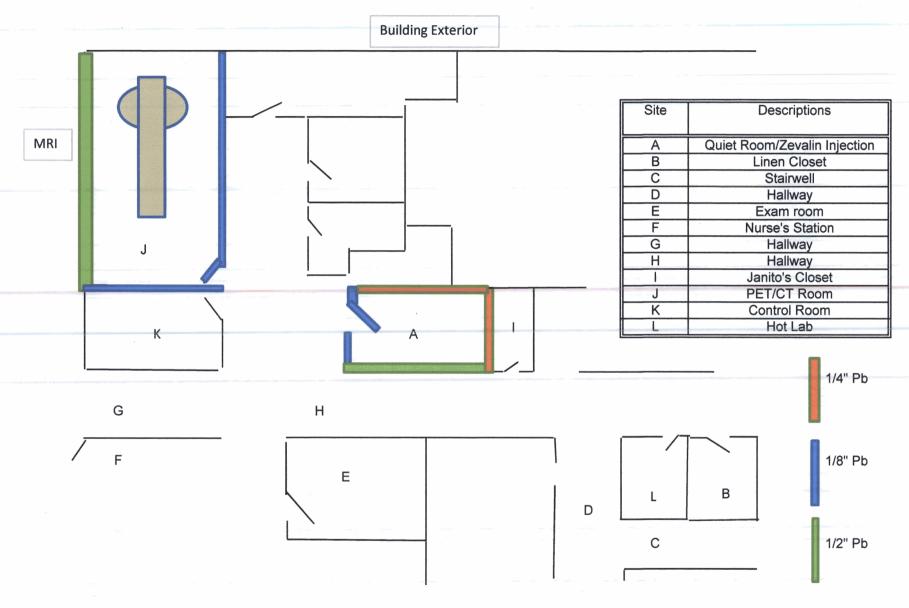
Zevalin)

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)



NRC FORM 374A	PAGE 2 OF 5 PAGE
MATERIALS LICENSE SUPPLEMENTARY SHEET	Licenso Number 29-10191-02
	Docket or Reference Number 030-02526
	29-10191-03
	Amendment No. 88

E. Strontlum-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 unik. 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 6.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 6.A., 8.B., and 6.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 Ilconse is J a m T. Plemo, 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 end Use
Vidor Bernstein, M.D.	<i>35.10</i> 0; 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.

Official Use Only - Security-Related Information

Official Use Only - Security-Related Information					
NRC FORM \$74A	PAGE 8 OF 5 PA 169				
	License Nuder 29-10191-02				
MATERIALS LICENSE	Dockel or Reference Number				
<b>SUPPLEMENTARY</b> SHEET	030-02526 29-10191-03				
	Amendment No. 88				
	, and an				
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 Afterioader Unit; Depleted Uranium				
Michael E. Kelly, M.D.	35.200				
Michael Joseph Pereira, M.D.	35.300: 35.400; Indium 192 for uses in a Migh Dose Rate Remote Afterloader Unit; Depleted Uranium				
ljaz R. <b>Vehra, M.D.</b>	35.200				
Roger Steinfield, M.D.	35.200				
Lawrence Weinstein, M.D.	35.200				
Frank Yuppa, M.D.	<b>3</b> 5.1 <b>0</b> 0; 35.200				
Mahendra R. Modi, M.D.	<b>35.100; 35.200</b> ; <b>35</b> 300				
Donna Konlian, M D.	35.200				
Daniel K. Ng, M.D	35.200				
Stewart Berkowitz, M.D.	lodine 125 for procedures permitted by 35.400				
Perry Williams, M.D.	logine 125 for procedures permitted by 35.400				
Patrick Conte. M.D.	35.100; 35.200; 35 300				
Robert T. Faillace, M.D.	35.100; 35.200				

Official Use Only - Security-Related Information

Official Use Only - Security-Related Information						
NRC FORM 374A		PAGE	4	OF'	5	PA
	License Number 29-10191-02					
MATERIALS LICENSE SUPPLEMENTARY SHEET	· - · · · · · · · · · · · · · · ·	De Number				
	Amendment N	lo. 88			_	

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

Authorized Medical Physicists	Material and Use
James T. Piemo, M.S.	Iridium-I92 in a High Dose Rate Remote Afterloader Unit for calibrations, spot-checks, and training; Strontium-90 ophthalmic sources for physical decay calculations end calibrations
Robert Buchanan, M.S.	Indium-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
Shymele Kanumalia, M.S.	Indium-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

- 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."

Official Use Only - Security-Reluted Information

	Official Use Only	Official Use Only - Security-Related Information						_	
FORM 374A				PAGE	5	OF	6	PA	)ES
			License Number 29-10191-02						
•				umber			_		
SUPPLEM	MENTARY SHEET		· · ·					,	•
				99					
			Amenunciuso	90					
accordance with the sincluding any enclosure that are required to be condition does not lim as provided for in 10 govern unless the state and correspondence.  A. Facsimile dated B. Letter dated Jul C. Letter dated Jul	statements, represent ures, listed below. The pe submitted in accordant the licensee's abilit CFR 35.26. The U.S. atements, representate are more restrictive that d April 7, 1994, pages ally 6, 2004, except attally 12, 2005, except H	ntations, and license dance with the make of the make of the make of the make of the man the man the man the man the man the machments of the facility of the man the	and procedures contained to condition applies only to the regulations. Additionally the changes to the radiation Regulatory Commission of procedures in the licensegulations.  and 18 [ML04202044 by drawings and shieldings]	d in the detection those prices in all y, the on protecting see's app	docul proce nis lic etion ation plicat	ment edura censo prograssha tion	ts, 88 e Iram all		128]
	Official Use Only	Ву	Penny Lanzistra Medical Branch Division of Nuclear Me Region I King of Prussia, Penns	aterials Sa sylvania 1 Friday, Ju	Gafety		081:	2:05	i:04
	Except as specifically accordance with the sincluding any enclose that are required to be condition does not limas provided for in 10 govern unless the stand correspondence.  A. Facsimile dated B. Letter dated Jul C. Letter dated Jul D. Facsimile dated  July 25,2008	Except as specifically provided otherwise is accordance with the statements, represent including any enclosures, listed below. The that are required to be submitted in accordance does not limit the licensee's abilities provided for in 10 CFR 35.26. The U.S govern unless the statements, representational correspondence are more restrictive to the detection of the condition of the	Except as specifically provided otherwise in this lice accordance with the statements, representations, as including any enclosures, listed below. This license that are required to be submitted in accordance will condition cloes not limit the licensee's ability to make as provided for in 10 CFR 35.26. The U.S. Nuclear govern unless the statements, representations, and and correspondence are more restrictive than the restrictive dated July 6, 2004, except attachments C. Letter dated July 12, 2005, except HDR facilit D. Facsimile dated September 27,2005 [N	MATERIALS LICENSE SUPPLEMENTARY SHEET  MATERIALS LICENSE SUPPLEMENTARY SHEET  Except as specifically provided otherwise in this license, the licensee shell a accordance with the statements, representations, and procedures contained including any enclosures, listed below. This license condition applies only that are required to be submitted in accordance with the regulations. Additional does not limit the licensee's ability to make changes to the radiational provers unless the statements, representations, and procedures in the license govern unless the statements, representations, and procedures in the license 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 [ML04202044 C. Letter dated July 12, 2005, except HDR facility drawings and shielding D. Facsimile dated September 27, 2005 [ML052730519]  For the U.S. Nuclear Regulate.  July 25,2008  By Penny Lanzistra Medical Branch Division of Nuclear Me Region   King of Prussia, Penns Region   King of Pru	MATERIALS LICENSE SUPPLEMENTARY SHEET  MATERIALS LICENSE SUPPLEMENTARY SHEET  MATERIALS LICENSE SUPPLEMENTARY SHEET  MATERIALS LICENSE SUPPLEMENTARY SHEET  Document Number 29-10191-02  Document No. 88   Except as specifically provided otherwise in this license, the licensee shell conduct accordance with the statements, representations, and procedures contained in the circluding any enclosures, listed below. This license condition applies only to those that are required to be submitted in accordance with the regulations. Additionally, the condition does not limit the licensee's ability to make changes to the radiation protect as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulatory correspondence are more restrictive than the regulations.  A. Facsimile dated April 7, 1994, pages 16.17, and 18  Letter dated July 6, 2004, except attachments A and B [ML042020446]  C. Letter dated July 12, 2005, except attachments A and B [ML042020446]  C. Letter dated July 12, 2005, except attachments A mile and shielding calculations.  Penny Lanziera Medical Branch Division of Nuclear Meterials S Region   Ricense Additional Pricessa, July 18, 2005, except attachments (NL052730619)  For the U.S. Nuclear Regulatory Commission's	MATERIALS LICENSE SUPPLEMENTARY SHEET  MATERIALS LICENSE SUPPLEMENTARY SHEET  MATERIALS LICENSE SUPPLEMENTARY SHEET  MATERIALS LICENSE SUPPLEMENTARY SHEET  Dozace or Reservor Number 030-02526  29-10191-03  Amendment No. 88  Except as specifically provided otherwise in this licensee, the licensee shell conduct its pracograme with the statements, representations, and procedures contained in the document including any enclosures, listed below. This licensee condition applies only to those proor that are required to be submitted in accordance with the regulations. Additionally, this licensee is ability to make changes to the radiation protection as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulation 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 8, 2004, except attachments A and B [ML042020446]  C. Letter dated July 12, 2005, except HDR facility drawings and shleiding calculations [ML052730519]  For the U.S. Nuclear Regulatory Commission of Nuclear Meterials Safety Region   King of Prussia, Pennsylvania 1940 Friday, July 2.	MATERIALS LICENSE SUPPLEMENTARY SHEET  MATERIALS LICENSE SUPPLEMENTARY SHEET  Except as specifically provided otherwise in this license, the licensee shell conduct its progras accordance with the statements, representations, and procedures contained in the document including any enclosures, listed below. This license condition applies only to those procedure that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the Icensee's ability to make changes to the radiation protection program unless the statements, representations, and procedures in the Ilcensee'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 attachments A and B [ML042020446] C. Letter dated July 12, 2005, except attachments A and B [ML042020446] C. Letter dated September 27, 2005 [ML052730519]  For the U.S. Nuclear Regulatory Commission  For the U.S. Nuclear Regulatory Commission  Madical Branch Division of Nuclear Meterials Safety Region 1  King of Prussia, Pennsylvania 19406 Friday, July 25, 20	MATERIALS LICENSE SUPPLEMENTARY SHEET  MATERIALS LICENSE SUPPLEMENTARY SHEET  MATERIALS LICENSE SUPPLEMENTARY SHEET  Doods or Reference Number 29-10/191-02  Doods or Reference Number 3030-0252/8  29-10/191-03  Amendment No. 88  Except as specifically provided otherwise in this license, the licensee shell conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, licited 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 Identical Society on the Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the Regulation program as provided for in 10 CPR 35-26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the Recent Society and Commission's regulations and correspondence are more restrictive than the regulations.  A. Facsimile dated April 7, 1994, pages 16-17, and 18  B. Letter dated July 12, 2005, except HDR facility drawings and shleiding calculations [ML0520 D. Facsimile dated September 27, 2005 [ML032730519]  For the U.S. Nuclear Requisitory Commission  For the U.S. Nuclear Requisitory Commission  Medical Branch Division of Nuclear Meterials Safety Region I King of Prussia, Pennsylvania 19406  Friday, July 25, 2008 12	MATERIALS LICENSE SUPPLEMENTARY SHEET  Except as specifically provided otherwise in this license, the licensee shell 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 itensees ability to make changes to the radiation protection protection as provided for in 10 CFR 53 28. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the illoensee'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 8, 2004, except attachments A and 8 (ML042020446) C. Letter dated July 12, 2005, except attachments A and 8 (ML042020446) C. Letter dated July 12, 2005, except HDR facility drawings and shielding calculations [ML0520104. Facsimile dated September 27, 2005 [ML052730519]  For the U.S. Nuclear Regulatory Commission  For the U.S. Nuclear Regulatory Commission  For the U.S. Nuclear Regulatory Commission  Letter dated July 12, 2005, except HDR facility drawings and shielding calculations [ML0520104. Facsimile dated September 27, 2005 [ML052730519]  For the U.S. Nuclear Regulatory Commission  For the U.S. Nuclear Regulatory Commission

This is to acknowledge the receipt	of your lettedapplication dated					
includes an administrative review h	and to inform you that the initial processing which as been performed.					
	nissions. Your application was assigned to a that the technical review may identify additional information.					
Please provide to this office within 30 days of your receipt of this card						
. , ,	warded to our License Fee & Accounts Receivable ately if there is a fee issue involved.					
Your action has been assigned <b>Mail Control Number</b> 143636. When calling to inquire about this action, please refer to this control number. You may call us on (610) 337-5398, or 337-5260.						
NRC FORM 532 (RI) (6-96)	Sincerely, Licensing Assistance Team Leader					