



SETON CANCER INSTITUTE

RADIATION ONCOLOGY

KHURSHID AHMAD, M.D., MEDICAL DIRECTOR

YOUNG H. KIM, M.D.

MICHAEL C. CAPPELLI, M.D.

TUSHAR R. SHAH, M.D.

800 SOUTH WASHINGTON AVENUE

SAGINAW, MI 48601-2524

PHONE: (989) 776-8115

TOLL FREE: 1-877-738-6672

FAX: (989) 776-8313

U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Section
2443 Warrenville Road Suite 210
Lisle, Illinois 60532-4351

RE: Amendment to NCR License

Dear Mrs Pelke,

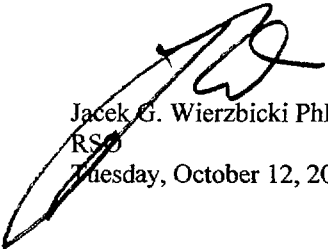
Please find attached an additional information to previous Control Number 313005.

We decided to narrow our request and to add .

Tushar Shah MD

as authorized user for 10 CFR 35.400 only.

Please contact the Radiation Safety Officer Jacek G. Wierzbicki PhD tel 989-776-8285 if you have any questions or require additional information.



Jacek G. Wierzbicki PhD

RSO

Tuesday, October 12, 2004



Service of the Poor • Reverence • Integrity
Wisdom • Creativity • Dedication
setoncancer.org



University of Michigan
Health System
Cancer Center Network

OCT 18 2004

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

PART II -- PRECEPTOR STATEMENT

Note: This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet the training requirements in 10 CFR 35.590.

Item 10 must be completed for Nuclear Pharmacists meeting the requirements of 10 CFR Part 35, Subpart J. Preceptors do not have to complete items 11a, 11b, or the certifying statements for other individuals meeting the requirements of 10 CFR Part 35, Subpart J.

YES 10. The individual named in item 1 has satisfactorily completed the training requirements in
 N/A 10 CFR 35.980 and is competent to independently operate a nuclear pharmacy.

YES 11a. The individual named in Item 1 has satisfactorily completed the requirements in Part 35, Section(s)
 N/A and Paragraph(s) 35.400 35.1000

YES 11b. The individual named in Item 1. is competent to independently function as an authorized
 N/A user for 35.400 35.1000 uses (or units).

12. PRECEPTOR APPROVAL AND CERTIFICATION

I certify the approval of item 10 and certify I am an Authorized Nuclear Pharmacist;

or

I certify the approval of items 11a and 11b, and certify I am an Authorized Nuclear Pharmacist;

or

I certify the approval of Items 11a and 11b, and I certify that I meet the requirements of 35.400 35.1000
or equivalent Agreement State requirements to be a preceptor authorized user
for the following uses (or units) of byproduct material: 35.400 35.1000

A. Address

Dept of Rad. Oncology
Henry Ford Hospital
2799 W Grand Blvd
Detroit, MI 48202

B. Materials License Number

21-0410916

C. NAME OF PRECEPTOR (print clearly)

MUNTHE AJLOUNI

D. SIGNATURE -- PRECEPTOR

E. DATE

8/25/04



DEPARTMENT OF RADIATION ONCOLOGY
Henry Ford Hospital & Medical Centers

August 24, 2004

Jae Ho Kim, MD, PhD, FACR

Chair
Herndon Chair

2799 West Grand Blvd.
Detroit, MI 48202-2689
(313) 916-1021 Appt.
(313) 916-3235 Fax

Henry Ford Medical Center
6777 W. Maple Road
West Bloomfield, MI 48322
(248) 661-6487 Appt.
(248) 661-7164 Fax

Downriver Center for Oncology
Brownstown Township
19675 Allen Road
Trenton, MI 48183
(734) 479-3311 Appts.
(734) 479-8009 Fax

St. Joseph's Mercy of Macomb
Cancer Care Center
15855 Nineteen Mile Road
Clinton Township, MI 48038
(810) 263-2230 Appts.
(810) 263-2239 Fax

Clinical Division

Education Division

Physics Division

Research Division

Jacek Wierzbicki, Ph.D.
Radiation Safety Officer
Saint Mary's Hospital
800 S. Washington Street
Saginaw, Michigan 48601

Dear Dr. Wierzbicki:

The purpose of this letter is to confirm that Dr. Munther Ajlouni is an authorized user per the authority of the Radiation Safety Committee of Henry Ford Hospital. The committee recognizes Dr. Ajlouni as an authorized user of the following radioactive sealed sources: Cesium-137, Iodine-125, and Iridium-192 (seeds and High Dose Rate). The Nuclear Regulatory Commission has issued broad license #21-04109-16 to Henry Ford Hospital.

Sincerely;

Flavious Martin
Chairman
Radiation Safety Committee
Henry Ford Hospital
2799 West Grand Blvd.,
Detroit, Michigan
48187





UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE ROAD STE 210
LISLE, ILLINOIS 60532-4352

MAY 06 2004

Jacek Wierzbicki, Ph.D.
Radiation Safety Officer
Saint Mary's
800 S. Washington Street
Saginaw, MI 48601

Dear Dr. Wierzbicki:

Enclosed is Amendment No. 50 to your NRC Material License No. 21-03646-03 in accordance with your request. Please note that the changes made to your license are printed in **bold font**.

Note in particular that we were unable to add Tushar Shah, M.D. to your license as an authorized user for 35.300 and 35.400 materials, HDR's, the Novoste and Guidant IVB devices and the Guidant Galileo device. In order to add Dr. Shah to your license, it will be necessary for you to provide the following:

1. The Preceptor Statement provided did not include any documented experience Dr. Shah received with materials in 10-CFR 35.300. It will be necessary for Dr. Shah to provide documentation which clearly demonstrates that he has received experience with 35.300 materials in order for us to authorize his use of those materials;
2. The Preceptor Statement provided was not accurately completed. Provide a letter from Henry Ford Hospital's Radiation Safety Committee which confirms that Dr. Ajlouni is an authorized user under that license (21-04109-16) and identifies the materials he is authorized to use at that institution; and
3. Please submit a completed page 4 of the Preceptor Statement (copy enclosed).

Information submitted in response to this letter should be addressed as additional information to previous Control Number 313005.

In addition, please note that the United States Nuclear Regulatory Commission Region III office has moved to a new location. The Region III telephone numbers will remain unchanged. Effective April 2, 2004, please send mail to our new address: United States Nuclear Regulatory Commission; Region III; 2443 Warrenville Road Suite 210; Lisle, IL 60532-4352.

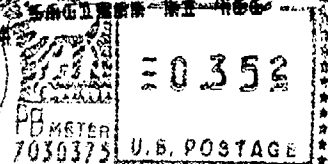
SAINT
MARYS

SETON CANCER INSTITUTE
800 SOUTH WASHINGTON AVENUE
SAGINAW, MI 48601-2524

PRESORTED FIRST CLASS

12-OCT-2004

OCT 12 '04



U.S. Nuclear Regulatory Comm.
Region III
Materials Licensing Section
2443 Warrenville Rd Suite 210
Lisle, Illinois
60558-4851

University Level Care
in Your Community

ATTN: Mrs. Felke

BETWEEN:
License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

: Program Code: 02240
: Status Code: 0
: Fee Category: 7C
: Exp. Date: 20140930
: Fee Comments: _____
: Decom Fin Assur Req: N
:

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: SAINT MARY'S
Received Date: 20041018
Docket No: 3002031
Control No.: 313825
License No.: 21-03646-03
Action Type: Amendment

2. FEE ATTACHED

Amount: _____
Check No.: _____

3. COMMENTS

Signed *K. J. Bernardini*
Date 10-27-04

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /_/_)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:
Amendment _____
Renewal _____
License _____

3. OTHER _____

Signed _____
Date _____