

## MATERIALS LICENSE

Amendment No. 35

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 30, 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 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 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.

OFFICIAL RECORD COPY

## Licensee

1. Elizabeth General Medical Center-West
2. 925 East Jersey Street  
Elizabeth, New Jersey 07201

In accordance with the letter dated  
October 2, 1996,  
3. License Number 29-01600-02 is amended in  
its entirety to read as follows:

4. Expiration Date January 31, 2002

5. Docket or  
Reference No. 030-024376. Byproduct, Source, and/or  
Special Nuclear Material7. Chemical and/or Physical  
Form8. Maximum Amount that Licensee  
May Possess at Any One Time  
Under This License

- A. Any byproduct material  
identified in 10 CFR  
35.100
- B. Any byproduct material  
identified in 10 CFR  
35.200
- C. Any byproduct material  
identified in 10 CFR  
35.300
- D. Any byproduct material  
identified in 10 CFR  
35.400
- E. Iridium 192

- A. Any radiopharmaceutical  
identified in 10 CFR  
35.100
- B. Any radiopharmaceutical  
identified in 10 CFR  
35.200
- C. Any radiopharmaceutical  
identified in 10 CFR  
35.300
- D. Any brachytherapy source  
identified in 10 CFR  
35.400
- E. Sealed source  
(Mallinckrodt,  
Model CI L-BV)

- A. As needed
- B. As needed
- C. 1 curie
- D. 2 curies
- E. 10 curies per source and  
20 curies total

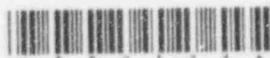
## 9. Authorized use

- A. Any uptake, dilution and excretion procedure approved in 10 CFR 35.100.
- B. Any imaging and localization procedure approved in 10 CFR 35.200.
- C. Any radiopharmaceutical therapy procedure approved in 10 CFR 35.300.
- D. Any brachytherapy procedure approved in 10 CFR 35.400.
- E. For use in a Nucletron Corp. microSelectron HDR 080.000 remote after loading brachytherapy unit for the treatment of humans. One source in its shipping container as necessary for the replacement of the source in the irradiation device only.

130044

## CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at  
925 East Jersey Street, Elizabeth, New Jersey



ML 10

MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License Number

29-01600-02

Docket or Reference Number

030-02437

Amendment No. 35

11. A. The Radiation Safety Officer for this license is Uvadee Chaibongsai, M.D.
- B. The Medical Physicists for this license are Linda Veldkamp and Daniel Alessandro.
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

Robert Silbey, M.D.	35.100; 35.200
Khee Tiang Oen, M.D.	35.100; 35.200
Uvadee Chaibongsai, M.D.	35.100; 35.200
Israel Rebarber, M.D.	35.100; 35.200
Peter Alan Ross, M.D.	35.100; 35.200
Donald R. Whitaker, M.D.	35.100; 35.200
Eli Finkelstein, M.D., Ph.D.	35.300; 35.400 Iridium 192 in remote after loading brachytherapy unit.

13. 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), 40.36(b), and 70.25(d) for establishing financial assurance for decommissioning.
14. A. Access to the treatment room housing each high dose rate remote afterloading brachytherapy unit shall be controlled by a door at each entrance.
- B. Each entrance to the treatment room shall be equipped with an electrical interlock system that will cause the source to return to the shielded position immediately upon opening of the entrance door. The interlock system shall be connected in such a manner that the source cannot be placed in the irradiation position until the entrance door is closed and the source "on-off" control is reset at the control panel.
- C. Electrical interlocks on each entrance door to the treatment room shall be tested for proper operation at least once a month. Records of test results shall be maintained for three years.
- D. In the event of malfunction of the door interlock, the unit shall be locked in the "off" position and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

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License Number

29 01600-02

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15. Prior to initiation of a treatment program, and subsequent to each source exchange for each high dose rate remote afterloading brachytherapy unit:
- A. A radiation survey shall be made of:
- (1) The source housing, with the source in the shielded position. The maximum radiation levels at 10 centimeters from the surface of the main source safe shall not exceed 1 milliroentgen per hour.
  - (2) All areas adjacent to the treatment room with the source in the exposed position. The survey shall clearly establish:
    - (a) That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in 10 CFR 20.101.
    - (b) That quantities of radiation in unrestricted areas do not exceed the limits specified in 10 CFR 20.105(b).
- B. Records of the survey results shall be maintained for inspection by the Commission for the duration of the license.
16. The following shall be performed only by persons specifically authorized by the Commission or an Agreement State to perform such service:
- A. Installation, and replacement of the sealed sources contained in each high dose rate remote afterloading brachytherapy unit.
  - B. Maintenance or repair operations on any high dose rate remote afterloading brachytherapy unit and associated equipment involving work on the source safe, the source driving unit, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.
17. A high dose rate afterloading brachytherapy unit shall be used in accordance with the following conditions:
- A. The unit may only be used in a permanently shielded treatment room.
  - B. Following removal of a source from a patient, the licensee shall make a radiation survey of the patient with an appropriate radiation detection survey instrument, as specified in 10 CFR 35.420, to confirm that the source has been removed.
  - C. During all patient treatments, both the authorized user and either the medical physicist or radiation safety officer must be physically present. Physical presence, for this purpose, is defined as within audible range of normal human speech.

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- D. The licensee shall have and post in the vicinity of the treatment console, written emergency procedures describing the actions to be taken, including surgical intervention, should the source not return to the shielded container at the conclusion of treatment. The licensee shall not begin any treatment procedure for which a decoupled or jammed source cannot be removed expeditiously from the patient and placed in a shielded condition.
- E. The licensee shall ensure that personnel are trained in both the routine use of the unit and emergency procedures necessary to return the source to a safe position.
- F. The licensee shall immediately, after implanting the source, visually check the permanently installed room radiation monitor to verify that it indicates an exposed radiation source.
- G. The licensee shall visually monitor the patient during treatment through a continuous observation system.
- H. The licensee shall permit no visitors in the treatment room.
18. In lieu of the source inventory described in 10 CFR 35.406, the licensee shall:
- A. Promptly determine that all sources have returned to the safe, shielded position at the conclusion of each high dose remote brachytherapy procedure.
- B. Promptly make a survey of the area of use to confirm that no sources have been misplaced.
- C. Make a record of the survey including the time, date and name of the individual making the survey.
- D. Retain the record of the survey for a period of three years.
19. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."



**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number

29-01600-02

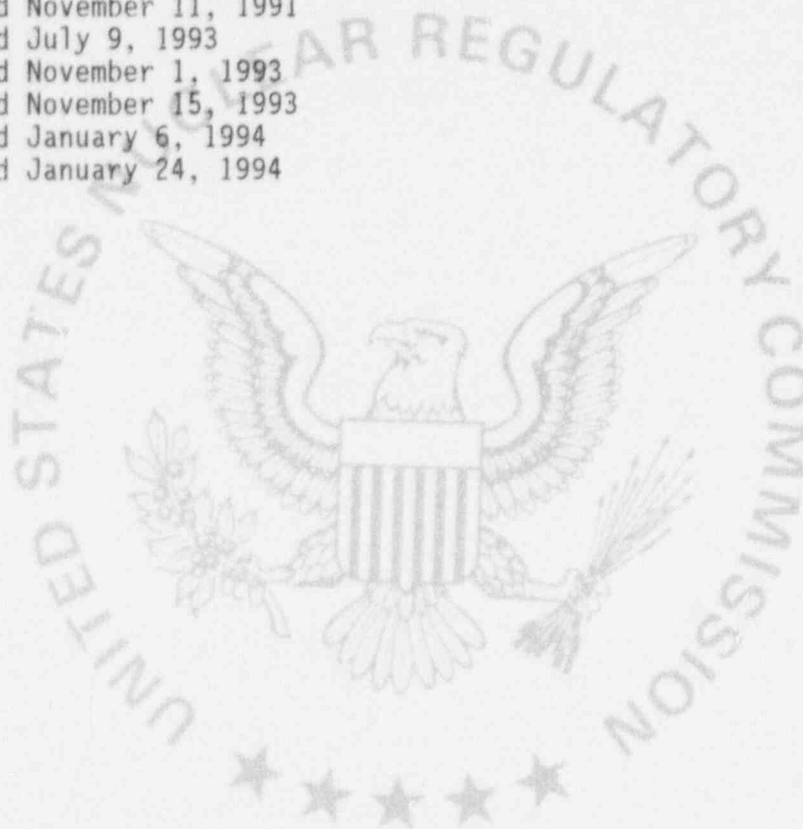
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20. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The 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. Application dated June 28, 1990
- B. Letter dated October 8, 1991
- C. Letter dated November 11, 1991
- D. Letter dated July 9, 1993
- E. Letter dated November 1, 1993
- F. Letter dated November 15, 1993
- G. Letter dated January 6, 1994
- H. Letter dated January 24, 1994



For the U.S. Nuclear Regulatory Commission

**ORIGINAL SIGNED BY:**  
**JO ANN V. STAMBAUGH**

By  
Nuclear Materials Safety Branch  
Region I  
King of Prussia, Pennsylvania 19406

DEC - 5 1996

Date \_\_\_\_\_

DEC - 5 1996

Mr. Robert Platt  
Senior Vice President  
Elizabeth General Medical Center-West  
925 East Jersey Street  
Elizabeth, NJ 07201-2789

Dear Mr. Platt:

This refers to your license amendment request. Enclosed with this letter is the amended license. Please note that as part of this amendment, in accordance with 10 CFR 30.36, effective February 15, 1996, the expiration date of your license has been extended by a period of five years. Your new expiration date is stated in Item 4 of the license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

**ORIGINAL SIGNED BY:  
JO ANN V. STAMBAUGH**

JoAnn V. Stambaugh  
Division of Nuclear Materials Safety

License No. 29-01600-02  
Docket No. 030 02437  
Control No. 123781

Enclosure:  
Amendment No. 35

DOCUMENT NAME: R:\WPS\MLTR\L2901600.02

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	<input checked="" type="checkbox"/> N	DNMS/RI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NAME	Stambaugh/jvs	9/10					
DATE	10/30/96	10/30/96	10/ /96	10/ /96	10/ /96	10/ /96	

OFFICIAL RECORD COPY

**ML 10**



030-02437

*Close to the heart of your community*

MAILING ADDRESS:  
925 East Jersey Street  
Elizabeth, New Jersey 07201-2789  
(908) 289-8600

October 2, 1996

US Nuclear Regulatory Commission  
Region I  
475 Allendale Road  
King of Prussia, PA 19406-1415

RE: **LICENSE # 29-01600-02**

To Whom it May Concern:

Elizabeth General Medical Center would like to amend our State radioactive materials license in the following manner:

Robert Silbey, M.D., will be stepping down as Radiation Safety Officer. We would like to list Uvadee Chaibongsai, M.D., as the new Radiation Safety Officer.

Dr. Chaibongsai is currently listed on the license as an authorized user. A copy of her curriculum vitae is attached for your review.

Also enclosed is a check in the amount of \$430.00 for the appropriate amendment fee.

Your immediate attention to this request would be greatly appreciated.

Sincerely,

Robert Platt  
Senior Vice President

RP/mlj  
attachment

cc: Uvadee Chaibongsai, M.D.  
Lorraine Greiner, R.T.

123781

OCT - 9 1996

UVADEE CHAIBONGSAI, M.D.

EDUCATION

M.D., 1968, MAHIDOL UNIVERSITY, SIRIRAJ HOSPITAL AND MEDICAL SCHOOL, BANGKOK, THAILAND

DIP. PRE-MED., 1964, CHULALONGKORN UNIVERSITY, FACULTY OF SCIENCES, BANGKOK, THAILAND

POSTGRADUATION TRAINING

INTERNSHIP, 1968-1969, MAHIDOL UNIVERSITY, SIRIRAJ HOSPITAL AND MEDICAL SCHOOL, BANGKOK, THAILAND

INTERNSHIP, 1969-1970, MOUNT SINAI MEDICAL CENTER, MIAMI BEACH, FLORIDA 33140

RESIDENCY, 1970-1973, IN GENERAL RADIOLOGY, MEDICAL SCHOOL OF WAYNE STATE UNIVERSITY, DETROIT, MI 48202

FELLOWSHIP, 1973-1974, IN ANGIOGRAPHY AND NEURORADIOLOGY, MEDICAL SCHOOL OF WAYNE STATE UNIVERSITY, DETROIT, MI 48202

SPECIAL TRAINING IN GENERAL DIAGNOSTIC RADIOLOGY INCLUDING NUCLEAR MEDICINE AND ULTRASONOGRAPHY

EXPERIENCES

STAFF, 1974-1976, GRACE HOSPITAL NORTHWEST UNIT, 18700 MEYERS ROAD, DETROIT, MI 48235, RESPONSIBLE FOR DIAGNOSTIC RADIOLOGY AND SPECIAL PROCEDURES

STAFF, 1976-1978, V.A. HOSPITAL, ALLEN PARK, MI 48101, RESPONSIBLE FOR DIAGNOSTIC RADIOLOGY AND SPECIAL PROCEDURES

INSTRUCTOR IN RADIOLOGY, (PART TIME) 1976-1978, MEDICAL SCHOOL OF WAYNE STATE UNIVERSITY, DETROIT, MI 48202

STAFF, 1978-7/31/80, OUTER DRIVE HOSPITAL, 26400 OUTER DRIVE, LINCOLN PARK, MI 48146 AND SEAWAY HOSPITAL, 5450 FORT, TRENTON, MI 48183, RESPONSIBLE FOR DIAGNOSTIC RADIOLOGY INCLUDING NUCLEAR MEDICINE AND ULTRASONOGRAPHY

STAFF, 1980-PRESENT, ELIZABETH GENERAL MEDICAL CENTER, ELIZABETH, NJ 07201, RESPONSIBLE FOR DIAGNOSTIC RADIOLOGY INCLUDING NUCLEAR MEDICINE AND ULTRASONOGRAPHY



SPECIALTY CERTIFICATION

AMERICAN BOARD OF RADIOLOGY (1974)

MEMBERSHIP

AMERICAN COLLEGE OF RADIOLOGY  
MICHIGAN RADIOLOGICAL SOCIETY

MEDICAL LICENSES

MICHIGAN (NO. 33509)  
NEW JERSEY (NO. 38081)

REFERENCES

DR. HERBERT SCHUNK, M.D., SUBURBAN RADIOLOGY, 3723 FORT ROAD,  
LINCOLN PARK, MI 48146, PHONE: (313) 383-7190

DR. NOCHOLAS JACKIW, M.D., SUBURBAN RADIOLOGY, 3723 FORT ROAD,  
LINCOLN PARK, MI 48146, PHONE: (313) 383-7190

DR 001-0-11-58

RECEIVED

123781

## LICENSE FEE REQUIREMENTS

LICENSE FEE AND DEBT COLLECTION BRANCH  
DIVISION OF ACCOUNTING AND FINANCE  
OFFICE OF THE CONTROLLER  
U.S. NUCLEAR REGULATORY COMMISSION  
WASHINGTON, DC 20555-0001ELIZABETH GENERAL MEDICAL CENTER - WEST  
ATTN: ROBERT PLATT  
SENIOR VICE PRESIDENT  
925 EAST JERSEY STREET  
ELIZABETH, NJ 07201-2789

## TYPE OF ACTION

- ☐
- NEW LICENSE
- 
- ☐
- RENEWAL OF LICENSE
- 
- ☒
- AMENDMENT TO LICENSE

## REQUESTED DATE

10-2-96

## LICENSE NUMBER

29-01600-02

## CONTROL NUMBER

123781

## I. APPLICATION FEE DUE

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of the enclosed Federal Register notice. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
7C	\$	\$	\$ 440.00
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$

FEE(s) DUE	\$	440.00
PAYMENT RECEIVED	\$	430.00
AMOUNT DUE	\$	10.00

☒ Your request was received without the prescribed application fee.☒ We received your Check No. 206067 in the amount of \$ 430.00. Payment of the additional fee noted above is required.☐ Your request will increase the scope of your license program. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(d)(2).☐ Your license was issued prior to the receipt of your application for renewal. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(a).

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS ACTION.

## II. FEE NOT REQUIRED

- ☐ Enclosed is Check No. \_\_\_\_\_ which accompanied your request. The fee is not required because:
- ☐ We received your Check No. \_\_\_\_\_ in payment of the fee.
- ☐ The Licensing staff has informed us that your request is to be considered as a continuation of your request dated \_\_\_\_\_, Control No. \_\_\_\_\_.
- ☐ Your request was combined, prior to review, with your request, Control No. \_\_\_\_\_.

## III. CHECK RETURNED

- ☐ Enclosed is Check No. \_\_\_\_\_ which was returned to us by the bank for:
- ☐ INSUFFICIENT FUNDS
- ☐ ACCOUNT CLOSED
- ☐ OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

## IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

- ☐ License No. \_\_\_\_\_ Amendment No. \_\_\_\_\_, issued on \_\_\_\_\_, was issued without the required fee being collected. The fee required is noted in Section I of this form.
- ☐ The scope of your licensed program was increased. Therefore, your request is subject to the application fee(s) noted in Section 1 of this form. Refer to Section 170.31 and Footnote 1(d)(2).
- ☐ Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section 1 of this form.

SIGNATURE - LICENSE FEE ANALYST

LFDCB

LFDCB

BRENDA BROWN (301-415-6055)

10/24/96

## Distribution:

Region I LFARB R/F  
Pending OC/DAF R/F  
BBrown OC/DAF S/F (LF-3.2.7)

DATE

10-24-96

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM  
AND  
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)  
INFORMATION FROM LTS  
-----

PROGRAM CODE: 02230  
STATUS CODE: 0  
FEE CATEGORY: 7C  
EXP. DATE: 20020131  
FEE COMMENTS: -----  
DECOM FIN ASSUR REQD: N  
.....

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: ELIZABETH GENERAL MED. CTR. - WEST  
RECEIVED DATE: 961009  
DOCKET NO: 3002437  
CONTROL NO.: 123781  
LICENSE NO.: 29-01600-02  
ACTION TYPE: AMENDMENT

2. FEE ATTACHED

AMOUNT: \$ 430.00  
CHECK NO.: 206067

3. COMMENTS

SIGNED  
DATE

*Rebecca J. Brown*  
10/15/96

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED N)

1. FEE CATEGORY AND AMOUNT: 7C

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:

AMENDMENT -----  
RENEWAL -----  
LICENSE -----

3. OTHER -----  
-----

SIGNED  
DATE

-----  
-----

Log	Oct 6
Remitter	
Check No.	206067/207286
Amount	\$ 430.00 F10
Fee Category	7C
Type of Fee	Amu
Date Check Rec'd	10/24/96
Date Completed	11/25/96
By	LB

1996 OCT 21 AM 11:37