

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

SNM-1525

Docket or Reference Number

070-01941

Amendment No. 06

The General Hospital Center at Passaic
350 Boulevard
Passaic, New Jersey 07055

In accordance with your letter dated July 31, 1996, License Number SNM-1525 is hereby terminated.



For the U.S. Nuclear Regulatory Commission

Original Signed By:
Michelle Beardsley

Date AUG 13 1996

By

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

OFFICIAL RECORD COPY

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PDR ADOCK 07001941
C PDR

ML 10 0/1

AUG 13 1996

Thomas D'Esmond, FACHE
Executive Vice President for Operations
The General Hospital Center at Passaic
350 Boulevard
Passaic, NJ 07055

Dear Mr. D'Esmond:

Please find enclosed Amendment No. 06 terminating License No. SNM-1525 as requested by your letter dated July 14, 1996.

Your cooperation with us is appreciated.

Sincerely,

Original Signed By:
Michelle Beardsley

Michelle R. Beardsley
Division of Nuclear Materials Safety

License No. SNM-1525
Docket No. 070-01941
Control No. 123514

Enclosure:
Amendment No. 06

DOCUMENT NAME: R:\WPS\MLTR\TSNM1525

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	N	DNMS/RI				
NAME	Beardsley <i>MB</i>						
DATE	08/04/96	08/	/96	08/	/96	08/	/96

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THE
GENERAL
HOSPITAL
CENTER
AT PASSAIC

350 BOULEVARD
PASSAIC
NEW JERSEY 07055
201 / 365-4300

ROBERT J. JABLONSKI
CHAIRMAN
BOARD OF GOVERNORS

DANIEL L. MARCANTUONO, FACHE
PRESIDENT AND
CHIEF EXECUTIVE OFFICER

July 31, 1996

United States Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, Pa., 19406-1415

070-01941

Attention: Licensing Assistance Section

To Whom It May Concern:

Please be advised that the General Hospital Center at Passaic wishes to terminate the NRC materials license of the same name, #SNM-1525 (copy attached). All nuclear powered pacemakers implanted under this license have been retrieved and returned to the manufacturer.

Thank you for your assistance in this matter. If you have any questions or require any further information, please contact myself or our consultant Health Physicist, Bill McAndrew at (908) 788-9440.

Sincerely,

Thomas D'Esmond, FACHE
Executive Vice President for Operations

OFFICIAL RECORD COPY

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123514



NRC FORM 374
(10-88)

U.S. NUCLEAR REGULATORY COMMISSION

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MATERIALS LICENSE

Amendment No. 05

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, 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 181 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.

Licensee		In accordance with letter dated April 4, 1991,	
1. The General Hospital Center at Passaic		3 License number SNM-1525 is amended in its entirety to read as follows:	
2. 350 Boulevard Passaic, New Jersey 07055		4 Expiration date July 31, 1996	
		5. Docket or Reference No 070-01941	
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. Plutonium (Principal radionuclide PU-238)	A. Sealed Source	A. 0.5 grams (1 source not to exceed 500 milligrams)	
B. Plutonium (Principal radionuclide PU-238)	B. Sealed Source	B. 0.25 grams (1 source not to exceed 250 milligrams)	
9. Authorized use			
A. As a component of ARCO Nuclear Model NU-5 nuclear-powered cardiac pacemaker for clinical evaluation. This authorization includes: follow-up, explantation, recovery and disposal, but not implantation.			
B. As a component of Coratomic Model C-101 nuclear-powered cardiac pacemaker for clinical evaluation. This authorization includes: follow-up, explantation, recovery and disposal, but not implantation.			

CONDITIONS

10. Licensed material shall be used only at The General Hospital Center at Passaic, 350 Boulevard, Passaic, New Jersey.
11. A. Physicians responsible for follow-up, explantation and return of nuclear-powered pacemakers to the manufacturer for proper disposal are Michael R. Ramundo, M.D., Hermogenes L. Ciocon, M.D., Manny E. Christakos, M.D., and Justin Ferando, M.D.
- B. The Radiation Safety Officer for this license is Arthur Weisel, M.D.

NRC Form 374A
(5-84)

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

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070-01941

Amendment No. 05

(Continued)

CONDITIONS

12. The specified possession limit includes all licensed material possessed by the licensee under this license whether in storage, implanted in patients, or otherwise in use.
13. The licensee shall report to the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406, ATT: Chief, Nuclear Material Safety Branch, within 24 hours of occurrence, the death of any nuclear pacemaker patient, and any adverse reaction and/or malfunction involving a pacemaker system, including the leads. A written report giving details of the adverse reaction and/or malfunction shall be submitted within 30 days.
14. The licensee shall report to the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406, within 10 days of loss of contact with a nuclear pacemaker patient.
15. The licensee shall continue patient follow-up and replacement procedures for the nuclear pacemaker during the life of the patient. Procedures for recovery and authorized disposal of the nuclear pacemaker by return to the manufacturer shall be followed upon the death of the patient.
16. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders or detector cells by the licensee.
17. The licensee may transport licensed material in accordance with the provisions of 10 CFR 71, "Packaging and Transportation of Radioactive Material."
18. The licensee shall not receive or transfer in any single transaction one (1) gram or more of plutonium 238 contained in nuclear-powered pacemakers without notifying the Division of Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and, in addition, completing and distributing Form NRC-741 as required by Section 70.54 of 10 CFR 70.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License number

SNM-1525

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070-01941

Amendment No. 05

(Continued)

CONDITIONS

19. 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. 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 February 19, 1975
- B. Application dated November 26, 1975
- C. Letter dated June 16, 1977
- D. Letter dated November 25, 1985
- E. Letter dated April 4, 1991

For the U.S. Nuclear Regulatory Commission

Original Signed By:
Jenny Johansen

By

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

Date JUL 19 1991

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

: (FOR LFMS USE)
: INFORMATION FROM LTS
: -----
: PROGRAM CODE: 22160
: STATUS CODE: 0
: FEE CATEGORY: EX 7C
: EXP. DATE: 20010731
: FEE COMMENTS: PACEMAKER/29-01040-03
: DECOM FIN ASSUR REQD: N
: ::::::::::::::::::::::::::::::

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: GENERAL HOSPITAL CENTER AT PASSAIC
RECEIVED DATE: 960731
DOCKET NO: 7001941
CONTROL NO.: 123514
LICENSE NO.: SNM-1525
ACTION TYPE: TERMINATION

2. FEE ATTACHED
AMOUNT: -----
CHECK NO.: -----

3. COMMENTS

SIGNED M.A. Perkins
DATE 7/31/96

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED 1)

1. FEE CATEGORY AND AMOUNT: EX 7C Termination

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT ✓
RENEWAL -----
LICENSE -----

3. OTHER -----

SIGNED BR
DATE -----

BY LFDCB
8/6/96
Aug 7
8/6/96
Completed 8/6/96

FEE EXEMPT

REC-5 MAR 11 1996

October 3, 1994

MEMORANDUM TO: Thomas T. Martin, Administrator, RI
Stewart G. Ebnetter, Administrator, RII
John B. Martin, Administrator, RIII
Leonard J. Callan, Administrator, RIV
Robert M. Bernero, Director
Office of Nuclear Material Safety
and Safeguards

FROM: Hugh L. Thompson, Jr. /s/
Deputy Executive Director for
Nuclear Materials Safety, Safeguards
and Operations Support

SUBJECT: RECORD RETENTION REQUIREMENTS FOR TRANSFERS AND TERMINATIONS

In order to address Congressional concerns regarding radioactive contamination at sewage treatment plants, the NRC is currently revising the record retention requirements of 10 CFR Parts 20, 30, 40, 70, and 72, to ensure the long-term availability of certain licensee records when a licensee terminates licensed activities or licensed activities are transferred to another licensee. Current regulations require licensees to maintain such records, but do not specify what happens to the records when a licensee transfers, assigns, or in any manner terminates a license, and another person continues licensed activities at the same site. The existing regulations are also unclear as to the final disposition of these records when licensed activities have ceased and the license is terminated. The proposed revisions would require a licensee to transfer all records pertaining to: (1) the decommissioning of the facility; (2) radiation doses to the public; and (3) waste disposal by release to sewers, incineration, radioactive material spills, and on-site burials, to the new licensee, if licensed activities will continue at the same location, or to the NRC for license terminations.

The regions are hereby advised that, until such time as the rulemaking is final, no transfers or changes of ownership or license terminations are to be authorized unless all records considered important to the safe and effective decommissioning of the facility, 10 CFR 30.35(g), 40.36(f), 70.25(g), and 72.30(d); and all records concerning public dose and waste disposal, have been transferred to the person continuing the licensed activity, or to the NRC for license terminations. Address any questions to Susan Greene, NMSS, at (301) 415-7843 or E-mail (SLG).

cc: J. Taylor, EDO
J. Milhoan, DEDR

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IMAB R/F IMNS Central File NRC File Center **BR&SL **PCV **RECHFS
**REGDIRS **REGSL **JDE1, RII **JLR1 G:\IMNS855.SLG
*SEE PREVIOUS CONCURRENCE **E-MAILED SENT

OFC	IMAB	IMAB	*	IMAB	*	IMOB	*	IMNS	IMNS	NMSS	NMSS
NAME	SGreene	JPiccone		JGlenn		FCombs		EBrach	CPaperiello	GArlotto	RBernero