MATERIALS LICENSE

Amendment No. 60

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. Shadyside Hospital	In accordance with the letter dated August 22, 1996, 3. License Number 37-02523-01 is amended in its entirety to read as follows:
2. 5230 Centre Avenue Pittsburgh, Pennsylvania 15232	4. Expiration Date June 30, 2001
	5. Docket or Reference No. 030-03021/37-02523-03

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. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200	B. As needed
C. Any byproduct material identified in 10 CFR 35.300	C. Any radiopharmaceutical identified in 10 CFR 35.300	C. 600 millicuries
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy source identified in 10 CFR 35.400	D. 2,000 millicuries
E. Any byproduct material identified in 10 CFR 31.11	E. Prepackaged Kits	E. 2 millicuries
F. Iodine 131	F. Iodomethylnorcholesterol	F. As needed
G. Iodine 131	G. Metaiodobenzylguanidine	G. As needed
H. Any byproduct material identified in 10 CFR 35.500	H. Any diagnostic source identified in 10 CFR 35.500	H. 1.5 curies per source and 6 curies total
I. Strontium 90	I. Sealed source (Nuclear Enterprises Model 2503/3A)	I. 12 millicuries
J. Iridium 192	J. Sealed sources (BYK Mallinckrodt Model CIL BV)	J. See Condition 24
K. Cesium	K. Sealed source (J.L. Shepherd and Associates Model 6310 or ORNL A-0096)	K. 600 curies

ML 10

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 37-02523-01

Docket or Reference Number: 030-03021/37-02523-03

Amendment No. 60

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
L. Gadolinium 153	L. Sealed Sources (North American Scientific Model MED 3601)	L. Not to exceed 250 millicuries per source and 1 curie total
M. Depleted Uranium 235	M. Metal	M. 999 kilograms

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. In vitro studies.
F and G. Adrenal imaging in accordance with IND 26,058 and 29,997.
H. Medical use of sealed sources included in 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).
I. Non-human use. For calibrations and checking of instruments.
J. One source to be used in a Nucletron Corporation MicroSelectron High Dose Rate Remote Afterloading Brachytherapy Device for interstitial, intracavitary, or bronchial therapy. One source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the irradiation device.
K. For use in a J.L. Shepherd & Associates, Model 143-45A for the irradiation of material except explosives and flammable materials.
L. For use in an ADAC Laboratories Model Vantage device for patient attenuation correction during S.P.E.C.T. Imaging.
M. For shielding in a linear accelerator.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 5230 Centre Avenue, Pittsburgh, Pennsylvania.

11. The Radiation Safety Officer for this license is Ronald J. Scala, M.S.

12. Medical Physicists shall meet the training criteria established in 10 CFR 35.961 and shall be designated in writing by the licensee's Radiation Safety Committee.

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number 37-02523-01

Docket or Reference Number 030-03021/37-02523-03

Amendment No. 60

13. 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 Users	Material and Use
Mark H. Wholey, M.D.	35.100; 35.200; 35.300; 35.500 In vitro studies
Ingrid Naugle, M.D.	35.100; 35.200; 35.300 In-vitro studies Strontium 90
Kevin R. O'Hara, M.D.	35.100; 35.200 In vitro studies Strontium 90
Chester R. Jarmolowski, M.D.	35.100; 35.200; 35.300; 35.500 In vitro studies Strontium 90; Gadolinium 153 for patient attenuation correction during S.P.E.C.T. Imaging
Vijay K. Bahl, M.D. 35.100;	35.100
Deborah L. Millar, M.D.	35.100; 35.200; 35.500 In vitro studies Strontium 90; Gadolinium 153 for patient attenuation correction during S.P.E.C.T. Imaging
Lawrence Cooperstein, M.D.	35.100; 35.200; 35.300; 35.500 In vitro studies Strontium 90; Gadolinium 153 for patient attenuation correction during S.P.E.C.T. Imaging
Russell Fuhrer, M.D.	35.400 Iridium 192 in a remote afterloader for the treatment of humans
Todd F. Stockstill, M.D.	35.400 Iridium 192 in a remote afterloader for the treatment of humans

14. Material listed in item 6.K. shall be used by individuals who have been trained as specified in the application dated April 16, 1995. The licensee shall maintain records of individuals designated as users.

15. 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.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
37-02523-01

Docket or Reference Number
030-03021/37-02523-03

Amendment No. 60

16. Notwithstanding the requirements of 10 CFR 35.400(d) and (g), the licensee may use iridium-192 as seeds encased in nylon ribbon and palladium-103 as a sealed source in seeds for topical, interstitial, and intracavitary treatment of cancer. The licensee may deviate from the manufacturer's radiation safety and handling instructions to the extent that the instructions are not applicable to the type of use proposed by the licensee.

17. Notwithstanding the provisions of 10 CFR 35.49 (a), "Suppliers," the licensee is authorized to receive Iodine-131 iodomethylnorcholesterol and metaiodobenzylguanidine from the University of Michigan, Ann Arbor, Michigan.

18. Radioactive waste containing microcurie amount of Iodine-125 may be disposed to the ordinary trash after being held for decay for a minimum of five (5) half-lives. Prior to disposal, these waste must be monitored in accordance with the procedures described in the licensee's application dated April 16, 1995. The survey conducted prior to disposal must confirm that the radioactivity of the waste cannot be distinguished from background.

19. 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 each day of use.

    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.

20. Prior to initiation of a treatment program, and subsequent to each source exchange for each high dose rate remote afterloading brachytherapy unit, a radiation survey shall be made of:

    A. 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 millirem per hour.

    B. All areas adjacent to the treatment room with the source in the exposed position. The survey shall clearly establish:

        (1) That radiation doses to occupationally exposed individuals do not exceed the limits specified in 10 CFR 20.1201(a), 20.1207 and 20.1208.

        (2) That radiation doses to individual members of the public do not exceed the limits specified in 10 CFR 20.1301(a)

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
37-02523-01

Docket or Reference Number
030-03021/37-02523-03

Amendment No. 60

21. 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.

22. 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 survey instrument used, dose rate, time, date and name of the individual making the survey.

D. Retain the record of the survey in lieu of the record required in 10 CFR 35.406(d).

23. In lieu of 10 CFR 35.404(a), immediately after retracting the source from the patient into its shielded position in the remote afterloading device, radiation survey shall be made of the patient and the remote afterloading device with a portable radiation detection survey instrument to confirm that the source has been removed from the patient. Records of the survey shall be maintained in lieu of the record required in 10 CFR 35.404(b).

24. The licensee may possess 24 curies of iridium-192 (not to exceed 12 curies per source) for use in a Nucletron MicroSelectron High-Dose-Rate-Remote-Afterloading Brachytherapy Device, provided the individual source activity does not exceed 10 curies at the time of installation, and the source is installed by an authorized individual.

25. A. Sealed sources and detector cells containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six months or at such other intervals as are specified by the certificate of registration referred to in 10 CFR 32.210, not to exceed three years.

B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.

C. In the absence of a certificate from a transferor indicating that a leak test has been made within six months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

D. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

E. Sealed sources and detector cells need not be leak tested if:

(i) they contain only hydrogen-3; or

(ii) they contain only a radioactive gas; or

(iii) the half-life of the isotope is 30 days or less; or

(iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or

(v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

F. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission and the source or detector cell shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within five days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source or detector cell involved, the test results, and corrective action taken.

G. The licensee is authorized to collect leak test samples for analysis by the licensee. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

26. The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Removal, replacement, and disposal of sealed sources in the irradiator shall be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

27. The licensee shall conduct a physical inventory every three months to account for all sealed sources and devices containing licensed material received and possessed pursuant to 10 CFR 35.59, 35.400 and 35.500 and every six months for all other sealed sources and devices.

28. The procedures contained in the manufacturer's instruction manual for the irradiator authorized by this license shall be followed and a copy of this manual shall be made available to each person using or having responsibility for the use of the device.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number: 37-02523-01

Docket or Reference Number: 030-03021/37-02523-03

Amendment No. 60

29. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

30. Replacement-exchange of the source/source-holder combination authorized in 10 CFR 35.500 devices may be performed by the licensee in accordance with the instructions contained in the manufacturer's manual

31. 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 April 16, 1995
B. Letter dated October 18, 1995
C. Letter dated March 14, 1996
D. Letter dated April 29, 1996
E. Letter dated February 2, 1996
F. Letter dated March 22, 1996
G. Letter dated April 29, 1996

Date SEP 27 1996

For the U.S. Nuclear Regulatory Commission

By Original Signed By:
Michelle Beardsley

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

SEP 27 1996

Ronald Scala, M.S.
Radiation Safety Officer
Shadyside Hospital
5230 Centre Avenue
Pittsburgh, PA 15232

Dear Mr. Scala:

This refers to your license amendment request. Enclosed with this letter is the amended 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:
Michelle Beardsley

Michelle R. Beardsley
Division of Nuclear Materials Safety

License No. 37-02523-01
Docket No. 030-03021
Control No. 123629

Enclosure:
Amendment No. 60

DOCUMENT NAME: R:\WPS\MLTR\L3702523.01
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 MB							
DATE	09/04/96		09/ /96		09/ /96		09/ /96	

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ML 10

SHADYSIDE HOSPITAL
5230 Centre Avenue
Pittsburgh, PA 15232
412-623-2078

DEPARTMENT OF RADIOLOGICAL SCIENCES AT DIAGNOSTIC IMAGING

030-03021

U.S. Nuclear Regulatory Commission
Region I
Nuclear Materials Safety Section
475 Allendale Road
King of Prussia, PA 19406

August 22, 1996

RE: Release of restricted area
License No. 37-02523-01

Dear Sirs:

In accordance with Regulatory Guide 10.8, the following is notification of release of previously restricted area, as a result the removal of all licensed sources as authorized by Amendment 59 to License No. 37-02523-01. Specifically, the HDR Brachytherapy Room on First Floor South, has been released. The HDR unit and source has been relocated in accordance with the above amendment. A radiation survey and wipe test were performed and are enclosed.

Should you have any questions regarding this notification, please contact me at (412) 623-1052.

Sincerely,

Ronald Scala, M.S.
Radiation Safety Officer
Shadyside Hospital

cc: file

enclosure

cc: file

123629

OFFICIAL RECORD COPY ML 10

SEP - 3 1996

CONTINUATION OF 122891

RADIATION SURVEY, SHADYSIDE HOSPITAL

DATE OF SURVEY: 7/12/94

PERSON PERFORMING SURVEY: R Scala

REASON FOR SURVEY: Closeout survey & Wipe

SURVEY LOCATION: 6MV LINAC Room 1 SOUTH (HDR)

SURVEY TYPE: GM + Wipe

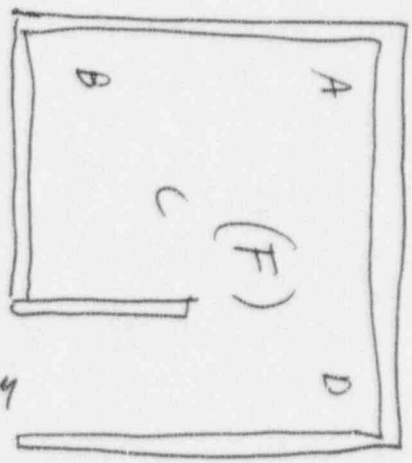
SURVEY INSTRUMENT: Ludlum 14C / Ludlum 2000 well

GM Check ✓ Battery ✓ Window NA Bkg 0.02 mR/hr

well NA NA full 574 CPM

ROOM(s) DIAGRAM:

NOTE: LINAC still in room and operable, HDR unit removed.



SURVEY RESULTS: GM

			WIPE
A	0.02 mR/hr	F	569 CPM
B	0.02	G	-------
C	0.02	H	-------
D	0.02	I	-------
E	-------	Bkg	574 CPM

NET 0 DPM

RESULTS/ACTIONS: No detectable radiation was measured nor any removable contamination found. Room Authorized for release once LINAC moved. RS

✓ NOTE: set ULD to full window to count Ir192 HD gamma

Signature R Scala Date 7/12/94

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 3E
EXP. DATE: 20010630
FEE COMMENTS: 3E EFF 9/20/93
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: SHADYSIDE HOSP
RECEIVED DATE: 960903
DOCKET NO: 3003021
CONTROL NO.: 123629
LICENSE NO.: 37-02523-01
ACTION TYPE: AMENDMENT

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

3. COMMENTS
Continuation of 122891.

SIGNED M. A. Perkins
DATE 9/4/96

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

FEE NOT REQUIRED /✓/

1. FEE CATEGORY AND AMOUNT: 7C 3E Cont'n 9122891

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

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

SIGNED ----------
DATE ----------

RECEIVED BY LFDCB
Date 9/19/96
Log Aug 19 I (96)
By EB
Date Completed 9/19/96

IRS SEP -9 AM 8:19