

MATERIALS LICENSE

Amendment No. 14

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. Beebe Medical Center 424 Savannah Road 2. Lewes, Delaware 19958		In accordance with the letter dated November 13, 1996, 3. License Number 07-17792-01 is amended in its entirety to read as follows: 4. Expiration Date November 30, 2003 5. Docket or Reference No. 030-13331	
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. Strontium 89	C. As identified in 10 CFR 35.300	C. As needed	
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy source identified in 10 CFR 35.400	D. 2 curies	
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 procedure approved in 10 CFR 35.300. D. Any brachytherapy procedure approved in 10 CFR 35.400.			

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 424 Savannah Road, Lewes, Delaware.
11. The Radiation Safety Officer for this license is Frances Esposito, M.D.
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 Users

Norman H. Boyer, M.D.

Carl J. Abramowicz, M.D.

9706180287 970513
PDR ADOCK 03013331
C PDRMaterial and Use

35.100; 35.200

35.100; 35.200

ML 10



MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

07-17792-01

Docket or Reference Number

030-13331

Amendment No. 14

Kisan Karapurkar, M.D.	35.100; 35.200
James W. Lockard, Jr., M.D.	35.100; 35.200
Frances Esposito, M.D.	35.100; 35.200 Strontium 89 for radiopharmaceutical procedures approved in 35.300
Jeffrey McCann, M.D.	35.100; 35.200
Andrejs Strauss, M.D.	35.400

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. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material at a single location to quantities below the limits specified in 10 CFR 30.72 which require consideration of the need for an emergency plan for responding to a release of licensed material.
15. 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.
16. 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

07-17792-01

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17. 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. Letter dated June 15, 1993
- B. Letter dated October 5, 1993
- C. Letter dated September 19, 1994
- D. Letter dated November 13, 1996
- E. Letter received April 17, 1997

Date MAY 13 1997

For the U.S. Nuclear Regulatory Commission

**ORIGINAL SIGNED BY:
TARA L. WEIDNER**

By

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

MAY 13 1997

Jeffrey M. Fried, FACHE
President/CEO
Beebe Medical Center
424 Savannah Road
Lewes, DE 19958-0226

Dear Mr. Fried:

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:
TARA L. WEIDNER

Tara L. Weidner
Division of Nuclear Materials Safety

License No. 07-17792-01
Docket No. 030-13331
Control No. 123960

Enclosure:
Amendment No. 14

DOCUMENT NAME: R:\WPS\MLTR\0717792.01

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	<input checked="" type="checkbox"/> N	DNMS/RI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NAME	Weidner						
DATE	04/10/97		04/ /97		04/ /97		04/ /97

OFFICIAL RECORD COPY

ML 10



Beebe Medical Center

ROBERT & EOLYNE

**Tunnell
Cancer
Center**

MS16

J-9

April 10, 1997

Tara Widner
U.S. Nuclear Regulatory Commission
Region I
275 Allendale Road
King of Prussia, Pa 19406-1415

Dear Ms. Widner,

This letter is in addendum to the previous letter sent providing information for our license amendment.

We requested brachytherapy sources listed in 10 CFR35 . 400. The possession limits on these sources would be no more than two to three Curies.

If you require additional information, please contact Joy Bartell at 302-645-3310 or Jack Merkin at 908-788-9440.

Sincerely,

Jeffery M. Fried, President
Beebe Medical Center

424 Savannah Road
Lewes, DE 19958-0226
Phone 302-645-3770
Fax 302-645-5718

OFFICIAL RECORD COPY
ML 10

123960
APR 17 1997



ROBERT & EOLYNE

**Tunnell
Cancer
Center**

MS-16

J9

Tara Widner
U.S. Nuclear Regulatory Commission
Region I
275 Allendale Road
King of Prussia, PA 19406-1415

RE: Mail control 123960

Dear Ms. Widner:

I am writing to provide you with the additional information which you requested regarding our request for license amendment.

The brachytherapy sources requested are all sources listed or available in 10 CFR35.400. The short-lived interstitial implant sources are requested with an "as needed" possession limit. There are no present plans to purchase Cobalt-60 or Strontium-90 sources, however, if a possession limit is necessary, please advise and the possession limit will be provided before purchase.

An additional NaI probe for the Ludlum survey meter specified in the application will be purchased. This will be used in surveys for Iodine-125 or Palladium-103 seeds. The probe is Ludlum model 44-3 NaI detector.

If you require any further information, please contact Joy A. Bartell, R.N. at (302) 645-3310, or Jack J. Merkin, M.S. at (908) 788-9440.

Sincerely,

Jeffery M. Fried, President
Beebe Medical Center

424 Savannah Road
Lewes, DE 19958-0226
Phone 302-645-3770
Fax 302-645-5718

OFFICIAL RECORD COPY ML 10

123960
APR 17 1997

February 20, 1997

Tara Widner
Nuclear Regulatory Commission

Dear Tara,

Last week per our telephone conversation, we discussed the items necessary for the amendment to our NRC license. I told you that I would fax it to by Friday. This did not turn out to be true!! Jack Merkins, our physicist, did not come on site last week and I was unable to get the letter stating we wanted all sources and the specific survey instrument as you requested. Jack is suppose to be here this week, and I hope to get the information from him then. In the meantime, I'm faxing the materials that I do have. I apologize for the delay. Please call me with any questions or problems. Thank you.

Joy Bartell, RN,BSN,OCN
Tunnell Cancer Center
Beebe Medical Center
Lewes, DE 19958

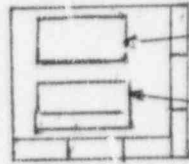
Telephone: 302-645-3310
Fax: 302-645-5718

Procedures for Preventing the Loss of I-125 Seeds

1. Supervise handling of the seeds at all stages and visually monitor the use of seeds during the implant procedure.
2. Collect and survey surgical sponges and drapes in the operating room.
3. Carefully survey the wound drainage apparatus including the collection vessel with drainage fluid.
4. Monitor operating room personnel prior to leaving the procedure room.
5. Visually inspect and survey implant instrumentation prior to removal from the operating room. An obturator may be passed through implant needles to discharge any seeds that may have been retained.
6. If the patient is catheterized and if urinary discharge is a possible route of seed migration, the catheter and urine bag should be saved and surveyed. Collect all urine for the duration of the patient's hospital stay and survey prior to disposal. If seed migration through the intestinal tract is possible (e.g., following a tongue implant) fecal monitoring should be performed.
7. Obtain radiographs of the implant site as soon after the implant as possible to confirm the number of implanted seeds and to identify seeds that could possibly become displaced.
8. During hospital confinement patient linen and bedclothes should be stored in the patient's room and surveyed prior to removal. Dressing material used around superficial implants should also be saved and surveyed.
9. Survey the patient's hospital room carefully prior to cleaning after the patient is discharged.
10. Communication with the patient and personnel involved with caring for the patient is extremely important.
11. Surveys for lost seeds should be conducted with a sensitive instrument, e.g., a portable survey meter with a NaI detector.

(EARTH)

(EARTH)



SAFE

L-BLOCK

LEAD BRICKS

DECAY LAB

Basement Level

Beebe Medical Center

Iodine-125 Implant Survey Form

Patient Name: _____ Patient Number: _____

Total number seeds/activity implanted: _____ Time and date of implant: _____

Operating Room

Survey Areas:	mR/hr	mR/hr	
Preparation table:	_____	Suction containers:	_____
Instrument table:	_____	Gauze & dressing:	_____
O.R. Table:	_____	Personnel within restricted area:	_____
Floor surrounding table:	_____	Background:	_____
Survey meter: _____		Date of last calibration: _____	
Surveyor: _____		Date: _____	

Patient Room

Location/Room Number: _____

Survey Areas:	mR/hr	mR/hr	
Bedside:	_____	One meter from patient:	_____
Implant Site:	_____	Doorway to room:	_____
Adjacent Room:	_____	Other:	_____
Background:	_____		_____
Survey meter: _____		Date of last calibration: _____	
Surveyor: _____		Date: _____	

Patient Discharge

Survey Areas:	mR/hr	mR/hr	
Bedside:	_____	One meter from patient:	_____
Background:	_____		_____
Survey meter: _____		Date of last calibration: _____	
Surveyor: _____		Date: _____	

Patient may be released when exposure rate is less than 5 mR/hr at 1 meter

Room Release

Location/Room Number: _____

A low-range GM survey of the room measured _____ mR/hr Background: _____ mR/hr

Comments: _____

Survey meter: _____ Date of last calibration: _____

Surveyor: _____ Date: _____

*Reverse side of "Source Seals" form***Disposal****Sources returned**

Manufacturer: _____

Total Activity: _____ mCi

Number of seeds: _____

Activity/seed: _____ mCi

Assay Date: _____

Package

Survey: _____ mR/hr at surface of outside package

Background: _____ mR/hr

Wipe: _____ (dpm)

Survey meter: _____ Date of last calibration: _____

Surveyor: _____ Date: _____

Patient Follow up

Date: _____

Number of seeds: _____

Counted by: _____

Probable Disposition: _____

Date: _____

Number of seeds: _____

Counted by: _____

Probable Disposition: _____

Date: _____

Number of seeds: _____

Counted by: _____

Probable Disposition: _____

Date: _____

Number of seeds: _____

Counted by: _____

Probable Disposition: _____

Iodine-125 Source Status

Order

Patient Name: _____ Patient Number: _____

Sources ordered

Manufacturer: _____

Total Activity: _____ mCi

Number of seeds: _____

Activity/seed: _____ mCi

Date ordered: _____ Order number: _____

Physician: _____ Ordered by: _____
(Authorized User)

Receipt

Sources received

Manufacturer: _____

Total Activity: _____ mCi

Number of seeds: _____

Activity/seed: _____ mCi

Assay Date: _____

Package Intact: ☐ yes ☐ no

Survey: _____ mR/hr at surface of outside package

Background: _____ mR/hr

Wipe: _____ (dpm)

Survey meter: _____ Date of last calibration: _____

Surveyor: _____ Date: _____

Implant Procedure

Implant date: _____

Number of seeds in OR: _____

Number of seeds implanted: _____

Number of seeds returned to hot lab: _____

Returned by: _____

Written Directive:Iodine-125 Permanent Implant**Must be completed before sources are implanted**

Patient Name: _____ Patient Number: _____
Radioisotope: _____ Treatment Site: _____
Prostate Volume (cc): _____ Total Activity Required: _____ mCi
(See nomogram on reverse side)
Activity per seed: _____ mCi Total Number of Seeds to be Ordered: _____
Ordered By: _____ Date: _____
(Authorized User)

Must be completed at the time of procedure

Is the Written Directive complete? _____ Yes _____ No
Are the received materials in agreement with the Written Directive? _____ Yes _____ No
Patient identity verified by two methods? _____ Yes _____ No

If any item is answered No, **DO NOT PROCEED**

Must be completed after sources are implanted

Implant Date: _____ Radioisotope: _____
Prostate Volume (cc): _____ Total Activity Required: _____ mCi
Activity per seed: _____ mCi Total Number of Seeds Required: _____
Total Number of Seeds Implanted: _____
Treatment in accordance with plan? _____ Yes _____ No
Comments: _____

Ordered By: _____ Date: _____
(Authorized User)



Beebe Medical Center

November 13, 1996

License Amendment Reviewer
Nuclear Materials Safety Section
Division of Safety & Safeguards
U.S.N.R.C. - Region 1
475 Allendale Road
King of Prussia, PA 19406

To Whom It May Concern:

Please find our \$440 check payable to the N.R.C. enclosed for the purpose of amending our by-product materials license (07-17792-01) to include Andrejs Strauss, M.D., A.B.R., certified in radiation therapy as an authorized user and the supervisor of any procedure in 10CFR 35.400. We are requesting a possession limit not to exceed 1 Ci for Cesium 137 brachytherapy seeds.

Dr. Strauss has been licensed under and within the last seven years at Peninsula Regional Medical Center, Salisbury, Maryland, Maryland License # MD-45-001-003.

1. Please find our diagram of the basement storage facility for the brachytherapy source storage room and handling equipment.
2. Our brachytherapy sources storage closet is locked at all times to prevent unauthorized access. The seeds will be stored in a 4" thick lead "safe". The closet will have 2" thick lead L-block. Additional 2"x4"x8" lead bricks will be configured to reduce exposure outside the sealed source storage and handling closet to less than 2.0mR in one hour at all times. Transportation carts for these radionuclides will be 1 1/2" thick lead. We also have remote-handling tongs and devices, as well as clinical after-loading equipment. Sources will be loaded in the patient's room. A mobile 1" thick lead shield will be positioned for optimal safety in the patient's room.
3. We confirm we will follow the model radiation safety procedures outlined in the N.R.C.'s Regulation Guide 10.8 Rev. 2, August 1987, Appendix Q, including nursing forms equivalent to Exb. 1.15, Exb. 1.16, and Exb. 1.17. We confirm we will follow all the regulations in 10CFR 35.404, 406, 415, 420 and 10CFR 35.59.
4. Nursing personnel attending to these patients will have an initial radiation safety in-service prior to actual patient handling along with ongoing in-service education annually as specified in 10CFR 35.410.
5. Brachytherapy use logs will be maintained to assure accountability following use. (Logging in and out will be required.)



Nuclear Materials Safety Section
November 13, 1996
Page Two

Beebe Medical Center

6. Quarterly surveys and inventories will be performed on all possessed brachytherapy sources.
7. Semi-annual wipe/leak tests will be performed to an accuracy of 0.005 uCi detectability.
8. All brachytherapy patient rooms will be surveyed following installation of the source, and this record kept in a log book.
9. The patient will be surveyed prior to discharge to assure all sources have been retrieved from temporary implants and to satisfy criteria in 35.75.
10. Our personnel handling and loading the applicators will be monitored with ring-type T.L.D. personnel monitors as well as total body badges, processed monthly. Personnel caring for the patient will wear personnel monitors.
11. Unused, retrieved, or expired sources will be returned to the manufacturer for disposal.

Enclosed is our amended Quality Management Plan to reflect this change.

Please include in this amendment a request to add a room for the sole purpose of imaging procedures.

Enclosed is our diagram that represents this change.

No radioactive materials will be stored in this room. The location will be included on our daily and weekly monitoring logs.

Please also include in this amendment to add Jeffrey McCann, M.D., A.B.R., as an authorized user of 10CFR 35.100 and 200 by-product materials. His A.B.R. certificate is enclosed.

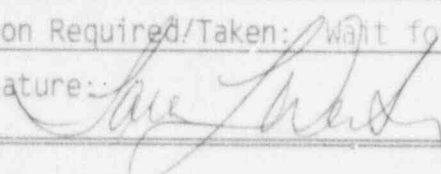
If you have any questions pertaining to the brachytherapy portion of the amendment, please contact our Consultant Radiation Physicist, Mr. Jack Merkin, at 901-788-9440.

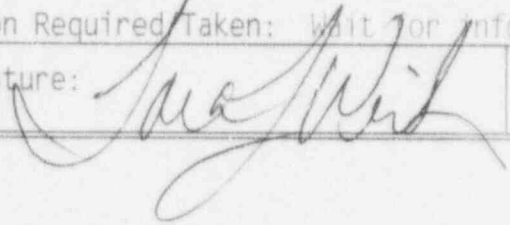
If you have any questions regarding other aspects of this amendment, please contact our Consultant Medical Radiation Health Physicist, Mr. Jack Olley, at 717-291-9813, vmb #3.

Sincerely,

Jeffrey M. Fried, FACHE
President/CEO

JMF/kw
Enclosures

TELEPHONE CONVERSATION RECORD	Date: 4-10-97	Time: 3:00
Mail Control No.: 123960	License No.: 07-17792-01	Docket No.: 030-13331
Person Called: Joy Bartell	Licensee: Beebe Medical Center	Telephone Number: 302-645-3537
Person Calling: Tara Weidner 337-5272		
Subject: Amendment		
Summary: She will state the possession limit for 35.400 and attach the procedures that were enclosed with the unsigned 2/97 fax. Also she will have everything signed by management.		
Action Required/Taken: Wait for info		
Signature: 	Date: 4-10-97	

TELEPHONE CONVERSATION RECORD		Date: 2-4-97	Time: 11:00
Mail Control No.: 1223960 123960		License No.: 07-17792-01	Docket No.: 030-13331
Person Called: Jack Merkin		Licensee: Beebe Medical Center	Telephone Number: 908- 788-9440
Person Calling: Tara Weidner 337-5272			
Subject: License amendment			
Summary: •Indicate where the brachy source storage is going to be in the basement; •confirm that they will survey the brachy patient's bed linen prior to laundering; •confirm whether they want 35,400 totally or just Cs-137. •If they want 1-125 seeds they need to provide a description of the survey procedures to locate dislodged seeds in the o.r. or the patient's room. •Indicate which survey instrument will be used (d091).			
Action Required/Taken: Wait for info			
Signature: 		Date: 2-4-97	

OFFICIAL RECORD COPY

ML 10



Beebe Medical Center
030-13331

November 13, 1996

License Amendment Reviewer
Nuclear Materials Safety Section
Division of Safety & Safeguards
U.S.N.R.C. - Region 1
475 Allendale Road
King of Prussia, PA 19406

To Whom It May Concern:

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5. Brachytherapy use logs will be maintained to assure accountability following use. (Logging in and out will be required.)

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NOV 27 1996

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6. Quarterly surveys and inventories will be performed on all possessed brachytherapy sources.
7. Semi-annual wipe/leak tests will be performed to an accuracy of 0.005 uCi detectability.
8. All brachytherapy patient rooms will be surveyed following installation of the source, and this record kept in a log book.
9. The patient will be surveyed prior to discharge to assure all sources have been retrieved from temporary implants and to satisfy criteria in 35.75.
10. Our personnel handling and loading the applicators will be monitored with ring-type T.L.D. personnel monitors as well as total body badges, processed monthly. Personnel caring for the patient will wear personnel monitors.
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Please include in this amendment a request to add a room for the sole purpose of imaging procedures.

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If you have any questions pertaining to the brachytherapy portion of the amendment, please contact our Consultant Radiation Physicist, Mr. Jack Merkin, at 901-788-9440.

If you have any questions regarding other aspects of this amendment, please contact our Consultant Medical Radiation Health Physicist, Mr. Jack Olley, at 717-291-9813, vmb #3.

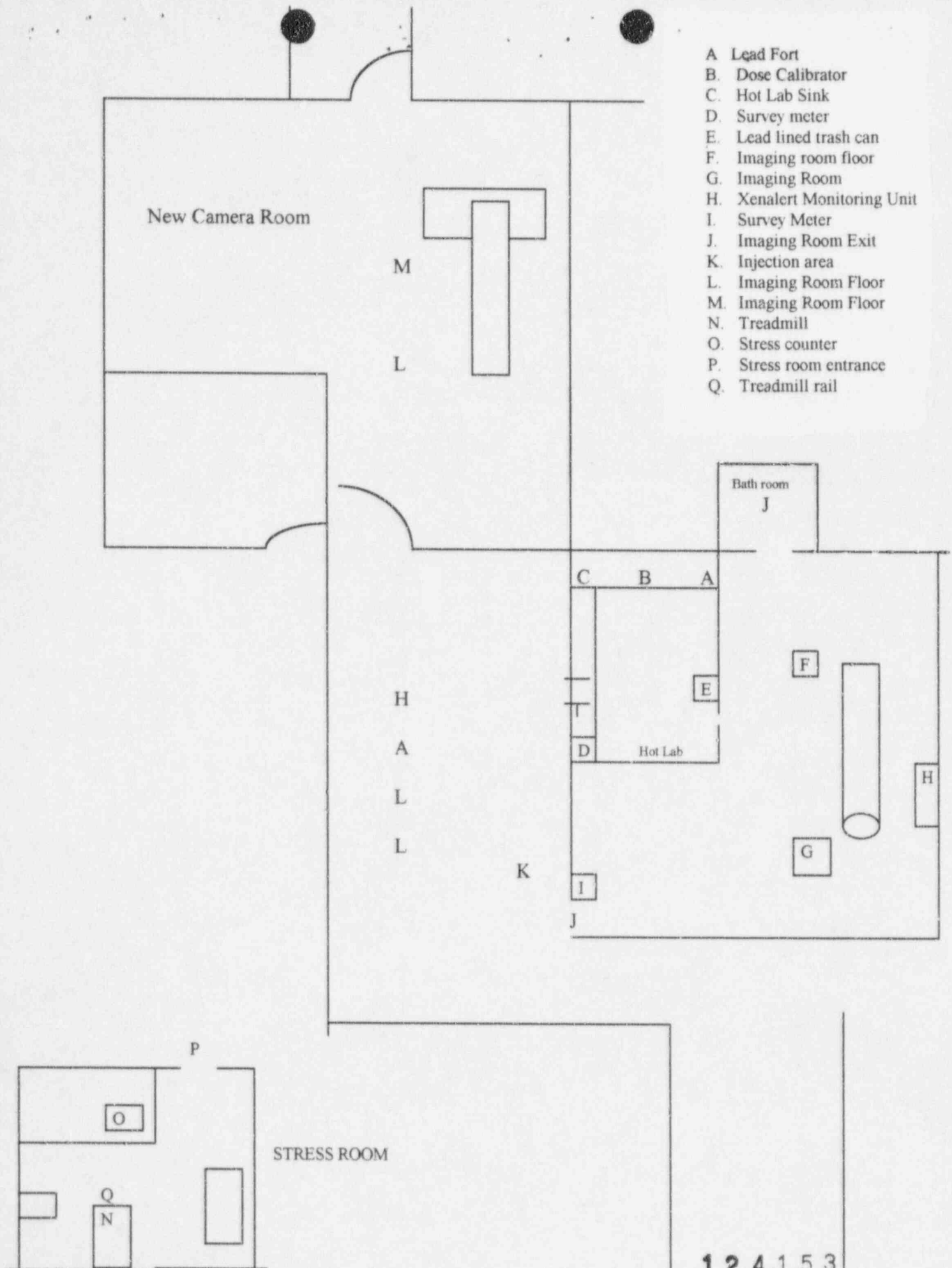
Sincerely,

Jeffrey M. Fried

Jeffrey M. Fried, FACHE
President/CEO

JMF/kw
Enclosures

- A. Lead Fort
- B. Dose Calibrator
- C. Hot Lab Sink
- D. Survey meter
- E. Lead lined trash can
- F. Imaging room floor
- G. Imaging Room
- H. Xenalert Monitoring Unit
- I. Survey Meter
- J. Imaging Room Exit
- K. Injection area
- L. Imaging Room Floor
- M. Imaging Room Floor
- N. Treadmill
- O. Stress counter
- P. Stress room entrance
- Q. Treadmill rail



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**DEPARTMENT OF THE ENVIRONMENT
RADIOLOGICAL HEALTH PROGRAM
RADIOACTIVE MATERIAL LICENSE**

Page 1 of 8 pages

Pursuant to the Maryland Radiation Act, 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 radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders of the Maryland State Department of the Environment, now or hereinafter in effect and to any conditions specified below. In accordance with application dated February 23, 1993 Radioactive Material License MD-45-001-05 is amended in its entirety.

<p style="text-align: center;">LICENSEE</p> <p>1. Name Peninsula Regional Medical Center 100 East Carroll Street Salisbury, MD 21801-5493</p> <p>2. Address</p>	<p>3. License No. MD-45-001-05</p> <p>4. Amendment No. 20</p> <p>5. Expiration Date November 30, 1998</p>	
<p>6. Radioactive material (element and mass number)</p> <p>A. Any radioactive material listed in Group IV of Schedule C, Part C, COMAR 26.12.01.01.</p> <p>B. Any radioactive material listed in Group V, of Schedule C, Part C, COMAR 26.12.01.01.</p> <p>C. Any source or device containing radioactive material listed in Group VI of Schedule C, Part C, COMAR 26.12.01.01.</p>	<p>7. Chemical and/or physical form</p> <p>A. Any radioactive material listed in Group IV of Schedule C, Part C, COMAR 26.12.01.01.</p> <p>B. Any radioactive material listed in Group V of Schedule C, Part C, COMAR 26.12.01.01.</p> <p>C. Any source or device listed in Group VI of Schedule C, Part C, COMAR 26.12.01.01.</p>	<p>8. Maximum amount of radioactivity which licensee may possess at any one time</p> <p>A. As needed for uses authorized in Item 9A</p> <p>B. As necessary for uses authorized in Item 9B.</p> <p>C. 7 curies total of sources and devices authorized in Item 9C.</p>
<p>9. Authorized Use</p> <p>A. For any therapeutic procedure listed in Group IV of Schedule C, Part C, COMAR 26.12.01.01.</p> <p>B. For any therapeutic procedure listed in Group V of Schedule C, Part C, COMAR 26.12.01.01.</p> <p>C. For any certain medical uses listed in Group VI of Schedule C, Part C, COMAR 26.12.01.01.</p>		



DEPARTMENT OF THE ENVIRONMENT
RADIOLOGICAL HEALTH PROGRAM
RADIOACTIVE MATERIAL LICENSE

Page 2 of 8 pages

Supplementary Sheet

License No.	MD-45-001-05	Amendment No.	20
1. Radioactive material (element symbol, mass number)	7. Chemical and/or physical form	8. Maximum amount of radioactivity which licensee may possess at any one time	
C. Iridium-192	D. Sealed source (Mallinckrodt model 252.20 001; or RTS Technology model 722 or 723)	D. No source to exceed 10 curies plus 20%; Total possession 2 sources.	
E. Depleted uranium	E. Steel encased metal shielding material	E. 40 kilograms.	

- D. For use in Gamma Med II-1 remote afterloader for treatment of humans; second source for replacement as needed.
- E. Shielding for Gamma Med II-1 remote afterloader.

CONDITIONS

10. The authorized place of use is the licensee's address stated in Item 2. The licensee must notify the Radiological Health Program 30 days prior to vacating a permanent use address as is required by Section D.407 of COMAR 26.12.01.01.
- 11A. The radiation protection program shall be under the supervision of Jeffrey Reed assisted by Stanley Skubic, Ph.D.

FOR THE MARYLAND DEPARTMENT OF THE ENVIRONMENT

Date _____

ADMINISTRATOR, RADIOLOGICAL HEALTH PROGRAM



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Supplementary Sheet

License No. MD-45-001-05

Amendment No. 20

CONDITION CONT'D

- 11B. Radioactive material shall be used by, or under the supervision of Andrejs V. Strauss, M.D.; Vincenzo De Nasi, M.D. and/or Catherine A. North, M.D.
12. The licensee shall comply with provisions of Part D, "Standards for Protection Against Radiation", Part G, "Use of Sealed Radioactive Sources in the Healing Arts" and Part J, "Notices, Instructions and Reports to Workers; Inspections of the Maryland Regulations 26.12.01.01 "Regulations for Control of Ionizing Radiation".
13. For a period not to exceed sixty (60) days in any calendar year, a visiting physician is authorized to use licensed material for human use under the terms of this license, provided the visiting physician:
- (A) Has the prior written permission of the hospital's Administrator and its Medical Isotopes Committee; and,
 - (B) Is authorized as a user by a specific license issued by the Department, the U.S. Nuclear Regulatory Commission, or another Agreement State authorizing human use, and performs only those procedures for which he is authorized by that license.

The licensee shall maintain for inspection by the Department, copies of the written permission specified in subitem (A) above and the license(s) specified in subitem (B) above. These records shall be maintained for five (5) years from the time the licensee grants its permission under subitem (A) above.

- 14A. Needles or standard medical applicator cells containing Cobalt-60 as wire shall not be opened by the licensee unless specifically authorized by a condition in this license.
- 14B. Patients containing Cesium-137 or Iridium-192 implants shall remain hospitalized until the implants are removed.

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Amendment No. 20

CONDITION CONT'D

- 15 Patients containing Iodine-131 for the treatment of thyroid carcinoma or patients containing therapeutic quantities of Gold-198 shall remain hospitalized until the residual activity is 30 millicuries or less.
- 16A. Each sealed source containing radioactive material, other than Hydrogen-3 with a half-life greater than thirty days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six (6) months. In the absence of a certificate from a transferor indicating that a test has been made within six (6) months prior to the transfer, the sealed source shall not be put into use until tested. If there is reason to suspect that a sealed source might have been damaged, or might be leaking, it shall be tested for leakage before further use.
- 16B. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of a device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate.
- 16C. Records of leak tests shall be kept in units of microcuries and maintained for inspection by the Department.
- 16D. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Department regulations. A report shall be filed within five (5) days of the test with the Administrator, Radiological Health Program, 2500 Broening Highway, Baltimore, Maryland 21224 describing the equipment involved, the test results, and the corrective action taken.

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DEPARTMENT OF THE ENVIRONMENT
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 Page ____ of ____ pages

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License No. MD-45-001-05

Amendment No. 20

CONDITIONS CONT'D

- 16E. Test for leakage and/or contamination shall be performed by the licensee or by other persons specifically authorized by the Department, the U.S. Nuclear Regulatory Commission or another Agreement State to perform such services.
17. Sealed sources containing radioactive material shall not be opened.
18. The licensee shall conduct a physical inventory every three (3) months to account for all sealed sources received and possessed under the license. The records of the inventories shall be maintained for two (2) years from the date of the inventory for inspection by the Department, and shall include the quantities and kinds of radioactive material, location of sealed sources, and the date of the inventory.
19. A set of written emergency instructions shall be posted at the Gamma Med II-1 operator console. These instructions shall inform the device operator of the procedures to be followed if the source fails to return to the shielded position.
- 20A. Access to the room housing the Gamma Med II-1 irradiation device shall be controlled by a door at each entrance. Such doors shall normally be closed.
- 20B. The entrance to the irradiation room shall be equipped with an electric 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.
- 20C. Electrical interlocks on the entrance door to the irradiator room shall be tested for proper operation at least once a month. Records of test results shall be maintained for inspection by the Radiological Health Program.

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CONDITIONS CONT'D

- 20D. In the event of malfunction of the door interlock, the irradiator shall be locked in the "off" condition 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.
21. Prior to initiation of treatment program, and subsequent to each source exchange for the Gamma Med II-i, radiation surveys and tests shall be performed in accordance with the following:
- A. A radiation survey shall be made of:
- (i) The irradiator source housing, with the sources in the shielded position. The maximum radiation levels at 20 centimeters from the surface of the source head shall not exceed 3 milliroentgens per hour.
 - (ii) All areas adjacent to the treatment room with the source in the "irradiation" position. The survey, except item (c), shall be performed with a phantom in the primary beam of radiation and shall clearly establish:
 - (a) That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in Section D.101 of COMAR 26.12.01.01 "Radiation Dose to Individuals in Restricted Areas".
 - (b) That quantities of radiation in unrestricted areas do not exceed the limits specified in Sec.D.105 of COMAR 26.12.01.01.
 - (c) The intensity of the primary beam of radiation at a specified distance from the source.

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CONDITIONS CONT'D

- B. Records of the survey results shall be maintained for inspection by the Radiological Health Program.
22. The following shall be performed only by persons specifically authorized by the U.S. Nuclear Regulatory Commission or and Agreement State to perform such services:
- A. Installation and replacement of sources contained in the Gamma Med II-1 radiation device.
- B. Any maintenance or repair operations on the irradiator involving work on the source head, 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.
23. Food and beverage containers shall not be discarded in radioactive or normal trash containers in licensee's areas utilizing radioactive materials.
- 24A. The licensee shall not make any false statement, representation, or certification in any application, record, report, plan, or other document regarding radiation levels, tests performed or radiation safety conditions or practices. Nor shall the licensee falsify, tamper with, or render inaccurate any monitoring device or method.
- 24B. Violation of any term, condition, or regulation could subject the licensee to administrative or civil penalty or criminal prosecution, as specified in Title 8, Radiation, of the Article Environment of the Annotated Code of Maryland.

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Pursuant to the Maryland Radiation Act, 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 radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders of the Maryland State Department of the Environment, now or hereinafter in effect and to any conditions specified below. In accordance with application dated September 27, 1990, Radioactive Material License MD-45-001-03 is renewed in its entirety.

LICENSEE

1. Name Peninsula General Hospital
100 Carroll Street
Salisbury, MD 21801

2. Address

3. License No. MD-45-001-03

4. Amendment No. 41

5. Expiration Date November 30, 1996

6. Radioactive material (element and mass number)

7. Chemical and/or physical form

8. Maximum amount of radioactivity which licensee may possess at any one time

A. Any radioactive material listed in Groups I & II of Schedule C, Part C, COMAR 26.12.01.01

A. Any radioactive material listed in Groups I & II of Schedule C, Part C, COMAR 26.12.01.01

A. As needed to perform diagnostic tests.

B. Any radioactive material listed in Group III of Schedule C, Part C, COMAR 26.12.01.01

B. Any form listed in Group III of Schedule C, Part C, COMAR 26.12.01.01

B. 6 curies of each radionuclide authorized in Item 6B.

C. Any radioactive material listed in Group IV of Schedule C, Part C, COMAR 26.12.01.01

C. Any radioactive material listed in Group IV of Schedule C, Part C, COMAR 26.12.01.01

C. As necessary for uses authorized in item 9C.

9. Authorized Use

A. Any diagnostic procedure listed in Groups I & II of Schedule C, Part C, COMAR 26.12.01.01

B. Preparation and use of radiopharmaceuticals for any diagnostic procedure listed in Group III of Schedule C, Part C, COMAR 26.12.01.01.

C. For any therapeutic procedure listed in Group IV of Schedule C, Part C, COMAR 26.12.01.01.



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RADIOACTIVE MATERIAL LICENSE

Page 2 of 6 pages

Supplementary Sheet

License No. MD-45-001-03	Amendment No. 41
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CONT'D

- | | | |
|--|--|---|
| 6. Radioactive material (element and mass number) | 7. Chemical and/or physical form | 8. Maximum amount of radioactivity which licensee may possess at any one time |
| D. Any radioactive material listed in Group V of Schedule C, Part C, COMAR 26.12.01.01 | D. Any radioactive material listed in Group V of Schedule C, Part C, COMAR 26.12.01.01 | D. As necessary for uses authorized in Item 9D. |
| E. Cobalt-57 | E. Sealed source (NEN models NES-392, NES-391, NES-206, Atomic products 062-297, 062-392, 063-261, Amersham models CPR.29, CPR.30, CTV.VI; Nuclear Associates models 67-297, 67-298, 67-206) | E. 30 millicuries |
| F. Xenon-133 | F. gas or gas in solution | F. 200 millicuries |
9. Authorized use
- D. For any therapeutic procedure listed in Group V of Schedule C, Part C, COMAR 26.12.01.01.
- E. Calibration standard
- F. Pulmonary ventilation studies

FOR THE MARYLAND DEPARTMENT OF THE ENVIRONMENT

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CONT'D

6. Radioactive material
(element and mass
number)

7. Chemical and/or
physical form

8. Maximum amount of
radioactivity which
licensee may possess at
any one time

G. Rubidium-81/
Krypton-81m

G. generator

G. 50 millicuries

H. Technetium-99m

H. Merteitide

H. 30 millicuries

I. Indium-111

I. Oxine

I. 10 millicuries

9. Authorized use

G. Pulmonary ventilation studies

H. Renal tubular imaging

I. Leukocyte and platelet labeling

CONDITIONS

10. The authorized place of use is the licensee's address stated in Item 2. The licensee must notify the Radiological Health Program 30 days prior to vacating a permanent use address as is required by Section D.407 of COMAR 26.12.01.01.

11. A. The radiation protection program shall be under the supervision of Jeffrey S. Reed.

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CONDITIONS CONT'D

- B. Radioactive material in Groups I, II, III and gases Xenon-133 and Krypton-85 may be used by or under the supervision of Robert Corcoran, M.D.; Christopher Conyers, M.D.; Charles Derrickson, M.D.; John P. Keane, M.D.; Theophane Doughrey, M.D.; William Reid, M.D.; Thomas Riccio, M.D.; William Van de Graaff, M.D.
- C. Radioactive materials in Groups IV and V may only be used by or under the supervision of Robert Corcoran, M.D. and/or Andrejs V. Strauss, M.D.
- D. Radioactive material used only for cardiology may be used by Clayton Raab, M.D.; John McLean, M.D. and/or Jeffrey Howard Etherton, M.D.
- 12. The licensee shall comply with provisions of Part D. "Standards for Protection Against Radiation" and Part J, "Notices, Instructions and Reports to Workers; Inspections" of the Maryland Regulations 26.12.01.01 "Regulations for Control of Ionizing Radiation".
- 13. For a period not to exceed sixty (60) days in any calendar year, a visiting physician is authorized to use licensed material for human use under the terms of this license, provided the visiting physician:
 - (A) Has the prior written permission of the hospital's Administrator and its Medical Isotopes Committee; and,
 - (B) Is authorized as a user by a specific license issued by the Department, the U.S. Nuclear Regulatory Commission, or another Agreement State authorizing human use, and performs only those procedures for which he is authorized by that license.

The licensee shall maintain for inspection by the Department, copies of the written permission specified in item 13 (A) above and of the license(s) specified in item 13 (B) above. These records shall be maintained for five (5) years from the time the licensee grants its permission under item 13 (A) above.

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CONDITIONS CONT'D

14. Patients containing Iodine-131 for the treatment of thyroid carcinoma or patients containing therapeutic quantities of Gold-198 shall remain hospitalized until the residual activity is 30 millicuries or less.
15. A. Each sealed source containing radioactive material, other than Hydrogen-3 with a half-life greater than thirty days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed 6 months. In the absence of a certificate from a transferor indicating that a test has been made within six (6) months prior to the transfer, the sealed source shall not be put into use until tested. If there is reason to suspect that a sealed source might have been damaged, or might be leaking, it shall be tested for leakage before further use.
- B. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material ~~on the test sample. The test sample shall be taken from the~~ sealed source or from the surfaces of a device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate.
- C. Records of leak tests shall be kept in units of microcuries and maintained for inspection by the Department.
- D. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Department regulations. A report shall be filed within five (5) days of the test with the Administrator, Radiological Health Program, 2500 Broening Highway, Baltimore, Maryland 21224 describing the equipment involved, the test results, and the corrective action taken.

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CONDITIONS CONT'D

2. Test for leakage and/or contamination shall be performed by Jeffrey Reed or by other persons specifically authorized by the Department, the U.S. Nuclear Regulatory Commission or another Agreement State to perform such services.
16. Sealed sources containing radioactive material shall not be opened.
17. The licensee may use the Lineator device manufactured by Atomic Products Corporation for doing linearity of his dose calibrator provided he follows the procedure in the Atomic Products Corporation Lineator Instruction Manual dated June 20, 1983.
18. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material authorized by this license in accordance with statements, representations, and procedures contained in application dated September 27, 1990, amendment request dated July 30, 1991, facsimile dated September 16, 1991, and letter dated September 17, 1991. COMAR 26.12.01.01 "Regulations for Control of Ionizing Radiation" shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

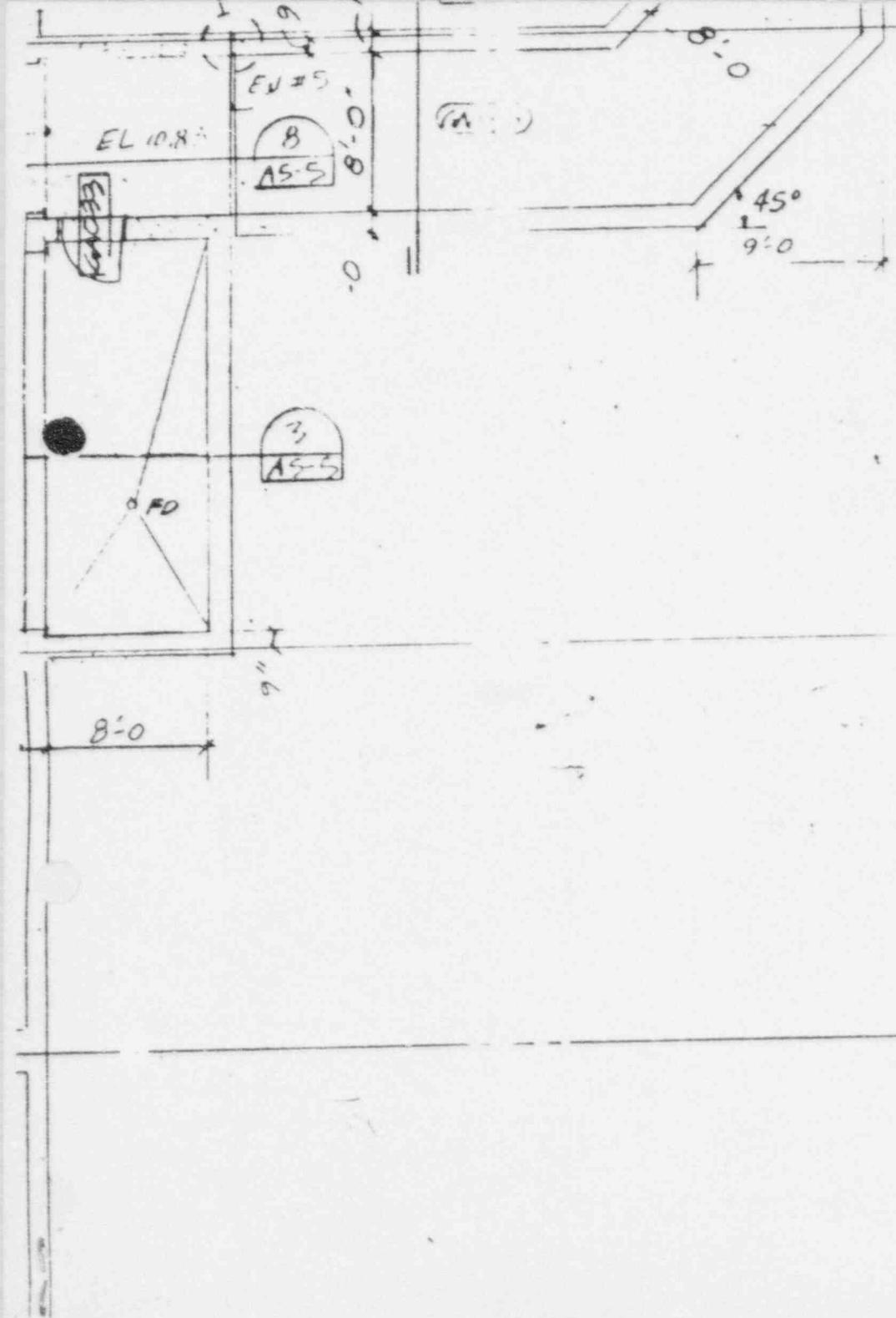
FOR THE MARYLAND DEPARTMENT OF THE ENVIRONMENT

Date November 1, 1991

CRF/AMC

ADMINISTRATOR, RADIOLOGICAL HEALTH PROGRAM

607 DF

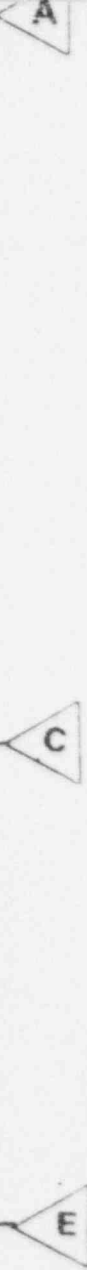


GA007	Office, Invoice Clerk
GA008	Work
GA009	Trash Room
GA010	Not Used
GA011	Print Shop/Form
GA012	Corridor
GA013	Corridor
GA014	Not Used
GA015	Not Used
GA016	Janitor Closet
GA017	Locker Room
GA018	Toilet - Staff
GA019	Toilet - Staff
GA020	Stair "A"
GA021	Locker Room
GA022	Not Used
GA023	Cart Hold/Retainer Area
GA024	Not Used
GA025	Not Used
GA026	Not Used
GA027	Corridor
GA028	Office, Storer Mgr.
GA029	Office
GA030	Not Used
GA031	Storage, General
GA032	Emergency Generator
GA033	Tunnel "B"
GA034	Corridor
GA035	Storage/X-Ray chives
GA036	Pump
GA037	Autopsy
GA038	Refrigerator
GA039	Toilet/Shower staff
GA040	Storage
GA041	Not Used
GA042	Not Used
GA043	Mechanical
GA044	Electrical
GA045	Stair "B"
GA046	Electrical

30'-0"

20'-0"

80'-0"



A FURNISH AS SUBMITTED



ANSTEC APERTURE CARD

Also Available on Aperture Card

GA035

EXTENT OF NEW CLG. & FLOOR FIN.

EXISTING PUMP

EXIST. DOOR

PUMP UP

GA039

LEG 2

GA038

GA037

GA040

GA036

GA034

GA035

EL 10.83

AM CLG. & FLOOR FIN.

13

13

13

ROOM # ROOM NAME

GA001 Tunnel, "A"

GA002 Elevator Lobby

GA003 Corridor, "A"

GA004 Mail Room, "A"

GA005 Rec. Secy. "Mail"

GA006 Off. Purchasing Agent

B H

A

MATCH LINE

1 2 3 9 6 0

NOTE: MOBILE REC. 585 SUP. UNIT

E

D

C

B

9706180287-01

ILDING
RUCTION

TP AB-2

FILM STORAGE

OFFICIAL RECORD COPY
ML 10

Blow-up
of
GA035



**ANSTEC
APERTURE
CARD**

Also Available on
Aperture Card

DECAY LAB

1 2 3 9 6 0

9706180287-02

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 20555-0001BEEBE MEDICAL CENTER
ATTN: JEFFREY M. FRIED, FACHE
PRESIDENT/CEO
424 SAVANNAH ROAD
P.O. BOX 226
LEWES, DE 19958

TYPE OF ACTION

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

REQUESTED DATE

11-13-96

LICENSE NUMBER

08-17792-01

CONTROL NUMBER

123960

*CHECK 77092 (\$440) DATED 9/20/96, IS BEING RETURNED
BECAUSE CHECK NOTES VOID IF NOT CASHED IN 30 DAYS.

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
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$

FEE(s) DUE \$
PAYMENT RECEIVED \$
AMOUNT DUE \$

- ☐ Your request was received without the prescribed application fee.
- ☐ We received your Check No. _____ in the amount of \$ _____. 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 expired 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. 77092 ⁵ (2440) ~~which accompanied your request. The fee is not required because:~~
- ☐ INSUFFICIENT FUNDS
- ☐ ACCOUNT CLOSED
- ☒ OTHER - SEE NOTE ABOVE*

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

Distribution:

DATE

BRENDA BROWN 301-415-6055

BBB
12/16/96Region I LPARS R/F
Pending OC/DAF R/F
BBrown OC/DAF S/F (LF-3.2.7)

12-16-96

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02120
STATUS CODE: 0
FEE CATEGORY: 7C
EXP. DATE: 20031130
FEE COMMENTS:
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: BEEBE MEDICAL CENTER
RECEIVED DATE: 961127
DOCKET NO: 3013331
CONTROL NO.: 123960
LICENSE NO.: 07-17792-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED

AMOUNT: \$440.00
CHECK NO.: 077092

3. COMMENTS

SIGNED
DATE

Rebecca J. Brown
12/10/96

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

1. FEE CATEGORY AND AMOUNT: 7C \$440

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

AMENDMENT
RENEWAL
LICENSE

3. OTHER

SIGNED
DATE

Replacement check

I(97)
Log Dec 10
Remitter
Check No. 077092
Amount \$440
Fee Category 7C
Type of Fee AMD
Date Check Rec'd 12/10/96
Date Completed 12/14/96
By: BR

* Check dated 9/20/96
VOID - Void if Not Cashed
W/in 30 days. I returned
check to licensee, requested
a replacement check.

BR
12/16/96

1996 DEC 16 PM 9:29