

OFFICIAL RECORD COPY MATERIALS LICENSE

Amendment No. 16

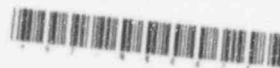
Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, 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.

Licensee		In accordance with the letter dated February 11, 1997	
1.	Monongalia General Hospital	3. License Number	47-16259-01
2. 1200 J. D. Anderson Drive Morgantown, West Virginia 26505		is amended in its entirety to read as follows:	
		4. Expiration Date	July 31, 2001
		5. Docket or Reference No.	030-10683
6. Byproduct, Source, and/or Special Nuclear Material		7. Chemical and/or Physical Form	
A.	Any byproduct material identified in 10 CFR 35.100	A.	Any radiopharmaceutical identified in 10 CFR 35.100
B.	Any byproduct material identified in 10 CFR 35.200	B.	Any radiopharmaceutical identified in 10 CFR 35.200
C.	Iodine 131	C.	Any unsealed form for preparation and administration as specified in §35.300
D.	Any byproduct material with a half-life less than 120 days, except iodine 131	D.	Any form for uses described in §35.300 initially distributed in accordance with a specific license issued to Section 32.72 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations.
E.	Any byproduct material identified in 10 CFR 31.11	E.	Prepackaged Kits
		8. Maximum Amount that Licensee May Possess at Any One Time Under This License	
		A.	As needed
		B.	As needed
		C.	55.5 gigabecquerels (1.5 curies)
		D.	As needed, not to exceed 3.7 gigabecquerels (100 millicuries) per container
		E.	As needed

9. Authorized Use:

- A. Medical use described in 10 CFR 35.100.
- B. Medical use described in 10 CFR 35.200.
- C. and D. Medical use described in 10 CFR 35.300.
- E. In vitro studies.

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License Number 47-16259-01

Docket or Reference Number 730-10683

Amendment No. 16

MATERIALS LICENSE
SUPPLEMENTARY SHEET

CONDITIONS

10. Location for use:
- A. Monongalia General Hospital, 1200 J. D. Anderson Drive, Morgantown, West Virginia
 - B. Wedgewood Imaging Center of Monongalia General Hospital, 300 Wedgewood Drive, Suite 105, Morgantown, West Virginia (see License No. 47-23390-01)
11. The Radiation Safety Officer for the activities authorized by this license is Susan M. (Midcap) Sypolt, M.D. and in her absence, Edward F. Downey, D.O.
12. Authorized users:
- A. William Almasy, M.D. Medical uses in 10 CFR 35.100, §35.200, §35.300 and §31.11
 - B. Edward F. Downey, Jr., D.O. Medical uses in 10 CFR 35.100, §35.200, §31.11, and iodine 131 as iodide for treatment of hyperthyroidism
 - C. Harry G. Kennedy, M.D. Medical uses in 10 CFR 35.100, §35.200, §35.300 and §31.11
 - D. John Leon, M.D. Medical uses in 10 CFR 35.100, §35.200, §35.300 and §31.11
 - E. Mack I. McClain, M.D. Medical uses in 10 CFR 35.100, §35.200, §35.300 and §31.11
 - F. Gary Marano, M.D. Medical uses in 10 CFR 35.100, §35.200, §35.300 and §31.11
 - G. Robert J. Tallaksen, M.D. Medical uses in 10 CFR 35.100, §35.200 and §31.11, and iodine 131 as iodide for the treatment of hyperthyroidism
 - H. Michael T. Hogan, M.D. Medical uses described in 10 CFR 35.100, §35.200, §31.11, iodine 131 as iodide for treatment of hyperthyroidism and/cardiac dysfunction, and phosphorus 32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases.
 - I. Claudia A. Goodwin, M.D. Medical uses described in 10 CFR 35.100, §35.200, §31.11, iodine 131 as iodide for treatment of hyperthyroidism and/cardiac dysfunction, and phosphorus 32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases.
 - J. Timothy B. Hetzer, M.D. Medical uses described in 10 CFR 35.100, §35.200, §31.11, iodine 131 as iodide for treatment of hyperthyroidism and/cardiac dysfunction, and phosphorus 32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases.
 - K. Charles David Burtner, M.D. Medical uses described in 10 CFR 35.100, §35.200, §35.300, and §31.11
 - L. Walter Parke Thrush, M.D. Medical uses described in 10 CFR 35.100, §35.200, §35.300, and §31.11
 - M. Susan M.(Midcap) Sypolt, M.D. Medical uses described in 10 CFR 35.100, §35.200, §35.300, and §31.11

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number 47-16259-01

Docket or Reference Number 070-10683

Amendment No. 16

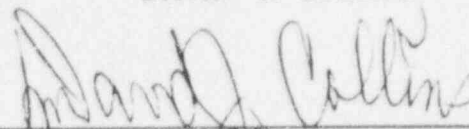
CONDITIONS

Continued -

13. No radiopharmaceutical therapy requiring confinement in accordance with 10 CFR 35.75 may be performed at the Wedgewood Drive facility.
14. 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) for establishing decommissioning financial assurance.
15. The licensee shall maintain records of information important to safe and effective decommissioning at the licensee's facilities listed in Condition 10 per the provision of 10 CFR 30.35(g) until this license is terminated by the Commission.
16. The licensee shall not release to unrestricted use the Nuclear Medicine facility in use on December 9, 1996 without prior NRC written approval. Reports of residual levels of contamination or other information concerning facility status may be required.
17. Except as specifically provided otherwise in the license and as provided in 10 CFR 35.51, the licensee shall conduct its program in accordance with 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 December 20, 1990
 - B. Letters dated
 - (1) July 2, 1991
 - (2) July 22, 1991
 - (3) June 7, 1993 [incorporate Wedgewood location, change users and authorizations, terminate Wedgewood Imaging Center license]
 - (4) March 1, 1996 [NRC letter extends expiration date in accordance with 10 CFR 30.36]
 - (5) October 23, 1996 [Describe new Nuclear Medicine Department facility, provisions for close-out and NRC approval of survey of old facility prior to unrestricted release]
 - (6) February 11, 1997 [Change RSO and alternate, change Dr. Sypolt's name]

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

DAVID J. COLLINS

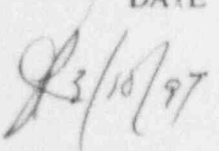


DATE MAR 10 1997

BY

Region II, Division of Nuclear Material Safety
101 Marietta Street, N.W., Suite 2900
Atlanta, GA 30323-0199

N:\MLICENSE\47-16259.A16





UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W., SUITE 2900
ATLANTA, GEORGIA 30323-0199

MAR 11 1997

INFORMATION FOR NRC MATERIAL LICENSEES

Please find enclosed:

- ☐ Your NRC material license
- ☒ Amendment to your NRC material license
- ☐ Amendment renewing your NRC material license
- ☐ Amendment terminating your NRC material license
- ☐ Notice for Radiographer Quality Assurance Approval Program

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify this office (ATTN: Ms. Diane Heim at (404) 331-4673) so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day in the month and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR 19, "Notice, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Not possess and use materials authorized in Items 6, 7, and 8, on the license until:
 - a. you have constructed the facilities and obtained the equipment described in the license application and supporting documentation; and
 - b. you have notified the U. S. Nuclear Regulatory Commission, Region II, ATTN: Materials Licensing/Inspection Branch, in writing, that activities authorized by the license will be initiated.
 - c. you have submitted and certified implementation of a Quality Management Program (10 CFR 35.32) for radiotherapy, or for administering > 30 uCi of I-125 or I-131.
3. Notify NRC, in writing, within 30 days:
 - a. when an authorized user, Radiation Safety Officer, or Teletherapy Physicist permanently discontinues performance of duties under the license or has a name change; or
 - b. when the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).
4. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:
 - a. when you decide to terminate all activities involving materials authorized under the license; or
 - b. if you decide not to complete the facility, acquire equipment, or possess and use authorized material.

5. Request and obtain a license amendment before you:
 - a. receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this part.
 - b. permit anyone, not authorized under 10 CFR 35, Subpart J, to work as an authorized user under a license for medical use of byproduct material.
 - c. permit anyone, not authorized under 10 CFR 35, Subpart J, to work as a Radiation Safety Officer, Teletherapy Physicist, or Nuclear Pharmacist, under a license for medical use of byproduct material.
 - d. order byproduct material in excess of the amount, or a different radionuclide or form, other than authorized on the license;
 - e. add or change the areas of use or address (or addresses) of use identified in the license application or on the license; or
 - f. change ownership of your organization.
6. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. Transfer of licensed materials must be consistent with 10 CFR 30.41, 40.51 or 70.42, as applicable. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a Notice of Violation, or imposition of a Civil Penalty, or an order suspending, modifying or revoking your license as specified in the "General Statement of Policy and Procedures for NRC Enforcement Actions," NUREG-1600, (7/95). Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken against those who do not achieve the necessary attention to detail and standard of compliance expected of licensees.

Thank you for your cooperation.

Enclosures:

1. NRC License
2. Category Marked Below for:
 - ☐ New licenses: NUREG-1600 (7/95); 19; 20; 30; 40 or 70, as appropriate; 71; 170; NRC Form 3; Agreement State list; and NRC Form 313.
 - ☐ New radiography licenses: Parts 34; 150.
 - ☐ New medical and teletherapy licenses: Part 35.
 - ☐ Amendments and renewals: NRC Form 313.

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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: 20010731
: Fee Comments: CODE 23
: Decom Fin Assur Req'd: N
: ::::::::::::::::::::::::::::::

1997 FEB 27 AM 8:59

LICENSE FEE TRANSMITTAL

A. REGION II

1. APPLICATION ATTACHED

Applicant/Licensee: MONONGALIA GENERAL HOSPITAL
Received Date: 970224
Docket No: 3010683
Control No.: 257397
License No.: 47-16259-01
Action Type: Amendment

2. FEE ATTACHED

Amount: 440.00
Check No.: 10432

3. COMMENTS

Signed DIANE HEIM
Date 2/24/97

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

1. Fee Category and Amount: 7C \$440

2. Correct Fee Paid. Application may be processed for:

Amendment ☒
Renewal ☐
License ☐

3. OTHER

Signed Rita Messia
Date 2/28/97

Log	<u>Feb 5 II</u>
Remitter	
Check No.	<u>10432</u>
Amount	<u>\$440</u>
Fee Category	<u>7C</u>
Type of Fee	<u>Am</u>
Date Check Rec'd.	<u>2/28/97</u>
Date Completed	<u>2/28/97</u>
By:	<u>ACM</u>

February 11, 1997

Attn: Licensing
U.S. Nuclear Regulatory Commission
Region II
101 Marietta St. N.W.
Atlanta, Ga. 30323



Monongalia
General
Hospital

1200
J.D. Anderson Drive
Morgantown, WV
26505

(304) 598-1200

RE: Radioactive Material License Nos. 47-16859-01
Monongalia General Hospital

Gentlemen;

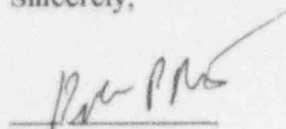
Please amend the above referenced license to reflect the following:

We would like to change the Radiation Safety Officer from Edward F. Downey, D.O. to Susan M. (Midcap) Sypolt, M.D. Dr. Sypolt's training and experience are already on file under this license number as Dr. Midcap. Dr. Downey will remain as an authorized user and will serve as RSO in her absence.

Enclosed is the \$440.00 amendment fee.

If you have any questions, please do not hesitate to contact the undersigned.

Sincerely,



Bob Ritz, CEO

257397