

DL-080796-04
Amendment No. 31

OFFICIAL RECORD COPY MATERIALS LICENSE

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.

<p style="text-align: center;">Licensee</p> <p>1. Carilion Roanoke Community Hospital</p> <p>2. P. O. Box 12946 Roanoke, Virginia 24029</p>	<p>In accordance with letter dated May 14, 1996</p> <p>3. License Number 45-12706-01</p> <p>is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration Date December 31, 2003 [extended]</p> <hr/> <p>5. Docket or Reference No. 030-03358</p>
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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. As needed (Except iodine not to exceed 370 GBq (10 curies))
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy source identified in 10 CFR 35.400	D. 37 GBq (1000 millicuries)
E. Carbon 14	E. Any	E. As needed
F. Any byproduct material identified in 10 CFR 31.11	F. Prepackaged kits	F. As needed

9. Authorized Use:

- A. Medical use described in 10 CFR 35.100
- B. Medical use described in 10 CFR 35.200
- C. Medical use described in 10 CFR 35.300
- D. Medical use described in 10 CFR 35.400
- E. For reconstitution and/or use in the diagnosis of disease of the GI tract in human patients
- F. In-vitro studies

9608230289 960807
PDR ADOCK 03003358
C PDR

CONDITIONS

10. Location of Use:

Carilion Roanoke Community Hospital
101 Elm Avenue, S.E., Roanoke, Virginia

ML20

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number 45-12706-01

Docket or Reference Number 50-03358

Amendment No. 31

CONDITIONS

Continued-

- 11. Radiation Safety Officer: James G. Mullet, M.D.
- 12. Licensed materials listed in Item 6. A. through F. above are only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users

Material and Use

- A. Witold Brozyna, M.D. Medical uses identified in 10 CFR 35.100, §35.200, and §31.11
- B. Anthony Cuzzocrea, M.D. Medical uses identified in 10 CFR 35.100, §31.11, and carbon 14 for diagnosis
- C. Michael J. Enright, M.D. Medical uses described in 10 CFR 35.100, §35.200, §31.11, and iodine 131 as iodide for treatment of hyperthyroidism, cardiac dysfunction and thyroid carcinoma
- D. J. Bruce Hauser, M.D. Medical uses identified in 10 CFR 35.100, §35.200, §31.11, and iodine 131 as iodide for treatment of hyperthyroidism, cardiac dysfunction and thyroid carcinoma
- E. Robert C. Heath, M.D. Medical uses identified in 10 CFR 35.300 and §35.400
- F. James G. Mullet, M.D. Medical use described in 10 CFR 35.100, §35.200, §31.11, and iodine 131 as iodide for treatment of hyperthyroidism, cardiac dysfunction and thyroid carcinoma
- G. James Davies Rice, M.D. Medical uses identified in 10 CFR 35.100, §35.200, §31.11, and iodine 131 as iodide for treatment of hyperthyroidism and cardiac dysfunction
- H. R. Lewis Royster, M.D. Medical uses identified in 10 CFR 35.400
- I. Hugh J. Scruggs, M.D. Medical uses identified in 10 CFR 35.400
- J. Marshall A. Wakat, M.D. Medical uses identified in 10 CFR 35.100, §35.200, §35.300, §35.400, and §31.11

- 13. The licensee shall maintain records of information important to safe and effective decommissioning at 101 Elm Avenue, S.E., Roanoke, Virginia pursuant to the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.
- 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 for establishing decommissioning financial assurance.
- 15. Notwithstanding the provisions of 10 CFR 35.49, "Suppliers," the licensee is authorized to receive carbon 14 urea from Tri-Med Specialties, Inc, in accordance with procedures outlined in IND 42,294, accepted by FDA on May 11, 1993.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number 45-12706-01

Docket or Reference Number 050-03358

Amendment No. 31

CONDITIONS

Continued-

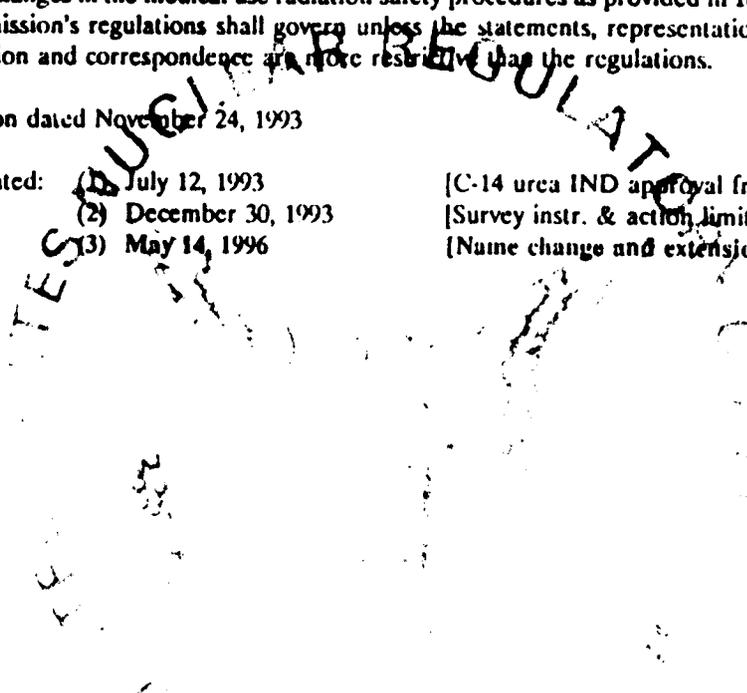
16. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee.

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 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 November 24, 1993

B. Letters dated: (1) July 12, 1993
(2) December 30, 1993
(3) May 14, 1996

[C-14 urea IND approval from FDA]
[Survey instr. & action limits]
[Name change and extension of expiration date]



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

EARL G. WRIGHT

DATE AUG 07 1996

BY Earl G. Wright

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

8/9/96



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

AUG 09 1996

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 Helm 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 & 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.

BETWEEN:

License Fee Management Branch, ARN
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LFS

Program Code: 02120
Status Code: 0
Fee Category: 7C
Exp. Date: 20031231
Fee Comments: CODE 23
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION II

1. APPLICATION ATTACHED

Applicant/Licensee: COMMUNITY HOSPITAL OF ROANOKE VALLE
Received Date: 960520
Docket No: 3003358
Control No.: 257076
License No.: 45-12706-01
Action Type: Amendment

2. FEE ATTACHED

Amount: NONE
Check No.: _____

3. COMMENTS

Signed [Signature]
Date 5/24/96

8 LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered 1/1)

1. Fee Category and Amount: 7C \$430

2. Correct fee paid. Application may be processed for:
Amendment _____
Renewal _____
License _____

3. OTHER

Signed [Signature]
Date 8/16/95

LOG	2244
Remitter	Community Hospital of Roanoke Valley
Check No.	601065
Amount	\$360
Fee Category	7C
Type of Fee	Amendment
Date Check Rec'd.	8/16/95
Date Completed	8/16/95
BY:	Keenan

See check for 2570769251017