UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

RIII

JUN 14 2002

National Health Physics Program (115HP/NLR)
ATTN: E. Lynn McGuire, Director
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
North Little Rock, AR 72114

Dear Mr. McGuire:

Enclosed is Amendment No. 23 renewing your NRC Material License No. 24-15235-03 in accordance with your request. Please note that the changes made to your license are printed in bold font.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

A. 1. During my review of your renewal I became concerned that some of the information needed to continue your currently authorized activities did not appear to be captured completely in the application dated December 5, 2001.

Therefore, I have continued all of your current "tie-down condition" documents in order to ensure a complete license, in addition to your application dated December 5, 2001. Your license has been renewed accordingly, except as noted below, for a ten year term and will not expire until June 30, 2012.

2. I noted that your self-shielded irradiator authorization had not apparently been renewed in accordance with NUREG 1556, Vol. 5, Final, which would have reduced your regulatory burden somewhat. It also did not appear that NUREG 1556, Vol. 7, Final, had been used to prepare your renewal application.

In the event that you cannot locate a copy of these documents we are including a copy of each as enclosures to this renewal. You may elect to amend the license and incorporate the guidance contained in NUREG 1556, Vol. 5, Final and NUREG 1556, Vol. 7, Final at a later date.

3. When newly revised 10 CFR Part 35 becomes effective later this year and when the accompanying NUREG 1556, Vol. 9, Final is published, you may also elect to amend the license and incorporate certain changes to further decrease your regulatory burden.

4. Please note that we were unable to authorize radium-224 at this time because the information submitted in your application dated December 5, 2001, was insufficient for us to complete our review. If you wish to pursue this authorization, please address the information requested below and submit it to

H/5

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4. Please note that we were unable to authorize radium-224 at this time because the information submitted in your application dated December 5, 2001, was insufficient for us to complete our review. If you wish to pursue this authorization, please address the information requested below and submit it to

us as additional information to Control No. 310024. We will then continue our review.

Please provide the following:

Please determine whether the radium-224 you wish to have authorization for is byproduct material or accelerator- or cyclotron-produced material. You may need to contact the vendor of the radium-224 to make this determination.

If it is byproduct material, as defined in 10 CFR 30.4, "Definitions," please advise us in writing and we will continue our review. If it is not byproduct material, you may need to contact the Veteran's Administration to determine how to gain authorization for the radium-224.

5. In preparing your renewal we "tied-down" your application dated December 5, 2001, and excluded:

   a. your request for radium-224 in items 5N. and 6N., as discussed above;

   b. attachment 10.3, "Quality Management Program" because the QMP will not be a condition of your license. (This allows you the flexibility to make changes to your quality management program without obtaining prior NRC approval. When modifications are made to your program, you should submit your modified QMP to this Office within 30 days after the modification is made, as required by 10 CFR 35.32(e).) ;and,

   c. attachment 8.3, part of the last sentence, "and/or the preceptor statement to evaluate clinical physician use." This was excluded because it appeared that if proposed physician user applicants' training and experience did not meet the requirements in 10 CFR 35, Subpart J, your Radiation Safety Committee would still consider their preceptor statements. This would be incorrect.

      If a proposed physician user applicant's training and experience do not meet the requirements in 10 CFR 35, Subpart J, your Radiation Safety Committee must make application to us through an amendment to review that applicant's training and experience. It is likely that such an application would have to be referred to NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) for evaluation.

6. In preparing your renewal we added two new standard Conditions for the use of [ ] nos. 28. and 29.

7. Please contact me at (630) 829-9841 if you have any questions or comments

concerning this renewal.

B. 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 Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify NRC, in writing, within 30 days:

   a. When the Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

   b. When the mailing address listed on the license changes.

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when a decision is made to terminate all activities involving materials authorized under the license.

4. Request and obtain a license amendment before you:

   a. Change Radiation Safety Officers

   b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

   c. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or

   d. Change ownership of your organization.

5. Submit a complete renewal application 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. 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 Procedure for NRC Enforcement Actions. 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 when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Colleen C. Casey

Colleen C. Casey
Materials Licensing Branch

License No. 24-15235-03
Docket No. 030-13378

Enclosures:

1. Amendment No. 23
2. NUREG 1556, Vol. 5, Final
3. NUREG 1556, Vol. 7, Final

Amendment No. 23

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. PC 02110 310024

Licensee	In accordance with the application dated December 5, 2001, and the letter dated December 6, 2001,
1. Harry S. Truman Memorial Veterans' Hospital 2. 800 Hospital Drive Columbia, MO 65201	3. License number 24-15235-03 is renewed in its entirety to read as follows: 4. Expiration date **June 30, 2012** 5. Docket No. 030-13378 Reference No.

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.		
B.		
C.		
D.		
E. Any byproduct material between Atomic Nos. 3 through 83; inclusive, except as listed	E. Any	E. 500 millicuries of each radionuclide, with a total possession limit not to exceed 25 curies, except as noted below:
F. Hydrogen-3	F. Any	F. 6 curies
G. Molybdenum-99	G. Any	G. 6 curies
H. Technetium-99m	H. Any	H. 6 curies
I. Cesium-137	I. Sealed source (Technical Operations Model 77302)	I. 135 millicuries

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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
J. Any byproduct material (Atomic Numbers 3-83, inclusive)	J. Sealed sources (manufactured pursuant to Section 32.74 of 10 CFR Part 32 or an Agreement State)	J. No single source to exceed 300 millicuries
K. Tungsten-188	K. Any	K. 1 curie
L. Rhenium-188	L. Any	L. 1.5 curies
M. Rhenium-186	M. Any	M. 1 curie
N. [redacted]		
O. Actinium-225	O. Any	O. 100 millicuries
P. Bismuth-213	P. Any	P. 100 millicuries

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 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).

E. through H. To be used for medical research and research and development as defined in 10 CFR Part 30, Section 30.4, including animal studies.

I. For use in a Technical Operations Model 773 calibration device for instrument calibration.

J. For use in Transmission Line Source Housing devices, for medical radiography in humans, which have been manufactured pursuant to Section 32.74 of 10 CFR Part 32 or an Agreement State and distributed in accordance with a NRC or Agreement State specific license to persons specifically licensed by the NRC to receive, possess and use the device.

K. through M. To be used for medical research and research and development as defined in 10 CFR Part 30, Section 30.4, including animal studies.

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N. For use in a [redacted] device for the irradiation of materials in research and development as defined in 10 CFR Part 30, Section 30.4, including animal studies (excluding explosives and flammable materials).

O. and P. For use in Actinium-225/Bismuth-213 Generators for research and development as defined in 10 CFR 30.4, including animal studies.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at [redacted] Columbia, Missouri.

11. A. Licensed material shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee, Wynn A. Volkert, Ph.D., Chairman.

    B. Physicians designated to use licensed material in or on humans shall meet the training and experience requirements in Subpart J of 10 CFR Part 35.

    C. Individuals designated to use licensed material for research and development (excluding human use) shall meet the training and experience requirements in 10 CFR Part 33, Section 33.15(b), (1) and (2).

    D. Individuals designated to use licensed material in Item 6.N. for research and development (excluding human use) shall meet the training and experience requirements described in letter dated September 26, 2000 (with attachments).

12. The Radiation Safety Officer for this license is Richard E. Poelling.

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material 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.

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. A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210.

    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 3 months.

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C. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 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 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 transferred 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 leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. 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, in accordance with 10 CFR 30.50(b)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351, ATTN: **Director, Division of Nuclear Materials Safety.** The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

G. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

16. The licensee shall conduct a physical inventory every 3 months to account for all sources and/or devices received and possessed pursuant to 10 CFR 35.59 and 10 CFR 35.500 and every 6 months for all other sources and/or devices.

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

18. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperature from exceeding that specified by the manufacturer and approved by NRC.

    B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

19. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

20. Notwithstanding the requirements of 10 CFR 35.49(a) and (b), 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300 and 10 CFR 35.500, the licensee may use for any medical use any byproduct material or reagent kit. The licensee shall possess and use byproduct material for medical use in accordance with the prescriptive and performance criteria in the other sections of 10 CFR 35. This does not relieve the licensee from complying with applicable United States Food and Drug Administration (FDA) and other Federal and State requirements.

21. The licensee shall possess and use byproduct material for human research use in accordance with the prescriptive and performance criteria in all sections of 10 CFR Part 35 except Sections 35.49(a) and (b), 35.100, 35.200, and 35.300.

22. The licensee shall not use licensed material in field applications except as provided otherwise by specific conditions of this license.

23. The licensee shall not acquire licensed material in a sealed source or device that contains a sealed source unless the source or device has been registered with the Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.

24. A. Pursuant to 10 CFR 20.1302(c) and 20.2002 of 10 CFR Part 20, the licensee is authorized to dispose of licensed material by incineration provided the gaseous effluent from incineration does not exceed the limits specified for air in Appendix B, Table II, 10 CFR Part 20.

    B. Pursuant to 10 CFR 20.2002, the licensee may dispose of incinerator ash containing radioactive materials with Atomic Nos. 1-83, except for phosphorus-32, sulfur-35, technetium-99m, iron-59, calcium-45, and other isotopes as identified below, as ordinary waste in a landfill provided the concentration of the radionuclides (in microcuries per gram of ash) at the time of disposal are no greater than the values in Table II, Column 2, 10 CFR Part 20, Appendix B. For hydrogen-3, carbon-14, aluminium-26, chlorine-36, silver-108m, niobium-94, iodine-129, technetium-99, and thallium-204, the concentration can be no greater than one-tenth of the value in Table II, Column 2, 10 CFR Part 20, Appendix B.

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25. The licensee is authorized to hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash provided:

    A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

    B. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate survey meter set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

    C. A record of each disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

    D. Radioactive waste possessed under this license shall be stored in accordance with the statements, representations, and procedures included with the licensee's waste storage plan described in the licensee's letters dated November 30, 1995 and March 25, 1996.

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 a person specifically licensed by the Commission or an Agreement State to perform such services.

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

28. **For the [ ] device: the licensee shall not repair, remove, replace or alter any of the following: electrical and mechanical systems that control source or shielding movement, the irradiator's shielding or sealed source, safety interlocks, or any component that may affect safe operation of the irradiator. These activities shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.**

29. **For the [ ] device: except for maintaining labeling as required by 10 CFR Part 20 or 71, the licensee shall obtain authorization from the U.S. Nuclear Regulatory Commission before making any changes in the sealed source, device, or source-device combination that would alter the description or specifications as indicated in the respective Registration Certificates issued either by the Commission pursuant to 10 CFR 32.210 or by an Agreement State.**

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30. 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. Applications dated August 17, 1994 (excluding attachments), December 7, 1995 (including attachments) **and December 5, 2001 (excluding request for radium-224 in items 5N. and 6N.; attachment 10.3, "Quality Management Program"; and attachment 8.3, part of last sentence, "and/or the preceptor statement to evaluate clinical physician use."); and**

B. Letters dated November 30, 1995, March 25, 1996, March 15, 1999, September 26, 2000, and **December 6, 2001; and,**

C. Facsimile dated December 11, 2000 (with attachments).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date JUN 14 2002

By Colleen C. Casey
Colleen C. Casey
Materials Licensing Branch
Region III

UNITED STATES
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801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

December 26, 2001

Richard E. Poelling, Radiation Safety Officer
V. A. Harry S. Truman Memorial Veteran's Hospital
800 Hospital Drive
Columbia, MO 65201

SUBJECT: LICENSE RENEWAL APPLICATION

Dear *Richard E. Poelling*:

This is to acknowledge receipt of your application for renewal of the material(s) license identified below. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

Any correspondence regarding the renewal application should reference the control number specified below, and your license number.

Materials Licensing Branch

License No. : *24-15235-03*
Control No. : *310024*