

Official Use Only –Security-Related Information – Withhold Under 10 CFR 2.390



DEPARTMENT OF RADIOLOGY
Henry Ford Hospital & Health Network

Radiation Safety Office

July 16, 2012

Henry Ford Hospital
2799 West Grand Blvd.
Detroit, Michigan 48202-2689
(313) 916-7042 Office
(313) 916-7329 Fax

Materials Licensing Branch
U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352
(800) 522-3025
(630) 515-1078 FAX

Dear Sir or Madam:

We are requesting an amendment to license No. 21-04108-16 for Henry Ford Hospital's broad scope medical license (Docket 030-02043). This amendment request is being made to allow the investigational use of ^{223}Ra . This license change is required because the atomic number of Radium (i.e. 88) falls outside of the range permitted under item 6.F of our license which permits "Any byproduct material with Atomic Nos. 1 through 83, inclusive". We believe that non investigational 10 CFR § 35.300 use of ^{223}Ra is already authorized under item 6.C of our license.

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) recently came to a consensus regarding licensing of ^{223}Ra on July 9, 2012. The draft ACMUI report for licensing radium-223 chloride is available on NRC's public website at:

<http://www.nrc.gov/reading-rm/doc-collections/acmui/meeting-slides/>

The summary recommendations for this treatment and the licensing are highly relevant to this amendment and are excerpted below.

ACMUI Summary Statement and Recommendations

Ra-223 Cl represents a first-in-class, alpha particle-emitting therapeutic radiopharmaceutical. Based on relevant physical and biological considerations as well as clinical data to date, it appears to be a safe, effective, and convenient treatment for skeletal metastases in advanced, castrate-resistant prostate cancer, delivering high biologically effective doses to malignant cells in bone with relative sparing of hematopoietic marrow and other normal tissues...Ra-223 Cl does not differ significantly

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in terms of clinical use and management, radiation safety, and logistics from currently approved radiopharmaceuticals. Therefore physicians already authorized to use therapeutic radiopharmaceuticals under § 35.390 or § 35.396 already have the requisite education, training, and experience to safely and effectively use Ra-223 Cl. As such licensing of authorized users of Ra-223 Cl under § 35.390 (Category (G)(3) or (G)(4)), or § 35.396(d)(2), is therefore recommended. Importantly, the foregoing considerations, including licensing, are likely to apply to any future alpha particle-emitting radiopharmaceuticals generally.

In fact, the NRC lead on this project, Michael Fuller, stated at the ACMUI meeting that ²²³Ra use “should be a routine license amendment”. Quite specifically, ²²³Ra use was not categorized by ACMUI as § 35.1000 use.

Amendment Application Details

The completed NRC form follows:

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<p>NRC FORM 913 05-2012 10 CFR 29.52, 53, 54, 55, 56, 59, and 60</p> <p style="text-align: center;">U.S. NUCLEAR REGULATORY COMMISSION</p> <p style="text-align: center;">APPLICATION FOR MATERIALS LICENSE</p>	<p>APPROVED BY OMB: NO. 3168-0130 Estimated burden per response to comply with this mandatory collection request: 4.5 hours. Submit all the application to NRC online to determine first the applicant to qualified and first subsequent procedures must be printed for public health and safety. Send comments regarding burden estimate to the Information Services Branch (7-5 F50), U.S. Nuclear Regulatory Commission, Washington, DC 20545-0001, or by Internet e-mail to Information.Services@nrc.gov, and to the Chief Officer, Office of Information and Regulatory Affairs, NRC-18022, (3150-0128), Office of Management and Budget, Washington, DC 20503. If a person uses to improve an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.</p>	<p style="text-align: right;">EXPIRES: 05/31/2016</p> <p>INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.</p>				
<p>APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:</p> <p style="text-align: center;">OFFICE OF FEDERAL & STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20545-0001</p> <p>ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:</p> <p>IF YOU ARE LOCATED IN:</p> <p>ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, RHODE ISLAND, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA.</p> <p>SEND APPLICATIONS TO:</p> <p style="text-align: center;">LICENSING ASSISTANCE TEAM DIVISION OF NUCLEAR MATERIALS SAFETY U.S. NUCLEAR REGULATORY COMMISSION, REGION I 2100 RENAISSANCE BOLLINGER, SUITE 100 KING OF PRUSSIA, PA 19396-5716</p>	<p>IF YOU ARE LOCATED IN:</p> <p>ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:</p> <p style="text-align: center;">MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION III 2645 WARRIENWALK LEONARD, SUITE 200 (Lisle, IL 60532)-4352</p> <p>ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, DC, WYOMING,</p> <p>SEND APPLICATIONS TO:</p> <p style="text-align: center;">NUCLEAR MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 1300 E. LAMAR BOULEVARD ARLINGTON, TX 76011-8511</p>					
<p>PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.</p>						
<p>1. THIS IS AN APPLICATION FOR: (Check appropriate box)</p> <p><input type="checkbox"/> A. NEW LICENSE</p> <p><input checked="" type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER <u>21-04109-16</u></p> <p><input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____</p>	<p>2. NAME AND MAILING ADDRESS OF APPLICANT (Please ZIP code)</p> <p style="text-align: center;">Henry Ford Hospital Radiation Safety Office, K-3 2799 West Grand Boulevard Detroit, MI 48202</p>					
<p>3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED</p> <p>No changes in the locations listed on the license.</p>	<p>4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION</p> <p style="text-align: center;">Alan M. Jackson, 34S CHP</p> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%;">BUSINESS TELEPHONE NUMBER (313) 916-2739</td> <td style="width:50%;">BUSINESS CELLULAR TELEPHONE NUMBER (734) 657-4133</td> </tr> <tr> <td colspan="2">BUSINESS EMAIL ADDRESS alanj@rad.hfh.edu</td> </tr> </table>		BUSINESS TELEPHONE NUMBER (313) 916-2739	BUSINESS CELLULAR TELEPHONE NUMBER (734) 657-4133	BUSINESS EMAIL ADDRESS alanj@rad.hfh.edu	
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BUSINESS EMAIL ADDRESS alanj@rad.hfh.edu						
<p>SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.</p>						
<p>5. RADIOACTIVE MATERIAL</p> <p>a. Element(s) and chemical form(s), chemical and physical form, and its activity amount which will be possessed in any one lot(s).</p>	<p>6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.</p>					
<p>7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.</p>	<p>8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.</p>					
<p>9. FACILITIES AND EQUIPMENT.</p>	<p>10. RADIATION SAFETY PROGRAM.</p>					
<p>11. WASTE MANAGEMENT.</p>	<p>12. LICENSE FEE (See 10 CFR 29.54 and 29.55a (1)(2))</p> <p style="text-align: center;">FEE CATEGORY NA AMOUNT ENCLOSED \$ 0.00</p>					
<p>13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BEING UPON THE APPLICANT.</p> <p>THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 5, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 29.53, 29.54, 29.55, 29.56, AND 29.59, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.</p> <p>WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1962 AS STAT. 740 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.</p>						
<p>CERTIFYING OFFICER – TYPEPRINTED NAME AND TITLE</p> <p>Donald Patek, Ph.D., DABR</p>	<p>SIGNATURE</p> 	<p>DATE</p> <p>7/16/2012</p>				
<p>FOR NRC USE ONLY</p>						
TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS	
			\$			
APPROVED BY				DATE		

NRC FORM 913 (05-2012)

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License Amendment Details**1. Application Type**

Amendment of License Number: 21-04109-16 (Docket 030-02043).

2. Applicant's Name and Mailing Address

Henry Ford Hospital
Radiation Safety Office, K-3
2799 West Grand Boulevard
Detroit, MI 48202-2689

3. Addresses Where Licensed Material Will Be Used or Possessed

There are no changes in the locations of use as a result of this amendment.

4. Name of the person to be contacted about this application

Alan M. Jackson, MS, CHP
Radiation Safety Office, K-3
Henry Ford Hospital
2799 W. Grand Boulevard
Detroit, MI 48202-2689
Phone: (313) 916-2739 Voice
Fax: (313) 916-8456
Cell : (734) 657-4133
E-mail: AlanJ@rad.hfh.edu

5. Radioactive Material

This amendment request is being made to allow the investigational use of ^{223}Ra . The alpha emissions of ^{223}Ra and its progeny are short-range, high-linear energy transfer (LET), and high-relative biological effectiveness (RBE) radiations and should deliver highly localized, highly cytotoxic radiation. We request that Item F. be changed to allow the use of 5 mCi of ^{223}Ra . This amount is much greater than the expected clinical use mainly to allow for NIST and other intercomparison samples.

While the anticipated investigational use involves only ^{223}Ra in the chloride form, it is not hard to imagine that other chemical forms of this compound may be used in future clinical trials due to the excellent dosimetric characteristics of ^{223}Ra . Therefore, we request the use of any chemical form of ^{223}Ra .

6. Purposes for Which Licensed Material will be Used

We plan to use ^{223}Ra for research and product development. We will comply

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with 10 CFR 35.6, "Provisions for the protection of human research subjects," and 10 CFR 35.7, "FDA, other Federal, and State requirements."

There are no other changes proposed in the purposes for which the licensed material will be used.

7. Individuals responsible for the Radiation Safety Program

There are no substantive changes proposed for the individuals responsible for the Radiation Safety Program (Donald Peck, PhD, DABR remains as the RSO). Alan M. Jackson, MS, CHP will continue as the Radiation Safety Committee Chair.

We note that as a broad scope medical licensee, we are able to internally approve a number of activities such as new usage and Authorized Users.

8. Training Program

There are no changes proposed for the training program. The 10 CFR 35.300 approved Authorized Users will be eligible to perform this work. Furthermore, initially we will participate in the vendor recommended training. When our Authorized Users and other clinical staff have become sufficiently experienced, as determined by our Radiation Safety Committee, they will be able to train new individuals in this process.

9. Facilities and Equipment

There are no changes proposed in the facilities and equipment. Our existing equipment is sufficient to handle these materials. We will need to calibrate equipment, especially the dose calibrator, to ^{223}Ra and its progeny but it is not expected that new equipment or facilities are needed to support this work.

9.1 Emergency Procedures

There are no changes proposed for the emergency procedures.

9.2 Shielding Analysis

The existing shielding is considered adequate as the use amounts are quite low and emitting radioisotopes are extremely easy to shield.

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10 Radiation Protection Program

There are no substantive changes proposed in the radiation protection program.

10.1 Security Information

There are no substantive changes proposed in the security program. The ²²³Ra usage amount is well below an increased controls quantity of material.

11 Radioactive Waste Management

There are no substantive changes in the radioactive waste program.

12 Fees

As a current broad scope medical licensee, no fee is assessed for this license amendment (see form 313).

13 Certification

Please see NRC form 313 on Page 3 (above).

Discussion

We believe that this request does not present any significant regulatory issues. If you should have any questions regarding the adequacy of this request, please contact Alan M. Jackson, MS, CHP at (313) 916-2739.

Please feel free to contact Alan Jackson at (313) 916-2739, (313) 916-7329 (FAX) or AlanJ@rad.hfh.edu if you have any questions.

Sincerely,



Donald Peck, PhD, DABR
Radiation Safety Officer



Alan M. Jackson, MS, CHP
Radiation Safety Committee Chair

Filename: nrc hfhra-223 7-12

**Radiology**

2799 West Grand Boulevard
 Detroit, Mi. 48202

Radiation Safety Office # (313) 916-7042

Radiation Safety Fax # (313) 916-8456

**Henry Ford Hospital
 Henry Ford Medical Group**

Facsimile Transmittal

To: Materials Licensing	Facility: USNRC Region III
Phone: (800) 515-9892	Fax: (630) 515-1078
From: Alan M. Jackson, MS, CHP	Dept: Radiation Safety Office
Phone: (313) 522-3025	Fax: (630) 515-1078
Pages: 7 including cover sheet	Date: July 17, 2012

Urgent **For Review** **Per your request** **Please Reply**

• **Comments:**

Please note that I am sending two separate requests today. This is for the use of Ra-223.

**** Confidentiality Notice ****

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