

## MATERIALS LICENSE

Amendment No. 32

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.

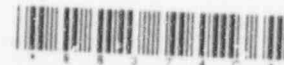
Licensee	In accordance with the letter dated April 21, 1997,
1. Veterans Administration Medical Center	3. License Number 37-13483-01 is amended in its entirety to read as follows:
2. 1111 East End Boulevard Wilkes-Barre, Pennsylvania 18711	4. Expiration Date March 31, 2002
	5. Docket or Reference No. 030-03190

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
D. Any byproduct material identified in 10 CFR 31.11	D. Prepackaged Kits	D. As needed
E. Americium 241	E. Sealed sources (Amersham Model No.AMC 24)	E. 14 millicuries

## 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 therapy procedure approved in 10 CFR 35.300 for which the patient can be released under the provisions of 10 CFR 35.75.  
D. In vitro studies.  
E. Use as an anatomical marker.

## CONDITIONS



10. Licensed material may be used only at the licensee's facilities located at 1111 East End Boulevard, Wilkes-Barre, Pennsylvania.
11. The Radiation Safety Officer for this license is Juan J. Roig, 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:

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PDR ADCK 03003190  
C PDR

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MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License number

37-13483-01

Docket or Reference number

030-03190

Amendment No. 32

Authorized Users

Juan J. Roig, M.D.

Riaz Baqir, M.D.

Arthur Liss, M.D.

Material and Use

35.100; 35.200; 35.300 except thyroid carcinoma  
In vitro studies  
Americium 241

35.200 for cardiovascular clinical procedures

35.100; 35.200  
In vitro studies

13. A. 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.
- B. 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. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
15. 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 8, 1990  
B. Letter dated December 14, 1990  
C. Letter dated December 5, 1991  
D. Letter dated January 16, 1992  
E. Letter dated April 21, 1997

For the U.S. Nuclear Regulatory Commission

Original Signed By:

By

Michelle Beardsley

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

Date JUN - 2 1997

Reedes Hurt  
Medical Center Director  
Department of Veterans Affairs Medical Center  
1111 East End Boulevard  
Wilkes-Barre, PA 18711

JUN - 2 1997

Dear Mr. Hurt:

This refers to your license amendment request. Enclosed with this letter is the amended license. Please note that as part of this amendment, in accordance with 10 CFR 30.36, effective February 15, 1996, the expiration date of your license has been extended by a period of five years. Your new expiration date is stated in Item 4 of the 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:**  
**Michelle Beardsley**

Michelle R. Beardsley  
Division of Nuclear Materials Safety

License No. 37-13483-01  
Docket No. 030-03190  
Control No. 124540

Enclosure:  
Amendment No. 32

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DOCUMENT NAME: R:\WPS\MLTR\L3713483.01

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	Beardsley						
DATE	06/02/97		06/ /97	06/ /97	06/ /97	06/ /97	

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DEPARTMENT OF VETERANS AFFAIRS  
Medical Center  
1111 East End Boulevard  
Wilkes-Barre PA 18711

030-03190

April 21, 1997

In Reply Refer To: 693/00C/115N

U.S. Nuclear Regulatory Commission  
Region 1  
Nuclear Material Safety Branch  
Division of Radiation Safety and Safeguards  
475 Allendale Road  
King of Prussia, PA 19406-1415

Dear Sirs:

Please amend our NRC License No. 37-13483-01 at the VA Medical Center, Wilkes-Barre, PA to include the use of Strontium-89 Chloride Injection for the treatment of pain in patients with multiple skeletal metastases.

We will obtain the dose of Strontium-89 from our radiopharmacy supplier as a unit dose. We will utilize a low atomic number material as shielding (i.e., Lucite or Plexiglas) during the injection of the radionuclide to minimize the production of bremsstrahlung.


We have modified our Quality Management Program to include the use of Strontium-89. A copy is enclosed for your review. We have also developed a Quality Management Checklist which will be completed prior to the administration of the dose of Strontium-89 Chloride. A copy of our checklist is enclosed.

The following authorized user has the training required under 10 CFR 35.300 for the use of this material: Juan J. Roig, M.D.

As we are a federal facility, an amendment fee is not required.

If you require any additional information in regard to this amendment request, please do not hesitate to contact our Nuclear Medicine Service at (717) 824-3521 Ext. 7611.

Sincerely,

  
REEDS HURT  
Chief Executive Officer

Enclosures: 2

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DEPARTMENT OF VETERANS AFFAIRS  
Medical Center  
St Louis MO 63125

April 30, 1997

In Reply Refer To:

U.S. Nuclear Regulatory Commission  
Region I  
475 Allendale Rd.  
King of Prussia, PA 19406-1415

SUBJECT: NRC License No. 37-13483-01

The enclosed correspondence from the Wilkes-Barre, Pennsylvania VA Medical Center has been received and is forwarded to your office for processing. If there are questions, please contact the facility.

Please provide a copy of any correspondence relative to licensing actions for this Medical Center to:

Department of Veterans Affairs  
Health Physics Programs (115HP)  
915 North Grand Blvd.  
St. Louis, MO 63106

Sincerely,

*Cindy Bukawsky*

*for*  
Francis K. Herbig  
Health Physics Programs

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MAY - 5 1997

(FOR LFMS USE)  
INFORMATION FROM LTS

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: Program Code: 02120
: Status Code: 0
: Fee Category: EX 7C
: Exp. Date: 20020331
: Fee Comments: V
: Decom Fin Assur Reqd: N

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10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100

Applicant/Licensee: V. A. MEDICAL CENTER  
Received Date: 970505  
Docket No: 3003190  
Control No.: 124540  
License No.: 37-13483-01  
Action Type: Amendment

Amount: \_\_\_\_\_  
Check No.: \_\_\_\_\_

Signed Brown, R. J.  
Date 5/7/97

Amendment  
Renewal  
License

Signed \_\_\_\_\_  
Date \_\_\_\_\_

V.A. Medical Center, Wilkes-Barre, Pennsylvania  
QUALITY MANAGEMENT PROGRAM

Policies for the Medical  
Use of Byproduct Materials

Therapeutic Dosage of Strontium-89 Chloride Injection

Per 10 CFR Part 35.32, the following Quality Management Program Shall be adopted.

***I. Written Directive***

Before the administration of a radiopharmaceutical dosage Strontium-89 Chloride Injection for the treatment of pain in patients with multiple skeletal metastases, a written directive is required from the authorized user per 10 CFR 35.32(a)(1), the directive will be dated and signed by the authorized user. Our technologist(s) will not order the radiopharmaceutical without the written directive from an authorized user approved for the use of this radiopharmaceutical.

The Written Directive shall contain the following information:

1. The Radiopharmaceutical
2. The Dosage
3. The Route of Administration
4. The Patients Name
5. The Authorized Users Signature
6. The Date of the order

Any revisions to a written directive may be made, however the revision must be dated and signed by the authorized user prior to the administration of the radiopharmaceutical dosage.

***II. VERIFICATION OF PATIENT IDENTITY***

Before the administration of the prescribed radiopharmaceutical dosage, our technologist shall verify the identity of the patient by more than one method as required under 10 CFR 35.32(a)(2). In addition, we will require that the patients identity is verified by another person. Confirmation will be in writing.

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The patients identity shall be verified in one of the following manners:

1. Comparison of Patients identity with corresponding information in patients record.
2. Birth Date
3. Address
4. Social Security Number
5. Signature
6. ID bracelet or Hospital ID card
7. Patient's name on medical insurance card

### ***III. CONFIRMATION OF WRITTEN DIRECTIVE***

Our Nuclear Medicine Staff will confirm the Authorized Users written directive by two (2) individuals.

The following items shall be confirmed by two individuals:

1. Patients Identity
2. Radiopharmaceutical
3. Dosage
4. Dose Calibrator Settings
5. Dose Calibrator measurement of dose
6. Confirmation that Dose Calibrator reading matches prescribed dose
7. Route of Administration

### ***IV. WORKER GUIDANCE***

Our Technologists shall be required to seek guidance from the ordering Authorized User if there is ANY QUESTION about the written directive. They will not continue a procedure when there is any doubt.

#### ***V. RECORD OF THE ADMINISTERED DOSAGE***

Per 10 CFR 35.32(d)(2), the authorized user or his designee, shall make the following written record in the patients chart or other appropriate record following the administration of the prescribed dosage.

1. Radiopharmaceutical
2. Dosage
3. Route of Administration

#### ***VI. QUALITY MANAGEMENT PROGRAM REVIEW***

Our RSO or his designee shall perform a periodic review of the Radiopharmaceutical QM Program as required by 10 CFR 35.32(b). This review shall be conducted at least annually. This review shall include patient therapeutic dosages of Strontium-89 Chloride Injection. The overall effectiveness of the Quality Management Program will be evaluated at this time and modifications to meet the objectives of the program will be suggested and implemented per 10 CFR 35.32(b)(2) upon approval of the RSO and the Radiation Safety Committee. Any approved modifications to the QMP will be submitted to the NRC within 30 days after the modification per 10 CFR 35.32(e).

QMP audits/program reviews shall be maintained for three years per 10 CFR 35.32(b)(3).

#### ***VII. ORAL REVISIONS TO WRITTEN DIRECTIVES***

If an oral revision to a written directive is required because a patient's health could be jeopardized if a delay in the order takes place, the oral revision will be documented immediately in the patient's record and a revised written directive shall be written, signed and dated by the authorized user. The revised written directive shall be made within 48 hours of the oral revision.

### ***VIII. ORAL DIRECTIVES***

In the event that a patient's health could be jeopardized if a study or treatment is not conducted immediately, an oral directive will be acceptable but must contain the following information:

The information provided in the oral directive must be immediately documented in the patient's record and the written directive must be prepared within 24 hours of the oral directive.

### ***IX. UNINTENDED DEVIATIONS FROM WRITTEN DIRECTIVES***

Staff members must notify the Authorized User or the Radiation Safety Officer (RSO) immediately upon the discovery of a deviation from an authorized users written order.

Upon the confirmation that a deviation has occurred, an immediate investigation as to the cause of the deviation shall be investigated by the RSO.

Per the requirements of 10 CFR 35.32(c), we shall:

- (a) assemble the relevant facts including the cause
- (b) identify what, if any, corrective action is required to prevent recurrence, and,
- (c) retain this report for three years. In addition the NRC shall be notified within 30 days of the event.

The effectiveness of our corrective actions shall be evaluated during the annual audit of the Quality Management Program.

Quality Management Checklist for  
Administration of Strontium-89 Chloride  
V.A. Medical Center

Patient Name \_\_\_\_\_  
Social Security # \_\_\_\_\_  
Date of Birth \_\_\_\_\_

*Note: Form to be completed for ALL Patients receiving Strontium-89 Chloride.*

**Patient Identification: (completed by Technologist verifying patient identity)**

*The above named patient's identity has been verified prior to the administration of the radiopharmaceutical and compared to the Authorized User's order for the procedure by at least two Technologists by at least two of the methods checked below:*

**Check:**

- ☐ Patient confirmed ID by spelling or stating his/her full name as compared with the patient's records.
- ☐ Patient confirmed ID by stating his/her date of birth as compared with the patient's records.
- ☐ Patient confirmed ID by stating his/her Social Security # as compared with the patient's records.
- ☐ Patient confirmed ID by stating his/her address as compared with the patient's records.
- ☐ Patient's ID was confirmed by providing a photographic identification (i.e., driver's license) as compared with patient's records.
- ☐ Patient's ID was confirmed for in-patient's by confirming ID wrist band with patient's records.
- ☐ Patient's ID was confirmed by a relative/friend attesting to patient's identity.

**Special Patient Conditions:**

Patient is Pregnant? Yes ☐ No ☐ N/A ☐

Pregnancy status confirmed by what method \_\_\_\_\_

Patient is Breast Feeding? Yes ☐ No ☐ N/A ☐

I hereby attest that the above information is correct and true and give my consent to the use of radioactive Sr-89 in the treatment of my bone pain at the discretion of the radiologist and the attending physician.

Patients Signature \_\_\_\_\_ Date \_\_\_\_\_  
Signature \_\_\_\_\_ Relation to Patient \_\_\_\_\_  
Witness \_\_\_\_\_ Witness \_\_\_\_\_

Quality Management Checklist

Page 2

**Strontium-89 Chloride Precautions:**

1. Patient has cancer with known bone involvement? Yes: ☐ No: ☐  
(If no, treatment should not be conducted)
2. Patient Platelet count is \_\_\_\_\_ (This should not be below 60,000)
3. Patient White Cell count is \_\_\_\_\_ (This should not be below 2400)
4. Is patient incontinent? No ☐ Yes ☐ (If yes, catheter should be considered)
5. Injection should be made slowly (1-2 mins): Injection time was: \_\_\_\_\_ min \_\_\_\_\_ sec.
6. Patients life expectancy is sufficiently long to conduct the procedure? Yes ☐ No ☐

**Radiopharmaceutical Dosage Verification:**

Radiopharmaceutical being administered: \_\_\_\_\_  
 Pharmaceutical Lot: \_\_\_\_\_  
 Calibrated at: \_\_\_\_\_ mCi at \_\_\_\_\_ am/pm.  
 Actual Dose from Dose Calibrator: \_\_\_\_\_ mCi at \_\_\_\_\_ am/pm  
 Dose Calibrator setting at: \_\_\_\_\_  
 Route of Administration: IV: ☐  
 Time and Date of administration: Time: \_\_\_\_\_ am / pm Date: \_\_\_\_ / \_\_\_\_ / 9\_\_\_\_  
  
 Dose Verified by: \_\_\_\_\_ Tech #1  
 Dose Verified by: \_\_\_\_\_ Tech #2  
  
 Dose Administered by: \_\_\_\_\_

**Radiopharmaceutical Prescription: (completed by person preparing radiopharmaceutical)**

(Note: This is to confirm that all information is recorded on the Authorized Users Prescription.)

Procedure: Yes: ☐ No: ☐  
 Authorized User: Yes: ☐ No: ☐  
 Prescribed Radiopharmaceutical: Yes: ☐ No: ☐  
 Route of Administration: Yes: ☐ No: ☐  
 Dosage Ordered: Yes: ☐ No: ☐  
 Was Dosage Modified?: Yes: ☐ No: ☐ (if yes, how and was it documented?)  
 (note modifications on back of this form)  
 Prescription Verified by: \_\_\_\_\_ Tech #1  
 Prescription Verified by: \_\_\_\_\_ Tech #2

Form Reviewed by: \_\_\_\_\_  
 Radiation Safety Officer

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BETWEEN:

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:   Program Code: 02120
:   Status Code: 0
:   Fee Category: EX 7C
:   Exp. Date: 20020331
:   Fee Comments: V
:   Decom Fin Assur Req'd: N

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## A. REGION

Applicant/Licensee: V. A. MEDICAL CENTER  
Received Date: 970527  
Docket No: 3003190  
Control No.: 124595  
License No.: 37-13483-01  
Action Type: QMP Submission

Amount: \_\_\_\_\_  
Check No.: \_\_\_\_\_

Reference 124540

Signed  
Date

Brown R. J.  
5/23/93

1. Fee Category and Amount:

Amendment  
Renewal  
License

3. OTHER \_\_\_\_\_

Signed  
Date

03001786

VOID SHEET

TO: License Fee Management Branch

FROM: RI

SUBJECT: VOIDED APPLICATION

Control Number: 124074

Applicant: Dept. of Health & Human Services (NIH)

Date Voided: 03-12-97

Reason for Void: Amendment requested by licensee is  
not required for Broadscope licenses  
per P&G-D 3.16, Rev.1 After review  
19-00296-10

Rebecca J. Brown 3/12/97  
Signature Date

Attachment:  
Official Record Copy of  
Voided Action

FOR LFMB USE ONLY

Final Review of VOID Completed:

Refund Authorized and processed

No Refund Due

☒ Fee Exempt or Fee Not Required

Comments: \_\_\_\_\_

Log completed

Processed by: \_\_\_\_\_



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U. S. Nuclear Regulatory Commission		Date: 2-26-97
Telephone or Verbal Conversation Record		Time: 10:12 a.m.
<input type="checkbox"/> Incoming Call <input checked="" type="checkbox"/> Outgoing Call <input type="checkbox"/> Visit		
<b>Person Calling:</b> Michelle Beardsley <i>MB</i> M. Shanbaky	<b>Office:</b> USNRC Region I	<b>Phone #:</b> (215) 337-6942
<b>Person Called:</b> Doug Broaddus	<b>Office:</b> NMSS/IMNS/SCDB	<b>Phone #:</b>
<b>Conversation</b>		
<b>Subject:</b> NIH-License amendment request /License No. 19-00296-10 Docket No. 030-01786    Control No. 124074		
<b>Summary:</b> Dr. Shanbaky informed Mr. Broaddus of a previous telephone conversation with Mr. Robert Zoon, RSO at NIH, in which Mr. Zoon stated that he had spoken to Steve Baggett of SCDB regarding his letter dated 1-3-97 (requesting to possess and use Gd-153 in a Trionix Step device) and a subsequent phone call from M. Beardsley to his assistant (see tele. conv. record in file) asking for additional information regarding the certification of this specific source/device combination, to which Mr. Baggett had replied that, due to their possessing a broadscope license, a license amendment would not be necessary. Mr. Broaddus stated that P&GD 84-22, Rev. 1 contains information that would support this statement.		
<b>Referred to:</b>		
<b>Action Requested:</b> Please advise.		

**Action Taken:**2-26-97, 10:45 a.m.

Follow-up call to Mr. Broaddus from Tom Thompson and M. Beardsley of Region 1; Mr.

Thompson stated that the region has been using P&GD 3-16 for guidance regarding this subject and that he has a record of a conference call with Sally Merchant of NMSS/IMNS in which this issue was addressed (i.e. broadscope licenses requiring line items) and was noted that Ms. Merchant would follow-up on this;

Mr. Broaddus stated that he was unaware of both items and that he would speak to Ms. Merchant and get back to us.

Voice-mail message from D. Broaddus received by M. Beardsley 2-26-97, 1:45 p.m., Mr. Broaddus stated that a revision to P&GD 3-16 is due to be released shortly (in concurrence currently) that will support P&GD 84-22, Rev. 1, in which a broadscope licensee is not required to amend their license for these source/device configurations.

124074





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health  
Bethesda, Maryland 20892

January 3, 1997

U.S. Nuclear Regulatory Commission  
Division of Radiation Safety and Safeguards  
Region I  
475 Allendale Rd.  
King of Prussia, PA 19406

030-01786

Ref: License No. 19-00296-10

*Please expedite review of this request!*

Dear Sir or Madam:

The National Institutes of Health requests an amendment to license 19-00296-10. This amendment is required to permit the NIH to obtain and use Gadolinium-153 in the form of a sealed source other than the already licensed item 7.JJ, North American Scientific Model MED 3601, and in a gamma camera device other than the already licensed item 9.JJ, ADAC Vantage System Model.

The newest Gd-153 source will be ordered from Isotopes Products Laboratories, model HEGL-153, and is intended for use in a Trionix Corporation Sesame gamma camera device. The source is nominally 300 mCi activity, and is registered with the NRC as #CA-0406-S-122-S.

*Note that license 19-00296-10, Section 9. Authorized Use should be changed to indicate that either gadolinium source type may be used in either gamma camera device.*

In addition, please increase the activity limit for Gd-153 from 800 mCi to 1200 mCi total for all above referenced sources with 400 mCi maximum per source. This newest source, as well as all other Gd-153 sealed sources covered under Item JJ, will be for performing patient attenuation measurements in order to correct gamma camera data for the effects of attenuation during SPECT imaging. All appropriate radiation safety procedures will be followed during the installation and use of these sources.

Thank you for your prompt consideration of this request. You may contact me at 301-496-2254 for additional information, if necessary.

Robert A. Zoon, M.E., M.S.  
Radiation Safety Officer

cc: Dr. Lance Liotta, Chairman, Radiation Safety Committee, NIH  
Dr. Stephen Bacharach, Department of Nuclear Medicine, NIH

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