

ACCEPTANCE REVIEW MEMO (ARM)

Licensee: Bozeman Deaconess Foundation **License No.:** 25-10994-04
Docket No.: 030-33305 **Mail Control No.:** 471433
Type of Action: Amend **Date of Requested Action:** 07-05-07
Reviewer Assigned: *Torres* **ARM reviewer(s):** Torres

Response	Deficiencies Noted During Acceptance Review
	[] Open ended possession limits. Limit possession. Submit inventory. [] Submit copies of most recent leak test results. [] Add - delete IC license condition. Add IC paragraph in cover letter. [] Split license from cover letter. Add SUNSI marking to license. [] Ask the licensee if they have any type-amount of EPAct Material.
	Licensee needs to submit NRC Form 313a to document T&E.

Reviewer's Initials: _____ **Date:** _____

<input type="checkbox"/> Yes <input type="checkbox"/> No	Unrestricted release Group 2 or >: Transfer memo to FCDB within 10 days.
<input type="checkbox"/> Yes <input type="checkbox"/> No	Decommissioning notification should be completed within 30 days.
<input type="checkbox"/> Yes <input type="checkbox"/> No	Termination request < 90 days from date of expiration
<input type="checkbox"/> Yes <input type="checkbox"/> No	Expedite (medical emergency, no RSO, location of use/storage not on license, RAM in possession not on license, other)
<input type="checkbox"/> Yes <input type="checkbox"/> No	TAR needed to complete action.

Branch Chief's and/or Sr. HP's Initials: _____ **Date:** _____

SUNSI Screening according to RIS 2005-31

Yes No **Non-Publicly Available, Sensitive** if any item below is checked

General guidance:

- _____ RAM = or > than Category 3 (Table 1, RIS 2005-31), use Unity Rule
- _____ Exact location of RAM (whether = or > than Category 3 or not)
- _____ Design of structure and/or equipment (site specific)
- _____ Information on nearby facilities
- _____ Detailed design drawings and/or performance information
- _____ Emergency planning and/or fire protection systems

Specific guidance for medical, industrial and academic (above Category 3):

- _____ RAM quantities and inventory
- _____ Manufacturer's name and model number of sealed sources & devices
- _____ Site drawings with exact location of RAM, description of facility
- _____ RAM security program information (locks, alarms, etc.)
- _____ Emergency Plan specifics (routes to/from RAM, response to security events)
- _____ Vulnerability/security assessment/accident-safety analysis/risk assess
- _____ Mailing lists related to security response

Branch Chief's and/or Sr. HP's Initials: *RITZ* **Date:** *7-20-07*

Pre-Licensing Screening

Applicant Information:

Control No. 471433

Name: Bozeman Deaconess Foundation	Type of Request: Amend Program Code(s):
Location: MT	License No.: 25-10994-04 Docket No.: 030-33305

STEP 1—Radioactive Materials and Quantities Requested:

Instructions for Step 1: Complete Step 1 for all applications. If all your responses in Step 1 are "No" then do not complete Step 2 (Screening Criteria). Sign and date the completed step-sheet and add it as the sensitive and non-publicly available OAR in ADAMS. If a "yes" response is indicated for any item in Step 1, also complete Step 2. If the type of use is subject to a Security Order or the requirements for increased controls, complete Step 3 (Item A or Item B) without delay.	Yes or No
A. The request is from a new applicant.	No
B. NUREG-1556, Volume 20, Section 4.9 indicates a licensing site visit is needed for the requested type of use, e.g., (1) Type A broad scope license, (2) panoramic irradiator containing > 10000 curies, (3) manufacturers or distributors using unsealed radioactive material or significant quantities of sealed material, (4) radioactive waste brokers, (5) radioactive waste incinerators, (6) commercial nuclear laundries, and (7) any other application that in the judgement of the reviewer and cognizant supervisor involves complex technical issues, complex safety questions, or unprecedented issues that warrant a site visit.	No
C. The applicant requested certain radionuclides and quantities that equal or exceed the Risk Significant Quantity (TBq) values in the table, below, that have been "highlighted" by the reviewer	No

Table of Risk Significant Quantities

(Category 2 Quantities, IAEA Safety Guide No. RS-G-1.9, Categorization of Radioactive Sources, August 2005)

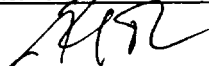
Radionuclide	Risk Significant Quantity (TBq) ¹	Risk Significant Quantity (Ci) ¹	Radionuclide	Risk Significant Quantity (TBq) ¹	Risk Significant Quantity (Ci) ¹
Am-241	0.6	16	Pm-147	400	11,000
Am-241/Be	0.6	16	Pu-238	0.6	16
Cf-252	0.2	5.4	Pu-239/Be	0.6	16
Cm-244	0.5	14	Ra-226 ²	0.4	11
Co-60	0.3	8.1	Se-75	2	54
Cs-137	1	27	Sr-90 (Y-90)	10	270
Gd-153	10	270	Tm-170	200	5,400
Ir-192	0.8	22	Yb-169	3	81

¹ The primary values are TBq. The curie (Ci) values are for informational purposes only.

² The Atomic Energy Act, as amended by the Energy Policy Act of 2005, authorizes NRC to regulate Ra-226 and NRC is in the process of amending its regulations for discrete sources of Ra-226.

Calculations of the Total Activity or the Unity Rule are attached to document whether or not the screening criteria in Step 2 were also completed to evaluate the application. NOTE—If an amendment of an existing license is being requested, the calculations will include the previously authorized quantities for the radionuclide(s).	Yes, No, or Not Applicable (NA)
Total Activity—multiple activities are requested for a single radionuclide and the sum of the activities equals or exceeds the quantity of concern for the radionuclide	—
Unity Rule—multiple radionuclides are requested and the sum of the ratios equals or exceeds unity, e.g., [(total activity for radionuclide A) ÷ (risk significant quantity for radionuclide A)] + [(total activity for radionuclide B) ÷ (risk significant quantity for radionuclide B)] ≥ 1.0.	—

Signature and Date for Step 1:

 JUL 20 2007

License Reviewer and Date



Bozeman Deaconess
HOSPITAL

July 5, 2007

Nuclear Material Licensing Branch
Region IV
United States Nuclear Regulatory Commission
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011-8064

RECEIVED

JUL 10 2007

DNMS

RE: Adding an authorized user to Bozeman Deaconess Hospital License #25-10994-04

Dear Sir/Madam;

We would like to amend our license to include Michael Robert Paradise, M.D.
For material and use for 35:100 and 35:200. (see attached sheets)

If you have any questions regarding this notification please call me at (406) 585-5033

Sincerely,

John Bratke C.N.M.T.
Nuclear Medicine
Bozeman Deaconess Hospital
915 Highland Blvd.
Bozeman, Montana 59715

**Texas Department of State Health Services
PRECEPTOR STATEMENT FOR LICENSE APPLICATION**

PREPARED FOR CONSIDERATION TO RAM LICENSE NUMBER: L00384

Statement must be completed and signed by the physician=s preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each. Equivalent forms, including those from other Regulatory Agencies, will be accepted. Print or type.

1. Applicant's full name and address: Michael Robert Paradise, M.D.	Dates of training: Feb. 1-28, 2002, Jan. 1-31, 2006, Feb. 1-28, 2006
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Clinical Training and Experience of the Proposed Physician User

	Column A Radionuclide	Column B Conditions Diagnosed or Evaluated	Column C Number of Cases Involving Personal Participation*	Column D Comments
1	I-125	Diagnosis of Thyroid Function	-	
2	or	Blood Volume or Blood Plasma Volume	-	
8	I-131	Liver Function	-	
9	or	Kidney Function Studies	-	
.	Co-57	<i>In vitro</i> Studies	-	
2	or	Schilling Test	-	
5	Co-58	<i>(other)</i>	-	
6	I-125	Detection of Thrombus	-	
(x)		Labelled WBC for Infection Imaging	21	
a	In-111	Cisternogram/Shunt Patency Imaging	1	
n	Ga-67	Abscess or Tumor Imaging	7	
d	Xe-133	Pulmonary Ventilation/Blood Flood Imaging	113	
(y)	I-123	Thyroid Imaging/Uptake	71	
	Tl-201	Cardiac Perfusion Imaging	145	
	Tc-99m	Cardiac Perfusion, E.F., Gated Wall Motion	61	
		Blood Pool Imaging	75	
		Bone Imaging	235	
		Sentinel Node Imaging	21	
		Breast (Mammoscintigraphy) Imaging	-	
		Cystography/Ureteral Reflux Imaging	-	
		Diverticulum Imaging	-	
		Gastric Emptying and Reflux Imaging	5	
		GI Bleed Imaging	15	
		Hepatobiliary Imaging	21	
		Liver/Spleen and Bone Marrow Imaging	2	
		Lung Perfusion Imaging	128	
		Myocardial Infarction Imaging	-	
		Renal Perfusion/GFR Imaging	47	
	Thyroid and Salivary Imaging	-		
	Venography/Thrombus Imaging	-		
		<i>Parathyroid</i> <i>(other)</i>	7	
	F-18(etc.)	P.E.T. Imaging	-	
RADIOPHARMACEUTICAL PREPARATION				
2	Mo/Tc	Generator Elution and Testing	-	
5	Tc-99m	Reagent Kit Preparation and Testing	-	
6		<i>(other)</i>	-	
(z)			-	

Proposed Physician User:

Column A Radionuclide	Column B Condition Treated	Column C Number of Cases Involving Personal	Column D Comments
I-131 (NaI)	Hyperthyroidism/Graves/Multinodular Goiters	21	
	Thyroid Cancer/Metastasis	7	
I-131 (MoAb)	Non-Hodgkin=s Lymphoma	-	
Y-90 (MoAb)	Non-Hodgkin=s Lymphoma	-	
P-32(soluble)	Polycythemia etc.	-	
P-32(colloidal)	Intracavitary malignant effusions etc.	-	
Sr-89	Palliative Bone Pain from Bone Metastasis	2	
Sm-153	Palliative Bone Pain from Bone Metastasis	-	
	(other e.g., Investigational Drugs)	-	
Sr-90	Superficial eye conditions	-	
I-125	Eye plaques	-	
I-125	Interstitial Cancer	-	
Pd-103	Interstitial Cancer	-	
Au-198	Interstitial Cancer	-	
Cs-137	Intercavitary Cancer	-	
Ir-192	Interstitial Cancer	-	
Co-60	External Beam Therapy	-	
Ir-192	High Dose Rate After-loader Therapy	-	System
Sr-90, P-32, Ir-192	Intravascular Brachytherapy	-	System
	(other) - Bone Density		

***KEY TO COLUMN AC#**

- 1) Supervise examination of patients to determine the suitability for radionuclide diagnosis and/or treatment and recommendation for prescribed dosage.
- 2) Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.
- 3) Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment

SEE 25 TAC '289.256(ff)

A. TOTAL HOURS OF TRAINING COMBINED CLINICAL AND WORK EXPERIENCE: _____ **HOURS** **WHERE OBTAINED** _____

- ! (DIAGNOSTIC PHYSICIAN USER TRAINING MUST HAVE INCLUDED THE FOLLOWING)
- ! ORDERING, RECEIVING, UNPACKAGING, SURVEYING
- ! CALIBRATING DOSE CALIBRATORS AND DIAGNOSTIC INSTRUMENTS
- ! CALIBRATING AND PREPARING PATIENT DOSES
- ! USING ADMINISTRATIVE CONTROLS TO PREVENT MISADMINISTRATIONS
- ! CONTAIN SPILLS AND PERFORM DECONTAMINATION
- ! ELUTE Mo/Tc GENERATORS, TEST ELUATE AND PREPARE KITS
- ! REVIEW PATIENT HISTORY; SELECT MEASURE AND ADMINISTER DOSAGES; COLLABORATIVE REPORTING; FOLLOW-UP
- ! PHYSICS AND INSTRUMENTATION; PROTECTION; MATHEMATICS; PHARMACEUTICAL CHEMISTRY; RADIATION BIOLOGY

TOTAL HOURS OF DIDACTIC (CLASSROOM AND LABORATORY TRAINING: _____ **HOURS** **WHERE ATTENDED** _____

[OR]

B. COMPLETE FULL-SCOPE NUCLEAR MEDICINE TRAINING IN A RESIDENCY ACCREDITED BY ACGME OR COPT-AOA. PROGRAM DIRECTOR _____ **TOTAL NO. OF MONTHS COMPLETED** _____

[OR]

C. ACCEPTED BOARD SPECIALTY: American Board of Radiology **DATE ISSUED** June, 2006

I CERTIFY THAT THE ABOVE NAMED PHYSICIAN SUCCESSFULLY COMPLETED THE SPECIFIED TRAINING WITHIN THE INSTITUTIONAL APPROVED TRAINING PROGRAM

William A. Erdman, M.D. , at UT Southwestern Medical Center - Radiology Dept.

NAME OF PHYSICIAN (PRECEPTOR)

INSTITUTION

SIGNATURE

L00384

5323 Harry Hines Boulevard

214-590-5120

INSTITUTIONAL RAM LICENSE No.

ADDRESS

TELEPHONE No.

NRC State

Agreement State

Expiration Date _____

Dallas, TX 75390-8896

April 30, 2007

CITY/STATE/ZIP

DATE

7-24-07
DATE

This is to acknowledge the receipt of your letter/application dated 7-05-07, and to inform you that the initial processing, which includes an administrative review, has been performed.

There were no administrative omissions. Your application will be assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card:

The action you requested is normally processed within 90 days.

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 4714.33.
When calling to inquire about this action, please refer to this mail control number.
You may call me at 817-860-8103.

Sincerely,

Colleen Murnahan
Licensing Assistant

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: 20150131
: Fee Comments:
: Decom Fin Assur Req: N
:

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: BOZEMAN DEACONESS FOUNDATION
Received Date: 20070710
Docket No: 3033305
Control No.: 471433
License No.: 25-10994-04
Action Type: Amendment

2. FEE ATTACHED

Amount: _____
Check No.: /

3. COMMENTS

Signed Colleen Murnahan
Date 7-18-07

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

1. Fee Category and Amount: _____

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

Amendment _____
Renewal _____
License _____

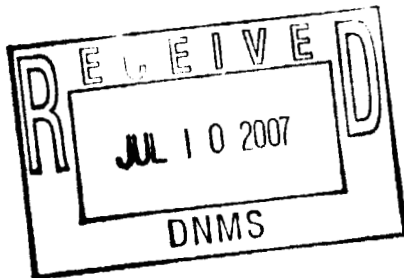
3. OTHER _____

Signed _____
Date _____

→ L22A TKE Nuc MED



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