

ACCEPTANCE REVIEW MEMO (ARM)

Licensee: Billings Clinic **License No.:** 25-01051-01
Docket No.: 030-02389 **Mail Control No.:** 471437
Type of Action: Amend **Date of Requested Action:** 07-17-07
Reviewer Assigned: Jackie Cook **ARM reviewer(s):** Torres

Response	Deficiencies Noted During Acceptance Review
	<input type="checkbox"/> Open ended possession limits. Limit possession. Submit inventory. <input type="checkbox"/> Submit copies of most recent leak test results. <input type="checkbox"/> Add - delete IC license condition. Add IC paragraph in cover letter. <input type="checkbox"/> Split license from cover letter. Add SUNSI marking to license. <input type="checkbox"/> Ask the licensee if they have any type-amount of EPAct Material.
7/23/07	Submit NRC Form 313a to document T&E for Dr. Ford. <i>received completed NRC Form 313a (210) P.A. Mukherjee</i>

Reviewer's Initials: JAC **Date:** 7/23/07

<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		
<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	Non-Publicly Available, Sensitive if <u>any</u> 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: <u>RJC</u>		
Date: JUL 20 2007		

Pre-Licensing Screening

Applicant Information:

Control No. 471437

Name: Billings Clinic	Type of Request: Amend Program Code(s):	
Location: MT	License No.: 25-01051-01	Docket No.: 030-02389

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:



 License Reviewer and Date

JUL 20 2007



Billings Clinic

JUL 23 2007

Department of Radiology

(406) 657-4190

657-3747

Front Desk Fax: (406) ~~247-6472~~ Room Fax: (406) 657-4194

FACSIMILE TRANSMITTAL SHEET

DATE: 7/23/07

TO: Jackie Cook

FAX #: 817-960-9263 Phone #: 406-672-6756

FROM: Chris Fitz

TOTAL NUMBER OF PAGES: 3

Urgent

For Review

Please Comment

Please Reply

COMMENTS:

Please find attached a copy of NRC Form 313A(AJO) for Dr. Ford-Muktamala.

Thank you for your help.

2800 10th Ave. N.
P.O. Box 37000
Billings, MT 59107-7000

JUL 23 2007

NRC FORM 313A (AUD) (3-2007)	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2008	
AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.190, 35.290, and 35.590]			
Name of Proposed Authorized User Laura Ford-Mukkamala, DO	State or Territory Where Licensed Montana		
Requested Authorization(s) (check all that apply)			
<input type="checkbox"/> 35.100 Uptake, dilution, and excretion studies <input checked="" type="checkbox"/> 35.200 Imaging and localization studies <input type="checkbox"/> 35.500 Sealed sources for diagnosis (specify device _____)			
PART I – TRAINING AND EXPERIENCE (Select one of the three methods below)			
* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.			
<input checked="" type="checkbox"/> 1. Board Certification			
a. Provide a copy of the board certification. b. If using only 35.500 materials, stop here. If using 35.100 and 35.200 materials, skip to and complete Part II Preceptor Attestation.			
<input type="checkbox"/> 2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization			
a. Authorized user on Materials License _____ meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290. b. Supervised Work Experience. (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)			
Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs			
Total Hours of Experience:			
Supervising Individual		License/Permit Number listing supervising individual as an authorized user	
Supervisor meets the requirements below, or equivalent Agreement State requirements (check all that apply).			
<input type="checkbox"/> 35.290 <input type="checkbox"/> 35.390 + generator experience in 32.290(c)(1)(ii)(G)			

JUL 23 2007

NRC FORM 313A (AUD) **U.S. NUCLEAR REGULATORY COMMISSION**
(3-2007) **AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

PART II -- PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. (Not required to meet training requirements in 35.590)

First Section

Check one of the following for each use requested:

For 35.190

Board Certification

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.190(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

OR

Training and Experience

I attest that _____ has satisfactorily completed the 60 hours of training and
Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

Board Certification

I attest that Laura Ford-Mukkamala DO has satisfactorily completed the requirements in
Name of Proposed Authorized User

10 CFR 35.290(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

OR

Training and Experience

I attest that _____ has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User


and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

Second Section

Complete the following for preceptor attestation and signature:

I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

- 35.190 35.290 35.390 35.390 + generator experience

Name of Preceptor Scott Sample, DO	Signature 	Telephone Number 406-237-2000	Date 7/23/07
---------------------------------------	--	----------------------------------	-----------------

License/Permit Number/Facility Name
NRC License Number 25-01051-01/Billings Clinic, Billings Montana



**BILLINGS CLINIC
DEPARTMENT OF RADIOLOGY**

PHONE: (406) 657-4588

FAX: (406) ~~657-4194~~ 247-6472

FACSIMILE TRANSMITTAL SHEET

TO:

Roberto Torres

FROM:

Chris Fitz

COMPANY:

USNRC

DATE:

7/17/07

FAX NUMBER:

817-860-8199

TOTAL # OF PAGES INCLUDING COVER:

3

PHONE #:

406-672-6756

RE:

Amendment Request for Lic # 25-01051-01

URGENT

FOR REVIEW

PLEASE COMMENT

PLEASE REPLY

NOTES/COMMENTS:

Thank you
7/23/07: spoke w/ Chris and he will forward when 15 days a completed Preceptor
Application for Dr. Ford-Mulhamala.
Suelee Carr

2800 TENTH AVE. NORTH
P.O. BOX 37000
BILLINGS, MT 59107-7000



2800 Tenth Avenue North
P.O. Box 37000
Billings, Montana 59107-7000

July 17, 2007

Roberto J. Torres, Senior Health Physicist
U.S. Nuclear Regulatory Commission, Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011
817-860-8188

Christopher K. Fitz, Radiation Safety Officer
Billings Clinic Health System
Department Of Nuclear Medicine
2800 10th Ave. North
P.O. Box 37000
Billings, MT 59107

Re: Amendment Request for Billings Clinic License Number 25-01051-01

Mr. Torres, we request to add a new authorized user to our license. Please accept this letter and the supporting material to add Laura L. Ford-Mukkamala, DO, as an authorized user for 10 CFR 35.200 use of radioactive material. Dr. Ford-Mukkamala has completed certification from the Certification Board of Nuclear Cardiology.

If you require addition information please call me at 406-672-6756/406

Sincerely,

A handwritten signature in black ink, appearing to read "C. Fitz".

Christopher K. Fitz, J.D., M.S.
Radiation Safety Officer

Cc: Peggy Wharton, VP Clinical Operations

THE CERTIFICATION BOARD OF NUCLEAR CARDIOLOGY

Incorporated 1996

CERTIFIES THAT

Laura L. Ford-Mukkamala, DO

HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS BOARD FOR PHYSICIANS RESIDING IN THE UNITED STATES AND HAVING SATISFACTORILY PASSED THE REQUIRED EXAMINATION,

IS HEREBY DESIGNATED

A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF

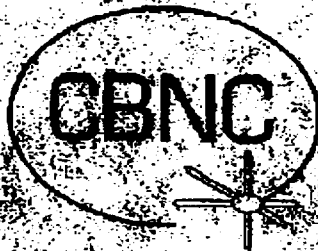
NUCLEAR CARDIOLOGY

FOR THE PERIOD 2004 THROUGH 2014

Paul D. Ferguson
PRESIDENT

[Signature]
SECRETARY

CERTIFICATE # 5304



October 24, 2004

471437

7-24-07
DATE

This is to acknowledge the receipt of your letter/application dated 7-23-07, 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** 471437.
When calling to inquire about this action, please refer to this mail control number.
You may call me at 817-860-8103.

Sincerely,

Licensing Assistant

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)

INFORMATION FROM LTS

Program Code: 02230
Status Code: 0
Fee Category: 7C
EXP. Date: 20150430
Fee Comments: CODE 23
Decom Fin Assur Req'd: N
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LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: BILLINGS CLINIC
Received Date: 20070717
Docket No: 3002389
Control No.: 471437
License No.: 25-01051-01
Action Type: Amendment

2. FEE ATTACHED

Amount: _____
Check No.: _____

3. COMMENTS

Signed *William Thurman*
Date *9-18-07*

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 _____