Torres, RobertoJ

From: ccarver1@rcrh.org
Sent: Monday, March 01, 2010 3:38 PM
To: Torres, RobertoJ
Subject: RE: AU Amendment for Dr. Swartz
Attachments: Swartz AU amendment.pdf

Hello Roberto,

Please find attached an amendment to add Dr. Swartz as an AU for 10CFR35.300, 35.400 and 35.600 (HDR) uses. It is in PDF format, however I can change that to another format if needed. As you may remember, this is a resubmission from late December / early January. I believe that all the documentation is complete now. Please contact me if you have any questions or require additional information.

Thank you for your assistance in this matter.

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Charles M. Carver, MS
Medical Physicist
Radiation Safety Officer
Rapid City Regional Hospital
Rapid City, SD
605-719-2369 (office)
605-310-8135 (cell)

ABR Certified Therapeutic and Diagnostic Physics
ABMP Certified Radiologic Oncology Physics

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REGIONAL HOSPITAL
P.O. Box 6000 Rapid City, SD 57709 (605) 719-1000

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March 1, 2010

Mr. Roberto J. Torres
Materials Licensing Section
U.S. Nuclear Regulatory Commission, Region IV
612 E. Lamar Blvd, Suite #400
Arlington, TX 76011-4125

RE: Addition of an Authorized User for 10CFR35.300, 35.400 and 35.600 Remote Afterloader materials

License #: 40-00238-04

Dear Mr. Torres:

We would like to request the following amendments to our NRC Materials License #40-00238-04:

1.) We would like to add Dr. Michael Swartz, MD to our Authorized User list for 10CFR35.300, 35.400, and 35.600 Remote Afterloader uses. We have documented his training and experience as referenced below. Although we have sent copies of Dr. Swartz's diploma, board certificate, residency documentation and South Dakota medical license previously, we have placed them in Attachment F for your reference.

In Summary:
We request the following additions to our NRC license:

Authorized User	*Authorized Uses*	*Basis*
Dr. Michael Swartz, MD	35.300	Training and experience documented on NRC Form 313A (AUT) in Attachment A
Dr. Michael Swartz, MD	35.400	Training and experience documented on NRC Form 313A (AUS) in Attachment B
Dr. Michael Swartz, MD	35.600	Training and experience documented on NRC Form 313A (AUS) in Attachment B

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Thank you for your attention to this matter. Please contact me if you have any questions or require further information at 605-719-2369.

Sincerely,

Charles M. Carver, MS
Radiation Safety Officer
Rapid City Regional Hospital

cc: Lowell Husman
Paul Clemments

Attachments: A.) NRC Form 313A (AUT)
B.) NRC Form 313A (AUS)
C.) Preceptor Letter from Dr. Deborah Frassica, MD
D.) Supervisor Document for 10CFR35.300 materials
E.) Training document from Nucletron for 10CFR35.600 materials
F.) Board Certificate, Medical school diploma, residency certificate and South Dakota medical license

Attachment A

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NRC FORM 313A (AUT)
(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.300)
[10 CFR 35.390, 35.392, 35.394, and 35.396]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 3/31/2012

Name of Proposed Authorized User	State or Territory Where Licensed
Michael J. Swartz, MD	South Dakota

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Requested Authorization(s) *(check all that apply)*:

- [✓] 35.300 Use of unsealed byproduct material for which a written directive is required

OR

- [ ] 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- [ ] 35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)
- [ ] 35.300 Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required
- [ ] 35.300 Parenteral administration of any other radionuclide for which a written directive is required

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 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.

[✓] **1. <u>Board Certification</u>**

a. Provide a copy of the board certification.

b. For 35.390, provide documentation on supervised clinical case experience. The table in section 3.c. may be used to document this experience.

c. For 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience.

d. Skip to and complete Part II Preceptor Attestation.

[ ] **2. <u>Current 35.300, 35.400, or 35.600 Authorized User Seeking Additional Authorization</u>**

a. Authorized User on Materials License _____ under the requirements below or equivalent Agreement State requirements *(check all that apply)*:

[ ] 35.390 [ ] 35.392 [ ] 35.394 [ ] 35.490 [ ] 35.690

b. If currently authorized for a subset of clinical uses under 35.300, provide documentation on additional required supervised case experience. The table in section 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

c. If currently authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

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AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

☐ **3. Training and Experience for Proposed Authorized User**

a. Classroom and Laboratory Training ☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use			
Radiation biology			
Total Hours of Training:			

b. Supervised Work Experience ☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396

If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.

Supervised Work Experience		**Total Hours of Experience:**	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		☐ Yes ☐ No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		☐ Yes ☐ No	
Calculating, measuring, and safely preparing patient or human research subject dosages		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		☐ Yes ☐ No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		☐ Yes ☐ No	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:

☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396	With experience administering dosages of: ☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) ☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) ☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required ☐ Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

c. Supervised Clinical Case Experience
If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	1	Johns Hopkins University	May 2005
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	1	Johns Hopkins University	May 2005
Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required			
Parenteral administration of any other radionuclide for which a written directive is required _____ (List radionuclides)			

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

c. Supervised Clinical Case Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
P. Ladenson (see Attachment D)	**Johns Hopkins University School of Medicine**

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:

☑ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396	With experience administering dosages of: ☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) ☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) ☑ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required ☑ Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

d. Provide completed Part II Preceptor Attestation.

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.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section
Check one of the following for each requested authorization:

For 35.390:

Board Certification

☑ I attest that **Michael J. Swartz, MD** has satisfactorily completed the training and experience
Name of Proposed Authorized User

requirements in 35.390(a)(1).

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 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:

☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396	With experience administering dosages of: ☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) ☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) ☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required ☐ Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

c. Supervised Clinical Case Experience
If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	2	Johns Hopkins University	June 2005
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	2	Johns Hopkins University	June 2005
Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required	1	Johns Hopkins University	May 2005
Parenteral administration of any other radionuclide for which a written directive is required _____ (List radionuclides)			

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

c. Supervised Clinical Case Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
M. Wharam (see Attachment D)	Johns Hopkins University School of Medicine

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:

☑ 35.390	With experience administering dosages of:
☐ 35.392	☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
☐ 35.394	☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
☐ 35.396	☑ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
	☑ Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

d. Provide completed Part II Preceptor Attestation.

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.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section
Check one of the following for each requested authorization:

For 35.390:

Board Certification

☑ I attest that Michael J. Swartz, MD has satisfactorily completed the training and experience
Name of Proposed Authorized User

requirements in 35.390(a)(1).

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 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:

- ☐ 35.390
- ☐ 35.392
- ☐ 35.394
- ☐ 35.396

With experience administering dosages of:

- ☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- ☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- ☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- ☐ Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

c. Supervised Clinical Case Experience
If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)			
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)			
Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required	1	Johns Hopkins University	July 2005
Parenteral administration of any other radionuclide for which a written directive is required _____ (List radionuclides)			

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

c. Supervised Clinical Case Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
T. DeWeese (see Attachment D)	Johns Hopkins University School of Medicine

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:

☑ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396	With experience administering dosages of: ☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) ☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) ☑ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required ☑ Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

d. Provide completed Part II Preceptor Attestation.

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.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section
Check one of the following for each requested authorization:

For 35.390:

Board Certification

☑ I attest that Michael J. Swartz, MD has satisfactorily completed the training and experience
Name of Proposed Authorized User

requirements in 35.390(a)(1).

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 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:

☐ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396	With experience administering dosages of: ☐ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) ☐ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) ☐ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required ☐ Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

c. Supervised Clinical Case Experience
If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)			
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)			
Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required			
Parenteral administration of any other radionuclide for which a written directive is required Y-90 (List radionuclides)	1	Johns Hopkins University	September 2007

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

c. Supervised Clinical Case Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
J. Herman (see Attachment D)	Johns Hopkins University School of Medicine

Supervising individual meets the requirements below, or equivalent Agreement State requirements *(check all that apply)***:

☑ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396	With experience administering dosages of: ☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) ☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) ☑ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required ☑ Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

d. Provide completed Part II Preceptor Attestation.

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.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section
Check one of the following for each requested authorization:

For 35.390:

Board Certification

☑ I attest that Michael J. Swartz, MD has satisfactorily completed the training and experience
Name of Proposed Authorized User

requirements in 35.390(a)(1).

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 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).

A 4 7 7 6 1 0

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)

For 35.392 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☐ I attest that _____ has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User

and laboratory training, as required by 10 CFR 35.392(c)(1), and the supervised work and clinical case experience required in 35.392(c)(2).

For 35.394 (Identical Attestation Statement Regardless of Training and Experience Pathway):

☐ I attest that _____ has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User

and laboratory training, as required by 10 CFR 35.394 (c)(1), and the supervised work and clinical case experience required in 35.394(c)(2).

Second Section

☑ I attest that **Michael J. Swartz, MD** has satisfactorily completed the required clinical case
Name of Proposed Authorized User

experience required in 35.390(b)(1)(ii)G listed below:

☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☑ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☑ Parenteral administration of any other radionuclide requiring a written directive

---

Third Section

☑ I attest that **Michael J. Swartz, MD** has satisfactorily achieved a level of competency to
Name of Proposed Authorized User

function independently as an authorized user for:

☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☑ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☑ Parenteral administration of any other radionuclide requiring a written directive

NRC FORM 313A (AUT) (3-2009) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Fourth Section

For 35.396:

Current 35.490 or 35.690 authorized user:

☐ I attest that _____ is an authorized user under 10 CFR 35.490 or 35.690
Name of Proposed Authorized User

or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.396 (d)(1), and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☐ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ Parenteral administration of any other radionuclide for which a written directive is required

OR

Board Certification:

☑ I attest that Michael J. Swartz, MD has satisfactorily completed the board certification
Name of Proposed Authorized User

requirements of 35.396(c), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (d)(1) and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

☑ Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☑ Parenteral adminstration of any other radionuclide for which a written directive is required

---

Fifth Section

Complete the following for preceptor attestation and signature:

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

☑ 35.390 ☐ 35.392 ☐ 35.394 ☐ 35.396

☑ I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization.

☑ Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

☑ Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)

☑ Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required

☑ Parenteral administration of any other radionuclide requiring a written directive

Name of Preceptor	Signature	Telephone Number	Date
Dr. Deborah Frassica, MD	Deborah Frassica, MD see Attachment #C	(410) 955-7390	06/30/2008

License/Permit Number/Facility Name
Johns Hopkins University School of Medicine #850

JHU USP RAD ONC Fax:4108473805 Feb 26 2010 10:48 P.13

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Attachment B

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NRC FORM 313A (AUS)
(3-2007)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 35.400 and 35.600)
[10 CFR 35.490, 35.491, and 35.690]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2008

Name of Proposed Authorized User	State or Territory Where Licensed
Michael J Swartz, MD	South Dakota

Requested Authorization(s) (check all that apply)

- [x] 35.400 Manual brachytherapy sources
- [ ] 35.600 Teletherapy unit(s)
- [ ] 35.400 Ophthalmic use of strontium-90
- [ ] 35.600 Gamma stereotactic radiosurgery unit(s)
- [x] 35.600 Remote afterloader unit(s)

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.

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[x] **1. Board Certification**

a. Provide a copy of the board certification.

b. For 35.600, go to the table in 3.e. and describe training provider and dates of training for each type of use for which authorization is sought.

c. Skip to and complete Part II Preceptor Attestation.

[ ] **2. Current 35.600 Authorized User Requesting Additional Authorization for 35.600 Use(s) Checked Above**

a. Go to the table in section 3.e. to document training for new device.

b. Skip to and complete Part II Preceptor Attestation.

[ ] **3. Training and Experience for Proposed Authorized User**

a. Classroom and Laboratory Training [ ] 35.490 [ ] 35.491 [ ] 35.690

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Radiation biology			
Total Hours of Training:			

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work and Clinical Experience for 10 CFR 35.490 *(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)*

Supervised Work Experience		**Total Hours of Experience:**	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		☐ Yes ☐ No	
Checking survey meters for proper operation		☐ Yes ☐ No	
Preparing, implanting, and safely removing brachytherapy sources		☐ Yes ☐ No	
Maintaining running inventories of material on hand		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of byproduct material		☐ Yes ☐ No	
Using emergency procedures to control byproduct material		☐ Yes ☐ No	

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Approved by: ☐ Residency Review Committee for Radiation Oncology of the ACGME ☐ Royal College of Physicians and Surgeons of Canada ☐ Committee on Postdoctoral Training of the American Osteopathic Association		
Supervising Individual	License/Permit Number listing supervising individual as an Authorized User	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

c. Supervised Clinical Experience for 10 CFR 35.491

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Use of strontium-90 for ophthalmic treatment, including: examination of each individual to be treated; calculation of the dose to be administered; administration of the dose; and follow up and review of each individual's case history			

Supervising Individual	License/Permit Number listing supervising individual as an Authorized User

d. Supervised Work and Clinical Experience for 10 CFR 35.690

☐ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

Supervised Work Experience	**Total Hours of Experience:**		
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Reviewing full calibration measurements and periodic spot-checks		☐ Yes ☐ No	
Preparing treatment plans and calculating treatment doses and times		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of byproduct material		☐ Yes ☐ No	
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console		☐ Yes ☐ No	
Checking and using survey meters		☐ Yes ☐ No	
Selecting the proper dose and how it is to be administered		☐ Yes ☐ No	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

d. Supervised Work and Clinical Experience for 10 CFR 35.690 (continued)

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Approved by: ☐ Residency Review Committee for Radiation Oncology of the ACGME ☐ Royal College of Physicians and Surgeons of Canada ☐ Committee on Postdoctoral Training of the American Osteopathic Association		

Supervising Individual	License/Permit Number listing supervising individual as an Authorized User

e. For 35.600, describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Device operation	July 2009		
Safety procedures for the device use	July 2009		
Clinical use of the device			

Supervising Individual. *If training provided by Supervising Individual (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)*	License/Permit Number listing supervising individual as an Authorized User
Hal Archibald	Nucletron Rep - see Attachment E

Authorized for the following types of use:

☑ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

f. Provide completed Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

d. Supervised Work and Clinical Experience for 10 CFR 35.690 (continued)

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Approved by: ☒ Residency Review Committee for Radiation Oncology of the ACGME ☐ Royal College of Physicians and Surgeons of Canada ☐ Committee on Postdoctoral Training of the American Osteopathic Association		

Supervising Individual	License/Permit Number listing supervising individual as an Authorized User

e. For 35.600, describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Device operation	Annual training 2004-2008		
Safety procedures for the device use	Annual training 2004-2008		
Clinical use of the device	July 2004 through June 2008		

Supervising Individual. *If training provided by Supervising Individual (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)*	License/Permit Number listing supervising individual as an Authorized User
Dr. Deborah Frassica, MD Deborah Frassica, MD	Johns Hopkins School of Medicine #856

Authorized for the following types of use:

☑ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

f. Provide completed Part II Preceptor Attestation.

JHU GSP RAD ONC Fax:4108473805 Feb 26 2010 10:47 P.05

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.

First Section
Check one of the following for each requested authorization:

For 35.490:

Board Certification

☑ I attest that Michael J. Swartz, MD has satisfactorily completed the requirements in
Name of Proposed Authorized User

35.490(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

OR

Training and Experience

☐ I attest that _____ has satisfactorily completed the 200 hours of
Name of Proposed Authorized User

classroom and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation oncology, as required by 10 CFR 35.490(b)(1) and (b)(2), and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

For 35.491:

☐ I attest that _____ has satisfactorily completed the 24 hours of
Name of Proposed Authorized User

classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy, has used strontium-90 for ophthalmic treatment of 5 individuals, as required by 10 CFR 35.491(b), and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Second Section

For 35.690:

Board Certification

☑ I attest that Michael J. Swartz, MD has satisfactorily completed the requirements in
Name of Proposed Authorized User

35.690(a)(1).

OR

Training and Experience

☐ I attest that _____ has satisfactorily completed 200 hours of classroom
Name of Proposed Authorized User

and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation therapy, as required by 10 CFR 35.690(b)(1) and (b)(2).

AND

NRC FORM 313A (AUS)
(3-2007)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

Third Section

For 35.690: (continued)

☑ I attest that Michael J. Swartz, MD has received training required in 35.690(c) for device
Name of Proposed Authorized User

operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought, as checked below.

☑ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

AND

Fourth Section

☑ I attest that Michael J. Swartz, MD has achieved a level of competency sufficient to
Name of Proposed Authorized User

achieve a level of competency sufficient to function independently as an authorized user for:

☑ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

Fifth Section

Complete the following for preceptor attestation and signature:

☑ I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as an authorized user for:

☑ 35.400 Manual brachytherapy sources ☐ 35.600 Teletherapy unit(s)

☐ 35.400 Ophthalmic use of strontium-90 ☐ 35.600 Gamma stereotactic radiosurgery unit(s)

☑ 35.600 Remote afterloader unit(s)

Name of Preceptor	Signature	Telephone Number	Date
Dr. Deborah Frassica, MD	Deborah Frassica, MD	410-955-7390	02/24/2010

License/Permit Number/Facility Name
Johns Hopkins University. # 8556

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Attachment C

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Deborah Frassica, M.D.
Associate Professor and
Residency Program Director

Radiation Oncology & Molecular
Radiation Sciences
401 North Broadway / Suite 1440
Baltimore, Maryland 21231
410-955-7390 T
410-847-3800 Green Spring
410-502-1419 F
frassde@jhmi.edu

JOHNS HOPKINS
MEDICINE
THE SIDNEY KIMMEL
COMPREHENSIVE
CANCER CENTER

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6/30/2008

Michael Swartz, M.D.
Department of Radiation Oncology and Molecular Radiation Sciences
The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins

Dear Dr. Swartz,

Congratulations on the successful completion of your residency training in the Department of Radiation Oncology and Molecular Radiation Sciences. This letter is provided to you to summarize your training, which occurred between July 1, 2004 and June 30, 2008. During the time of your training, the residency program was fully accredited by the ACGME.

During the four years of training, you completed 39 months of clinical radiation oncology rotations in the following areas: Breast, CNS (including stereotactic RT and GammaKnife), Head and Neck (including eye and skin), Gastrointestinal, Genitourinary, Gynecologic, Lung, Lymphoma/Leukemia, Musculoskeletal, and Pediatric malignancy. You have treated 528 adult and 20 pediatric patients with external beam therapy. You have met the requirements for training in brachytherapy techniques completing 25 intracavitary procedures, 19 interstitial procedures and 9 unsealed source procedures. To fulfill the requirements for instruction in pathology, imaging and medical/pediatric oncology, you attended multidisciplinary conferences throughout your four years that were the equivalent of 1, 1 and 2 month rotations, respectively. You also received didactic instruction in radiation physics, radiation biology and the core competencies, and attended the required clinical conferences in the department and the Oncology Center. In addition to your clinical rotations, you spent 9 months on research rotations. Your active involvement in research projects has resulted in numerous national presentations and publications.

During training, your performance was assessed by faculty evaluations, 360° evaluations, annual oral examinations, annual national in-training examinations, annual national RAPHEX examination (physics) and performance in conferences. You have consistently performed in an exemplary manner, receiving excellent scores on objective examinations and superlative subjective evaluations. You have been a dedicated and knowledgeable resident who has taken all of your responsibilities very seriously. The quality of your patient care has been excellent, including documentation in the medical records. You have worked well with the faculty and staff in the department and throughout the

institution. You have also been active in the teaching activities of the department, assisting the faculty with the education of junior residents and medical students. Your leadership and organizational skills were recognized by your appointment as Co-Chief Resident during your final year of training. You have not been the subject of any disciplinary action or medical malpractice.

In summary, you have completed the required training for board certification in radiation oncology and have been judged by the faculty to have demonstrated sufficient competence to enter practice without direct supervision. We look forward to your continued success as you embark on your career in as a full-time Radiation Oncologist in South Dakota.

Sincerely,

Deborah Frassica, MD

Deborah A. Frassica, M.D.

I hereby acknowledge receipt of this letter.

6/16/08

Michael Swartz, M.D. Date

Attachment D

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Radiation Oncology
Oral I-131 & Parenteral Administration Log

Michael Swartz, MD — Resident Name
Johns Hopkins — Program
Program #

Date	Disorder	Radionuclide	Dose Administered	Preceptor Name/Signature
Oral I-131 (>33 mCi)				
1. 6/15/05	Papillary Thyroid Cancer	I-131	354 mCi	M. Wharam
2. 6/22/05	Papillary Thyroid Cancer	I-131	413 mCi	M. Wharam
3. 5/1/08	Thyroid Cancer	I-131	75 mCi	P. Ladenson
Parenteral				
1. 5/18/05	Thyroid cancer	Sm^{153}	60.8 mCi	M. Wharam
2. 7/7/05	Prostate cancer	Sm^{153}	76.8 mCi	T. DeWeese
3. 9/5/07	Metastatic Rectal Cancer	Y^{90} (theraspheres)	113.7 Gy	J. Herman

1/31/07

Attachment E

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Nucletron®

Nucletron Corporation
7080 Columbia Gateway Drive
Columbia, MD 21046-2133

Telephone: 410-312-4100
Toll Free: 800-336-2249
Canada Toll Free: 800-445-2249
FAX: 410-312-4196

Nucletron Training Seminar

Institution: Cancer Care Institute

City, State/Province, Zip: Rapid City, SD 57701

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1 Teaching Aids Used

- User's Manual ☑
- Applicators and Accessories ☐
- Source Container and Dummy Sources ☑
- Other ☑

2 Topics Covered

- Explanation of Remote Afterloading ☑
- Explanation of Radiation Protection ☑

3 Applications

- Bronchus ☐
- Interstitial ☐
- Intracavitary ☐
- Intraoperative ☐

4 Applicators/Accessories

- Bronchus ☐
- GYN ☐
- Esophagus ☐
- Interstitial ☐
- Other ☐

5 Equipment Operation

- Treatment Unit ☐
- Handling ☐
- Power Requirements ☐
- Console ☐
- Treatment ☑
- Start ☑
- Interrupt ☑
- Emergency Stop ☑
- Alarm and Error Codes ☑

Radioactive Source: Ir192

6 Receiving

- Unpacking ☐
- Acceptance ☐
- Calibration ☐
- Installation ☐

7 Shipping

- Release ☐
- Packing ☐
- Documents ☐
- Measurements ☐

- Emergency Procedures ☑

All areas marked were covered during training

Wed Jul 2009 07/29/09 14:02:29
Instructor

Wed Jul 2009 07/29/09 14:13:59
Department Head

Service Engineer
Title

Physicist
Title

*** List of all attendees accompanies this form**

Nucletron®

Nucletron Corporation
7080 Columbia Gateway Drive
Columbia, MD 21046-2133

Telephone: 410-312-4100
Toll Free: 800-336-2249
Canada Toll Free: 800-445-2249
FAX: 410-312-4196

Nucletron Training Seminar
Attendance Registration

Hospital: Cancer Care Institute Date: Wednesday, July 29, 2009

Course: M-HDR Radiation Safety

Instructor: Hal Archibald

	Name	Department	Title	Signature
1	Michael Swartz	Radiation Oncology	MD	Wed Jul 2009 07/29/09 13:15:46
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				

I certify that the above individuals have been instructed in Equipment Operation, Safety Precautions and Emergency Procedures in accordance with Nucletron Corporation Training Standards.

Instructor Signature: Wed Jul 2009 07/29/09 14:02:06

Instructor Title: Service Engineer

Attachment F

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The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association,
the American Society for Radiation Oncology, the Association of
University Radiologists, and the American Association of Physicists in Medicine
Hereby certifies that

Michael John Swartz, MD

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of
The American Board of Radiology
On this third day of June, 2009
Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of

Radiation Oncology

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AM Eligible

THE AMERICAN BOARD OF RADIOLOGY
INCORPORATED IN THE DISTRICT OF COLUMBIA
1934

M. Reed Dennis, MD
President

Richard T. Morin
Secretary-Treasurer

Executive Director

AMERICAN BOARD OF MEDICAL SPECIALTIES
EXCELLENCE
QUIS UT DEUS

Certificate No. 58647

Valid through 2019

The Johns Hopkins University

Upon the recommendation of the Faculty of

The School of Medicine

has conferred upon

Michael John Swartz

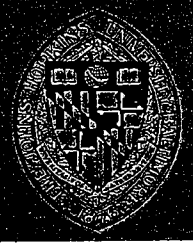
the degree of

Doctor of Medicine

with all the rights, honors and privileges appertaining thereto

Given under the seal of the University at Baltimore, Maryland

on May twenty-second, two thousand and three



President

Dean of the School of Medicine

Secretary

Trustee

The Johns Hopkins Hospital

Baltimore Maryland

This certifies that

Michael J. Swartz, MD

served on the Resident Staff

of The Johns Hopkins Hospital as a

Chief Resident

on the

Radiation Oncology and Molecular Radiation Sciences Service

from July 1, 2007 to June 30, 2008

PRESIDENT

CHIEF OF SERVICE

CHAIRMAN, BOARD OF TRUSTEES

THIS IS YOUR LICENSE

Detach and retain card for your records.

Michael John Swartz, MD

Rapid City, SD 57701-7375

Cut out card

Cut out card

SOUTH DAKOTA BOARD OF MEDICAL AND OSTEOPATHIC EXAMINERS

SD License Number: **7285**

Michael John Swartz, MD

is licensed to practice Medicine or Osteopathy as provided by the laws of the State of South Dakota.

Not Valid After: **March 1, 2010**

Milton Mutch, MD, Secretary MM

Initialed By

0 4 7 9 6 1 0

3-19-2010
DATE

This is to acknowledge the receipt of your letter/application dated 3-01-2010, 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 other 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** 472610.
When calling to inquire about this action, please refer to this mail control number.
You may call me at 817-860-8103.

Sincerely,

Colleen Burnahan

Licensing Assistant

NRC FORM 532 (RIV)
(10-2008)

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: 20101031
Fee Comments: CAL THEIR OWN INSTRUMENTS
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
Applicant/Licensee: RAPID CITY REGIONAL HOSPITAL, INC.
Received Date: 20100301
Docket No: 3003231
Control No.: 472610
License No.: 40-00238-04
Action Type: Amendment

2. FEE ATTACHED
Amount: /
Check No.: /

3. COMMENTS

Signed Colleen Murnahan
Date 3-12-2010

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 _____