

CRITTENTON**Get Better Here™**

February 2, 2010


UNITED STATES NUCLEAR REGULATORY COMMISSION
Region III, Materials Licensing Section
2443 Warrenville Road
Suite 210
Lisle, IL 60532-4352

Re: License No. 21-13562-01, Crittenton Hospital.

Please add Annie Kalapparambath, M.D. as an authorized user for 35.100, 35.200, and 35.300. Please find the enclosed NRC Form 313A (AUD) and 313A (AUT) for your review.

Thank you for your cooperation with this matter. If you have any questions or require additional information please contact our physicist, Michelle L. Kritzman, at (734) 662-3197.

Respectfully,



William Bell, Jr.
Administrative Director Imaging & Diagnostics
Crittenton Hospital Medical Center
Rochester, Michigan 48307

1101 W. University Dr.

Rochester MI 48307

NRC FORM 313A (AUT) (3-2009)		U.S. NUCLEAR REGULATORY COMMISSION		APPROVED BY OMB: NO. 3150-0120 EXPIRES: 3/31/2012	
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]					
Name of Proposed Authorized User			State or Territory Where Licensed		
Annie Kalapparambath, MD			Michigan		
Requested Authorization(s) (check all that apply):					
<input checked="" type="checkbox"/> 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)					
<ul style="list-style-type: none"> ▪ 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.					

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	William Beaumont Hospital, Nuclear Medicine Dept. 3601 W. 13 Mile Rd, Royal Oak, MI 48073	67	August 1, 2003 -July 31, 2004
Radiation protection	William Beaumont Hospital, Nuclear Medicine Dept. 3601 W. 13 Mile Rd, Royal Oak, MI 48073	10	August 1, 2003 -July 31, 2004
Mathematics pertaining to the use and measurement of radioactivity	William Beaumont Hospital, Nuclear Medicine Dept. 3601 W. 13 Mile Rd, Royal Oak, MI 48073	8	August 1, 2003 -July 31, 2004
Chemistry of byproduct material for medical use	William Beaumont Hospital, Nuclear Medicine Dept. 3601 W. 13 Mile Rd, Royal Oak, MI 48073	40	August 1, 2003 -July 31, 2004
Radiation biology	William Beaumont Hospital, Nuclear Medicine Dept. 3601 W. 13 Mile Rd, Royal Oak, MI 48073	10	August 1, 2003 -July 31, 2004

Total Hours of Training: 135

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: 1,920

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	William Beaumont Hospital, Nuclear Medicine Dept. 3601 W. 13 Mile Rd, Royal Oak, MI 48073 21-01333-01	✓ Yes No	August 1, 2003 -July 31, 2004
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	William Beaumont Hospital, Nuclear Medicine Dept. 3601 W. 13 Mile Rd, Royal Oak, MI 48073 21-01333-01	✓ Yes No	August 1, 2003 -July 31, 2004
Calculating, measuring, and safely preparing patient or human research subject dosages	William Beaumont Hospital, Nuclear Medicine Dept. 3601 W. 13 Mile Rd, Royal Oak, MI 48073 21-01333-01	✓ Yes No	August 1, 2003 -July 31, 2004
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	William Beaumont Hospital, Nuclear Medicine Dept. 3601 W. 13 Mile Rd, Royal Oak, MI 48073 21-01333-01	✓ Yes No	August 1, 2003 -July 31, 2004
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	William Beaumont Hospital, Nuclear Medicine Dept. 3601 W. 13 Mile Rd, Royal Oak, MI 48073 21-01333-01	✓ Yes No	August 1, 2003 -July 31, 2004

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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

Helena Balon, M.D.

NRC License: 21-01333-01

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.

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)	22	William Beaumont Hospital, Nuclear Medicine Dept. 3601 W. 13 Mile Rd, Royal Oak, MI 48073 21-01333-01	August 1, 2003 -July 31, 2004
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	8	William Beaumont Hospital, Nuclear Medicine Dept. 3601 W. 13 Mile Rd, Royal Oak, MI 48073 21-01333-01	August 1, 2003 -July 31, 2004
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)

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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

Helena Baton, MD

NRC license: 21-01333-01

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 Annie Kalapparambath, MD has satisfactorily completed the training and experience requirements in 35.390(a)(1).
Name of Proposed Authorized User

OR

Training and Experience

I attest that _____ has satisfactorily completed the 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).
Name of Proposed Authorized User

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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 **Annie Kalapparambath, 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 **Annie Kalapparambath, 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

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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 _____ 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 administration 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

Helena Balon, M.D.

Signature



Telephone Number

(248) 898-4126

Date

01/25/2010

License/Permit Number/Facility Name

21-01333-01 William Beaumont Hospital

NRC FORM 313A (AUD) (3-2009)	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 3/31/2012
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 Annic Kalappambath, MD	State or Territory Where Licensed Michigan
Requested Authorization(s) (check all that apply)	
<input checked="" 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.

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.
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
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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)	
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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

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	William Beaumont Hospital, Nuclear Medicine Dept. 3601 W. 13 Mile Rd, Royal Oak, MI 48073 21-01333-01	67	August 1, 2003-July 31, 2004
Radiation protection	William Beaumont Hospital, Nuclear Medicine Dept. 3601 W. 13 Mile Rd, Royal Oak, MI 48073 21-01333-01	10	August 1, 2003-July 31, 2004
Mathematics pertaining to the use and measurement of radioactivity	William Beaumont Hospital, Nuclear Medicine Dept. 3601 W. 13 Mile Rd, Royal Oak, MI 48073 21-01333-01	8	August 1, 2003-July 31, 2004
Chemistry of byproduct material for medical use (not required for 35.590)	William Beaumont Hospital, Nuclear Medicine Dept. 3601 W. 13 Mile Rd, Royal Oak, MI 48073 21-01333-01	40	August 1, 2003-July 31, 2004
Radiation biology	William Beaumont Hospital, Nuclear Medicine Dept. 3601 W. 13 Mile Rd, Royal Oak, MI 48073 21-01333-01	10	August 1, 2003-July 31, 2004

Total Hours of Training: 135

b. Supervised Work Experience (completion of this table is not required for 35.590).
 (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervised Work Experience Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Total Hours of 1920 Experience:		Dates of Experience*
		Confirm		
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	William Beaumont Hospital, Nuclear Medicine Dept. 3601 W. 13 Mile Rd, Royal Oak, MI 48073 21-01333-01	✓ Yes	No	August 1, 2003-July 31, 2004
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	William Beaumont Hospital, Nuclear Medicine Dept. 3601 W. 13 Mile Rd, Royal Oak, MI 48073 21-01333-01	✓ Yes	No	August 1, 2003-July 31, 2004

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AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

b. Supervised Work Experience. (continued)

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages	William Beaumont Hospital, Nuclear Med Dept. 3601 W. 13 Mile Rd, Royal Oak, MI 48073 21-01333-01	✓ Yes No	August 1, 2003-July 31, 2004
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material	William Beaumont Hospital, Nuclear Med Dept. 3601 W. 13 Mile Rd, Royal Oak, MI 48073 21-01333-01	✓ Yes No	August 1, 2003-July 31, 2004
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures	William Beaumont Hospital, Nuclear Medicine Dept. 3601 W. 13 Mile Rd, Royal Oak, MI 48073 21-01333-01	✓ Yes No	August 1, 2003-July 31, 2004
Administering dosages of radioactive drugs to patients or human research subjects	William Beaumont Hospital, Nuclear Med Dept. 3601 W. 13 Mile Rd, Royal Oak, MI 48073 21-01333-01	✓ Yes No	August 1, 2003-July 31, 2004
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	William Beaumont Hospital, Nuclear Med Dept. 3601 W. 13 Mile Rd, Royal Oak, MI 48073 21-01333-01	✓ Yes No	August 1, 2003-July 31, 2004

Supervising Individual: **Helen Balon, M.D.**
 License/Permit Number listing supervising individual as an authorized user: **21-01333-01**

Supervisor meets the requirements below, or equivalent Agreement State requirements (*check one*).

- 35.190 35.290 35.390 ✓ 35.390 + generator experience in 35.290(c)(1)(ii)(G)

c. For 35.590 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates
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d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete 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. (Not required to meet training requirements in 35.590)

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 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 Annie Kalapparambath MD 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 _____ 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 Annie Kalapparambath MD 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

Helen Balon, M.D.

Signature

Helen Balon, MD

Telephone Number

(248) 898-4126

Date

01/25/2010

License/Permit Number/Facility Name

21-01333-01 William Beaumont Hospital



FACSIMILE TRANSMITTAL SHEET

TO: ATTN: Region III Material Licensing Section	FROM: William Bell, Jr.
COMPANY: NRC	DATE: 2/2/2010
FAX NUMBER: (630) 829-9782	TOTAL NO. OF PAGES INCLUDING COVER: Eleven (11)
PHONE NUMBER: (248) 652-5111	SENDER'S REFERENCE NUMBER: License No. 21-13562-01
RE: Remove License Amendment Request	YOUR REFERENCE NUMBER: N/A

URGENT FOR REVIEW PLEASE COMMENT PLEASE REPLY PLEASE RECYCLE

NOTES/COMMENTS:

ATTN: Region III Material Licensing Section

Thank you for your assistance with our license amendment request.

Have a Blessed Day