



Ball Memorial Hospital, Inc.

United States Nuclear Regulatory Commission
Region III
2443 Warrenville Road
Lisle, IL 60532-4352

April 10, 2007

Re: USNRC Materials License No. 13-00951-03

Dear Sir or Madam,

I am re-submitting a request that Nathan M. Strabala, MD be added to our license for 10CFR 35.100, 200 and 300 materials uses. Pursuant to a NRC letter of November 30, 2006 denying the previous request, I have reviewed 10 CFR 35.290, as well as the list of approved medical specialty boards presented on the NRC's website.

Please note that Specialty Board(s) Certification Recognized by NRC Under 10 CFR Part 35 as listed at <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html> includes the American Board of Radiology (ABR) certification process from June 2006 forward for the Diagnostic Radiology certificates issued before and after that date with the words "AU eligible" appearing above the ABR seal. I have included a letter from the American Board of Radiology to Dr. Strabala granting his certification in June 2006 and indicating he has the AU eligible designation on his certificate as per this process. Also included are forms 313A (AUD) with an attached preceptor attestation form documenting I-131 therapy experience for quantities equal to or below 33 mCi. In addition, 313A (AUT) is enclosed indicating Dr. Strabala's supervised preceptorship for cases above 33 mCi.

The institution's Radiation Safety Committee has approved these requests.

If you have any questions, please feel free to contact me at 765-747-4440

Sincerely,

Alvis E. Foster, MS
Radiation Safety Officer

Terry Pence, RPh, MBA
Senior Administrative Director, CHS Cancer Service Line

Enclosures: 3

cc: Radiation Safety Committee File

RECEIVED APR 16 2007

The American Board of Radiology

Diagnostic Radiology

Radiation Oncology

Radiologic Physics



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52365 / DR / 12 / 11

Nathan Michael Strabala, MD
18060 Snow Ave.
Dearborn, MI 48124

Dear Dr. Strabala:

I am pleased to inform you that you passed the oral examination held on June 11-14, 2006. The American Board of Radiology grants you its Certificate in Diagnostic Radiology. This is a ten-year time-limited certificate. In addition, because you received the appropriate training to make you AU-Eligible and [REDACTED], you will receive the [REDACTED].

The certificate will be sent to the above address in approximately three months from our printer, Jim Henry, Inc. Your name will appear on the certificate as shown above. If you wish your name to appear differently or you have an address change, please notify the Board office in writing by July 12, 2006. Your name and demographic information will be included in a Directory published by the American Board of Medical Specialties. It is your responsibility to notify other local and state or national organizations of your certification.

Important information about your Maintenance of Certification process is enclosed. Please review it and respond as requested.

Personally and on behalf of the Board of Trustees of The American Board of Radiology, I wish to congratulate you for this distinguished achievement. You have accomplished one of the most significant milestones in your career.

Sincerely,

Robert R. Hattery, MD

Enclosures

Robert R. Hattery, M.D., *Executive Director*
Lawrence W. Davis, M.D., *Associate Executive Director*

Assistant Executive Directors Primary Certification

Anthony V. Datto, M.D., *Diagnostic Radiology*
Beth A. Erickson, M.D., *Radiation Oncology*
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Assistant Executive Directors Maintenance of Certification

John F. Madewell, M.D., *Diagnostic Radiology*
Larry E. Kim, M.D., *Radiation Oncology*
Stephen R. Thomas, Ph.D., *Radiologic Physics*
Gary J. Becker, M.D., *Subspecialty Certification*

5441 E. WILLIAMS BOULEVARD, SUITE 200 • TUCSON, ARIZONA 85711-4493 • PHONE (520) 790-2900 • FAX (520) 790-3200
E-mail: information@theabr.org • Web Site: www.theabr.org

**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]

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

Name of Proposed Authorized User

State or Territory Where Licensed

NATHAN M. STRABALA, MD

INDIANA

Requested Authorization(s) (check all that apply)

- 35.100 Uptake, dilution, and excretion studies
- 35.200 Imaging and localization studies
- 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

Supervisor meets the requirements below, or equivalent Agreement State requirements (check all that apply).

- 35.290
- 35.390 + generator experience in 32.290(c)(1)(ii)(G)

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			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use <i>(not required for 35.590)</i>			
Radiation biology			
Total Hours of Training:			

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.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys			
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters			
Calculating, measuring, and safely preparing patient or human research subject dosages			

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	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material			
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures			
Administering dosages of radioactive drugs to patients or human research subjects			
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 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

d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.

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 NATHAN M. STRABALA 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 NATHAN M. STRABALA 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 → Reza Abghari	Signature [Signature]	Telephone Number 313-593-7320	Date 2-14-07
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→ License/Permit Number/Facility Name
B Oakwood Hospital NRC # 21-04515-01

American Board of Radiology – Program Director Attestation

COMPLIANCE WITH NRC TRAINING AND EXPERIENCE REQUIREMENTS

More information can be found at the following link:

<http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0290.html>

Nathan Strabala
Resident Name

Oakwood Hospital
Program

4202512092
Program #

	YES	NO
By the time of the ABR oral examination, this applicant will have successfully completed the hours of training and experience as outlined in 10 CFR 35.290 and 35.392.....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
This applicant has taken part in ≥ 3 cases of oral administration of I-131 therapy ($\leq 33\text{mCi}$).....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The resident's logbook of these therapy experiences (date, dose, and preceptor) is attached.....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The work and experience cited above for § 35.290 was obtained under the supervision of an Authorized User (AU) who meets the requirements under relevant sections of § 35.290 or equivalent Agreement State requirements.....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The work and experience cited above for § 35.392 was obtained under the supervision of an Authorized User (AU) who meets the requirements under § 35.390, 35.392 or 35.394 or equivalent Agreement State requirements.....	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Sharon R. Helmer, MD
Residency Program Director
(Print Name)

Sharon R. Helmer
Program Director
(Signature)

1/14/06
Date

I-131 Therapy Experience

Nathan Strabala
Resident Name

Oakwood Hospital
4202512092
Program & Number

<u>Date</u>	<u>Dose Administered</u>	<u>Preceptor (AU) Print & Sign Name</u>
1. <u>3/9/06</u>	<u>18 mCi I-131</u>	<u>Reza Abghari, MD</u> Print Name <u>Reza Abghari</u> Sign Name
2. <u>3/23/06</u>	<u>18 mCi I-131</u>	<u>Reza Abghari, MD</u> Print Name <u>Reza Abghari</u> Sign Name
3. <u>4/11/06</u>	<u>15 mCi I-131</u>	<u>Reza Abghari, MD</u> Print Name <u>Reza Abghari</u> Sign Name
4. <u>4/11/06</u>	<u>18 mCi I-131</u>	<u>Reza Abghari, MD</u> Print Name <u>Reza Abghari</u> Sign Name

**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: 10/31/2008

Name of Proposed Authorized User

State or Territory Where Licensed

NATHAN M. STRABALA, MD

INDIANA

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. Board Certification

- 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. Current 35.300, 35.400, or 35.600 Authorized User Seeking Additional Authorization

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			
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.

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys			
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters			
Calculating, measuring, and safely preparing patient or human research subject dosages			
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material			
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures			

Total Hours of Supervised Work Experience:

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 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)			
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	3	BALL MEMORIAL HOSPITAL LICENSE 13-00951-03	9-13-06 9-21-06 10-25-06
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 WILLIAM C. MASON, MD	License/Permit Number listing supervising individual as an authorized user 13-00951-03
---	--

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.

First Section

Check one of the following for each requested authorization:

For 35.390:

Board Certification

I attest that NATHAN M. STRABALA 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)

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 NATHAN M. STRABALA 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 NATHAN M. STRABALA 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

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	Signature	Telephone Number	Date
William C. Mason, M.D.	William C. Mason, M.D.	765-747-3049	1/15/07

License/Permit Number/Facility Name
BALL MEMORIAL HOSPITAL 13-00951-03

Alvis E. Foster, MS
Ball Memorial Hospital
2401 W. University Ave.
Muncie, IN 47303

RETURN RECEIPT
REQUESTED

PLACE STICKER AT TOP OF ENVELOPE TO THE RIGHT
OF THE RETURN ADDRESS, FOLD AT DOTTED LINE
CERTIFIED MAIL™



7004 2890 0000 0267 5279

United States Nuclear Regulatory Commission
Region III
2443 Warrenville Road
Lisle, IL 60532-4352

