

gfr



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

September 28, 2009

Roberto J. Torres, Senior Health Physicist
U.S. Nuclear Regulatory Commission, Region IV
612 E. Lamar Blvd. Suite 400
Arlington, TX 76011
817-860-8188

RECEIVED

OCT 15 2009

DNMS

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

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

Mr. Torres, we request to add a new authorized user to our license. Please accept this letter and the supporting material to add Zachary M. Bland, MD, as an authorized user for 10 CFR 35.100, 200, and 300 uses. Dr. Bland is board certified by the American Board of Radiology and AU eligible. NRC 313a (AUD and AUT) have been completed for Dr. Bland.

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

Sincerely,

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

Christopher K. Fitz, JD, MS
Medical Physicist/Radiation Safety Officer

A handwritten signature in black ink, appearing to read "Peggy Wharton".

Peggy Wharton
VP for Clinic Operations

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

Zachary M. Bland, 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*

Diagnostic Radiology

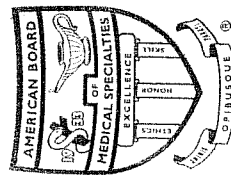
AM Eligible



N. Reed Spinnick, MD
President

Richard A. Morin
Secretary-Treasurer

Hayden Schultz
Executive Director



Certificate No. 55106

Valid through 2019

**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: 3/31/2012

Name of Proposed Authorized User

Zachary M. Bland, M.D.

State or Territory Where Licensed

Montana

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 (not required for 35.590)			
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.)

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		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	

(3-2009)

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		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Administering dosages of radioactive drugs to patients or human research subjects		<input type="checkbox"/> Yes <input type="checkbox"/> No	
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		<input type="checkbox"/> Yes <input type="checkbox"/> No	

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)

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 Zachary M. Bland, M.D. 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 Zachary M. Bland, M.D. 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

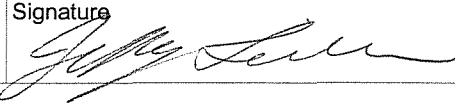
and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

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 Jeffry O. Lindenbaum, M.D.	Signature 	Telephone Number (406) 237-1350	Date 09/14/2009
License/Permit Number/Facility Name 25-010151-01 Billings Clinic			

**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

Zachary M. Bland, M.D.

State or Territory Where Licensed

Montana

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.*

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		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Calculating, measuring, and safely preparing patient or human research subject dosages		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<input type="checkbox"/> Yes <input type="checkbox"/> 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 (<i>check all that apply</i>)**:	
<input type="checkbox"/> 35.390 <input type="checkbox"/> 35.392 <input type="checkbox"/> 35.394 <input type="checkbox"/> 35.396	With experience administering dosages of: <input type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) <input type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) <input type="checkbox"/> Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required <input type="checkbox"/> 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			
_____ (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
Supervising individual meets the requirements below, or equivalent Agreement State requirements (<i>check all that apply</i>)**:	
<input type="checkbox"/> 35.390	With experience administering dosages of:
<input type="checkbox"/> 35.392	<input type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
<input type="checkbox"/> 35.394	<input type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
<input type="checkbox"/> 35.396	<input type="checkbox"/> Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
	<input type="checkbox"/> 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 Zachary M. Bland, M.D. 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 _____ 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 _____ 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

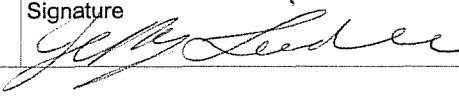
☒ I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization.

☒ 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 Jeffrey O. Lindenbaum, M.D., Ph.D.	Signature 	Telephone Number (406) 237-1350	Date 09/14/2009
License/Permit Number/Facility Name 25-010151-01 Billings Clinic			

ACCEPTANCE REVIEW MEMO (ARM)

Licensee: Billings Clinic

License: 25-01051-01

Docket: 030-02389

Mail Control: 472449

Type of Action: Amend

Date of Requested Action: 9/28/09

Reviewer Assigned: *Rache I*

ARM reviewer(s): Torres

Response	Deficiencies Noted During Acceptance Review
	<p>[] Confirm with licensee if they have NARM material.</p> <p>[] Change of contact information (RSO), send request to update IC database.</p> <p>Reviewer: Board Certification not adequate for 35.300 material. Have preceptor complete NRC Form 313a(AUT) for alternate pathway.</p>

Reviewer's Initials: *Mued Partial for 35.100 + 35.200 until T+E is received* **Date:** *12/17/09*

- ☐ Yes ☐ No Request for unrestricted release Group 2 or >. Consult with Bravo Branch.
- ☐ Yes ☐ No Termination request < 90 days from date of expiration
- ☐ Yes ☐ No Expedite (medical emergency, no RSO, location of use/storage not on license, RAM in possession not on license, other)
- ☐ Yes ☐ No TAR needed to complete action.

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

SUNSI Screening according to RIS 2005-31

☐ Yes ☒ No **Sensitive and Non-Publicly Available** if any item below is checked

General guidance:

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

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

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

Branch Chief's and/or HP's Initials: *QOC* **Date:** *10/30/09*

ORIGIN ID: BILA (406) 657-4067
SHIPPING&RECEIVING
BILLINGS CLINIC
2800 10TH AVE N
BILLINGS, MT 59101
UNITED STATES US

Ship Date: 14OCT09
ActWgt: 0.2 LB
System#: 598565/CAFE2361
Account: S *****

Part # 156297-435 RIT 06/09

TO

US NUCLEAR REGULATORY COMMISSION
612 E. LAMAR BLVD

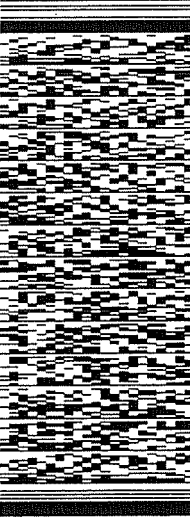
ARLINGTON, TX 76011

Ref: 7050
Dept: NUC. MED

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