



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

February 27, 2014

Atheir Amarrah
Owner and Manager
A A & A Medical Co.
29600 Northwestern Hwy.
Southfield, MI 48034

Dear Mr. Amarrah:

This refers to: (1) the January 7, 2014, letter from your listed Radiation Safety Officer (RSO), Henry A. Shevitz, M.D., withdrawing himself as RSO for your U.S. Nuclear Regulatory Commission (NRC) Radioactive Materials License No. 21-32818-01, (2) the January 14, 2014, phone conversation in which you indicated to a member of my staff that you would be submitting an amendment indicating a replacement RSO promptly, and (3) the February 4, 2014, phone conversation in which you indicated that Dr. Shevitz had agreed to remain as the listed RSO for your Radioactive Materials License. In the February 4, 2014, phone conversation, my staff understood that you would submit a letter, signed and dated by you and Dr. Shevitz, confirming Dr. Shevitz's continued status as your appointed RSO. We expected to receive that letter by February 7, 2014. To date, we have not received such a letter at our office.

As an NRC licensee, Title 10 of the *Code of Federal Regulations* Section 30.9(a) requires you to provide the NRC with complete and accurate information. Under 10 CFR 35.24(b), you are required to appoint an RSO, who agrees in writing, to be responsible for implementing the radiation protection program.

To continue operations under your NRC License No. 21-32818-01, submit the following information as soon as possible but no later than fourteen days after the date of this letter:

1. **Cover letter**, signed and dated by you, including the name of your appointed RSO
2. **Current Delegation of Authority (DOA)**, signed and dated by both you and your appointed RSO (see attached for a Model DOA from our regulatory guidance).
3. **RSO Qualifications** (License No. on which the RSO is a named RSO, or other training and experience as outlined in 10 CFR 35.50, which may be submitted via NRC Form 313A (RSO); copy attached for your convenience)

In the alternative, you may terminate your NRC License No. 21-32818-01, by submitting a signed and dated NRC Form 314 (copy attached for your convenience). Additional information regarding final area closeout surveys and disposition of material may be required to complete a termination request.

Please submit your request to either continue or terminate operations via facsimile to the attention of my staff member, Sara Forster, referencing Control Number 582808, at (630) 515-1078. We expect to receive all required information on or before March 12, 2014. You may also scan your response and submit as a pdf file attachment to an email, directed to Ms. Forster at sara.forster@nrc.gov. If you have any questions or require clarification on any of the information stated above, please contact Ms. Forster immediately at (630) 829-9892.

A. Amarrah

- 2 -

In accordance with 10 CFR 2.390, a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

A handwritten signature in cursive script, appearing to read "Patricia J. Pelke".

Patricia J. Pelke, Chief
Materials Licensing Branch
Division of Nuclear Materials Safety

License No. 21-32818-01
Docket No. 030-38423

Enclosures: Model DOA (from NUREG 1556, Vol. 9, Rev. 2, Appendix I)
NRC Form 313A (RSO)
NRC Form 314

A. Amarrah

- 2 -

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Sincerely,

/RA/

Patricia J. Pelke, Chief
Materials Licensing Branch
Division of Nuclear Materials Safety

License No. 21-32818-01
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ADAMS Accession Number:

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OFFICE	RIII DNMS <i>C-108</i>	RIII DNMS <i>C</i>	RIII	RIII
NAME	Forster/trt	Pelke <i>PJP</i>		
DATE	02/20/14	02/21/14		

OFFICIAL RECORD COPY

Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority

Model Radiation Safety Officer Duties and Responsibilities

The duties and responsibilities of the Radiation Safety Officer (RSO) include ensuring radiological safety and compliance with NRC and DOT regulations and the conditions of the license. Model procedures for describing the RSO's duties and responsibilities appear below. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of 10 CFR 35.24. As a result of implementation of the EPAct, licensed material now includes accelerator-produced radioactive materials and discrete sources of Ra-226. Licensees authorized under 10 CFR 30.32(j) to produce and noncommercially transfer PET radioactive drugs to consortium members should review the model duties and responsibilities below, expanding on them as necessary to ensure radiation safety oversight of the production and transfer only to medical use consortium members.

Typically, these duties and responsibilities include ensuring the following:

- Unsafe activities involving licensed material are stopped;
- Radiation exposures are ALARA;
- Up-to-date radiation protection procedures in the daily operation of the licensee's byproduct material program are developed, distributed, and implemented;
- Possession, use, and storage of licensed material are consistent with the limitations in the license, the regulations, the SSDR certificate(s), and the manufacturer's recommendations and instructions;
- Individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license;
- Personnel training is conducted and is commensurate with the individual's duties regarding licensed material;
- Documentation is maintained to demonstrate that individuals are not likely to receive, in 1 year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided;
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained;
- Licensed material is properly secured;
- Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public;
- Proper authorities are notified of incidents such as loss or theft of licensed material, damage to or malfunction of sealed sources, and fire;

APPENDIX I

- Medical events and precursor events are investigated and reported to NRC, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
- Audits of the Radiation Protection Program are performed at least annually and documented;
- If violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented;
- Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;
- Licensed material is disposed of properly;
- Appropriate records are maintained; and
- An up-to-date license is maintained, and amendment and renewal requests are submitted in a timely manner.

Model Delegation of Authority

Memo To: Radiation Safety Officer
From: Chief Executive Officer
Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the Radiation Protection Program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations where justified to maintain radiation safety. You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the Nuclear Regulatory Commission at any time. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

Signature of Management Representative

Date

I accept the above responsibilities,

Signature of Radiation Safety Officer

Date

cc: Affected department heads

**RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION
[10 CFR 35.50]**

APPROVED BY OMB: NO. 3150-0120
EXPIRES: (05/31/2015)

Name of Proposed Radiation Safety Officer

Requested Authorization(s) *The license authorizes the following medical uses (check all that apply):*

- 35.100 35.200 35.300 35.400 35.500 35.600 (remote afterloader)
 35.600 (teletherapy) 35.600 (gamma stereotactic radiosurgery) 35.1000 (_____)

**PART I -- TRAINING AND EXPERIENCE
(Select one of the four 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. Use Table 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.
- c. Skip to and complete Part II Preceptor Attestation.

OR

2. Current Radiation Safety Officer Seeking Authorization to Be Recognized as a Radiation Safety Officer for the Additional Medical Uses Checked Above

- a. Use the table in section 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for the additional types of medical use for which recognition as RSO is sought.
- b. Skip to and complete Part II Preceptor Attestation.

OR

3. Structured Educational Program for Proposed Radiation Safety Officer

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			
Radiation biology			
Radiation dosimetry			

Total Hours of Training:

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

b. Supervised Radiation Safety 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 Training/ License or Permit Number of Facility	Dates of Training*
Shipping, receiving, and performing related radiation surveys		
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides		
Securing and controlling byproduct material		
Using administrative controls to avoid mistakes in administration of byproduct material		
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures		
Using emergency procedures to control byproduct material		
Disposing of byproduct material		
Licensed Material Used (e.g., 35.100, 35.200, etc.)+ <div style="border: 1px solid black; height: 40px; width: 100%; margin-top: 5px;"></div>		

+ Choose all applicable sections of 10 CFR Part 35 to describe radioisotopes and quantities used: 35.100, 35.200, 35.300, 35.400, 35.500, 35.600 remote afterloader units, 35.600 teletherapy units, 35.600 gamma stereotactic radiosurgery units, emerging technologies (provide list of devices).

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

b. Supervised Radiation Safety Experience (continued)

(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervising Individual	License/Permit Number listing supervising individual as a Radiation Safety Officer
------------------------	--

This license authorizes the following medical uses:

- | | | | |
|---|--|---|---------------------------------|
| <input type="checkbox"/> 35.100 | <input type="checkbox"/> 35.200 | <input type="checkbox"/> 35.300 | <input type="checkbox"/> 35.400 |
| <input type="checkbox"/> 35.500 | <input type="checkbox"/> 35.600 (remote afterloader) | <input type="checkbox"/> 35.600 (teletherapy) | |
| <input type="checkbox"/> 35.600 (gamma stereotactic radiosurgery) | <input type="checkbox"/> 35.1000 () | | |

c. Describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.

Description of Training	Training Provided By	Dates of Training*
Radiation safety, regulatory issues, and emergency procedures for 35.100, 35.200, and 35.500 uses		
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses		
Radiation safety, regulatory issues, and emergency procedures for 35.400 uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - teletherapy uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - remote afterloader uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - gamma stereotactic radiosurgery uses		
Radiation safety, regulatory issues, and emergency procedures for 35.1000, specify use(s):		

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

c. Training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license (continued)

Supervising Individual *If training was provided by supervising RSO, AU, AMP, or ANP. (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)* License/Permit Number listing supervising individual

License/Permit lists supervising individual as:

- Radiation Safety Officer Authorized User Authorized Nuclear Pharmacist Authorized Medical Physicist

Authorized as RSO, AU, ANP, or AMP for the following medical uses:

- 35.100 35.200 35.300 35.400 35.500 35.600 (remote afterloader) 35.600 (teletherapy) 35.600 (gamma stereotactic radiosurgery) 35.1000 ()

d. Skip to and complete Part II Preceptor Attestation.

OR

4. Authorized User, Authorized Medical Physicist, or Authorized Nuclear Pharmacist identified on the licensee's license

- a. Provide license number. b. Use the table in section 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license. c. 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.

First Section

Check one of the following:

1. Board Certification

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Radiation Safety Officer

10 CFR 35.50(a)(1)(i) and (a)(1)(ii); or 35.50 (a)(2)(i) and (a)(2)(ii); or 35.50(c)(1).

OR

2. Structured Educational Program for Proposed Radiation Safety Officers

I attest that _____ has satisfactorily completed a structural educational
Name of Proposed Radiation Safety Officer

program consisting of both 200 hours of classroom and laboratory training and one year of full-time radiation safety experience as required by 10 CFR 35.50(b)(1).

OR

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

First Section (continued)

Check one of the following:

3. Additional Authorization as Radiation Safety Officer

I attest that _____ is an

Name of Proposed Radiation Safety Officer

Authorized User

Authorized Nuclear Pharmacist

Authorized Medical Physicist

identified on the Licensee's license and has experience with the radiation safety aspects of similar type of use of byproduct material for which the individual has Radiation Safety Officer responsibilities

AND

Second Section

Complete for all (*check all that apply*):

I attest that _____ has training in the radiation safety, regulatory issues, and

Name of Proposed Radiation Safety Officer

emergency procedures for the following types of use:

35.100

35.200

35.300 oral administration of less than or equal to 33 millicuries of sodium iodide I-131, for which a written directive is required

35.300 oral administration of greater than 33 millicuries of sodium iodide I-131

35.300 parenteral administration of any beta-emitter, or a 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

35.400

35.500

35.600 remote afterloader units

35.600 teletherapy units

35.600 gamma stereotactic radiosurgery units

35.1000 emerging technologies, including:

[Empty rectangular box for emerging technologies]

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

AND

**Third Section
Complete for ALL**

I attest that _____ has achieved a level of radiation safety knowledge
Name of Proposed Radiation Safety Officer
sufficient to function independently as a Radiation Safety Officer for a medical use licensee.

**Fourth Section
Complete the following for Preceptor Attestation and signature**

I am the Radiation Safety Officer for _____
Name of Facility

License/Permit Number: _____

Name of Preceptor	Signature	Telephone Number	Date



**CERTIFICATE OF DISPOSITION
OF MATERIALS**

Estimated burden per response to comply with this mandatory collection request: 30 minutes. This submittal is used by NRC as part of the basis for its determination that the facility is released for unrestricted use. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NE08-10202, (3150-0028), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

LICENSEE NAME AND ADDRESS

LICENSE NUMBER

DOCKET NUMBER

LICENSE EXPIRATION DATE

A. LICENSE STATUS (Check the appropriate box)

- This license has expired. This license has not yet expired; please terminate it.

B. DISPOSAL OF RADIOACTIVE MATERIAL

(Check the appropriate boxes and complete as necessary. If additional space is needed, provide attachments)

The licensee, or any individual executing this certificate on behalf of the licensee, certifies that:

- 1. No radioactive materials have ever been procured or possessed by the licensee under this license.
- 2. All activities authorized by this license have ceased, and all radioactive materials procured and/or possessed by the licensee under this license number cited above have been disposed of in the following manner:
 - a. Transfer of radioactive materials to the licensee listed below:
 - b. Disposal of radioactive materials:
 - 1. Directly by the licensee:
 - 2. By licensed disposal site:
 - 3. By waste contractor:
 - c. All radioactive materials have been removed such that any remaining residual radioactivity is within the limits of 10 CFR Part 20, Subpart E, and is ALARA.

C. SURVEYS PERFORMED AND REPORTED

- 1. A radiation survey was conducted by the licensee. The survey confirms:
 - a. the absence of licensed radioactive materials
 - b. that any remaining residual radioactivity is within the limits of 10 CFR 20, Subpart E, and is ALARA.
- 2. A copy of the radiation survey results:
 - a. is attached; or b. is not attached (Provide explanation); or c. was forwarded to NRC on: _____ Date
- 3. A radiation survey is not required as only sealed sources were ever possessed under this license, and
 - a. The results of the latest leak test are attached; and/or
 - b. No leaking sources have ever been identified.

The person to be contacted regarding the information provided on this form:

NAME	TITLE	TELEPHONE (Include Area Code)	E-MAIL ADDRESS
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Mail all future correspondence regarding this license to:

C. CERTIFYING OFFICIAL

I CERTIFY UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT

PRINTED NAME AND TITLE	SIGNATURE	DATE
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WARNING: FALSE STATEMENTS IN THIS CERTIFICATE MAY BE SUBJECT TO CIVIL AND/OR CRIMINAL PENALTIES. NRC REGULATIONS REQUIRE THAT SUBMISSIONS TO THE NRC BE COMPLETE AND ACCURATE IN ALL MATERIAL RESPECT. 18 U.S.C. SECTION 1001 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFICATE OF DISPOSITION OF MATERIALS

PLEASE READ THESE INSTRUCTIONS BEFORE COMPLETING NRC FORM 314.

Subpart E of 10 CFR Part 20 establishes the radiological criteria for license terminations/decommissioning of facilities licensed under 10 CFR Parts 30, 40, 50, 60, 61, 70, and 72, as well as other facilities subject to the Commission's jurisdiction under the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended.

INSTRUCTIONS

Section B, Item 2.

Licensees should describe the specific radioactive material transfer actions. If radioactive wastes were generated in terminating this license, the licensee should describe the disposal actions taken, including the disposition of low-level radioactive waste, mixed waste, greater-than-Class-C waste, and sealed sources.

Section B, Item 2.a.

The information provided concerning the transfer of radioactive material to another licensee should specify the date of the transfer, the name of the licensee recipient, an individual contact name and telephone number for the licensee recipient, and the recipient's NRC or Agreement State license number.

Section B, Item 2.b.

For disposal of radioactive materials, licensees should describe the specific disposal method or procedure (e.g., decay-in-storage). For those cases when radioactive materials are disposed of by a licensed disposal site or by a waste contractor, the licensee should specify the name, address, and telephone number of the licensed disposal site operator or waste contractor.

Section B, Item 2.c.

"Residual radioactivity," as defined in 10 CFR 20.1003, means radioactivity in 'areas' (structures, materials, soils, etc.) remaining as a result of activities (licensed and unlicensed) under the licensee's control from sources used by the licensee, excluding background radiation. ALARA is defined in 10 CFR 20.1003.

FILE CERTIFICATES AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND CERTIFICATES TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U. S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND CERTIFICATES TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

IF YOU ARE LOCATED IN:

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND CERTIFICATES TO:

MATERIAL RADIATION PROTECTION SECTION
U. S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511