



March 14, 2016

Vered Anzenberg Shaffer, Ph.D., Health Physicist
Materials Licensing Section
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road Suite 210
Lisle, IL 60532-4352
Vered.shaffer@nrc.org
630-829-9862 (Office)
630-515-1078 (Fax)

Re: License No. 21-32186-01 Transfer of Control and License Termination

Dear Dr. Shaffer:

In response to your email of March 9, 2016 (see following) the following information is provided:

Also, in a signed and dated cover letter, please provide a history of all the radionuclides used at the facility, including current copy of leak test results for any sealed sources that were used. Please provide a statement as to where any sealed sources were transferred to, and the license number for the place they were transferred to. If the location had no sealed sources at any time, please make that statement.

Three sealed sources were used at this facility. Please see attached SEALED SOURCE LEAK TEST. Unsealed Tc-99m sources were clinically used on a routine basis. All of those unsealed sources and waste material have been decayed-in-storage to background levels.

The Three sealed sources were transferred to Mercy Health-St. Vincent Medical Center, 2213 Cherry Street, Toledo, OH 43608 on March 2, 2016. Contact Person: Ann Dollman, Nuclear Medicine Department, 419-251-9070. A copy of their materials license, issued by the Ohio Department of Health, is attached.

A comprehensive area survey and surface area contamination survey was performed on March 3, 2016. That report is also attached. No residual activity was detected.

Please call Dr. Schneider at 419-266-7530 with any technical questions.
Please call Jennifer Haaser at 419-251-8091 with any administrative questions.

Thank you,

Todd Warner
VP and COO
Mercy Health Physicians-North, LLC



**CERTIFICATE OF DISPOSITION
OF MATERIALS**

Estimated burden per response to comply with this mandatory collection request: 30 minutes. This submitted 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 (7-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollect@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 Mercy, Advanced Heart Care 1414 Stewart Road Monroe, MI 48161	LICENSE NUMBER	DOCKET NUMBER
	LICENSE EXPIRATION DATE June 30, 2019	

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:
State of Ohio ODH License No. 02120490000
 - b. Disposal of radioactive materials:
 - 1. Directly by the licensee:
Transported on March 2, 2016 from 1414 Stewart Rd., Monroe, MI to Mercy Health-St Vincent Medical Center, 2213 Cherry Street, Toledo, OH 43608 by Triad Isotopes.
 - 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
Andrew Schneider, Ph.D.	Medical Physicist	419-266-7530	deltamlk@gmail.com

Mail all future correspondence regarding this license to:

Nuclear Medicine Department, Mercy Health-St Vincent Medical Center, 2233 Cherry Street, Toledo, OH

C. CERTIFYING OFFICIAL

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

PRINTED NAME AND TITLE	SIGNATURE	DATE
Todd M. Warner COO	<i>Todd M. Warner</i>	3/15/12

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.

Sealed Source Leak Test

Licensee: Mercy Heart & Vascular Diagnostics

Date: 3/1/2016

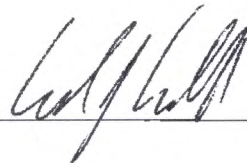
Performed by: Andrew Schneider

Nuclide	Type	Activity	Date	Location	M/N	S/N	CPM
Cs-137	Vial	204.9uCi	05/01/00	Hot Lab	SRU137200U	710-1-18	52
Current Activity:		143.8uCi					
Ba-133	Vial	278.2uCi	05/01/02	Hot Lab	IPL	787-65-3	54
Current Activity:		114.7uCi					
Co-57	Flood	10mCi	05/05/11	Hot Lab	BM01-10	01013178204	56
Current Activity:		.160mCi					

Comment: The sources listed above were leak tested using a dry wipe technique and were found to have less than 0.005 microCi removable activity. The following Minimum Detectable Activities are based upon a background at the indicated value. Background was at or below these levels when above tests were completed.
Well Counter: Captus 3000

<u>Nuclide</u>	<u>MDA</u>	<u>Background</u>
Cs-137	2.1×10^{-4} microCi	1440 counts/1min
Ba-133	7.9×10^{-5} microCi	206 counts/1min
Co-57	1.8×10^{-5} microCi	56 counts/1 min

Andrew Schneider, Ph.D.


3-1-2016

Mercy Advanced Heart Care, 1414 Stewart Rd., Monroe, MI 48161

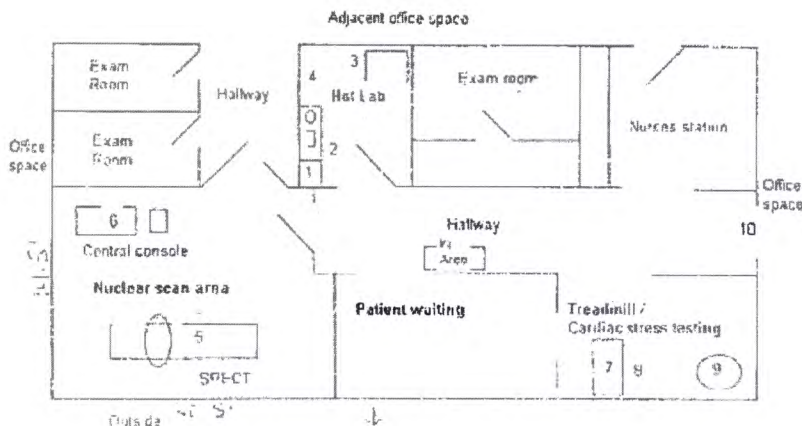
License No. 21-32186-01

Close-Out Survey for license termination, Survey performed March 3, 2016

Survey meter used: Biodex Model 3. S/N 051-003, Calibrated 10/20/15, Background 0.02 mR/hr

Well counter: Picker Spectroscaler, Efficiency 17% for Tc-99m, Background: 137 CPM

Minimum Detectable Activity (MDA) (5 minute count): 4.2 E-6 microCi



<u>Location</u>	<u>mR/hr</u>	<u>Activity of Wipe sample</u>
1. Counter by DC	0.02	less than the MDA
2. Floor by DC	0.02	less than the MDA
3. Injection Area	0.02	less than the MDA
4. Package Receipt Area	0.02	less than the MDA
5. Camera area floor	0.02	less than the MDA
6. Camera control area	0.02	less than the MDA
7. Treadmill area	0.02	Less than the MDA
8. Floor of stress room	0.02	less than the MDA
9. Chair area in stress room	0.02	less than the MDA
10. Doorway into area	0.02	less than the MDA

Conclusion: No residual radioactivity is detectable. Area can be returned to any and all occupancy with no radiation safety restrictions.

Andrew Schneider, Ph.D., DABR (R,T), CMD, CRE (R,T,M), AMP, CSD

OHIO DEPARTMENT OF HEALTH
LICENSE FOR RADIOACTIVE MATERIAL

Pursuant to Chapter 3748 of the Ohio Revised Code, and in reliance on statements and representations made by the licensee, a license is hereby issued authorizing the licensee named herein to receive, acquire, possess, and transfer radioactive material as designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the applications of Chapter 3748 of the Ohio Revised Code and all applicable rules promulgated thereunder. This license is subject to all applicable rules, regulations and orders of the Ohio Department of Health now or hereinafter in effect and to any conditions specified below.

LICENSEE	LICENSE NUMBER
1. Mercy Health - St. Vincent Medical Center, LLC	3. 02120490006
2. 2213 Cherry Street Toledo, Ohio 43608	EXPIRATION DATE
	4. January 1, 2021
	FILE / ID NUMBER
	5. 501207 / 11727

6. RADIOACTIVE MATERIAL	7. CHEMICAL AND/OR PHYSICAL FORM	8. MAXIMUM QUANTITY THAT LICENSEE MAY POSSESS AT ANY ONE TIME UNDER THIS LICENSE
A. Any radioactive material permitted by rule 3701:1-58-32 of the Ohio Administrative Code	A. Any radiopharmaceutical form	A. As needed
B. Any radioactive material permitted by rule 3701:1-58-34 of the Ohio Administrative Code	B. Any radiopharmaceutical form	B. As needed
C. Any radioactive material permitted by rule 3701:1-58-37 of the Ohio Administrative Code	C. Any radiopharmaceutical form	C. 111 GBq (3 Ci)
D. Iridium-192 permitted by rule 3701:1-58-55 of the Ohio Administrative Code	D. Sealed source (Nucletron model 105.002)	D. Two sources 795.5 GBq (21.5 Ci) total, one source not to exceed 481 GBq (13 Ci)
E. Any radioactive material permitted by rule 3701:1-58-26 of the Ohio Administrative Code	E. Sealed Sources	E. 37GBq (1Ci) total
F. Gadolinium-153	F. Sealed source, (IPL NES 8412/ GE-68 or equivalent)	F. 74 GBq (2 Ci)

9. Authorized Use

- A. Any uptake, dilution, and excretion study permitted by rule 3701:1-58-32 of the Ohio Administrative Code.
- B. Any imaging and localization study permitted by rule 3701:1-58-34 of the Ohio Administrative Code.
- C. Any medical use permitted by rule 3701:1-58-37 of the Ohio Administrative Code.
- D. One sealed source for therapeutic medical use permitted by rule 3701:1-58-55 of the Ohio Administrative Code, in a Nucletron microSelectron remote afterloader unit, model 105.999. The activity may not exceed 444 GBq (12.0 Ci) at the time of installation. One source may be in its shipping container for source replacement.
- E. Check, calibration and reference sources permitted by rule 3701:1-58-26 of the Ohio Administrative Code.
- F. Two sources to be used in each imaging camera for medical radiology in humans. Two sources in shipping container for replacement of the sources in camera.

OHIO DEPARTMENT OF HEALTH LICENSE FOR RADIOACTIVE MATERIALS SUPPLEMENTARY SHEET	Page 2 of 4
	License Number: 02120490000
	File / ID Number: 501207 / 11727
	Amendment Number: 45

CONDITIONS

10. Licensed material may only be used at the licensee's facilities located at:
- | | |
|-----------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| <p>A. Mercy Health - St. Vincent Medical Center, LLC
 2213 Cherry Street
 Toledo, Ohio 43608</p> | <p>B. Regional Heart Center
 2400 Cherry Street
 Toledo, Ohio 43608</p> |
| <p>C. Mercy Health- St. Vincent Medical Cancer Center
 2600 Navarre Avenue
 Oregon, Ohio 43616</p> | |

11. The Radiation Safety Officer for this license is: **David Close**
 The Alternate Radiation Safety Officer for this license is: **Colln Kelly Stoneberg**

12. Licensed material shall be used by, or under the supervision of, individuals designated in writing:

<u>Authorized Users</u>	<u>Materials and Use</u>
A. Abdullah, Asif, M.D.	A. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 (limited to the oral administration of sodium iodide Iodine-131) of the Ohio Administrative Code.
B. Ahmad, Faheem, M.D.	B. Uses permitted by rules 3701:1-58-37 of the Ohio Administrative Code.
C. Ahuja, Rajender K., M.D.	C. Uses permitted by rules 3701:1-58-37 and 3701:1-58-55 (limited to Iridium-192 in a HDR device) of the Ohio Administrative Code.
D. Avram, Raluca, M.D.	D. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 (limited to the oral administration of sodium iodide Iodine-131 in quantities less than or equal to 33 mCi) of the Ohio Administrative Code.
E. Bakru, Pauldeep, M.D.	E. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 of the Ohio Administrative Code.
F. Burton, Dennis, M.D.	F. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 of the Ohio Administrative Code.
G. Court, Wayne S., M.D.	G. Uses permitted by rules 3701:1-58-37 and 3701:1-58-55 (limited to Iridium-192 in a HDR device) of the Ohio Administrative Code.
H. Ergun, Hulusi, M.D.	H. Uses permitted by rules 3701:1-58-32 and 3701:1-58-34 of the Ohio Administrative Code.
I. Fakir, Sami, M.D.	I. Uses permitted by rules 3701:1-58-32, 3701:1-58-34, and 3701:1-58-37 of the Ohio Administrative Code.
J. Fernando, Shanell A., M.D.	J. Uses permitted by rules 3701:1-58-37 and 3701:1-58-55 (limited to Iridium-192 in a HDR device) of the Ohio Administrative Code.
K. Ferquer, Jeffrey, M.D.	K. Use permitted by rule 3701:1-58-55 (limited to Iridium-192 in a HDR device) of the Ohio Administrative Code.
L. Fugazzi, James A., M.D.	L. Uses permitted by rules 3701:1-58-37 of the Ohio Administrative Code.
M. Godfrey, William Thomas, M.D.	M. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 (limited to the oral administration of sodium iodide Iodine-131) of the Ohio Administrative Code.
N. Hernandez Dionisio, Pia-Jolina, M.D.	N. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 of the Ohio Administrative Code.
O. Hertzfield, Karen, M.D.	O. Use permitted by rule 3701:1-58-55 (limited to Iridium-192 in a HDR device) of the Ohio Administrative Code.
P. Jaggernauth, Walawright, M.D.	P. Use permitted by rule 3701:1-58-55 (limited to Iridium-192 in a HDR device) of the Ohio Administrative Code.
Q. Jia, Ryan, M.D.	Q. Uses permitted by rule 3701:1-58-37 and 3701:1-58-55 (limited to Iridium-192 in a HDR device) of the Ohio Administrative Code.

OHIO DEPARTMENT OF HEALTH LICENSE FOR RADIOACTIVE MATERIALS SUPPLEMENTARY SHEET	Page 3 of 4
	License Number: 02120490000
	File / ID Number: 501207 / 11727
	Amendment Number: 45

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| <p>R. Kielhorn, Eric, M.D.</p> <p>S. Kucway, Roger T., M.D.</p> <p>T. Marna, Gerald Wayne, M.D.</p> <p>U. Parikh, Dhaval K., M.D.</p> <p>V. Pietryga, Jason Alan, M.D.</p> <p>W. Rahn, Andrew, M.D.</p> <p>X. Saleh, Bilal Ahmad M., M.D.</p> <p>Y. Siddiqi, Atif, M.D.</p> <p>Z. Wang, Jenny H., D.O.</p> <p>AA. Wilson, Michael Dean, M.D.</p> <p>BB. Zeldner, Steven Robert, M.D.</p> | <p>R. Use permitted by rule 3701:1-58-55 (limited to Iridium-192 in a HDR device) of the Ohio Administrative Code.</p> <p>S. Uses permitted by rule 3701:1-58-37 and 3701:1-58-55 (limited to Iridium-192 in a HDR device) of the Ohio Administrative Code.</p> <p>T. Uses permitted by rules 3701:1-58-37 of the Ohio Administrative Code.</p> <p>U. Uses permitted by rules 3701:1-58-37 and 3701:1-58-55 (limited to Iridium-192 in a HDR device) of the Ohio Administrative Code.</p> <p>V. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 (limited to the oral administration of sodium iodide Iodine-131) of the Ohio Administrative Code.</p> <p>W. Uses permitted by rules 3701:1-58-32 and 3701:1-58-34 of the Ohio Administrative Code.</p> <p>X. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 (limited to the oral administration of sodium iodide Iodine-131) of the Ohio Administrative Code.</p> <p>Y. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 (limited to the oral administration of sodium iodide Iodine-131) of the Ohio Administrative Code.</p> <p>Z. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 (limited to the oral administration of sodium iodide Iodine-131 in quantities less than or equal to 33 mCi) of the Ohio Administrative Code.</p> <p>AA. Uses permitted by rules 3701:1-58-32, 3701:1-58-34 and 3701:1-58-37 (limited to the oral administration of sodium iodide Iodine-131 in quantities less than or equal to 33 mCi) of the Ohio Administrative Code.</p> <p>BB. Uses permitted by rules 3701:1-58-37 of the Ohio Administrative Code.</p> |
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Authorized Medical Physicists

- A. Natividad, Recto L., Jr., M.S.
- B. Schneider, Andrew, Ph.D.
- C. Schneider, Austin A., M.S.
- D. Walton, Dean, M.S.

Material and Use

- A. Iridium-192 for use in a High Dose Rate Remote Afterloader Unit
- B. Iridium-192 for use in a High Dose Rate Remote Afterloader Unit
- C. Iridium-192 for use in a High Dose Rate Remote Afterloader Unit
- D. Iridium-192 for use in a High Dose Rate Remote Afterloader Unit

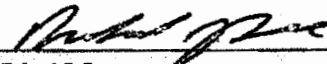
- 13. All persons performing activities meeting the definition of "Nuclear Medicine Technologist" as specified in R.C. 4773.01 shall be licensed and in good standing with the State of Ohio.
- 14. Notwithstanding the possession limits in Item 8, the licensee shall further restrict the possession of licensed materials to quantities below the minimum limit specified in rule 3701:1-40-17 of the Ohio Administrative Code, for establishing decommissioning financial assurance.
- 15. In accordance with the requirements in rule 3701:1-58-30 of the Ohio Administrative Code, any patient administered gamma emitting radiopharmaceuticals or permanent brachytherapy sources shall be provided a patient release card to include:
 - 1) The patient's name.
 - 2) The radionuclide administered and its activity.
 - 3) The facility name which administered the radionuclide.
 - 4) The date of the administration of the radionuclide.
 - 5) The expiration date of the card.

The card is not applicable to those patients who are institutionalized (Hospitals, Nursing Homes, Correctional Institutions, etc.) or whose radiation levels do not exceed 0.1 mR/hr at one meter.
- 16. The licensee is authorized to transport licensed material in accordance with the provisions of Chapter 3701:1-50 of the Ohio Administrative Code.

OHIO DEPARTMENT OF HEALTH LICENSE FOR RADIOACTIVE MATERIALS SUPPLEMENTARY SHEET	Page 4 of 4
	License Number: 62126499560
	File / ID Number: 501267 / 11727
	Amendment Number: 45

17. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Ohio Department of Health's statutes, rules, and orders shall govern unless statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated September 15, 2015, electronic correspondence September 30, 2015
 - B. Renewed in its entirety; (Amendment 45)

For the Ohio Department of Health

DATE: 10/21/15 BY: 
 Michael J. Snee
 Bureau of Environmental Health and Radiation Protection
 on behalf of the Director of Health



OHIO DEPARTMENT OF HEALTH

246 North High Street
Columbus, Ohio 43215

614/466-3543
www.odh.ohio.gov

John R. Kasich/Governor

Richard Hodges/Director of Health

October 22, 2015

Mercy Health - St. Vincent Medical Center, LLC
Attn: Radiation Safety Officer
2213 Cherry Street,
Toledo, OH 43608

Dear Radiation Safety Officer:

Enclosed is Amendment 45, the renewal to your State of Ohio Radioactive Materials License No. 02120490000, in accordance with your license renewal application. Please review the license document to ensure that you understand all of the conditions. If you have any questions or detect any errors, please contact the Bureau of Environmental Health and Radiation Protection (BEH&RP) at (614) 644-2727.

Your license will expire on 01/01/2021. You must conduct your radioactive material program in accordance with your license, representations made in your license application and the Ohio Administrative Code. In particular, you must:

1. Notify the BEH&RP in writing, within the appropriate time frames, when:
 - a. An authorized user or Radiation Safety Officer discontinues duties under the license or has a name change;
 - b. The licensee's mailing address changes;
 - c. You decide to terminate all activities involving radioactive materials authorized under your license; or
 - d. If you decide not to possess or use the authorized radioactive material.
2. Request to obtain a license amendment before you:
 - a. Receive or use radioactive material not authorized on your license;
 - b. Change Radiation Safety Officer;
 - c. Order radioactive material of a different form or in excess of the amount authorized on your license;
 - d. Add or change areas of use, which involve the use of radioactive materials requiring a written directive;
 - e. Add or change areas or addresses of use identified in the license application or on the license;
 - f. Change ownership of the organization; or
 - g. Permit anyone to work as an authorized user who is not listed on your license.
3. Submit a complete license Renewal Application at least 90 days before the expiration date of your license (180 days for broad-scope licenses).

The BEH&RP will periodically inspect your operations involving licensed materials. Failure to conduct your radioactive material program in accordance with State of Ohio regulations, license conditions and representations made in your license application may result in enforcement actions against you.

The Ohio Department of Health (ODH) has recently adopted a new Safety Culture Policy Statement. While this policy statement is not a regulation, it sets forth the agency's expectations for individuals and organizations to establish and maintain a positive safety culture for regulated programs using radioactive materials and/or radiation-generating equipment in Ohio. You may access the policy statement on the BEH&RP home page of the ODH web-site at: <http://www.odh.ohio.gov/odhprograms/rp/radprot/radppub1.aspx>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture within your organization.

Sincerely,

Stephen James
BEH&RP Supervisor

Shaffer, Vered

From: Haaser, Jennifer <Jennifer_Haaser@mercy.com>
Sent: Tuesday, March 15, 2016 11:00 AM
To: Shaffer, Vered
Cc: andrew schneider
Subject: [External_Sender] NRC License No. 21-32186-01
Attachments: NRC License Termination (3-15-16).pdf

Dr. Shaffer,

Please see attached letter and documentation in response to your email.

Thanks!

Jennifer Haaser

Regional Manager
Mercy- Northern Region
2409 Cherry Street | MOB 1, 1st Floor, Suite 107 | Toledo, OH 43608
P: 419-251-6939 | C: 419-276-6595 | F: 419-251-5819
jennifer_haaser@mercy.com
mercyweb.org

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