



September 2, 2015

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

**Re: Amendment to License No. 21-01078-01, Mercy Health Saint Mary's**

Dear Sir or Madam:

Please amend our license as follows:

1. Remove Dale J. Schippers, M.S. as Radiation Safety Officer. He is no longer at our facility.
2. Add Tewfik J. Bichay, Ph.D. as Radiation Safety Officer. He is currently listed as an Authorized Medical Physicist on our license and has helped as assistant RSO to Mr. Schippers. Form 313(a) is enclosed for your review. Also enclosed is a copy of the management/RSO agreement letter.

If you have any questions, please contact Teresa LaLonde, Radiology Director, at 616-685-6439 or [lalondtm@mercyhealth.com](mailto:lalondtm@mercyhealth.com).

Sincerely,

Bill Manns  
President

**RSO / EXECUTIVE MANAGEMENT  
LETTER OF UNDERSTANDING**

September 2, 2015

Tewfik J. Bichay, Ph.D.  
Mercy Health Saint Mary'sRe: Radiation Safety Officer / Executive Management  
Letter of Understanding

Dear Dr. Bichay:

You have been appointed the Radiation Safety Officer (RSO) of this facility for our United States Nuclear Regulatory Commission Materials License. This "Letter of Understanding" is prepared to comply with Title 10 Code of Federal Regulations (CFR) Part 35.24(b). This section of the regulations requires that you agree in writing to the following:

- Assume responsibility for implementing the Radiation Protection Program
- Ensure that radiation safety activities are being performed in accordance with our own approved procedures and all regulatory requirements

Furthermore, in compliance with 10 CFR 35.24(e)(g), the executive management of this facility agrees to provide you as RSO:

- Specific written notation of your authority, duties and responsibilities, see attached.
- Sufficient authority, organizational freedom, time, resources and management prerogative to:
  1. Identify radiation safety problems
  2. Initiate, recommend or provide corrective actions
  3. Stop unsafe operations
  4. Verify implementation of corrective actions.

Our signatures noted below will attest to the issues noted above. Please make a copy of this document for your files and return the original to my attention.

Sincerely,

  
\_\_\_\_\_  
Bill Manns  
President  
\_\_\_\_\_  
Tewfik J. Bichay, Ph. D.  
Radiation Safety Officer





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

APPROVED BY OMB: NO. 3150-0120  
EXPIRES: (09/30/2015)

Name of Proposed Radiation Safety Officer

Tewfik J. Bichay, Ph.D.

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 (Theraspheres )

**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  |                      |                      |                    |
| <b>Total Hours of Training:</b>                                    |                      | <input type="text"/> |                    |



**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/<br>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.)+<br><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 (gamma stereotactic radiosurgery) | <input type="checkbox"/> 35.600 (teletherapy)                                      |
|   | <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               | Dale Schippers                              | Aug 2008-<br>Aug 2015                          |
| Radiation safety, regulatory issues, and emergency procedures for 35.300 uses                                   | Dale Schippers<br>Nucletron Inc/Elekta Inc. | Aug 2008-<br>Aug 2015<br>Sep 1999-<br>Mar 2015 |
| Radiation safety, regulatory issues, and emergency procedures for 35.400 uses                                   | Dale Schippers                              | Aug 2002-<br>Aug 2015                          |
| Radiation safety, regulatory issues, and emergency procedures for 35.600 - teletherapy uses                     | NA  |  |
| Radiation safety, regulatory issues, and emergency procedures for 35.600 - remote afterloader uses              | Dale Schippers<br>Nucletron Inc/Elekta Inc. | Aug 2008-<br>Aug 2015<br>Sep 1999-<br>Mar 2015 |
| Radiation safety, regulatory issues, and emergency procedures for 35.600 - gamma stereotactic radiosurgery uses | NA  |  |
| Radiation safety, regulatory issues, and emergency procedures for 35.1000, specify use(s):                      | Dale Schippers<br><br>MDS Nordion           | Mar 2012-<br>Aug 2015<br><br>May 2012          |



**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 <i>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.)</i>  | License/Permit Number listing supervising individual |
| Dale J. Schippers, M.S.  | 21-01078-01  |
| License/Permit lists supervising individual as:  |  |
| <input checked="" type="checkbox"/> Radiation Safety Officer <input type="checkbox"/> Authorized User <input type="checkbox"/> Authorized Nuclear Pharmacist<br><input type="checkbox"/> Authorized Medical Physicist  |  |
| Authorized as RSO, AU, ANP, or AMP for the following medical uses:   |  |
| <input checked="" type="checkbox"/> 35.100 <input checked="" type="checkbox"/> 35.200 <input checked="" type="checkbox"/> 35.300 <input checked="" type="checkbox"/> 35.400<br><input checked="" type="checkbox"/> 35.500 <input type="checkbox"/> 35.600 (remote afterloader) <input type="checkbox"/> 35.600 (teletherapy)<br><input type="checkbox"/> 35.600 (gamma stereotactic radiosurgery) <input checked="" type="checkbox"/> 35.1000 (TheraSpheres) |  |

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 Tewfik J. Bichay, Ph.D. is an  
Name of Proposed Radiation Safety Officer

Authorized User  Authorized Nuclear Pharmacist

Authorized Medical Physicist

identified on the Licensees 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 Tewfik J. Bichay, Ph.D. 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:

Theraspheres  
Radioactive Seed Localization



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

**AND**

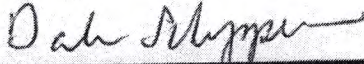
**Third Section  
Complete for ALL**

I attest that Tewfik J. Bichay, Ph.D. 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 Mercy Health Saint Mary's  
Name of Facility

License/Permit Number: 21-01078-01

| Name of Preceptor | Signature   | Telephone Number | Date       |
|-------------------|---|------------------|------------|
| Dale Schippers    |  | (808) 691-4884   | 09/01/2015 |



To: Dale Schippers, Radiation Safety Officer  
Dr. Tewfik Bichay, Alternate Radiation Safety Officer

From: Philip McCorkle, President and Chief Executive Officer

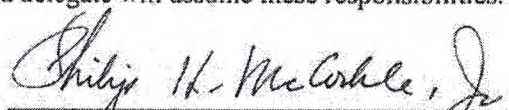
Subject: Delegation of Authority

Date: November 26, 2002

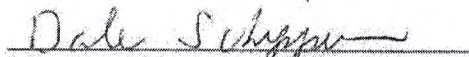
You have been appointed Radiation Safety Officer (RSO), and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation protection program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation 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 by radiation safety. You are required to notify management of situations where staff are not cooperating and not addressing radiation safety issues. In addition, you are free to raise issues with the Nuclear Regulatory Commission at anytime. It is estimated that you will spend 10 hours per week conducting radiation protection activities.


In the absence of the RSO, the alternate RSO or a delegate will assume these responsibilities.

Date: 2-17-03

  
Signature of Management Representative

I accept the above responsibilities.

  
Signature of Radiation Safety Officer  
Date: 2/17/03

  
Signature of Alternate Radiation Safety Officer  
Date: FEB 18-03

cc: Affected Department Heads  
John Schwartz  
Carol Dwyer  
Dan Stickle  
Kenda Klotz  
James Miller



# FEDEX

# Express

FedEx carbon-neutral envelope shipping

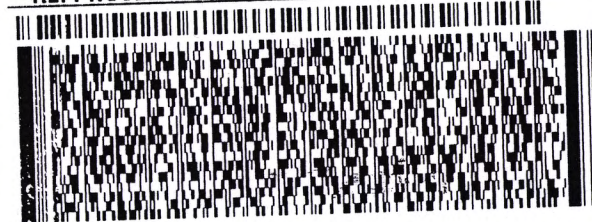
200 JEFFERSON AVE --  
GRAND RAPIDS, MI 49503  
UNITED STATES US

BILL SENDER

TO **MATERIALS LICENSING REGION 111**  
**US NUCLEAR REGULATORY COMM. REGION3**  
**2443 WARRENVILLE ROAD**  
**SUITE 210**  
**LISLE IL 605324352**

50123/CRNR/CF03  
JT41214073001111

REF: NUCLEAR MED(CHRIS SPALLER)



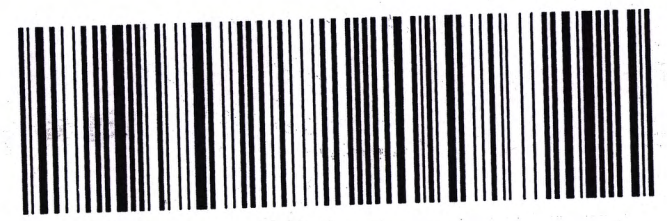
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TUE - 15 SEP AA  
STANDARD OVERNIGHT

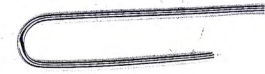
## XH ENLA

60532  
IL-US ORD

Part # 156148-434 RIT2 08/12



RT **493**  
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