

Sara Forster

From: Sara Forster
Sent: Monday, April 24, 2023 10:45 AM
To: tkayembe@aol.com
Subject: Additional Information Request for Midwest Health Professionals, P.C. Renewal, NRC License No. 24-32391-01, CN 633955
Attachments: 02201.633955.24-32391-01.RFAI email attachment NRC Form 313_ML13083A072Dated20230401.pdf; 02201.633955.24-32391-01.RFAI email attachment NUREG1556Vol9rev3_ML19256C219AppendixC checklist.pdf

Good morning, Dr. Kayembe:

Our office is in receipt of the November 15, 2022 application requesting renewal of the referenced license. Regarding the NRC Form 313 and the guidance referenced in preparing the application, please note that those documents have been superseded. Accordingly, additional information is needed to complete the review.

Regarding the renewal application, please resubmit it, including information as requested in NRC's NUREG 1556, Volume 9, revision 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses," dated September 2019. Please include a current, signed-and-dated NRC Form 313, using the version updated April 1, 2023, "Application for Materials License." Please also assure that all facility diagrams show all radioactive materials work areas and show the dimensions of the facility. If diagrams already show the dimensions and all areas of radioactive materials use, they need not be resubmitted with the revised application.

In preparing your responses, please note that detailed procedures need not be submitted as part of the license application. Limiting responses to the requested information is expected to provide you with flexibility to update your program as needs change.

The guidance and the updated NRC Form 313 may be found at the NRC's website at <https://www.nrc.gov/docs/ML1925/ML19256C219.pdf> and <https://www.nrc.gov/docs/ML1308/ML13083A072.pdf>, respectively.

For your convenience, copies of the applicable documents are attached to this message.

Please provide a response via a signed and dated letter within 30 days (on or before May 24, 2023). If you are unable to provide a response before then, please provide a signed and dated letter by that date indicating the date by which you will be able to provide a written response to the items outlined in this request. For quickest processing, please submit your response as a pdf file attached to an email message. You may also submit a response via fax or via regular mail. If you have any questions regarding this message, please do not hesitate to reach out to me by phone or email.

Sincerely yours,

Sara A. Forster, Health Physicist

U.S. Nuclear Regulatory Commission - Region III
Division of Radiological Safety & Security
Materials Licensing Branch
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Lisle, IL 60532-4352
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Table C-2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

Item 8: Training for Individuals Working In or Frequenting Restricted Areas

Provide the following:

- A statement that, “We have developed and will implement and maintain written procedures for a program for training required under 10 CFR 19.12 for each group of workers, including (i) topics covered, (ii) qualifications of the instructors, (iii) method of training, (iv) method for assessing the success of the training, (v) initial training, and (vi) annual refresher training.”

Table C-2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

Item 9: Facility Diagram

Provide the following:

- Facility diagrams. Drawings should be to scale, and the scale used should be indicated. The direction of north should be indicated.
- Location, room numbers, and principal use of each room, including patient treatment rooms or area where byproduct material is prepared, used, and stored.
- Principal use of adjacent rooms (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms and Positron Emission Tomography (PET). ** Please confirm that no PET radionuclides will be used under the license.
- Doors should be indicated, and specify which doors are access controlled (i.e., locked).
- Shielding calculations for PET facilities, in-patient rooms for 10 CFR 35.300 and 10 CFR 35.400 use, High Dose-Rate/Pulsed Dose Rate & Low Dose Rate Remote Afterloaders, Teletherapy, and Gamma stereotactic radiosurgery (GSR). Include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, and a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy, including the dimensions of any portable shield, if one is used; source storage safe). The calculations should include the workload assumptions used.
- For PET, radiopharmaceutical, and sealed-source therapies, provide a description of surrounding areas, including the occupancy factors, and indicate whether the areas are restricted or unrestricted, as defined in [10 CFR 20.1003](#). For calculations of the maximum exposure in any given hour, an occupancy factor will not be used.
- For teletherapy facilities, applicants should provide the directions of primary beam use and, in the case of an isocentric unit, the plane of beam rotation is identified in the shielding calculations.
- For [10 CFR 35.1000](#) (e.g., Perfexion, View-Ray), applicants should provide information described in the guidance on the [Medical Uses Licensee Toolkit](#) Web page.

Table C-2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

Item 9: Radiation Monitoring Instruments

Provide the following:

- A statement that: "Radiation monitoring instruments will be calibrated by a vendor who is licensed by the NRC or an Agreement State to perform instrument calibrations."

AND/OR

- A statement that: "We have developed and will implement and maintain written radiation survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61."

AND

- A description of the instrumentation (e.g., gamma counter, solid-state detector, portable or stationary count-rate meter, portable or stationary dose-rate or exposure-rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys is attached.

Item 9: Dose Calibrator and Other Dosage Measuring Equipment

For the administration of alpha, gamma, and beta emitting unsealed byproduct materials, we are providing the following:

- A statement that: "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."

AND

- A description of the equipment used to measure the dosages.

AND

- For measurement of alpha emitters where gamma or beta emissions are not measurable in a traditional dose calibrator, identify specialized measurement equipment and the nationally recognized standard used to calibrate the instrument or provide a copy of the manufacturer's instructions to calibrate the instrument.

Item 9: Sealed Sources in Therapy Unit - Calibration and Use

- ~~Provide the procedures required by 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645, if applicable to the license application.~~
- ~~The applicant for a medical use under 35.1000 should provide the procedures required by 10 CFR 35.12(b)(2) that are described in the licensing guidance posted for that 10 CFR 35.1000 medical use on NRC's [Medical Uses Licensee Toolkit](#) Web page, or explain why the procedure is not provided.~~

Table C-2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

Item 10: Occupational Dose

Provide the following:

- A statement that: "We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502."

OR

- A statement that: "We will monitor individuals in accordance with the criteria in the section titled, 'Radiation Safety Program—Occupational Dose' in NUREG-1556, Vol. 9, Rev. 3, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees.'"

OR

- A description of an alternative method for demonstrating compliance with the referenced regulations.

Item 10: Spill/Contamination Procedures

Provide the following:

- A statement that: "We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101."

Item 10: Emergency Procedures for Therapy Devices Containing Sealed Sources

~~Provide the following:~~

- ~~Attach procedures required by 10 CFR 35.610.~~

~~**AND**~~

- ~~If appropriate, review 10 CFR 35.1000 medical use licensing guidance on NRC's [Medical Uses Licensee Toolkit](#) Web page, and provide safety and emergency procedures requested for the particular 10 CFR 35.1000 medical use.~~

Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources

~~If requesting that the applicant's own employee(s), who are trained by the manufacturer, be authorized to perform the activities noted in section 8.10.7 of this NUREG, provide the following:~~

- ~~Name of the proposed employee(s) and types of activities requested:~~

~~**AND**~~

Table C-2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

~~Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested.~~

AND

~~Copy of the manufacturer's training certification and an outline of the training in procedures to be followed.~~

AND

~~Written commitment from the licensee that the trained employee will follow manufacturer procedures.~~

Item 10: Material Receipt and Accountability

Provide the following:

A statement that: "We will develop, implement, and maintain written procedures for licensed material accountability and control to ensure that:

license possession limits are not exceeded

licensed material in storage is secured from unauthorized access or removal

licensed material not in storage is maintained under constant surveillance and control

records of receipt (either from the licensee's own production operations or from another licensee), transfer, and disposal of licensed material, are maintained."

AND

~~If applicable, a statement that "We will comply with the National Source Tracking System (NSTS) reporting requirement, as described in 10 CFR 20.2207."~~

Item 10: Leak Tests

Provide the following:

For in-house leak testing of sealed sources used pursuant to 10 CFR Part 35:

A statement that: "We have developed and will implement and maintain written procedures for sealed-source leak testing that meet the requirements of 10 CFR 35.67."

OR

For in-house leak testing of sealed sources other than those authorized pursuant to 10 CFR Part 35 (e.g., self-shielded irradiators, calibration sources):

A statement that: "We will conduct leak tests in-house."

AND

A statement that: "The attached leak test procedures will be followed for leak tests conducted in-house."

AND

Attach leak test procedures.

Table C-2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

OR

- ~~A statement that the applicant will implement the model leak test program of the appendix of the appropriate NUREG 1556 volume for the type of use. For instance, if an applicant possesses a self shielded irradiator, the applicant may state, "We will implement the model leak test program published in Appendix N of NUREG 1556, Volume 5, Rev. 1, "Consolidated Guidance About Materials Licenses: Program Specific Guidance About Self Shielded Irradiator Licenses."~~

OR

- If a contractor is used to perform leak testing, a statement that: "Leak test sample collection and analysis will be performed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees; or by using a leak test sample collection kit supplied by an organization licensed by the NRC or an Agreement State to provide leak test kits or sample analysis services to other licensees and according to the instructions provided in the leak test sample collection kit."

Item 10: Area Surveys

Provide the following:

- A statement that: "We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70."

Item 10: Safe Use of Unsealed Licensed Material

Provide the following:

- A statement that: "We have developed and will implement and maintain written procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1201."

Item 10: Mobile medical service

- Review the guidance in Appendix V of this NUREG to determine the response required.

Item 10: Minimization of Contamination

A response is not required under the following condition: The NRC will consider that the criteria have been met if the information provided in the applicant's responses satisfies the criteria for the following sections in this NUREG: Sections 8.9, 8.9.1, 8.10, 8.10.5, 8.10.12, and 8.11 on the following topics: facilities and equipment, facility diagram, radiation safety program, spill and contamination procedures, area surveys, and waste management.

Table C-2. Items 7 Through 11 on NRC Form 313: Training and Experience, Facilities and Equipment, Radiation Protection Program, and Waste Disposal (Continued)

Item 11: Waste Management

Provide the following:

- A statement that: “We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of 10 CFR Part 20, Subpart K, and of 10 CFR 35.92.”

AND

- ~~Contact the appropriate NRC Regional Office for guidance on treatment or disposal of waste by incineration or compaction.~~

(04-01-2023)
10 CFR 30, 32,
33, 34, 35, 36,
37, 39, and 40



APPLICATION FOR MATERIALS LICENSE

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Library, and Information Collections Branch (T-6 A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by email to Infocollections.Resource@nrc.gov, and the OMB Reviewer at: OMB Office of Information and Regulatory Affairs, (3150-0120), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503; email: oir_submission@omb.eop.gov. The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

INSTRUCTIONS: SEE THE CURRENT VOLUMES OF THE NUREG-1556 TECHNICAL REPORT SERIES ("CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES") FOR DETAILED INSTRUCTIONS FOR COMPLETING THIS FORM: <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>. SEND TWO COPIES OF THE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

MATERIALS SAFETY AND TRIBAL LIAISON BRANCH
DIVISION OF MATERIALS SAFETY, SECURITY, STATE AND TRIBAL PROGRAMS
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS 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 APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF RADIOLOGICAL SAFETY AND SECURITY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD, SUITE 102
KING OF PRUSSIA, PA 19406-1415
R1DRSSMail.Resource@nrc.gov

*Note: The preferred method to submit NRC Form 313 is email. Any other document (e.g., financial assurance documents) should be sent via mail.

IF YOU ARE LOCATED IN:

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

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352
R3-DRSSMail.Resource@nrc.gov

*Note: The preferred method to submit NRC Form 313 is email. Any other documents (e.g., financial assurance documents) should be sent via mail.

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 APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511
rl4licensingactionsubmittals@nrc.gov

*Note: The preferred method to submit NRC Form 313 is email. Any other document (e.g., financial assurance documents) should be sent via mail.

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

<p>1. THIS IS AN APPLICATION FOR (Check appropriate item)</p> <p><input type="checkbox"/> A. NEW LICENSE</p> <p><input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____</p> <p><input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____</p>	<p>2. NAME AND MAILING ADDRESS OF APPLICANT (Include zip code)</p>
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<p>3. ADDRESS WHERE LICENSED MATERIALS WILL BE USED OR POSSESSED</p>	<p>4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION</p>	
	<p>BUSINESS TELEPHONE NUMBER</p>	<p>BUSINESS CELLULAR TELEPHONE NUMBER</p>
	<p>BUSINESS E-MAIL ADDRESS</p>	

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE [LICENSE APPLICATION GUIDE](#).

<p>5. RADIOACTIVE MATERIAL</p> <p>a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.</p>	<p>6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.</p>
<p>8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.</p>	<p>7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.</p>
<p>10. RADIATION SAFETY PROGRAM.</p>	<p>9. FACILITIES AND EQUIPMENT.</p>
<p>12. LICENSE FEES (Fees required only for new applications, with few exceptions*) (See 10 CFR 170 and Section 170.31) *Amendments/Renewals that increase the scope of the existing license to a new or higher fee category will require a fee.</p>	<p>11. WASTE MANAGEMENT.</p>

<p>FEE CATEGORY</p>	<p>AMOUNT ENCLOSED \$</p>
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PER THE DEBT COLLECTION IMPROVEMENT ACT OF 1996 (PUBLIC LAW 104-134), YOU ARE REQUIRED TO PROVIDE YOUR TAXPAYER IDENTIFICATION NUMBER. PROVIDE THIS INFORMATION BY COMPLETING NRC FORM 531: <https://www.nrc.gov/reading-rm/doc-collections/forms/nrc531info.html>.

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 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.

<p>CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE</p>	<p>SIGNATURE</p>	<p>DATE</p>
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FOR NRC USE ONLY

<p>TYPE OF FEE</p>	<p>FEE LOG</p>	<p>FEE CATEGORY</p>	<p>AMOUNT RECEIVED \$</p>	<p>CHECK NUMBER</p>	<p>COMMENTS</p>
<p>APPROVED BY</p>				<p>DATE</p>	