UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

TELEFAX TRANSMITTAL

DATE August 5, 2014 NUMBER OF PAGES 5

SEND TO Donna Wenzel, Chief Technologist, Nuclear Medicine -regarding license renewal for Ronald Stewart, D.O. - NRC license 21-26489-01

LOCATION Sterling Heights, Michigan

FAX NUMBER (586) 254-5973 ☑ VERIFY BY CALLING
O.K. Received

FROM: Bill Reichhold
(Sender)

TELEPHONE NUMBER (630) 829-9839 FAX NUMBER (630) 515-1078

If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above.

MESSAGE See accompanying documents.

Thank you for your response letter dated July 13, 2014,(with attachments) regarding the renewal for Ronald Stewart, M.D.'s NRC license 21-26489-01. We need clarification on the following items to complete the review of the request to renew the NRC license.

Facility Diagram

Please include the following information on the facility diagram:

1. Your response indicated you would show the location of direct transfer delivery tubes from a PET radionuclide/radioactive drug production facility on the facility diagram. However it appears that your facility diagram does not include this detail and may be an error. If this is an error, please confirm that you do not have a direct transfer delivery tubes from a PET radionuclide/radioactive drug production facility. Please see attached.

2. Please specify the scale of the facility diagram, or the room dimensions where radionuclides are used and/or stored. For example, the imaging room is 12 feet by 8 feet.

3. Please specify if you use PET radionuclides. If you do not use PET radionuclides, please state so. If you do use PET radionuclides please indicate a quiet room, additional shielding, remote handling devices, shielding calculations, etc.

4. Please specify the room numbers where radionuclides are use and/or stored. If there are no room numbers please state so.

5. Please specify what is above and below rooms where radionuclides are used and/or stored. For example, there is a basement below and a roof above the rooms where radionuclides are used or stored.

Occupational Dose

Please update your "Occupational Dose" statement to indicate that you will meet the requirements under 'Criteria' in NUREG-1556, Volume 9, **Revision 2.**

For example, please confirm that "Either we will perform a prospective evaluation Occupational Dose demonstrating that unmonitored individuals are not likely to receive, in 1 year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or We will provide dosimetry that meets the requirements listed under 'Criteria' in NUREG- 1556, Vol. 9, **Rev. 2**, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses." Please see attached.

Please send a facsimile (630- 515-1078) of your response to the above within 7 days and state, Response to Control 583612. Please include a cover letter on company letterhead, dated and signed (signed by an individual who is authorized to sign official documents on behalf of the licensee) with your response letter. Please call me at 630-829-9839 if you have any questions.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this facsimile and the attached documents will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room).

From the desk of:

Bill Reichhold

APPENDIX C

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
	• Location, room numbers, and principal use of each room or area where byproduct material is prepared, used or stored, location of direct transfer delivery tubes from a PET radionuclide/radioactive drug production facility or production area of PET radioactive drugs under 10 CFR 30.32(j), and areas where higher energy gamma- emitting radionuclides (e.g., PET radionuclides) are used;	☒
	• Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms, indicating whether the room is a restricted or unrestricted area as defined in 10 CFR 20.1003; and	☐
	• Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, including 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).	☐
	In addition to the above, for teletherapy and GSR facilities, applicants should provide the directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation.	☐
Item 9: Radiation Monitoring Instruments	A statement that: "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations."	☒
	AND/OR	
	A statement that: "We have developed and will implement and maintain written 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.	☒
	AND	
	A statement that: "We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used."	☒
Item 9: Dose Calibrator and Other Dosage Measuring Equipment	A statement that: "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."	☒

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This selection appears to match your Facility Diagram

APPENDIX C

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	Suggested Response	Check box to indicate material included in application
Item 10: Safety Procedures and Instructions	Attached are procedures required by 10 CFR 35.610.	☐
	Guidance in Section 5.2 was reviewed and security-related sensitive information provided is marked accordingly.	☐
Item 10: Occupational Dose	A statement that: "Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in 1 year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under 'Criteria' in NUREG-1556, Vol. 9, Rev. 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses.' " **OR**	X Revision 2
	A description of an alternative method for demonstrating compliance with the referenced regulations.	☐
Item 10: Area Surveys	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."	X
Item 10: Safe Use of Unsealed Licensed Material	A statement that: "We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301."	X
Item 10: Spill/Contamination Procedures	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."	X
Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources	Name of the proposed employee and types of activities requested: **AND**	☐
	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.	☐
Item 10: Minimization of Contamination	A response is not required under the following condition: the NRC will consider that the above criteria have been met if the information provided in applicant's responses satisfy the criteria in Sections 8.15, 8.16, 8.21, 8.25, 8.27, and 8.29, on the topics: facilities and equipment, facility diagram, Radiation Protection Program, safety program, and waste management.	N/A