Gryglak, Magdalena

From: Gryglak, Magdalena
Sent: Monday, September 30, 2019 8:17 AM
To: Fuhrman, Wally
Subject: Renewal Application, NRC License no. 24-32760-01, SSM Ambulatory Cardiac Imaging
Attachments: Request for Additional Information.docx; NUREG 1556 Vol 9, Rev 3 Table C.2.pdf; Model Delegation of Authority to RSO.docx

Good morning Mr. Fuhrman,

I reviewed the renewal application. Please provide additional information as outlined in the attached document.

Please provide a signed (by management) and dated letter transmitting the additional information by October 16, 2019.

You may submit your response directly to me via email. Please let me know if you have any questions.

Thank you

Magdalena R. Gryglak
U.S. NRC Region III
630-829-9875

Request for Additional Information (CN 612326):

1. Delegation of Authority Memo:

   Provide the RSO Delegation of Authority Letter. A model letter can be found in Appendix I of NUREG 1556, Volume 9, Revision 3. Please ensure that the RSO and senior management official date and sign the letter.

2. Resubmit the facility diagram labeling/describing the following:

   - Illustrate the well counter (#7) and sink (#10)
   - Illustrate on the diagram and describe adjacent to the rooms where radioactive material is used and stored (label outside, hallway, room east to the nuclear medicine)
   - Illustrate on the diagram and describe all rooms/areas above and below the rooms where radioactive material is used and stored
   - Describe/illustrate measures to secure radioactive material (i.e. locked doors, locked storage in a hot lab)

3. Please confirm that no PET material will be used.

4. Please explain the need to authorize Authorized Users for nonmedical use.

5. Radiation Monitoring Instruments:

   Please provide required commitments for Radiation Monitoring Instruments as described in NUREG 1556, Volume 9, Revision 3, Section 8.9.2 and Table C.2.

   Please also describe the equipment (e.g. well counter, types of survey meters, manufacturer name, serial numbers) that you will use to perform required surveys.

6. Dose Calibrator and Other Dosage Measuring Equipment:

   Please provide required commitments for Dose Calibrator and Other Dosage Measuring Equipment as described in NUREG 1556, Volume 9, Revision 3, Section 8.9.3, and Table C.2.

   Please also describe the equipment (e.g. dose calibrator, manufacturer name, serial number) that you will use to perform required surveys.

7. Occupational Dose:

   Please provide the required commitment for Occupational Dose as described in NUREG 1556, Volume 9, Revision 3, Section 8.10.2 and Table C.2.

8. Spill/Contamination Procedures:

   Please provide the required commitment for Spill/Contamination Procedure as described in NUREG 1556, Volume 9, Revision 3, Section 8.10.5 and Table C.2.

9. Material Receipt and Accountability:

   Please provide the required commitment for Material Receipt and Accountability as described in NUREG 1556, Volume 9, Revision 3, Section 8.10.10 and Table C.2.

10. Leak Tests:

    Please provide the required commitment for Leak Tests as described in NUREG 1556, Volume 9, Revision 3, Section 8.10.11 and Table C.2.

11. Area Surveys:

    Please provide the required commitment for Area Surveys as described in NUREG 1556, Volume 9, Revision 3, Section 8.10.12 and Table C.2.

12. Safe Use of Unsealed Licensed Material:

    Please provide the required commitment for Safe Use of Unsealed Licensed Material as described in NUREG 1556, Volume 9, Revision 3, Section 8.10.14 and Table C.2.

13. Waste Management:

    Please provide the required commitment for Waste Management as described in NUREG 1556, Volume 9, Revision 3, Section 8.11 and Table C.2.

Model Delegation of Authority to Radiation Safety Officer

Memo To: Name of Radiation Safety Officer
From: Name of Chief Executive Officer/Senior Management
Subject: Delegation of Authority

You, _____, have been appointed the Radiation Safety Officer for our U.S. NRC license no. XXXXX and you are responsible for ensuring the safe and secure use of radiation and radioactive material. 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, when 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 U.S. Nuclear Regulatory Commission at any time.

_____ _____
Signature of Management Representative Date
Print name/Title

I accept the above responsibilities,

_____ _____
Signature of Radiation Safety Officer Date
Print name/ RSO

cc: Affected department heads

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 CFR35.1000 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.