



CONVERSATION RECORD

| | | | | |
|--|------------------|------------------------|---|--|
| NAME OF PERSON(S)/TITLE CONTACTED OR IN CONTACT WITH YOU | | DATE OF CONTACT | TYPE OF CONVERSATION | |
| Edward B. Kline | | 10/01/2019 | <input type="checkbox"/> E-MAIL | <input type="checkbox"/> INCOMING <input type="checkbox"/> OUTGOING |
| E-MAIL ADDRESS | TELEPHONE NUMBER | | <input checked="" type="checkbox"/> TELEPHONE | |
| ed@uscancertherapies.com | | (505) 980-1314 | | |
| ORGANIZATION | | DOCKET NUMBER(S) | | |
| Arch Cancer Care | | 030-39196 | | |
| LICENSE NAME AND NUMBER(S) | | MAIL CONTROL NUMBER(S) | | |
| Arch Cancer Care/ 24-35567-01 | | 615298 | | |

SUBJECT
Request for additional information dated 10/1/19

SUMMARY AND ACTION REQUIRED (IF ANY)
On 10/01/19 M. Gryglak and E. Kline discussed the information needed to continue the NRC review of the applicant's letter dated 8/15/19 requesting a new NRC license to perform Xofigo treatments. See the attached list of items discussed. In addition, M. Gryglak inquired about the owners of Arch Cancer Care their relationship with US Cancer Therapies LLC. Mr. Kline explained that Urology of St. Louis is a group of physicians that own a number of cancer treatment facilities/clinics in the St. Louis area. Arch Cancer Care is one of their facilities. US Cancer Therapies LLC manages some of those facilities including Arch Cancer Care.

| | |
|---|-------------------|
| NAME OF PERSON DOCUMENTING CONVERSATION | |
| M. Gryglak | |
| SIGNATURE | DATE OF SIGNATURE |
| | 10/1/19 |

In order to continue our review of your renewal, we need additional information. Please refer to NUREG 1556, Volume 9, Revision 3, "Consolidated Guidance About Materials Licenses," which is accessible at <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/r3/> and Table C.2.

Please provide the following information:

1. Registration/License with Federal/State/local government:

Provide registration certificate or license authorizing to practice medicine in the State of Missouri and any documentation of site inspections conducted by Federal/State/local government.

2. Describe the history of Arch Cancer Care (e.g. how long the clinic has been operating, its management structure and staffing) and the scope of current services.

3. Provide the Delegation of Authority Memo:

Provide the Radiation Safety Officer (RSO) Delegation of Authority Memo (attached). 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 memo.

4. Resubmit the facility diagram to include the following details:

- a. Indicate the direction of north;
- b. Provide the room dimensions or scale for all rooms where radioactive material is stored (i.e. the exam rooms and the hot lab);
- c. Illustrate on the diagram and describe all rooms/areas adjacent to the rooms where radioactive material is used and stored;
- d. Illustrate on the diagram and describe all rooms/areas above and below the rooms where radioactive material is used and stored;
- e. Illustrate on the diagram and describe areas inside the rooms where radioactive material is used or stored such as radioactive waste storage, material receipt area, work area, L-shield, sinks, fume hoods, etc.;
- f. Label "locked door" to the hot lab.

Please refer to NUREG 1556, Volume 9, Revision 3, Section 8.9.1 for examples of facility diagrams.

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 instrumentation that will be used 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 describe the equipment.

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. 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.

11. 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.

12. 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

Gryglak, Magdalena

From: Gryglak, Magdalena
Sent: Monday, September 30, 2019 11:08 AM
To: 'ed@uscancertherapies.com'
Subject: New License Application, NRC License no. 24-35567-01- Arch Cancer Care
Attachments: Model Delegation of Authority to RSO.docx; Request for Additional Information CN615298 Rev 1.docx; Arch Cancer Care NUREG 1556 Table C.2.pdf

Good morning Mr. Kline,

I reviewed the application for a new NRC license. 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 17, 2019. You may submit your response directly to me via email.

Please acknowledge the receipt of my email.

I would like to discuss the information before you respond in writing. I am available tomorrow from 7 am to 11:30 am. Please let me know your availability.

Thank you

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