NRC FORM 699
(11-2017)

U.S. NUCLEAR REGULATORY COMMISSION

CONVERSATION RECORD

NAME OF PERSON(S)/TITLE CONTACTED OR IN CONTACT WITH YOU	DATE OF CONTACT	TYPE OF CONVERSATION
Hualei Jiang, Ph.D.	10/05/2022	☐ E-MAIL ☑ TELEPHONE ☐ INCOMING ☑ OUTGOING
E-MAIL ADDRESS	**TELEPHONE NUMBER**	
jiangh@karmanos.org	(313) 576-9918	
ORGANIZATION	**DOCKET NUMBER(S)**	
Karmanos Cancer Center	030-38328	
LICENSE NAME AND NUMBER(S)	**MAIL CONTROL NUMBER(S)**	
Karmanos Cancer Center 21-03298-06	CN 631446	

SUBJECT

Pending NRC License Renewal - Additional Information Requested

SUMMARY AND ACTION REQUIRED (IF ANY)

This is a record of the conversation between Laura Cender and Huailei Jiang, Ph.D. regarding the pending license renewal for Karmanos Cancer Center.

1. Unsealed and Sealed Byproduct Material
   a.) For unsealed radioactive material, indicate whether isotopes will be produced in volatile or non-volatile forms and the maximum amount of material that is requested for each form.
   b.) For specifically licensed instrument calibration sources provide the manufacturer and model number.
   c.) Confirm that each sealed source, device, or source/device combination is registered as an approved sealed source, device, or discrete source by NRC or an Agreement State, and will be possessed and used in accordance with the conditions specified in the registration certificate. Provide the SSD registration certificate number, if available.
   d.) Please confirm that you will not be distributing PET labeled radioactive drugs.

2. Financial Assurance and Recordkeeping for Decommissioning
   a.) State the following: "Pursuant to 10 CFR 30.35(g), we will maintain records important to decommissioning and transfer these records to an NRC or Agreement State licensee before licensed activities are transferred or assigned, in accordance with 10 CFR 30.34(b). Furthermore, pursuant to 10 CFR 30.51(f), prior to license termination, we will forward the records required by 10 CFR 30.35(g) to the appropriate NRC regional office or assign the records to the appropriate NRC regional office before the license is terminated."

NAME OF PERSON DOCUMENTING CONVERSATION

Laura B. Cender

SIGNATURE	DATE OF SIGNATURE
Laura B. Cender Digitally signed by Laura B. Cender Date: 2022.10.05 14:53:08 -05'00'	Oct. 5, 2022

CONVERSATION RECORD (continued)

LICENSE NAME AND NUMBER(S)	MAIL CONTROL NUMBER(S)
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SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

2. Financial Assurance and Recordkeeping for Decommissioning
   b.) The quantities of material requested require submittal of decommissioning financial assurance information in accordance with 10 CFR 30.35. The quantities of material requested exceed the quantities described in 10 CFR 30.35(d) and a decommissioning funding plan is required. Note that decommissioning funding plans are required to be updated at the time of license renewal.

3. Radiation Safety Officer
   Provide a Delegation of Authority memo for Huailei Jiang, Ph.D. A copy of the original Delegation of Authority is acceptable, or a new memo may be provided. An example memo is attached for your use.

4. Individuals Authorized to Handle Licensed Material
   a.) For each individual, indicate the types and quantities of licensed material, including the activated targets and activated products to be possessed and handled.
   b.) Please provide additional details into the experience and training completed by each proposed Authorized User. Indicate the types and quantities of materials that they have experience handling. Additionally, please include the hours of cyclotron operation training and and radiation safety training. Training certificates are not required, but may be provided if available.

5. Facilities and Equipment
   a.) Please resubmit facility diagrams as the submitted files are excessively dark and blurry.
   b.) Please ensure that areas assigned for production, transfer, storage, preparation, shipping, security, and measurement of radioactive material are clearly indicated.
   c.) In addition to describing the location of delivery lines, shielded areas, and equipment (i.e. hot cells, waste, etc.) please ensure their proximity to unrestricted areas is also clearly indicated on the diagrams.
   d.) Submit surveys of areas adjacent to, above, and below the cyclotrons, hot cells, and synthesis cells when production is at its peak to demonstrate that expected radiation levels that workers will be exposed to. Include the instrument used and the date of the last calibration.
   e.) Submit a diagram of the ventilation systems that service both cyclotrons. Confirm that the systems are independent of other ventilation systems in the building. Describe the location of the nearest intake for building's main ventilation system in relation to the exhaust point for both cyclotrons. Provide a description of the effluent air filtration system and provide procedures for checking filter saturation and the frequency of filter exchange. Provide recent air sampling data for the operating to demonstrate that air effluent released is within the requirements described in 10 CFR Part 20 including 20.1101(d) and 20.1301.
   f.) Provide a description of how and by whom air effluent monitoring systems will be calibrated.

6. Radiation Monitoring Instruments
   State that: "We will use instruments that meet the radiation-monitoring instrument specifications published in Appendix F of NUREG 1556 Vol. 21, 'Program-Specific Guidance About Possession License for Production of Radioactive Materials Using and Accelerator.'"

CONVERSATION RECORD (continued)

LICENSE NAME AND NUMBER(S)	MAIL CONTROL NUMBER(S)
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SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

7. Occupational Dose
   a.) Provide the criteria for issuing extremity dosimeters, self-reading dosimeters, and alarming dosimeters.
   b.) Describe how internal doses would be evaluated in a timely manners if an accidental airborne release were to occur.
   c.) Provide one of the following statements:
   - "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(a)." OR
   - "We will provide and require the use of individual monitoring devices (dosimetry). All personnel dosimeters that require processing to determine the radiation dose will be processed and evaluated by an NVLAP-accredited processor."
   d.) Radiation worker hazards from cyclotron operations are significantly attributable to operations on and maintenance of, radioactive components/targets, handling and moving of activated items, and handling of radioactive waste. Please describe the procedures that are in place to control, limit, and monitor worker radiation dose that may be received from these operations.

8. Safe Operating and Emergency Procedures:
   a.) State the following: "Operating and emergency procedures will be implemented and maintained."
   b.) State the following: "Leak tests will be performed at the intervals approved by the NRC or an Agreement State and specified in the SSD registration certificate. Leak tests will be performed by an organization authorized by the NRC or an Agreement State to provide leak testing services to other licensees. Alternatively, we may perform leak tests using a leak-test kit and the kit supplier's instructions. Such leak test kits will be supplied by an organization authorized by the NRC or an Agreement State to provide leak testing services. As an alternative to either of these leak test implementation methods, we will implement the model leak-test program published in Appendix K of NUREG 1556, Vol. 21, "Consolidated Guidance About Material Licenses: Program-Specific Guidance About Possession License for Production of Radioactive Materials Using an Accelerator

9. In your application, you request authorization for use of Germanium-68, which exceeds the 120 day half life period that is appropriate for use of decay-in-storage waste management. Please provide additional information describing management of waste and contaminated products that will in place for materials that do not qualify for decay in storage. Please review NUREG 1556 Vol. 21 Rev. Section 8.11 "Waste Management" (pgs. 8-51 - 8-56) in preparing your response.

Please provide your response to the above items by no later than Friday, November 4th, 2022.