



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

October 5, 2021

Kay Kassel, M.S., C.N.M.T.
Radiation Safety Officer
Alliance HealthCare Services, Inc.
18201 Von Karmen Ave.
Ste. 600
Irvine, CA 92612

Dear Mr. Kassel:

We have reviewed the licensee's request dated June 3, 2021, to renew its U.S. Nuclear Regulatory Commission (NRC) Material License No. 47-25570-01 for Alliance HealthCare Services, Inc. Based on our review of the information, we have identified that additional information is needed to proceed with the renewal process. Please refer to NUREG 1556, Volume 9, Revision 3, "Consolidated Guidance About Materials Licenses," which is accessible at <https://nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/index.html> for guidance when preparing your response.

In a signed by management and dated letter, please provide the following information by November 5, 2021:

1. Please describe the origin/source of strontium-82 and strontium-85 material.
2. Please describe the origin/source of the germanium-68 material and the purpose of use.
3. Please confirm that the sealed sources listed in your June 3, 2021 request for instrument quality and imaging equipment quality control do not exceed quantities listed in Title 10 of the *Code of Federal Regulations* (CFR) 35.65 and will be used in accordance with the provisions in 10 CFR 35.65.
4. Describe the process of operating the mobile medical service. Specifically, describe:
 - the number of mobile units you operate and the states you operate in;
 - confirm all mobile units have the same facility layout;
 - the location where the mobile units are parked during off hours (hospital site, public street, private property, etc.);
 - secured-off street parking is under the licensee's control, if applicable;
 - describe the receipt of radioactive material process (i.e. material delivered directly to the mobile units parked at the hospital site or another location, licensee personnel is present and accepts the radioactive material, etc.).
5. Please describe measures to secure the radioactive material when in use and when in storage and unattended in the mobile units from unauthorized access (i.e.

describe material storage, waste storage, door/cabinet locks, storage of keys, personnel with access, etc.)

6. Clearly illustrate on the mobile unit diagram the storage of unsealed material, the storage of sealed material, storage of radioactive waste, use and storage of the strontium-82/rubidium-82 generator area.
7. Please clarify if patient waiting areas, "quiet rooms" or restrooms will be utilized inside the clients' facilities. Indicate if end-of-day surveys will be completed for client-controlled areas where patients were released to.
8. Please provide a statement, "Alliance HealthCare Services, Inc. will obtain an agreement letter signed by the management of each client for which services will be rendered that permits the use of byproduct material at the client's address and clearly delineates the authority and responsibility of the licensee and the client. This agreement will be applicable for the entire period of time over which the service is to be provided. The letter will be retained for 3 years after the last provision of service.

Additionally, we will survey all areas of use, including client-controlled areas, to ensure compliance with the requirements in 10 CFR Part 20 before leaving a client's address.

Please see NUREG 1556, Volume 9, Revision 3, Appendix V for an example of an agreement letter.

9. Please provide a shielding evaluation for the mobile Positron Emission Tomography (PET) units:
 - a. Provide a shielding evaluation for the PET imaging room, the hot lab/ injection room to demonstrate that the dose rates in the adjacent areas including above and below do not exceed the 10 CFR Part 20 dose limits for members of the public and radiation workers.
 - b. In your evaluation, indicate the following:
 - the radioisotope/s used, the amount/s, and the intake/imaging duration, the number of patients per day and per week;
 - the adjacent rooms/areas are whether the adjacent rooms/areas are restricted or unrestricted in accordance with 10 CFR 20.1003;
 - the occupancy factors for all adjacent rooms/areas including above and below;
 - distances between the source and the adjacent rooms in all directions;
 - the type and thickness of the shielding material in all directions from the source;
 - if other controls (i.e. shielding, administrative controls) are used to ensure the 10 CFR Part 20 dose limits are met in adjacent rooms/areas, please describe;
 - any other assumptions made in your evaluation

- the resultant dose rates in all directions from the source (include the mobile unit diagram with the calculated/measured dose rates).
- c. Describe any other administrative/physical controls you will have in place to ensure 10 CFR Part 20 dose limits are met in the unrestricted areas (e.g. the use of ropes/cones, ensuring the driver is not present in the driver's cab during imaging etc.).

10. Facility at 525 S Gould St., Owasso, Michigan:

- Please describe the radioactive material to be used at 525 S Gould St., Owasso, Michigan and the purpose of use;
- Please describe the location of use (e.g. commercial facility, medical facility, etc.);
- Please resubmit the facility diagram illustrating all adjacent areas including below and providing the dimensions of the storage room where radioactive material will be used;
- List radiation monitoring instruments available at this location.

11. Describe measures to secure the radioactive material when in use and when in storage and unattended at 525 S. Gould St. Owasso, Michigan (e.g. locked doors/cabinets, storage of keys, personnel access).

12. Please provide the applicable commitment/s regarding Radiation Monitoring Instruments:

"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

"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."

13. Please provide the applicable commitments regarding Dose Calibrator and Other Dosage Measuring Equipment:

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

14. Please confirm that the instrumentation listed in your June 3, 2021 request is available at each mobile unit.

15. Please provide the applicable commitments regarding Occupational Dose:

"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

- "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.'"
16. Please provide the commitment regarding Spill/Contamination Procedures:
- "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."
17. Please provide the commitment regarding Material Receipt and Accountability:
- "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."
18. Please provide the commitment/s regarding Leak Tests: See NUREG 1556, Volume 9, Revision 3, Section 8.10.11, Response from Applicant.
19. Please provide the commitment regarding Area Surveys:
- "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."
20. Please provide the commitment regarding Safe Use of Unsealed Licensed Material:
- "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."
21. Please provide the commitment regarding Waste Management:
- "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."
22. Please provide the commitment regarding Emergency Procedures:
- "We will develop, implement, and maintain emergency procedures in accordance with the radiation protection program required by 10 CFR 20.1101. The emergency procedures will address accident scenarios including transportation accidents as licensee response as described in Appendix V of NUREG 1556, Volume 9, Revision 3, "Emergency Procedures."

23. Please provide the commitment regarding Transportation:

"We will develop, document, and implement procedures to assure that radioactive material is transported in accordance with 49 CFR Parts 171–177, "Transportation." Procedures will include use of approved packages, use of approved labeling, conduct of proper surveys, complete and accurate shipping papers, bracing of packages, security provisions, written emergency instructions.

Management (or management's designee will perform audits, at least annually, of transportation documentation (e.g., shipping papers and survey reports) and activities at client facilities. Licensed material is secured during transport and use at the client's facilities. Radioactive waste is handled properly during transport. The transport vehicle, including the driver's compartment, if separate, will be secured at all times from any unauthorized access when the vehicle is unattended."

24. Please provide the commitment regarding Training:

"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."

"Drivers and technologists will be properly trained in applicable transportation regulations and emergency procedures, in addition to the training requirements of 10 CFR 19.12, 10 CFR 35.27. The training for these individuals will include, at a minimum, Department of Transportation regulations, shielding, as low as is reasonably achievable (ALARA), basic radiation protection, and emergency response.

25. Please list each Authorized User (AU) to be retained on your license, the AU's current medical license and State, and material use for the physician.

In accordance with 10 CFR 2.390, a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from ADAMS, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

Magdalena R. Gryglak
Health Physicist
Materials Licensing Branch