



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

August 8, 2022

Christopher Ritter
Senior Radiochemist, Spectron Rx for
Arizona Isotope Science Research Corp.
dba AZ Isotopes Corp.
7796 S Innovation Way
Bunker Hill, IN 46914

SUBJECT: ADDITIONAL INFORMATION NEEDED REGARDING AMENDMENT TO
ARIZONA ISOTOPE SCIENCE RESEARCH CORP. DBA AZ ISOTOPES CORP.,
NRC LICENSE NO. 13-35624-02

Dear Mr. Ritter:

Our office has reviewed the May 23, 2022 request to amend Arizona Isotope Science Research Corp. dba AZ Isotopes Corp.'s (your) U.S. Nuclear Regulatory Commission (NRC) Materials License No. 13-35624-02. Your amendment request is available electronically from NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML22147A100. The NRC's ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

For additional guidance, please refer to NUREG 1556 Volume 21, revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses," Sections 8.5.1, "Unsealed and Sealed Byproduct Material," pp. 8-4 to 8-8, 8.6, "Purpose(s) for Which Licensed Material Will Be Used," pp. 8-11 to 8-14, and Section 8.9, "Facilities and Equipment," pp. 8-21 to 8-23.

RADIOACTIVE MATERIAL TO BE AUTHORIZED ON THE LICENSE:

1. The list of elements with mass numbers to be authorized on the license appears to include both accelerator-produced material to be produced, possessed and transferred under the license and material that will be acquired from external sources, and used under a separate license, in a building that will not be authorized under this license. **As we discussed via phone on August 5, 2022, please update the list of radionuclides to be limited to those requested to be authorized for production, possession, and transfer under the accelerator production license, within the building to be authorized, under the license. Specifically:**
 - a. **Fluorine-18 and Gallium-67: If these radionuclides are being produced in the licensed facilities, please describe. If these radionuclides are being retained, and they are not being produced in the licensed facilities, please describe how this radionuclide will be received and stored in the licensed facilities, including the area of use to be indicated or described in a facility diagram.**

- b. Thorium-232: Please confirm that this radionuclide is being obtained and used in the accelerator to produce actinium-225. Please indicate any special handling procedures for this radionuclide, if any.**
 - c. Lead-212, lead-202, radium-224, radium-226 & thorium-228: If these radionuclides are being produced in the licensed facilities, please describe. If these radionuclides are being retained, and they are not being produced in the licensed facilities, please describe how this radionuclide will be received and stored in the licensed facilities, including the area of use to be indicated or described in a facility diagram.**
2. The general request for atomic number 3-83 sealed sources was not limited to a possession limit adequate to meet the Title 10 of the *Code of Federal Regulations* (10 CFR) Section 32.210(g)(1) criteria for sources not registered in the sealed source and device registry. **Please either reduce the single source possession limit for sealed sources containing beta/gamma and alpha emitters to 1 millicurie and 10 microcuries, respectively. In the alternative, you may confirm that any sealed sources with exceeding the possession limit will be transferred by a distributor authorized to do so.**
3. The general request for atomic number 1-92 non-volatile unsealed material was not clear as to the possession limits needed for incidentally activated products in addition to those intentionally obtained or produced, under the license. **Please provide per-radionuclide and total possession limits for each of (a) any non-volatile produced or obtained under the license and (b) incidentally activated products.**

Please provide a response via a signed and dated letter within 14 days (on or prior to August 14, 2022) of our recent phone conversation. For quickest processing, please submit your response as a pdf file attached to an email message. You may also submit a response via fax or via regular mail. If you have any questions regarding this message, please do not hesitate to reach out to me at 630-829-9892.

In accordance with 10 CFR Section 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS.

Sincerely,

Sara A. Forster, M.S.
Health Physicist
Materials Licensing Branch
Division of Nuclear Materials Safety

Docket No.: 030-36259
License No.: 13-35624-02

Control No.: 631401