Advanced Isotopes of Idaho

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January 14, 2022

Dear Ms Alldredge,

I received your questions via email regarding our request for a new radiopharmacy license (Docket No. 030-339297) on January 12, 2022. My responses are detailed below:

1. **Can you please explain/provide any paperwork that documents any affiliation between Advanced Isotopes of Montana and Advanced Isotopes of Idaho?**

   Advanced Isotopes of Idaho is owned and operated by Catherine Heyneman-Cashmore and Nicole Chopski.

   Advanced Isotopes of Montana is owned and operated by Catherine Heyneman-Cashmore, Nicole Chopski, Mike Hart and Kevin Permann.

   Mike Hart and Kevin Permann worked at Advanced Isotopes of Idaho for a long time and expressed a desire to replicate that business in Montana. Cathy Heyneman-Cashmore and Nicole Chopski saw the value in this since it is an area not well serviced by the existing pharmacies in Missoula MT and Casper WY. We are helping Mike Hart and Kevin Permann get their feet under them financially with the expectation that they will eventually buy out the Idaho pharmacy – which gives us an exit strategy that we've been lacking. We expect both businesses to operate independently.

2. **For the Cs-137 or any other sealed sources that you will have, please provide the manufacturer's or distributor's name and model number for each sealed source and/or device?**

   We anticipate ordering the following from RadQual (Distributor):

Cs-137 DC Reference source	BenchMark BM06S-37	0.2 mCi
Co-57 DC Reference source	BenchMark BM06S-57	5 mCi
Cs-137 Rod source	BenchMark BM08-3705	0.5 uCi
Ba-133 Puck source	RadQual RQBA133EDCE10	0.1 uCi

3. **For Kevin Permann, you checked the boxes indicating he was Board Certified, but then provide a preceptor form showing his qualification using the training and experience specified in 10 CFR35.55(b). Is he Board Certified?**

   That was my error. Dr. Permann is not board certified.

4. **Your application indicated that your registration or license from a State Board of Pharmacy as a licensed pharmacy was pending. Is it still pending? If not, please provide the registration or provide evidence that the facility is operating as a nuclear pharmacy within a Federal medical institution.**

Our facility is under construction and nearing completion. We are in the process of applying for our Montana State Board of Pharmacy license, so it is still pending. We will forward that to you as soon as it is approved.

5. **Please confirm that you have developed and will implement and maintain written procedures for the safe and secure use of radioactive materials that address: Posting the operating procedures applicable to commercial radiopharmacies (10 CFR19.11(a)(3))**

We have developed and will implement and maintain written procedures for the safe and secure use of radioactive materials that address: Posting the operating procedures applicable to commercial radiopharmacies (10 CFR19.11(a)(3)).

6. **Can you please confirm that in Item 6.1 in your application, when you state that the original paperwork will be retrieved and will be paperclipped to the label and to the bill of lading, that you are talking about the manufacturer-supplied leaflet or brochure that provides radiation safety instructions for handling and using the generator?**

The documents referred to as the "original generator paperwork" include both the package insert (the manufacturer-supplied leaflet) as well as the packing list from the manufacturer that contains specifics such as lot #, date of manufacture, and expiration date.

7. **For dosage measurement, it appears that you will use measurement for the measurement of alpha-, beta-, gamma-, and photon-emitting radioactive drugs vs a combination of combination of measurement and calculation. Can you confirm that is accurate? If you do use a combination, please submit the calculations to demonstrate the ability to accurately dispense low-energy photon-, beta-, and alpha-emitting radionuclides for radiopharmacies that intend to initially distribute (i.e., measure, prepare, and label) these materials.**

For dosage measurement, we will use a combination of measurement and calculation for the measurement of alpha-, beta-, gamma-, and photon-emitting radioactive drugs. For the vast majority of products typically dispensed (Tc-99m, Tl-201, I-131, etc) we will use measurement in our AtomLab 500 dose calibrator.

We plan to use calculations to determine the correction factor in the rare instance that we are dispensing low-energy photon-, beta-, and alpha-emitting radionuclides, and only when we are not redistributing these radionuclides that have been previously prepared and distributed by other persons licensed pursuant to 10 CFR 32.72.

The Atom Lab 500 dose calibrator we plan to use allows us to enter the correction factors in manually using the instructions provided by the manufacturers below. Sample calculations are also provided below. The values provided in the sample calculation are entirely fictional and for demonstration only.

Dial Value Settings and Source Containers (Glass Vial, Glass Syringe, etc.)

The Atomlab Dial Value (DV) settings enable the software to convert ion chamber current into a displayed activity value for the isotope corresponding to the DV selected. The displayed activity value is directly proportional to the DV.

The isotope's "*source container*" is either a vial or syringe; the composition of the vial or syringe MAY influence the accuracy of the activity measurement. The DV supplied in the Atomlab User Guide (Instruction Manual), or pre-programmed into the isotope buttons, *are calibrated for use with the source material in an un-shielded plastic syringe (nominal 1mm wall)*, while hanging in the supplied "source dipper" syringe support. For isotopes contained in sealed long lived QA sources (Cs-137, etc.), the DV supplied are calibrated for use with type Vial E epoxy sources or equivalent.

Accurate measurement of unsealed sources in any other configuration must be with a new Container Dial Value *"CDV", determined by the USER* with the following procedure.

NOTE: This is important to determine the appropriate Dial Value for Beta and low energy gammas when the container (syringe or vial) changes.

During following steps, set DV to the Atomlab published value.

Container with no source material

1. Assay a quantity of isotope source material in a plastic syringe, nominal wall thickness of 1mm, record as *(Plastic Syringe Activity)*$_1$.
2. Transfer part or all of the source material from the plastic syringe into the empty Container.
3. Assay the Container with the isotope source material, record as *(Container Activity)*.
4. Assay the partial or "empty" plastic syringe for residual activity, record as *(Plastic Syringe Activity)*$_2$.
5. Calculate the Container Dial Value for use with isotope assayed in that type of container,

$$CDV = DV \cdot \frac{(PSA)_1 - (PSA)_2}{(Container\ Activity)}$$

where *PSA = Plastic Syringe Activity*.

Container with source material

1. Assay Container with the isotope source material, record as *(Container Activity)*$_1$.
2. Transfer part or all of the source material from the Container into a plastic syringe, nominal wall thickness of 1mm.
3. Assay the plastic syringe with the isotope source material, record as *(Plastic Syringe Activity)*.
4. Assay the partial or "empty" Container for residual activity, record as *(Container Activity)*$_2$.
5. Calculate the Container Dial Value for use with isotope assayed,

$$CDV = DV \cdot \frac{(PSA)}{(CA)_1 - (CA)_2}$$

where *PSA* = Plastic Syringe Activity and *CA* = Container Activity.

Typically, for glass wall source Containers, CDV will be higher than DV when the isotope has a significant portion of low energy photons in its emission spectrum.

Sample Calculation – Sr-89 received in a glass vial but dispensed in a plastic syringe:

Isotope Sr-89:
Atomlab 500 provided dial value 686.0
Activity in the original glass vial: 5 mCi in 2mL. This is CA_1
After transfer of all the source material from the glass vial into a plastic syringe, the plastic syringe activity (PSA) reads as 5.23 mCi
The empty glass vial has a residual container activity of 0.27 mCi. This is CA_2

$$CDV = DV \times \frac{(PSA)}{(CA_1) - (CA_2)}$$

$$CDV = 686.0 \times \frac{5.23}{(5.0) - (0.27)}$$

$$CDV = 686 \times 1.105 = 758.5$$

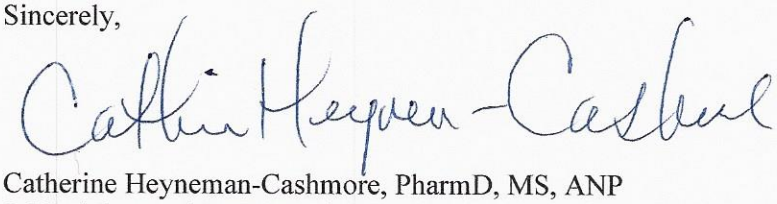
8. You described the radioactive drug labelling for materials in lead syringe pigs. Can you describe the labeling for materials transported in vial pigs that you reference in Item 10.12 of your application?

The vial pig will be labeled exactly the same as the syringe pigs. The circular label will be placed on top for easy viewing with the prescription number, facility name, patient name, product, isotope, strength, calibration date and time as well as a scannable barcode. The remainder of the label will be folded over, wrapped around the base and secured with a

rubber band. This lower label contains all the same information as the top label but also includes the name, address and phone number of the dispenser, name of prescriber, name of patient, name and strength of the drug, directions for use and date of filling. It will also include the precise mCi amount and volume dispensed, identity of the pharmacist, lot number of the compounded kit, and expiration date/time of the product. The lower label also contains any special notes (such as the use of blunt cannulas) and any special warning verbiage required by the Montana State Board of Pharmacy on all prescriptions.

If you have any questions or need clarification on anything don't hesitate to contact me 24/7 at (208) 390-3961 or via email at nukedoses@gmail.com.

Sincerely,



Catherine Heyneman-Cashmore, PharmD, MS, ANP
RSO, Advanced Isotopes of Idaho
Partner, Advanced Isotopes of Montana

From:	Advanced Isotopes
To:	Alldredge, Casey
Subject:	[External_Sender] Re: Advanced Isotopes of Montana; NRC License Application; Request for Additional Information
Date:	Friday, January 14, 2022 2:10:03 PM
Attachments:	NRC Response New License App 2022.pdf

Hi Casey,

I've attached the responses requested - don't hesitate to reach out if you need more information!

If you have any idea of the timeframe for approval that would be great - we are nearing the end of construction.

Have a great day,

Cathy Heyneman

On Wed, Jan 12, 2022 at 5:37 AM Alldredge, Casey <Casey.Alldredge@nrc.gov> wrote:

> Good morning,
>
> I am reviewing your license application for Advanced Isotopes and have a few requests for additional information. Please provide the responses to the following attached in a signed and dated letter. You can email me a copy of the signed letter if that is easiest for you.
>
> 1. Can you please explain/provide any paperwork that documents any affiliation between Advanced Isotopes of Montana and Advanced Isotopes of Idaho?
> 2. For the Cs-137 or any other sealed sources that you will have, please provide the manufacturer's or distributor's name and model number for each sealed source and/or device?
> 3. For Kevin Permann, you checked the boxes indicating he was Board Certified, but then provide a preceptor form showing his qualification using the training and experience specified in 10 CFR35.55(b). Is he Board Certified?
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radionuclides for radiopharmacies that intend to initially distribute (i.e., measure, prepare, and label) these materials.

8. You described the radioactive drug labelling for materials in lead syringe pigs. Can you describe the labeling for materials transported in vial pigs that you reference in Item 10.12 of your application?

Thanks very much. If you have any questions, please feel free to reach out via email or phone at 817-200-1546.

Casey Alldredge

Health Physicist

Materials Licensing and Decommissioning Branch

Region IV, USNRC

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