

Isotopia USA Inc.
17075 Oak Ridge Road
Westfield, IN 46074

March 7, 2025

Materials Licensing Branch
Division of Radiological Safety and Security
U.S. Nuclear Regulatory Commission, Region III
2433 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Subject: Isotopia USA Inc. NRC RAM License Amendment Request

Dear Ms. Cender,

Isotopia USA Inc. is currently authorized for the following RAM license / fees:

- The 3M code R&D license (\$18,400)
- The 3B code Commercial license (\$12,900)

We received our original RAM license authorization starting with the R&D license, as we were pre-commercial. However, once we increased our possession limits in our most recent amendment, we also requested and were granted authorization for Commercial activities.

Under 10 CFR 30.4, the definition of research and development is as follows:

Research and development means: (1) Theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials and processes. "Research and development" as used in this part and parts 31 through 35 does not include the internal or external administration of byproduct material, or the radiation therefrom, to human beings;

Given that we are past the experimental production and testing phase as defined above and now in the commercial manufacturing phase, we are requesting that the R&D license be removed from the RAM authorization, leaving only the Commercial license. We are requesting that the authorized use (2) for Lutetium-177 (D), "Research and development as defined in 10 CFR 30.4" be removed from the license, as this is the only research and development authorization, and falls outside the scope of activities now being performed on our site.

Additionally, upon your review, we respectfully request the addition of Tb-161, as well as impurities formed during the production of Tb-161 (Gd-159 and Tb-160) in the amounts listed in the table below:

Element and Mass Number	Chemical / Physical Form	Maximum Possession Limit	Proposed Use
Terbium-161	Any	100 curies	[1,2,3]
Gadolinium-159	Any	5 curies	[1,2,3]
Terbium-160	Any	1 curie	[1,2,3]

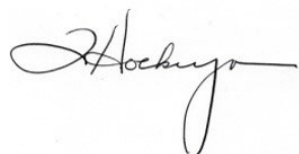
The half-life for Terbium-161 is similar to lutetium at 6.95 days. The half-lives of the impurities are 18.5 hours for Gadolinium-159, and 72.3 days for Terbium-160 (although this isotope is only produced in trace amounts during the irradiation process).

These possession limits were selected based on feedback from the irradiator (MURR), as they are already irradiating ampoules for our Israel location. An exemplar irradiation certificate is copied below for reference:

Isotope	Activity	Units
Tb-161	2.01031477	curie
Gd-159	0.08846961	curie
Tb-160	0.00001217	curie
Gd-153	0	curie
Gd-161	0	curie

Thank you in advance for your review. We look forward to hearing from you.

Sincerely,



Todd Hockemeyer
CEO

Isotopia USA Inc.
(317) 417-2860
thockemeyer@isotopia-global.com

Martha Pavon

From: Laura Cender
Sent: Monday, March 10, 2025 11:55 AM
To: Martha Pavon; Tammy Tomczak
Cc: Sandy Pavon
Subject: FW: Isotopia USA RAM License Amendment
Attachments: NRC RAM License Amendment Request 07Mar2025.pdf

Hello Martha and Tammy,

Please see the attached incoming license amendment request for Isotopia USA Inc. to be processed in as a new licensing amendment request for Isotopia USA Inc.

Tammy, please assign this case to me.

Licensee: Isotopia USA Inc.
License No. 13-35729-01MD
Docket No. 030-39365

Thank you!
Laura

From: Todd Hockemeyer <thockemeyer@isotopia-global.com>
Sent: Friday, March 7, 2025 5:02 PM
To: Laura Cender <Laura.Cender@nrc.gov>
Cc: Jared Jaksik <jjaksik@isotopia-global.com>
Subject: [External_Sender] Isotopia USA RAM License Amendment

Hello Ms. Cender,

Per your request, please see attached amendment to our RAM license. Thank you in advance to your attention to this request.

We look forward to hearing back from you.

Have a great weekend.

Best regards,

Todd Hockemeyer
CEO
Isotopia USA Inc.
Cell (317) 417-2860
thockemeyer@isotopia-global.com

