

From: [Betsy Ullrich](#)
To: [Western, Evan](#)
Subject: RE: RE: a couple of questions about the amendment submitted for 34-32780-01
Date: Thursday, October 5, 2023 9:59:00 AM
Attachments: [image001.png](#)

Evan,

Please think about revising/explaining the authorized use for the Cu/Ga/Zr radionuclides to make it clear that you are interested in producing them by cyclotron; as this is R&D, I will check with our program office but may have to add that R&D program code to the license.

Also, are you doing this under any of your other cyclotron licenses in other regions, because if so, it would be good for all of us to know so that we are consistent in the licensing of this activity.

Betsy

Betsy

From: Western, Evan <evan.western@cardinalhealth.com>
Sent: Wednesday, October 4, 2023 2:37 PM
To: Betsy Ullrich <Elizabeth.Ullrich@nrc.gov>
Subject: [External_Sender] RE: a couple of questions about the amendment submitted for 34-32780-01

Hi Betsy,

Thanks for passing along your questions. I will get a response to you shortly.

As an informal FYI: we are not intending to receive waste for DIS – the DIS request was made to ensure that there was no question about us holding these analytical samples for DIS following analysis. Additionally, for the three new nuclides we requested, we are indeed working on methods to produce each of these on cyclotrons. Ga-68 looks like the one that is nearest to actual production.

If you have any concerns about the above, please let me know. In the meantime, I will work on drafting a formal response letter and sending it over to you shortly.

Thanks,
Evan



Evan T. Western, CHP
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From: Betsy Ullrich <Elizabeth.Ullrich@nrc.gov>

Sent: Wednesday, October 4, 2023 1:41 PM

To: Western, Evan <evan.western@cardinalhealth.com>

Subject: a couple of questions about the amendment submitted for 34-32780-01

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Evan,

A couple of questions about the amendment request:

1. You requested 6-7-8F to be authorized for an increase, with a slight change in the authorized uses that
 - now states use for decay-in-storage: as an authorized use, that usually implies you are receiving waste for DIS. Is that your intention? If not, as with all your licensed materials with half-lives 120 days or less, DIS is covered by LC 17
 - does not include as calibration/reference standards etc...did you mean to have those calibration uses removed from 6-7-8F?

2. You requested to add Cu64, Ga68 and Zr89 for possession/use incident to manufacture/distribution of radiopharmaceuticals etc and for R&D. Neither of these would usually be on the cyclotron license. The first would be on the radiopharmacy license; you are not producing these radionuclides in the cyclotron, are you? Radiopharmacy authorization would be program code 02500, not 03210 cyclotron production of RAM. R&D authorization is usually program code 03620. This could be a problem because the NRC has required production cyclotron licenses to be separated from the radiopharmacy licenses. Also, both these program codes would result in additional fees.

Let me know what you want to do about these sections of the request. I will need a signed letter, which you can attach as a pdf to an email directly to me.

Please note that, as of July 3, 2023, I will be working part-time only Monday through Thursday.

Thanks,
Betsy

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