



IONETIX

¹³N Ammonia, Anytime, Anywhere

July 14, 2021

Mr. Frank Tran
Health Physicist
USNRC Region III

Re: Ionetix response for more information email request on July 8, 2021 for amendment for License # 04-35412-01, Mail Control No. 627089.

Dear Mr. Tran,

Ionetix Corporation (Ionetix) has evaluated our F-18 increased possession limit request. We have designed the facility to utilize engineering and administrative controls to maintain ALARA principles. The delivery line conduit from the cyclotron is encased in concrete. The line is directed into the back of a shielded Comecer Hot Cell which is designed to handle 10 curies of PET isotopes. The line is shielded 100% of the time. The increase in F-18 possession limits is needed to optimize our F-18 targets and delivery system.

Our Florida facility, which is licensed for F-18 targetry research and development, has provided data on employee exposures. Dose Rate on the target side at the external operator station, which is at least 15 feet from the vault wall, is less than 2 mR/hr (which is a restricted area) and less than 0.2 mR/hr in public areas. Badge data was reviewed for our cyclotron operators and we saw less than a 100 mR total increase in whole body exposure per quarter based on 15 runs per month. We are anticipating to further reduce that total exposure by administratively limiting our Lansing testing to no more than 10 runs per month, maximum of 2 runs per day. A 33% reduction which would translate to a total exposure increase of 67 mR per quarter. An annual increase of less than 300 mR total exposure. We will evaluate the whole body exposure quarterly to ensure ALARA considerations are maintained.

Additionally, our cyclotron operators will wear realtime electronic pocket dosimeters (EPDs) in addition to badges, to ensure dose rates are maintained ALARA. The Lansing vault public dose areas have passive dosimeters which are reviewed quarterly to ensure we are maintaining public dose exposures and the target side has real time monitors which are reviewed in real time to ensure we are maintaining ALARA during the runs. The data will be evaluated to ensure we maintain our ALARA culture.

During the first 10 runs we will log the start and stop EPD dosimetry data as well as the real time monitors. The data will be reviewed to ensure we maintain ALARA. Once the data is reviewed and confirms our Florida data we will continue with our normal quarterly reviews.



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If you have any additional comments or questions please let me know.

Sincerely,

Frank L. Plastini
Corporate Radiation Safety Officer
Ionetix Corporation
(518) 603-4803
fplastini@ionetix.com

cc:Eric Mollon, RSO

From: [Tran, Frank](#)
To: [Pavon, Sandy](#); [Willour, Jeffrey](#)
Cc: [Tomczak, Tammy](#)
Subject: FW: Re: Request for additional information for NRC License No. 04-35412-01
Date: Wednesday, July 14, 2021 3:35:34 PM
Attachments: [NRC Possession Limit Increase Response 2021-07-14 155955.pdf](#)
[NRC 665 Additional information dated July 14 2021.pdf](#)

Dear IM Center:

Please add the attachment to ADAMS as an additional information. A 665 is also attached. Let me know if you have any question.

Thanks,
Frank

From: Frank Plastini <fplastini@ionetix.com>
Sent: Wednesday, July 14, 2021 3:18 PM
To: Tran, Frank <Frank.Tran@nrc.gov>
Subject: [External_Sender] Re: Request for additional information for NRC License No. 04-35412-01

Mr. Tran,

Please see the attached response to your questions regarding our possession limit increase.

Let me know if you have any questions.

Frank Plastini
Director Radiation Compliance & EHS/CRSO
Ionetix Corporation
(518) 603-4803 (m)
fplastini@ionetix.com

On Thu, Jul 8, 2021 at 3:22 PM Tran, Frank <Frank.Tran@nrc.gov> wrote:

Dear Mr. Plastini:

We have reviewed your letter dated June 23, 2021 requesting an increase in the possession limit for NRC License No. 04-35412-0

In evaluating your request, we reviewed the previous submitted facility diagram and equipment, including the letter dated December 31, 2018 regarding the radiation shielding assessment. Based on your request to increase the quantity of F-18 from 5 millicuries to 1500 millicuries, a 300 times increasing, we would like additional information regarding the radiation shielding (engineering and/or administrative controls or an evaluation) for the new quantity limit to ensure that the increasing in radiation dose, if any, to the workers and members of the public from your operations is within the NRC limits and ALARA.

To continue review of your application, we request that you submit your response with date and authorized signature to this correspondence by August 9, 2021. In your response, please refer the license number, docket number and Mail Control No. 627089. If you have questions, require additional time to respond, or require clarification on any of the information stated above, please contact me at 630-829-9623 or reply to this email.

In accordance with Title 10 of the Code of Federal Regulations (10 CFR) 2.390 of the NRC's "Rules of Practice," a copy of this correspondence will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <https://www.nrc.gov/reading-rm/adams.html>.

Best regards,

Frank Tran

Health Physicist/License Reviewer
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