

Parker, Bryan

From: Parker, Bryan
Sent: Tuesday, May 23, 2017 4:14 PM
To: 'ksmith@class7training.com'; 'ghorner@ionetix.com'
Subject: Request for Additional Information
Attachments: Ionetix new cyclotron 593155 RAI.docx

Hey Ken and Gary,

Attached is the Request for Additional Information (RAI) for the Ionetix facility in Lansing, MI. Hopefully, this captures everything we discussed during the site visit on May 17, 2017. If possible, please provide your response by end-of-business June 6, 2017. If you end up needing more time, just let me know.

As discussed, you may respond via email by attaching the response as a **signed** PDF file and sending it to me. Please mark the response as "**Additional Information for CN593155**".

Please let me know if you have any questions.

Thanks.
Bryan

Bryan A. Parker
Senior Health Physicist
USNRC Region III
bryan.parker@nrc.gov
678-828-7050
630-515-1078 (fax)



Request for Additional Information

Ionetix Corporation **Lansing, MI (CN 593155)**

1. As discussed during the site visit on May 17, 2017, please review the Radiation Safety Manual (RSM) attached to your application dated February 22, 2017 and determine if there are any commitments that can be "pulled into" Items 5-11 of the application so that you may exclude the RSM from the application as a whole. This will allow you more flexibility in making programmatic changes without the need to amend your license.

NOTE: Please do NOT re-submit the entire application – simply reference any changes and/or provide updated language to affected sections.

2. With regard to Item 6 of your application dated February 22, 2017 (page 12, last paragraph), please revise the "Purpose" language to only include that pertaining to possession and use, and removing language related to servicing (i.e., returns, repair etc.).
3. With regard to Item 7 of your application dated February 22, 2017 (pages 15-16), please provide a Delegation of Authority for Mr. Gary Horner as Site Radiation Safety Officer (RSO).

Please also provide training and experience for Mr. Horner *as it relates to radiation safety*.

4. With regard to Item 7 of your application dated February 22, 2017, please confirm that, as discussed during the site visit on May 17, 2017, Mr. Horner will be listed as the primary RSO on the license and Mr. Ken Smith will be listed as the Alternate RSO in his capacity as the overall Corporate RSO for Ionetix.

Please also indicate and clarify the duties and responsibilities of the Site RSO and the Corporate RSO.

5. With regard to Item 8 of your application dated February 22, 2017 (pages 19-20), please provide additional training and experience for each of the proposed Authorized Users. Please avoid sending resumes and/or CVs. Only provide information relevant to the individuals' experience (types of use, activity amounts, etc.) related to radioactive materials, especially those that were accelerator-produced.
6. With regard to Item 8 of your application dated February 22, 2017 (pages 21-24), please confirm that an examination will be provided as a knowledge check of training. Please describe the exam in general terms and what the passing grade will be.
7. With regard to Item 9 of your application dated February 22, 2017 (page 29, see also page 11), please provide calculations for estimating "worst case" radiation levels from radioactive materials transferred within the Research & Development area through the transfer lines from the cyclotron to the storage container.

8. With regard to Item 9 of your application dated February 22, 2017 (page 32), please clarify the term "Cyclotron Exclusion Zone" as it pertains to the Personal Safety System.
9. With regard to Item 9 of your application dated February 22, 2017 (page 33), please provide additional information regarding the actual air exchanges in the cyclotron room, and how this data correlates to the effluent calculation provided.

Please also confirm that you will conduct an evaluation to verify public dose and show that you will meet the Constraint Rule in 10 CFR 20.1101(d) – (i.e., COMPLY calculation or equivalent).

10. With regard to Item 10 of your application dated February 22, 2017 (page 35), please clarify the term "lonetix management" as it pertains to reviewing procedural changes.