SpectronRx

April 14, 2020

Sara A. Forster, Health Physicist Materials Licensing Branch Division of Nuclear Materials Safety, Region III 630-829-9892

E-mail to: Sara.Forster@nrc.gov

RE: License No. 13-32726 Docket No. 030-38044

Ms. Forster,

Thank you for your letter. We have begun work on the questions by re-engaged our third-party Health Physicist to help. Unfortunately, it is not likely he will be able to complete his work by April 17, 2020.

Questions 1 thru 4:

As a result of the time needed by our HP and per your suggestion in your letter, we confirm that responses to Questions 1 thru 4 will be submitted withing 30 days, on or before May 11, 2020.

Question 5:

We do request flexibility for updating of procedures submitted in our amendment request and responses.

As requested under question 5, the following is a description of the process that will be used to revise and implement these submitted procedures. When seeking changes:

- 1) Any changes or request for change will be reviewed by the RSO and management to be deemed appropriate.
- 2) Once a change is deemed appropriate, we commit that changes made to submitted procedures will follow the following rules:

(1) The revision is not contrary to regulations contained in Title 10 of the Code of Federal Regulations;

(2) The revision does not require a license amendment under 10 CFR Part 30;

(3) The revision has been reviewed and approved by the licensee's Radiation Safety Officer and management;

(4) The affected individuals are instructed on the revised procedures before the changes are implemented;



(5) The licensee shall retain a record of each change for 5 years; and

(6) The record will include a copy of the old procedure, the new procedure, the date of the change, and the signature of the licensee management representative who reviewed and approved the change."

Please feel free to contact me with any questions at 317-459-8315 or my email <u>JZehner@SpectronRx.com</u>.

Sincerely,

1RQZ

John A. Zehner CEO and Radiation Safety Officer NukeMed, Inc., dba SpectronRx

Song, Taehoon

From:	Forster, Sara
Sent:	Tuesday, April 14, 2020 2:27 PM
То:	Song, Taehoon; Pavon, Sandy
Cc:	Tomczak, Tammy
Subject:	FW: Re: Additional Information for Spectron Rx Lic. No. 13-32726-01MD, CN617986.pdf
Attachments:	NRC response April 14 2020.pdf
Follow Up Flag:	Follow up
Flag Status:	Flagged

Good afternoon, Tae and Sandy:

Attached is Additional Information for CN617986. Could you please place the document in ADAMS. The ADAMS file may either include this transmittal email message or a date stamp indicating "date received."

Thank you,

Sara A. Forster, Health Physicist Licensing Reviewer

U.S. Nuclear Regulatory Commission - Region III Division of Nuclear Materials Safety 2443 Warrenville Rd. - Ste. 210 Lisle, IL 60532-4352 <u>sara.forster@nrc.gov</u> Direct: (630) 829-9892 Facsimile: (630) 515-1078



From: John Zehner <jzehner@spectronrx.com>
Sent: Tuesday, April 14, 2020 9:19 AM
To: Forster, Sara <Sara.Forster@nrc.gov>
Cc: Christopher Ritter <critter@spectronrx.com>
Subject: [External_Sender] Re: Additional Information Request for Spectron Rx Lic. No. 13-32726-01MD, CN617986.pdf

Ms. Forster,

Attached is our response to your letter dated April 11, 2020. In the response, we are asking for more time with Questions 1 thru 4 and have committed to have them answered within the 30 days you suggested. In Question number 5, we requested flexibility for updating of procedures.

Thank you for your help, we appreciate the flexibility in offering the additional 30 days. Please confirm you received this email.

Sincerely,

John Zehner

On Sat, Apr 11, 2020 at 3:52 PM Forster, Sara <<u>Sara.Forster@nrc.gov</u>> wrote:

Dear Mr. Zehner:

As we discussed yesterday via phone, please provide additional information as soon as possible so we may complete our review of your request to expand your radioiodine program. Please do not hesitate to contact me if you have any questions.

Sincerely,

Sara A. Forster, Health Physicist Licensing Reviewer

U.S. Nuclear Regulatory Commission - Region III

Division of Nuclear Materials Safety

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John A. Zehner

Chief Executive Officer