



November 2, 2022

Bryan Parker
U.S. Nuclear Regulatory Commission
Region III – Division of Nuclear Materials Safety
2443 Warrenville Rd, Suite 210
Lisle, IL 60532-4352

Re: Additional Information for Amendment Request for Radioactive Materials License 34-32780-04MD, CN632058, Cardinal Health Nuclear & Precision Health Solutions, Indianapolis, IN.

Licensing:

To support the amendment request for the above referenced radioactive materials license, Cardinal Health 414, LLC (Nuclear & Precision Health Solutions and Indianapolis Manufacturing Site [IMS], hereafter Cardinal Health) submits this letter with additional information.

Please see attached for additional training documentation for Benjamin Ellert, R.Ph. to support the request to add him as an Authorized User on this license.

If you have any questions regarding this request, please contact me at 614.553.4555.

Sincerely,

A handwritten signature in black ink, appearing to read "Evan T. Western", written over a white background.

Evan T. Western, CHP
Manager, Health Physics
Nuclear & Precision Health Solutions

Encl: Attachment A – Benjamin Ellert R.Ph. Training Documentation

cc: License File, Loc. 5889 (3)
Ian Schaller, MRSO, Loc. 5889

ATTACHMENT A

Benjamin Ellert, R.Ph. Training Documentation

Qualification for Authorized User Training

TRAINEE: Benjamin Ellert

This document signifies the listed trainee has been trained on the following:

Activity performed	Time spent (in hours)	Notes
Batch Production: Set-up and column preparation, drug substance, drug product, and vial filling.	200	Observation performed under supervision of site AUs and Production SMEs
Batch Inspection and Packaging: QA inspection, packing and shipping of bulk vials.	200	Observation performed under supervision of site AUs and Production SMEs

Training Date(s):

I, Jesse Fisher Jesse Fisher, (trainer), certify that
Benjamin Ellert, (trainee), participated in the above training session. The trainee was afforded time for a question and answer session to ensure knowledge comprehension.

Jesse Fisher
(Trainer signature)

02 Nov 2022
(Date)

Benjamin Ellert
(Trainee signature)

02 NOV 2022
(Date)

RADIOISOTOPE HANDLING EXPERIENCE

Name: Benjamin Elliot

Date: 02 Nov 2022

Document the actual use/handling of radioactive material under the supervision of an Authorized Nuclear Pharmacist.

ISOTOPE	SINGLE HIGHEST mCi ACTIVITY HANDLED	USE See key below: 1,2,3,4,5,6,7,8	EXPERIENCE Actual clock hours (Include date range of experience)	WHERE EXPERIENCE GAINED
<u>Ra-223</u>	<u>150</u>	<u>1,2,3,4,5,6</u>	<u>10,000 15/04/2015 - 02/11/2022</u>	<u>Cardinal Health</u>
<u>Ac-227</u>	<u>135</u>	<u>5,6</u>	<u>1,000 11/04/2022 - 02/11/2022</u>	<u>Cardinal Health</u>
<u>Th-227</u>	<u>3</u>	<u>1,2,5,6</u>	<u>1,000 11/04/2022 - 02/11/2022</u>	<u>Cardinal Health</u>
<u>Mo-99/Tc99m</u>	<u>10,000</u>	<u>1,2,3,4,5,6,8</u>	<u>40,000 01/06/1999 - 11/04/2022</u>	<u>Cardinal Health</u>
<u>I-131</u>	<u>5,000</u>	<u>1,2,3,4,5,6</u>	<u>5,000 01/06/1999 - 11/04/2022</u>	<u>Amersham / GE</u>
				<u>Cardinal Health</u>
				<u>Amersham / GE</u>

Key for "Use": the number, or numbers, entered under "Use" should correspond to the handling experience for each isotope.

- Ordering, shipping, receiving radioactive materials and performing related radiation surveys
- Calibrating, using and performing checks for proper operation of dose calibrators, scintillation detectors, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides
- Calculating, assaying and safely preparing dosages for manufactured vials for patients or human research subjects
- Using appropriate internal controls to avoid mistakes in the labeling and/or administration of by product material
- Using procedures to prevent or minimize contamination and using proper decontamination procedures
- Learning emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys, and wipe tests
- Eluting Ra-223 from generator systems and reconstitution of Actinium generator system
- Quality Control testing of in process samples or finished product vials

Martha Pavon

From: Western, Evan <evan.western@cardinalhealth.com>
Sent: Wednesday, November 2, 2022 2:17 PM
To: Bryan Parker
Cc: Sullivan, Glenn; Schaller, Ian
Subject: [External_Sender] RE: Need info for 34-32780-04MD (CN632058)
Attachments: 221102 Ellert Additional Training.pdf

Hi Bryan,

Please see the additional training documentation for Ben Ellert RPh as you requested. Please let me know if you need anything else!

Thanks,
Evan



Evan T. Western, CHP
Manager, Health Physics
7000 Cardinal Place, SC6
Dublin, OH 43017
614.553.4555 tel / 614.553.9763 fax

Learner | Analytical | Woo | Individualization | Input

I am *Essential to care™*

From: Bryan Parker <Bryan.Parker@nrc.gov>
Sent: Wednesday, November 2, 2022 8:30 AM
To: Western, Evan <evan.western@cardinalhealth.com>
Cc: Sullivan, Glenn <glenn.sullivan@cardinalhealth.com>
Subject: Need info for 34-32780-04MD (CN632058)

External Email – Please use caution before opening attachments or clicking links

Hey Evan & Glenn,

I trying to finish up Control No. 632058 – amendment request for the Ra-223 manufacturing license to add Ac-225 and the Th-227 production area. But I have a question about one of the AUs you requested also. I know Benjamin Ellert is listed on the other Ra license, but I not seeing “equivalent” training for him that is similar to the other proposed AUs. I know Mr. Ellert has had some Ra training, but is it equivalent to the -04MD license training under one of the listed AUs?

I need to complete this by tomorrow, so if it may take a bit to resolve this, I may leave him off as AU, but I can still list him as ARSO as requested.

Please advise.

Thanks.

Bryan

Bryan A. Parker

Senior Health Physicist

USNRC Region III

bryan.parker@nrc.gov

678-828-7050

630-515-1078 (fax)



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Svenska: <http://www.cardinalhealth.com/en/support/terms-and-conditions-english.html>

Martha Pavon

From: Bryan Parker
Sent: Wednesday, November 2, 2022 2:30 PM
To: Sandy Pavon; Martha Pavon
Subject: Please add to ADAMS
Attachments: [External_Sender] RE: Need info for 34-32780-04MD (CN632058); 632058 AI 665.pdf

Hey Sandy and Martha,

Please add the attached Additional Information to CN632058. A 665 is also attached. I need it to complete an action asap.

Please let me know if you have any questions.

Thanks.

Bryan