

Cardinal Health  
Nuclear & Precision Health Solutions  
Quality & Regulatory  
7000 Cardinal Place  
Dublin, OH 43017  
tel 614.757.4120  
fax 614.652.4598



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".

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 Ellett

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
Ra-223	150	1,2,3,4,5,6	10,000 15/04/2015 - 02/11/2022	Cardinal Health
Ac-227	135	5,6	1,000 11/04/2022 - 02/11/2022	Cardinal Health
Th-227	3	1,2,5,6	1,000 11/04/2022 - 02/11/2022	Cardinal Health
Mo-99/Tc99m	10,000	1,2,3,4,5,6,8	40,000 01/06/1999 - 11/04/2022	Cardinal Health Amersham / GE
I-131	5,000	1,2,3,4,5,6	5,000 01/06/1999 - 11/04/2022	Cardinal Health Amersham / GE

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

1. Ordering, shipping, receiving radioactive materials and performing related radiation surveys
2. 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
3. Calculating, assaying and safely preparing dosages for manufactured vials for patients or human research subjects
4. Using appropriate internal controls to avoid mistakes in the labeling and/or administration of by product material
5. Using procedures to prevent or minimize contamination and using proper decontamination procedures
6. Learning emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys, and wipe tests
7. Eluting Ra-223 from generator systems and reconstitution of Actinium generator system
8. Quality Control testing of in process samples or finished product vials

## Martha Pavon

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**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

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Learner | Analytical | Woo | Individualization | Input

**I am** *Essential to care™*

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**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'm 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'm 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](mailto:bryan.parker@nrc.gov)

678-828-7050

630-515-1078 (fax)



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Dansk - Deutsch - Espanol - Francais - Italiano - Japanese - Nederlands - Norsk - Portuguese - Chinese  
Svenska: <http://www.cardinalhealth.com/en/support/terms-and-conditions-english.html>

## Martha Pavon

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**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*