



June 18, 2025

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

Re: Amendment Request for Radioactive Materials License 34-32780-05, Cardinal Health,  
Indianapolis, IN.

Licensing:

Cardinal Health 414, LLC (hereafter Cardinal Health) requests an amendment to the radioactive materials license referenced above.

1. Cardinal Health requests that Jacob Farkas be named as Radiation Safety Officer on this license, replacing Evan Western. Mr. Farkas is currently an Authorized User on this license. RSO training/preceptor certification and a signed Delegation of Authority letter are enclosed as Attachment A.
2. Cardinal Health requests the ability to self-approve Authorized Users of radioactive materials for this license. Please see Attachment B for more information about this request.
3. While the request in item (2) above is pending, Cardinal Health requests that the following changes be made to the list of Authorized Users on this license. If self-approval is granted, please disregard this item as Cardinal Health will work through the self-approval process to make these changes.
  - a. Please add Cody Apple and Greg McCreary as AUs. Training documentation for these individuals is enclosed as Attachment C.
  - b. Please remove Teskyiiler McCoy and Blake Murrell from the list of AUs.
  - c. Troy S. Sambyal's name appears to be misspelled on the license (spelled incorrectly as "Troy S. Sambayal").

If you have any questions about 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

Attachments: A: RSO Training Documentation & Delegation of Authority  
B: AU Self-Approval Process  
C: AU Training Documentation

cc: Michael Stoner, Loc. 7238  
Jacob Farkas, Loc. 7238  
License File 7238 (3)

# **ATTACHMENT A**

## **RSO Training Documentation**



Cardinal Health 414, LLC  
7000 Cardinal Place  
Dublin, OH 43017  
tel 614.757.5000  
fax 614.652.4598

**TO:** All Employees, Location 7238 – Commercial Manufacturing Center  
Indianapolis, Indiana

**FROM:** David W. Pellicciarini  
Corporate Radiation Safety Officer  
Vice President, Industry Affairs  
Cardinal Health 414, LLC

**DATE:** May 30, 2025

**SUBJECT:** Delegation of Authority


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**Jacob Farkas** has been appointed Manufacturing Radiation Safety Officer and is responsible for ensuring the safe use of radioactive materials. The Manufacturing Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations. The Manufacturing Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibilities. This specifically includes having sufficient authority, organizational freedom, and management prerogative to:

1. Have unhampered access to all activities at his or her facility involving radioactive materials to identify radiation safety problems;
2. Immediately stop, without coordination with management, any activity at his or her facility involving the use of licensed materials by any user that might result in an unsafe situation or a violation of NRC or Agreement State requirements;
3. Initiate, recommend, or implement appropriate corrective actions; and
4. Verify the implementation of actions taken to correct radiation safety problems.

The Manufacturing Radiation Safety Officer is also responsible for assisting the Corporate Radiation Safety Committee and Corporate Radiation Safety Officer in the performance of their duties. All of us have a critical responsibility in ensuring the safe use of radioactive materials. I ask that you lend your full support to this important function.

I understand and agree to the duties and responsibilities above,

  
\_\_\_\_\_  
Jacob Farkas, MRSO

10 Jun 2025  
Date

  
\_\_\_\_\_  
David W. Pellicciarini, CRSO Date

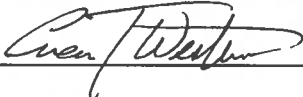
May 30, 2025



## DOCUMENTATION OF MANUFACTURING RADIATION SAFETY OFFICER TRAINING

I hereby attest that the individual designee below has satisfactorily completed a structural educational program with 200 hours didactic training and at least 500 hours of practical radioisotope handling experience. The individual designee has achieved a level of radiation safety related knowledge of regulatory issues and emergency procedures sufficient to be an authorized user and function as a Manufacturing Radiation Safety Officer in accordance with the requirements of the U.S. NRC in 10 CFR 35.50(b) or equivalent Agreement State regulations. This includes at least one year of training as radiation safety officer under supervision of a current radiation safety officer.

RSO Name (Print) Evan T. Western, CHP

RSO Signature:  Date: 6/10/2025

RSO Designee Name (Print) Jacob Farkas

RSO Designee Signature:  Date: 6/10/2025

# **ATTACHMENT B**

## **AU Self-Approval Process**

## **AU Self-Approval Request**

Cardinal Health requests the ability to self-approve authorized users (AUs) for radioactive materials license 34-32780-05.

The U.S. NRC currently authorizes Cardinal Health to self-approve AUs and Authorized Nuclear Pharmacists (ANPs) for our master nuclear pharmacy license, no. 34-29200-01MD. This authorization was originally issued to Syncor International Corporation in an approval letter from the NRC dated May 22, 1996. The exemption for listing each ANP name on that license and self-approval of ANP's was followed by a confirmatory letter from NRC dated June 16, 1999.

Cardinal Health further submitted to NRC in December 2006 for self-approval of non-pharmacist authorized users (AU) upon review of the Radiation Safety Committee (similar to the process used for ANP). This request was granted on Amendment 11 to license 34-29200-01MD, issued on March 20, 2007.

## **Approval Process**

Approval of an AU will be by vote of the Radiation Safety Committee (RSC), which is described in Item 10 of the license application dated November 18, 2021. A majority of members of the RSC must vote affirmatively for an AU to be approved, and the Corporate Radiation Safety Officer (CRSO) must be one of those to vote affirmatively. Once approved, the AU will be added to a Master AU Listing and a Notification of Approval will be forwarded to the licensed facility. Documentation of training and RSC approval is filed for inspection at Cardinal Health's corporate offices in Dublin, Ohio. Documentation of Notification of Approval will be maintained as well at the licensed facility. All documentation is maintained for three years after the last date of employment as an AU.

The Master AU Listing will be a formal document similar to the Master ANP Listing utilized by Cardinal Health for license 34-29200-01MD. This proprietary listing will be available for inspection at the licensed facility.

## **Training and Experience Requirements**

For this license, Cardinal Health commits to the following minimum AU training and experience requirements for new AUs, as defined in the license application dated November 18, 2021, which was subsequently approved by the NRC upon issuance of license 34-32780-05 on October 7, 2022.

1. 200 didactic hours of classroom and laboratory training relating to radiation safety with specific emphasis on:
  - a. Radiation mathematics
  - b. Radiation physics and nuclear physics
  - c. Radiation biology and radiation related health effects
  - d. Nuclear instrumentation with applications to health physics
  - e. Cyclotron theory and systems training
  - f. Radiation safety and ALARA techniques
2. A minimum of six months of experience with types, forms, quantities, and uses of radioactive materials similar to those at this facility.

Cardinal Health commits to the following requirements for individuals who are experienced AUs on other radioactive materials licenses:

1. The individual is listed by name as an AU on a license authorizing types, forms, quantities, and uses of radioactive materials that are similar to those at this facility; or,
2. The individual meets both of the following requirements:
  - a. The individual is listed by name as an AU on a license authorizing types, forms, quantities, and uses of radioactive materials that are not directly similar to those at this facility; and,
  - b. The individual has a minimum of three months of experience working at this facility in a role that includes handling or ensuring the safe use of radioactive materials.

Finally, Cardinal Health commits to ensuring that training and/or work experience has been obtained within 7 years of the date of approval.

# **ATTACHMENT C**

## **AU Training Documentation**

## TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name: **Cody Apple**

Location of Training	Date(s) of Accordance	Course Title	Total Clock Hours of Course	BREAKDOWN OF COURSE CONTENT IN CLOCK HOURS*				
				Radiation Physics & Instrumentation	Radiation Protection	Math Pertaining to Radio-activity	Radiation Biology	Radiopharmaceutical Chemistry
CARDINAL HEALTH Indianapolis, IN	12/13/2024 – 04/24/2025	CARDINAL HEALTH AUTHORIZED USER/ANP EDUCATION PROGRAM	230	85	58	25	32	30
*Note: Show a breakdown of hours by institution, dates, and subjects. List each hour only once (i.e., under the most applicable subject category)		<b>TOTAL HOURS</b>	230	85	58	25	32	30

Signature:



Evan T. Western, CHP  
Manager, Health Physics

Date: 05/29/2025

## RADIOISOTOPE HANDLING EXPERIENCE

Name: Cody Apple

Date: 29 May 2025

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

ISOTOPE	SINGLE HIGHEST mCi ACTIVITY HANDLED	USE See key below: 1,2,3,4,5,6,7	EXPERIENCE Actual clock hours (Include date range of experience)	WHERE EXPERIENCE GAINED
Ac-225	50	1,3,4,5,6	1 July 2024 To 29 May 2025  > 1000 hours	Cardinal Health CMC Indianapolis, IN
Ac-227				
Co-57	5	2,6		
Cs-137	0.25	2,6		
Cu-64				
F-18				
In-111				
Lu-177	1000	1,3,4,5,6		
Ra-223				
Tc-99m				
Th-228	300	4,5,6		
Th-229	150	4,5,6		

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 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. Manufacturing of radiochemicals and/or radiopharmaceuticals

## TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name: **Greg McCreary**

Location of Training	Date(s) of Accordance	Course Title	Total Clock Hours of Course	BREAKDOWN OF COURSE CONTENT IN CLOCK HOURS*				
				Radiation Physics & Instrumentation	Radiation Protection	Math Pertaining to Radio-activity	Radiation Biology	Radiopharmaceutical Chemistry
CARDINAL HEALTH INDIANAPOLIS, IN	12/3/2024 – 2/27/2025	CARDINAL HEALTH AUTHORIZED USER EDUCATION PROGRAM	200	85	58	25	32	0
*Note: Show a breakdown of hours by institution, dates, and subjects. List each hour only once (i.e., under the most applicable subject category)		<b>TOTAL HOURS</b>	200	85	58	25	32	0

Signature:



Evan T. Western, CHP  
Manager, Health Physics

Date: 6/11/2025

## RADIOISOTOPE HANDLING EXPERIENCE

Name: Greg McCreary

Date: 11 June 2025

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

ISOTOPE	SINGLE HIGHEST mCi ACTIVITY HANDLED	USE See key below: 1,2,3,4,5,6,7	EXPERIENCE Actual clock hours (Include date range of experience)	WHERE EXPERIENCE GAINED
Ac-225	1.5	3,4,5,6	28 Oct 2024 To 11 June 2025  ~1000 hours	Cardinal Health CMC Indianapolis, IN
Ac-227				
Co-57	5.2	2,4		
Cs-137	0.3	2,4		
Cu-64				
F-18				
In-111				
Lu-177	1.5	3,4,5,6		
Ra-223				
Tc-99m	600	2,4		
Th-228	0.6	3,4,5,6		
Th-229	0.2	3,4,5,6		

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 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. Manufacturing of radiochemicals and/or radiopharmaceuticals

## Martha Pavon

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**From:** Tammy Tomczak  
**Sent:** Wednesday, June 18, 2025 8:48 AM  
**To:** Martha Pavon  
**Cc:** Sandy Pavon  
**Subject:** FW: Amendment Request RAML 34-32780-05  
**Attachments:** 250618 AU Self-Approval-RSO Change.pdf

Good morning, Martha 😊

Can you please add the attached to ADAMS?

Thank you!!  
Tammy

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**From:** Western, Evan <evan.western@cardinalhealth.com>  
**Sent:** Wednesday, June 18, 2025 8:38 AM  
**To:** R3-DRSSMail Resource <R3-DRSSMail.Resource@nrc.gov>  
**Cc:** Farkas, Jacob <jacob.farkas@cardinalhealth.com>  
**Subject:** [External\_Sender] Amendment Request RAML 34-32780-05

Licensing,

Please find attached an amendment request letter for radioactive materials license 34-32780-05, the Cardinal Health manufacturing facility in Indianapolis, IN. Please contact me if you have any questions about this request.

Sincerely,  
Evan Western



**Evan T. Western, CHP**  
*Manager, Health Physics*  
7000 Cardinal Place, Dublin, OH 43017  
614.553.4555 tel

Upcoming PTO: June 19-20  
Upcoming Business Travel: July 14-17

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