

Cardinal Health
Nuclear Pharmacy Services
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Dublin, OH 43017
tel 614.757.4120
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www.cardinalhealth.com

October 20, 2015

Bryan A. Parker
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 34-31473-03MD, Cardinal Health Nuclear Pharmacy Services, Dublin, OH.

Licensing / Mr. Parker:

Cardinal Health 414, LLC (Nuclear Pharmacy Services, hereafter Cardinal Health) requests a clarification and amendment if necessary to use radioactive material as reference standards at the Cardinal Health Radium-223 manufacturing facility located at 4343 West 62nd Street, Indianapolis, Indiana for the above referenced license.

Our previous request dated June 8, 2015 refers to unsealed materials used as reference standards at the Cardinal Health Radium-223 manufacturing facility, however, the license amendment number 1 restricts the use of byproduct material authorized under 10 CFR 35.65(a) to sealed sources only (according to 10.B.) and does not include our letter dated June 8, 2015 as a tie down condition in 20.B.

Cardinal Health requests expedited review of the above referenced license amendment request. If you have any questions regarding this request, please contact me at 614.757.9586.

Sincerely,

Glenn Sullivan
Manager, Health Physics
Quality and Regulatory
Nuclear Pharmacy Services

/dh

Enclosure: Request dated June 8, 2015

cc: Gregory Even, PRSO, Loc. 7220
Ben Ellert, Loc. 7220
License File 7220 (3)
Rick Hasselkus
Katherine Benson
Scott Claunch, CRSO



CardinalHealth

INFORMATION ONLY

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June 8, 2015

Bryan A. Parker
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 34-31473-03MD, Cardinal Health Nuclear Pharmacy Services, Dublin, OH.

Licensing / Mr. Parker:

Cardinal Health 414, LLC (Nuclear Pharmacy Services, hereafter Cardinal Health) requests the addition of temporary job sites for the above referenced license to use sealed sources and radioactive material as reference standards for quality assurance testing of instruments at the Cardinal Health Radium-223 manufacturing facility located at 4343 West 62nd Street, Indianapolis, Indiana.

In addition, Cardinal Health requests the addition of Cami Still as a non-pharmacist authorized user (AU). Documentation of training is enclosed.

An updated organization chart is enclosed in Attachment A. If you have any questions regarding this request, please contact me at 614.757.9586.

Sincerely,

Glen Sullivan
Manager, Health Physics
Quality and Regulatory
Nuclear Pharmacy Services

/dh

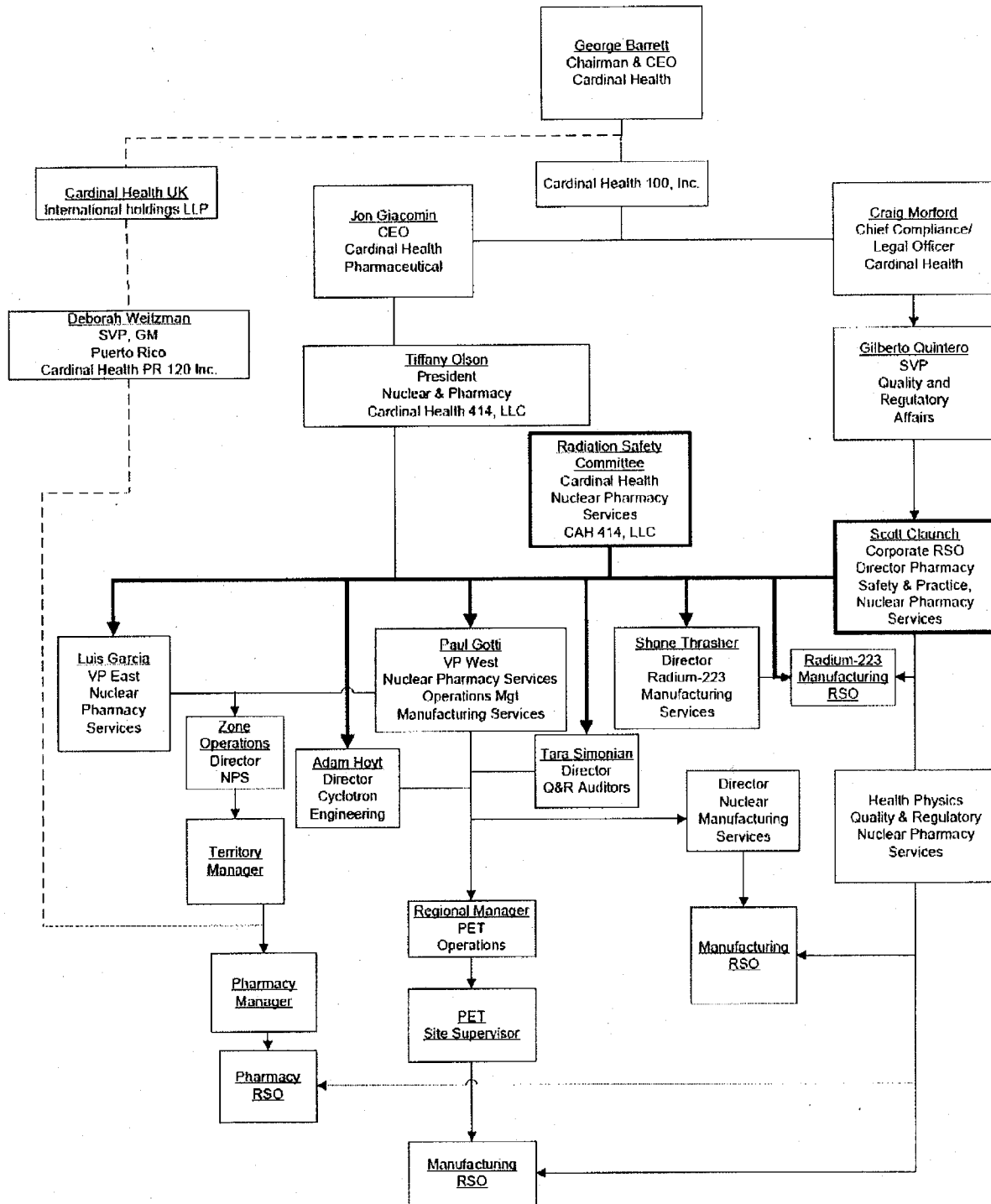
Enclosure: Attachment A – Organizational Chart
Training Documents

cc: Gregory Even, PRSO, Loc. 7220
License File 7220 (3)
Cami Still
Rick Hasselkus
Katherine Benson
Scott Claunch, CRSO

ATTACHMENT A

Radiation Safety Program Organizational Chart

Training Documents



RADIOISOTOPE HANDLING EXPERIENCE

Name: Cami Still Date: 5/29/15

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

ISOTOPE	MAXIMUM 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
Cs-137	200 uCi	2	200 hrs (6/05 – 5/07)	CAH, Dublin, OH
Co-57	10 mCi	2	200 hrs (6/05 – 5/07)	
Tc-99m	2 Ci	1,2,3,4,5,6,7	200 hrs (6/05 – 5/07)	
Ba-133	200 uCi	2	200 hrs (6/05 – 5/07)	

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. Eluting Tc-99m from generator systems, assaying the eluate for Tc-99m and for Mo-99 contaminations, and processing the eluate with reagent kits to prepare Tc-99m labeled radioactive drugs.

RADIOISOTOPE HANDLING EXPERIENCE

Name: Cami Still

Date 4/29/15

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

ISOTOPE	MAXIMUM 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
F-18	5 Ci	1,2,3,4,5,6	1000 hrs (5/07 – 11/07)	CAH Beltsville, MD
Na-22	50 uCi	2	1000 hrs (5/07 – 11/07)	CAH Beltsville, MD
Cs-137	200 uCi	2	1000 hrs (5/07 – 11/07)	CAH Beltsville, MD

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 or accelerator 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. Production of radioactive materials via bombardment in a nuclear reaction.

TRAINING RECEIVED IN BASIC RADIOSOTOPE HANDLING TECHNIQUES

Name: Cami Still

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 Radioactivity	Radiation Biology	Radiopharmaceutical Chemistry
Purdue University, West Lafayette, IN	2001 - 2005	Radiation Science	36	12		12	12	
		Intro to Radiotracers	24			12	12	12
		Radiation Dosimetry	36		12	12	12	
		Radiation Biology	24	6	6	6	6	
		Radiation Instrumentation Lab	12	12				
		Nuclear Engineering	36	24		12		
		Radiation Dosimetry Lab	12		6		6	
		Reactor Health Physics	36	12	12	12		
		Environmental Health Physics	24	8	8	8		
		Reactor HP Lab	12	4	4	4		
*Note: Show a breakdown of hours by institution, dates, and subjects. List each hour only once (i.e., under the most applicable subject category)			252	78	48	66	48	12
TOTAL HOURS								

Tomczak, Tammy

From: Parker, Bryan
Sent: Tuesday, October 20, 2015 10:11 AM
To: Tomczak, Tammy; Pelke, Patricia
Subject: FW: 34-31473-03MD request
Attachments: 151020 Request reference standards.pdf

Importance: High

Tammy – please process this submission from Cardinal in as amendment request and assign to me.

Patty – I discussed this with Glenn and I believe we need to adjust Items 6.B. and 7.B. from this:

6.B. Any byproduct material authorized under 10 CFR 35.65(a). *7.B. Sealed sources*

to this:

6.B. Any byproduct material authorized under 10 CFR 35.65. *7.B. Any*

As it is currently worded, they cannot order the liquid sources (in ampules) needed for the equipment checks at the manufacturing location.

Let me know what you think, and if you agree, I'll expedite it.

Thanks.
Bryan

From: Hill, Dan (NPS Q&R) [mailto:dan.hill01@cardinalhealth.com]
Sent: Tuesday, October 20, 2015 10:50 AM
To: Parker, Bryan <Bryan.Parker@nrc.gov>; Sullivan, Glenn <glenn.sullivan@cardinalhealth.com>
Cc: Claunch, Scott <Scott.Claunch@cardinalhealth.com>; Still, Cami <Cami.Still@Cardinalhealth.com>; Even, Greg <Greg.Even@cardinalhealth.com>; Ellert, Benjamin <benjamin.ellert@cardinalhealth.com>; Hasselkus, Rick <Rick.Hasselkus@cardinalhealth.com>; Benson, Katherine <Katherine.Benson@cardinalhealth.com>
Subject: [External_Sender] 34-31473-03MD request
Importance: High

Bryan,
Glenn Sullivan has spoken to you about the changes in the NRC license 34-31473-03MD which are needed to allow unsealed material and sealed sources used as calibration and reference standards at our Ra-223 manufacturing facility under construction for instrument QA testing purposes.

Please contact Glenn Sullivan by calling 614.757.9586 if you have any questions, and see attached and expedite the review for the testing which is scheduled as soon as possible.

Thank you.

Dan

Dan Hill
Quality & Regulatory
Nuclear Pharmacy Services
614.757.5074
614.652.4598 fax

Encl.

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