

Cardinal Health
Nuclear Pharmacy Services
7000 Cardinal Place
Dublin, OH 43017
614.757.5000 main
800.234.8701 toll free



CardinalHealth

cardinalhealth.com

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,

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

/dh

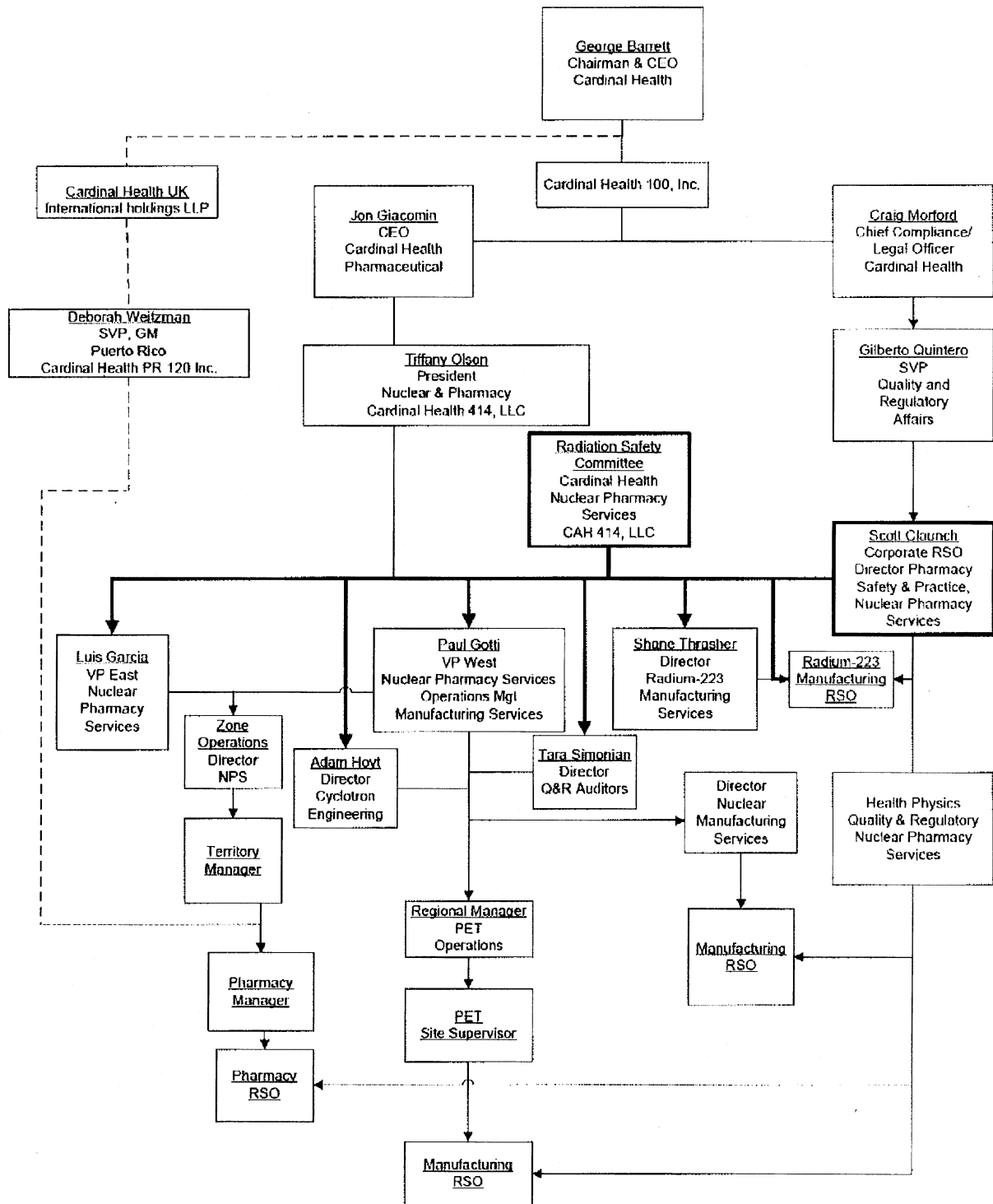
Enclosure: Attachment A – Organizational Chart
Training Documents

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	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: Pelke, Patricia
Sent: Tuesday, June 16, 2015 3:41 PM
To: Tomczak, Tammy
Cc: Parker, Bryan
Subject: Cardinal Health 414, LLC FW: Message from "RNP002673616C91"
Attachments: 20150616151814891.pdf

Importance: High

Hi Tammy,
Please have the attached request entered into ADAMs and processed-in as an amendment. The request was received today via email. If you have any questions, please let me know. Thanks - Patty

-----Original Message-----

From: Sullivan, Glenn [<mailto:glenn.sullivan@cardinalhealth.com>]
Sent: Tuesday, June 16, 2015 2:48 PM
To: Parker, Bryan
Cc: Pelke, Patricia
Subject: FW: Message from "RNP002673616C91"

Thanks for the help. I have attached a copy of an amendment request and will send one in the mail as well. It is to add a nonpharmacist authorized user as well as the manufacturing site for sealed sources.

Thanks

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Glenn P. Sullivan, MBA
Manager, Regulatory Management, NPS
7200 Cardinal Place West, Dublin, OH 43017
614.757.9586 dir | 614.652.4838 fax

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