

Fax

MS16  
J-6



45-25221-01MD

03032974

Date | 5/4/07

Our Reference | Control No. 140337

From | Jim Kostka

Phone | 703-787-7900 (c) 202-207-5437

Fax Number | 703-787-4079

E-Mail | jim.kostka@iba-group.com

Pages | | including cover |

Your Reference | Docket 03032974

To | Denise Lawyer - Commercial R&D Branch

Phone | 610-337-5366

Fax Number | 610-337-5367

E-Mail |

5393

pages 8 - 7 + cover

Dennis Lawyer

Following are Preceptor Training statements and grids for the three ANP submittals - those three that you had pointed out in your April 17th letter as being short of documentation. However - you should have received by now - our letter withdrawing these three (for now). Please VOID the letter from Mark Soffing dated April 30, 2007 - that letter that asked you to withdraw two of these three Pharmacists from consideration as Authorized Nuclear Pharmacists (just put that in the trash). The following seven pages should complete the documentation for : Darren Patti, Michael Tingle and Shannon Pratschler.

thank you

Jim Kostka

Mark Soffing

140337

111

NMSS/RGN1 MATERIALS-002

Darren

Control #140337  
Docket 03032974



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### Documentation of Authorized Nuclear Pharmacist Training

The training outline in the Authorized Nuclear Pharmacist Guidelines has been completed. The Pharmacist is qualified to assume the duties and responsibilities outlined in the guideline.

The training included:

- Using administrative controls to avoid medical events in the administration of radioactive material
- Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures

I Hereby certify that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

Pharmacist Name (Print) Darren Patti  
Pharmacist Signature [Signature] Date 5/3/07  
Preceptor Name (Print) ERNESTO SAMUEL  
Preceptor Signature [Signature] Date 5/3/07



Control # 140 337  
Doc # 03032979



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Pharmacist Name (Print) MIKE TINDER  
 Pharmacist Signature M. Tinger Date 5/04/07

Preceptor Name (Print) ERNESTO SAMUEL  
 Preceptor Signature Ernesto Samuel Date 5/3/07

Control # 140337  
Doclet 03032974



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**The training included:**

Using administrative controls to avoid medical events in the administration of radioactive material

Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures

I Hereby certify that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

Pharmacist Name (Print) Shannon L. Pratschler  
Pharmacist Signature *Shannon L. Pratschler* Date 5/3/07

Preceptor Name (Print) ERNESTO SAMUEL  
Preceptor Signature *Ernesto Samuel* Date 5/3/07

Cardinal Health  
6464 Canoga Avenue  
Woodland Hills, CA 91367  
818 737 4000 tel

www.cardinal.com



## CardinalHealth

January 13, 2005

Ohio Department of Health  
Bureau of Radiation Control  
246 North High Street  
Columbus, OH 43215

Re: **Amendment Request for Cardinal Health Radioactive Materials License Numbers:**



Columbus  
Dayton  
Uniontown  
Girard  
Oakwood Village  
Holland  
Cincinnati

Attention Licensing:

Please amend the above referenced licenses to add [redacted] Shannon Pratschler and [redacted] as authorized nuclear pharmacists. A copy of their training documentation is enclosed. Please note that these individuals have been employed as Nuclear Pharmacists since the time of their training and have been authorized under the Cardinal Health Consolidated NRC Radioactive Materials License.

If you have any questions concerning this request, please contact Alison Atkiels at (818) 737-4540.

Sincerely,

Kofy Kodimer, Ph.D.  
Manager, Health Physics

Cc: PRSO Loc. 1, 5, 8, 9, 23, 27, 96  
License Files 1, 5, 8, 9, 23, 27, 96 (3)

Encl: Training documents



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**RADIOISOTOPE HANDLING EXPERIENCE**

Name: Shannon Pratschler

Date: 3/24/99

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
Mo-99	15Ci	1	5/97 to 5/98 620 hours	Syncor International Pittsburgh, PA
Tc-99m	15Ci	1,2,3,4,5,6,7		
I-131	100mCi	1,2,3,4,5,6		
Xe-133	100mCi	1,2,3,4,5,6		
I-123	1mCi	1,2,3,4,5,6		
Ga-67	20mCi	1,2,3,4,5,6		
Tl-201	100mCi	1,2,3,4,5,6		
Cs-137	100mCi	2		
Co-57	20mCi			

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

Preceptor: Joe Antifolia

3/24/99

\*\* TOTAL PAGE: 04 \*\*

Page 9-2

FIGURE 9-1

TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

Name: Shannon Pratschler

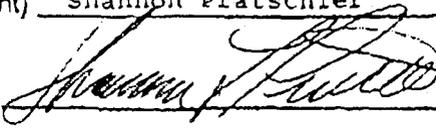
Location of Training	Date(s) of Attendance	Course Title	Total Clock Hours of Course	BREAKDOWN OF COURSE CONTENT IN CLOCK HOURS*					
				Radiation Physics & Instrumentation	Radiation Protection	Math Pertaining to Radioactivity	Radiation Biology	Radiopharmaceutical Chemistry	
Duquesne Univ Pittsburgh, PA	8/96 - 12/96	Bionucleonics	96	32	26	32	6		
	1/97 - 5/97	Advanced Bionucleonics + Radiopharmacy	96	53		13		30	
	9/97 - 12/97	Health Physics	48		30		18		
*Note: Show a breakdown of hours by institution, dates, and subjects. List each hour only once (i.e., under the most applicable subject category)			TOTAL HOURS	240	85	56	45	24	30

### DOCUMENTATION OF AUTHORIZED NUCLEAR PHARMACIST TRAINING

The training outline in the Authorized Nuclear Pharmacist Guideline has been completed. The Pharmacist is qualified to assume the duties and responsibilities outlined in the guideline.

I Hereby certify that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

Pharmacist Name (print) Shannon Pratschler

Pharmacist Signature  Date 4-8-99

Preceptor Name (print) Dan Littlefield

Preceptor Signature  Date 3/24/99

Send this document with a completed Radioisotope Handling Experience form and a photocopy of the pharmacist's license to the Quality and Regulatory Department.