PETNET Solutions

This form is to document that _____Mickey Latham_____has the following experience performing work in a restricted area or handling radioactive material under the supervision of an Authorized User or Authorized Nuclear Pharmacist.

Isotope and Activity Handled	Uše/Tasks	Experience Hours	Where Experience Gained
Cs-137 110nCi	Daily constancy on SCA	10/15-11/17	PETNET
			Indianapolis
F-18 1-200	Monthly, Quarterly, Semi-annual	10/15-11/17	PETNET
mRem/hr	and annual cyclotron PM's		Indianapolis
Activated tantalum	Average every 2 weeks and when	10/15-11/17	PETNET
targets 1-200	needed		Indianapolis
mR/hr			
lon source	Replaced every 2-3 weeks	10/15-11/17	PETNET
replacement 1-200			Indianapolis
mR/hr			
F-18 1-100mCi	Decontamination of	10/15-11/17	PETNET
	components/tools as needed		Indianapolis
F-18 1-50 mR/hr	Reset of chemistry modules used	10/15-11/17	PETNET
	in FDG procuction		Indianapolis

Signature

Joel Readinger Printed Name

i.

PETNET Solutions, Inc. A Siemens Company 810 Innovation Drive Knoxville, TN 37932

1-16-18 Date

Tel: (800) 738-0488 Fax: (865) 218-3018

This form is to document that ____Heather Fry_____has the following experience performing work in a restricted area or handling radioactive material under the supervision of an Authorized User or Authorized Nuclear Pharmacist.

Isotope and Activity Handled	Üse/Täsks	Experience Hours	Where Experience Gained
F-18, N-13 1mCi-	Daily handling of unit dose	9/16-current	PETNET
10Ci	production tasks		Indianapolis
F-18, N-13	Daily handling of DOT packaging	9/16-current	PETNET
1-700mCi	and processing		Indianapolis
F-18 1mCi – 20mCi	Daily break down of hot cell prior	9/16-current	PETNET
	to production(on 3 week rotation)		Indianapolis
F-18 1-700 mCi	Sunday production-(involves	9/16-current	PETNET
	cyclotron operation, FDG		Indianapolis
	production, QC, dispensing,		
	packaging and DOT processing (3		
	week rotation)		
Cs-137 110 nCi –	Daily constancy on SCA and dose	9/16-current	PETNET
175 uCi	calibrator(3 week rotation)		Indianapolis

Signature

1-16-18 Date

Printed Name

PETNET Solutions, Inc. A Siemens Company

810 Innovation Drive Knoxville, TN 37932

Tel: (800) 738-0488 Fax: (865) 218-3018

<u>/ - /6 -/8</u> Title

Parker, Bryan

From:	Still, Cami <cami.still@siemens-healthineers.com></cami.still@siemens-healthineers.com>
Sent:	Tuesday, January 16, 2018 9:14 AM
To:	Parker, Bryan
Subject:	[External_Sender] RE: Follow up to PETNET Indianapolis amendment questions
Attachments:	2018-01-16 Latham and Fry handling hours.pdf

Good morning Bryan,

Attached is the requested handling experience for Heather Fry and Mickey Latham. The site RSO, Joel, recorded Mickey's quantity handled in exposure rate as the activity of the cyclotron components vary. His job entails working with quantities in the uCi range for some components to delivering Ci amounts of activity to the hot cell or for testing purposes.

If you have additional questions, please don't hesitate to call.

Thanks, Cami

From: Parker, Bryan [mailto:Bryan.Parker@nrc.gov]
Sent: Friday, January 12, 2018 9:31 AM
To: Still, Cami (HC DI MI QT QA EHSFO)
Subject: RE: Follow up to PETNET Indianapolis amendment questions

Thank you, Cami. I will call you a little later this morning.

Bryan

From: Still, Cami [mailto:cami.still@siemens-healthineers.com]
Sent: Friday, January 12, 2018 8:42 AM
To: Parker, Bryan <<u>Bryan.Parker@nrc.gov</u>>
Subject: [External_Sender] Follow up to PETNET Indianapolis amendment questions

Hi Bryan,

Sorry for missing your calls the last couple of days, I've been tied up on another project this week. I spoke to Elizabeth who informed me of some of the additional details you are looking for, which I'll outline below. If you still have additional questions, feel free to give me a call – I will be in the office all day today.

Job Responsibilities for Heather Fry (ANP) and Mickey Latham (CE): ANP -

Tasks Qualified to Perform: These individuals are required for dispensing radiopharmaceuticals for distribution under a prescription to authorized licensees. They will also use and supervise the use of licensed material, including (depending on their training and qualifications) work on the cyclotron for routine maintenance; target rebuilds; setup, maintenance and troubleshooting automated chemistry modules; Quality Control testing of radiopharmaceuticals; DOT package preparation and shipping. Tasks Qualified to Perform: These individuals are required for production of radiochemicals with the cyclotron, manufacturing radiopharmaceuticals under FDA cGMPs and distribution of bulk radiopharmaceuticals to authorized recipients. In addition, depending on specific training and qualification, they may work on the cyclotron; rebuild targets; perform automated chemistry module setup, maintenance and troubleshooting; perform Quality Control testing of radiopharmaceuticals; prepare and ship DOT packages; and, supervise and use radioactive materials authorized by the license.

Training covered in courses for submitted completion certificates is outlined in the attached pdf document. Both Heather and Mickey have been working at PETNET Indianapolis for over a year.

Please let me know if you need more detail on anything else.

Thanks!

Cami Still Regional Health Physicist

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