RNP of New Jersey, LLC 30 Murray Hill Pkwy. Suite 450 East Rutherford, New Jersey 07073 (201) 438-4044 (201)438-0607 FAX

K-4

October 31, 2004

License Assistance Section Nuclear Medicine Safety Branch Division of Radiation Safety & Safeguards U.S. Nuclear Regulatory Commission, Region I 475 Allendale Road King of Prussia, PA 19406-1415

RE: Amendment Request RNP of New Jersey, LLC 03036472 License Number: 29-30867-01

Dear License Reviewer:

Please amend the above mentioned license to delete Randal L. Watt as authorized user. In Addition, please add Daniel Fernandez as authorized user for all materials and applications currently listed on our byproduct material license. Documentation attesting to their training and experience has been enclosed within Attachment A. Please refer to this section for details.

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NOV 16

A9 :3

/35987 NMSS/RGNI MATERIALS-002 If you require additional information, please contact Michael W. Lairmore or myself. Mr. Lairmore may be reached at (201) 447-3303.

We thank you in advance for your assistance with this licensing action.

Sincerely,

Charles S. Talarico Facility Manager

marchael danne

Michael W. Lairmore, M.S. Radiation Safety Officer

Attachment A

I. <u>Aleksandr Bardov</u> Employment Date: November11, 2003

- a. Training and Experience Summary
- b. Training Documentation

II. Daniel Fernandez Employment Date: Febuary 2, 2004

- a. Training and Experience Summary
- b. Training Documentation

I. a. Aleksandr Bardov's Training and Experience Summary

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Aleksandr Bardov TRAINING AND EXPERIENCE

	CLASSROOM	LABORTORY	PLACE/	
DATES	HOURS	HOURS	TRAINER	SUBJECT
11/12/03-11/28/03	68		RNP of New Jersey - Charles S. Talarico	Cyclotron Theory, Operation, & Maintenance
11/17/03-11/21/03	8		RNP of New Jersey - Charles S. Talarico	Materials Control
12/01/03-12/19/03	59		RNP of New Jersey - Charles S. Talarico	Quality Control
12/23/03-12/28/03	20		RNP of New Jersey - Charles S. Talarico	Radiation Safety
1/05/04-1/09/04	40		GE Medical at RNP of NJ - Stephen Downey	Cyclotron Theory, Operation, Applications
4/07/04-4/08/04	8		RNP of New Jersey - Scott Lucas	Radiation Safety
6/16/04-6/17/04	6		RNP of New Jersey - Scott Lucas	Radiopharmaceutical Manufacturing
6/18/2004	4		RNP of New Jersey - Self	Continuing Education
7/19/04-7/23/04	20		RNP of New Jersey - Patricia Owens	SOP Training
8/16/2004	4		RNP of New Jersey - Self	Continuing Education
8/18/2004	4		RNP of New Jersey - Self	Continuing Education
11/11/04-10/08/04		1920	RNP New Jersey lab operations experience	FDG Production & Laboratory Operation
TOTAL HOURS	241	~ 1920		
GRAND TOTAL	~	2161 hours of train	ning and Lab Experience	updated: 10/08/04

I. b. Aleksandr Bardov's Training Documentation



- 12. The Radiation Safety Officer for this license is Michael W. Lairmore.
- 13. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.

Standard Operating Procedure SOP Number A007 Radiopharmaceutical Manufacturing SOP Number A007 Operator Training Operator Training PRO Document Control QA/RA	REG	IONAL NUCLEAR PHARMACEUTI	ICALS
Compliantificetulical Manufacturing Effective I Operator Training 06/15 PRO Document Control QA/RA Supersedes 06/01	~~~	Standard Operating Procedure	SOP Number: A007F
PRO Document Control QA/RA Supersedes		Operator Training	Effective Date: 06/15/03
Kauchel allot John Jagnon John Vagno 00/01		PRO Document Control QA/RA Candal High John Hayne John Varne	Supersedes: 06/01/03

TRAINING RECORD

Page 1 of 2

Employee Ale K Sandr Bardor

Subject	Section	Date Completed	Hours	Trainer	Employee Initials
Accelerator Theory			35877 (r.		
	Control System Overview	11-12/11-25-03	4	Ciclarico	A.R
	User Command Files	1	4		A.B.
	Interlocks and safety switches		4		AB
	Vacuum system	_	4	1	A.B.
	RF system		4	<u>├</u>	A.B.
	Cooling system		1		AB
	Magnet		2		A.B.
	Ion source		4		4 B
	Beam extraction system		8		4 B
	Target systems	<u> </u>	- q	<u> </u>	AR
	Accelerator maintenance	<u> </u>			AR
	Target maintenance				AB
Aseptic Processing		AND AND AND AND AND	Service (
	Controlling the environment	<u> Nation Berletting in the Constantion of </u>			and the second second second
	Laminar flow hood maintenance		}	1	
	Sterile filter sterilization			1	
	Filter hubble test				}
	Media fill simulation		<u> </u> -		
	Endotoxin testing		· · · · · · · · · · · · · · · · · · ·		
cGMP, 21 CFR 210					
	210.1 - Status		<u>nationalitation</u>	······································	
	210.2 - Applicability			· · · · · · · · · · · · · · · · · · ·	
	210.3 – Definitions				
Materials Control					
	Receiving and marantine	1. 57 - 11 21-2	<u>)</u>	CT	A 0
	Accentance testing	11-11-11-21-03	2	- Jajarico	7.8
	First-in-first-out		<u>a</u>	1	
	Inventory control		2		A D
Synthesis System			<u> </u>	Y Y	
	EDG Radiochemister		99700000000000000000000000000000000000		
······	Raw materials and components				·
	Synthesizer control system				
	Hardware settings and adjustments				
······································	Command files			 	·
······································	Cleaning the suctor			 	
	System		ļ		
	synulesis program				



REG	IONAL NUCLEAR PHARMACEUT	ICALS
r:^;~	Standard Operating Procedure	SOP Number: A007F
	Operator Training	Effective Date: 06/15/03
	PRO Document Control QA/RA langel floor for for the layner	Supersedes: 06/01/03

Page 2 of 2

Subject	Section	Date Completed	Hours	Trainer	Employee Initials
Quality control					
	Sampling	12-1/12-5-03	l i	Citabrico	A.B.
	Reserve samples				+B
	Specific concentration		2		AB
	Sterility test	12-16-03	8		A.B
	LAL pyrogen test	12-17-03	8		AB
	Radiochemical purity, Radio-TLC	12-8-03	8		A.B
	Chemical punity, Kryptofix TLC		8		A.B
	Solvents, Gas Chromatography		8		A.B
	Radionuclidic Identity, half-life		2		AB
	Radionuclidic purity, MCA	12-12-03	8		A.B
	pH determination	12-1-03	1		AB
	Isotonicity				AB
	Visual inspection	12-5-03	1		AB
	Manufacturing trend analysis	12-19-03	2	X	AB
CGMP, 21 CFR 211					
	Subpart A – General				
	Subpart B - Organization & Personnel				
·	Subpart C - Buildings & Facilities				
	Subpart D - Equipment				
	Subpart E - Control of Components				
	Subpart F - Production/Process Control				
	Subpart G - Packaging & Labeling				
	Subpart H - Holding & Distribution				
	Subpart I – Laboratory Controls				
	Subpart J – Records & Reports				•
	Subpart K - Returns & Salvage				
PET Radiopharmaceuticals					
	Compliance Guidelines				



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~~~	Form Rediction Sefects Training Decord	Form Number: RS009F
	Kadiation Safety Training Record	Effective Date: 01/07/03
	PRO Document Control QA/RA	Supersedes:
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	$\checkmark$	Page 1 of 2

#### RADIATION SAFETY TRAINING RECORD Regional Nuclear Pharmaceuticals

Employee Name:	Aleksands Bardov	Training for:	New Employee	
			New Duties	
			Kefresher License Terms	

Training	:	Subject
Required	Date	
× .		
$\sim$	12-28-03 1.	Regulations for control of radiation.
$\checkmark$	12-23-032.	Terms of the License.
$\checkmark$	12-23-033.	Radiation hazards in the workplace.
$\checkmark$	12-23-03 4.	General radiation safety procedures.
	5.	The concept of ALARA.
	12-28-03 6.	Individual responsibility for radiation safety.
$\overline{\mathbf{v}}$	12-23-03 7.	Emergency procedures.
	12-28-03 8.	Workers right to be informed.
V	12-23-039.	Location of License, regulations, applications, correspondence.
	10.	Characteristics of radiation.
	11	Units of radiation dose and quantity of radioactivity.
	12.	Math and calculations basic to measurement of radioactivity.
	13.	Significance of radiation dose.
	14.	Radiation protection standards.
	15.	Biological effects of radiation.
	12-23-03 16	Levels of radiation exposure from various sources.
$\overline{}$	12-23-03 17.	Methods of controlling radiation dose; time, distance and shielding.
$\sim$	12-23-03 18.	Radiation detection instruments to be used.
V	12-23-03 19	Operation, calibration, and limitations of survey instruments.
$\overline{\mathbf{V}}$	12-23-03 20	Survey techniques.



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		21.	Use of personnel mon	utoring equipment	; film badges, TLDs,
i/	12-23-03	_	dosimeters.		
	12-23-03	23.	Procedures and instru	ctions for equipm	ent to be used.
V	12-23-03	24.	Standard operating pro	ocedures.	
V	12-23-03	25.	Radiation levels expec	ted from the cyclo	otron.
		26.	Cyclotron shielding.	·**	
	·····	27.	Cyclotron safety interl	ocks.	
$\overline{\checkmark}$	12-27-03	28.	Cyclotron computer c	ontrol system.	
		- 20	Crelatron emergener	procedures	

29.

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Cyclotron emergency procedures. On the job training - one month minimum (attach list of topics covered). 30.

Employee:

Instructor:

Badar

104 ____ Date: _//2/ Date: 01-02-04



~~~	Form	intion Safaty Training Desard	Form Number: RS009F	
		Radi	lation Safety I raining Record	Effective Date: 01/01/03
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	RAJ	DIAT R	ION SAFETY TRAINING RECORD Legional Nuclear Pharmaceuticals	
Employee Nam	e: Alek	sand	Lo Bardov Training for: New Employe	ee
			New Duties	
			Refresher	
			License 1 em	s
Training: Required	Date		Subject	
•		1.	Regulations for control of radiation.	· .
		_ 2.	Terms of the License.	
		3.	Radiation hazards in the workplace.	
		_ 4.	General radiation safety procedures.	
		_ 5.	The concept of ALARA.	
		_ 6.	Individual responsibility for radiation safety.	
		_ 7.	Emergency procedures.	
		- 8.	workers right to be informed.	
		- 9 . - 10	Characteristics of rediction	, correspondence.
		- 10. - 11	Units of radiation dose and quantity of radia:	ctivity
	-	- 12	Math and calculations basic to measurement	of radioactivity
		- 13.	Significance of radiation dose.	
		- 14.	Radiation protection standards.	
	-	15.	Biological effects of radiation.	
		- 16	Levels of radiation exposure from various so	irces.
		- 17.	Methods of controlling radiation dose; time,	distance and shiel
		18.	Radiation detection instruments to be used.	
		- 18. - 19.	Radiation detection instruments to be used. Operation, calibration, and limitations of sur-	vey instruments.



S	Form	Form Number: RS009F
	Radiation Safety Training Record	Effective Date: 0/07/03
	PRO Document Control QA/RA	Supersedes: N/A
		Page 2 of 2
	 21. Use of personnel monitoring equipment; findosimeters. 23. Procedures and instructions for equipment 24. Standard operating procedures. 25. Radiation levels expected from the cyclotron 26. Cyclotron shielding. 26. Cyclotron safety interlocks. 27. Cyclotron safety interlocks. 28. Cyclotron computer control system. 29. Cyclotron emergency procedures. 30. On the job training - one month minimum 	lm badges, TLDs, pock to be used. m. (attach list of topics co
mployee:	Bardon Date: 1/09/20	104

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3	Form	Radi	iation Safety Training Record	Form Number: RS009F
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			New Duties	
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			License Terr	ns
Training	7		Subject	
Required	Date			
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	4/7/04-4/8/0	41.	Regulations for control of radiation.	
√	1	2.	Terms of the License.	
<u> </u>		3.	Radiation hazards in the workplace.	
<u> </u>		4.	General radiation safety procedures.	
<u> </u>		5.	The concept of ALARA.	
<u> </u>		6.	Individual responsibility for radiation safety.	
		7.	Emergency procedures.	
<u> </u>		8.	Workers right to be informed.	
<u> </u>		9.	Location of License, regulations, application	s, correspondenc
		10.	Characteristics of radiation.	· · ·
1		_ 11	Units of radiation dose and quantity of radio	activity.
	·	12.	Math and calculations basic to measurement	of radioactivity.
<u> </u>		13.	Significance of radiation dose.	
		. 14.	Radiation protection standards.	
V		15.	Biological effects of radiation.	
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<u> </u>		18.	Radiation detection instruments to be used.	
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		21. Use of personnel monitoring equipment	nt; film badges, TLDs,
¥	2 1 <u>7104 - 41810</u> 4	21. Use of personnel monitoring equipment dosimeters.	nt; film badges, TLDs,
¥	1 <u>7/04-4/8/0</u> 4	 Use of personnel monitoring equipment dosimeters. Procedures and instructions for equipr 	nt; film badges, TLDs, nent to be used.
¥	1 <u>7/04 - 4/8/0</u> 4	 Use of personnel monitoring equipmendosimeters. Procedures and instructions for equipmendosity. Standard operating procedures. 	nt; film badges, TLDs, nent to be used.
¥	17104-418/04	 Use of personnel monitoring equipmendosimeters. Procedures and instructions for equipmendosity. Standard operating procedures. Radiation levels expected from the cyclic distribution. 	nt; film badges, TLDs, nent to be used. lotron.
¥	<u>17104 - 41810</u> 4	 Use of personnel monitoring equipmendosimeters. Procedures and instructions for equipmendosimeters. Standard operating procedures. Radiation levels expected from the cyclotron shielding. 	nt; film badges, TLDs, nent to be used. lotron.
4 <u>4</u>	1 <u>7/04 - 4/8/0</u> 4	 Use of personnel monitoring equipmendosimeters. Procedures and instructions for equipmendosimeters. Standard operating procedures. Radiation levels expected from the cyclotron shielding. Cyclotron safety interlocks. 	nt; film badges, TLDs, nent to be used. lotron.
\L	17/04-418/04	 Use of personnel monitoring equipmendosimeters. Procedures and instructions for equipmendosis. Standard operating procedures. Radiation levels expected from the cyclotron shielding. Cyclotron safety interlocks. Cyclotron computer control system. 	nt; film badges, TLDs <u>,</u> nent to be used. lotron.
\L	17104-418/04	 Use of personnel monitoring equipmendosimeters. Procedures and instructions for equipmendosimeters. Standard operating procedures. Radiation levels expected from the cyclotron shielding. Cyclotron safety interlocks. Cyclotron computer control system. Cyclotron emergency procedures 	nt; film badges, TLDs, nent to be used. lotron.

ABarolo Date: 4-8-04 Boott Lucas Date: 4-8-04 Employee: Instructor:



4-9.04 (Barda) 28/29 = 97%

1. Alpha emitters present serious hazards when:

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- b) exposed to direct sunlight
- c) placed near other radioactive materials
- d) skin is exposed to them
- 2. Plexiglas should be used when shielding high-energy beta emitters such as phosphorus-32:
 - a) to make it easier for other lab workers to see the work being done
 - b) because Plexiglas shields are easier to move than metal shields
 - () to reduce the occurrence of bremsstrahlung radiation
 - d) only when no other shielding material is available
- 3. Half-life is a measurement of:
 - (a) the amount of time necessary for a given amount of radioactive material to be reduced to one-half of its original activity.
 - b) The amount of time necessary for a given amount of radioactive material to be reduced to one-half of its original mass.
 - c) The amount of time necessary to complete an experiment using radioactive materials.
 - d) The amount of time necessary for a radioactive material to become nonradioactive.
- 4. The most common units used to express the activity of a radioactive substance are:
 - a) alpha and beta
 - b) milligrams and micrograms
 - c) Curie and Becquerel
 - d) Roentgen and Sievert
- 5. As a radiation worker, you are responsible for following safe work practices and:
 - a) knowing how to respond to a spill
 - b) maintaining survey records
 - c) securing radioactive materials
 - d) All of the above
- 6. Which of the following will show the greatest sensitivity to radiation effects?

a) An embryo exposed in utero at 8 weeks

- b) A fetus exposed in utero at 36 weeks
- c) An adolescent girl
- d) A 55-year old man

- If a group of humans are exposed to an acute dose of radiation, what dose will be 7. lethal to 50% of the group within 60 days?
 - a) Approximately 500 millirem
 - b) Approximately 400 rem
 - c) Approximately 25 rem

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- 8. What is the average radiation dose to the U.S. population (from all sources of exposure)?
 - a) 360 millirem per year
 - (b) 10 millirem per year
 - c) 5.25 rem per vear
- Nuclear Regulatory Commission regulations require that the occupational dose a 9. radiation worker received be limited to:
 - a) a whole body dose of no more than 5000 millirem per year.
 - b) A whole body dose of no more than 5000 millirem for the worker's lifetime.
 - c) A skin dose of no more than 5 millirem per year.
 - d) There are no specified dose limits. The NRC requires that a radiation worker's dose be limited to the lowest possible dose, in accordance with the ALARA philosophy.
- The TI (Transport Index) is a measure of: 10.
 - a) radiation levels inside the passenger compartment of the transport vehicle
 - b) amount of maximum radioactivity allowed per package
 - c) exposure rate as measured at 1 meter from package surface d) package integrity for withstanding accident
- 11. The rem is a unit used to measure:
 - radiation dose in terms of the amount of energy absorbed
 - b) radioactivity
 - c) radiation dose in terms of the amount of the biological effect caused by the amount of energy absorbed
 - d) radiation exposure
- X-Rays were discovered by: 12.
 - a) Curie
 - b) Edison
 - c) Bequerel
 - d)) Roentgen

13. Warning labels for transporting radioactive materials include all but:

- (a) grave danger labels
 - b) white I labels
 - c) yellow II labels
 - d) yellow III labels
- 14. The unit of absorbed dose is the:
 - a) R
 - b) rem
 - c) rad
 - d) Curie
- 15. Exposure in air is quantified by the:



16. By regulations, personnel monitoring is required for those workers likely to exceed \sqrt{O} % of annual dose limits:

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- a) .08
- b) 10
- c) 8
- d) 5
- 17. Acute radiation sickness occurs beginning at doses greater than:
 - (a) 100 rem b) 100 mrem
 - c) 7000 mrem
 - d) 300 mrem
- 18. An atom which is positively or negatively charged is referred to as being:
 - a) reverse polarity
 - b) ionized
 - c) excited
 - d) stable

- Gamma radiation is best stopped by: 19.
 - a) low Z elements concrete b)
 - high Z elements boronated plastics
- The principle ways gamma radiation interacts with matter are photoeffect, <u>Compton</u> and <u>puic</u> 20.
- 21.

NaI(TI) crystals Scintillate when exposed to gamma or X-ray radiation. 22.

- 23. GM counters are best suited to detect:
 - a) neutrons
 - gamma rays ЪÌ
 - positrons c)
 - d) alpha particles
- 24. One Curie is equal to:
 - a) 3.7×10^7 dps b) 3.7×10^8 dps c) 3.7×10^9 dps (d) 3.7 x 10¹⁰ dps
- Given 40 mC of radioactive material (half life 85 min), how much activity will 25. , remain after 400 min?



Radiation Safety Practice and Principles Aleksandr Bardov

Certificate of Training

has on this sixteenth day of June, 2004 at Regional Nuclear Pharmaceuticals, in the city of East Rutherford, New Jersey successfully completed a prescribed eight hour course of instruction and has been tested in Radiation Safety Practice and Principles

RNP, Inc. 2245-E First Street N.W. Birmingham, AL 35215

Latt Lucas

Scott Lucas Director of Operations

~~~~	Standard Operating Procedure	SOP Number A007F
	Operator Training	Effective Date 06/15/02
<u>.</u>	PRO Document Control QA/RA	Supersedes: 06/01/03

TRAINING RECORD

### Employee ALEKSANDR BARDOV

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Subject	Section	D Com	ate pleted	Hours	Train	er Employ Initia	yee Is
Accelerator Theory			e sestos gr			8 - 4 83 364 F	
	Control System Overview	6/16-	6/17/04	5	S. LUC	AS A.B	>
	User Command Files		1	1	1	A-B	•
	Interlocks and safety switches	[	1			A-B	, ,
	Vacuum system					A.B	,
	RF system					A.B	
	Cooling system	1	1			A.B	
	Magnet					A.B	
	Ion source		1			A.B	
	Beam extraction system	[				A.B	, ,
	Target systems					A.B	
	Accelerator maintenance	, ,	<u>ل</u>	T T	L L	A.B	•
	Target maintenance	6/16-	6/17/04	5	S. LUC	AS A.B	
Aseptic Processing		17. 18 J.C.	a ha				
	Controlling the environment			1	[		<u>,                                     </u>
····	Laminar flow hood maintenance	1	*				
	Sterile filter sterilization	1					
	Filter bubble test				1		
	Media fill simulation						
	Endotoxin testing	1	······		1		
cGMP, 21 CFR 210		83.3	2				
•	210.1 - Status						
	210.2 – Applicability						
	210.3 – Definitions						
Materials Control							
	Receiving and quarantine				1		
	Acceptance testing						
	First-in-first-out				1		
	Inventory control				1		
Synthesis System		The second			200		
	FDG Radiochemistry	6/16-	6/17/04	1	5. LU	AS A.B	
	Raw materials and components	S1.5	i	1	1	A. B	
	Synthesizer control system		1			A.B	
	Hardware settings and adjustments	<b></b>				p.B	
	Command files		1			A.B	
	Cleaning the system	ļ	$\downarrow$			A.B	,
•	Synthesis program	6/16-	6 ha los	1	5100	AS A.B	 >



HKaldov,

#### **CYCLOTRON/CHEMISTRY BOX TEST**

1. What is the purpose of the collimator plates?

A. for focuses dean. (2) inderactions. (beam gid.)

2. Which part(s) of the ion source are likely to wear quickly?

anode, catode.

- 3. What is replaced during a target rebuild? - target. - vaccome foi! - kelidin expling. - witton on Fing seals
- 4. The HCl reagent vessel fails to empty during a synthesis. What is the most likely compound to be seen in the R-TLC test?

unkydrolyzed product

5. The master station signals that the helium cooling system is refilling every few minutes. What does this indicate and what is usually the most common cause?

- Helium cooling pump diaphragen.

6. What are the most common reasons for a TARGET PRESSURE FAULT while filling?

- empty system

#### **CYCLOTRON/CHEMISTRY BOX TEST**

7. What are the most common reasons for the RF to fail to set STANDBY mode?

8. The compressed air pressure line fails. What will happen to the vacuum system?

HW closed. vacenne system closed too

- hight voltage and full.

9. The diffusion pump fails to heat. What is the most likely problem(s)?

air compresser doew't work

10. The ion source starts to turn on and the current increases until the cutoff setpoint is reached (approx. 1500 mA), the ion source shuts down and the error message NO BEAM ON PROBE appears. What is the most likely cause?

- proken catode.

11. How are the helium sensors bypassed if the need arises?

- Jump the septem. evited wires and connection.

12. A low yield is obtained from the synthesis box. What are some of the general steps

- chech pt in the first product - make supe all rails vorking correctly - and presence in the reaction - change bars in the reaction 10 11. Vessels. 1 1:000

NAME:	Alexsanda Bardoc			
NUMBER	TITLE	TRAINEE	TRAINER	DATE
		SIGNATURE	SIGNATURE	7/19/04
A001	Quality System Administration	Harday,	Patricialtelan	
A001F1	Document Change Request Form	J.B	A.V.	
A001F2	Document Change Order Form	A.B	PN.	
A002	Release Authority: Quality Control	A.B	P.O.	
A002F1	Quality Control Release	A.M	I.V.	
A002F2	Manufacturing Deviation Report	A.12	P.D.	
A003	Retention of Records and Samples	A.B	All	
A004	Drug Product Complaints	A.B	AN.	
A004F	Drug Product Compliant Form	A.B.	PD.	
A005	Final Product Recall	A.B	AU.	
A005F	Final Product Recall Documentation Form	A.D	P.U.	
A006	Batch Trend Analysis	A.3	P.N	
A007	Manufacturing Operator Training	A.B	AQ.	
A007F	Manufacturing Operator Training Record	A.B	P.D.	
A008	Facility Maintenance and Sanitation	A.B.	P.U.	
A008F	Facility Maintenance and Sanitation Documentation	A.B	P.O.	
A009	Facility Security	A.B	P.O.	
A010	Raw Material Control	A.B	P.U.	
A010F2	Labels	A·B	AV.	
A011	FDG Batch Control Numbers	A.B	Pla	
A012	Analytical Method Validation	A.B	Y.V.	
A014	How to Write a Standard Operating Procedure	F.D	P.V.	
A015	Quality Awareness Training Record	A.B	Y.11_	
A017	GMP and Quality System Training	A.M	L.V.	
A017F1	Quality Awareness Training Record	K.B	1.Va_	
A017F2	Employee Training Requirements	A.B	<i>4.0</i>	
A018	Document and Data Control	4.B	20,	_
A019	Product Recall	A.B	P.U.	
E001	Bioburden	J.B	All.	
E001F	Bioburden Data Summary	A.D	140.	

7/16/04

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		<i>b b</i>	
E002	Radiochromatography Scanner	A. 15	<u> </u>
E003	Gas Chromatograph	A.S	P.D.
E004	Multichannel Analyzer	A.B.	£10.
M001	Manufacturing Instructions - ¹⁸ FDG	A.B	P.D.
M001F1	Fludeoxyglucose [ ¹⁸ F] Injection Batch Record PETtrace	A.B	P.N.
M001F2	Fludeoxyglucose [ ¹⁸ F] Injection Batch Record RDS-111 NI		NA
M001F3	Fludeoxyglucose [ ¹⁸ F] Injection Batch Record RDS-111 Coincidence		N/A
M001F4	Fludeoxyglucose [ ¹⁸ F] Injection Batch Record MINItrace		NIA
M001F5	Fludeoxyglucose [ ¹⁸ F] Injection Batch Record PETtrace with Coincidence Synthesis		NA
M002	Asceptic Processing	A.B	PR.
M003	Packaging, Labeling and Distribution	A.D	$\mathcal{P}$
M004	MINItrace Manufacturing Instructions - [ ¹⁸ F]F	A.B	NIA
M005	RDS-111 Manufacturing Instructions - [18F]F		WIA
M006	PETtrace Manufacturing Instructions - [ ¹⁸ F]F	A.B	P.V.
M007F	Manufacturing Incident Report	\$-B	P.D
M008	MINItrace Target and Delivery Line Maintenance		NIA
M009	PETtrace Target and Delivery Line Maintenance	A-B	P.Q
M010	RDS-111 Target and Delivery Line Maintenance		NA
M011	Potassium Carbonate, 6mg/ml, Solution	A-B	AU I
M011F	Potassium Carbonate, 6mg/ml, Solution, Data Summary	A.B	RU.
M012	Pharmacy Packaging, Labeling and Distribution	A.B	P.D.
M013	Finished Product Released for Distribution Under Quarantine	A. B	P.Q.
M014F1	RDS-111 Pre-Installation Check log		NIA
M014F2	RDS-111 Post-Installation Check log		NA
M015	Reagent Kit Assembly		NIA
M015F	Reagent Kit Assembly Log		NIA
Q001	[ ¹⁸ O]H ₂ O Acceptance	A.B	AQ.
Q002	Kryptofix Acceptance	A. 5	A.V.
Q003	Mannose Triflate Acceptance	A.B	f.V.
Q004	Vial, Sterile, 30 ml	H.D	f.Vn
Q005	Sodium Chloride Injection, 0.9% Acceptance	HIB	1.0
Q006	Sodium Chloride Injection, 4 mEq/ml, Acceptance	A.B	P.N.

			and the second	
Q008	Potassium Carbonate, Acceptance	A.H	P.U.	
Q010	Acetonitrile, Anhydrous Acceptance	H.B	P.V.	
Q011	HCL, 1N Acceptance	4.B	PN	
Q012	Ethyl Alcohol Acceptance	H.B	P.D.	
Q013	¹⁸ F Separation Column Acceptance	A.B	P.Q	
Q021	Vented Filter, 22µm, Acceptance	A.B	PQ.	
Q022	Filter, 22 µm, 25mm o.d. Acceptance	A.15	PD.	
Q023	Filter, 22 µm, 4mm o.d. Acceptance	A.B	PD.	
Q051	Acetonitrile, HPLC Acceptance	A.B	P.D	
Q053	Acetone Acceptance	A.M	7.Q	
Q061	Sodium Carbonate Acceptance	A.B	PN	
Q093	Confirmation of LAL Label Claim Sensitivity	A.B	<u>ID</u>	
Q093F	LAL Label Claim Sensitivity Data Summary	A.12	<u>, A</u>	
Q100	Radiochemical Identity & Purity R-TLC	A.B	P.C.	
Q100F	Radiochemical Identity & Purity Data Summary	A.B	Î.	
Q101	Chemical Purity Residual Solvent GC	A.B	P.D.	
Q101F	GC Data Summary	A.B	I PR	
Q102	Chemical Purity K-TLC	A.B	I.V.	<u> </u>
Q102F	Chemical Purity K-TLC Data Summary	A.B	P.N.	
Q103	Determination of FDG Radionuclidic Identity - T 1/2	A.B	f.D.	
Q103F	Determination of FDG Radionuclidic Identity - T 1/2 Data Summary	t.B	PN	
Q104	Bacterial Endotoxin Testing	A. B	IN.	
Q104F	Bacterial Endotoxins Test Data Summary	A.B	PU	
Q105	pH Test	A.B	1.0	
Q105F	pH Test Data Summary	A.B	P.V.	
Q106	Radionuclidic Purity - MCA	K.D	LO.	
Q107	Final Product Sterility Testing	A.B	P.N.	
Q107F	Final Product Sterility Testing Data Summary	A.B	<u>LO</u>	
Q108	Sterilizing Filter Test - Bubble Point	A.B	<i><u><u> </u></u></i>	
Q108F	Sterilizing Filter Test - Bubble Point Data Summary	A.B	Pla	
Q109	Visual Inspection of Final Product	A.B	LAN.	
Q110	Non Conformance	A.B.	P.A.	
Q110F	Non Conformance Report Form	A.B.	P.N.	
0111	Aseptic Assembly of Final product Vial	A.B	P.N.	

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#### MANUFACTURING SOP TRAINING RECORD

Q112F	Temperature Log	A.B	P.D.	
Q113	Glassware Depyrogenation	A-B	PQ.	
Q201	Preparation of GC Standard Solution	A.B	P.Q	
Q301	LAL - Determination of the Non-Interfering Concentration	A.B	IN	
Q301F	LAL - Determination of the Non-Interfering Concentration Data Summary	\$.07	AQ.	
Q406	Aseptic Processing Training	A.17	P.V.	
Q406F	Aseptic Processing Training Data Summary	A.D	AD.	
Q501	Multichannel Analyzer Calibration	A.B	P.N.	
Q501F	Multichannel Analyzer Calibration Data Summary	1.3	$\mathcal{P}$	
Q502	Analytical Balance Maintenance	A.B	P.O.	
Q502F	Analytical Balance Maintenance Log*	A.B	P.Q.	
Q504	Final Product Re-filtering	J.B	PA.	
Q505	Radiopharmaceutical Stability Testing	A.B	P.O.	
Q511	Dose Calibrator Accuracy	A.13	P.D.	
Q512	Dose Calibrator Constancy	A.B	<i>P.O.</i>	
Q513	Dose Calibrator Linearity	A-B	-20_	
Q514	Dose Calibrator Geometry	A.B	<i>40.</i>	
Q515F	Acceptance of Responsibility	A.B	P.O.	
Q516	Cleaning of the Hot Cell	A.B	<i>P.O.</i>	
Q516F	Hot Cell Cleaning Log	A.B	AD.	
Q5.17	Cyclotron Preventive Maintenance	A-B	PO.	
Q518	Stock Recovery	A.B	P.U.	

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#### **Regional Nuclear Pharmaceuticals**

	Continuing Educatio	n/Radiation Safety Lo	og File	
Date	Description of CE	Name (Print)	Signature	
	Accs, Q004, Q100,	Daniel Fernandez	Much	
r	RS013, SB050, SB076,	Aleksandr Bardov	Barda,	
6-18-04	56087, 5B088, 5B102,	Chuck Tolavico	Churthans	
	SB103, SB112;			
·	ADDI, ADDIEL, ADD4	Daniel Formanloz	Dutters	
	Q112F, QSO7,QSO2F	Araire a legar dor	ABart	
8-16-04	Q 505, Q 513, Q 515 + A 5017, R5020, R5020 FL 58020	ALERSANDI RUBAUV		
	58021,58032-1,58033-1	CHVER JOLDSICU	Murgen	
	58034-1,58035-1,58085 58090,58091.58125	a si canalaz	Dutter	
	10	Vaniel restrances	Bergen	
8-18-04	M002, 25.012	HLEKSandy Bardov		
		Chuck Talariro	(len Clans	
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II. a. Daniel Fernandez's Training and Experience Summary

#### **Daniel Fernandez** TRAINING AND EXPERIENCE

	CLASSROOM	LABORTORY	PLACE/	
DATES	HOURS	HOURS	TRAINER	SUBJECT
2/2/2004	8		RNP of New Jersey - Charles S. Talarico	Cyclotron Theory and Operation
3/15/04 - 3/26/04	58		RNP of New Jersey - Charles S. Talarico	Cyclotron Maintenance
2/23/2004	8		RNP of New Jersey - Charles S. Talarico	Materials Control
2/10/04 - 2/19/04	61		RNP of New Jersey - Charles S. Talarico	Quality Control
2/3/04 - 2/6/04	20		RNP of New Jersey - Charles S. Talarico	Radiation Safety
6/8/2004	40		RNP of Birmingham - Cecil Knight	Radiation Safety
4/7/04 - 4/8/04	8		RNP of New Jersey - Scott Lucas	Radiation Safety
6/16/04 - 6/17/04	6		RNP of New Jersey - Scott Lucas	Radiopharmaceutical Manufacturing
6/18/2004	4		RNP of New Jersey - Self	Continuing Education
7/19/04 - 7/23/04	20		RNP of New Jersey - Patricia Owens	SOP Training
8/16/2004	4		RNP of New Jersey - Self	Continuing Education
8/18/2004	4		RNP of New Jersey - Self	Continuing Education
2/2/04 - 10/8/04		1280	RNP New Jersey lab operations experience	FDG Production & Laboratory Operation
TOTAL HOURS	241	~ 1280		
GRAND TOTAL	*	1521 hours of train	ning and Lab Experience	updated: 10/08/04

II. b. Daniel Fernandez's Training Documentation

REG	IONAL N	<b>JUCLEAR PHARMACEUT</b>	ICALS
<u>.</u>	Form	diation Safety Training Record	Form Number: RS009F
		Effective Date: 01/07/03	
	pro <i>landel M</i>	Document Control QA/RA	Supersedes:
			Page 1 of 2
	RADIA	<b>LION SAFETY TRAINING RECORD</b> Regional Nuclear Pharmaceuticals	
Employee Nam	ue: <u>Daniel</u>	Fernandez Training for: New Employ New Duties Refresher License Terr	ns
Training: Required	Date	Subject	
	2-3-04 1.	Regulations for control of radiation.	
	$\frac{2-5-04}{2-5-04}$ 2	Terms of the License. Rediation hazards in the workplace	
	2-3-04 4.	General radiation safety procedures.	
	2-4-04 5.	The concept of ALARA.	
	2-4-04 6.	Individual responsibility for radiation safety.	
· · · ·	2-4-04 7.	Emergency procedures.	
	8.	Workers right to be informed.	
	2-5-0+ 9	Characteristics of radiation	s, correspondence.
	2 5 -04 10	Units of radiation dose and quantity of radio	activity.
	2-5-04 12	Math and calculations basic to measurement	of radioactivity.
	13	Significance of radiation dose.	· · · · · · · · · · · · · · · · · · ·
	14	. Radiation protection standards.	
	15.	Biological effects of radiation.	
	16	Levels of radiation exposure from various so	ources.
	17.	Methods of controlling radiation dose; time,	distance and shield
	2-6-04 18	Radiation detection instruments to be used.	
	2-6-04 19	Operation, calibration, and limitations of sur	vey instruments.
<u> </u>	2-6-04 20.	Survey techniques.	



<u>.</u>	Form	Form Number: RS009F	
		adiation Safety Training Record	Effective Date: 0//07/03
	PRO	Document Control QA/RA	Supersedes:
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			Page 2 of 2
	~	M IT'S C. I I I I MA	
	2-2-04	dosimeters	n badges, TLDs, pocket
V	2-6-04 2	<ol> <li>Procedures and instructions for equipment t</li> </ol>	o be used
	2-4-04 2	24. Standard operating procedures.	
	2-3-04 2	5. Radiation levels expected from the cyclotror	1.
	2	6. Cyclotron shielding.	
	2	7. Cyclotron safety interlocks.	
	2	28. Cyclotron computer control system.	
	2	9. Cyclotron emergency procedures.	
·····	3	0. On the job training - one month minimum (	attach list of topics cover
	A #7		
mployee: <u>(</u>	Stuppe	Date: 2-9-04	
-	$\sim \alpha$		-

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	Standard Operating Procee	dure	· · ·	SOP Number:
	Radiopharmaceutical Manufacturing Operator Training		nufacturing ng	A007F Effective Date: 06/15/03
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#### TRAINING RECORD

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Subject	Section	Date Completed	Hours	Trainer	Employee Initials
Accelerator Theory					
	Control System Overview	- 2-2-04	8	CST	DF
	User Command Files		1	1	
	Interlocks and safety switches				1
· · · · · · · · · · · · · · · · · · ·	Vacuum system				1
	RF system				
	Cooling system			V	y
	Magnet	2-2-04	V	CST	DF
	Ion source			······	
	Beam extraction system				
	Target systems				
	Accelerator maintenance				
	Target maintenance				
Aseptic Processing					
	Controlling the environment				
	Laminar flow hood maintenance				
	Sterile filter sterilization				
	Filter bubble test			]	
	Media fill simulation				
	Endotoxin testing				
cGMP, 21 CFR 210		<b>来我们在我们的</b>		San Carlos	
•	210.1 Status		·····		
	210.2 - Applicability				
	210.3 – Definitions				
Materials Control					
	Receiving and quarantine	2-23-04	8	CST	DE
	Acceptance testing		1		1
	First-in-first-out				N.
	Inventory control	2-23-04		est	DA
Synthesis System			1. S. K. S. A. A.		States and
	FDG Radiochemistry		and the second second		<u>,</u>
	Raw materials and components				
	Synthesizer control system				
	Hardware settings and adjustments			<u> </u>	1
******	Command files			<u></u>	
······································	Cleaning the system				1
······································	Synthesis program	[	<b> </b>		



REC	GIONAL NUCLEAR PHARMACEUT	ICALS
•	Standard Operating Procedure	SOP Number: A007F
	Radiopharmaceutical Manufacturing Operator Training	Effective Date: 06/15/03
	PRO Document Control QA/RA	Supersedes: 06/01/03

Page 2 of 2

Subject	Section	Date	Hours	Trainer	Employee
		Completed			Initials
Quality control					
	Sampling	2-10-04	2:.	CST	DF
	Reserve samples		2	4	N.
	Specific concentration	2-10-04	2	CST	DF
	Sterility test	2-11-04	8.	CST	NF
	LAL pyrogen test	2-13-04	8.	CST	DE
	Radiochemical purity, Radio-TLC	212-04	8.	CST	DF
	Chemical purity, Kryptofix TLC	2-16-04	8	CST	DE
	Solvents, Gas Chromatography	2-14-04	8	COT	DF
	Radionuclidic Identity, half-life	2-18-04	2	CST	D5
·	Radionuclidic purity, MCA	2-17-04	8.	CST	DF
	pH determination	2-18-04	{·	CST	DE
	Isotonicity		1:		J
	Visual inspection		۱	cšt	ØF
	Manufacturing trend analysis	2-19-04	2	C>T	DF
CGMP, 21 CFR 211					
	Subpart A – General				
	Subpart B - Organization & Personnel				
	Subpart C - Buildings & Facilities				
	Subpart D - Equipment				
	Subpart E – Control of Components				
	Subpart F – Production/Process Control				
	Subpart G – Packaging & Labeling				
	Subpart H - Holding & Distribution				
	Subpart I Laboratory Controls				
	Subpart J - Records & Reports				ļ
	Subpart K - Returns & Salvage				
PEI Radiopharmaceuticals				· · · · · · ·	
	Compliance Guidelines				

Standard Operating Procedure	SOP Number:
Radiopharmaceutical Manufacturing Operator Training	A007F Effective Date: 06/15/03
PRO Document Control OA/RA	Supersedes: 06/01/03

TRAINING RECORD

Page 1 of 2 =

Employee Daniel Fe	rhandez
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Subject	Section	Date Completed	Hours	Trainer	Employee Initials
Accelerator Theory					
	Control System Overview				
	User Command Files				
	Interlocks and safety switches				
	Vacuum system				
	RF system				
	Cooling system	3-15-04	8	CST	DF
	Magnet				
	Ion source	3-16-04	10	CST	DF
	Beam extraction system		10	1	1
	Target systems	1	(0)		
	Accelerator maintenance		10		
	Target maintenance	2-26-04	10		DF
Aseptic Processing			100 A		
	Controlling the environment	4-2-04	8	CST	OF
	Laminar flow hood maintenance		Ĭ		
	Sterile filter sterilization				
	Filter bubble test			11	
	Media fill simulation				N N
	Endotoxin testing	4-3-04		CST	DE
cGMP, 21 CFR 210				1	
•	210.1 - Status				
	210.2 - Applicability				
	210.3 – Definitions				
Materials Control		e. Mier Marse	State of a		NUMBER OF STR
	Receiving and quarantine			1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.	
	Acceptance testing			······	
	First-in-first-out				<u> </u>
	Inventory control				
-Synthesis System					S 224514 1933
	FDG Radiochemistry	and the a second statement of the second state	1.12-12-12-12-12-12-12-12-12-12-12-12-12-1		C. AT STREET STREET AND THE CONST.
	Raw materials and components				
	Synthesizer control system				
	Hardware settings and adjustments			·	
	Command files				
	Cleaning the system				1
	Synthesis program				



REG	IONAL N	UCLEAR PHARMACEUT	<b>FICALS</b>
	Form		Form Number: RS009F
	Rad	iation Safety Training Record	Effective Date: 01/07/03
i A.S	PRO Randel Ma	Document Control QA/RA	Supersedes:
	,		Page 1 of
	RADIAT F	<b>ION SAFETY TRAINING RECORD</b> Regional Nuclear Pharmaceuticals	
Employee Nar	ne: <u>DANIEL</u> F	ERNANDEZ Training for: New Emplo New Duties Refresher License Ter	byee
Taciala		Subject	
Required	Date	Subject	
	4/7/04-4/8/041.	Regulations for control of radiation.	
	2.	Terms of the License.	
	3.	Radiation hazards in the workplace.	
	4.	General radiation safety procedures.	
	5.	The concept of ALARA.	,
		Individual responsibility for radiation safet	y.
		Emergency procedures.	
<u>_</u>		Logation of Ligona completions application	ne correctiondence
	<u> </u>	Characteristics of radiation	iis, conceptindence
<u>`</u>		Units of radiation dose and quantity of rad	ioactivity.
		Math and calculations basic to measurement	nt of radioactivity.
V-,	13.	Significance of radiation dose.	
		Radiation protection standards.	
	14.		
	14.	Biological effects of radiation.	
	14. 15. 16	Biological effects of radiation. Levels of radiation exposure from various	sources.
	14. 15. 16 17.	Biological effects of radiation. Levels of radiation exposure from various Methods of controlling radiation dose; time	sources. e, distance and shiel
	14. 15. 16 17. 18.	Biological effects of radiation. Levels of radiation exposure from various Methods of controlling radiation dose; tim Radiation detection instruments to be used	sources. e, distance and shiel
	14. 15. 16 17. 18. 19.	Biological effects of radiation. Levels of radiation exposure from various Methods of controlling radiation dose; tim Radiation detection instruments to be used Operation, calibration, and limitations of st	sources. e, distance and shiel urvey instruments.



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		mation Safety Training Record	Effective Date: 01/07/03
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			Page 2 of 2
	,	1 TOLEDUIES WRITISTIC DUITS TOT PUBLICATION	t to be used
	24. 25. 26. 27. 28. 28.	 Standard operating procedures. Radiation levels expected from the cyclotr Cyclotron shielding. Cyclotron safety interlocks. Cyclotron computer control system. 	it to be used. on.
	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	 Standard operating procedures. Radiation levels expected from the cyclotre Cyclotron shielding. Cyclotron safety interlocks. Cyclotron computer control system. Cyclotron emergency procedures. On the job training - one month minimum 	it to be used. ion. n (attach list of topics co



Daniel ternance & 4-8-04

 $\frac{26}{29} = 90\%$

1. Alpha emitters present serious hazards when:

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- (a)) inhaled, ingested, or injected
- b) exposed to direct sunlight
- c) placed near other radioactive materials
- d) skin is exposed to them
- 2. Plexiglas should be used when shielding high-energy beta emitters such as phosphorus-32:
 - a) to make it easier for other lab workers to see the work being done
 - b) because Plexiglas shields are easier to move than metal shields
 - (c) to reduce the occurrence of bremsstrahlung radiation
 - d) only when no other shielding material is available
- 3. Half-life is a measurement of:
 - (a) the amount of time necessary for a given amount of radioactive material to be reduced to one-half of its original activity.

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- b) The amount of time necessary for a given amount of radioactive material to be reduced to one-half of its original mass.
- c) The amount of time necessary to complete an experiment using radioactive materials.
- d) The amount of time necessary for a radioactive material to become non-radioactive.
- 4. The most common units used to express the activity of a radioactive substance are:
 - a) alpha and beta
 - b) milligrams and micrograms
 - C Curie and Becquerel
 - d) Roentgen and Sievert
- 5. As a radiation worker, you are responsible for following safe work practices and:
 - a) knowing how to respond to a spill
 - b) maintaining survey records
 - c) securing radioactive materials
 - (d) All of the above
- 6. Which of the following will show the greatest sensitivity to radiation effects?
 - (a) An embryo exposed in utero at 8 weeks
 - b) A fetus exposed in utero at 36 weeks
 - c) An adolescent girl
 - d) A 55-year old man

- 7. If a group of humans are exposed to an acute dose of radiation, what dose will be lethal to 50% of the group within 60 days?
 - a) Approximately 500 millirem
 - b) Approximately 400 rem
 - c) Approximately 25 rem

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- 8. What is the average radiation dose to the U.S. population (from <u>all</u> sources of exposure)?
 - (a) 360 millirem per year
 - b) 10 millirem per year
 - c) 5.25 rem per year
- 9. Nuclear Regulatory Commission regulations require that the occupational dose a radiation worker received be limited to:
 - (a) a whole body dose of no more than 5000 millirem per year.
 - b) A whole body dose of no more than 5000 millirem for the worker's lifetime.
 - c) A skin dose of no more than 5 millirem per year.
 - d) There are no specified dose limits. The NRC requires that a radiation worker's dose be limited to the lowest possible dose, in accordance with the ALARA philosophy.
- 10. The TI (Transport Index) is a measure of:
 - a) radiation levels inside the passenger compartment of the transport vehicle
 - b) amount of maximum radioactivity allowed per package
 - (c) exposure rate as measured at 1 meter from package surface
 - d) package integrity for withstanding accident
- 11. The rem is a unit used to measure:

(a) radiation dose in terms of the amount of energy absorbed

- b) radioactivity
- c) radiation dose in terms of the amount of the biological effect caused by the amount of energy absorbed
- d) radiation exposure
- 12. X-Rays were discovered by:



13. Warning labels for transporting radioactive materials include all but:

- (a) grave danger labels
- b) white I labels
- c) yellow II labels
- d) yellow III labels
- 14. The unit of absorbed dose is the:



15. Exposure in air is quantified by the:



By regulations, personnel monitoring is required for those workers likely to exceed % of annual dose limits:

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- 17. Acute radiation sickness occurs beginning at doses greater than:
 - (a) 100 rem
 - b) 100 mrem
 - c) 7000 mrem
 - d) 300 mrem

18. An atom which is positively or negatively charged is referred to as being:

a) reverse polarity

(b) ionized

- c) excited
- d) stable

- 19. Gamma radiation is best stopped by:
 - a) low Z elements
 - b) concrete

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- c) high Z elements
- d) boronated plastics
- 20. The key to effective radiation protection is <u>Distounce</u>, <u>Time</u>, and <u>Shield</u>.
- 21. The principle ways gamma radiation interacts with matter are <u>*Photodectric*</u>, <u>Scottering</u> and <u>*Porty*</u>.
- 22. NaI(Tl) crystals <u>florece</u> when exposed to gamma or X-ray radiation.
- 23. GM counters are best suited to detect:
 - a) neutrons
 - b) gamma rays
 - c) positrons
 - d) alpha particles
- 24. One Curie is equal to:
 - a) 3.7×10^7 dps b) 3.7×10^8 dps c) 3.7×10^9 dps
 - (d) $3.7 \times 10^{10} \text{ dps}$
- 25. Given 40 mC of radioactive material (half life 85 min), how much activity will remain after 400 min?

X

- a) 14.5 mC
- b) 4.8 mC
- (c) 1.5 mC
- d) 670 μC

Certificate of TRUIN

Ward Ward In Ward Star Ward St

Radiation Safety Practice and Principles *Daniel Fernandez*

has on this eighth day of June, 2004 at Regional Nuclear Pharmaceuticals, in the city of Birmingham, Alabama successfully completed a prescribed course of instruction and has been tested in Radiation Safety Practice and Principles

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RNP, Inc. 2245-E First Street N.W. Birmingham, AL 35215

Ceild Knift

Cecil D. Knight, Jr., MSPH, RRPT RNP, Inc. Radiation Safety Officer

		ICILLO
(fr)	Radiopharmacentical Manufacturing	SOP Number: A007F
	Operator Training	Effective Date 06/15/03
0.0.1	PRO Document Control OA/RA	Supersedes: 06/01/03

TRAINING RECORD

Page 1 of 2

Employee DANIEL FERNANDEZ

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Subject	Section	Cor	Date mpleted	Hours	Trainer	Employee	
Accelerator Theory					· · · · · · · · · · · · · · ·		
	Control System Overview	6/16	-6/17/04	r c	C INCAS	1 AF	
	User Command Files	10/10	UNITOT]	J. LUCH		
	Interlocks and safety switches	+			<u> </u>	+	
	Vacuum system	<u> </u>			+	+	
······································	RF system		1	<u>├</u>	<u> </u>	+ <i> </i>	
	Cooling system	1	1	┠───┣────	+	+	
	Magnet		1		┼──┼───		
	Ion source	<u> </u>			<u> </u>	┼	
	Beam extraction system	1	1	├ ── ┠───	<u>├</u>	·	
	Target systems	<u> </u>			┼──┼───	·	
	Accelerator maintenance	t	£				
	Target maintenance	6116-	-1. 117/Ali	<u> </u>	CLUCAS	- OF	
Aseptic Processing		0.00	0/1/04	an a the state	J. LULA		
	Controlling the environment	1.1.2 1.1.24	A REAL PROPERTY.) MARCELL GRADE	
	Laminar flow hood maintenance	<u> </u>	·····				
	Sterile filter sterilization						
	Filter bubble test						
	Media fill simulation						
	Endotoxin testing	<u> </u>					
cGMP, 21 CFR 210		an Franka	a talénté		Alexandra Alexandra	and the second second	
4	210.1 - Status	i de la cela	1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 1949 - 194			A CARLER GALLER SALLER	
	210.2 - Applicability					[
	210.3 – Definitions						
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	Receiving and quarantine	arende se	ાય તે સંસ્થાને મેં તે તે છે.				
	Acceptance testing						
	First-in-first-out						
	Inventory control						
Synthesis System		Red Stri	20520000	The second second			
	FDG Radiochemistry	6 111 -	1 1.71 1.10	1			
	Raw materials and components	0/10	PRIMA		J. LUCHS	1 25	
-	Synthesizer control system		<u>+</u> +				
	Hardware settings and adjustments		╉───┤		 		
	Command files		╉╼╼╾┥				
······	Cleaning the system		<u>}</u> ,			,	
	Synthesis program	The Y	V 157 Jak		¥		
	- Jan Program	M/10*	NUICH		S LUCAS	1 1211	



6-17-04

CYCLOTRON/CHEMISTRY BOX TEST

1. What is the purpose of the collimator plates?

Focus the Beam, Beam Direction. "Feedback for guiding the beam"

- 2. Which part(s) of the ion source are likely to wear quickly? Catodes
- 3. What is replaced during a target rebuild?

-Target Foils "Body, Helium vacuum" - Helicoflex seals. -rubber viton 0 pings seals.

4. The HCl reagent vessel fails to empty during a synthesis. What is the most likely compound to be seen in the R-TLC test?

- unhydrolized Product.

5. The master station signals that the helium cooling system is refilling every few minutes. What does this indicate and what is usually the most common cause?

-Herium cooling pump draphragm

6. What are the most common reasons for a TARGET PRESSURE FAULT while filling?

-No water in the target.

-Helicoflex seal.

CYCLOTRON/CHEMISTRY BOX TEST

- 7. What are the most common reasons for the RF to fail to set STANDBY mode? - High Voltage and fore.
- 8. The compressed air pressure line fails. What will happen to the vacuum system? HVV CLOSES, and vacuum system shuts down
- 9. The diffusion pump fails to heat. What is the most likely problem(s)? Failure on compressor Line.
- The ion source starts to turn on and the current increases until the cutoff setpoint is reached (approx. 1500 mA), the ion source shuts down and the error message NO BEAM ON PROBE appears. What is the most likely cause?
- 11. How are the helium sensors bypassed if the need arises? Jump the circuit. Short the two conductors to close the circuit.
- 12. A low yield is obtained from the synthesis box. What are some of the general steps one would go through to troubleshoot the problem?
 -Check the precessure of the reaction Vioil.
 make sure out the values are working Correctly, by Looking.
 make sure out the reagent viols and Elecring that they all empfy.
 Gheck Helium pressure.
 Check all of the lines for leaks or wips

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NAME:	DANKL E. FERNANDEZ			
NUMBER	TITLE	TRAINEE SIGNATURE	TRAINER SIGNATURE	DATE 7/19/04
A001	Quality System Administration	ather	Patricial del	La .
A001F1	Document Change Request Form	Df	ДŊ.	
A001F2	Document Change Order Form	DF	PN.	
A002	Release Authority: Quality Control	Dr	Al.	
A002F1	Quality Control Release	DF	PD:	
A002F2	Manufacturing Deviation Report	DF	PU.	
A003	Retention of Records and Samples	DF	AV.	
A004	Drug Product Complaints	Df	PD.	
A004F	Drug Product Compliant Form	Øf	AN.	
A005	Final Product Recall	DE	P.D.	
A005F	Final Product Recall Documentation Form	ÐF	ĻQ.	
A006	Batch Trend Analysis	ÐÐ	PDo	
A007	Manufacturing Operator Training	DE.	A.	
A007F	Manufacturing Operator Training Record	DF	<i>40</i>	
A008	Facility Maintenance and Sanitation	ĐF	40	
A008F	Facility Maintenance and Sanitation Documentation	ØF	AU.	
A009	Facility Security	DF	A.D.	
A010	Raw Material Control	sOF	P.O.	
A010F2	Labels	DF	A.V.	
A011	FDG Batch Control Numbers	DF	P.Q.	
A012	Analytical Method Validation	ØF	A.V.	
A014	How to Write a Standard Operating Procedure	£	P.V.	
A015	Quality Awareness Training Record	ØF	A.U.	
A017	GMP and Quality System Training	ØF	P.0 .	
A017F1	Quality Awareness Training Record	ØF	P.U.	
A017F2	Employee Training Requirements	ØF	4.0.	
Å018	Document and Data Control	DF	7.0-	
A019	Product Recall	ØF	<i>4.0.</i>	
E001	Bioburden	DF	P.O.	
E001F	Bioburden Data Summary	OF	1 AN	

7/16/04

MANUFACTURING SOP TRAINING RECORD

E002	Radiochromatography Scanner		A. Da	DF
E003	Gas Chromatograph		Y.V.	DF
E004	Multichannel Analyzer		AU.	DF
M001	Manufacturing Instructions - ¹⁸ FDG		AV.	.OF
M001F1	Fludeoxyglucose [¹⁸ F] Injection Batch Record PETtrace		All	DF
M001F2	Fludeoxyglucose [¹⁸ F] Injection Batch Record RDS-111 NI		N/A	
M001F3	Fludeoxyglucose [¹⁸ F] Injection Batch Record RDS-111 Coincidence		NIA	
M001F4	Fludeoxyglucose [¹⁸ F] Injection Batch Record MINItrace		NIA	
M001F5	Fludeoxyglucose [¹⁸ F] Injection Batch Record PETtrace with Coincidence Synthesis		N/A	
M002	Asceptic Processing		PR.	DF
M003	Packaging, Labeling and Distribution		P.D	OF
M004	MINItrace Manufacturing Instructions - [¹⁸ F]F		NIA	
M005	RDS-111 Manufacturing Instructions - [18F]F		IV/A	
M006	PETtrace Manufacturing Instructions - [¹⁸ F]F		PQ.	OF
M007F	Manufacturing Incident Report		PA	DF
M008	MINItrace Target and Delivery Line Maintenance		NIA	
M009	PETtrace Target and Delivery Line Maintenance		JA.	DF
M010	RDS-111 Target and Delivery Line Maintenance		NÍA	
M011	Potassium Carbonate, 6mg/ml, Solution		P.Q.	DF
M011F	Potassium Carbonate, 6mg/ml, Solution, Data Summary		AR.	DF
M012	Pharmacy Packaging, Labeling and Distribution		P.Q.	DF
M013	Finished Product Released for Distribution Under Quarantine		P.Q.	DF
M014F1	RDS-111 Pre-Installation Check log		/x/A	
M014F2	RDS-111 Post-Installation Check log		/A	
M015	Reagent Kit Assembly		NA	
M015F	Reagent Kit Assembly Log		NIA	
Q001	[¹⁸ O]H ₂ O Acceptance		PQ.	OF
Q002	Kryptofix Acceptance		<u>IN</u>	aOF
Q003	Mannose Triflate Acceptance		<u>PA</u>	DF
Q004	Vial, Sterile, 30 ml		P.U	OF
Q005	Sodium Chloride Injection, 0.9% Acceptance		<u> 211</u>	#OF
Q006	Sodium Chloride Injection, 4 mEq/ml, Acceptance		HA.	DF

MANUFACTURING SOP TRAINING RECORD

Q008	Potassium Carbonate, Acceptance	P.Q.	-0F
Q010	Acetonitrile, Anhydrous Acceptance	P.U.	DF
Q011	HCL, 1N Acceptance	A.V.	DP
Q012	Ethyl Alcohol Acceptance	P.N.	ØF
Q013	¹⁸ F Separation Column Acceptance	AU.	DF
Q021	Vented Filter, 22µm, Acceptance	PD.	.OF
Q022	Filter, 22 µm, 25mm o.d. Acceptance	P.D.	D5-
Q023	Filter, 22 µm, 4mm o.d. Acceptance	A.D.	DF
Q051	Acetonitrile, HPLC Acceptance	P.O.	ØF
Q053	Acetone Acceptance	AD	ØF
Q061	Sodium Carbonate Acceptance	P.V.	DF
Q093	Confirmation of LAL Label Claim Sensitivity	PIV.	.OF
Q093F	LAL Label Claim Sensitivity Data Summary	P.D.	OF
Q100	Radiochemical Identity & Purity R-TLC	AU.	.DF
Q100F	Radiochemical Identity & Purity Data Summary	AN .	OF
Q101	Chemical Purity Residual Solvent GC	P.W.	DF
Q101F	GC Data Summary	P.O.	DF
Q102	Chemical Purity K-TLC	PN.	DF
Q102F	Chemical Purity K-TLC Data Summary	P.O.	DF
Q103	Determination of FDG Radionuclidic Identity - T 1/2	P.U.	DF
Q103F	Determination of FDG Radionuclidic Identity - T 1/2 Data Summary	P.O.	OF
Q104	Bacterial Endotoxin Testing	PD.	DF
Q104F	Bacterial Endotoxins Test Data Summary	PO	DF
Q105	pH Test	PR.	DF
Q105F	pH Test Data Summary	P.O.	DG
Q106	Radionuclidic Purity - MCA	Phi	DE
Q107	Final Product Sterility Testing	P.V.	DE
Q107F	Final Product Sterility Testing Data Summary	P.V.	DE
Q108	Sterilizing Filter Test - Bubble Point	L.O.	DF
Q108F	Sterilizing Filter Test - Bubble Point Data Summary	P.O.	205
Q109	Visual Inspection of Final Product	P.V.	ØF
Q110	Non Conformance	P.N.	DF
Q110F	Non Conformance Report Form	LI,	DF
Q111	Aseptic Assembly of Final product Vial	<u>PO.</u>	DF

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MANUFACTURING SOP TRAINING RECORD

Q112F	Temperature Log	P.N.	DF
Q113	Glassware Depyrogenation	AU.	DF
Q201	Preparation of GC Standard Solution	P.V.	<i>OF</i>
Q301	LAL - Determination of the Non-Interfering Concentration	Y.N.	\$){-
Q301F	LAL - Determination of the Non-Interfering Concentration Data Summary	-AR	D F
Q406	Aseptic Processing Training	Ĥ.	DC
Q406F	Aseptic Processing Training Data Summary	P.V.	DE
Q501	Multichannel Analyzer Calibration	P.O.	Ø¢
Q501F	Multichannel Analyzer Calibration Data Summary	<i>4.0</i>	DF
Q502	Analytical Balance Maintenance	A.O.	DE
Q502F	Analytical Balance Maintenance Log	AN.	DF
Q504	Final Product Re-filtering	<i>4.0.</i>	1)F
Q505	Radiopharmaceutical Stability Testing	4.0.	DF
Q511	Dose Calibrator Accuracy	<u> </u>	DF
Q512	Dose Calibrator Constancy	LO.	DF
Q513	Dose Calibrator Linearity	<u>AV.</u>	DF
Q514	Dose Calibrator Geometry	<u> </u>	DE
Q515F	Acceptance of Responsibility	P.N.	DF
Q516	Cleaning of the Hot Cell	40.	DF
Q516F	Hot Cell Cleaning Log	P.O.	DF
Q517	Cyclotron Preventive Maintenance	PO.	DF
Q518	Stock Recovery	A.D.	DF

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Regional Nuclear Pharmaceuticals

	Continuing Educatio	n/Radiation Safety Lo	og File	
Date	Description of CE	Name (Print)	Signature	
	A003, Q004, Q100,	Daniel Fernandez	Suche	
	RS013, SB050, SB076,	Aleksandr Bardor	Bizda,	
6-18-04	56087, 53088, 58102,	Chuck Tolavico	Chuthins	
	SB103, SB112,			
	A001, A001 F1, A 004	Daniel Fernandez	Suther	
a lai	Q112F, Q507, Q502F	Alexandreaxdor	Bost	
8-10-07	A 5017, R5020, R5020F, 58020	Churk Talaxira	A Day	
	SBO21,58032-1,58033-1	CALLEN JULIO ILC	Canton	
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This is to acknowledge the receipt of your letter/application dated

RECEIVED) 11/16/2004 and to inform you that the initial processing which includes an administrative review has been performed.

There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

135987 Your action has been assigned Mail Control Number When calling to inquire about this action, please refer to this control number. You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI) (6-96)

V

Sincerely, Licensing Assistance Team Leader

	: (FOR LFMS USE)
	: INFORMATION FROM LTS
BETWEEN:	:
	:
License Fee Management Branch, ARM	: Program Code: 03124
and	: Status Code: 0
Regional Licensing Sections	: Fee Category: 3P
	: Exp. Date: 20140131
	: Fee Comments:
	: Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

- A. REGION 📕
- 1. APPLICATION ATTACHED Applicant/Licensee: REGIONAL NUCLEAR PHARMACEUTICALS Received Date: 20041116 Docket No: 3036472 Control No.: 135987 License No.: 29-30867-01 Action Type: Amendment
- 2. FEE ATTACHED Amount: Check No.:
- 3. COMMENTS

Signed M. a. Parking Date 11/16/2004

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /__/)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment	
Renewal	
License	

3. OTHER _____

Signed ______ Date _____