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.

'04 NOV 16 A9:31
RECEIVED
REGION I

135987
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

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

Attachment A

I. **Aleksandr Bardov** 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

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 training and Lab Experience		updated: 10/08/04

I. b. **Aleksandr Bardov's** Training Documentation

NRC FORM 374 U.S. NUCLEAR REGULATORY COMMISSION PAGE 1 OF 3 PAGES

CORRECTED COPY

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Regional Nuclear Pharmaceuticals	3. License number 29-30867-01
2. 30 Murray Hill Parkway Suite 450 East Rutherford, New Jersey 07073	4. Expiration date January 31, 2014 5. Docket No. 030[illegible]472 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Cesium 137	A. Sealed Sources (IPL Models RV-137 and GF-137)	A. No single source to exceed the maximum activity specified in the certificate of registration issued by U.S. Nuclear Regulatory Commission or an Agreement State

9. Authorized use:

A. For calibration of the licensee's instruments.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 30 Murray Hill Parkway, Suite 450, East Rutherford, New Jersey.

11. Licensed material shall be used by, or under the supervision of, Harvey Doane, Charles S. Talarico, Randall Watt, [redacted] and Michael W. Lairmore.

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.

REGIONAL NUCLEAR PHARMACEUTICALS

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

TRAINING RECORD

Employee Aleksandr Bardov

Subject	Section	Date Completed	Hours	Trainer	Employee Initials
Accelerator Theory					
	Control System Overview	11-12/11-28-03	4	C. Talarico	A.B
	User Command Files	↓	4	↓	A.B
	Interlocks and safety switches		4		A.B
	Vacuum system		4		A.B
	RF system		4		A.B
	Cooling system		2		A.B
	Magnet		2		A.B
	Ion source		4		A.B
	Beam extraction system		8		A.B
	Target systems		8		A.B.
	Accelerator maintenance		16		A.B
	Target maintenance	↓	8	↓	A.B
Aseptic Processing					
	Controlling the environment				
	Laminar flow hood maintenance				
	Sterile filter sterilization				
	Filter bubble test				
	Media fill simulation				
	Endotoxin testing				
cGMP, 21 CFR 210					
	210.1 – Status				
	210.2 – Applicability				
	210.3 – Definitions				
Materials Control					
	Receiving and quarantine	11-17-11-21-03	2	C. Talarico	A.B
	Acceptance testing	↓	2	↓	A.B
	First-in-first-out		2		A.B
	Inventory control	↓	2	↓	A.B
Synthesis System					
	FDG Radiochemistry				
	Raw materials and components				
	Synthesizer control system				
	Hardware settings and adjustments				
	Command files				
	Cleaning the system				
	Synthesis program				

ORIGINAL

REGIONAL NUCLEAR PHARMACEUTICALS

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

Subject	Section	Date Completed	Hours	Trainer	Employee Initials
Quality control					
	Sampling	12-1/12-5-03	1	C Tabrico	AB
	Reserve samples	"	1	"	AB
	Specific concentration	"	2	"	AB
	Sterility test	12-16-03	8	"	AB
	LAL pyrogen test	12-17-03	8	"	AB
	Radiochemical purity, Radio-TLC	12-8-03	8	"	AB
	Chemical purity, Kryptofix TLC	"	8	"	AB
	Solvents, Gas Chromatography	"	8	"	AB
	Radionuclidic Identity, half-life	"	2	"	AB
	Radionuclidic purity, MCA	12-12-03	8	"	AB
	pH determination	12-1-03	1	"	AB
	Isotonicity	"	1	"	AB
	Visual inspection	12-5-03	1	"	AB
	Manufacturing trend analysis	12-19-03	2	"	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				

ORIGINAL

REGIONAL NUCLEAR PHARMACEUTICALS

Form	Form Number:
Radiation Safety Training Record	**RS009F**
	Effective Date: 01/07/03

PRO	Document Control	QA/RA	Supersedes:
			N/A

RADIATION SAFETY TRAINING RECORD

Regional Nuclear Pharmaceuticals

Employee Name: Aleksandr Bardov Training for: New Employee ✓
New Duties
Refresher
License Terms ✓

Training: Required	Date		Subject
✓			
✓	12-28-03	1.	Regulations for control of radiation.
✓	12-23-03	2.	Terms of the License.
✓	12-23-03	3.	Radiation hazards in the workplace.
✓	12-23-03	4.	General radiation safety procedures.
		5.	The concept of ALARA.
✓	12-28-03	6.	Individual responsibility for radiation safety.
✓	12-23-03	7.	Emergency procedures.
✓	12-28-03	8.	Workers right to be informed.
✓	12-23-03	9.	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.
✓	12-23-03	17.	Methods of controlling radiation dose; time, distance and shielding.
✓	12-23-03	18.	Radiation detection instruments to be used.
✓	12-23-03	19.	Operation, calibration, and limitations of survey instruments.
✓	12-23-03	20.	Survey techniques.

ORIGINAL

REGIONAL NUCLEAR PHARMACEUTICALS

	Form	Form Number:
	Radiation Safety Training Record	**RS009F**
		Effective Date: 01/07/03
PRO	Document Control	QA/RA	Supersedes:
			N/A

✓	12-23-03	21.	Use of personnel monitoring equipment; film badges, TLDs, pocket dosimeters.
✓	12-23-03	23.	Procedures and instructions for equipment to be used.
✓	12-23-03	24.	Standard operating procedures.
✓	12-23-03	25.	Radiation levels expected from the cyclotron.
		26.	Cyclotron shielding.
		27.	Cyclotron safety interlocks.
✓	12-27-03	28.	Cyclotron computer control system.
		29.	Cyclotron emergency procedures.
		30.	On the job training - one month minimum (attach list of topics covered).

Employee: DBarlow Date: 1/2/04

Instructor: _____ Date: 01-02-04

ORIGINAL

REGIONAL NUCLEAR PHARMACEUTICALS				
	Form: **Radiation Safety Training Record**			Form Number: **RS009F**
				Effective Date: 01/07/03
	PRO	Document Control	QA/RA	Supersedes: N/A

RADIATION SAFETY TRAINING RECORD

Regional Nuclear Pharmaceuticals

Employee Name: Aleksandr Bardov Training for: New Employee ✓
New Duties _____
Refresher _____
License Terms _____

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.	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.
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_____	_____	15.	Biological effects of radiation.
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_____	_____	17.	Methods of controlling radiation dose; time, distance and shielding.
_____	_____	18.	Radiation detection instruments to be used.
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_____	_____	20.	Survey techniques.

ORIGINAL

REGIONAL NUCLEAR PHARMACEUTICALS

	Form	Form Number:
	Radiation Safety Training Record	**RS009F**
		Effective Date: 01/07/03
PRO	Document Control	QA/RA	Supersedes:
			N/A

		21.	Use of personnel monitoring equipment; film badges, TLDs, pocket dosimeters.
		23.	Procedures and instructions for equipment to be used.
		24.	Standard operating procedures.
		25.	Radiation levels expected from the cyclotron.
✓	20040109	26.	Cyclotron shielding.
✓	20040109	27.	Cyclotron safety interlocks.
✓	20040109	28.	Cyclotron computer control system.
		29.	Cyclotron emergency procedures.
		30.	On the job training - one month minimum (attach list of topics covered).

Employee: [signature] Date: 1/09/2004

Instructor: [signature] Date: 20040109

S.P.M.J. DOWNEY, GE MEDICAL SYSTEMS

ORIGINAL

REGIONAL NUCLEAR PHARMACEUTICALS

Form	Form Number:
Radiation Safety Training Record	RS009F
	Effective Date: 01/07/03
PRO / Document Control / QA/RA	Supersedes: N/A

RADIATION SAFETY TRAINING RECORD

Regional Nuclear Pharmaceuticals

Employee Name: ALEKSANDR BARDOV Training for: New Employee ✓
New Duties
Refresher
License Terms

Training: Required	Date		Subject
✓			
✓	4/7/04 - 4/8/04	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.	Location of License, regulations, applications, correspondence.
✓		10.	Characteristics of radiation.
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✓		19.	Operation, calibration, and limitations of survey instruments.
✓		20.	Survey techniques.

ORIGINAL

REGIONAL NUCLEAR PHARMACEUTICALS

Form	Form Number:
Radiation Safety Training Record	**RS009F**
	Effective Date: 01/07/03
PRO / Document Control / QA/RA	Supersedes: N/A

✓	4/7/04 - 4/8/04	21.	Use of personnel monitoring equipment; film badges, TLDs, pocket dosimeters.
✓		23.	Procedures and instructions for equipment to be used.
✓		24.	Standard operating procedures.
✓		25.	Radiation levels expected from the cyclotron.
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✓		27.	Cyclotron safety interlocks.
✓		28.	Cyclotron computer control system.
✓		29.	Cyclotron emergency procedures.
✓		30.	On the job training - one month minimum (attach list of topics covered).

Employee: A Barlow Date: 4-8-04

Instructor: Scott Lucas Date: 4-8-04

ORIGINAL

4-8-04 (Barda) 28/29 = 97%

1. Alpha emitters present serious hazards when:

   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.
   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

RADIATION SAFETY TEST

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

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 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:

    a) Curie
    b) Edison
    c) Bequerel
    d) Roentgen

RADIATION SAFETY TEST

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:

a) rem
b) R
c) rad
d) Curie

16. By regulations, personnel monitoring is required for those workers likely to exceed __10__ % of annual dose limits:

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

RADIATION SAFETY TEST

19. Gamma radiation is best stopped by:

    a) low Z elements
    b) concrete
    c) high Z elements
    d) boronated plastics

20. The key to effective radiation protection is time, distance and shielding.

21. The principle ways gamma radiation interacts with matter are photoeffect, Compton and pair.

22. NaI(Tl) crystals scintillate 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) 3.7×10^{10} dps

25. Given 40 mC of radioactive material (half life 85 min), how much activity will remain after 400 min?

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

Certificate of

Training

Radiation Safety Practice and Principles

Aleksandr Bardov

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

Scott Lucas
Director of Operations

REGIONAL NUCLEAR PHARMACEUTICALS

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

TRAINING RECORD

Employee ALEKSANDR BARDOV

Subject	Section	Date Completed	Hours	Trainer	Employee Initials
Accelerator Theory					
	Control System Overview	6/16-6/17/04	5	S. LUCAS	A. B
	User Command Files	↓	↓	↓	A. B
	Interlocks and safety switches				A. B
	Vacuum system				A. B
	RF system				A. B
	Cooling system				A. B
	Magnet				A. B
	Ion source				A. B
	Beam extraction system				A. B
	Target systems				A. B
	Accelerator maintenance				A. B
	Target maintenance	6/16-6/17/04	5	S. LUCAS	A. B
Aseptic Processing					
	Controlling the environment				
	Laminar flow hood maintenance				
	Sterile filter sterilization				
	Filter bubble test				
	Media fill simulation				
	Endotoxin testing				
cGMP, 21 CFR 210					
	210.1 – Status				
	210.2 – Applicability				
	210.3 – Definitions				
Materials Control					
	Receiving and quarantine				
	Acceptance testing				
	First-in-first-out				
	Inventory control				
Synthesis System					
	FDG Radiochemistry	6/16-6/17/04	1	S. LUCAS	A. B
	Raw materials and components	↓	↓	↓	A. B
	Synthesizer control system				A. B
	Hardware settings and adjustments				A. B
	Command files				A. B
	Cleaning the system				A. B
	Synthesis program	6/16-6/17/04	1	S. LUCAS	A. B

ORIGINAL

A. Baldwin

CYCLOTRON/CHEMISTRY BOX TEST

1. What is the purpose of the collimator plates?

   1. for focusing beam.
   2. interactions. (beam grid.)

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

   anode, cathode.

3. What is replaced during a target rebuild?

   - target foil
   - vacuum foil
   - helium cooling
   - viton o-ring 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?

   unhydrolyzed 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 diaphragm.

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?

— hight voltage anode fuse.

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

— HVV closed. vacuum system closed too.

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

— air compresser don't work good.

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?

— broken catode.

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

— Jump ~~the system~~. cutted wires and connect~~ion~~.

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 pH in the final product
— make sure all vails working correctly
— Check pressure in the reaction
— change Hiney vial. ✓ bars in the reaction vessels.

7/16/04

MANUFACTURING
SOP TRAINING RECORD

NAME:	Alexandra Bardov			
NUMBER	**TITLE**	**TRAINEE SIGNATURE**	**TRAINER SIGNATURE**	**DATE** 7/19/04
A001	Quality System Administration	ABardov	Patricia Walden	
A001F1	Document Change Request Form	A. B	P.D.	
A001F2	Document Change Order Form	A. B	P.D.	
A002	Release Authority: Quality Control	A. B	P.D.	
A002F1	Quality Control Release	A. B	P.D.	
A002F2	Manufacturing Deviation Report	A. B	P.D.	
A003	Retention of Records and Samples	A. B	P.D.	
A004	Drug Product Complaints	A. B	P.D.	
A004F	Drug Product Compliant Form	A. B	P.D.	
A005	Final Product Recall	A. B	P.D.	
A005F	*Final Product Recall Documentation Form*	A. B	P.D.	
A006	Batch Trend Analysis	A. B	P.D.	
A007	Manufacturing Operator Training	A. B	P.D.	
A007F	Manufacturing Operator Training Record	A. B	P.D.	
A008	Facility Maintenance and Sanitation	A. B	P.D.	
A008F	Facility Maintenance and Sanitation Documentation	A. B	P.D.	
A009	Facility Security	A. B	P.D.	
A010	Raw Material Control	A. B	P.D.	
A010F2	Labels	A. B	P.D.	
A011	FDG Batch Control Numbers	A. B	P.D.	
A012	Analytical Method Validation	A. B	P.D.	
A014	How to Write a Standard Operating Procedure	A. B	P.D.	
A015	Quality Awareness Training Record	A. B	P.D.	
A017	GMP and Quality System Training	A. B	P.D.	
A017F1	Quality Awareness Training Record	A. B	P.D.	
A017F2	Employee Training Requirements	A. B	P.D.	
A018	Document and Data Control	A. B	P.D.	
A019	Product Recall	A. B	P.D.	
E001	Bioburden	A. B	P.D.	
E001F	Bioburden Data Summary	A. B	P.D.	

MANUFACTURING
SOP TRAINING RECORD

E002	Radiochromatography Scanner	A.B		
E003	Gas Chromatograph	A.B		
E004	Multichannel Analyzer	A.B		
M001	Manufacturing Instructions - ^{18}FDG	A.B		
M001F1	Fludeoxyglucose [^{18}F] Injection Batch Record PETtrace	A.B		
M001F2	Fludeoxyglucose [^{18}F] Injection Batch Record RDS-111 NI		N/A	
M001F3	Fludeoxyglucose [^{18}F] Injection Batch Record RDS-111 Coincidence		N/A	
M001F4	Fludeoxyglucose [^{18}F] Injection Batch Record MINItrace		N/A	
M001F5	Fludeoxyglucose [^{18}F] Injection Batch Record PETtrace with Coincidence Synthesis		N/A	
M002	Asceptic Processing	A.B		
M003	Packaging, Labeling and Distribution	A.B		
M004	MINItrace Manufacturing Instructions - [^{18}F]F	A.B	N/A	
M005	RDS-111 Manufacturing Instructions - [^{18}F]F		N/A	
M006	PETtrace Manufacturing Instructions - [^{18}F]F	A.B		
M007F	Manufacturing Incident Report	A.B		
M008	MINItrace Target and Delivery Line Maintenance		N/A	
M009	PETtrace Target and Delivery Line Maintenance	A.B		
M010	RDS-111 Target and Delivery Line Maintenance		N/A	
M011	Potassium Carbonate, 6mg/ml, Solution	A.B		
M011F	Potassium Carbonate, 6mg/ml, Solution, Data Summary	A.B		
M012	Pharmacy Packaging, Labeling and Distribution	A.B		
M013	Finished Product Released for Distribution Under Quarantine	A.B		
M014F1	RDS-111 Pre-Installation Check log		N/A	
M014F2	RDS-111 Post-Installation Check log		N/A	
M015	Reagent Kit Assembly		N/A	
M015F	Reagent Kit Assembly Log		N/A	
Q001	[^{18}O]H_2O Acceptance	A.B		
Q002	Kryptofix Acceptance	A.B		
Q003	Mannose Triflate Acceptance	A.B		
Q004	Vial, Sterile, 30 ml	A.B		
Q005	Sodium Chloride Injection, 0.9% Acceptance	A.B		
Q006	Sodium Chloride Injection, 4 mEq/ml, Acceptance	A.B		

MANUFACTURING
SOP TRAINING RECORD

7/16/04

Q008	Potassium Carbonate, Acceptance	A.B	P.D	
Q010	Acetonitrile, Anhydrous Acceptance	A.B	P.D	
Q011	HCL, 1N Acceptance	A.B	P.D	
Q012	Ethyl Alcohol Acceptance	A.B	P.D	
Q013	^{18}F Separation Column Acceptance	A.B	P.D	
Q021	Vented Filter, 22µm, Acceptance	A.B	P.D	
Q022	Filter, 22 µm, 25mm o.d. Acceptance	A.B	P.D	
Q023	Filter, 22 µm, 4mm o.d. Acceptance	A.B	P.D	
Q051	Acetonitrile, HPLC Acceptance	A.B	P.D	
Q053	Acetone Acceptance	A.B	P.D	
Q061	Sodium Carbonate Acceptance	A.B	P.D	
Q093	Confirmation of LAL Label Claim Sensitivity	A.B	P.D	
Q093F	LAL Label Claim Sensitivity Data Summary	A.B	P.D	
Q100	Radiochemical Identity & Purity R-TLC	A.B	P.D	
Q100F	Radiochemical Identity & Purity Data Summary	A.B	P.D	
Q101	Chemical Purity Residual Solvent GC	A.B	P.D	
Q101F	GC Data Summary	A.B	P.D	
Q102	Chemical Purity K-TLC	A.B	P.D	
Q102F	Chemical Purity K-TLC Data Summary	A.B	P.D	
Q103	Determination of FDG Radionuclidic Identity - $T_{1/2}$	A.B	P.D	
Q103F	Determination of FDG Radionuclidic Identity - $T_{1/2}$ Data Summary	A.B	P.D	
Q104	Bacterial Endotoxin Testing	A.B	P.D	
Q104F	Bacterial Endotoxins Test Data Summary	A.B	P.D	
Q105	pH Test	A.B	P.D	
Q105F	pH Test Data Summary	A.B	P.D	
Q106	Radionuclidic Purity - MCA	A.B	P.D	
Q107	Final Product Sterility Testing	A.B	P.D	
Q107F	Final Product Sterility Testing Data Summary	A.B	P.D	
Q108	Sterilizing Filter Test - Bubble Point	A.B	P.D	
Q108F	Sterilizing Filter Test - Bubble Point Data Summary	A.B	P.D	
Q109	Visual Inspection of Final Product	A.B	P.D	
Q110	Non Conformance	A.B	P.D	
Q110F	Non Conformance Report Form	A.B	P.D	
Q111	Aseptic Assembly of Final product Vial	A.B	P.D	

MANUFACTURING
SOP TRAINING RECORD

Q112F	Temperature Log *	A.B	L.D.	
Q113	Glassware Depyrogenation	A.B	L.D.	
Q201	Preparation of GC Standard Solution	A.B	L.D.	
Q301	LAL - Determination of the Non-Interfering Concentration	A.B	L.D.	
Q301F	LAL - Determination of the Non-Interfering Concentration *Data Summary*	A.B	L.D.	
Q406	Aseptic Processing Training	A.B	L.D.	
Q406F	Aseptic Processing Training Data Summary	A.B	L.D.	
Q501	Multichannel Analyzer Calibration	A.B	L.D.	
Q501F	Multichannel Analyzer Calibration Data Summary	A.B	L.D.	
Q502	Analytical Balance Maintenance	A.B	L.D.	
Q502F	Analytical Balance Maintenance Log*	A.B	L.D.	
Q504	Final Product Re-filtering	A.B	L.D.	
Q505	Radiopharmaceutical Stability Testing	A.B	L.D.	
Q511	Dose Calibrator Accuracy	A.B	L.D.	
Q512	Dose Calibrator Constancy	A.B	L.D.	
Q513	Dose Calibrator Linearity	A.B	L.D.	
Q514	Dose Calibrator Geometry	A.B	L.D.	
Q515F	Acceptance of Responsibility	A.B	L.D.	
Q516	Cleaning of the Hot Cell	A.B	L.D.	
Q516F	Hot Cell Cleaning Log	A.B	L.D.	
Q517	Cyclotron Preventive Maintenance	A.B	L.D.	
Q518	Stock Recovery	A.B	L.D.	

Regional Nuclear Pharmaceuticals

Continuing Education/Radiation Safety Log File

Date	Description of CE	Name (Print)	Signature
6-18-04	A003, Q004, Q100, RS013, SB050, SB076, SB087, SB088, SB102, SB103, SB112,	Daniel Fernandez Aleksandr Bardov Chuck Talarico	
8-16-04	A001, A001F1, A004, Q112F, Q507, Q502F, Q505, Q513, Q515F, RS017, RS020, RS020F, SB020, SB021, SB032-1, SB033-1, SB034-1, SB035-1, SB085	Daniel Fernandez Aleksandr Bardov Chuck Talarico	
8-18-04	SB090, SB091, SB125 M002, RS012	Daniel Fernandez Aleksandr Bardov Chuck Talarico	

II. a. **Daniel Fernandez's** Training and Experience Summary

Daniel Fernandez
TRAINING AND EXPERIENCE

DATES	CLASSROOM HOURS	LABORTORY HOURS	PLACE/ 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 training and Lab Experience		updated: 10/08/04

II. b. **Daniel Fernandez's** Training Documentation

REGIONAL NUCLEAR PHARMACEUTICALS

Form	Form Number:
Radiation Safety Training Record	**RS009F**
	Effective Date: 01/07/03
PRO / Document Control / QA/RA	Supersedes: N/A

RADIATION SAFETY TRAINING RECORD

Regional Nuclear Pharmaceuticals

Employee Name: Daniel Fernandez Training for: New Employee ✓
New Duties _____
Refresher _____
License Terms _____

Training: Required ✓	Date		Subject
✓	2-3-04	1.	Regulations for control of radiation.
✓	2-3-04	2.	Terms of the License.
✓	2-3-04	3.	Radiation 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.
✓	2-3-04	9.	Location of License, regulations, applications, correspondence.
✓	2-5-04	10.	Characteristics of radiation.
✓	2-5-04	11	Units of radiation dose and quantity of radioactivity.
✓	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 sources.
		17.	Methods of controlling radiation dose; time, distance and shielding.
✓	2-6-04	18.	Radiation detection instruments to be used.
✓	2-6-04	19.	Operation, calibration, and limitations of survey instruments.
✓	2-6-04	20.	Survey techniques.

ORIGINAL

REGIONAL NUCLEAR PHARMACEUTICALS

Form	Form Number:
Radiation Safety Training Record	**RS009F**
	Effective Date: 01/07/03
PRO / Document Control / QA/RA	Supersedes: N/A

✓	2-3-04	21.	Use of personnel monitoring equipment; film badges, TLDs, pocket dosimeters.
✓	2-6-04	23.	Procedures and instructions for equipment to be used.
✓	2-4-04	24.	Standard operating procedures.
✓	2-3-04	25.	Radiation levels expected from the cyclotron.
		26.	Cyclotron shielding.
		27.	Cyclotron safety interlocks.
		28.	Cyclotron computer control system.
		29.	Cyclotron emergency procedures.
		30.	On the job training - one month minimum (attach list of topics covered).

Employee: _____ Date: 2-9-04

Instructor: _____ Date: 2-9-04

REGIONAL NUCLEAR PHARMACEUTICALS

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

TRAINING RECORD

Employee Daniel Fernandez

Subject	Section	Date Completed	Hours	Trainer	Employee Initials
Accelerator Theory					
	Control System Overview	2-2-04	8	CST	DF
	User Command Files	↓	↓	↓	↓
	Interlocks and safety switches				
	Vacuum system				
	RF system				
	Cooling system	↓		↓	↓
	Magnet	2-2-04	↓	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					
	210.1 – Status				
	210.2 – Applicability				
	210.3 – Definitions				
Materials Control					
	Receiving and quarantine	2-23-04	8	CST	DF
	Acceptance testing	↓	↓	↓	↓
	First-in-first-out				
	Inventory control	2-23-04	↓	CST	DF
Synthesis System					
	FDG Radiochemistry				
	Raw materials and components				
	Synthesizer control system				
	Hardware settings and adjustments				
	Command files				
	Cleaning the system				
	Synthesis program				

ORIGINAL

REGIONAL NUCLEAR PHARMACEUTICALS

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

Subject	Section	Date Completed	Hours	Trainer	Employee Initials
Quality control					
	Sampling	2-10-04	2	CST	DF
	Reserve samples	↓	2	↓	↓
	Specific concentration	2-10-04	2	CST	DF
	Sterility test	2-11-04	8	CST	DF
	LAL pyrogen test	2-13-04	8	CST	DF
	Radiochemical purity, Radio-TLC	2-12-04	8	CST	DF
	Chemical purity, Kryptofix TLC	2-16-04	8	CST	DF
	Solvents, Gas Chromatography	2-14-04	8	CST	DF
	Radionuclidic Identity, half-life	2-18-04	2	CST	DF
	Radionuclidic purity, MCA	2-17-04	8	CST	DF
	pH determination	2-18-04	1	CST	DF
	Isotonicity	↓	1	↓	↓
	Visual inspection	↓	1	CST	DF
	Manufacturing trend analysis	2-19-04	2	CST	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				
	Subpart K - Returns & Salvage				
PET Radiopharmaceuticals					
	Compliance Guidelines				

REGIONAL NUCLEAR PHARMACEUTICALS

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

TRAINING RECORD

Employee Daniel Fernandez

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	↓	↓
	Target systems	↓	10	↓	↓
	Accelerator maintenance	↓	10	↓	↓
	Target maintenance	3-26-04	10	CST	DF
Aseptic Processing					
	Controlling the environment	4-3-04	8	CST	DF
	Laminar flow hood maintenance	↓	↓	↓	↓
	Sterile filter sterilization	↓	↓	↓	↓
	Filter bubble test	↓	↓	↓	↓
	Media fill simulation	↓	↓	↓	↓
	Endotoxin testing	4-3-04	↓	CST	DF
cGMP, 21 CFR 210					
	210.1 – Status				
	210.2 – Applicability				
	210.3 – Definitions				
Materials Control					
	Receiving and quarantine				
	Acceptance testing				
	First-in-first-out				
	Inventory control				
Synthesis System					
	FDG Radiochemistry				
	Raw materials and components				
	Synthesizer control system				
	Hardware settings and adjustments				
	Command files				
	Cleaning the system				
	Synthesis program				

ORIGINAL

REGIONAL NUCLEAR PHARMACEUTICALS

	Form	Form Number:
	Radiation Safety Training Record	**RS009F**
		Effective Date: 01/07/03
PRO	Document Control	QA/RA	Supersedes: N/A

RADIATION SAFETY TRAINING RECORD

Regional Nuclear Pharmaceuticals

Employee Name: DANIEL FERNANDEZ Training for: New Employee ✓
New Duties
Refresher
License Terms

Training: Required	Date		Subject
✓			
✓	4/7/04-4/8/04	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.	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.
✓		16	Levels of radiation exposure from various sources.
✓		17.	Methods of controlling radiation dose; time, distance and shielding.
✓		18.	Radiation detection instruments to be used.
✓		19.	Operation, calibration, and limitations of survey instruments.
✓		20.	Survey techniques.

ORIGINAL

REGIONAL NUCLEAR PHARMACEUTICALS

	Form	Form Number:
	Radiation Safety Training Record	**RS009F**
		Effective Date: 01/07/03
PRO	Document Control	QA/RA	Supersedes:
			N/A

✓	4/7/04-4/8/04	21.	Use of personnel monitoring equipment; film badges, TLDs, pocket dosimeters.
✓		23.	Procedures and instructions for equipment to be used.
✓		24.	Standard operating procedures.
✓		25.	Radiation levels expected from the cyclotron.
✓		26.	Cyclotron shielding.
✓		27.	Cyclotron safety interlocks.
✓		28.	Cyclotron computer control system.
✓		29.	Cyclotron emergency procedures.
✓		30.	On the job training - one month minimum (attach list of topics covered).

Employee: _____ Date: 4-8-04

Instructor: Scott Lucas Date: 4-8-04

ORIGINAL

Daniel Hernandez
4-8-04

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

1. Alpha emitters present serious hazards when:

   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.
   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

RADIATION SAFETY TEST

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

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 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:

    a) Curie
    b) Edison
    c) Bequerel
    d) Roentgen

RADIATION SAFETY TEST

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:

a) rem
b) R
c) rad
d) Curie

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

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

RADIATION SAFETY TEST

19. Gamma radiation is best stopped by:

    a) low Z elements
    b) concrete
    c) high Z elements
    d) boronated plastics

20. The key to effective radiation protection is Distance, Time, and Shield.

21. The principle ways gamma radiation interacts with matter are Photoelectric, Scattering and Pair.

22. NaI(Tl) crystals Flouresce 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) 3.7×10^{10} dps

25. Given 40 mC of radioactive material (half life 85 min), how much activity will remain after 400 min?

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

Certificate of

Training

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

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

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

REGIONAL NUCLEAR PHARMACEUTICALS

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

TRAINING RECORD

Employee DANIEL FERNANDEZ

Subject	Section	Date Completed	Hours	Trainer	Employee Initials
Accelerator Theory					
	Control System Overview	6/16-6/17/04	5	S. LUCAS	DF
	User Command Files	↓	↓	↓	↓
	Interlocks and safety switches				
	Vacuum system				
	RF system				
	Cooling system				
	Magnet				
	Ion source				
	Beam extraction system				
	Target systems				
	Accelerator maintenance	↓	↓	↓	↓
	Target maintenance	6/16-6/17/04	5	S. LUCAS	DF
Aseptic Processing					
	Controlling the environment				
	Laminar flow hood maintenance				
	Sterile filter sterilization				
	Filter bubble test				
	Media fill simulation				
	Endotoxin testing				
cGMP, 21 CFR 210					
	210.1 – Status				
	210.2 – Applicability				
	210.3 – Definitions				
Materials Control					
	Receiving and quarantine				
	Acceptance testing				
	First-in-first-out				
	Inventory control				
Synthesis System					
	FDG Radiochemistry	6/16-6/17/04	1	S. LUCAS	DF
	Raw materials and components	↓	↓	↓	↓
	Synthesizer control system				
	Hardware settings and adjustments				
	Command files				
	Cleaning the system	↓	↓	↓	↓
	Synthesis program	6/16-6/17/04	1	S. LUCAS	DF

ORIGINAL

6-17-04

CYCLOTRON/CHEMISTRY BOX TEST

1. What is the purpose of the collimator plates?
   Focus the Beam, Beam Direction. "Feed back 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 O rings 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?
   - Helium cooling pump diaphragm

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 anode fuse.

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.

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?
Broken catodes.

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 pressure of the reaction vial.
- make sure all the valves are working correctly, by looking at the reagent vials and hearing that they all empty.
- Check stirring bars.
- Check Helium pressure.
- Check all of the lines for leaks or kinks

MANUFACTURING
SOP TRAINING RECORD

7/16/04

NAME:	DANIEL E. FERNANDEZ			
NUMBER	**TITLE**	**TRAINEE SIGNATURE**	**TRAINER SIGNATURE**	**DATE** 7/19/04
A001	Quality System Administration			
A001F1	Document Change Request Form	DF		
A001F2	Document Change Order Form	DF		
A002	Release Authority: Quality Control	DF		
A002F1	Quality Control Release	DF		
A002F2	Manufacturing Deviation Report	DF		
A003	Retention of Records and Samples	DF		
A004	Drug Product Complaints	DF		
A004F	Drug Product Compliant Form	DF		
A005	Final Product Recall	DF		
A005F	*Final Product Recall Documentation Form*	DF		
A006	Batch Trend Analysis	DF		
A007	Manufacturing Operator Training	DF		
A007F	Manufacturing Operator Training Record	DF		
A008	Facility Maintenance and Sanitation	DF		
A008F	Facility Maintenance and Sanitation Documentation	DF		
A009	Facility Security	DF		
A010	Raw Material Control	DF		
A010F2	Labels	DF		
A011	FDG Batch Control Numbers	DF		
A012	Analytical Method Validation	DF		
A014	How to Write a Standard Operating Procedure	DF		
A015	Quality Awareness Training Record	DF		
A017	GMP and Quality System Training	DF		
A017F1	Quality Awareness Training Record	DF		
A017F2	Employee Training Requirements	DF		
A018	Document and Data Control	DF		
A019	Product Recall	DF		
E001	Bioburden	DF		
E001F	Bioburden Data Summary	DF		

MANUFACTURING
SOP TRAINING RECORD

7/16/04

E002	Radiochromatography Scanner		[illegible]	DF
E003	Gas Chromatograph		[illegible]	DF
E004	Multichannel Analyzer		[illegible]	DF
M001	Manufacturing Instructions - ^{18}FDG		[illegible]	DF
M001F1	Fludeoxyglucose [^{18}F] Injection Batch Record PETtrace		[illegible]	DF
M001F2	Fludeoxyglucose [^{18}F] Injection Batch Record RDS-111 NI		N/A	
M001F3	Fludeoxyglucose [^{18}F] Injection Batch Record RDS-111 Coincidence		N/A	
M001F4	Fludeoxyglucose [^{18}F] Injection Batch Record MINItrace		N/A	
M001F5	Fludeoxyglucose [^{18}F] Injection Batch Record PETtrace with Coincidence Synthesis		N/A	
M002	Asceptic Processing		[illegible]	DF
M003	Packaging, Labeling and Distribution		[illegible]	DF
M004	MINItrace Manufacturing Instructions - [^{18}F]F		N/A	
M005	RDS-111 Manufacturing Instructions - [^{18}F]F		N/A	
M006	PETtrace Manufacturing Instructions - [^{18}F]F		[illegible]	DF
M007F	Manufacturing Incident Report		[illegible]	DF
M008	MINItrace Target and Delivery Line Maintenance		N/A	
M009	PETtrace Target and Delivery Line Maintenance		[illegible]	DF
M010	RDS-111 Target and Delivery Line Maintenance		N/A	
M011	Potassium Carbonate, 6mg/ml, Solution		[illegible]	DF
M011F	Potassium Carbonate, 6mg/ml, Solution, Data Summary		[illegible]	DF
M012	Pharmacy Packaging, Labeling and Distribution		[illegible]	DF
M013	Finished Product Released for Distribution Under Quarantine		[illegible]	DF
M014F1	RDS-111 Pre-Installation Check log		N/A	
M014F2	RDS-111 Post-Installation Check log		N/A	
M015	Reagent Kit Assembly		N/A	
M015F	Reagent Kit Assembly Log		N/A	
Q001	[^{18}O]H_2O Acceptance		[illegible]	DF
Q002	Kryptofix Acceptance		[illegible]	DF
Q003	Mannose Triflate Acceptance		[illegible]	DF
Q004	Vial, Sterile, 30 ml		[illegible]	DF
Q005	Sodium Chloride Injection, 0.9% Acceptance		[illegible]	DF
Q006	Sodium Chloride Injection, 4 mEq/ml, Acceptance		[illegible]	DF

MANUFACTURING
SOP TRAINING RECORD

Q008	Potassium Carbonate, Acceptance			
Q010	Acetonitrile, Anhydrous Acceptance			
Q011	HCL, 1N Acceptance			
Q012	Ethyl Alcohol Acceptance			
Q013	^{18}F Separation Column Acceptance			
Q021	*Vented Filter, 22µm, Acceptance*			
Q022	Filter, 22 µm, 25mm o.d. Acceptance			
Q023	Filter, 22 µm, 4mm o.d. Acceptance			
Q051	Acetonitrile, HPLC Acceptance			
Q053	Acetone Acceptance			
Q061	Sodium Carbonate Acceptance			
Q093	Confirmation of LAL Label Claim Sensitivity			
Q093F	LAL Label Claim Sensitivity Data Summary			
Q100	Radiochemical Identity & Purity R-TLC			
Q100F	Radiochemical Identity & Purity Data Summary			
Q101	Chemical Purity Residual Solvent GC			
Q101F	GC Data Summary			
Q102	Chemical Purity K-TLC			
Q102F	Chemical Purity K-TLC Data Summary			
Q103	Determination of FDG Radionuclidic Identity - $T_{1/2}$			
Q103F	Determination of FDG Radionuclidic Identity - $T_{1/2}$ Data Summary			
Q104	Bacterial Endotoxin Testing			
Q104F	Bacterial Endotoxins Test Data Summary			
Q105	pH Test			
Q105F	pH Test Data Summary			
Q106	Radionuclidic Purity - MCA			
Q107	Final Product Sterility Testing			
Q107F	Final Product Sterility Testing Data Summary			
Q108	Sterilizing Filter Test - Bubble Point			
Q108F	Sterilizing Filter Test - Bubble Point Data Summary			
Q109	Visual Inspection of Final Product			
Q110	Non Conformance			
Q110F	Non Conformance Report Form			
Q111	Aseptic Assembly of Final product Vial			

MANUFACTURING
SOP TRAINING RECORD

7/16/04

Q112F	Temperature Log			
Q113	Glassware Depyrogenation			
Q201	Preparation of GC Standard Solution			
Q301	LAL - Determination of the Non-Interfering Concentration			
Q301F	LAL - Determination of the Non-Interfering Concentration Data Summary			
Q406	Aseptic Processing Training			
Q406F	Aseptic Processing Training Data Summary			
Q501	Multichannel Analyzer Calibration			
Q501F	Multichannel Analyzer Calibration Data Summary			
Q502	Analytical Balance Maintenance			
Q502F	Analytical Balance Maintenance Log			
Q504	Final Product Re-filtering			
Q505	Radiopharmaceutical Stability Testing			
Q511	Dose Calibrator Accuracy			
Q512	Dose Calibrator Constancy			
Q513	Dose Calibrator Linearity			
Q514	Dose Calibrator Geometry			
Q515F	Acceptance of Responsibility			
Q516	Cleaning of the Hot Cell			
Q516F	Hot Cell Cleaning Log			
Q517	Cyclotron Preventive Maintenance			
Q518	Stock Recovery			

Regional Nuclear Pharmaceuticals

Continuing Education/Radiation Safety Log File

Date	Description of CE	Name (Print)	Signature
6-18-04	A003, Q004, Q100, RS013, SB050, SB076, SB087, SB088, SB102, SB103, SB112,	Daniel Fernandez Aleksandr Bardov Chuck Talarico	
8-16-04	A001, A001F1, A004, Q112F, Q502, Q502F, Q505, Q513, Q515F, RS019, RS020, RS020F, SB020, SB021, SB032-1, SB033-1, SB034-1, SB035-1, SB085	Daniel Fernandez Aleksandr Bardov Chuck Talarico	
8-18-04	SB090, SB091, SB125 M002, RS012	Daniel Fernandez Aleksandr Bardov Chuck Talarico	

This is to acknowledge the receipt of your letter/application dated 10/31/2004 (RECEIVED 11/16/2004) and to inform you that the initial processing which includes an administrative review has been performed.

☑ AMEND. 29-30867-01
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

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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.

Your action has been assigned **Mail Control Number** 135987.
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)

Sincerely,
Licensing Assistance Team Leader

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 03124
Status Code: 0
Fee Category: 3P
Exp. Date: 20140131
Fee Comments: _____
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION I

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. Parkins
Date 11/16/04

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 _____