

December 7, 1990

Mohamed M. Shanbaky, Chief Nuclear Material Safety Section A Division of Radiation Safety and Safeguards U. S. Nuclear Regulatory Commission Region 1 475 Allendale Road King of Prussia, Pennsylvania 19406

Re: Docket No. 030-15134 License No. 37-18467-01MD

Following is our response to the apparent violations identified as a result of routine inspection No. 030-15134-001 performed on August 29, 1990.

VIOLATION A1

1. Corrective steps taken and results achieved.

All employees were given an instructional program over the items specified in 10 CFR 19.12. Attendance for the program was documented on Syncor's RS-59 form for documenting inservice training. This training session will establish a baseline date for entry into a reminder program in the computer which will be used to indicate when annual training must be given again.

2. Corrective action to prevent a further violation.

The dates of the above program have been entered into each employee's file in the computer. These files as well as the reminder program mentioned above will be used to alert the facility RSO when annual refresher training should be held.

Full compliance was achieved August 30, 1990.

VIOLATION 2

1. Corrective steps taken and results achieved.

An inservice was held instructing all individuals who perform package opening procedures that the one meter radiation level reading has to be obtained before obtaining the surface radiation level reading when performing these procedures.

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Innovators in high-tech pharmacy services

page 2

2. Corrective action to prevent a further violation.

The facility RSO will monitor package opening procedures to insure that they are being performed in accordance with those commitments made in the August 15, 1984 application.

Full Compliance was achieved December 1, 1990.

VIOLATION B

This violation is denied. Your notice of violation states that "
no results of test and engineering evaluation of comparative data
was maintained which addressed Type A containers packed with
excess weight, (i.e additional unit dose containers placed into
containers that were originally tested.)

The reason for this denial is as follows:

- 1. There was specification testing on hand for the packaging in question at this facility which was not asked for nor given to the inspector.
- 2. This testing was for multiple loadings of various types of shielding used up to a gross weight of 28.5 pounds.
- 3. As per my conversation with the inspector there were 10 white unit dose shields placed in the package in question, however he did not identify whether the shields were 1 and 1/2 pound shields or 3 pound shields. If the combination of shields and package did not exceed a weight of 28.5 pounds then no violation was committed.
- 4. Different shield sizes are used for transporting different quantities of Tc-99m products. The 1 and 1/2 pound shield is used for Tc-99m activities up to 20 millicuries and the 3 pound shield is used for Tc-99m activities over 20 millicuries.

To support our argument I have enclosed portions of our specification testing documentation which demonstrate the various types of lead shielding that could be loaded into this Type A packaging and the information as to the authorized gross weight of this packaging.

In addition this location generates a packing list which identifies what has been loaded into each brief case. While I cannot supply the packing list for the package observed by the inspector I can send you examples of various loadings taken at random which demonstrates what may have been observed by the inspector.

With all due respect, if the inspector had looked at the packing list and the specification testing he would have been able to factually identify whether a violation had occurred. He apparently felt because he saw ten unit dose shields in the brief case that the case was overloaded.

As you can see from the attached data a mechanism was and is in place to identify what is placed into the packaging to insure that over loading is prevented.

VIOLATION C

1. Corrective steps taken and results achieved.

A directive has been given to all individuals responsible for completing radioactive waste disposal records specifying that all records entries must be completed when surveys are done. All records generated since the August 29th inspection are complete with no entry omissions.

2. Corrective actions to prevent a further violation.

The facility RSO or his designate will monitor these records to insure compliance.

Full compliance was achieved August 30, 1990.

If further information is necessary concerning these violations do not hesitate to contact me.

Sincerely,

Frank M Comer

Manager, Regulatory Compliance

cc: Dan Littlefield, RSO Rodney Prosser License file

DOT SPEC. 7A CERTIFICATION

1. Common Name of Container

Samsonite Briefcase Model No. 040345 or equivalent modified with internal packing as shown in Figures 1 & 2.

2. <u>Authorized Contents</u>

2. 20

Type A quantities of radiopharmaceuticals including solid. liquid, and passous material packaged in several types of internal packagings. There are no restrictions with regard to isotope and form as long as there is adherence to the general material forms and specific inner containers and packaging techniques as described in Section 3 and other sections of this certification document.

3. Description of Containers and Inner Packaging

The container tested was a Samsonite Diplomat attache case, Model 040345. The dimensions are as follows:

18.25" x 13" x 5"

The inner containars tested were as follows:

- a. A lead pipe containing (5) sealed glass vials designed to hold XE-133 gas. The lead pipe is sealed with slip-on plastic end caps. See Figures 1 & 2.
- b. An inner containment system consisting of a plastic, leadlined jar with a screw-on, plastic lid. This pig contains a plastic vial with a snap-on lid that would hold approximately 15 capsules of Sodium Iodide 131 or other solid radiopharmaceuticals. See Figures 1 & 2.
- c. An inner containment system consisting of a sealed glass vial containing 10cc of a liquid radiopharmaceutical. This glass vial with its sealed rubber/metal cap is placed inside of a lead pig with a drop-on lid. This lid is taped on with black electrical tape or equivalent. This pig is then inserted inside of a plastic container with a metal screw on lid. See Figures 1 & 2.
- d. An inner containment system consisting of a sealed glass vial containing 10cc of a liquid radiopharmaceutical. This glass vial with its sealed rubber/metal cap is placed inside of a lead pig with a slip-on, lead lid. This lid is taped on. See Figures 1 & 2.

- e. An inner containment system consisting of a lead pig with a drop-on, lead lid. This pig contains a glass vial with a snap-on, plastic lid that would hold approximately 15 capsules of Sodium Iodide 131 or other solid radiopharmaceuticals. The lid is taped on. See Figures 1 & 2.
- f. An inner containment system consisting of lcc-5cc syringes with end caps, containing liquid radiopharmaceutical and placed inside of plastic, lead-lined pigs with screw-on lids. See Figures 1 & 2.

4. Tust Results

For the tests required for Type A packaging as noted in 49 CFR 173.398(b), the case was loaded as shown in Figures 1 & 2. The case was then closed and secured with a strap as shown in Figures 3 & 4. The case was weighed and had a gross weight of 28.5 lbs. This is the authorized gross weight. The results of the tests are as follows:

a. <u>Heat</u> - Direct sunlight at an ambient temperature of 130°F. in still air.

The case passed. There was no loss of contents or decrease in package effectiveness. The cushioning material acts as a thermal barrier. See Figures 1-5.

b. <u>Cold</u> - An ambient temperature of -40°F. in still air and shade.

The case passed. There was no loss of contents or decrease in package effectiveness. See Figures 1-4, 6.

c. Reduced Pressure - Ambient atmospheric pressure of 0.5 atmospheres.

Not applicable since the package breathes. Even a small differential cannot be maintained.

d. <u>Vibration</u> - Vibration normally incident to transport.

Case passed. The case and contents were subjected to normal transport and handling vibration. There was no loss of contents or indication of reduction of integrity, i.e., loosening of lids, etc.

e. Water Spray - Not applicable.



Figure 2

Case showing inner containers packaged for testing



Figure 12

Case showing inner contents after 4' Free Drop Test

No da. _ or loss of contents

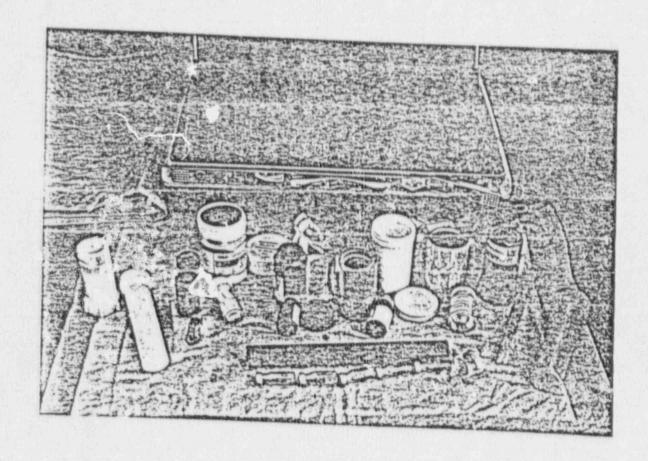


Figure 27

Case showing contents after 30' Drop Test

No damage or loss of contents

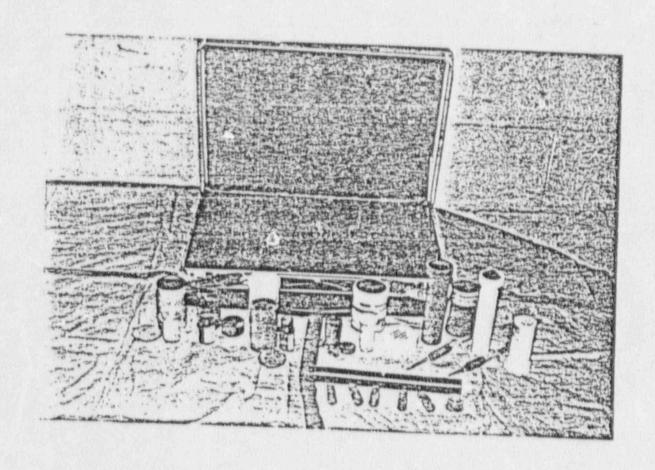


Figure 1

Case showing contents of inner containers

BILL No! 4945



Sync in Corp Pharmacy Service Center 2911 Penn Avenue Pittsburgh PA 15201 412/261-6200

PACKING LIST

SHIP TO: WESTERN PENNSTLVANIA HOSP Auclear Medicine Dept. 4800 Friendship Avenue PITTSBURGH PA 15224

CUST #1 0006 CASE #: 150 ROUTE #: 06

RX DATE/TIME FROD # DESCRIPTION

DUANTITY VOLUME F.O. NUMBER RX/ORD# PATIENT NAME

AGE RETN

EX DATE/TIME UDM 1D#

ACTIVITY

11/20/90 14:00 0111-001

4,000 mCi

11/20/90 15:00 0109-001

30,000 mCi

THIS IS A "PACKING LIST", NOT AN INVOICE. Mark 'X' in RETN column for Returned Doses.

Shir part Syncor Corp Pharmacy Service Center 2911 Penn Avenue Pittsburgh PA 15201 412/261-6200 Consignee Name And Address: WESTERN PENNSYLVANIA HOSP Nuclear Medicine Dept. 4800 Friendship Avenue PITTSBURGH PA 15224 412/578-5155

Proper Shipping Name/Classification: X RADIDACTIVE MATERIALS N.O.S. UN 2982

CASE NO. 150

ROUTE NO. 06

674229 674230

RADIONUCLIDE	CHEMICAL FORM/PHYSICAL STATE	ACTIVITY (mCi)	(GEq)
Tc99m Tc99m	Protein/Liquid Organic Compound/Liquid	8.702 54.911	0.322 2.032
	Total	63.613	2.354
LABEL CATEGORY	Radioactive WHITE/YELLOW		
	TRANSPORTATION INDEX :		

på ——cbu	wipe lest	INE INE	c cpm	
Action Level (6600dpm per 300sq	.cm x EF of	0.905) = 59	73 Net cpm/300sq.c	m
Surface Readingmr/t ^	Wipe Test, In	ner Source Co	ntainerNet	cpm
This is to certify that the above described, packaged, marked and transportation according to the Transportation.	labeled, and	are in proper	condition for	
Signature		Date//	Time:	

The radioactive contents of each package is within the limits indicated for A2 classification according to 49CFR 173.435.

412/261+6200

BILL No: 4944



PACKING LIST

Franco Service Center

1911 Penn Avenue Pittsburgh PA 15201

SHIP TO: WESTERN PENNSYLVANIA HOSP Muclear Medicine Dept. 4800 Friendship Avenue PITTSBURGH PA 15224

CLIST #1 0006 CASE #1 140 ROUTE #: 06 24115

RX D/JE/TIME PROD # DESCRIPTION

QUANTITY VOLUME P.D. NUMBER RX/DRD#

PATIENT NAME

AGE RETN

EX DATE/TIME UDM ID#

11/20/90 12:00 TL2011 T1201 mCi DUP 1.00 mCi .71 ml C123 11/27/90 12:00 0301-001

1.000 mCi

Large

11/20/90 12:00 TL2011 T1201 1mCi DUP

1.00 mCi

Lauge

11/27/90 12:00 0301-001

1.000 mCi

Large

11/20/90 to 00 TL2011 T1201 1mCi DUP 1.00 mCi 11/27/90 12:00 0301-001

1,000 mCi

11/20/90 12:00 TL2011 T1201 1mCi DUP

1.00 mCi

.71 ml C123

Large

11/27/90 12:00 0301-001

1,000 aCi

Large

11/20/90 12:00 TL2011 T1201 ImCi DUP 11/27/90 12:00 0301-001

1.00 mCi

1,000 mCi

.71 ml C123

Large

11/20/90 12:00 TL2011 | T1201 1mCi DUF 11/27/90 12400 0301-001

1.00 mCi 1,000 műi

.71 ml C123

THIS IS A PACKING LIST , NOT AN INVOICE. Mark 'A' in RETN column for Returned Doses.

PACKING LIST CONTAINS ADDITIONAL PAGES

BILL Not 4944



Phermacy Service Center 2911 Penn Avenue Pittsburgh PA 15201 412/261-6200

PACKING LIST

SHIP TO: WESTERN PERMSYLVANIA HOSP Nuclear Medicine Dept. 4800 Friendship Avenue PITTSBURGH PA 15224

CUST #1 0006 CASE #1 - 140 ROUTE #1 06

RX DATE/TIME PROD # DESCRIPTION

QUANTITY VOLUME P.D. NUMBER RX/ORD# PATIENT NAME

AGE RETN

EX DATE/TIME UDM ID#

11/20/90 13:00 TCD404 TaD4 Thyroid 10.00 aCi .45 ml C123 11/20/90 14:00 0102-001

10,000 mCi

Small

11/20/90 13:45 TC0404 Tc04 Thyroid

10.00 mC1

11/20/90 14:00 0102-001

10.000 mCi

Small

11/20/90 14:30 TCD404 TcB4 Thyroid 11/20/90 16:00 0102-001

10.00 mCi

10,000 mCi

.27 ml C123

11/20/90 09:00 TC99:8 Choletec Tc99m 5.00 mCi .47 ml C123

11/20/90 20:00 0116-001

5,000 mCi

THIS IS A PACKING LIST , NOT AN INVOICE. Mark 'X' in RETN column for Returned Doses. Shipperi

Syncar Corp Pharmacy Service Center 2911 Penn Avenue Fittsburgh PA 15201 412/261-6200

Consignee Name And Address: WESTERN PENNSYLVANIA HOSP Nuclear Medicine Dept. 4800 Friendship Avenue PITTSBURBH PA 15224 412/576-5155

Proper Shipping Name/Classification: X RADIOACTIVE MATERIALS N.O.S. UN 2982

classification according to 49CFR 173.435.

CASE NO. 140 ROUTE ND. 06

674070 674071 674072 674073 674074 674075 674083 674084 674085 674087

RADIONUCLIDE	CHEMICAL FORM/PHYSICAL STA	TE ACTIVITY (mCi)	(094)
T1-201 Tc99m	Inorganic Salt/Liquid Inorganic Salt/Liquid	6.456 98.437	0.239
	Total	104.893	3.881
LABEL CATEGORY:	Radioactive WHITE/YELLOW	MATERIAL PROPERTY AND	
	TRANSPORTATION INDEX :	AND ADDRESS AND AD	

Egcpm	Wipe TestNet cpm
Action Level (&&OOdpm per 300sc	.cm x EF of 0.905) = 5973 Net cpm/300sq.cm
Surface Readingmr/hr	Wipe Test, Inner Source ContainerNet cpr
described, packaged, marked and	e named materials are properly classified, labeled, and are in proper condition for applicable regulations for the Department of
Signature	Date/ Time:_

The radioactive contents of each package is within the limits indicated for A2

412/261-6200

BILL No: 4943



PACKING LIST

Pharmacy Service Center 2911 Penn Avenue

Pittsburgh PA 15201

SHIP TO: MESTERN PENNSYLVANIA HOSP Nuclear Medicine Dept. 4800 Friendship Avenue PITTEBURGH PA 15224

CUST #: 0006 CASE #1 103 ROUTE #1 06 27 2 (1) 2

EX DATE/TIME UDM 1D#

RX DATE/TIME PROD # DESCRIPTION

QUANTITY VOLUME P.O. NUMBER RX/ORD# PATIENT NAME

AGE RETN

11/20/90 07:00 TCO401 Tc99m mC. Srce .50 mC: .09 ml 11/20/90 24:00 0102-001

.500 aCi

Small

11/20/90 12:00 TL2011 T1201 1mCi DUP 11/25/90 24:00 0301-001

11/20/90 12:00 TL2011 T1201 1mCi DUP

Large

2,800 mC1

Large

11/25/90 24:00 0301-001

2.80 aCi 1.99 ml C123

2,800 aCi

11/20/90 12:00 TL2011 T1201 1mC1 DUP

11/25/90 24:00 0301-001

2.80 mCi 2.800 mCi

11/20/90 12:00 TL2011 T1201 1mCi DUP 2.80 mCi 1.99 mi C123 11/27/90 12:00 0301-001

2.800 mCi

large

11/27/90 12:00 0301-001

2,800 mC:

large.

THIS IS A 'PACKING LIST', NOT AN INVOICE. Mark X in RETM column for Returned Doses.

PACKING LIST CONTAINS ADDITIONAL PASES

BILL No: 4943



Pharmacy Service Center 2911 Penn Avenue Pittsburgh PA 15201 412/261-6200

PACKING LIST

SHIP TO: WESTERN PENNSYLVANIA HOSP Nuclear Medicine Dept. 4800 Friendship Avenue PITTSBURGH PA 15224

D'ST #: 0006 CASE #: 103 ROUTE #1 06

RX DATE/TIME PROD # DESCRIPTION

QUANTITY VOLUME P.D. NUMBER RX/ORD# PATIENT NAME AGE RETN

EX DATE/TIME UDM ID#

ACTIVITY

11/27/90 12:00 0301-001

11/20/90 12:00 TL2011 T1201 1mCi DUP 2.80 mCi 1.99 ml C123

2,800 mCi

11/20/90 12:00 113114 1131Cap 7uui 2.00 Cap

11/22/90 12:00 0420-001 16.224 uCi

THIS IS A 'PACKING LIST', NOT AN INVOICE. Mark 'X' in RETN column for Returned Doses. Shipper:

Syncor Corp Pharmacy Service Center 2911 Penn Avenue Pittsburgh PA 15201 412/261-6200

Consignee Name And Address: WESTERN PENNSYLVANIA HOSP Nuclear Medicine Dept. 4800 Friendship Avenue PITTSBURGH PA 15224 412/578-5155

Proper Shipping Name/Classification: X RADIDACTIVE MATERIALS N.O.S. UN 2982

CASE ND. 103 ROUTE ND. 06

673358 674064 674065 674066 674067 674068 674069 674086

RADIONUCLIDE	CHEMICAL FORM/PHYSICAL STATE	ACTIVITY (mCi)	(GBq)
Tc⊅9m T1-201 I-131	Inorganic Salt/Liquid Inorganic Salt/Liquid Inorganic Salt/Solid	0.686 18.072 0.017	0.025 0.669 0.001
	Total	18.775	0.695
LABEL CATEGORY	Radioactive WHITE/YELLOW		
	TRANSPORTATION INDEX :		

Du	wibe lest	wer chui	
Action Level (6600dpm per 300sq	.cm x EF of 0.	.905) = 5973 Net	cpm/300sq.cm
Surface Readingmr/hr	Wipe Test, Inner	Source Containe	erNet cpm
This is to certify .nat the above described, packaged, marked and transportation according to the Transportation.	labeled, and are	e in proper condi	tion for
Signature	Dat		Time:

The radioactive contents of each package is within the limits indicated for AZ classification according to 490FR 173.435.

BILL No: 4942



Syncor Corp Pharmacy Service Center 2911 Penn Avenue Pittsburgh PA 15201 412/261-6200

PACKING LIST

SHIP TO: WESTERN PENNSYLVANIA HOSP Muclear Medicine Dept. 4800 Friendship Avenue PITTSBURGH PA 15224

CUST #1 0006 CASE #: 63 ROUTE #1 06

************************************ EX DATE/TIME UDM ID#

ACTIVITY

RX DATE/TIME PROD # DESCRIPTION QUANTITY VOLUME P.O. NUMBER RX/ORD#

11/20/90 10:45 TC9918 Choletec Tc99m 5.00 mCi 11/20/90 24:00 0116-001

5.000 mCi

.Shipper:

Syncor Corp Pharmacy Service Center 2911 Penn Avenue Pittsburgh PA 15201 412/261-6200

Consignee Name And Address: WESTERN PENNSYLVANIA HOSP Nuclear Medicine Dept. 4800 Friendship Avenue PITTSBURGH PA 15224 412/578-5155

Proper Shipping Name/Classification: X RADIDACTIVE MATERIALS N.O.S. UN 2982

CASE NO. 63 ROUTE NO. 06

674246

RADIONUCLIDE	CHEMICAL FORM/PHYSICAL STATE	ACTIVITY (mCi)	(GBq)
		We see that the first term are the first term and	
Tc99m	Inonganic Salt/Liquid	10.568	0.391
	Total	10.568	0.391
LABEL CATEGORY:	Radioactive WHITE/YELLOW		
	TRANSPORTATION INDEX :		

Bg	cpm	Wipe Test	N	et cpm	
Action	Level (6600dpm per	300sq.cm x EF 0	of $0.905) = 5$	973 Net cpm/300sq.o	C m
Surface	Readingmr	/hr Wipe Test, 1	Inner Source C	ontainer Ne	t cpm
describ transpo	to certify that the ed, packaged, marked ortation according to ortation.	and labeled, and	are in proper	r condition for	F
Signatu	Me		Date/	/ Time:_	

The radioactive contents of each package is within the limits indicated for A2 classification according to 49CFR 173.435.

BILL Not 4941



Syncor Corp Phantacy Service Center 2911 Penn Avenue Pittsburgh PA 15201 412/261~6200

PACKING LIST

SHIP TO: WESTERN PENNSYLVANIA HOSE Nuclear Medicine Dept. 4800 Friendship Avenue PITTSBURGH PA 15224

CUST #1 0006 CASE #1 34 ROUTE #1 06

22.5 lbs

EX DATE/TIME UDM ID#

RX DATE/TIME PROD # DESCRIPTION

QUANTITY VOLUME P.O. NUMBER RX/ORD#

PATIENT NAME

AGE RETN

11/20/90 11:00 TC9918 Cholesec Tc99m 5.00 mCi .59 ml C123 11/20/90 24:00 0116-001

5.000 aCi

Small

11/20/90 12:00 TL2011 T1201 1mCi DUP 11/27/90 12:00 0301-001

2.80 mCi

1.99 ml C123

Large

2.800 mCi

11/20/90 12:00 TL2011 T1201 1mCi DUP 2.80 mCi 1.99 ml C123 11/27/90 12:00 0301-001

Large

2.800 mCi

.71 ml C123

Large

11/20/90 12:00 TL2011 T1201 1mCi DUP 11/27/90 12:00 6301-001

1.00 mCi 1.000 mCi

11/20/90 12:00 TL2011 T1201 1mC1 DUP 1.00 mCi

1.000 mCi

.71 ml C123

Large.

Large

11/20/90 11:00 TC0403 Tc04 Cardiac 27.00 mCi 11/20/90 19:30 0102-001

11/27/90 12:00 0301-001

27.000 mCi

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PACKING LIST CONTAINS ADDITIONAL PAGES

Pharmacy Service Center 2911 Penn Avenue

Pittsburgh PA 15201

412/261-6200

PACKING LIST

SHIP TO: WESTERN PENNSTLVANIA HOSP Nuclear Medicine Dept. 4800 Friendship Avenue

PITTIQUEGH PA 15224

CUST #1 0006 CASE #1 34 ROUTE #1 06

RX DATE/TIME PROD # DESCRIPTION

QUANTITY VOLUME P.O. NUMBER RX/ORD# PATIENT NAME

AGE RETN

EX DATE/TIME UDM ID#

ACTIVITY

11/20/90 12:00 TCD403 TcD4 Cardiac 27.00 mCi .54 ml C123

11/20/90 19:30 0107-001

27,000 mCi

11/20/90 09:00 TC9920 Sulf Col Tc99m 6.00 mC1

11/20/90 10:00 0110-001

6.000 mCi

11/20/90 10:00 TC9980 Pyro Tc99m 15.00 mCi .95 ml C123 674127 11/20/90 14:00 0104-001

15,000 mCi

THIS IS A 'PACKING LIST', NOT AN INVOICE. Mark 'X' in RETN column for Returned Doses. Consignee Name And Address:

Shipper: Syncor Corp Pharmacy Service Center 2911 Fenn Avenue

WESTERN PENNSYLVANIA HOSP Nuclear Medicine Dept. 4800 Friendship Avenue PITTSBURGH PA 15224 412/578-5155

Pittsburgh PA 15201 412/261-6200

Proper Shipping Name/Classification: RADIDACTIVE MATERIALS N.O.S. UN 2982

CASE NO. 34 ROUTE NO. 06

674088 674120 674121 674122 674128 674124 674125 674126 674127

RADIONUCLIDE	CHEMICAL FORM/PHYSICAL STAT	TE ACTIVITY (mCi)	(GBq)
Tc99m T1-201 Tc99m	Inorganic Salt/Liquid Inorganic Salt/Liquid Organic Compound/Liquid	145.894 8.176 29.082	5.398 0.303 1.076
	Total	183.142	6.776
LABEL CATEGORY:	Radioactive WHITE/YELLOW	Non-control of the section of	
	TRANSPORTATION INDEX :		

Bgcr	am.	Wipe Test _		Net cpm	
Action Level (6	600dpm per 300sg.	cm x EF of	0.905) =	5973 Net cpm/300sq.cm	
Surface Reading	mr/hr W	lipe Test, Inc	ner Source	Container /t cpr	11
described, packa	aged, marked and 1	abeled, and #	are in prop	operly classified, er condition for or the Department of	
Signature			Date/_	/ Time:	

The radioactive contents of each package is within the limits indicated for A2 classification according to 490FR 173.435.