

MATERIALS LICENSE

Amendment No. 29

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, 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		In accordance with the letters dated June 16, 1995 and June 30, 1995, License number 20-00320-19 is amended in its entirety to read as follows:	
1. Du Pont Merck Pharmaceutical Company		3. Expiration date September 30, 1999	
2. 331 Treble Cove Road North Billerica, Massachusetts 01862		5. Docket or Reference No 030-13288	
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. Phosphorus 32	A. Prepackaged organic salts in aqueous solutions	A. 10 curies	
B. Molybdenum 99/ Technetium 99m	B. In Tc99m Generators	B. 300 curies	
C. Xenon 133	C. Gas Calidose refills	C. 160 curies	
9. Authorized use			
A. through C. For possession, storage, and packaging incident to distribution to persons authorized to receive the licensed material pursuant to terms and conditions of a specific license issued by the Nuclear Regulatory Commission or an Agreement State.			

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 1909 Beltway Drive, Overland, Missouri; 8555 Sweet Valley Drive, Valley View, Ohio; and Ronson Aviation, Inc., Mercer County Airport, Trenton, New Jersey.
11. A. Licensed material shall be used by, or under the supervision of, Michael Rielly or individuals designated by the Radiopharmaceutical Division's Manager of Safety and Environmental Engineering.
- B. The Radiation Safety Officer for this license is Michael Rielly.

210047

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ML 10

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

20-00320-19

Docket or Reference number

030-13288

Amendment No. 29

(Continued)

CONDITIONS

12. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Letter dated July 11, 1986
- B. Letter dated June 16, 1989
- C. Letter dated October 29, 1991
- D. Letter dated June 9, 1992
- E. Letter dated August 25, 1992
- F. Letter dated February 25, 1993
- G. Letter dated April 4, 1993
- H. Facsimile dated September 23, 1994
- I. Letter dated April 14, 1995

Date JUL 14 1995

For the U.S. Nuclear Regulatory Commission

ORIGINAL SIGNED BY:

By SHERI A. ARREDONDO

Nuclear Materials Safety Branch
Region I

King of Prussia, Pennsylvania 19406

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JUL 14 1995

Francis E. Roy, Jr.
Development Health Physicist
DuPont Merck Pharmaceutical Company
331 Treble Cove Road
North Billerica, Massachusetts 01862

Dear Mr. Roy:

This refers to your license amendment request. Enclosed with this letter is the amended license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I office, the Licensing Assistance Section, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

ORIGINAL SIGNED BY:

SHERI A. ARREDONDO

Sheri A. Arredondo
Nuclear Materials Safety Branch
Division of Radiation Safety
and Safeguards

License No. 20-00320-19
Docket No. 030-13288
Control No. 121925

Enclosure:

1. Amendment No. 29

DOCUMENT NAME: P:\DUPONT

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DRSS/RI	N					
NAME	Arredondo/sa	SA					
DATE	07/14/95	07/ /95	07/ /95	07/ /95	07/ /95	07/ /95	

OFFICIAL RECORD COPY

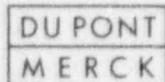
ML 10

030-13288

June 16, 1995

U.S. Nuclear Regulatory Commission
Region I

Attn.: John R. McGrath
Nuclear Materials Safety Branch
Division of Radiation Safety and Safeguards
475 Allendale Road
King of Prussia, PA 19406



Reference: Materials License # 20-00320-19

Dear Mr. McGrath:

I have enclosed for your review our close-out survey for the facility to be deleted from our license at 72 Weldon Parkway, Maryland Heights, Missouri.

On Friday, June 9, an initial radiological survey of the facility was conducted prior to the removal of all furniture and supplies and then a final survey was completed once all materials were removed from the facility. The radiation level survey was conducted using a Ludlum Model 3 GM survey meter. The radiological contamination survey was conducted with a NICO Ratemeter Model MD3 with an end-window GM detector, followed by wipe tests for removable contamination using paper towels fashioned into wipe samples. The results of the surveys and the locations of the instrument readings and wipe samples are indicated on the attached maps. The wipe samples were qualitatively checked for any gross contamination at the facility and then were sent to our Health Physics Laboratory at the division headquarters here in Billerica, Massachusetts. The wipes were counted using a high purity germanium detector, serial number 5922805, connected to a Canberra MCA Series 90 system. Each wipe sample was contained in its own plastic envelope and 10 of these samples were counted for 10 minutes at a time on the crystal. The raw data from this analysis is attached for your review.

The survey results indicate there were no radiation levels above background and no removable or fixed contamination found in the facility.

As we requested in a previous communication to your office please remove the Maryland Heights address from our license. A communication concerning our facility at St. Paul, Minnesota will be forwarded for your consideration in a separate letter. Your prompt attention to our previous license amendment request is greatly appreciated.

Sincerely,

Francis E. Roy, Jr.
Francis E. Roy, Jr. (Skip)
Development Health Physicist

TO: United States Nuclear Regulatory Commission, Region III
799 Roosevelt Road
Glen Ellyn, IL 60137-5927

The following documents and information are being used as

Facility Close-Out Survey and Wipe Contamination Reports.

Name Of Business: DuPont Merck Radiopharmaceutical Co.
Address: 72 Weldon Parkway
Maryland Heights, MO 63043
Phone: (314) 567-0114

Date Survey and Wipes taken: 6/9/95

Name of Person Performing all test: MARK Gatewood / Mike Lattimer

Position of Person Performing all test: Distribution Manager

Name of 2nd Person verifying all test: MIKE BLAKE / Mike Blake

Position of 2nd Person verifying all test: Distribution Supervisor

Type and Model # of Survey instrument used: Ludlum Model 3

Serial # of Survey instrument used: 34392

Last calibration date of Survey instrument used: 1-26-95

Type and model # of Wipe Contamination Analyzer used: NICO Ratchman MD 3

Serial # of Wipe Contamination Analyzer used: 4160

Last calibration date of Wipe Contamination Analyzer used: 1-26-95

The following wipe and survey information was gathered before removal of furniture, supplies, and or products.

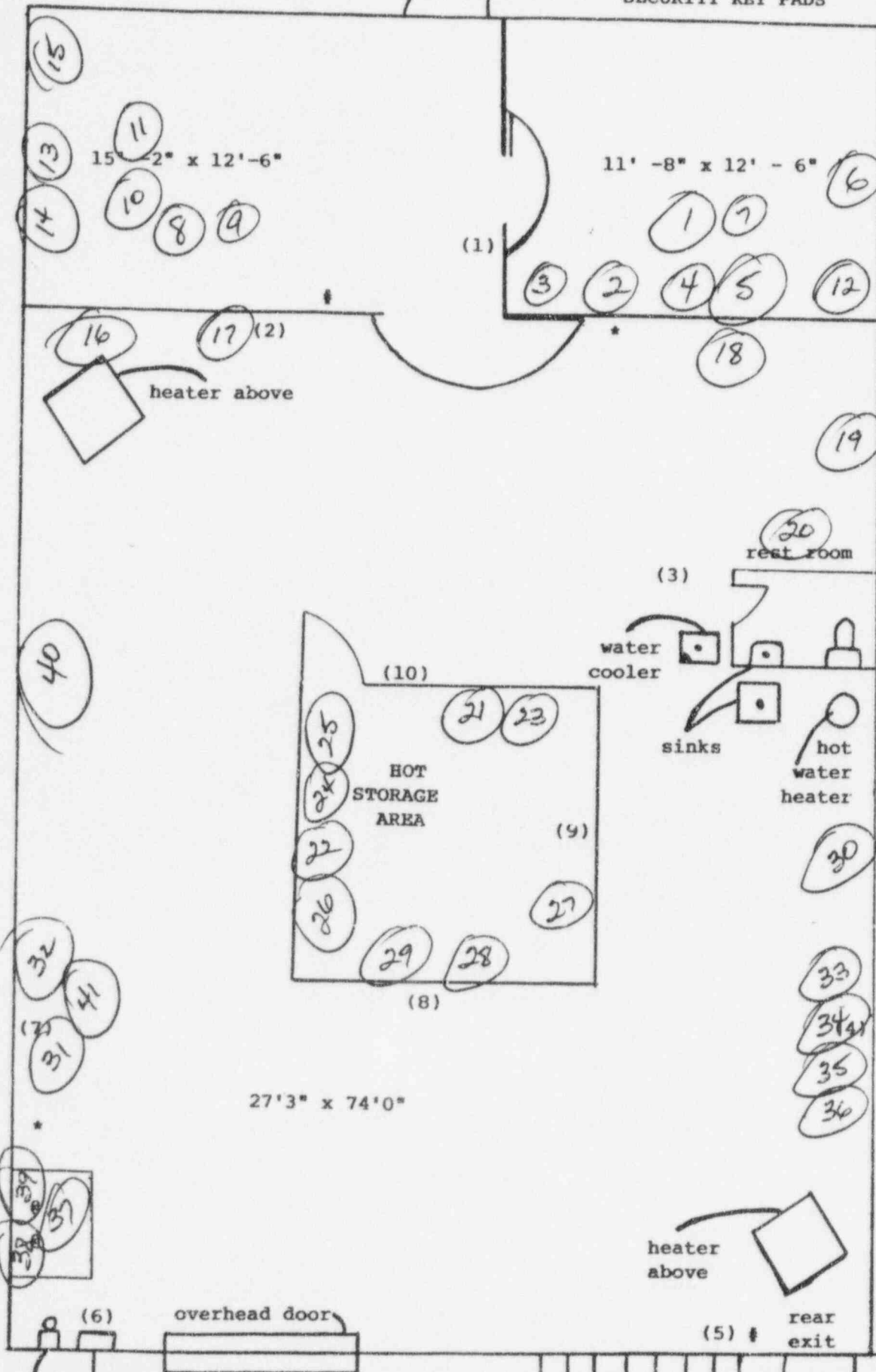
1. Front office (Desk # 1)
2. Computer table in office # 1
3. Computer printer and stand
4. Computer # 1 keyboard and terminal
5. Computer codex's X 2
6. Book shelve in office # 1
7. Chair in office # 1
8. Front office (Desk # 2)
9. Chair in office # 2
10. Typewriter
11. Fax Machine
12. Copy Machine and stand
13. Folding table in front office # 2
14. Coffee machine
15. 2-filing cabinets in front office # 2
16. 2-filing cabinets in warehouse
17. visitors log table (Desk # 3)
18. Heavy metal storage shelves set # 1
19. Heavy metal storage shelves set # 2
20. Office supplies storage shelves
21. Packaging table # 1
22. Packaging table # 2
23. 2-package sealing tape dispensers
24. Laser scanning gun
25. Temperature monitor
26. Computer # 2 keyboard and terminal
27. Product storage cabinet, handles, shelves, and exterior (# 1)
28. Product storage cabinet, handles, shelves, and exterior (# 2)
29. Product storage cabinet, handles, shelves, and exterior (# 3)
30. 4-filing cabinets in warehouse (not used)
31. 2-emergency responsepak fibre drums
32. 2-fire extinguishers
33. 2-two wheel dollies
34. 1-vacuum
35. 1-4 wheel metal cart for package moving
36. 3-phones
37. Package survey check in station (Desk # 4)
38. Survey meter
39. Ratemeter analyzer, and moly coddle
40. All boxes and styrofoams not used yet for packaging
41. Cuttie Pie

	mR/hr	cpm	dpm
1.	<u>0.03</u>	<u>30</u>	<u>0</u>
2.	<u>0.03</u>	<u>30</u>	<u>0</u>
3.	<u>0.03</u>	<u>30</u>	<u>0</u>
4.	<u>0.03</u>	<u>30</u>	<u>0</u>
5.	<u>0.03</u>	<u>30</u>	<u>0</u>
6.	<u>0.03</u>	<u>30</u>	<u>0</u>
7.	<u>0.03</u>	<u>30</u>	<u>0</u>
8.	<u>0.03</u>	<u>30</u>	<u>0</u>
9.	<u>0.03</u>	<u>30</u>	<u>0</u>
10.	<u>0.03</u>	<u>30</u>	<u>0</u>
11.	<u>0.03</u>	<u>30</u>	<u>0</u>
12.	<u>0.03</u>	<u>30</u>	<u>0</u>
13.	<u>0.03</u>	<u>30</u>	<u>0</u>
14.	<u>0.03</u>	<u>30</u>	<u>0</u>
15.	<u>0.03</u>	<u>30</u>	<u>0</u>
16.	<u>0.03</u>	<u>30</u>	<u>0</u>
17.	<u>0.03</u>	<u>30</u>	<u>0</u>
18.	<u>0.03</u>	<u>30</u>	<u>0</u>
19.	<u>0.03</u>	<u>30</u>	<u>0</u>
20.	<u>0.03</u>	<u>30</u>	<u>0</u>
21.	<u>0.03</u>	<u>30</u>	<u>0</u>
22.	<u>0.03</u>	<u>30</u>	<u>0</u>
23.	<u>0.03</u>	<u>30</u>	<u>0</u>
24.	<u>0.03</u>	<u>30</u>	<u>0</u>
25.	<u>0.03</u>	<u>30</u>	<u>0</u>
26.	<u>0.03</u>	<u>30</u>	<u>0</u>
27.	<u>0.03</u>	<u>30</u>	<u>0</u>
28.	<u>0.03</u>	<u>30</u>	<u>0</u>
29.	<u>0.03</u>	<u>30</u>	<u>0</u>
30.	<u>0.03</u>	<u>30</u>	<u>0</u>
31.	<u>0.03</u>	<u>30</u>	<u>0</u>
32.	<u>0.03</u>	<u>30</u>	<u>0</u>
33.	<u>0.03</u>	<u>30</u>	<u>0</u>
34.	<u>0.03</u>	<u>30</u>	<u>0</u>
35.	<u>0.03</u>	<u>30</u>	<u>0</u>
36.	<u>0.03</u>	<u>30</u>	<u>0</u>
37.	<u>0.03</u>	<u>30</u>	<u>0</u>
38.	<u>0.03</u>	<u>30</u>	<u>0</u>
39.	<u>0.03</u>	<u>30</u>	<u>0</u>
40.	<u>0.03</u>	<u>30</u>	<u>0</u>
41.	<u>0.03</u>	<u>30</u>	<u>0</u>
BKG	<u>0.03</u>	<u>30</u>	<u>0</u>

#72 Weldon Parkway
Area Designation Map
NOT TO SCALE

FRONT ENTRANCE

TLD LOGS IN () WITH AREA NUMBER
FIRE EXTINGUISHERS *
RATEMETER/SURVEY EQUIPMENT @
SECURITY KEY PADS #



The following wipe and survey information was gathered after removal of all furniture, supplies, and products. General janitorial cleaning had been accomplished.

- I 1. Exterior front entrance door, handles, and key locks.
- I 2. Exterior rear entrance door, handles, and key locks.
- I 3. Exterior dock, lifting type garage door, handles, and key locks.
- 4. Interior front office door and handle, between two offices.
- 5. Interior front office door and handle, between offices and restricted area.
- 6. Interior restroom entrance door and handles.
- 7. Interior entrance door and handle to radiopharmaceutical storage room.
- 8. Floor in # 1 front office.
- 9. Floor in # 2 front office.
- 10. Floor in restroom.
- 11. Floor in radiopharmaceutical storage room.
- 12. Position # 1 warehouse floor.
- 13. Position # 2 warehouse floor.
- 14. Position # 3 warehouse floor.
- 15. Position # 4 warehouse floor.
- 16. Position # 5 warehouse floor.
- 17. Position # 6 warehouse floor.
- 18. Position # 7 warehouse floor.
- 19. Position # 8 warehouse floor.
- 20. Position # 9 warehouse floor.
- 21. Restroom sink, faucet handles, toilet handle.
- 22. Janitorial sink, faucet and handles.
- 23. Thermostat, front and sides.
- 24. 2-Alarm system key pads-1 at front entrance 1 at rear.
- 25. All light switches.
- I 26. Drinking water cooler, push button, water drip tray, and sides.

THESE DOCUMENTS HAVE BEEN REVIEWED BY:

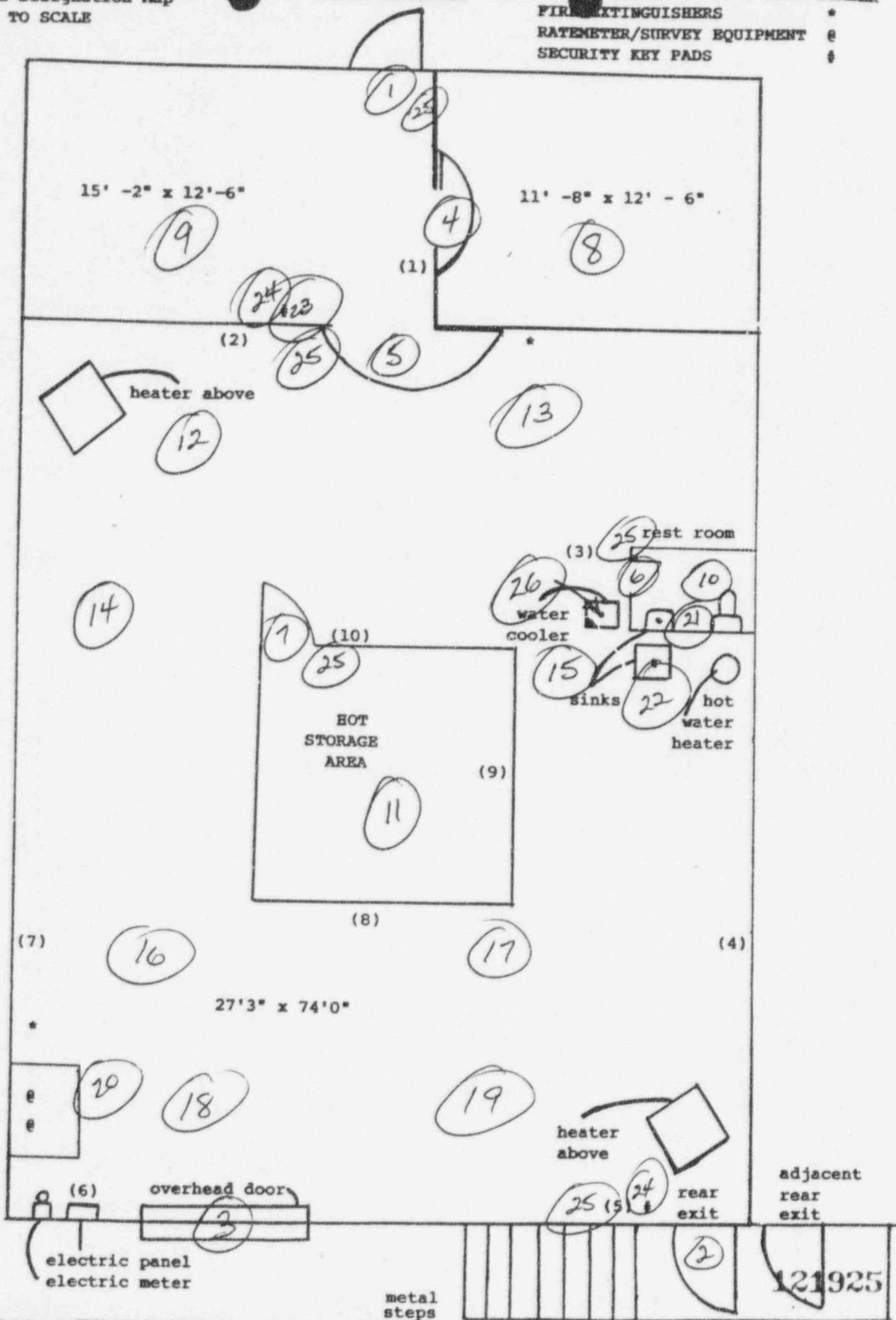
TITLE:

DATE:

J C Roy
Health Physicist
6/16/95

	mR/hr	cpm	dpm
I 1.	<u>0.03</u>	<u>30</u>	<u>0</u>
I 2.	<u>0.03</u>	<u>30</u>	<u>0</u>
I 3.	<u>0.03</u>	<u>30</u>	<u>0</u>
I 4.	<u>0.03</u>	<u>30</u>	<u>0</u>
5.	<u>0.03</u>	<u>30</u>	<u>0</u>
6.	<u>0.03</u>	<u>30</u>	<u>0</u>
7.	<u>0.03</u>	<u>30</u>	<u>0</u>
8.	<u>0.03</u>	<u>30</u>	<u>0</u>
9.	<u>0.03</u>	<u>30</u>	<u>0</u>
10.	<u>0.03</u>	<u>30</u>	<u>0</u>
11.	<u>0.03</u>	<u>30</u>	<u>0</u>
12.	<u>0.03</u>	<u>30</u>	<u>0</u>
13.	<u>0.03</u>	<u>30</u>	<u>0</u>
14.	<u>0.03</u>	<u>30</u>	<u>0</u>
15.	<u>0.03</u>	<u>30</u>	<u>0</u>
16.	<u>0.03</u>	<u>30</u>	<u>0</u>
17.	<u>0.03</u>	<u>30</u>	<u>0</u>
18.	<u>0.03</u>	<u>30</u>	<u>0</u>
19.	<u>0.03</u>	<u>30</u>	<u>0</u>
20.	<u>0.03</u>	<u>30</u>	<u>0</u>
21.	<u>0.03</u>	<u>30</u>	<u>0</u>
22.	<u>0.03</u>	<u>30</u>	<u>0</u>
23.	<u>0.03</u>	<u>30</u>	<u>0</u>
24.	<u>0.03</u>	<u>30</u>	<u>0</u>
25.	<u>0.03</u>	<u>30</u>	<u>0</u>
I 26.	<u>0.03</u>	<u>30</u>	<u>0</u>
BKG	<u>0.03</u>	<u>0.03/30</u>	<u>0</u>

MAP #2

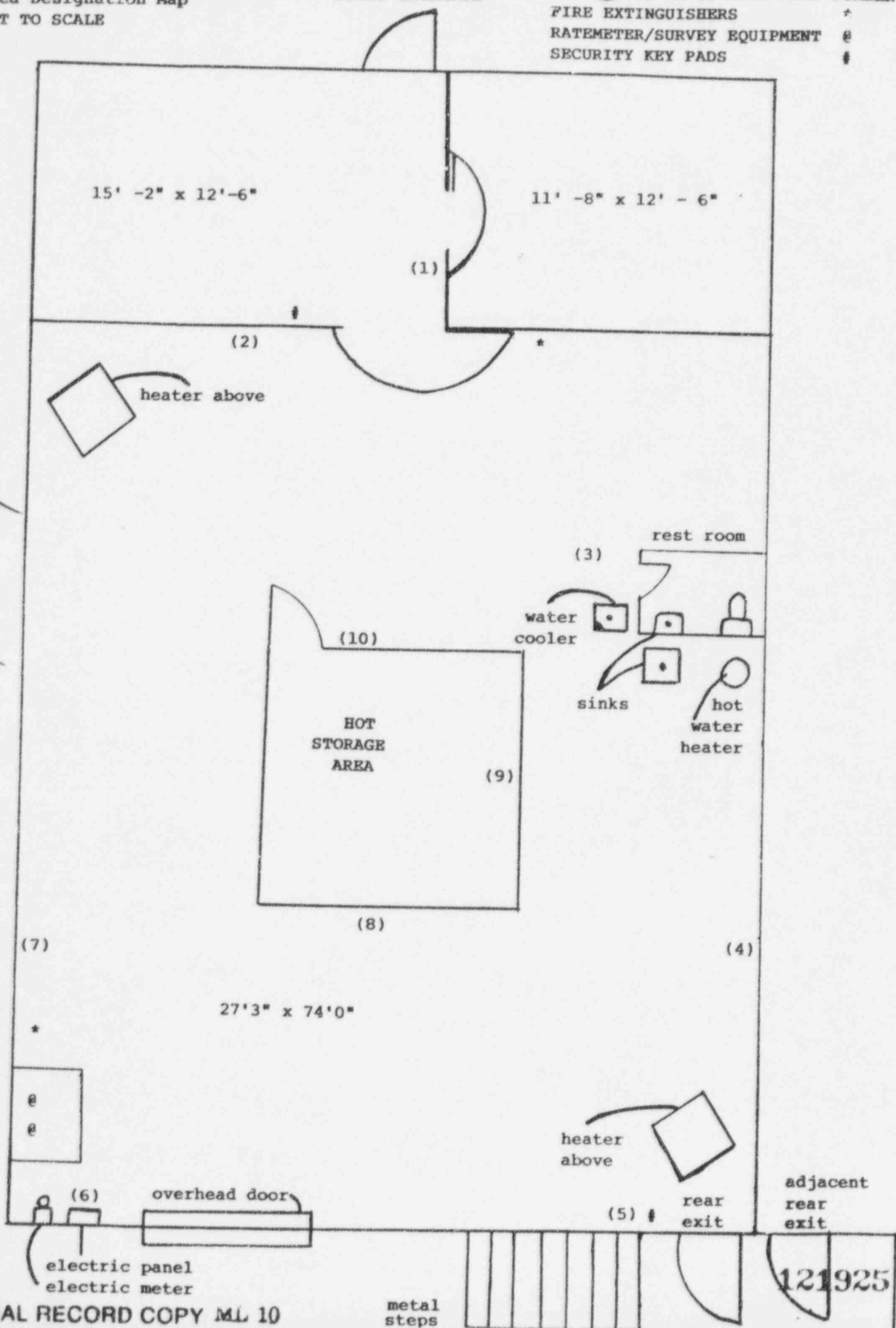


#72 Weldon Parkway
Area Designation Map
NOT TO SCALE

FRONT ENTRANCE

TLD LOGS IN () WITH AREA NUMBER
FIRE EXTINGUISHERS *
RATEMETER/SURVEY EQUIPMENT @
SECURITY KEY PADS #

MAP #3
All floors surveyed every 2 feet.



G A M M A S P E C T R U M A N A L Y S I S

CANBERRA APOGEE V2.0A

1 → 10

Canberra Industries, Inc.

14-JUN-95 14:49:01

A N A L Y S I S P A R A M E T E R S

```

spectrum file number      : 3004.0
MCA unit number          : 1          ADC unit number      : 3.0
detector number          : 3          Geometry number     : 1

Search discrimination level #1 : 2.5          level #2      : 3.0
Search FROM channel      : 51          TO channel   : 4096
Identification energy tolerance : 1.0      order of background : linear

Confidence levels      LLD : 1.645 (95.0%)      MDA : 1.645 (95.0%)

analysis library        : SPF$LIBRARY:SPFANL.LIB;1
background subtract     : disabled      Random sum corr : 0.0000

sample description      : samp 1-10          Sample no.      : 3
analyzed by            : Jed

sample size             : 1.000000E+00 EA
conversion factor       : 1.000
standard size           : 1.000000E+00 EA

sample taken on         : 14-JUN-95      at 14:38:08
collect started on      : 14-JUN-95      at 14:38:08
Decay time              : 0.0 minutes

live time               : 600.0 seconds
real time               : 600.0 seconds
dead time               : 0.00 %

energy calibration used done on 12 / 12 / 1994
efficiency calibration used done on 12 / 14 / 1994
  
```

*** P E A K S E A R C H R E P O R T ***

14-JUN-95 14:49:01

```

first search channel      : 51
last search channel       : 4096
first significance limit for found peaks: 2.50
second significance limit for found peaks: 3.00
average Gaussian peak width (in channels): 1.61
  
```

i	peak channel	peak energy	signif of peak	check-1 signif	check-2 shape	accept channels number
1	224.335	114.9	2.627	small		

*** P E A K I T R E P O R T *** 14-JUN-95 14:49:01

peak no.	nuclide(s)	centroid channel	energy keV	FWHM keV	net area counts	error %	gammas per second	error %
-------------	------------	---------------------	---------------	-------------	--------------------	------------	----------------------	------------

1 → 10

*** R A D I O N U C L I D E R E P O R T *** 14-JUN-95 14:49:01

Sample description :samp 1-10
 analyzed by :Jed

number	nuclide	conf.value	Activity (uCi/EA)	
			measured	decay corrected

Errors quoted at 1.650 sigma (90.1%)

G A M M A S P E C T R U M A N A L Y S I S

CANBERRA APOGEE V2.0A

11 → 20

Canberra Industries, Inc.

14-JUN-95 15:01:23

A N A L Y S I S P A R A M E T E R S

```

spectrum file number      : 3004.0
MCA unit number           : 1          ADC unit number      : 3.0
detector number           : 3          Geometry number     : 1

search discrimination level #1 : 2.5          level #2      : 3.0
search FROM channel       : 51              TO channel   : 4096
identification energy tolerance : 1.0      order of background : linear

Confidence levels        LLD : 1.645 (95.0%)      MDA : 1.645 (95.0%)

analysis library          : SPF$LIBRARY:SPFANL.LIB;1
background subtract       : disabled              Random sum corr : 0.0000

sample description        : samp 11-20           Sample no.      : 3
analyzed by               : Jed

sample size               : 1.000000E+00      EA
conversion factor         : 1.000
standard size             : 1.000000E+00      EA

sample taken on           : 14-JUN-95          at 14:50:29
collect started on        : 14-JUN-95          at 14:50:29
decay time                : 0.0 minutes

live time                 : 600.0      seconds
real time                 : 600.0      seconds
dead time                 : 0.00 %

Energy calibration used done on 12 / 12 / 1994
Efficiency calibration used done on 12 / 14 / 1994
  
```

*** P E A K S E A R C H R E P O R T *** 14-JUN-95 15:01:23

```

first search channel      : 51
last search channel       : 4096
first significance limit for found peaks: 2.50
second significance limit for found peaks: 3.00
average Gaussian peak width (in channels): 1.61
  
```

i	peak channel	peak energy	signif of peak	check-1 signif	check-2 shape	accept channels number
---	-----------------	----------------	-------------------	-------------------	------------------	---------------------------

peak no.	nuclide(s)	centroid channel	energy keV	FWHM keV	net area counts	error %	gammas per second	error %
-------------	------------	---------------------	---------------	-------------	--------------------	------------	----------------------	------------

11 → 20

*** R A D I O N U C L I D E R E P O R T ***

14-JUN-95 15:01:23

sample description : samp 11-20
 analyzed by : Jed

number	nuclide	conf.value	----- measured	Activity (uCi/EA) decay corrected
--------	---------	------------	-------------------	--

errors quoted at 1.650 sigma (90.1%)

 GAMMA SPECTRUM ANALYSIS

CANBERRA APOGEE V2.0A

21 → 30

Canberra Industries, Inc.

14-JUN-95 15:15:21

ANALYSIS PARAMETERS

Spectrum file number : 3004.0
 MCA unit number : 1 ADC unit number : 3.0
 Detector number : 3 Geometry number : 1
 Search discrimination level #1 : 2.5 level #2 : 3.0
 Search FROM channel : 51 TO channel : 4096
 Identification energy tolerance : 1.0 order of background : linear
 Confidence levels LLD : 1.645 (95.0%) MDA : 1.645 (95.0%)
 Analysis library : SPF\$LIBRARY:SPFANL.LIB;1
 Background subtract : disabled Random sum corr : 0.0000
 Sample description : samp 21-30 Sample no. : 3
 Analyzed by : Jed
 Sample size : 1.000000E+00 EA
 Conversion factor : 1.000
 Standard size : 1.000000E+00 EA
 Sample taken on : 14-JUN-95 at 15:04:28
 Collect started on : 14-JUN-95 at 15:04:28
 Decay time : 0.0 minutes
 live time : 600.0 seconds
 real time : 600.0 seconds
 dead time : 0.00 %
 Energy calibration used done on 12 / 12 / 1994
 Efficiency calibration used done on 12 / 14 / 1994

*** P E A K S E A R C H R E P O R T *** 14-JUN-95 15:15:21

first search channel : 51
 last search channel : 4096
 first significance limit for found peaks: 2.50
 second significance limit for found peaks: 3.00
 average Gaussian peak width (in channels): 1.61

i	peak channel	peak energy	signif of peak	check-1 signif	check-2 shape	accept channels number
1	282.902	143.5	2.728	small		

peak no.	nuclide(s)	centroid channel	energy keV	FWHM keV	net area counts	error %	gammas per second	error %
-------------	------------	---------------------	---------------	-------------	--------------------	------------	----------------------	------------

21 → 30

*** R A D I O N U C L I D E R E P O R T *** 14-JUN-95 15:15:21

sample description : samp 21-30
analyzed by : Jed

number	nuclide	conf.value	-----	Activity (uCi/EA)	-----
			measured		decay corrected

Errors quoted at 1.650 sigma (90.1%)

G A M M A S P E C T R U M A N A L Y S I S

ANBERRA APOGEE V2.0A

31 → 41

anberra Industries, Inc.

14-JUN-95 15:28:04

A N A L Y S I S P A R A M E T E R S

```

spectrum file number      : 3004.0
CA unit number           : 1      ADC unit number      : 3.0
detector number          : 3      Geometry number     : 1

search discrimination level #1 : 2.5      level #2      : 3.0
search FROM channel      : 51      TO channel    : 4096
identification energy tolerance : 1.0      order of background : linear

confidence levels      LLD : 1.645 (95.0%)      MDA : 1.645 (95.0%)

analysis library       : SPFL$LIBRARY:SPFANL.LIB;1
background subtract    : disabled      Random sum corr : 0.0000

sample description     : samp 31-41      Sample no.      : 3
analyzed by           : Jed

sample size            : 1.000000E+00  EA
conversion factor      : 1.000
standard size          : 1.000000E+00  EA

sample taken on        : 14-JUN-95      at 15:17:11
collect started on     : 14-JUN-95      at 15:17:11
Decay time             : 0.0 minutes

live time              : 600.0 seconds
real time              : 600.0 seconds
dead time              : 0.00 %

energy calibration used done on 12 / 12 / 1994
efficiency calibration used done on 12 / 14 / 1994
    
```

*** P E A K S E A R C H R E P O R T *** 14-JUN-95 15:28:04

```

first search channel      : 51
last search channel       : 4096
first significance limit for found peaks: 2.50
second significance limit for found peaks: 3.00
average Gaussian peak width (in channels): 1.61
    
```

i	peak channel	peak energy	signif of peak	check-1 signif	check-2 shape	accept channels number
---	-----------------	----------------	-------------------	-------------------	------------------	---------------------------

121925

peak no.	nuclide(s)	centroid channel	energy keV	FWHM keV	net area counts	error %	gammas per second	error %
-------------	------------	---------------------	---------------	-------------	--------------------	------------	----------------------	------------

31 → 41

*** R A D I O N U C L I D E R E P O R T ***

14-JUN-95 15:28:04

Sample description :samp 31-41
 Analyzed by :Jed

number	nuclide	conf.value	Activity (uCi/EA)	
			measured	decay corrected

Errors quoted at 1.650 sigma (90.1%)

 GAMMA SPECTRUM ANALYSIS

CANBERRA APOGEE V2.0A

Canberra Industries, Inc.

14-JUN-95 13:37:22

ANALYSIS PARAMETERS

Spectrum file number : 3004.0
 MCA unit number : 1 ADC unit number : 3.0
 Detector number : 3 Geometry number : 1
 Search discrimination level #1 : 2.5 level #2 : 3.0
 Search FROM channel : 51 TO channel : 4096
 Identification energy tolerance : 1.0 order of background : linear
 Confidence levels LLD : 1.645 (95.0%) MDA : 1.645 (95.0%)
 Analysis library : SPF\$LIBRARY:SPFANL.LIB;1
 Background subtract : disabled Random sum corr : 0.0000
 Sample description : samp I1-I10 Sample no. : 3
 Analyzed by : Jed
 Sample size : 1.000000E+00 FA

Standard size

Sample taken on : 14-JUN-95 at 13:26:28
Collect started on : 14-JUN-95 at 13:26:28
Decay time : 0.0 minutes
live time : 600.0 seconds
real time : 600.0 seconds
dead time : 0.00 %

I1 → I10

Energy calibration used done on 12 / 12 / 1994
Efficiency calibration used done on 12 / 14 / 1994

*** P E A K S E A R C H R E P O R T *** 14-JUN-95 13:37:22

first search channel : 51
last search channel : 4096
first significance limit for found peaks: 2.50
second significance limit for found peaks: 3.00
average Gaussian peak width (in channels): 1.61

i	peak channel	peak energy	signif of peak	check-1 signif	check-2 shape	accept channels number
---	-----------------	----------------	-------------------	-------------------	------------------	---------------------------

*** P E A K F I T R E P O R T *** 14-JUN-95 13:37:22

peak no.	nuclide(s)	centroid channel	energy keV	FWHM keV	net area counts	error %	gammas per second	error %
-------------	------------	---------------------	---------------	-------------	--------------------	------------	----------------------	------------

*** R A D I O N U C L I D E R E P O R T *** 14-JUN-95 13:37:22

Sample description : samp I1-I10

number	nuclide	conf.value	Activity (uCi/EA)	
			measured	decay corrected

Errors quoted at 1.650 sigma (90.1%)

 GAMMA SPECTRUM ANALYSIS

ANBERRA APOGEE V2.0A

I 11 → I 20

Anberra Industries, Inc.

14-JUN-95 14:04:08

ANALYSIS PARAMETERS

```

spectrum file number      : 3004.0
MCA unit number          : 1      ADC unit number   : 3.0
detector number           : 3      Geometry number  : 1

search discrimination level #1 : 2.5      level #2      : 3.0
search FROM channel       : 51      TO channel    : 4096
identification energy tolerance : 1.0    order of background : linear

Confidence levels        LLD : 1.645 (95.0%)      MDA : 1.645 (95.0%)

Analysis library          : SPF$LIBRARY:SPFANL.LIB;1
background subtract       : disabled      Random sum corr : 0.0000

Sample description        : samp I11-I20      Sample no.    : 3
analyzed by               : Jed

Sample size               : 1.000000E+00 EA
Conversion factor         : 1.000
Standard size             : 1.000000E+00 EA

Sample taken on           : 14-JUN-95      at 13:53:15
Collect started on        : 14-JUN-95      at 13:53:15
Decay time                : 0.0 minutes

live time                 : 600.0 seconds
real time                 : 600.0 seconds
dead time                 : 0.00 %

Energy calibration used done on 12 / 12 / 1994
Efficiency calibration used done on 12 / 14 / 1994
  
```

*** P E A K S E A R C H R E P O R T *** 14-JUN-95 14:04:08

```

first search channel      : 51
last search channel       : 4096
first significance limit for found peaks: 2.50
second significance limit for found peaks: 3.00
average Gaussian peak width (in channels): 1.61
  
```

i	peak channel	peak energy	signif of peak	check-1 signif	check-2 shape	accept channels number
---	-----------------	----------------	-------------------	-------------------	------------------	---------------------------

peak no.	nuclide(s)	centroid channel	energy keV	FWHM keV	net area counts	error %	gammas per second	error %
-------------	------------	---------------------	---------------	-------------	--------------------	------------	----------------------	------------

I 11 → I 20

*** R A D I O N U C L I D E R E P O R T ***

14-JUN-95 14:04:08

Sample description : samp I11-I20
Analyzed by : Jed

number	nuclide	conf.value	----- measured	Activity (uCi/EA) decay corrected
--------	---------	------------	-------------------	--

Errors quoted at 1.650 sigma (90.1%)

 GAMMA SPECTRUM ANALYSIS

ANBERRA APOGEE V2.0A

I 21 → I 26

anberra Industries, Inc.

14-JUN-95 14:22:19

ANALYSIS PARAMETERS

```

spectrum file number      : 3004.0
CA unit number            : 1      ADC unit number      : 3.0
detector number           : 3      Geometry number     : 1

search discrimination level #1 : 2.5      level #2      : 3.0
search FROM channel        : 51      TO channel    : 4096
identification energy tolerance : 1.0    order of background : linear

confidence levels          LLD : 1.645 (95.0%)      MDA : 1.645 (95.0%)

analysis library           : SPF$LIBRARY:SPFANL.LIB;1
background subtract        : disabled      Random sum corr : 0.0000

sample description         : samp I21-I26      Sample no.      : 3
analyzed by                : Jed

sample size                : 1.000000E+00 EA
conversion factor          : 1.000
standard size              : 1.000000E+00 EA

sample taken on            : 14-JUN-95      at 14:11:26
collect started on         : 14-JUN-95      at 14:11:26
Decay time                 : 0.0 minutes

live time                  : 600.0 seconds
real time                  : 600.0 seconds
dead time                  : 0.00 %
  
```

```

energy calibration used done on 12 / 12 / 1994
efficiency calibration used done on 12 / 14 / 1994
  
```

*** P E A K S E A R C H R E P O R T *** 14-JUN-95 14:22:19

```

first search channel      : 51
last search channel       : 4096
first significance limit for found peaks: 2.50
second significance limit for found peaks: 3.00
average Gaussian peak width (in channels): 1.61
  
```

i	peak channel	peak energy	signif of peak	check-1 signif	check-2 shape	accept channels number
---	-----------------	----------------	-------------------	-------------------	------------------	---------------------------

peak no.	nuclide(s)	centroid channel	energy keV	FWHM keV	net area counts	error %	gammas per second	error %
-------------	------------	---------------------	---------------	-------------	--------------------	------------	----------------------	------------

I 21 → I 26

*** R A D I O N U C L I D E R E P O R T *** 14-JUN-95 14:22:19

sample description :samp I21-I26
analyzed by :Jed

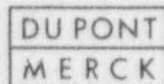
number	nuclide	conf.value	-----	Activity (uCi/EA)	-----
			measured	decay corrected	

Errors quoted at 1.650 sigma (90.1%)

121925

030-13288

June 30, 1995



U.S. Nuclear Regulatory Commission
Region I
Attn.: John R. McGrath
Nuclear Materials Safety Branch
Division of Radiation Safety and Safeguards
475 Allendale Road
King of Prussia, PA 19406

Reference: Materials License # 20-00320-19

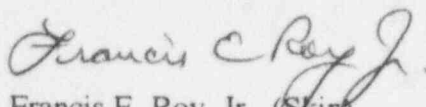
Dear Mr. McGrath:

As previously communicated in the letter dated April 14, 1995, we request the facility at 1045 Westgate Drive, Suite 100, St. Paul, Minnesota, be deleted from our Materials License referenced above.

I have attached for your information the license amendment recently issued to Syncor Corporation by NRC Region III authorizing Syncor's ownership and complete responsibility for the licensed operation previously belonging to DuPont Merck. Thus, please remove the facility on Westgate Drive in St. Paul from our Materials License.

Feel free to contact me if you need any additional information.

Sincerely,


Francis E. Roy, Jr. (Skip)
Development Health Physicist

Telephone: 508-671-8242

Toll Free: 1-800-362-2668, ext. 8242.



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

Syncor International
Corporation
ATTN: David W. Pellicciarini
Senior Health Physicist
Radioactive Material Licensing
1045 Westgate Drive, Suite 100
St. Paul, MN 55114

Dear Mr. Pellicciarini:

Enclosed is Amendment No. 18 to your NRC Material License No. 22-19174-01MD in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office so that we can provide appropriate corrections and answers.

Please be advised that we cannot authorize you to release your old nuclear medicine space for unrestricted use (even by other members of your staff) until we have received and reviewed a copy of the results of your close-out survey. The survey should consist of exposure rate measurements to show that all sources of radioactive material have been removed, and contamination checks of areas where radioactive materials were used or stored. Average radiation levels associated with surface contamination and removable contamination should not exceed those specified in the enclosed decontamination guide. Please submit the following information with your close-out survey:

- a. A diagram of your old facility with survey and wipe test results keyed to specific locations.
- b. The name of the person performing the survey.
- c. The date the survey was performed.
- d. The instrument(s) used for exposure rate measurements and for analysis of the wipes.
- e. Background readings.
- f. The date that the survey instrument was last calibrated.

Please review all materials you possess and distribute/redistribute to assure that your NRC license encompasses the activity, as required.

Syncor International
Corporation

-2-

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify NRC, in writing, within 30 days:
 - a. When Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or
 - b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).
3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:
 - a. When you decide to terminate all activities involving materials authorized under the license; or
 - b. If you decide not to complete the facility, acquire equipment, or possess and use authorized material.
4. Request and obtain a license amendment before you:
 - a. Change Radiation Safety Officers;
 - b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
 - c. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or
 - d. Change ownership of your organization.
5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

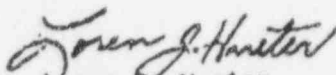
Syncor International
Corporation

-3-

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,



Loren S. Hueter
Nuclear Materials Licensing Section

License No. 22-19174-01MD
Docket No. 030-17084

Enclosures:

1. NRC Form 313
2. Amendment No. 18
3. Decontamination Guide

NRC FORM 874
(10-88)

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 1 OF 9 PAGES
Amendment No. 18

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 39, 40 made by the licensee, a license is hereby issued authorizing the licensee to use nuclear material designated below; to use such material for the purpose(s) and to persons authorized to receive it in accordance with the regulations of the act specified in Section 183 of the Atomic Energy Act of 1954, as amended, and the Regulatory Commission now or hereafter in effect and to any conditions specified below.

OPTIONAL FORM 89 (7-80)

FAX TRANSMITTAL

of pages: 12

To: D. PELLICCIARINI From: L. HUETER
 Use/Agency: _____ Phone: 708-829-9829
 Fax: 818-886-2972
 NEN 7640 01-317-7666 5089-1111

CENTRAL SERVICES ADMINISTRATION

Licensee

1. Syncor International Corporation

2. Suite 100
 1045 Westgate Drive
 St. Paul, MN 55114

In accordance with letters dated
 February 17, 1995

3. License number 22-19174-01MD is amended in
 its entirety to read as follows:

4. Expiration date July 31, 1996

5. Docket or Reference No. 030-17084

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. Molybdenum-99

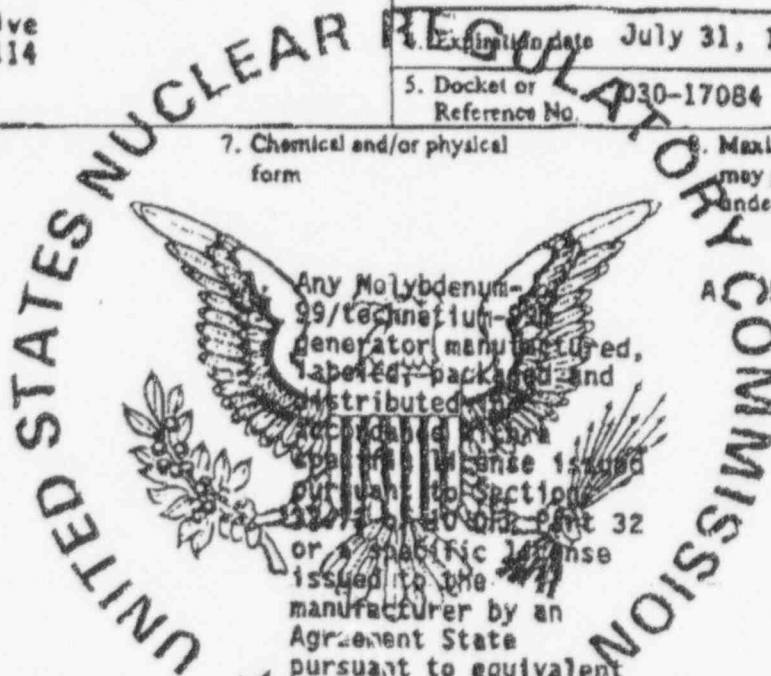
A. 50 curies

Any Molybdenum-99/technetium-99 generator manufactured, labeled, packaged and distributed in accordance with the license issued pursuant to Section 32.11(a) of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations.

B. Any byproduct
 material listed in
 Paragraph 31.11(a)
 of 10 CFR Part 31

B. Prepackaged in vitro
 diagnostic test kits

B. 50 millicuries
 total possession
 limit



MATERIALS LICENSE SUPPLEMENTARY SHEET

License number

22-19174-01MD

Docket or Reference number

030-17084

Amendment No. 18

5. 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
- C. Any byproduct material authorized under Paragraph 35.14(d)(4) of 10 CFR Part 35 (superseded) or Paragraph 35.57(a) of 10 CFR Part 35 (effective April 1, 1987)
- C. Any sealed source listed in Paragraph 35.14(d)(4) of 10 CFR Part 35 (superseded) or Paragraph 35.57(a) of 10 CFR Part 35 (effective April 1, 1987) that has been manufactured, labeled, packaged and distributed in accordance with a specific license issued pursuant to Section 32.77 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations.
- C. 50 millicuries total for all sources authorized under Subitem 6.C.
- D. Xenon-133
- D. Unit dose containers of gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA
- D. 3.0 curies

OPTIONAL FORM NO. (7-80)

FAX TRANSMITTAL

of pages to

David Belluscini
Deputy Director
NRC
818-886-2972
NRN 7640-01-117 7368

From: Loren Hunter
Phone: 718-829-9829
Fax: 718-829-9829

GENERAL SERVICES ADMINISTRATION

JUN 29 '95 08:07

708 515 1259

PAGE.01

Received Time

Jun. 29. 1:34PM

NRC Form 374A
(5-84)

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 3 OF 9 PAGES

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

22-19174-01MD

Docket or Reference number

030-17084

Amendment No. 18

5. Byproduct, source,
and/or special nuclear
material7. Chemical and/or physical
form8. Maximum amount
that licensee
may possess at
any one time
under this
license

E. Iodine-131

E. 990 millicuries

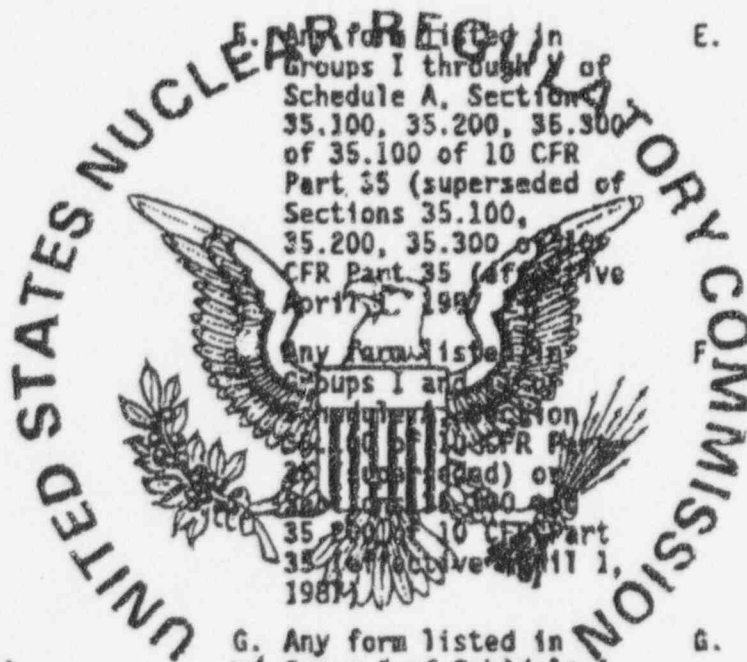
F. Technetium-99m

F. 50 curies

G. Any product
material, except
iodine-131 and
technetium-99m,
listed in Group I of
Schedule A, Section
35.100 of 10 CFR
Part 35 (superseded)
or Section 35.100 of
10 CFR Part 36
(effective April 1,
1987)

G. Any form listed in
Group I of Schedule A,
Section 35.100 of 10
CFR Part 35
(superseded) or Section
35.100 of 109 CFR Part
35 (effective April 1,
1987)

G. 50 millicuries
total possession
limit



NRC Form 374A
(8-84)

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 4 OF 9 PAGES

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

22-19174-01MD

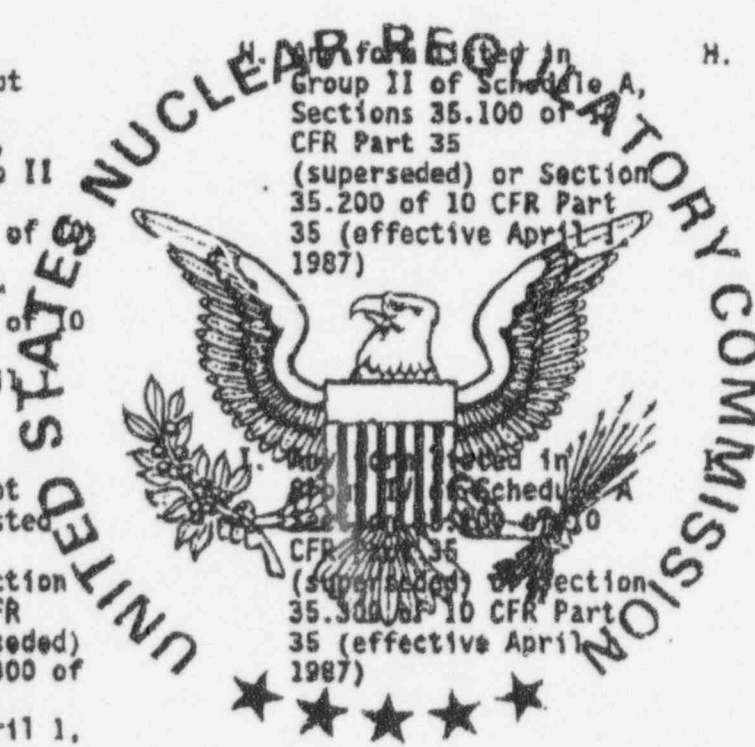
Docket or Reference number

030-17084

Amendment No. 18

5. Byproduct, source,
and/or special nuclear
material7. Chemical and/or physical
form8. Maximum amount
that licensee
may possess at
any one time
under this
licenseH. Any byproduct
material, except
iodine-131 and
technetium-99m,
listed in Group II
of Schedule A,
Section 35.100 of
10 CFR Part 35
(superseded) or
Section 35.200 of
10 CFR Part 35
(effective April
1, 1987)H. Any form listed in
Group II of Schedule A,
Sections 35.100 of
10 CFR Part 35
(superseded) or Section
35.200 of 10 CFR Part
35 (effective April
1, 1987)H. 100 millicuries
total possession
limitI. Any byproduct
material, except
iodine-131, listed
in Group IV of
Schedule A, Section
35.100 of 10 CFR
Part 35 (superseded)
or Section 35.300 of
10 CFR Part 35
(effective April 1,
1987)I. Any form listed in
Group IV of Schedule A,
Sections 35.100 of
10 CFR Part 35
(superseded) or Section
35.300 of 10 CFR Part
35 (effective April
1, 1987)500 millicuries
total possession
limitJ. Any byproduct
material listed in
Group VI of Schedule
A, Section 35.100 of
10 CFR Part 35
(superseded) or
Section 35.400 of 10
CFR Part 35
(effective April 1,
1987)J. Any sealed source that
has been manufactured,
labeled, packaged and
distributed in
accordance with a
specific license issued
pursuant to Section
32.74 of 10 CFR Part 32
or a specific license
issued to the
manufacturer by an
Agreement State
pursuant to equivalent
State regulations

J. 500 millicuries



NRC Form 374A
(5-84)

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 5 OF 9 PAGES

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

22-19174-01MD

Docket or Reference number

030-17084

Amendment No. 18

5. Byproduct, source,
and/or special nuclear
material7. Chemical and/or physical
form8. Maximum amount
that licensee
may possess at
any one time
under this
license

K. Gadolinium-153

K. Sealed sources (Gulf
Nuclear Model G0-2,
Amersham GDC-CV1, and
New England Nuclear
Models 430 or 431)K. No single source
exceed 1.5
curies, 4.5
curies total

L. Iodine-125

L. Sealed source (Amersham
Model IMC-P2, and AECL
Model, C-324 or 325)No single source
to exceed 500
millicuries, 1.0
curies totalM. Uranium (depleted in
the isotope Uranium
235)Metal, encased
stainless steel

M. 100 Kilograms

9. Authorized Use:

A. Production of technetium-99m, for use in medical diagnosis. Redistribution of unused generators to authorized recipients in accordance with statements, representations and procedures contained in application dated October 15, 1990.

B. Redistribution to general and specific licensees in accordance with statements, representations and procedures contained in application dated October 15, 1990.

C. Instrument calibration. Redistribution of sources to specifically authorized recipients. Pursuant to Section 32.74 of 10 CFR Part 32, the licensee is authorized to redistribute sources to persons licensed pursuant to Section 35.14 and 35.100 of 10 CFR Part 35 (superseded) or Section 35.57(a) of 10 CFR Part 35 (effective April 1, 1987) or under equivalent licenses of Agreement States.

D. Distribution to authorized recipients.

E. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients. Compounding of Iodine-131 capsules and distribution of these capsules to authorized recipients in accordance with the statements, representations and to authorized recipients in accordance with the statements, representations and procedures contained in application dated October 15, 1990.

NRC Form 374A
(6-84)

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 6 OF 9 PAGES

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

22-19174-01MD

Docket or Reference Number

030-17084

Amendment No. 18

F. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients. Use of technetium-99m pertechnetate for processing with reagent kits in preparing radiopharmaceuticals.

G. through I. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients.

J. through L. Redistribution of sealed sources received from the manufacturer in the manufacturer's original packaging and shielding and accompanied by the manufacturer's approved instructions to authorized recipients for use and storage.

M. Shielding of Molybdenum 99/technetium 99m generators.

Pursuant to 10 CFR, Parts 32.72, 32.73, 32.74, and notwithstanding 10 CFR 32.72(a)(2), the licensee is authorized to distribute the byproduct material described in Items 6 and 7 and prepared in accordance with License Conditions 16, 17, and 22 of this license to persons licensed in accordance with Sections 35.14 and 35.400 of 10 CFR Part 35 (superseded) or Sections 35.100, 35.200, 35.300, 35.400, and 35.500 of 10 CFR Part 35 (effective April 1, 1987), or under a valid Agreement with State licenses, for Groups or Sections indicated below.

A. Unused molybdenum-99/technetium-99m generators may be redistributed to persons licensed pursuant to Group I of Sections 35.100 and 35.400.

D. Gas or gas in saline may be distributed to persons licensed pursuant to 10 CFR 35.200 (effective April 1, 1987).

E. through I. Any form listed in each group, Groups I, II, III and IV of Schedule A, Section 35.100 of 10 CFR Part 35 (superseded) or authorized by Section 35.100, 35.200 and 35.300 (effective April 1, 1987), may be distributed to persons licensed pursuant to that Group or section.

J. through L. Sealed sources may be redistributed to persons licensed pursuant to Sections 35.400 and 35.500. (effective April 1, 1987).

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 1045 Westgate Drive, Suite 100, St. Paul, Minnesota.

NRC Form 374a
(5-84)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE
SUPPLEMENTARY SHEET

PAGE	7	OF	9	PAGES
License number	22-19174-01MD			
Booklet or Reference number	030-17084			
Amendment No.	18			

11. A. Licensed material shall be used by, or under the supervision of, individuals who are specifically named as users in Conditions 11.A. of License Number 34-16654-01MD. The licensee shall verify that each individual selected as a user is specifically named in Condition 11.A. of License Number 34-16654-01MD and, for this purpose, shall maintain for inspection by the Commission copies of License Number 34-16654-01MD.
- B. At least one individual named in Condition 11.A. shall be physically present at the authorized place of use whenever licensed material is being used.
- C. The Radiation Protection Officer for the activities authorized by this license is Brenda K. Norkoski.
12. A. (1) The sources specified in Item 7.C., J. through L. shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer shall not be put into use until tested.
- (2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.
- B. Any source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer.
- C. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351, ATTN: Chief, Nuclear Materials Safety Branch. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.
- D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.
13. Sealed sources containing licensed material shall not be opened or removed from their respective source holders by the licensee.

NRC Form 374A
(2-84)

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 8 OF 9 PAGES

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

22-19174-01MD

Docket or Reference number

030-17084

Amendment No. 18

14. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 2 years from the date of each inventory.
15. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
16. A. Radiopharmaceuticals dispensed and/or distributed for human use shall be either:

(i) Repackaged from prepared radiopharmaceuticals that are the subject of an FDA-approved "New Drug Application" (NDA) or for which FDA has accepted a "Notice of Claimed Investigational Exemption for New Drug" (IND), or

(ii) Prepared from generators and reagent kits that are the subject of an FDA-approved NDA or for which FDA has accepted an IND.

B. Prepared radiopharmaceuticals for which FDA has accepted an IND and radiopharmaceuticals prepared from generators or reagent kits for which FDA has accepted an IND shall be dispensed and/or distributed:

(i) In accordance with the procedures provided by the sponsor of the IND, and

(ii) Only to physicians who have been accepted by the sponsor of the IND to participate in clinical evaluation of the drug.

The licensee shall inform in writing each physician who participates in an IND evaluation that the physician is responsible to the sponsor of the IND for use of the drug in accordance with protocols established by the sponsor and for reporting to the sponsor the clinical information obtained through use of the drug.

17. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements and representations in its application dated October 15, 1990.

18. The licensee shall elute generators and process radioactive material with reagent kits in accordance with instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit; or not withstanding 10 CFR 32.72(a)(2), the licensee may prepare radiopharmaceuticals in accordance with the specific departures authorized in License Condition 17. of License Number 34-16654-01MD, provided that the licensee has all current specific departure directions and equipment required by License Condition 17. of License Number 34-16654-01MD and they are available for inspection by the commission.

NRC Form 374A
(5-84)

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 9 OF 9 PAGES

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

22-19174-01MD

Docket or Reference Number

030-17084

Amendment No. 18

19. Reagent kits may be redistributed to persons licensed pursuant to Sections 35.14 and 35.100 of 10 CFR Part 35, or under equivalent licenses of Agreement States, for Group III.
20. Any proposed changes in packaging, shielding or labeling shall be submitted for review to the U.S. Nuclear Regulatory Commission, Region III, Materials Licensing Section, 801 Warrenville Road, Lisle, Illinois 60532-4351.
21. The licensee shall maintain records of information important to safe and effective decommissioning at 1045 Westgate Drive, Suite 100, St. Paul, Minnesota per the provisions of 10 CFR 30.36(g) until this license is terminated by the Commission.
22. Notwithstanding 10 CFR 32.72(a)(2), the licensee may make departures to prepared iodine 131 (as sodium iodide) therapy dose radiopharmaceuticals, provided that the departures are made in accordance with License Condition 24. of License Number 34-16654-01MD and that the licensee has all current specific departure directions and required equipment and they are available for inspection.
23. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including the following, listed below. The Nuclear Regulatory Commission's Regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the Regulations.
- A. Application dated October 15, 1980, and
- B. Letters dated September 26, 1988, January 24, 1989, and July 10, 1991, July 30, 1991, August 12, 1991, and August 26, 1991 (with attachments contained in License No. 34-16654-01MD, letter dated April 4, 1991), June 10, 1992, August 10, 1992, September 24, 1992 (with attached closeout survey for facility at Suite 220, 2233 University Avenue, St. Paul, Minnesota), October 29, 1992, February 25, 1994, February 17, 1995, June 22, 1995, and June 28, 1995.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date JUN 29 1995

By

Loren J. Hunter

Materials Licensing Section, Region III

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03214
STATUS CODE: 0
FEE CATEGORY: 3P
EXP. DATE: 19990930
FEE COMMENTS: 3P OK 10/8/87 NOTE T
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION

I

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: DU PONT MERCK PHARMACEUTICAL CO.
RECEIVED DATE: 950703
DOCKET NO: 3013288
CONTROL NO.: 121998
LICENSE NO.: 20-00320-19
ACTION TYPE: AMENDMENT

2. FEE ATTACHED

AMOUNT: -----
CHECK NO.: 4

3. COMMENTS

SIGNED M. A. Perkins
DATE 7/14/95

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED ☒)

1. FEE CATEGORY AND AMOUNT: 3P \$360

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:

AMENDMENT ☒
RENEWAL -----
LICENSE -----

3. OTHER -----

SIGNED Bruce Brown
DATE 8/11/95

I (95)

Log	July 6
Remitter	
Check No.	203625
Amount	\$360
Fee Category	3P
Type of Fee	Amo
Date Check Rec'd	8/11/95
Date Completed	
By:	Bruce Brown

LICENSE FEE REQUIREMENTS

LICENSE FEE AND DEBT COLLECTION BRANCH
DIVISION OF ACCOUNTING AND FINANCE
OFFICE OF THE CONTROLLER
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ATTN: BRENDA BROWN

DU PONT MERCK PHARMACEUTICAL CO.
ATTN: FRANCIS E. ROY, JR. (SKIP)
RADIO PHARMACEUTICAL DIVISION
331 TREBLE COVE ROAD
NORTH BILLERICA, MA 01862

TYPE OF ACTION

NEW LICENSE

RENEWAL OF LICENSE

☒ AMENDMENT TO LICENSE

REQUESTED DATE

LETTER DATED 6/30/95

LICENSE NUMBER

20-00320-19

CONTROL NUMBER

121998

I. APPLICATION FEE DUE

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of the enclosed Federal Register notice. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
3P	\$	\$	\$ 360
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$

FEE(s) DUE	\$ 360
PAYMENT RECEIVED	\$ -0-
AMOUNT DUE	\$ 360

☒ Your request was received without the prescribed application fee.☐ We received your Check No. _____ in the amount of \$ _____. Payment of the additional fee noted above is required.☐ Your request will increase the scope of your license program. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(d)(2).☐ Your license expired prior to the receipt of your application for renewal. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(a).

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS ACTION.

SIGNATURE -- LICENSE FEE ANALYST

Brenda Brown

II. FEE NOT REQUIRED

☐ Enclosed is Check No. _____ which accompanied your request. The fee is not required because:☐ We received your Check No. _____ in payment of the fee.☐ The Licensing staff has informed us that your request is to be considered as a continuation of your request dated _____, Control No. _____.☐ Your request was combined, prior to review, with your _____ request, Control No. _____.

III. CHECK RETURNED

☐ Enclosed is Check No. _____ which was returned to us by the bank for:☐ INSUFFICIENT FUNDS☐ ACCOUNT CLOSED☐ OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

☐ License No. _____, Amendment No. _____, issued on _____ was issued without the required fee being collected. The fee required is noted in Section I of this form.☐ The scope of your licensed program was increased. Therefore, your request is subject to the application fee(s) noted in Section I of this form. Refer to Section 170.31 and Footnote 1(d)(2).☐ Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section I of this form.

DATE

7/27/95

VOID SHEET

TO: License Fee Management Branch
FROM: Region I
SUBJECT: VOIDED APPLICATION

Control Number: 121998
Applicant: DuPont Merck Pharmaceuticals
Date Voided: 7/14/95
Reason for Void: void & Combine w/ mctL# 121925-
Before Review

Cynthia Daniel 7/14/95
Signature Date

Attachment:
Official Record Copy of
Voided Action

FOR LFMB USE ONLY

Final Review of VOID Completed:

☐ Refund Authorized and processed

☐ No Refund Due

☐ Fee Exempt or Fee Not Required

Comments: After Review

Log completed

Processed by: _____

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

: PROGRAM CODE: 03214
: STATUS CODE: 0
: FEE CATEGORY: 3P
: EXP. DATE: 19990930
: FEE COMMENTS: 3P OK 10/8/87 NOTE TO
: DECOM FIN ASSUR REQD: N
:

LICENSE FEE TRANSMITTAL

A. REGION

I

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: DU PONT MERCK PHARMACEUTICAL CO.
RECEIVED DATE: 950619
DOCKET NO: 3013288
CONTROL NO.: 121925
LICENSE NO.: 20-00320-19
ACTION TYPE: AMENDMENT

2. FEE ATTACHED

AMOUNT: -----
CHECK NO.: -----

3. COMMENTS

SIGNED *M. A. Carlson*
DATE *6/20/95*

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED) *11/13*

1. FEE CATEGORY AND AMOUNT: *3P* *Cont'n of 127653*

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:

AMENDMENT -----
RENEWAL -----
LICENSE -----

3. OTHER -----

SIGNED *Burt L...*
DATE *6/23/95*

RECEIVED BY LFDCB	
Date	<i>6/23/95</i>
By	<i>June 14 1995</i>
	<i>B. Brown</i>
	<i>6/23/95</i>

1995 JUN 22 PM 4 53