



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

January 19, 2017

License: 19-00296-21

Br. 2
03037773

U.S. Nuclear Regulatory Commission
Division of Radiation Safety and Safeguards
2100 Renaissance Blvd
King of Prussia, PA 19406

Dear Sir or Madam:

This is a request to amend conditions 8B, 8C, 8D, and 8E of NIH Cyclotron Production License 19-00296-21. The NIH Cyclotron Facility has recently received targetry upgrades for both of its GE PETtrace units. The main purpose of the upgrades is to be able to produce PET radionuclides at a higher specific activity. However, it will also be possible to produce a larger quantity than has been previously possible. Although there is no immediate demand to deliver more activity overall, it would be prudent to have the license limits be commensurate with what is possible. The requested amounts are as follows:

- 8B – Carbon-11: 30 Ci total
- 8C – Nitrogen-13: 20 Ci total
- 8D – Oxygen-15: 20 Ci total
- 8E – Fluorine-18: 40 Ci total
-

Attached is an evaluation of the (unrealistic) worst case scenario for the cyclotron vaults: 40 Ci of F-18 placed against the inside wall of the vault. The vault is shielded with a minimum of 4 feet of concrete on its thinnest side and can easily handle this amount of radioactivity.

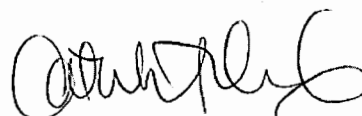
Also attached is an updated hot cell shielding evaluation for the nuclide with the highest hot cell delivery amount, C-11 which is typically 3 Ci. The evaluation is under the same conditions as was set in the original license application. Activity amounts were evaluated up to 6 Ci for 2-inch hot cells and 40 Ci for 3-inch hot cells, respectively. The results show that 2-inch hot cells are adequate for up to 6 Ci if this amount were ever needed to be delivered. The Division of Radiation Safety (DRS) will re-evaluate on a case-by-case basis the 2-inch hot cells should more than 6 Ci ever be requested. The 3-inch hot cells are adequate for any amount up to the license limit.

REC'D IN LAT *01/19/2017*

592836
NMSS/RGNI MATERIALS-002

Additionally, DRS will re-evaluate any shielded gas transfer line prior to allowing delivery of a larger amount of activity than is currently done.

If you have any questions or need additional clarification on this amendment request, please contact me at 301-594-1303 or via email at cribaudo@nih.gov.

A handwritten signature in black ink, appearing to read 'Catherine A. Ribaudo', with a stylized flourish at the end.

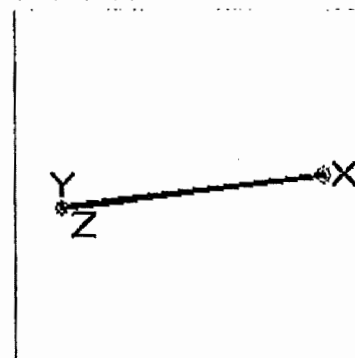
Catherine A. Ribaudo

cc: Dr. Bradford Wood, Chair, NIH Radiation Safety Committee

MicroShield 8.02
NIH/ORS (8.02-0000)

Date	By	Checked	
Filename	Run Date	Run Time	Duration
Case1	November 30, 2016	4:06:15 PM	00:00:00
Project Info			
Case Title	Cyclotron Vaults		
Description	40 Ci F-18 at inside surface of 4 ft concrete wall		
Geometry	1 - Point		

Dose Points			
A	X	Y	Z
#1	121.92 cm (4 ft)	0.0 cm (0 in)	0.0 cm (0 in)
Shields			
Shield N	Dimension	Material	Density
Shield 1	4.0 ft	Concrete	2.35
Air Gap		Air	0.00122



Source Input: Grouping Method - Actual Photon Energies					
Nuclide	Cl		Bq		
F-18	4.0000e+001		1.4800e+012		
Buildup: The material reference is Shield 1					
Integration Parameters					
Results					
Energy (MeV)	Activity (Photons/sec)	Fluence Rate MeV/cm²/sec No Buildup	Fluence Rate MeV/cm²/sec With Buildup	Exposure Rate mR/hr No Buildup	Exposure Rate mR/hr With Buildup
0.0005	2.650e+08	0.000e+00	7.238e-27	0.000e+00	4.225e-26
0.511	2.863e+12	1.359e-04	2.640e-02	2.667e-07	5.181e-05
Totals	2.863e+12	1.359e-04	2.640e-02	2.667e-07	5.181e-05

MicroShield 8.02
NIH/ORS (8.02-0000)

Date	By	Checked	
Filename	Run Date	Run Time	Duration
Case2	December 1, 2016	7:10:04 AM	00:00:01
Project Info			
Case Title	50 mm Pb Hot Cell		
Description	6 Ci C-11 in stainless steel coil		
Geometry	12 - Annular Cylinder - External Dose Point		

Source Dimensions

Height	8.0 cm (3.1 in)
Inner Cyl Radius	2.0 cm (0.8 in)
Inner Cyl Thickness	0.079 cm (0.0 in)
Outer Cyl Thickness	0.079 cm (0.0 in)
Source	0.159 cm (0.1 in)

Dose Points

A	X	Y	Z
#1	66.0 cm (2 ft 2.0 in)	4.0 cm (1.6 in)	0.0 cm (0 in)

Shields

Shield N	Dimension	Material	Density
Cyl. Radius	2.0 cm	Air	0.00122
Shield 1	.079 cm	Iron	7.86
Source	17.251 cm ³	Air	0.00122
Shield 3	.079 cm	Iron	7.86
Transition	30.0 cm	Air	0.00122
Shield 6	5.0 cm	Lead	11.34
Air Gap		Air	0.00122



Source Input: Grouping Method - Actual Photon Energies

Nuclide	Ci	Bq	μCi/cm ³	Bq/cm ³
C-11	6.0000e+000	2.2200e+011	3.4780e+005	1.2869e+010

Buildup: The material reference is Shield 6

Integration Parameters

Radial	10
Circumferential	20
Y Direction (axial)	20

Results

Energy (MeV)	Activity (Photons/sec)	Fluence Rate MeV/cm ² /sec No Buildup	Fluence Rate MeV/cm ² /sec With Buildup	Exposure Rate mR/hr No Buildup	Exposure Rate mR/hr With Buildup
0.0002	4.928e+05	0.000e+00	1.443e-29	0.000e+00	2.415e-28

0.511	4.430e+11	8.426e+02	1.701e+03	1.654e+00	3.338e+00
Totals	4.430e+11	8.426e+02	1.701e+03	1.654e+00	3.338e+00
	Sensitivity	Variable	X Dose Point 1	(1 of 3)	(66 cm)
0.0002	4.928e+05	0.000e+00	1.443e-29	0.000e+00	2.415e-28
0.511	4.430e+11	8.426e+02	1.701e+03	1.654e+00	3.338e+00
Totals	4.430e+11	8.426e+02	1.701e+03	1.654e+00	3.338e+00
	Sensitivity	Variable	X Dose Point 1	(2 of 3)	(56 cm)
0.0002	4.928e+05	0.000e+00	2.004e-29	0.000e+00	3.355e-28
0.511	4.430e+11	1.170e+03	2.362e+03	2.296e+00	4.636e+00
Totals	4.430e+11	1.170e+03	2.362e+03	2.296e+00	4.636e+00
	Sensitivity	Variable	X Dose Point 1	(3 of 3)	(46 cm)
0.0002	4.928e+05	0.000e+00	2.969e-29	0.000e+00	4.971e-28
0.511	4.430e+11	1.730e+03	3.493e+03	3.396e+00	6.856e+00
Totals	4.430e+11	1.730e+03	3.493e+03	3.396e+00	6.856e+00

Sensitivity Analysis Summary - X Dose Point 1

Dose Point #	Sensitivity	Sensitivity Dimension	Fluence Rate	Fluence Rate	Exposure Rate	Exposure Rate
			MeV/cm ² /sec No Buildup	MeV/cm ² /sec With Buildup	mR/hr No Buildup	mR/hr With Buildup
1	(1 of 3)	(66 cm)	8.426e+02	1.701e+03	1.654e+00	3.338e+00
1	(2 of 3)	(56 cm)	1.170e+03	2.362e+03	2.296e+00	4.636e+00
1	(3 of 3)	(46 cm)	1.730e+03	3.493e+03	3.396e+00	6.856e+00

MicroShield 8.02
NIH/ORS (8.02-0000)

Date	By	Checked	
Filename	Run Date	Run Time	Duration
Case2	December 1, 2016	7:03:12 AM	00:00:01
Project Info			
Case Title	75 mm Pb Hot Cell		
Description	40 Ci C-11 in stainless steel coil		
Geometry	12 - Annular Cylinder - External Dose Point		

Source Dimensions

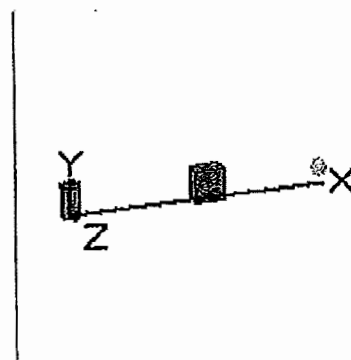
Height	8.0 cm (3.1 in)
Inner Cyl Radius	2.0 cm (0.8 in)
Inner Cyl Thickness	0.079 cm (0.0 in)
Outer Cyl Thickness	0.079 cm (0.0 in)
Source	0.159 cm (0.1 in)

Dose Points

A	X	Y	Z
#1	66.0 cm (2 ft 2.0 in)	4.0 cm (1.6 in)	0.0 cm (0 in)

Shields

Shield N	Dimension	Material	Density
Cyl. Radius	2.0 cm	Air	0.00122
Shield 1	.079 cm	Iron	7.86
Source	17.251 cm ³	Air	0.00122
Shield 3	.079 cm	Iron	7.86
Transition	30.0 cm	Air	0.00122
Shield 6	7.5 cm	Lead	11.34
Air Gap		Air	0.00122



Source Input: Grouping Method - Actual Photon Energies

Nuclide	Ci	Bq	$\mu\text{Ci/cm}^3$	Bq/cm^3
C-11	4.0000e+001	1.4800e+012	2.3187e+006	8.5791e+010

Buildup: The material reference is Shield 6

Integration Parameters

Radial	10
Circumferential	20
Y Direction (axial)	20

Results

Energy (MeV)	Activity (Photons/sec)	Fluence Rate MeV/cm ² /sec No Buildup	Fluence Rate MeV/cm ² /sec With Buildup	Exposure Rate mR/hr No Buildup	Exposure Rate mR/hr With Buildup
0.0002	3.286e+06	0.000e+00	9.617e-29	0.000e+00	1.610e-27

0.511	2.953e+12	8.762e+01	2.018e+02	1.720e-01	3.961e-01
Totals	2.953e+12	8.762e+01	2.018e+02	1.720e-01	3.961e-01
	Sensitivity	Variable	X Dose Point 1	(1 of 3)	(66 cm)
0.0002	3.286e+06	0.000e+00	9.617e-29	0.000e+00	1.610e-27
0.511	2.953e+12	8.762e+01	2.018e+02	1.720e-01	3.961e-01
Totals	2.953e+12	8.762e+01	2.018e+02	1.720e-01	3.961e-01
	Sensitivity	Variable	X Dose Point 1	(2 of 3)	(56 cm)
0.0002	3.286e+06	0.000e+00	1.336e-28	0.000e+00	2.236e-27
0.511	2.953e+12	1.215e+02	2.799e+02	2.385e-01	5.493e-01
Totals	2.953e+12	1.215e+02	2.799e+02	2.385e-01	5.493e-01
	Sensitivity	Variable	X Dose Point 1	(3 of 3)	(46 cm)
0.0002	3.286e+06	0.000e+00	1.979e-28	0.000e+00	3.314e-27
0.511	2.953e+12	1.792e+02	4.129e+02	3.518e-01	8.105e-01
Totals	2.953e+12	1.792e+02	4.129e+02	3.518e-01	8.105e-01

Sensitivity Analysis Summary - X Dose Point 1

Dose Point #	Sensitivity	Sensitivity Dimension	Fluence Rate MeV/cm ² /sec No Buildup	Fluence Rate MeV/cm ² /sec With Buildup	Exposure Rate mR/hr No Buildup	Exposure Rate mR/hr With Buildup
1	(1 of 3)	(66 cm)	8.762e+01	2.018e+02	1.720e-01	3.961e-01
1	(2 of 3)	(56 cm)	1.215e+02	2.799e+02	2.385e-01	5.493e-01
1	(3 of 3)	(46 cm)	1.792e+02	4.129e+02	3.518e-01	8.105e-01



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Department of Health & Human Services
ATTN: Catherine Ribaud, Radiation Safety
Officer
21 Wilson Drive MSC 6780
National Institutes of Health
Bethesda, MD 20892-6780

Date

January 24, 2017

License Number(s)

19-00296-21

Mail Control Number(s)

592836

Licensing and/or Technical Reviewer or Branch

Commercial, Industrial, R&D, & Academic Branch
Branch (Branch 2)

This is to acknowledge receipt of your: ☒ Letter and/or ☐ Application Dated: 01/19/2017

The initial processing, which included an administrative review, has been performed.

☒ Amendment ☐ Termination ☐ New License ☐ Renewal

☒ There were no administrative omissions identified during our initial review.

☐ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

☐ Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>
Follow the instructions on the form for submission.

☐ The following administrative omissions have been identified:

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
U. S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713
(610) 337-5260, (610) 337-5313,
(610) 337-5398, or (610) 337-5239



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- 8C – Nitrogen-13: 20 Ci total
- 8D – Oxygen-15: 20 Ci total
- 8E – Fluorine-18: 40 Ci total
-

Attached is an evaluation of the (unrealistic) worst case scenario for the cyclotron vaults: 40 Ci of F-18 placed against the inside wall of the vault. The vault is shielded with a minimum of 4 feet of concrete on its thinnest side and can easily handle this amount of radioactivity.

Also attached is an updated hot cell shielding evaluation for the nuclide with the highest hot cell delivery amount, C-11 which is typically 3 Ci. The evaluation is under the same conditions as was set in the original license application. Activity amounts were evaluated up to 6 Ci for 2-inch hot cells and 40 Ci for 3-inch hot cells, respectively. The results show that 2-inch hot cells are adequate for up to 6 Ci if this amount were ever needed to be delivered. The Division of Radiation Safety (DRS) will re-evaluate on a case-by-case basis the 2-inch hot cells should more than 6 Ci ever be requested. The 3-inch hot cells are adequate for any amount up to the license limit.

REC'D IN LAT *01/19/2017*

592836
NUCLEAR MATERIALS-002