

20 July 2009

BORGESS
Medical Center

Toye Simmons
Materials Licensing Section
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Rd.
Lisle, IL 60532-4352

Subject: Amendment requests for license number 21-12275-02

On July 7, 2008 we requested an amendment to our license to delete reference to animal research from our license. We received a request from you on October 23, 2009 for further information and were instructed to refer to Control # 317345.

The following additional information was requested:

1. A historical review of the animal research program. This is given in Attachment 1.
2. Address and areas used for animal research. This is given in Attachment 1.
3. What radioisotopes were used and for what experiments and with what animals. This is given in Attachment 1.
4. The kinds of animals used. This is given in Attachment 1.
5. The dates when radioisotopes were used. This is given in Attachment 1.
6. Describe the final disposition of the animal tissue. This is given in Attachment 1.
7. Results of the close-out survey with requested details. This is given in Attachment 2

If there are any further questions please do not hesitate to contact me at (269) 373-7407.

Sincerely,



Paul Jursinic, Ph.D.
Radiation Safety Officer
Borgess Medical Center



Tom Mushett
Director, Radiology Services
Borgess Medical Center

RECEIVED JUL 27 2009

Attachment 1

Borgess Medical Center Animal Research

Type of Experiment	Address of Use and Areas of Use	Radioisotope	When	Chemical Form	Physical Form	Animal	Final disposition of animal tissues/carcasses and radioactive waste
The Effect of Endovascular Irradiation via a Novel Balloon Expandable β Particle Emitting Stent on Neointimal Formation in a Porcine Model	1521 Gull Road Research Lab Level C Kalamazoo, MI 49048	Phosphorus-32	1997	NA	Solid	Swine	Coronary arteries collected and shipped to the Armed Forces Institute of Pathology. Remaining tissues discarded in usual manner.
A Comparison of Strategies for the Treatment of In-Stent Restenosis	1521 Gull Road Research Lab Level C Kalamazoo, MI 49048	Phosphorus-32	1997	NA	Solid	Swine	Coronary arteries collected and shipped to the Armed Forces Institute of Pathology. Remaining tissues discarded in usual manner.
The Effect of Y-90 Endovascular Irradiation Delivery via a Balloon Expandable Stent on Neo-intimal Formation in a Porcine Model	1521 Gull Road Research Lab Level C Kalamazoo, MI 49048	Yttrium-90	1997	NA	Solid	Swine	Coronary arteries collected and shipped to the Armed Forces Institute of Pathology. Remaining tissues discarded in usual manner.
The Effects of Barotrauma on Neointimal Formation at the Edges of Radioactive Stents for Prevention of Restenosis	1521 Gull Road Research Lab Level C Kalamazoo, MI 49048	Phosphorus-32	1999	NA	Solid	Rabbit	Iliac arteries collected and shipped for analysis. Remaining tissues discarded in usual manner.
The effects of a novel low energy gamma radioisotope stent (Pd-103) on neointimal formation for prevention of restenosis	1521 Gull Road Research Lab Level C Nuclear Radiology Hot Lab N461 Kalamazoo, MI 49048	Palladium-103	10/26/1999- 11/18/1999	NA	Solid	Rabbit	After necropsy, stent harvested and remained in lead containing plastic storage container until transported for histologic analysis. Urine blood and tissue of animal not contaminated and disposed as usual. Tissue sent to Dr. Tio in Texas. Remaining materials returned to manufacturer.
Feasibility and safety of a new P-32 self expandable radioisotope stent (SMART stent) implantation in a porcine model of restenosis	1521 Gull Road Research Lab Level C Nuclear Radiology Hot Lab N461 Kalamazoo, MI 49048	Phosphorus-32	1/2000- 6/29/2000	NA	Solid	Swine	Iliac artery segments placed in radiation shielded containers and express shipped to pathology lab at University of Texas San Antonio (Dr. Tio). Pigs euthanized. Urine, blood, tissue of animal not contaminated, discard in usual manner. Remaining materials returned to Nordion.
A 120-day Safety Evaluation comparing the Interaction of Brachytherapy with Cordis Cypher Stents and Polymer Stents in Porcine Coronary Arteries	1521 Gull Road Research Lab Level C Cardiology Hot Lab Kalamazoo, MI 49048	Strontium-90	08/27/2003- 12/2004	NA	Special form solid	Swine	After euthanization, heart was removed and delivered to Dr. Tio, Biomedical Research Foundation of South Texas. Carcasses were discarded. Remaining materials returned to vender in original container.

Attachment 2

Close-out Survey

Previous Cardiology Hot Lab-5W
Borgess Medical Center
1521 Gull Road
Kalamazoo, Michigan 49048

Date Performed: May 22, 2009
Performed by: Angela Burandt, BS, CNMT, RT(N)

Visual Check

The area was check to ensure that all radioactive materials had been removed.

Radiation Level Survey

Surveys were performed using a Ludlum 14C survey meter.

Calibration: August 11, 2008

Range used was 0-0.02 mR/hr.

No area within the room demonstrated radiation levels in excess of the background reading of 0.02 mR/hr.

Removable Contamination

Wipe test were analyzed with a Capintec Well Counter.

Calibration: May 6, 2009

Minimum detectable activity = 36 dpm

1 minute counts

Background 0 dpm

Wipe test results for all areas show a maximum removable contamination of 98 dpm.

See attached results and diagrams.

Conclusion

No removable contamination is present.

Close-out Survey

Previous Animal Research Lab C
Borgess Medical Center
1521 Gull Road
Kalamazoo, Michigan 49048

Date Performed: May 22, 2009 and July 9, 2009
Performed by: Angela Burandt, BS, CNMT, RT(N)

Visual Check

The area was checked to ensure that all radioactive materials had been removed.

Radiation Level Survey

Surveys were performed using a Ludlum 14C survey meter.

Calibration Date: August 11, 2008

Range used was 0-0.02 mR/hr.

No area within the room demonstrated radiation levels in excess of the background reading of 0.02 mR/hr.

Removable Contamination

Wipe tests were analyzed with a Capintec Well Counter.

Calibration Date: May 6, 2009

Minimum detectable activity = 36 dpm

1 minute counts

Background 0 dpm

Wipe test results for all areas show a maximum removable contamination of 162 dpm.

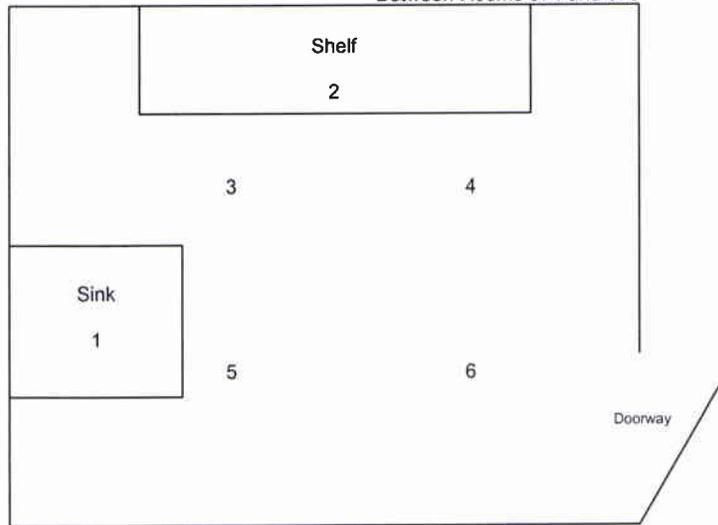
See attached results and diagrams.

Conclusion

No removable contamination is present.

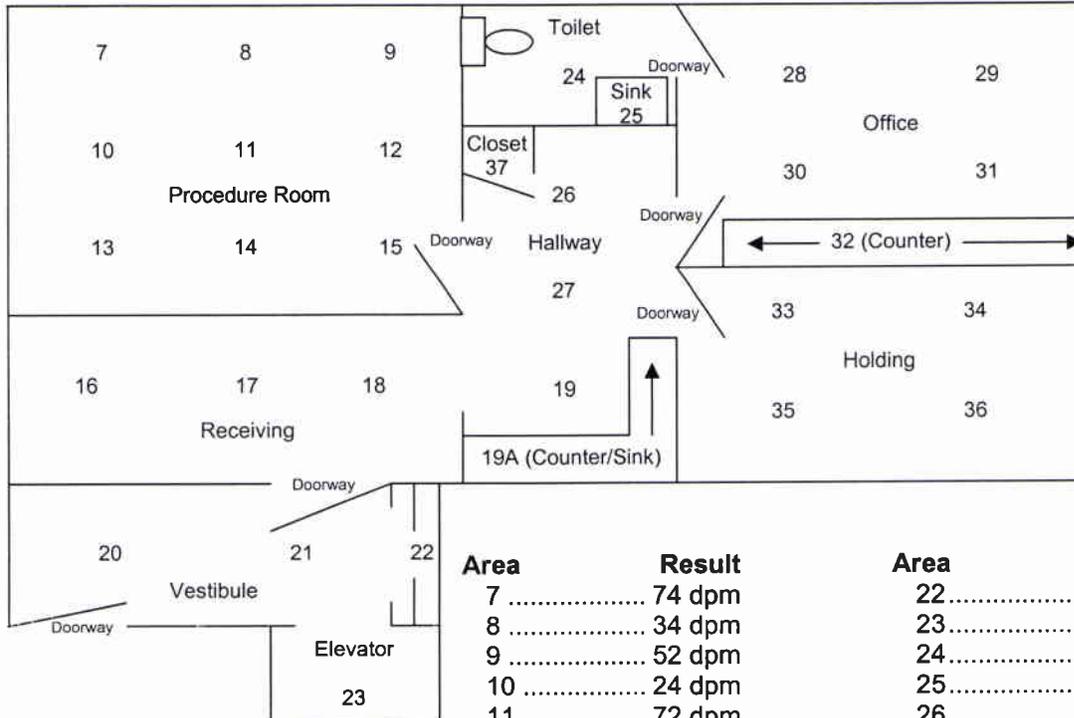
Close-out Survey
 Borgess Medical Center
 1521 Gull Road
 Kalamazoo, Michigan 49048

Cardiology Hot Lab
 Fifth Floor West
 Between Rooms 574 and 575



Area	Result
1.....	40 dpm
2.....	54 dpm
3.....	40 dpm
4.....	98 dpm
5.....	16 dpm
6.....	50 dpm

Animal Research Lab
 Level C



Area	Result	Area	Result
7	74 dpm	22	84 dpm (floor and shelves)
8	34 dpm	23	70 dpm
9	52 dpm	24	116 dpm
10	24 dpm	25	44 dpm
11	72 dpm	26	60 dpm
12	2 dpm	27	92 dpm
13	88 dpm	28	42 dpm
14	18 dpm	29	30 dpm
15	68 dpm	30	28 dpm
16	46 dpm	31	26 dpm
17	50 dpm	32	56 dpm
18	20 dpm	33	66 dpm
19	118 dpm	34	78 dpm
19A	154 dpm	35	138 dpm
20	96 dpm	36	66 dpm
21	162 dpm	37	26 dpm

BORGESS
Medical Center
RADIOLOGY

1521 Gull Road
Kalamazoo, MI 49048

RESORTED
FIRST CLASS



02 1M
0004256818

\$ 00.50⁷
JUL 22 2009

MAILED FROM ZIP CODE 49048

TEMP-RETURN SERVICE REQUESTED - PRSRT 1STCLASS 07/22/09

Toye Simmons
Materials Licensing Section
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Rd.
Lisle, IL 60532-4352



EAGFPM1 60532

