

June 15, 2010

U.S. Nuclear Regulatory Commission
Region III
Material Licensing Section
2443 Warrensville Road, suite 210
Lisle, Illinois 60532-4352

RE: Deletion of Two Items From List of Approved Radionuclides
License #: 24-18625-01

To Whom It May Concern:

Research Medical Center would like to make the following changes in authorized radionuclides.

1. Deletion of Item 6. G, Strontium-90 permitted by 10 CFR 35.1000.
2. Deletion of item 6. E, Any byproduct material permitted by 10 CFR 31.11 as pre-packaged kits.

Detail for the deletion of item 6. G, Strontium-90:

These were sealed sources used in an applicator for intravenous brachytherapy to prevent restenosis in stents placed in coronary arteries. Drug-coated stents have eliminated the need for the item.

Amendment 25 covering these sources was issued in July, 2001 and modified by Amendment 27 in June, 2002. The sources and applicators were exchanged every six (6) months. The last applicator and set of sources was removed by Novoste (the vendor) in 2003. The files containing the transfer documents cannot be located at this time.

Novoste's vascular brachytherapy business was acquired by Best Industries (now doing business as Best Vascular) in March, 2006. Novoste's computed records indicate that all devices shipped to us were received back by Novoste. A copy of their confirmation letter is attached.

The room where the sources were stored was decommissioned by Amendment 38 in August, 2006.

Detail for deletion of item 6. E, Any by product material permitted by 10 CFR 31.11. as prepackaged kits:

No use of these prepackaged kits has been made since 1997. In 1997, the Radiation Safety Officer (RSO) decommissioned the area where the kits were used. His results were reported to the Radiation Safety Committee in May 1997. However, the result was never communicated to the Nuclear Regulatory

Radiology

Commission nor was the item deleted from the facilities license. The result of his decommissioning survey (Attachment IV, "Decommissioning Survey of RMC Chem Lab" dated March 25, 1997) from the meeting minutes is enclosed.

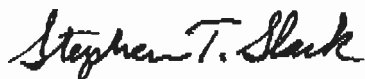
Please note two survey instruments were used, both of which are still in use. The Ludlum 14C does not have a detailed efficiency curve for use at low photon energies, so the RSO used the Victoreen 450 P from the Gamma Knife area. The response curve is attached. This unit's efficiency is greater than 50% at I-125 energies.

The wipes were counted using a Picker well counter and scaler. The wipes were compared to an I-125 source. Decontamination of some parts and removal and decay of others was undertaken. The contaminated drain pipe and trap were held for greater than ten (10) half-lives, monitored and then correctly disposed.

10 CFR 31.11 covers a variety of radionuclides. I-125 was the only radionuclide used at the location surveyed in 1997. If there were any use of any other radionuclides permitted under this item, it was in another laboratory decommissioned in 1980-81, when the Nuclear Medicine area and Hot Lab moved to its present location. Between 1981 and 1997, I-125 was the only radionuclide used under item 6. E.

Please feel free to contact me if you need additional information or have questions.

Sincerely,



Stephen T. Slack, Ph.D.
Radiation Safety Officer
Stephen.Slack@hcahealthcare.com
816-276-4449



Jackie DeSouza
Chief Operating Officer
Research Medical Center

Attachments

Cc: Michael Scott, R.T., MBA
Imaging Director

Jane Peck, RN
Radiation Oncology Director

File

Best[®]vascular

March 31, 2010

Stephen Slack, PhD/Radiation Safety Officer
Research Medical Center
2316 E. Meyer Blvd.
Kansas City, MO 64132

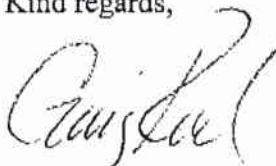
Dear Dr. Slack:

This letter is in response to the request by Jackie Phillips for written confirmation for Novoste radioactive material transfer device records relating to Research Medical Center (a former Novoste Corporation Customer, #20000771).

Best Vascular, Inc. acquired the Novoste Corporation vascular brachytherapy business in March 2006. The Novoste Corp vascular brachytherapy business records indicate that all devices shipped to Research Medical Center were received back at Novoste Corporation on or before Jan 4, 2006. For completeness, Best Vascular, Inc. has not shipped or received any radioactive material to/from the Research Medical Center.

Please note that Best Vascular, Inc. continues to provide hospitals with the Novoste™ Beta-Cath™ System - the only system approved and available for the treatment of in-stent coronary restenosis - and we would welcome your facility as a Best Vascular, Inc. customer if physicians and patients in your community have a need.

Kind regards,



Craig Reed, RSO (RAML No. GA 1350-1&2)
Best Vascular, Inc.

4350 International Blvd., Norcross, GA 30093 USA
phone 770 717 0904 800 NOVOSTE (668 6783) fax 770 717 1283 877 753 8537
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Jun. 16. 2010 10:00AM
Radiology Admin.
4/9
816276163

Internal Communication

Date: March 25, 1997

To: Research Medical Center Radiation Safety Committee

From: Edmund P. Cytacki, Ph.D.
Radiation Oncology, RMC

PPC

Subject: Decommissioning Survey of RMC Chem Lab

1. On March 7, 1997 I surveyed the sink used for radionuclide disposal in the RMC Chem Lab and the counter tops surrounding this sink. Background radiation levels (see report) were measured at all locations surveyed except at the bottom of the sink directly above the drain. A reading at this position was 20 microR/hr or about 10 microR/hr above background radiation levels. This low level of external exposure will pose no hazard.
2. Wipe tests were taken from the counter and sink tops as well as the sink bottom and inside the sink drain pipe. (see reports) Less than 20 dpm removable activity (essentially the minimal detectable level) was found at all positions except the sink bottom and the sink drain pipe. The level at the sink bottom was 500 dpm removable activity. After cleaning the sink the removable activity was reduced to 198 dpm which is less than the maximum allowed for iodine. The removable activity from the sink drain pipe was 1.5 nCi or 3220 dpm.
3. Actions that have been taken:
 - a. The sink has been taken out and disposed in a normal way.
 - b. The counter tops in the lab can be used for any unrestricted purposes.
 - c. The drain pipe and trap from the sink has been carefully removed, sealed in a plastic bag, labeled as containing iodine-125 and dated, and stored in the radiation storage area on B-level. It will be held for 600 days or ten half lives of I-125.
 - d. The end of the drain pipe left in the wall has been capped and finished over with new construction.
 - e. No more radionuclides will be used in this area and the lab is now used for Microbiology.
- cc. John Schario, RMC Vice-President
David Rood, Construction Contractor

Radiation Survey

Source Receipt/Return Survey

Nuclide: ¹²⁵Iodine

Supplier: _____

Location: RMC Chem Lab Hot Sink
+ counter tops

Current Activity: _____

Date: 3/7/97

Instrument: Make: Ludlum GM thin window
Model No.: 140
Ser. No.: 106562

Chk Source Rdg: 7.1 mR/hr

Results

Also used GM knife survey meter
Victrean -
(Ionization meter) Ser # 2292

Location	Reading	
	Ludlum	Victrean
Counter top at Sink	~0.3 mR/hr	~10 µR/hr
Counter Top NAK	~0.03 mR/hr	~10 µR/hr
Counter Top South	0-0.3 mR/hr	~10 µR/hr
Bottom of Sink	~0.3 mR/hr	~20 µR/hr

Surveyor: Edward B. Cytanki, PhD

Wipe Test Form

Ⓟ Bottom of sink
Ⓟ Sink cracks
Ⓟ Down to North
Ⓟ Counter top to sink

Description of Sample: Cotton Swabs Wipes at DMC Lab

Nuclide Monitored: Iodine-125

Date Sample Taken: 3/12/97

Date Sample Counted: 3/13/97

NV - 363V
0.2 Range

Well Counter ---
Make: Pickvev
Model No.: SpectroScaler II
Ser. No.: CE 1431

Energy Window: 10 - 40 keV

Calibration for monitored nuclide: _____ nCi/cpm

Background Count Rate: 14, 8, 16, 14 cpm → ave 13 cpm
(1) - 277, 278 (2) - 16, 18

3√13 = 11 → 20 dpm
15 mDA
20.01 nCi

Sample Count Rate: 7, 14 cpm
(3) - 7, 14 (4) - 10, 16

Sample Activity: (_____) x _____ = _____ nCi

Decay Factor: _____

Activity at Time of sampling: 500 dpm 20 dpm 20 dpm
(1) 500 dpm (2) 20 dpm (3) 20 dpm

Sample D = 0.23 nCi

Standard Nuclide and Sample Calibration

Nuclide: I¹²⁵

Gammas/disi.: _____

Activity: 10 nCi

Date: Oct. 96

Current Activity: 1.5 nCi

13 March 97

Sample and standard as same nuclide

Background: 14, 8, 16, 14 cpm

Sample Nuclide

Standard: 1767, 1719 cpm

Gammas/dist.: _____

Standard Calib: 1.89 nCi/cpm

Rel Sensitivity: _____ sample/stan

Sample Calib.: _____ nCi/cpm

Performed by: Cheryl P. Gotsch, PhD

Checked by: _____

Residue of sink on 3/14/97 after cleaning

123, 116, 128, 112 cpm

By 16, 15, 14

> Net cpm = 105 cpm ⇒

198 dpm

~ 0.09 nCi

Wipe Test Form

Description of Sample: Contaminant of Run. Lab Spike drain pipe

Nuclide Monitored: ¹³⁷I

Date Sample Taken: 3/7/97

Well Counter — Make: Pickup SpectroScan
Model No.: 4R
Ser. No. CE 1436

Energy Window 10 - 40 keV
Standard (Nuclide/Activity) 9.2 nCi I¹³⁷
Standard CPM: 10,533 10577 10577 10577
Standard Eff: (std/dist): 1,150 cpm/nCi
(should be between 0.25 - 0.40)

Sensitivity for monitored nuclide: 0.0014 nCi/cpm (assumes 2.1 gammas/dist and effic. of 0.5)

Background Count Rate: 7, 14, 13 cpm *ave 11*

Sample Count Rate: 1748, 1653, 1590, 1731 cpm *10-40 keV → 1681 ave*

Sample Activity: (1681 - 11) × 1/1150 cpm/nCi = 1.5 nCi

Activity at Time of sampling: 1.5 nCi

Performed by: Edward P. Gifford, PhD

Checked by: _____

Wider Windows

10 - 150 keV → 1757, 1677 Signal 35, 35

100 - 1000 → 77, 94 Signal 86, 79

↪ A < 0.04 nCi removable
contaminant for energies higher than 100 keV

no high level activity
3/7/97

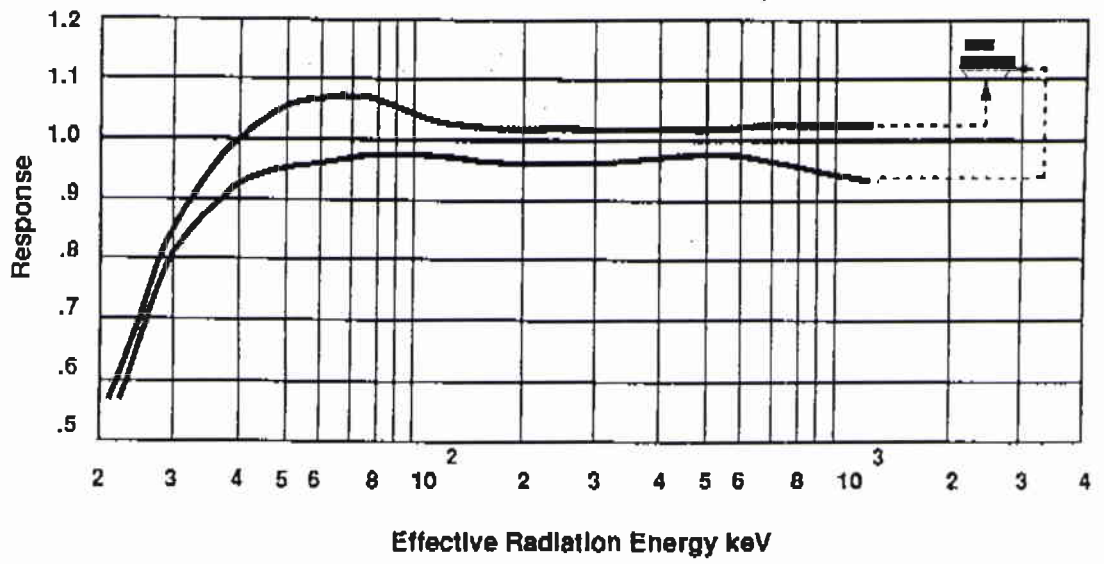


Figure 1-2. Survey Meter Energy Response

**RESEARCH MEDICAL CENTER
RADIOLOGY DEPARTMENT**

- TO: NUCLEAR REGULATORY
COMMISSION

FROM: Research Medical Center -& Brookside
Campus Imaging / Michael Scott, Rad. Dir.

COMPANY:

HCA

DATE:

6/16/2010

FAX NUMBER:

1 630 - 515 - 1078

TOTAL NO. OF PAGES INCLUDING COVER:

9

PHONE NUMBER:

SENDER'S REFERENCE NUMBER:

816-276-4141 phone

RE:

License # 24 - 18625-01

YOUR REFERENCE NUMBER:

816-276-3637 fax

URGENT FOR REVIEW PLEASE COMMENT PLEASE REPLY PLEASE RECYCLED

See attached – letter and supporting documents for deletion of two items from the list of Approved Radionuclides.

Michael Scott, R.T., M.B.A.

Imaging Director

816 276 4404 – phone

816 276 3637 - fax

Michael.scott2@hcahealthcare.com

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