

816

17 June 2013

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

Re: Changes in the scope of approval of authorized users, decommissioning of an area and removal of Sr-90 eye applicator from license.

Research Medical Center, license number 24-18625-01, would like to make a number of changes in the license.

- 1. Reinstatement of Part 300 use by Jay S. Robinow, M. D.
- Addition of TheraSpheres to the approval for use of Y-90 microspheres for Jay S. Robinow, M. D., David Shaeffer, M. D. and John M. Sheldon, M. D.
- 3. Decommissioning of the area that has been used for storage of brachytherapy sources by Radiation Oncology.
- 4. Deletion of Sr-90 eye applicator from the license.

Because these are all very different items, they may be considered severable, so that difficulty with one does not impede consideration of the others.

1. Reinstatement of Part 300 use by Jay S. Robinow, M. D.

From the time he was first approved for use of radionuclides under this license until February 01, 2012, Jay S. Robinow, M. D. was an authorized user for Part 300 materials on this license. We asked that his approval be rescinded because he was not active in prescribing I-131 therapy and there were, at that time, no radiopharmaceuticals we anticipated using for Radiation Oncology patients. This changed with the approval of Ra-223 for bone metastases. Therefore, we would like to request his reinstatement. We feel it is advantageous to patients to have the treatment of bone metastases controlled by a physician treating the primary disease and other metastases. Dr. Robinow will take whatever training the vendor provides in the safe use of this radiopharmaceutical. The actual administration of the Ra-223 will take place in Nuclear Medicine using registered Nuclear Medicine technologists under the supervision of Dr. Robinow or one of the other physicians approved for Part 300 use.

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2. Addition of TheraSpheres to the approval for use of Y-90 microspheres for Jay S. Robinow, M. D., David Shaeffer, M. D. and John M. Sheldon, M. D.

We are currently licensed for Y-90 microspheres, both as SirSpheres and TheraSpheres, but our authorized users have not yet been trained on and are not yet approved for TheraSpheres. We now wish to add approval for the use of Y-90 microspheres as TheraSpheres for Jay S. Robinow, M. D., David Shaeffer, M. D. and John M. Sheldon, M. D., subject to their receiving training in the safe use of TheraSpheres and having three proctored cases. Conditional approval of at least one of them is necessary in order for the vendor to provide the microspheres necessary for on-site training since the trainer is not an authorized user. Documentation will be provided as each completes his training and experience. Our microsphere handling and radiation safety procedures remain in place, but will be modified for TheraSpheres to the degree required by the vendor's instructions.

3. Decommissioning of the area that has been used for storage of brachytherapy sources by Radiation Oncology.

We wish to decommission the area on Level B of Research Medical Center adjacent to the Nuclear Medicine waste storage area formerly used as a Radiation Oncology radioactive materials storage and preparation area. The decommissioning report is attached, labeled "Radiation Therapy Storage Area."

4. Deletion of Sr-90 eye applicator from the license.

The Sr-90 eye applicator, (3M, 6 Dia, listed in our license, line 7.D as Model 6D1A) was disposed of along with a number of other sources in 2007-2008. They were picked up by a representative of ENVIROSOLVE of Tulsa, Oklahoma on 11/26/07. We received acknowledgement of receipt and disposal in South Carolina in March 2008, one letter dated 3/13/08 and the other 3/8/08. Copies of these are attached. Since the wording of the letters is vague, it is necessary to tie these letters to our shipment of the eye applicator. This is done using the manifest number, 2007-2. Enclosed is a copy of page 1 of this manifest. Unfortunately, it is minified enough to be virtually illegible. The second item (on the third line) designates it as generated by RMC, which stands for Research Medical Center. A magnified version of the middle of this page is also enclosed, from which you may be able to read from column 14 that this is for a "S-90 eye appl & Cs 137 /seeds\. "Our file copies, obtained from the electronic versions kept by ENVIROSOLVE, may be easier to read than FAX transmittals; they can be supplied upon request. This material was submitted on 12/1/08 with our request to delete the Cs-137 and other items disposed of at this time, but the Sr-90 eye applicator was inadvertently left off the list. Therefore, we request that it be deleted from our list of licensed materials at this time.

The wipe test performed on this source at the time of shipment was less than adequate. In the haste to test all of the sources being shipped, no one recalled that Sr-90 is a beta

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emitter and therefore it was only tested for photon emission. A copy of the test results is included for reference. However, the source was kept in a wooden carrying case for decades and never used in anyone's memory, so if there were any contamination, it was well contained at the time of shipment.

Should you need any further information, please feel free to contact us at (816) 276-4449.

Sincerely,

Matt J. Sogard

Chief Operating Officer

Stephen T. Slack, Ph. D.

Radiation Safety Officer

attachments

16-JUN-2013 22:20 From:

# **Radiation Therapy Storage Area**

This is the decommissioning survey for the former Radiation Oncology hot lab adjacent to the Nuclear Medicine waste storage area on Level B of Research Medical Center. The area was used between July 2006 and August 2012 for the storage and preparation of:

Cs-137 sealed sources, stored until disposal 12/28/11

Sr-90 eye applicator stored in its carrying case until disposal 11/27/07

(not included in this survey)

I-125 and Pd-103 sealed sources, prepared for implants, stored and prepared

for return of unused sources to the vendor.

The room was marked with a grid of approximately two foot by two foot squares for the floor, tabletop and two shelves. Wipes of all external surfaces were taken on 27 February 2013 and counted 28 February by Stephen T. Slack. The source wells in the drawers in the safe were wiped in groups such that the surface area of a group approximated 100 cm² using damp pipe cleaners. (The intention was to resample any group showing significant activity, but this proved unnecessary.) Wipes of the source wells were taken by Jennifer Miles and counted by Jennifer Miles under the direction of Stephen T. Slack on 11 March 2013.

A preliminary GM survey was taken in November 2012 and repeated March 28, 2013. The results of the latter are reported here.

## **Equipment**

A Capintec Captus 3000 well counter, serial number 900302, due for calibration 11 February 2014, was used to count the wipes using three windows, a low energy window appropriate for the I-125 and Pd-103 sources, a Cs-137 window and a window that encompassed both of these windows and the energies in between. For the counting of the wipes taken from the drawer wells, the third window was replaced by the full energy range of the counter.

#### Calibration sources

I-129 86 nanoCuries 12/1980

Cs-137 104.9 nanoCuries 3/16/1994

The GM counter was a Ludlum Model 3, (serial number 180461) with a Model CE probe (serial number PR 186114) due for calibration January 17, 2014.

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Because the Sr-90 eye applicator was never removed from its carrying case from the day it was placed in the room until the day of its disposal, no attempt was made to survey for beta-emitting contaminants.

### Statistical Considerations

Minimum Detectable Activity for each window is, in all cases, less than 220 dpm/100 cm<sup>2</sup>.

$$MDA = [2.71 + 4.65 * SQRT(B t)] / (t * E)$$

Where B is the measured background for the window t is the counting time (here 5 minutes for all samples), and E is the counting efficiency

The MDA is listed for each window in the results.

The decision limit for counts, as defined in NCRP Report No. 58, of

$$L = BKG + 2.32 * SQRT(BKG)$$

applied to the gross counts per minute, was use to determine any difference from background. In the results section, LDL indicates that the count in each of the three windows of the wipe test was less than or equal to the decision limit.

### Summary of results

Two of the grid squares, involving three measurements, show activity in excess of the decision limit, in each case by one count per minute. These were considered statistical variations since the decision limit formula is based on significance at the 0.05 level and we have over 200 individual data points.

Stephen T. Slack, Ph. D., Radiation Safety Officer

3 June 2013

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# **Counting Results**

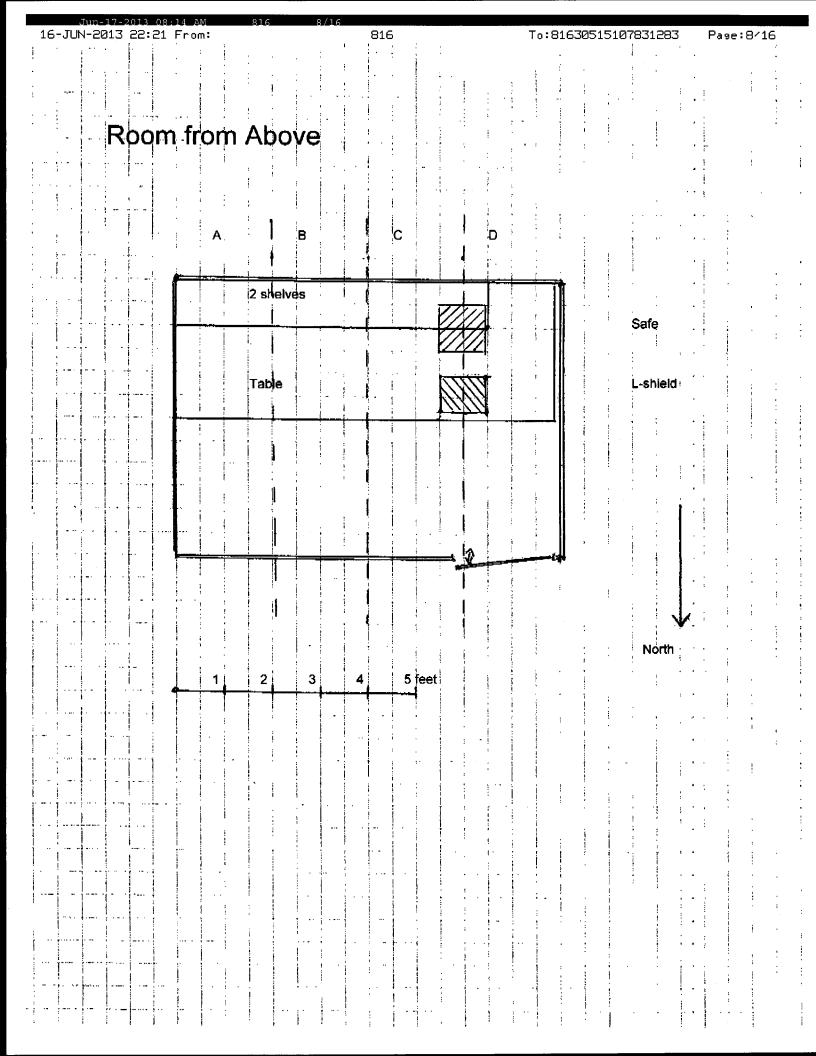
## Wipes from 2/28/13

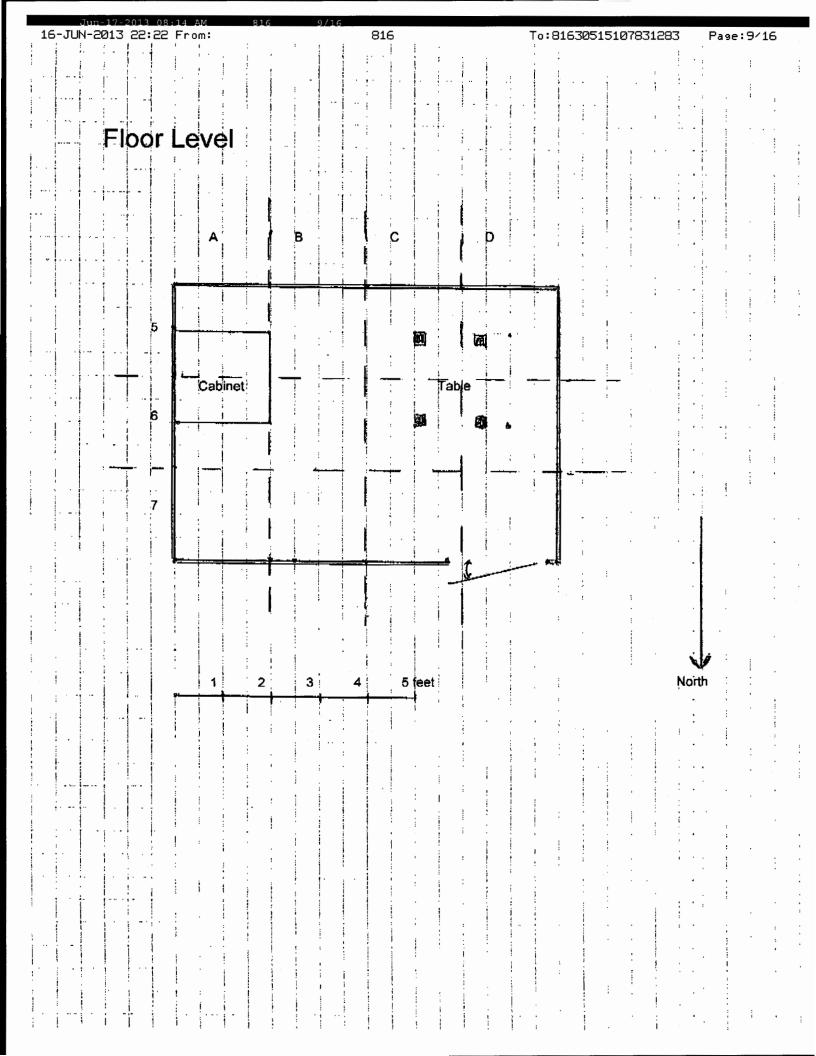
Sample	Window 1 (I-129)	Window 2 (Cs-137)	Window 3 to top of Cs-137 window	GM	RESULT net dpm
Efficiency	0.476	0.117	0.374		per 100 cm²
MDA	10 dpm	44 dpm	11 dpm		100 Gm
Decision Limit	7 cpm	7 cpm	76 cpm	mR/hr	dpm
Dockeround	<b>cpm</b> 5	<b>cpm</b> 5	<b>cpm</b> 68	0.01	ref
Background A 1	4	4	65	0.01	LDL
A2	5	5	71	0.01	LDL
A 3	7	4	67	0.01	LDL
A 4	6	<b>5</b>	66	0.01	LDL
A 5	5	3	73	0.01	LDL
A 6	5	4	68	0.01	LDL
A 7	6	4	75	0.01	LDL
B1	4	5	67	0.01	LDL
B 2	4	5	67	0.01	LDL
B3	4	3	60	0.01	LDL
B 4	5	4	65	0.01	LDL
B 5	5	5	70	0.01	LDL
B 6	6	3	73	0.01	LDL
B 7	5	6	68	0.01	LDL
	4	3	69	0.01	LDL
C 2	6	4	68	0.01	LDL
C 3	6	6	70	0.01	LDL
C 4	5	3	57	0.01	LDL
C 5	6	5	69	0.01	ĻÐL
C 6	5	4	66	0.02	LDL
C 7	7	3	74	0.02	LDL
D 1	6	6	71	0.01	LDL
D 2	5	5	75	0.01	LDL
D3	8	4	67	0.01	6
D 4	7	5	71	0.01	LDL
D 5	8	6	77	0.01	24
D 6	7	5	74	0.02	LDL
D 7	6	4	69	0.02	LDL
<ol> <li>Cabinet drawer</li> </ol>	5	5	67	0.01	LDL
<ol><li>Cabinet drawer</li></ol>	7	3	68	0.01	LDL
<ol><li>Cabinet top shelf</li></ol>	7	3	74	0.01	LDL
4. Cabinet bottom shell		5	70	0.01	LDL
<ol><li>Cabinet door</li></ol>	6	3	69	0.01	LDL
6. Safe top	7	4	75	0.01	LDL
7. Safe E side	7	4	72	0.01	LDL

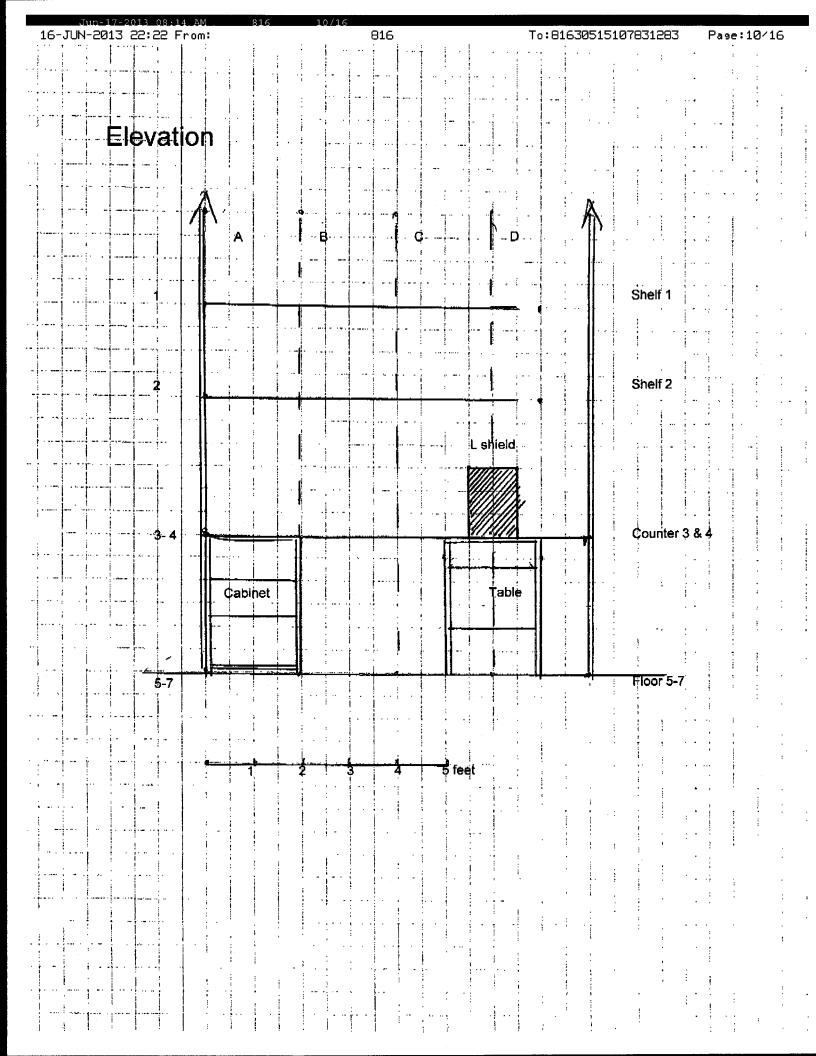
Sample	Window 1 (I-129)	Window 2 (Cs-137)	Window 3 to top of	GM	RESULT	
			Cs-137 window		dpm	
Efficiency	0.476	0.117	0.374		per	
MDA	10 dpm	44 dpm	- 11 dpm		100 cm²	
Decision Limit	7 cpm	7 cpm	76 cpm			
	cpm	cpm	cpm	mR/hr		
8. Safe W side	5	2	68	0.01	LDL	
9. Safe N side	7	4	66	0.01	LDL	
10. Safe drawer 1	7	4	71	0.01	LDL	
11. Safe drawer 2	5	4	60	0.01	LDL	
12. Safe drawer 3	6	6	68	0.01	LDL	
13. Safe drawer 4	7	4	70	0.01	LDL	
14. Lamp top	4	4	67	0.02	LDL	
15. Lamp bottom	3	6	68	0.02	LDL	
16. no sample						
17. L-shield lens	5	4	69	0.01	LDL	
18. L-shied front	5	5	68	0.01	LDL	
19. L-shield lens	5	4	63	0.01	LDL	
20. L-shield back	4	5	64	0.01	LDL	
21. L-shield base	5	4	64	0.01	LDL	
22. Door handle	5	5	62	0.01	LDL	
23. Table drawer	4	4	69	0.01	LDL	
24. Table drawer	6	4	66	0.01	LDL	
25. Table base	5	4	70	0.01	LDL	

## Counting of wipes from safe drawers, 3/11/13

Sample	Window 1	Window 2	Window 3	RESULT	
•	(I-129)	(Cs-137)	full spectrum		
Efficiency	0.476	0.117	0.477	dpm	
MDA	10 dpm	44 dpm	40 dpm	per	
Decision Limit	12 cpm	9 cpm	<b>1</b> 01 cpm	100 cm²	
	cpm	çpm	cpm		
Background	6	4	80		
Drawer 1	4	3	70	LDL	
Drawer 2A	6	3	74	LDL	
Drawer 2B	8	4	80	LDL	
Drawer 3 A	. 4	4	69	LDL	
Drawer 3 B	6	4	73	LDL	
Drawer 4	6	4	71	LDL	









## ENVIRONMENTAL MANAGEMENT AND CONTROLS, INC.

3106 SOUTH FAITH HOME ROAD TURLOCK, CALIFORNIA 95380 E-MAIL:emc1ga@aol.com

816

PHONE (800) 552-6121 PHONE (209) 667-1102 FAX (209) 667-1583

Mr. Stephen Slack Research Medical Center 2316 E Meyer Blvd Kansas City, MO 64132

Dear Mr. Slack:

The following is a list of the radioactive waste drum(s) that were sent for disposal to the Barnwell, South Carolina disposal site on our shipment 08-SC-1. Enclosed is the Form 542 and acknowledgement of receipt.

<u>Manifest</u>

Drum#

2007-2

1R, 2R, 4R, 5R

If you require any further information, please do not hesitate to contact me.

Sincerely,

Gaye Nelson

Manager

**EMC** 





March 5, 2008

ATTN: GAYE NELSON ENVIRONMENTAL MANAGEMENT & CONTROLS 3106 S. FAITH HOME ROAD TURLOCK, CA 95380

Reference: Radioactive Waste Shipment - Shipment ID Number 13590

Dear GAYE NELSON,

As required by 10 CFR Part 20, South Carolina Title A (3.55.3.4.1), and Barnwell Waste Management Facility Disposal Criteria (\$20-AD-010), this letter is notification that the shipment referenced above has been disposed of at the Barnwell Waste Management Facility. This waste meets all the Barnwell Waste Management Facility criteria for acceptance and was disposed of in accordance with the Barnwell Site's License.

If you have any questions regarding this letter, please contact the Prior Notification Plan Department at (803) 541-5017.

Sincerely

James W. Latham

Vice President, Barnwell Operations

APPROVED BY DIK3: LO, 2154-0HE EXPIRES: 05/21/MOS

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Wipe Test Form

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16-JUN-2013 22: 23 From:

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