

*Ballas Outpatient Surgery Center*  
450 N. New Ballas Rd.  
St. Louis, MO 63141

February 9, 2010

Response to James Mullauer email concerning Ballas Outpatient Surgery Center,  
Dated February 5, 2010

Questions asked:

1. How Dr. Keys determined the counting efficiency of the wipe test counter,

The Ludlum Model 1000 scaler, SN 154234 Well Counter efficiency was determined by comparing the disintegration per minute of a known Cs-137 rod source (Syncor Cs 137 rod source 1.072  $\mu$ ci on Aug 1, 1999, SN 644-74) corrected to the date of measurements to the average counts per minute measured using the Ludlum Scaler (based on three 1.0 minute readings minus the background counts per minute). From these measurements an effective efficiency of 25% was determined. This efficiency is consistent with past measurements.

2. A copy of the last test for sealed sources, the ones over 100 microcuries, and

See Attachment A. The leak test was reported as part of the Physics Quarterly review and utilized the Ludlum scaler to determine the activity. The Efficiency calibration was previously performed in March 2009.

3. Documentation that St. Anthony's Medical Center did receive the sources that were transferred, when, by whom, etc.

Please see Attachment B.

If you have further questions, please do not hesitate to email me or to call.

Sincerely,

David J. Keys, Ph.D.

Radiation Safety Officer  
Ballas Outpatient Surgery Center



Attachment A  
Documentation of Leak Test  
**MEDICAL PHYSICS SERVICES, LTD.**

Providing Services In  
Radiation Oncology Physics · Diagnostic Imaging · Radiation Safety

17295 Chesterfield Airport Road  
Suite 200  
Chesterfield, MO 63005  
(314) 799-9081  
(636) 530-0596 fax  
[www.med-phys.com](http://www.med-phys.com)

David J. Keys, PhD, FACR  
Rich Keys, MA, DABR  
James Monroe, PhD, DABR  
Beth Caspari, MS  
Timothy Keys, MS

### NUCLEAR MEDICINE REVIEW

Site: Ballas Outpatient Surgery Center  
Surgery Center  
450 N. New Ballas Rd. Ste. 103  
St. Louis, MO 63141

Date: 7/17/09

Contacts: Bob Morgan (Robert.Morgan@scasurgery.com)  
Tabatha  
314-991-0776

NRC License: 24-32139-01

Expiration Date: May 31, 2019

Last Amendment: 8

Last Inspection: April 16, 2004

Isotope Vendor: Cardinal Health

<u>Authorized Users</u>	<u>Uses</u>
Karen Goodhope, M.D.	10 CFR 35.200
M.Afzal Riaz, M.D.	10 CFR 35.200

RSO  
David J. Keys, Ph.D.

#### Items of Note

3rd Quarter 2009 Activities to be done

#### Staff Activities

1. Continue current activities
2. Survey meter to be sent out for calibration by 9/24/09.
3. Update procedures to reflect 4.00 efficiency factor.

#### Physicist Activity

1. Physicist Review
2. Linearity by physicist due 9/09

#	Code	Description	Yes	No	N/A
---	------	-------------	-----	----	-----

10CFR Part 20 - Standards for Protection Against Radiation

#	Code	Description	Yes	No	N/A
1.	20.1201	Annual limits for all radiation workers less than 0.05 SV (5rem)TEDE 0.5 SV (50 rem) Organ dose 0.15 SV (15 rem) Eye dose 0.5SV (50 rem) Skin Dose NVLAP approved	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	20.1201(d)20.21045	Occupational dose for new employees	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
3.	20.1206	Any planned special exposures	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4.	20.1208	Any exposed pregnant women If yes, fetal exposure less than 5 mSV (film badge review) Employee formally declare pregnancy	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
5.	20.1301	Dose level in any unrestricted area (<0.02mSV/hr and less than 1 mSV/year (2 mRem/hr and 1000 mRem/yr)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.	20.1302	Surveys available demonstrating compliance (measurement and/or calculation showing less than 0.02 mSV in one hour and less than 0.51 m/yr to an individual) <b>Comment:</b> Surveyed adjacent areas: 0.02 mR/hr 07/17/09 Ludlum 14c SN: 159286	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.	20.1502	Dosimetry badges available, frequency Bi-monthly Monitoring for individuals entering high radiation areas (1 mSV/hr or 100 mRem/hr at 30 cm from the source) <b>Comment:</b> Bi-Monthly, Signed off by RSO Comment: Signed through 03/31/09 (6/30/09 not returned yet)	<input checked="" type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>
8.	20.1801,20.1802	Recommendation Dosimetry badge worn chest high or at collar. Ring badge worn All radioactive material recorded and under constant surveillance	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
9.	20.1902	All rooms with radioactive materials posted with a "radioactive materials signs" All room with exposure rates >0.02 mSV/hr posted	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
10.	20.1906(b), (c)	All radioactive material external surfaces are to be monitored for contamination and radiation level within 3 hours or on the next working day <b>Comment:</b> Reviewed through 7/15/09	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
11.	20.1906(e)	Procedures for opening are available Comment: Contained in <u>Hot Lab for Dummies</u> ring binder	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12.	20.2001	Waste materials disposed by transfer to an authorized recipient – manufacturer Transfer to authorized waste disposal to effluents <b>Comment:</b> Reviewed through 07/13/09.	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
13.	35.92	by decay - 10 half-lives, at background	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14.	20.2102(b)	Records retained for 3 years	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15.	20.2201	Reports of stolen, lost or missing sources or other incidents on file	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

10CFR Part 35 - Medical Use of Byproduct Material

16.	35.13(b)	All nuclear medicine physicians are on the license	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17.	35.13(c)	Facility RSO on the license Name: David J. Keys, Ph.D. Comment:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

#	Code	Description	Yes	No	N/A
18.	35.14	Notifications of AU, AMP within 30 days	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
19.	35.24	Radiation Protection Program Available (ALARA program retained)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20.	35.26	Radiation Protection Program Changes	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	35.26(3)	Radiation Protection Program Reviewed by RSO & Administration	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21.	35.40	Written Directives			
22.	35.40(a)	Signed and dated by A.U. for I-131	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
23.	35.40(b)(1)	Dosage for I-131	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
24.	35.40(b)(2)	Dosage and Route for other therapeutic dosage	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
25.	35.40(d)	Copy of written directive available	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
26.	35.41	Procedures requiring written directives	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
27.	35.41(a)(1)	Patient Identity verified	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
28.	35.41(a)(2)	Administration per written directive	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
29.	35.41(b)(3)	Calculations verified	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
30.	35.41(c)	Copy of procedure maintained	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
31.	35.60(b)	Daily Dose Calibrator constancy each station used, more than 50μCi	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		+/- 5% levels indicated	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
32.	35.60(b)	Annual Accuracy check	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		RSO signed (to be signed)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Last done: 12/17/08			
33.	35.60(b)	Quarterly linearity	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		RSO signed	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Last done: 7/17/09			
34.	35.60(b)	Geometry test	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		RSO signed	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Last done: 7/1999			
35.	35.61	Survey instruments available, calibrated within 12 months	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Min 0.05 mR/hr Max 1000 mR/hr (exposure rates = mR/hr)			
		<u>Model</u> <u>SN</u> <u>Min</u> <u>Max</u> <u>Ck Src</u> <u>Last Cal</u> <u>Battery</u>			
		Ludlum 14C 155399 0.01 2000 8.8 9/24/08 07/17/09			
		<b>Comment:</b> Standard Chk source reading = 0.85 x 10 mr/hr			
36.	35.63(a)(e)	Patient doses determined and recorded properly	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
37.	35.67(a) (1)	All beta/gamma sealed sources wipe tested written 6 months	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<u>Sealed Sources Available</u> <u>Last Wipe Test</u>			
		Cs-137 SN: 584-72-41 7/17/09			
		214.1 uCi on 6/01/99			
		Exceptions – less than 3.7 MBq (100 μCi) in storage or Ir-192 in ribbons			
		Comment: Measured by DJK 7/17/09			
		Data 544, 553, 562 cpm, 504, ave 553			
		562, 595 bkg cpm; ave 578.5 cpm Net cpm = 0: Net dpm = 0: leakage < 0.0005 uCi pm/cpm factor = 4.0)			
38.	35.67(f)	Less than 185 Bq (0.005 μCi) leaking from sealed sources	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Equipment used: Ludlum model 1000			
		Comment: Efficiency measured to be 0.25 on 9/28/07			
		Example Net cpm = 9 cpm * 4 dpm/cpm			
		Net dpm = 36 dpm			
39.	35.67(g)	Semi-Annual Source Inventory	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Sources Inventoried by: David J. Keys, PhD. (7/17/09)			
		Cs-137 SN: 584-72-41			
		Cs-137 button (meter)			
		Cs 137 rod source (1 μci) SN 644-74			
		RSO Signature	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
40.	35.69	Syringe or syringe shields labeled	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Vial shields labeled	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

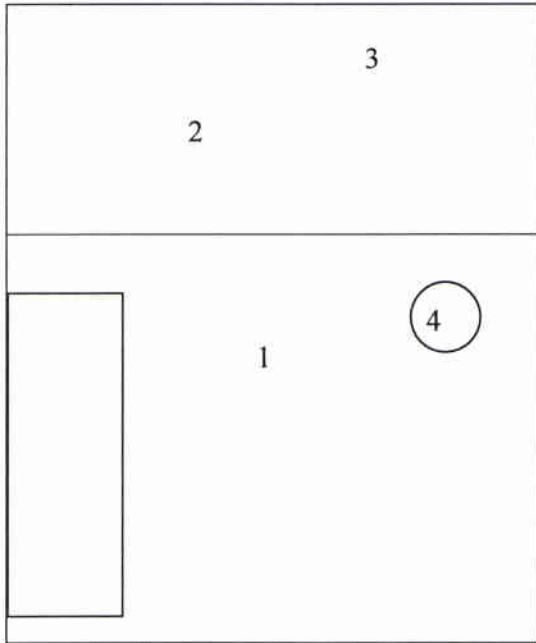
#	Code	Description	Yes	No	N/A
41.	35.70(a)	Surveyed at the end of each day of use areas of prep and administration Comment: Also surveyed between cases. Reviewed through 07/15/09. Area surveys above background needs to be decontaminated and re-surveyed. When the reading goes above 2.0, change scales in order to determine the actual exposure rate.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
42.	35.75	Compliance with release criteria of less than 5mSv (TEDE) exposure to any individual from patients released post administration of radiopharmaceuticals or permanent implants	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
43.	35.75 (b)	Instructions, including written instructions, given to released individuals per guidelines of Reg Guide 8.39. Breast feeding individuals provided with guidance and information to reduce dose to breast feeding infants or children per Reg. Guide 8.39	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
44.	35.75 (c)	Records maintained for 3 years for basis of release	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
45.	35.92(a)	Decay in Storage performed	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
46.	35.92(a)(1)	Survey prior to disposal	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
47.	35.92(a)(2)	Records for 3 years	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
48.	35.204	<0.15 $\mu$ Ci of Mo-99 per mCi of Tc-99m	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
49.	35.310	Safety instruction provided to personnel caring for patients who can not be released under 35.75 Subpart L – Records	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
50.	35.2024	Record of Radiation Safety Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
51.	35.2026	Record of Radiation Safety Program Changes	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
52.	35.2041	Records for procedures requiring written directive	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
53.	35.2060	Records of Calibrations of Dose Calibrators	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
54.	35.2061	Records of Survey Instrument Calibrations	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
55.	35.2063	Records of doses of unsealed byproduct material	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
56.	35.2067	Records of leak tests of sealed sources	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
57.	35.2070	Records of surveys of ambient exposure rate	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
58.	35.2075	Records of release of patients containing unsealed byproduct material	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
59.	35.2092	Records of Decay in Storage	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
60.	35.2310	Records of Safety instruction to those caring for patients not released under 35.310, 35.410, 35.610 Comment: In Hot Lab	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
62.	EPA 40CFR61	Clean Air Act Emissions evaluated annually Comment:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
63.	General	Records of Annual Safety instruction to Radiation Workers. Last Instruction – 12/15/08 Comment:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Reviewed by:

David J. Keys, Ph.D.  
 David J. Keys, Ph.D.  
 Medical Physicist

**Attachment A**  
**Documentation of Leak Test**  
**Ballas Outpatient Surgery**  
**Quarterly Survey About Sealed Source Storage Area (Hot Lab)**

Diagram: Hot Lab



<u>Location</u>	<u>mR/hr</u>	<u>S/U</u>
1. Floor	< 0.02	S
2. Counter/Dose Calibrator	< 0.02	S
3. Storage Area	< 0.02	S
4. Radioactive Waste	< 0.02	S

Surveys were performed with Ludlum 14c, SN 159286; check source reading 0.85 x 10 mR/hr.

Date: 07/17/09

*David J. Keys, Ph.D.*  
 \_\_\_\_\_  
 David J. Keys, Ph.D.

Note: This document may be electronically signed.

## Attachment B

### Saint Anthony's Medical Center

10020 Kennerly Rd  
St. Louis, MO 63128

#### Receipt of Transferred Radioactive Material

##### Radioactive Materials to Be Transferred:

One Syncor 1.072 uCi Cesium Rod  
One Cs-137 SN: 584-72-41 214.1 uCi on 6/01/99, last wipe 7/17/2009  
One Cs-137 1 uCi Survey Meter Button

##### Original Licensee:

Surgical Care Associates – Ballas Surgery Center  
450 N. New Ballas Rd. Ste. 103  
St. Louis, MO 63141

NRC License: 24-32139-01

Authorizing Agent: David J. Keys, PhD  
Radiation Safety Officer  
Tanya McMullen RN, MSN, MHA  
Administrator  
Surgical Care Associates – Ballas Surgery Center

##### Receiving Licensee:

Saint Anthony's Medical Center  
10020 Kennerly Rd  
St. Louis, MO 63128

NRC License: 24-01041-04

Date/Time of Transfer: January 19, 2010  
11:30 AM

St Anthony's Medical Center authorizing Agent:



David J Keys, PhD  
Radiation Safety Officer