MU

HIRO MAKINO, M.D. MICHAEL W. CHAN, M.D. SPECIALIZING IN CARDIOLOGY

KMC AT PALI MOMI 98-1079 MOANALUA ROAD. #655 AIEA, HAWAII 96701 PHONE: (808) 486-6116 WAHIAWA BUSINESS CENTER 302 CALIFORNIA AVENUE, #214 WAHIAWA, HAWAII 96786 PHONE: (808) 621-8773 ST. FRANCIS MEDICAL PLAZA-WEST 91-2139 FORT WEAVER ROAD, #308 EWA BEACH, HAWAII 96706 PHONE: (808) 677-5585

February 7, 2012

Nuclear Materials Licensing Branch U.S. Nuclear Regulatory Commission, Region IV 1600 E. Lamar Blvd. Arlington, TX 76011-4511

FEB - 9 2012 DNMS

Subject: License Termination NRC License No. 53-29263-01 Docket No. 030-37462

Dear License Reviewer:

We have discontinued use of byproduct material, and are requesting the termination of our materials license. We have enclosed NRC Form 314 and the results of the decommissioning survey.

If you require any additional information please contact our Radiation Safety Officer, Ronald Frick at 808-373-7009.

Sincerely

Hiro Makino, M.D. President

Enclosures

U.S. NUCLEAR REGULATORY COMMISSION (1-2012) 10 CFR 30 38(j)(1): 40 42(j)(1): 70 38(j)(1): and 72 54(k)(5)(1)(1) CERTIFICATE OF DISPOSITION OF MATERIALS	This submittal is used by NRC as part of the released for unrestricted use. Send comment Services Branch (T-5 F53), U.S. Nuclear Regu or by internet e-mail to Infocollects Resource Information and Regulatory Affairs, NEOB-1 Budget, Washington, DC 20503. If a means to	th this mandatory collection request: 30 minutes the basis for its determination that the facility is ts regarding burden estimate to the Information latery Commission, Washington, DC 20555-0001 e@nrc.gov, and to the Desk Officer, Office of 0202, (3150-0028), Office of Management and sed to impose an information collection does no r, the NRC may not conduct or sponsor, and a
LICENSEE NAME AND ADDRESS	LICENSE NUMBER	DOCKET NUMBER
Hiro Makino, M.D., Inc.	53-29263-01	030-37462
98-1079 Moanalua Road	LICENSE EXPIRATION DATE	
Aiea, HI 96701	May 3	1, 2017
A. LICENSE STATUS (Check the	appropriate box)	
This license has expired. This license has not yet expired; please	e terminate it.	
B. DISPOSAL OF RADIOACT		
(Check the appropriate boxes and complete as necessary. If an The licensee, or any individual executing this certificate on behalf of the licens		e attachments)
No radioactive materials have ever been procured or possessed by		
 2. All activities authorized by this license have ceased, and all radioac 		ossessed by the licensee
under this license number cited above have been disposed of in the		
a. Transfer of radioactive materials to the licensee listed below:		
Cs-137 and Co-57 calibration sources transferred to Wahiawa G	· · · · · · · · · · · · · · · · · · ·	
✓ b. Disposal of radioactive materials: Gary	Ropert, 808-621-4	233
1. Directly by the licensee:		
Decay in storage		
2. By licensed disposal site:	DECE DEFEB-	- 9 2012
3. By waste contractor:		NMS
c. All radioactive materials have been removed such that any remain Part 20, Subpart E, and is ALARA.	ning residual radioactivity is with	in the limits of 10 CFR
C. SURVEYS PERFORMED A		
✓ 1. A radiation survey was conducted by the licensee. The survey confirm	ns:	
 a. the absence of licensed radioactive materials 		
✓ b. that any remaining residual radioactivity is within the limits of 10 C	CFR 20, Subpart E, and is ALAF	łA.
2. A copy of the radiation survey results:		
✓ a. is attached; or b. is not attached (Provide explanation); or [c. was forwarded to NRC or	
3. A radiation survey is not required as only sealed sources were ever po	ossessed under this license, and	Date
a. The results of the latest leak test are attached; and/or	b. No leaking sources have ev	ver been identified.
he person to be contacted regarding the information provided on this form:		
IAME TITLE	TELEPHONE (Include Area Code) E-MA	IL ADDRESS
Ronald Frick Radiation Safety Officer	808-282-0169 rfri	ck@gammacorp.com
tal all future correspondence regarding this license to. 18-1079 Moanalua Road, Suite 655, Aiea, HI 96701		
C. CERTIFYING OFFI		RECT
RINTED NAME AND TITLE SIGNATURE		DATE 2712
diro Makino, M.D.		
VARNING: FALSE STATEMENTS IN THIS CERTIFICATE MAY BE SUBJECT TO CIVIL AND/OR UBMISSIONS TO THE NRC BE COMPLETE AND ACCURATE IN ALL MATERIAL RESPECT. 18 VILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY (RC FORM 314 (1-2012)	U.S.C. SECTION 1001 MAKES IT A CR	IMINAL OFFENSE TO MAKE A

^{1 576912}



Phone (808) 373-7009 FAX (808) 373-7017

Decommissioning Survey

Facility:	Hiro Makino, M.D. Inc.
Address:	98-1079 Moanalua Road Aiea, HI 96701
Survey Area:	Radioactive materials use areas in Suites 350 and 655
Survey dates:	1/31/2012
Report date:	2/7/2012
Performed By:	Ronald Frick, M.S., CHP, DABR

Background

This facility was issued a license for use of byproduct material listed in 10 CFR 35.200 on May 14, 2007. This facility exclusively used Tc-99m for myocardial perfusion studies. Radiopharmaceuticals were provided in unit doses and bulk vials on a daily basis from the local radiopharmacy. The last delivery of Tc-99m was received on January 25, 2012. The facility also possessed one 200 uCi Cs-137 dose calibrator reference source, one 10 mCi Co-57 flood source, and one 0.5 uCi Cs-137 rod source for calibration of the NaI well counter. The most recent leak test (see attached) shows no leakage. The facility is discontinuing its nuclear medicine service.

All radioactive materials have now been removed from the facility. This report details the results of the final status survey.

Room Use history

Hot lab - Used for storage and preparation of radiopharmaceuticals (Tc-99m) and storage of sealed sources (Co-57 and Cs-137).

Imaging - Sealed sources (Co-57) and radiopharmaceuticals (Tc-99m) used for camera QC. No injections performed in this room.

Treadmill - Injection of radiopharmaceuticals (Tc-99m) for myocardial perfusion imaging.

Exam rooms (3) - Occasionally used for injection of radiopharmaceuticals (Tc-99m) for myocardial perfusion imaging.

The last Tc-99m delivery was received 6 days before the decommissioning survey.

Approximately 24 half-lives of Tc-99m have passed.

Survey Guidelines

The dose rate survey trigger level was set at the level distinguishable from background.

The removable contamination trigger level was set at $129 \text{ dpm}/100 \text{ cm}^2$, which is the minimum detectable activity for the instrument used.

Instrumentation

All equipment, work surfaces, and floors within each surveyed room were surveyed with a Bicron Microrem survey meter. This meter contains a tissue-equivalent organic scintillator which can measure environmental levels of 0-20 μ rem/hr. Background for this meter is approximately 5 μ rem/hr. This meter was last calibrated on December 13, 2011 (see enclosed certificate).

Wipe samples were analyzed using a Capintec Caprac NaI well counter. Efficiency and Minimum Detectable Activity determinations are attached.

Survey Description

All floors, walls, work benches, sinks, and fume hoods within each lab were surveyed using the Bicron Microrem survey meter. The meter was held approximately 2 inches away from the surface.

Wipe samples were taken in the numbered locations indicated on the attached survey diagram. All wipes were performed using dry filter paper over at least 100 cm², and counted in the well counter.

Survey Results

Surveys revealed no areas with dose rates exceeding background level. All wipe samples were below the minimum detectable activity. Tabulated wipe results are attached.

Conclusion

No detectable contamination remains within the facility. It is recommended that this facility be released for unrestricted use.

Efficiency/MDA Determinations

Well counter

Detection efficiency for Tc-899m gammas was determined using a Co-57 standard. Minimum detectable activity for a 20 second (0.33 minute) count was determined using the following equation:

$$MDA(dpm) = \frac{2.71 + 3.29 \sqrt{R_B t_S [1 + \frac{t_S}{t_B}]}}{\epsilon \times t_S}$$

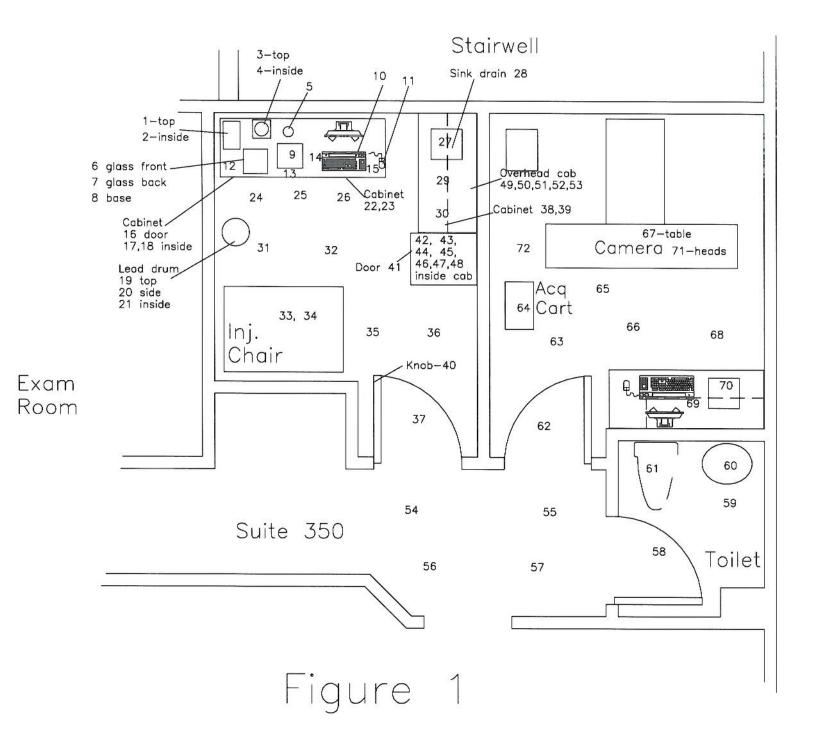
 $T_{B} = 1 \text{ minute}$ $T_{S} = 0.33 \text{ minute}$ Co-57 Standard current activity = 12,410 dpm Measured net cpm = 11,110 cpm Detection efficiency = 89.5% Background count rate(R_B) = 265 cpm Wipe area = 100 cm² MDA = 129 dpm/100cm²

List of Figures

- 1.
- Hot lab/Imaging area (3rd floor) Treadmill/Exam rooms (6th floor) 2.

List of Tables

- Wipe test data (3rd floor) Wipe test data (6th floor) 1.
- 2.



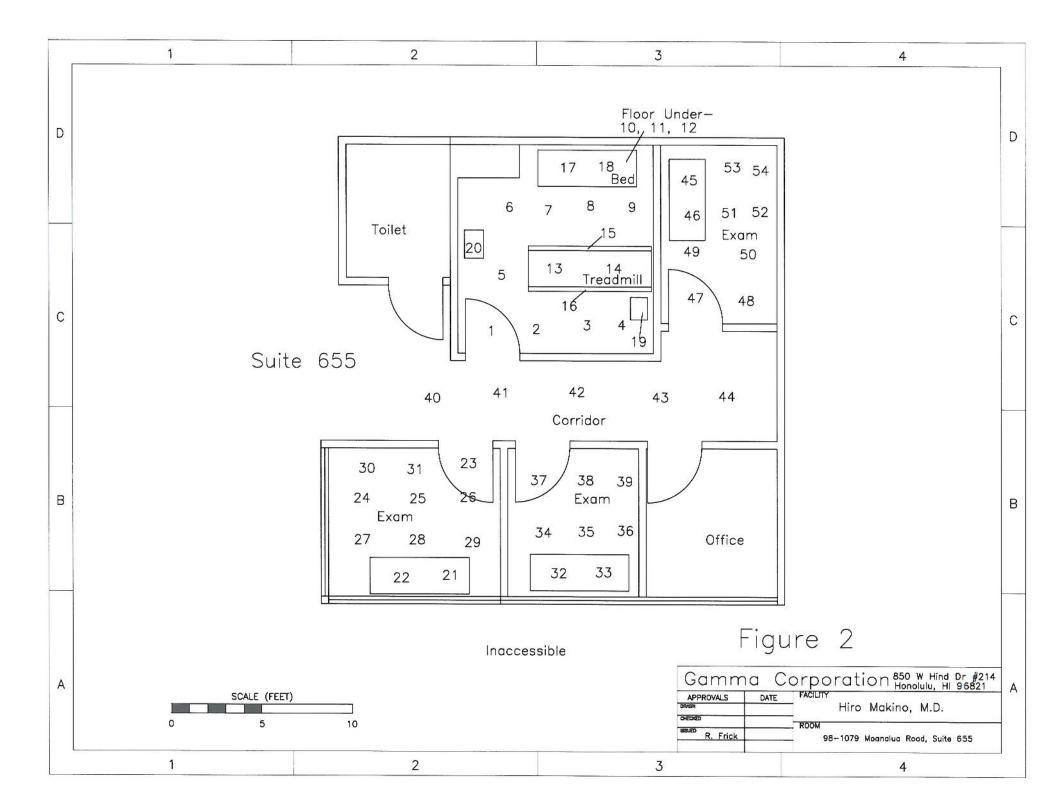


Table 1: Wipe Test Data (locations from Figure 1)Background=265 cpmMDA=129 net dpm/100 cm²

Wipe Number	Net cpm/100 cm ²	Net dpm/100 cm ²	Wipe Number	Net cpm/100 cm ²	Net dpm/100 cm ²
1	-2	0	26	-13	0
2	-38	0	27	26	29
3	-41	0	28	44	49
4	4	4	29	-25	0
5	-35	0	30	14	16
6	-20	0	31	17	19
7	-47	0	32	-13	0
8	1	1	33	-35	0
9	-47	0	34	-1	0
10	-10	0	35	-1	0
11	1	1	36	-31	0
12	-56	0	37	-1	0
13	-20	0	38	-7	0
14	-11	0	39	26	29
15	-37	0	40	-13	0
16	20	22	41	-7	0
17	-34	0	42	14	16
18	-16	0	43	20	22
19	17	19	44	-35	0
20	23	26	45	44	49
21	-25	0	46	-1	0
22	2	2	47	2	2
23	-52	0	48	4	4
24	-49	0	49	-2	0
25	-28	0	50	17	19

Table 1, Cont'd

Wipe Number	Net cpm/100 cm ²	Net dpm/100 cm ²
51	-25	0
52	23	26
53	-28	0
54	-4	0
55	-40	0
56	-49	0
57	-19	0
58	4	4
59	-25	0
60	-4	0
61	-1	0
62	-46	0
63	-4	0
64	8	9
65	32	36
66	-28	0
67	-10	0
68	-34	0
69	50	56
70	-19	0
71	-43	0
72	35	39

Table 2: Wipe Test Data (locations from Figure 2) Background=265 cpm

 MDA=129 net dpm/100 cm²

 Wipe
 Net cpm/100
 Net dpm/100
 Wipe
 Net cpm/100

 Number
 cm²
 cm²
 28
 -15

Number	cm	cm	Number	CIII	Cin
1	-9	0	28	-15	0
2	51	57	29	6	7
3	-3	0	30	-18	0
4	6	7	31	0	0
5	9	10	32	-27	0
6	3	3	33	-12	0
7	33	37	34	-3	0
8	-15	0	35	-33	0
9	6	7	36	-45	0
10	18	20	37	18	20
11	-51	0	38	6	7
12	12	13	39	3	3
13	15	17	40	30	33
14	18	20	41	-33	0
15	-36	0	42	-21	0
16	29	32	43	-33	0
17	-66	0	44	-6	0
18	-6	0	45	-27	0
19	-45	0	46	-9	0
20	6	7	47	42	47
21	-6	0	48	-21	0
22	-45	0	49	-18	0
23	9	10	50	-24	0
24	-12	0	51	-27	0
25	12	13	52	-18	0
26	15	17	53	-3	0
27	3	3	54	18	20

Net dpm/100

cm²



Phone (808) 373-7009 FAX (808) 373-7017

Leak Test Certificate

Facility: Niro Makino, M.D., Inc. Department:

	[1
Number	: 1320	
Fac ID:	MAKINO	

Address: 98-1079 Moanalua Rd. Ste 655

Aiea ΗI

96701

Wipe Date: October 27, 2011 Analysis Date: October 27, 2011

The following sources were leak tested according to the procedures described in NRC License No. 53-23207-01.

All sources used for calibration are traceable to NTIS.

Isotope	Model Nu	nber	Serial Number	Activity (MBq)	Results (Bq)
Cs-137	MED 35	50	119829	7.46	< 4
<u>Co-57</u>	MED 37	27	1469-151	370	<4

This report must be on file for review by the NRC or state regulatory authorities.

A

Performed by:

Ronald Frick, M.S., CHP, DABR

Radiation Safety Officer:

P. O. Box 240370 . Honolulu, HI 96824

A

			C	ertif	icate	of C	alib	ration						
Escility	Ca	mma Corneration			Dept.					Batte	PLANE A			
Facility	Ga	mma Corporation				Dobr 1		F		OK	Replaced			
Mfgr/Mo	del	Bicron Microrem		S/N	B393E	F	Probe		Detec Volta	,				
	Calib	rated with Cs-137 rated with electron rated with electron	ic pulser	for scal	es below			out: 44.8 mR/h	r @ 1 mete	r on 10/6	6/95.			
Range	3	Calculated Value	As Fou	nd Valu	e Accer	oted Valu	e Co	rrection Factor	Corrected	Value	% Error			
X1000)	160000	17(0000	1	70000		1.0	1700	00	6%			
X1000	כ	40000	38	000	3	38000		1.0	3800	0	5%			
X100	l.	16000	16	000	1	6000	4	1.0	1600	0	0%			
X100	4000		38	800		3800		1.0	3800)	5%			
X10	X10 1600		X10 1600		1600			1600		1.0	1600)	0%	
X10	X10 400		3	80		380		1.0	380		5%			
X1		160 155		55		155		1.0	155		3%			
X1		40	40		40 40		40 40 4		40		1	40		0%
X0.1		4		4		4		1.0	4		0%			
Detector	Туре	e G.M.		Pla	stic Scint	: 🗌 I	Nal Sci	nt. 🗋 P	roportional		lon Chamber			
Detector	Exp	osure Orientation			🗌 Par	allel		Perpendi	cular	Inter	nal			
Conditio	n Re	eceived			📕 In to	lerance			Out of to	lerance				
Commen	nts:	new check source	e Cs137	1 uCis	n 1792									
Calibrate	ed by	: Sugar No	Onu		-			Check Source	·····	650 u				
					1- 1			Calibration Da	ate D	ecembe	er 13, 2011			
Review:	L			Date	17/1	8/11		Calibration D	ue C)ecembe	er 12, 2012			
Acceptat	ole to	plerance is stated a	is ±10%	of calcu	lated value	ue at eac	h calib	ration point.						

Gamma Corporation 850 West Hind Drive, Suite 214, Honolulu, HI 96821

HIRO MAKINO, M.D. MICHAEL W. CHAN, M.D. SPECIALIZING IN CARDIOLOGY

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NRC FORM 314 U.S. (1-2012) 10 CFR 30 36(j)(1), 40.42(j)(1), 70 36(j)(1), and 72.54(k)(5)(1)(1) CERTIFICATE OF DISP	NUCLEAR REGULATOR		This submittal is used by NRC as pareleased for unrestricted use. Send o Services Branch (T-5 F53), U.S. Nuclear or by internet e-mail to Infoccilacts. Information and Regulatory Affairs, h Budget, Washington, DC 20503. If a m	nply with this mandatory collection request: 30 minutes. an of the basis for its determination that the facility is comments regarding burden estimate to the Information ar Regulatory Commission, Washington, DC 20555-0001, Resource@nrc.gov, and to the Desk Officer, Office of IEOB-10202, (3150-0028), Office of Management and leans used to impose an information collection does not number, the NRC may not conduct or sponsor, and a
LICENSEE NAME AND ADDRESS			LICENSE NUMBER	DOCKET NUMBER
Hiro Makino, M.D., Inc.			53-29263-01	030-37462
98-1079 Moanalua Road			LICENSE EXPIRATION DATE	
Aiea, HI 96701			N	fay 31, 2017
	A. LICENSE STA	TUS (Check the	appropriate box)	
This license has expired.	This license has not ye	et expired; please	terminate it.	
(Check the engrande		OF RADIOACT	VE MATERIAL ditional space is needed, pr	muido attachmante)
The licensee, or any individual execut				ovide statemients;
1. No radioactive materials ha				nse.
2. All activities authorized by t	his license have ceased	l, and all radioact	ive materials procured and	l/or possessed by the licensee
under this license number of		ala ang ang ang ang ang ang ang ang ang an	following manner.	
✓ a. Transfer of radioactive m				1 2012 #22 17820 01
			eneral Hospital, January 3 Ropert, 808-621	
✓ b. Disposal of radioactive m		Gary	Roperc, 000 02.	1200
1. Directly by the lice	ensee:			
Decay in storage				
2. By licensed dispo	sal site:			
☐ 3. By waste contract ✓ c. All radioactive materials I Part 20, Subpart E, and is	have been removed suc	h that any remain	ing residual radioactivity is	s within the limits of 10 CFR
	C. SURVEYS	PERFORMED AI	ND REPORTED	
1. A radiation survey was condu	icted by the licensee. T	he survey confirm	ns:	
a. the absence of licensed r	adioactive materials			
J b. that any remaining residu	al radioactivity is within	the limits of 10 C	FR 20, Subpart E, and is /	ALARA.
✓ 2. A copy of the radiation survey	results:			
🖌 a. is attached; or 🔲 b. is r	not attached (Provide ex	planation); or	c. was forwarded to NF	
3. A radiation survey is not requi	ired as only sealed sour	rces were ever po	ssessed under this license	e, and
a. The results of the latest le	eak test are attached; a	nd/or	b. No leaking sources ha	ve ever been identified.
The person to be contacted regarding t	the information provided	on this form:		
NAME Demold Erick	TITLE Dediction Colory Office		TELEPHONE (Include Area Code)	E-MAIL ADDRESS
Ronald Frick Mail all future correspondence regarding this license to:	Radiation Safety Offic	er	808-282-0169	rfrick@gammacorp.com
98-1079 Moanalua Road, Suite 655, A	iea, HI 96701			
LCEPTER II		CERTIFYING OFFIC		2000507
PRINTED NAME AND TITLE	NUCK PERALITUP PER	SIGNATURE	OREGOING IS TRUE AND	DATE
Hiro Makino, M.D.	T			27/12
WARNING: FALSE STATEMENTS IN THIS CER SUBMISSIONS TO THE NRC BE COMPLETE A WILLFULLY FALSE STATEMENT OR REPRESE	ND ACCURATE IN ALL MATE	ERIAL RESPECT. 18	U.S.C. SECTION 1001 MAKES IT	A CRIMINAL OFFENSE TO MAKE A
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Gamma Corporation

850 West Hind Drive #214, Honolulu, HI 96821

Phone (808) 373-7009 FAX (808) 373-7017

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Survey Results

Surveys revealed no areas with dose rates exceeding background level. All wipe samples were below the minimum detectable activity. Tabulated wipe results are attached.

Conclusion

No detectable contamination remains within the facility. It is recommended that this facility be released for unrestricted use.

Efficiency/MDA Determinations

Well counter

Detection efficiency for Tc-899m gammas was determined using a Co-57 standard. Minimum detectable activity for a 20 second (0.33 minute) count was determined using the following equation:

$$MDA(dpm) = \frac{2.71 + 3.29 \sqrt{R_B t_S [1 + \frac{t_S}{t_B}]}}{\epsilon \times t_S}$$

$$\begin{split} T_{\rm B} &= 1 \text{ minute} \\ T_{\rm S} &= 0.33 \text{ minute} \\ \text{Co-57 Standard current activity} &= 12,410 \text{ dpm} \\ \text{Measured net cpm} &= 11,110 \text{ cpm} \\ \text{Detection efficiency} &= 89.5\% \\ \text{Background count rate}(R_{\rm B}) &= 265 \text{ cpm} \\ \text{Wipe area} &= 100 \text{ cm}^2 \\ \text{MDA} &= 129 \text{ dpm}/100 \text{cm}^2 \end{split}$$

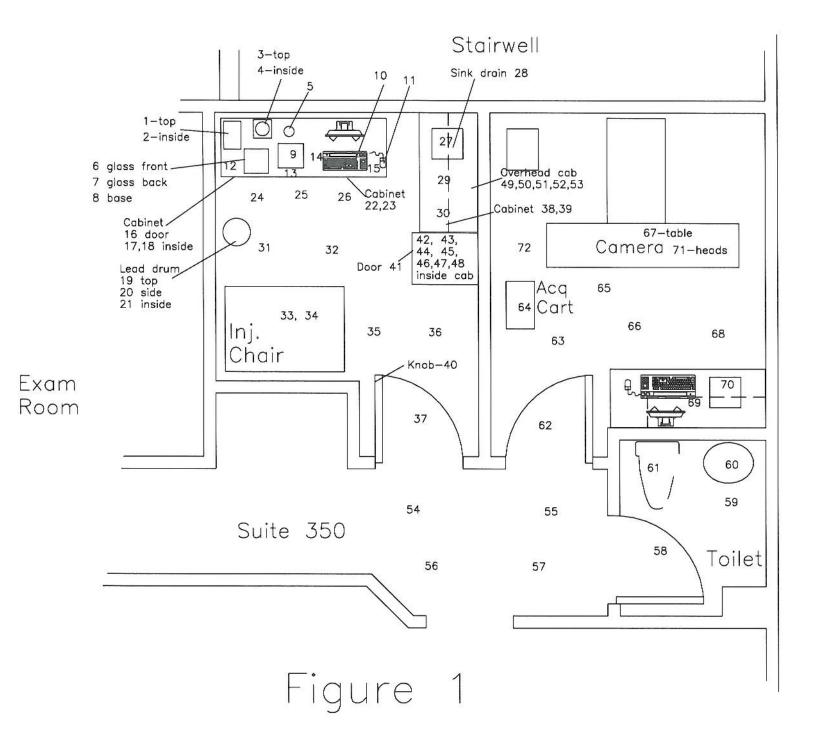
Decommissioning Survey Hiro Makino, M.D., Inc.

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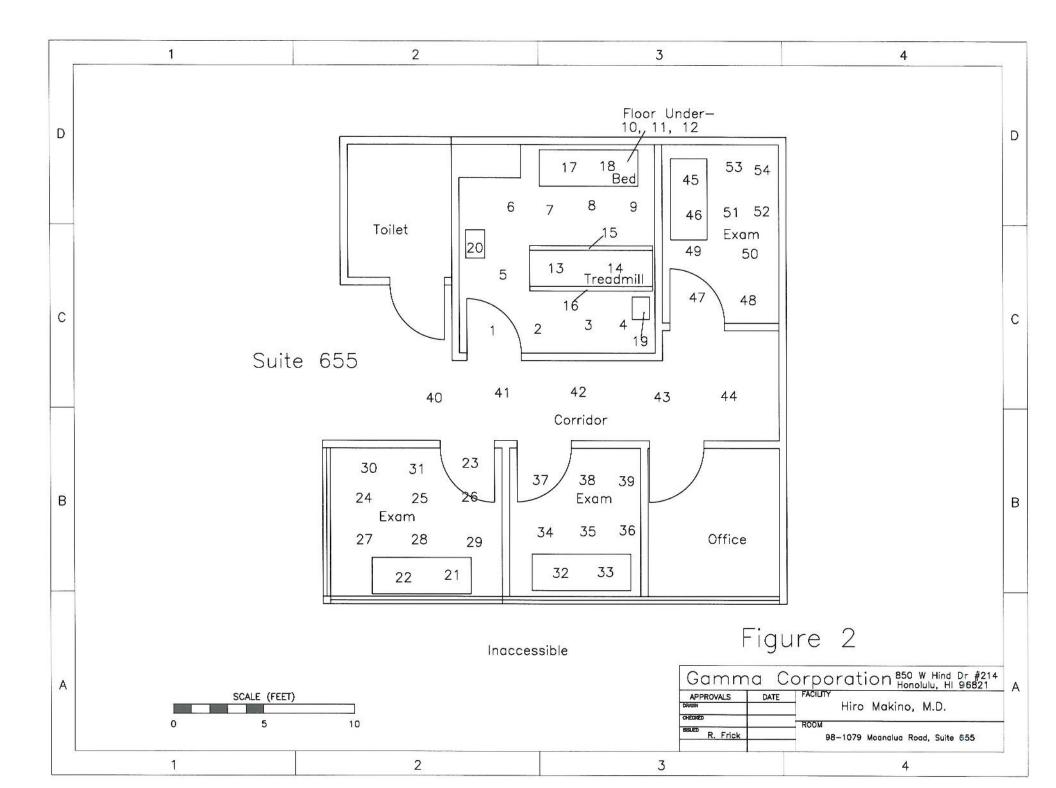


Table 1: Wipe Test Data (locations from Figure 1)Background=265 cpmMDA=129 net dpm/100 cm²

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Table 1, Cont'd

Wipe Number	Net cpm/100 cm ²	Net dpm/100 cm ²
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52	23	26
53	-28	0
54	-4	0
55	-40	0
56	-49	0
57	-19	0
58	4	4
59	-25	0
60	-4	0
61	-1	0
62	-46	0
63	-4	0
64	8	9
65	32	36
66	-28	0
67	-10	0
68	-34	0
69	50	56
70	-19	0
71	-43	0
72	35	39

Table 2: Wipe Test Data (locations from Figure 2) Background=265 cpm MDA=129 net dpm/100 cm²

Wipe Number	Net cpm/100 cm ²	Net dpm/100 cm ²	Wipe Number	Net cpm/100 cm ²	Net dpm/100 cm ²
1	-9	0	28	-15	0
2	51	57	29	6	7
3	-3	0	30	-18	0
4	6	7	31	0	0
5	9	10	32	-27	0
6	3	3	33	-12	0
7	33	37	34	-3	0
8	-15	0	35	-33	0
9	6	7	36	-45	0
10	18	20	37	18	20
11	-51	0	38	6	7
12	12	13	39	3	3
13	15	17	40	30	33
14	18	20	41	-33	0
15	-36	0	42	-21	0
16	29	32	43	-33	0
17	-66	0	44	-6	0
18	-6	0	45	-27	0
19	-45	0	46	-9	0
20	6	7	47	42	47
21	-6	0	48	-21	0
22	-45	0	49	-18	0
23	9	10	50	-24	0
24	-12	0	51	-27	0
25	12	13	52	-18	0
26	15	17	53	-3	0
27	3	3	54	18	20



Phone (808) 373-7009 FAX (808) 373-7017

Leak Test Certificate

Facility: Hiro Makino, M.D., Inc

Department:

Number: 1320 Fac ID: MAKINO

Address: 98-1079 Moanalua Rd. Ste 655

Aiea HI 96701

Wipe Date: October 27, 2011 Analysis Date: October 27, 2011

The following sources were leak tested according to the procedures described in NRC License No. 53-23207-01.

All sources used for calibration are traceable to NTIS.

Model Number	Serial Number	Activity (MBq)	Results (Bg)
MED 3550	119829	7.46	< 4
MED 3727	1469-151	370	<4
·····	1999-1999 (1997) - 1997 (1997) - 1999 (1997) - 1999		· · · · · · · · · · · · · · · · · · ·
	MED 3550	MED 3550 119829 MED 3727 1469-151	Model Number Serial Number (MBq) MED 3550 119829 7.46 MED 3727 1469-151 370

This report must be on file for review by the NRC or state regulatory authorities.

Performed by:

Ronald Frick, M.S., CHP, DABR

Radiation Safety Officer:

P. O. Box 240370 • Honolulu, HI 96824

			Certif	icate of C	alibration		
Facility	0	mmo Corneration		Dent			Batteries
Facility	Ga	mma Corporation		Dept.		ОК	Replaced
Mfgr/Model Bicron Microrem S/N		B393E F	Probe	Detector Voltage			
	Calib	orated with Cs-137 orated with electron orated with electron	ic pulser for sca	les below 0.1 mR/l	ble output: 44.8 mR/h hr.	r @ 1 meter on	10/6/95.
Range	е	Calculated Value	As Found Valu	e Accepted Valu	e Correction Factor	Corrected Val	ue % Error
X100	0	160000	170000	170000	1.0	170000	6%
X100	0	40000	38000	38000	1.0	38000	5%
X100)	16000	16000	16000	1.0	16000	0%
X100)	4000	3800	3800	1.0	3800	5%
X10		1600	1600	1600	1.0	1600	0%
X10		400	380	380	1.0	380	5%
X1		160	155	155	1.0	155	3%
X1		40	40	40	1	40	0%
X0.1		4	4	4	1.0	4	0%
Detector	Туре	e G.M.	Pla	astic Scint.	Val Scint.	roportional	Ion Chamber
Detector	r Exp	oosure Orientation		Parallel	Perpendi	cular	Internal
Conditio	on Re	eceived		In tolerance		Out of tolera	ince
Commer	nts:	new check source	e Cs137 1 uCis	n 1792			
Calibrate	ed by	: Dayarendo	Onu	e	Check Source	Reading 6	50 uR/hr
			Calibration Dat		ate Dece	mber 13, 2011	
Review:	6	I	Date	(2/18/11	Calibration D	ue Dece	ember 12, 2012
Acceptal	ble to	plerance is stated a	s ±10% of calcu	lated value at eac	h calibration point.		

Gamma Corporation 850 West Hind Drive, Suite 214, Honolulu, HI 96821

TELECONFERENCE MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

February 7, 2011

MEETING SUMMARY

PURPOSE

To discuss the Advisory Committee on the Medical Uses of Isotopes (ACMUI) Permanent Implant Brachytherapy Subcommittee Report as it relates to the implementation of the medical regulations in Title 10, Code of Federal Regulations (CFR) Part 35, "Medical Use of Byproduct Material."

OUTCOME

The ACMUI Permanent Implant Brachytherapy Subcommittee (PIBS) provided a draft report for the ACMUI's consideration. During the meeting, the PIBS made recommendations to revise the report, and the revisions were approved by the full committee, as described below. The PIBS draft report was endorsed by the full ACMUI with one dissenting opinion. The U.S. Nuclear Regulatory Commission (NRC) staff gained a better understanding of the views and opinions of the ACMUI, as well as other stakeholders' views and opinions. The staff will consider these views in its continuing effort to make 10 CFR Part 35 more useful, practical, and not overly burdensome on licensees, while maintaining public health and safety.

Full transcripts of the ACMUI meeting can be found on NRC's public website: <u>http://www.nrc.gov/reading-rm/doc-collections/acmui/tr/</u>

Handouts from the ACMUI meeting can be found on NRC's public website: http://www.nrc.gov/reading-rm/doc-collections/acmui/meeting-slides/

Permanent Implant Brachytherapy Rulemaking Final Report (2012) can be found on NRC's public website under "Related Information": <u>http://www.nrc.gov/about-nrc/regulatory/advisory/acmui.html</u>

ATTENDEES

ACMUI

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Member Member Chairman Member Member Member Vice Chairman Member Member Member

<u>NRC</u>

Brian McDermott	Director, Division of Materials Safety and State Agreements
Pamela Henderson	Acting Deputy Director, Division of Materials Safety and State Agreements
Michael Fuller	Designated Federal Officer
Ashley Cockerham	Alternate Designated Federal Officer and ACMUI Coordinator
Maria Arribas-Colon	NRC staff
Susan Chidakel	NRC staff
Said Daibes, Ph.D.	NRC staff
Sandra Gabriel, Ph.D.	NRC staff Region I
Latischa Hanson	NRC staff Region IV
Donna-Beth Howe, Ph.D.	NRC staff
Patricia Pelke	NRC staff Region III
Gretchen Rivera-Capella	NRC staff
Lizette Roldan	NRC staff Region IV
Ronald Zelac, Ph.D.	NRC staff

MEMBERS OF THE PUBLIC:

Dr. Keith Brown - University of Pennsylvania Karen Colucci – Albert Einstein Healthcare Network Robert Dansereau - New York State Department of Health William Davidson - University of Pennsylvania Dr. Ronald Ennis – American Society for Radiation Oncology Lynne Fairobent – American Association of Physicist in Medicine Peter Goyer - Albert Einstein Healthcare Network Dr. Thomas Huston - Veterans Health Administration Dennis Kehoe - Jeppensen Radiation Oncology Center Ralph Lieto - St. Joseph Mercy Hospital Janette Merrill - Society of Nuclear Medicine Dr. Subir Nag - Kaiser Permanente Michael Peters – American College of Radiology Dr. Bradley Prestidge - American Brachytherapy Society Joseph Rodgers - Theragenics Corporation Gloria Romanelli – American College of Radiology Karen Sheehan - Fox Chase Cancer Center Michael Sheetz – University of Pittsburgh Eric Soltvcki – Albert Einstein Healthcare Network Cindy Tomlinson – American Society for Radiation Oncology

AGENDA TOPIC

Permanent Implant Brachytherapy Subcommittee Report

RECOMMENDATIONS AND ACTIONS

The subcommittee made the following changes to the draft report show in italics below:

- Page 1, "Recommendations" A.2.a. For neighboring structures (such as the bladder or rectum in prostate implants as an example), the dose to at least 5 *contiguous* cm³ (*contiguously*) exceeds 150% of the dose prescribed to the CTV or PTV.
- Page 1, "Recommendations" A.2.b. For intra-target structures (such as the urethra in prostate implants as an example), the dose to at least 5 *contiguous* cm³ (*contiguously*) exceeds 150% of that structure's expected dose based on the approved pre-implant, dose distribution.
- 3. Page 2, "Recommendations" B. The Authorized User should provide a statement in this Written Directive Completion attesting that the permanently implanted sources have been placed in accordance with the *final* planned distribution.

The first two changes were unanimously approved by the ACMUI. The third change was approved by the ACMUI; however, Dr. Thomadsen abstained because he did not support the concept of attestations in the Written Directive.

The Draft ACMUI Permanent Implant Brachytherapy Subcommitee Report modified January 2012, (ML12019A196) was approved by the ACMUI with the three changes noted above and one opposing vote. Dr. Thomadsen voted against the current report and stated his continued support for the October 18, 2011 version (ML11292A139). Dr. Thomadsen's comments are summarized in the "Minority Report" section of the current report dated February 7, 2012 (ML12038A279).

Murnahan, Colleen

From:	Ronald Frick [rfrick@gammacorp.com]
Sent:	Thursday, February 09, 2012 1:52 PM
To:	Murnahan, Colleen
Cc:	Whitten, Jack
Subject:	Hiro Makino M.D. Inc License termination
Attachments:	DECOM_mak.pdf

Colleen,

I have attached the license termination request for Hiro Makino, M.D. Inc., License #53-29263-01. Please contact me if you need additional information. Thank you,

Ron Frick Gamma Corporation rfrick@gammacorp.com 808-282-0169

NRC FORM 532 (1-2012)	U. S. NUCLEAR REGULATORY COMMISSION
Volter REGULATO DATE	
February 13,	2012
NAME AND ADDRESS OF APPLICANT AND/OR LICENSEE	LICENSE NUMBER
	53-29263-01
Hiro Makino, M.D., Inc. ATTN: Hiro Makino, M.D.	MAIL CONTROL NUMBER
President	576912
98-1079 Moahalua Rd, Suite 655	LICENSING AND/OR TECHNICAL REVIEWER
Aiea, Hawaii 96701	
This is to acknowledge the receipt of your:	
✓ LETTER and/or APPLICATION	DATED: 02/09/2012
The initial processing, which included an administrative	review, has been performed.
AMENDMENT ✓ TERMINATION NE	W LICENSE RENEWAL
There were no administrative omissions identified during	ng our initial review.
This is to acknowledge receipt of your application for reabove. Your application is deemed timely filed, and acc final action has been taken by this office.	enewal of the material(s) license identified cordingly, the license will not expire until
Your application for a new NRC license did not include Please fill out NRC Form 531, located at the following l	
http://www.nrc.gov/reading-rm/doc-c	ollections/forms/nrc531.pdf
Send the completed NRC Form 531, by facsimile, to the	ne following number: (301) 415-5387
A copy of your action has been emailed to our License our Headquarters office in Rockville, MD. You will be o involved.	Fee and Accounts Receivable Branch, in contacted separately if there is a fee issue
Your application has been assigned the above listed M calling to inquire about this action, please refer to this of been forwarded to a technical reviewer. Please note the normally completed within 180 days for a renewal application application our context of the processing of your application, our context of the processing of your application, our context of the processing of your application.	control number. Your application has nat the technical review, which is ication (90 days for all other requests), information. If you have any questions
Region IV U. S. Nuclear Regulatory Commiss DNMS/NMSB - B 1600 E. Lamar Boulevard Arlington, TX 76011-4511 (817) 200-1103 or (817) 200-1140	

BETWEEN:		[FOR ARPB USE] INFORMATION FROM LTS	
Accounts Receivable/P	avable	INFORMATION FROM LTS	
and	ayable	Program Code: 02201	
Regional Licensing Branches		Status Code: Pending Termination	
		Fee Category: 7C	
		Exp. Date:	
		Fee Comments: Decom Fin Assur Regd N	
License Fee Wo	orksheet - Licenso	e Fee Transmittal	
A. REGION			
1. APPLICATION ATTAC	HED		
Applicant/Licensee:	HIRO MAKINO, M.D., IN	C.	
Received Date:	02/09/2012		
Docket Number:	3037462		
Mail Control Number:	576912 53-29263-01		
License Number: Action Type:	Termination		
2. FEE ATTACHED	Λ		
Amount:	1		
Check No.:			
3. COMMENTS			
	Signed:	leen Murnahan	
	Signed.	-10-2012	
B. LICENSE FEE MANA		when milestone 03 is entered / /)	
1. Fee Category and A	mount:		
2. Correct Fee Paid. App	plication may be processed	for:	
Amendment:		×.	
Renewal:			
License:			
3 OTHER			
	Signed:		
	Date:		