

RIT

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

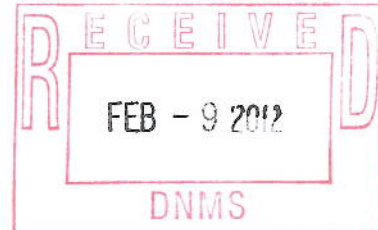
KMC AT PALI MOMI
98-1079 MOANALUA ROAD, #655
AIEA, HAWAII 96701
PHONE: (808) 486-6116

WAHIAWA BUSINESS CENTER
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WAHIAWA, HAWAII 96786
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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



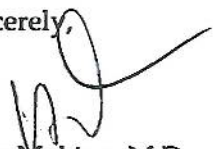
Subject: License Termination
NRC License No. 53-29263-01
Docket No. 030-37462

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

576912



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., CIIP, 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 dpm/100 cm², 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 Bicon Microrem survey meter. This meter contains a tissue-equivalent organic scintillator which can measure environmental levels of 0-20 µrem/hr. Background for this meter is approximately 5 µrem/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 Bicon 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:

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

$T_B = 1$ minute

$T_S = 0.33$ 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)
2. Treadmill/Exam rooms (6th floor)

List of Tables

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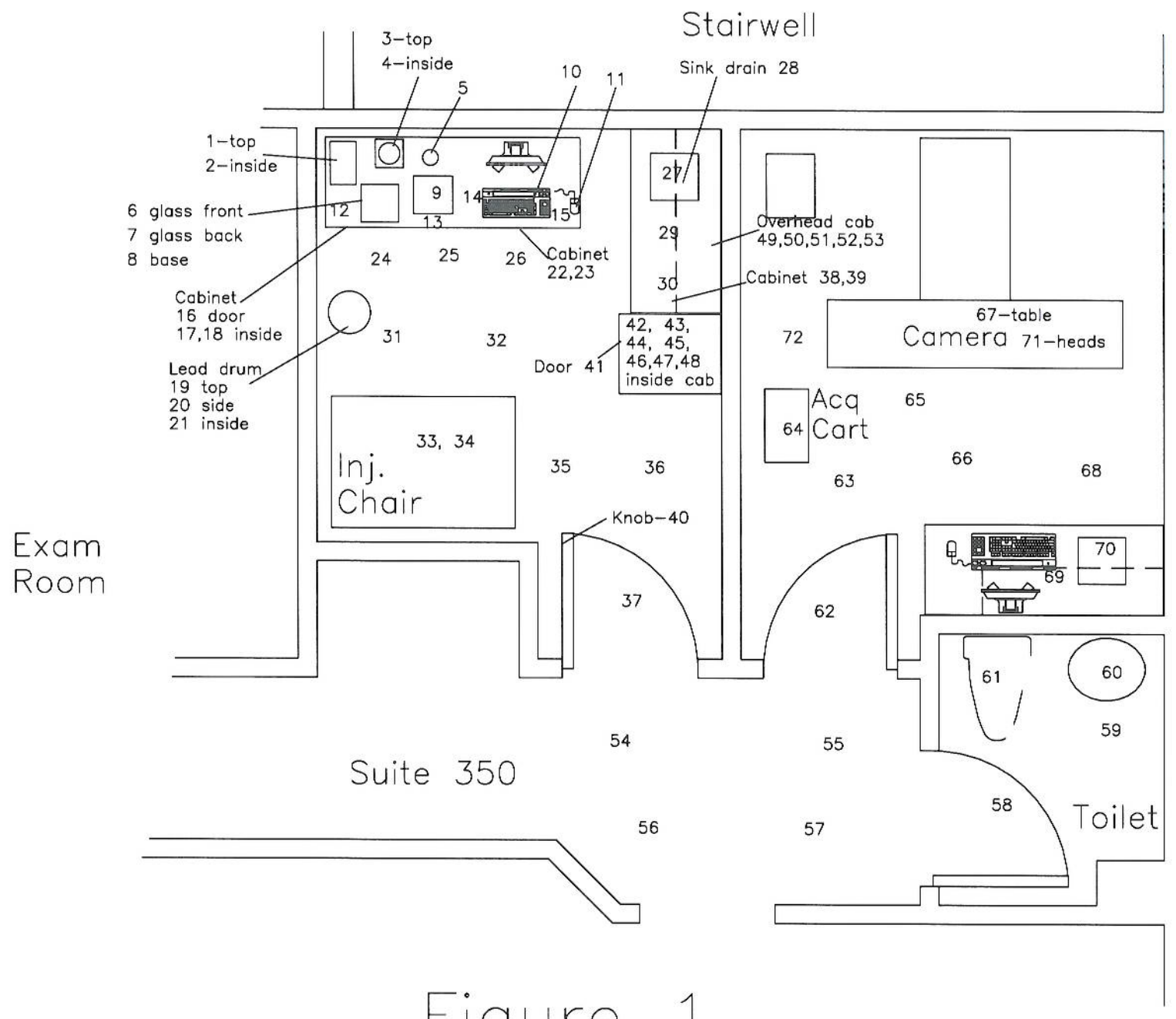


Figure 1

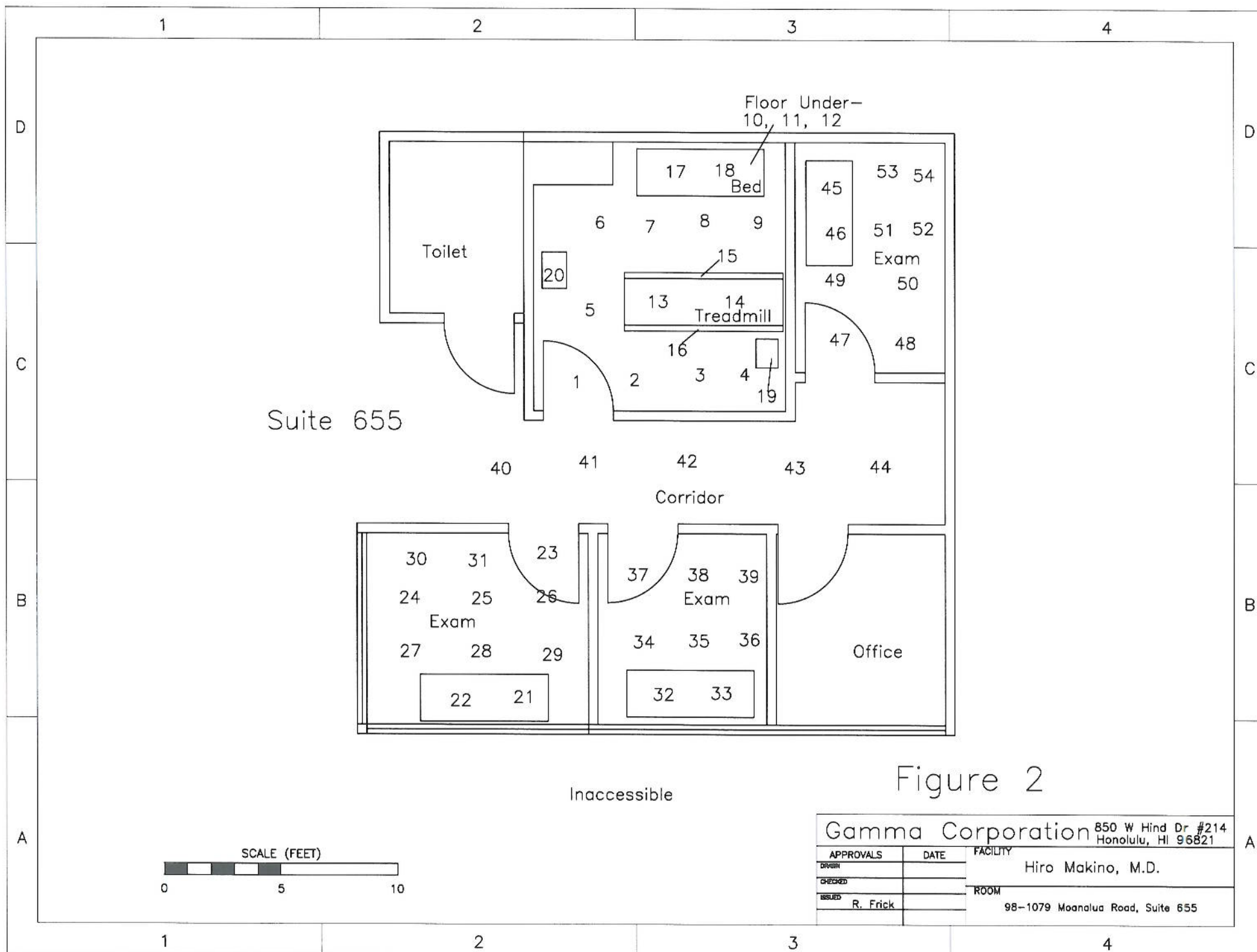


Table 1: Wipe Test Data (locations from Figure 1)

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	-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 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



Gamma Corporation

850 West Hind Drive #214, Honolulu, HI 96821

Phone (808) 373-7009

FAX (808) 373-7017

Leak Test Certificate

Facility: Hiro Makino, M.D., Inc

Number: 1320

Department:

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 NIST.

Isotope	Model Number	Serial Number	Activity (MBq)	Results (Bq)
Cs-137	MED 3550	119829	7.46	<4
Co-57	MED 3727	1469-151	370	<4



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:

Certificate of Calibration

Facility		Gamma Corporation		Dept.		Batteries	
						<input checked="" type="checkbox"/> OK <input type="checkbox"/> Replaced	
Mfgr/Model		Bicron Microrem		S/N		B393E	
				Probe		Detector Voltage	
<input checked="" type="checkbox"/> Calibrated with Cs-137 radiation source with NIST traceable output: 44.8 mR/hr @ 1 meter on 10/6/95. <input type="checkbox"/> Calibrated with electronic pulser for scales below 0.1 mR/hr. <input type="checkbox"/> Calibrated with electronic pulser for all scales.							
Range	Calculated Value	As Found Value	Accepted Value	Correction Factor	Corrected Value	% Error	
X1000	160000	170000	170000	1.0	170000	6%	
X1000	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 Type		<input type="checkbox"/> G.M. <input checked="" type="checkbox"/> Plastic Scint. <input type="checkbox"/> Nal Scint. <input type="checkbox"/> Proportional <input type="checkbox"/> Ion Chamber					
Detector Exposure Orientation		<input type="checkbox"/> Parallel <input type="checkbox"/> Perpendicular <input checked="" type="checkbox"/> Internal					
Condition Received		<input checked="" type="checkbox"/> In tolerance <input type="checkbox"/> Out of tolerance					
Comments:		new check source Cs137 1 uCi sn 1792					
Calibrated by: 				Check Source Reading		650 uR/hr	
Review:  Date: 12/18/11				Calibration Date		December 13, 2011	
				Calibration Due		December 12, 2012	
Acceptable tolerance is stated as $\pm 10\%$ of calculated value at each calibration point.							

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Address: 98-1079 Moanalua Road
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Measured net cpm = 11,110 cpm

Detection efficiency = 89.5%

Background count rate(R_B) = 265 cpm

Wipe area = 100 cm²

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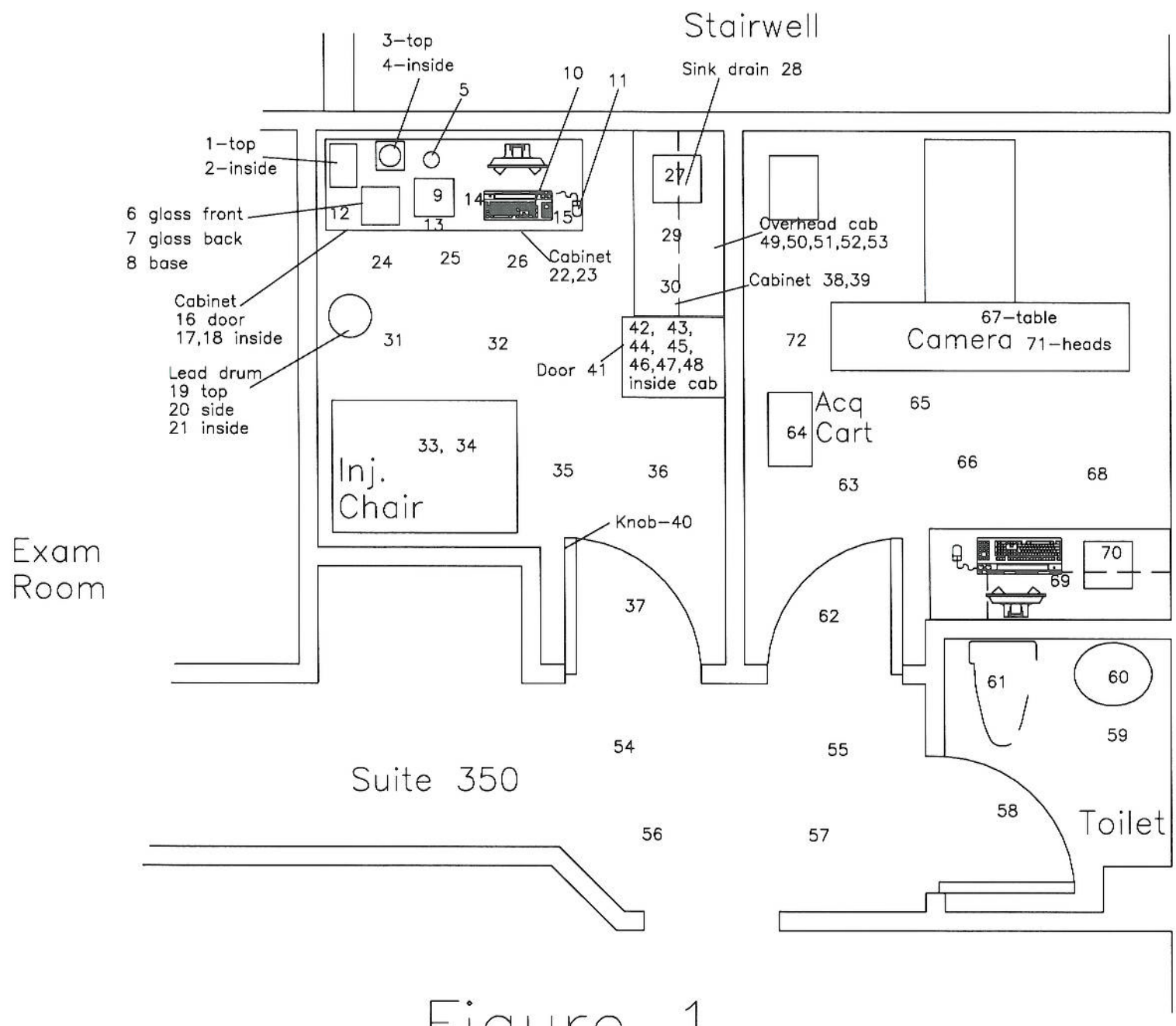


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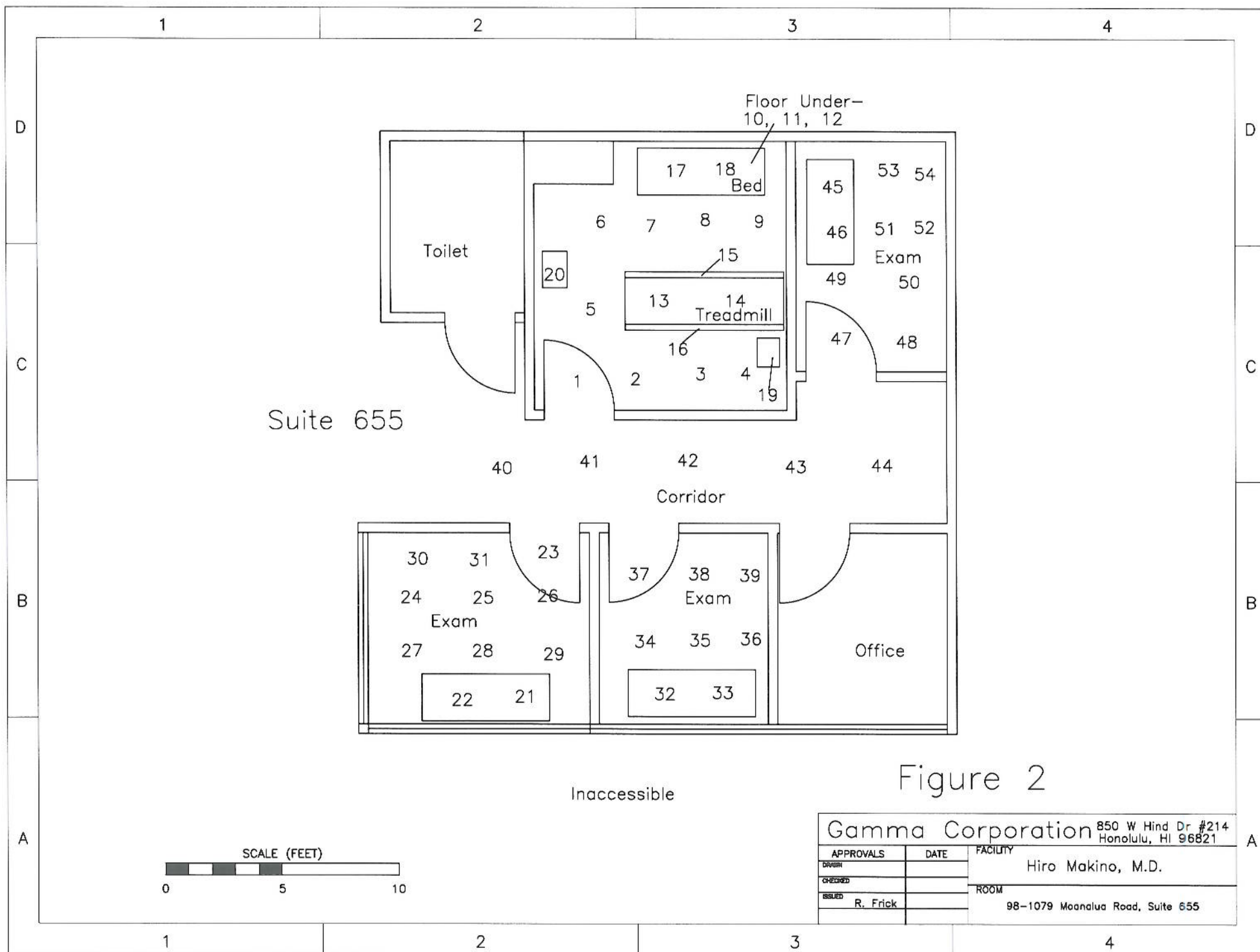


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63	-4	0
64	8	9
65	32	36
66	-28	0
67	-10	0
68	-34	0
69	50	56
70	-19	0
71	-43	0
72	35	39

Table 2: Wipe Test Data (locations from Figure 2)

Background=265 cpm

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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
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26	15	17	53	-3	0
27	3	3	54	18	20



Gamma Corporation

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FAX (808) 373-7017

Leak Test Certificate

Facility: Hiro Makino, M.D., Inc

Number: 1320

Department:

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 NIST.

Isotope	Model Number	Serial Number	Activity (MBq)	Results (Bq)
Cs-137	MED 3550	119829	7.46	<4
Co-57	MED 3727	1469-151	370	<4

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:



Certificate of Calibration

Facility	Gamma Corporation	Dept.					Batteries
							<input checked="" type="checkbox"/> OK <input type="checkbox"/> Replaced
Mfgr/Model	Bicron Microrem	S/N	B393E	Probe		Detector Voltage	
<input checked="" type="checkbox"/> Calibrated with Cs-137 radiation source with NIST traceable output: 44.8 mR/hr @ 1 meter on 10/6/95. <input type="checkbox"/> Calibrated with electronic pulser for scales below 0.1 mR/hr. <input type="checkbox"/> Calibrated with electronic pulser for all scales.							
Range	Calculated Value	As Found Value	Accepted Value	Correction Factor	Corrected Value	% Error	
X1000	160000	170000	170000	1.0	170000	6%	
X1000	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 Type	<input type="checkbox"/> G.M. <input checked="" type="checkbox"/> Plastic Scint. <input type="checkbox"/> Nal Scint. <input type="checkbox"/> Proportional <input type="checkbox"/> Ion Chamber						
Detector Exposure Orientation	<input type="checkbox"/> Parallel <input type="checkbox"/> Perpendicular <input checked="" type="checkbox"/> Internal						
Condition Received	<input checked="" type="checkbox"/> In tolerance <input type="checkbox"/> Out of tolerance						
Comments:	new check source Cs137 1 uCi sn 1792						
Calibrated by:	 Review: Date: 12/18/11			Check Source Reading	650 uR/hr		
				Calibration Date	December 13, 2011		
				Calibration Due	December 12, 2012		
Acceptable tolerance is stated as $\pm 10\%$ of calculated value at each calibration point.							

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:

<http://www.nrc.gov/reading-rm/doc-collections/acmui/tr/>

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": <http://www.nrc.gov/about-nrc/regulatory/advisory/acmui.html>

ATTENDEES

ACMUI

Darice G. Bailey	Member
Milton S. Guiberteau, M.D.	Member
Susan M. Langhorst, Ph.D.	Member
Leon S. Malmud, M.D.	Chairman
Steve R. Mattmuller	Member
Christopher J. Palestro, M.D.	Member
John H. Suh, M.D.	Member
Orhan H. Suleiman, Ph.D.	Member
Bruce R. Thomadsen Ph.D.	Vice Chairman
Laura Weil	Member
James S. Welsh, M.D.	Member
Pat Zanzonico, Ph.D	Member

NRC

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 Soltycki – 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:

1. 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.
2. 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 Subcommittee 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



DATE
February 13, 2012

NAME AND ADDRESS OF APPLICANT AND/OR LICENSEE

Hiro Makino, M.D., Inc.
ATTN: Hiro Makino, M.D.
President
98-1079 Moahalua Rd, Suite 655
Aiea, Hawaii 96701

LICENSE NUMBER

53-29263-01

MAIL CONTROL NUMBER

576912

LICENSING AND/OR TECHNICAL REVIEWER

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 ☐ NEW LICENSE ☐ RENEWAL

- ☒ There were no administrative omissions identified during our initial review.
- ☐ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.
- ☐ Your application for a new NRC license did not include your taxpayer identification number. Please fill out NRC Form 531, located at the following link:

<http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>

Send the completed NRC Form 531, by facsimile, to the following number: (301) 415-5387

A copy of your action has been emailed to our License Fee and Accounts Receivable Branch, in our Headquarters office in Rockville, MD. You will be contacted separately if there is a fee issue involved.

Your application has been assigned the above listed **MAIL CONTROL NUMBER**. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region IV
U. S. Nuclear Regulatory Commission
DNMS/NMSB - B
1600 E. Lamar Boulevard
Arlington, TX 76011-4511
(817) 200-1103 or (817) 200-1140

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM LTS

Program Code: 02201
Status Code: Pending Termination
Fee Category: 7C
Exp. Date:
Fee Comments:
Decom Fin Assur Req'd N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: HIRO MAKINO, M.D., INC.
Received Date: 02/09/2012
Docket Number: 3037462
Mail Control Number: 576912
License Number: 53-29263-01
Action Type: Termination

2. FEE ATTACHED

Amount: _____

Check No.: _____

3. COMMENTS

Signed: _____

Date: _____

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / /)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment: _____

Renewal: _____

License: _____

3. OTHER _____

Signed: _____

Date: _____