

Hill, Carol

From: Schippers, Dale <dschippers@Queens.Org>
Sent: Friday, April 22, 2016 5:44 PM
To: Hill, Carol
Cc: Goerner, Frank; Hirata, Emily
Subject: [External_Sender] License Amendment
Attachments: Cardinal Health RAM Summary listing Stacey Murakami.pdf; Douglas Prager Training letter 3-2016.pdf; 2012-10-26 ANP Approval Memo for ANP Murakami.pdf; NRC letter, adding Stacey as ANP, remove AU & AMPs, Apr2016.pdf; Shay Lee Training letter 4-2016.pdf; Cardinal Health NRC License, Amendment 47.pdf

Attached is a letter and supporting documents requesting amendments to our NRC licenses. We discussed these amendments, specifically the documentation needed to add Stacey Murakami as an ANP, on April 11.

Thank you,

Dale Schippers, MS DABR
Medical Physicist / RSO
Queen's Medical Center
Office: (808) 691-4884
Fax: (808) 691-4507

PUBLIC
☐ Immediate Release
☐ Normal Release
NON-PUBLIC
☒ A.3 Sensitive-Security Related
☐ A.7 Sensitive Internal
☐ Other: _____
Reviewer: DKC Date: 4/28/16

PUBLIC
☐ Immediate Release
☐ Normal Release
NON-PUBLIC
☐ A.3 Sensitive-Security Related
☐ A.7 Sensitive Internal
☐ Other: _____
Reviewer: _____ Date: _____



THE QUEEN'S MEDICAL CENTER

1301 Punchbowl Street ▪ Honolulu, Hawaii 96813 ▪ Phone (808) 538-9011 ▪ FAX: (808) 691-4646 ▪ www.queens.org

April 19, 2016

United States Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011-4005

RE: **New Authorized Nuclear Pharmacist**
The Queen's Medical Center
NRC License No. **53-16533-02,**
53-16533-04MD, and
53-29377-03

Dear Carol Hill:

License Number 53-16533-04MD

Please add Stacey Murakami as an Authorized Nuclear Pharmacist to our cyclotron distribution license. She is listed as an ANP on the Cardinal Health license number 34-29200-01MD. A copy of that license is attached.

License Number 53-16533-02

Please remove the following Authorized Medical Physicists:

Alan Cassady, Harold Palmer, Ed Price, Rebecca Middleton, Jessica Fagerstrom, and Jon Wetzel. They are no longer employed at The Queen's Medical Center.

Douglas A. Prager, MD and Shay J. Lee, MD have completed their training requirements to be an Authorized User for Y-90 TheraSpheres. Letters documenting their training, including the three supervised hands-on cases, are attached.

License Number 53-29377-03

Please remove Koshrow Behjati, MD from our cyclotron production license. He is also no longer with The Queen's Medical Center.

Thank you for your assistance. If you have any questions or require additional information, please contact our Radiation Safety Officer, Dale Schippers at 808-691-4884 or Darlena Chadwick at 808-691-4742.

Sincerely,

Darlena Chadwick, MSN, MBA, FACHE
Vice President, Patient Care

Cardinal Health Radioactive Material License, Registration, Permit Summary

Location **7232** **Honolulu** **HI**
Licenses Name **CAH 414, LLC**
Agreement State - NRC **NRC** License Type **RAM** License / Registration / Permit Number **34-28200-01MD**

Administrative Information

License Exp Date	1/31/2022	Services Provided	Y	Multi-sites on license	N
Timely Renewal Date		Co-located	N	Other site	NRC
Address	525 Kokee Street	Suite	Suite B-2		
City	Honolulu	State	HI	Zip Code	96817
Manager / Site Supervisor	Stacey Murakami	Phone	808.845.5141		
Pharmacy RSO	Stacey Murakami	Manufacturing RSO			

License / Registration / Permit Detail

Amendment Number	46	Amendment Date	5/8/2014	Request Date	2/25/2014	Received Date	5/19/2014
Amendment Description	removes non-pharm AU						
Floor Plan Date	7/25/2011	Remodel Date		Cs-137 Calibrator	N	Surety Bond	N/A
Amendment Number	46	Condition(s)	12, 14	Special Condition	Y		
Unique Condition if applicable:	self-approval of ANP-AU						

Revision Date **8/21/2014**Annual License / Registration / Permit Fee **\$1,038.00**

BTG International Canada Inc.
Roy Errington Building
3rd Floor
447 March Road
Ottawa, Ontario
Canada
K2K 1X8

Tel: +1 613 801 1880
Fax: +1 613 701 4086
Email: info@btgplc.com
www.btgplc.com



To: Douglas A. Prager MD c/o Dale Schippers RSO
From: Mark Moe
Date: 3/24/16
Subject: TheraSphere® In-vitro Administration Training

I am pleased to confirm that Douglas A. Prager MD has successfully completed manufacturer provided training of: A total of three in-vitro administrations and three supervised hands-on *in-vivo* cases. Training encompassed the operation of the delivery system, safety procedures and A-G training for TheraSphere® Y-90 Glass Microspheres System:

In-vitro training was done on 1/6/15; three in-vivo cases were done on 3/3/16; 3/23/16; 3/24/16
All of these areas will be covered completing via vendor training:

- a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- b) Performing quality control procedures on instruments used to determine the activity of Y-90 microspheres and performing checks for proper operation of survey meters;
- c) Evaluation of each patient or human research subject for the dose/activity of Y-90 microspheres to be administered to each treatment site;
- d) Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient or human research subject;
- e) Using administrative controls to prevent a medical event involving the use of byproduct material;
- f) Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures; and
- g) Follow up and review of each patient's or human research subject's case history for Y-90 microspheres; and:
The user has successfully completed training in the operation of the delivery system, safety procedures and 3 in vivo cases.

Sincerely,

Mark Moe

Interventional Oncology Proctor, TheraSphere
BTG Inc.

Cardinal Health
Nuclear Pharmacy Services
Quality & Regulatory
7000 Cardinal Place
Dublin, OH 43017
tel 614.757.5000
fax 614.652.4598

www.cardinal.com



TO: Michael Chee, Manager, Honolulu, HI loc. 1199
CC: Alan Kim
FROM: Dan Hill, Quality & Regulatory
DATE: October 26, 2012
SUBJECT: ANP Status

As of October 26, 2012, **Stacy E. Murakami, R.Ph.** has been approved by the Radiation Safety Committee as an Authorized Nuclear Pharmacist on the Cardinal Health U.S. NRC license 34-29200-01MD master listing for ANP's. Please keep a copy of the enclosed listing in your file for inspections.

If you have any questions, please contact me at 614.757.5074.

BTG International Canada Inc.
Roy Errington Building
3rd Floor
447 March Road
Ottawa, Ontario
Canada
K2K 1X8

Tel: +1 613 801 1880
Fax: +1 613 701 4086
Email: info@btgplc.com
www.btgplc.com



To: Shay J. Lee MD c/o Dale Schippers RSO
From: Mark Moe
Date: 4/16/16
Subject: TheraSphere® In-vitro Administration Training

I am pleased to confirm that Shay Lee MD has successfully completed manufacturer provided training of: A total of three in-vitro administrations and three supervised hands-on *in-vivo* cases . Training encompassed the operation of the delivery system, safety procedures and A-G training for TheraSphere® Y-90 Glass Microspheres System:

In-vitro training was done on 1/6/15; three in-vivo cases were done on 2/2/16 ; 4/15/16; 4/15/16
All of these areas will be covered completing via vendor training:

- a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- b) Performing quality control procedures on instruments used to determine the activity of Y-90 microspheres and performing checks for proper operation of survey meters;
- c) Evaluation of each patient or human research subject for the dose/activity of Y-90 microspheres to be administered to each treatment site;
- d) Calculating and measuring the activity and safely preparing the Y-90 microspheres to be delivered to the patient or human research subject;
- e) Using administrative controls to prevent a medical event involving the use of byproduct material;
- f) Using procedures to control and to contain spilled byproduct material, including Y-90 microspheres, safely and using proper decontamination procedures; and
- g) Follow up and review of each patient's or human research subject's case history for Y-90 microspheres; and:
The user has successfully completed training in the operation of the delivery system, safety procedures and 3 in vivo cases.

Sincerely,

Interventional Oncology Proctor, TheraSphere
BTG Inc.

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NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 1 of 6 PAGES
Amendment No. 47

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p align="center">Licensee</p> <p>1. Cardinal Health Nuclear Pharmacy Services</p> <p>2. 7000 Cardinal Place Dublin, Ohio 43017</p>	<p>In accordance with letters dated November 18 and 25, 2014,</p> <p>3. License No. 34-29200-01MD is amended in its entirety to read as follows:</p> <p>4. Expiration Date: January 31, 2022</p> <p>5. Docket No. 030-36973 Reference No.: Docket No. 030-33224 and License No. 04-26507-01MD</p>
---	--

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
		Maximum amount per licensed facility identified in Condition 10
A. Any byproduct material with atomic numbers 3 through 83 with half-life less than 120 days, except iodine-131, fluorine-18, rubidium-82, molybdenum-99, strontium-82, technetium-99m, xenon-133, and strontium-85	A. Solid or liquid	A. 5 curies
B. Molybdenum-99	B. Any	B. 200 curies
C. Technetium-99m	C. Any	C. 200 curies
D. Xenon-133	D. Any	D. 7 curies
E. Iodine-131	E. Any	E. 6 curies
F. Any byproduct material in a brachytherapy source listed in 10 CFR 35.400	F. Sealed sources	F. 500 millicuries
G. Any byproduct material in a sealed source for diagnosis listed in 10 CFR 35.500	G. Sealed sources	G. 4.5 curies total and no single source to exceed 1.5 curies

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MATERIALS LICENSE SUPPLEMENTARY SHEET

License No.

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Docket or Reference No.

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Amendment No. 47

6. Byproduct, source, and/or special nuclear material

7. Chemical and/or physical form

8. Maximum amount that licensee may possess at any one time under this license

Maximum amount per licensed facility identified in Condition 10

H. Any byproduct material authorized under 10 CFR 35.65(a)

H. Sealed sources

H. 100 millicuries total, and no single source to exceed 30 millicuries

I. Depleted Uranium

I. Solid

I. 660 kilograms

J. Any byproduct material with Atomic Nos. 1-83, inclusive

J. Solid or liquid (Analytical samples)

J. Not to exceed 10 millicuries per analytical sample and 100 millicuries total

K. Fluorine-18

K. Any

K. 10 curies

L. Strontium-82

L. Solid

L. 400 millicuries

M. Rubidium-82

M. Any

M. 400 millicuries

N. Strontium-85

N. Any

N. 2 curies

O. Radium-223

O. Liquid

O. 5 millicuries

9. Authorized use:

A. through E., K., L., and M.

Preparation and distribution of radioactive drugs including compounding of iodine-131 and redistribution of used and unused molybdenum-99/technetium-99m generators and strontium-82/rubidium-82 generators to authorized recipients in accordance with 10 CFR 32.72. Preparation and distribution of radioactive drugs and radiochemicals including compounding of iodine-131 and redistribution of used and unused molybdenum 99/technetium 99m generators to authorized recipients for non-medical use.

F. and G. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74. Redistribution of sealed sources that have been registered either with NRC under 10 CFR 32.210 or with an Agreement State and have been distributed in accordance with an NRC or Agreement State specific license authorizing distribution to persons specifically authorized by an NRC or Agreement State license to receive, possess, and use the devices.

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- H. Calibration and checking of the licensee's instruments. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74 to authorized recipients and to authorized recipients for non-medical use.
- I. Shielding for Mo99/Tc99m generators.
- J. Possession incident to the performance of swipe testing of customer's sealed sources.
- N. Impurity in Sr-82/Rb-82 generators.
- C. and H. To be used for client instrument calibrations.
- O. For distribution to authorized recipients.

CONDITIONS

10. Except as specified otherwise in this license, licensed material identified in Items 6.A. through 6.O. shall be used only at the licensee's facilities located at:
- A. 34 New Hope Road #4, Princeton, West Virginia 24740
 - B. 1100 Airport North Office Park, Suite D, Fort Wayne, Indiana 46825
 - C. 7920 Georgetown Road, Suite 100, Indianapolis, Indiana 46268
 - D. 1864 Pine Ridge Drive, #A, Jenison, Michigan 49428
 - E. Marion Ridge Business Park, 9668 Marion Ridge, Kansas City, Missouri 64137
 - F. 131 Hartland Street, East Hartford, Connecticut 06108
 - G. 5630 Silverado Way, #1, Anchorage, Alaska 99518
 - H. 1603 "C" Avenue, Sioux Falls, South Dakota 57104
 - I. 3305 Lathrop Street, Suite 100, South Bend, Indiana 46628
 - J. 21681 Melrose Avenue, Southfield, Michigan 48075
 - K. 3040 East Elm Street, Springfield, Missouri 65802
 - L. 1909 Beltway Drive, St. Louis, Missouri 63114
 - M. 28 Omega Drive, Building #7, Stamford, Connecticut 06907
 - N. 5370 Miller Road, Suite #25, Swartz Creek, Michigan 48473
 - O. 115 Dingess Street, Barboursville, West Virginia 25504
 - P. 2141 Airport Way, Suite 900, Boise, Idaho 83705
 - Q. 10250 Stone Creek Drive, Laurel, Delaware 19956
 - R. 2715 West Main Street, Highland, Indiana 46322
 - S. 846 Service Road, Room E137, East Lansing, Michigan 48824
 - T. 525 Kokea Street, Suite B-2, Honolulu, Hawaii 96817

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11. Licensed material identified in Subitem Nos. 6.C., 6.H. and 6.J. may be used at the licensee's facilities listed in Condition 10 and at temporary job sites of the licensee anywhere in the United States where the U. S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material.
12. A Licensed material shall be used by, or under the supervision of a pharmacist working or designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(2)(i) or (4).
- B. (1) Licensed material for other than radiopharmaceutical use shall be used by or under the supervision of individuals approved in accordance with letters, dated December 18, 2006, February 8, 2007, January 21, 2013 (with attachments) and May 1, 2013.
- (2) Licensed material for other than radiopharmaceutical use shall be used by or under the supervision of:
- | | | |
|---------------------|--------------------|---------------------------|
| Tony Adamo | Asma Abbasi | Cami Still |
| T. John Alexander | Anjuni Mingus | Michael Koniski |
| Kory Kodimer, Ph.D. | Matthew Komornik | W. Dan Hill |
| Edward A. Corros | Robert E. Lewis | Michael Young |
| W. Robert Davis | Evan T. Western | Adam J. Fleshner |
| Tara J. Simonian | Robert Lapena | James T. Chimelewski, Jr. |
| Candice Goodyear | Corey W. Woods | Carl Collier |
| Dean Polar | Jason K. Steincamp | Lonze Townsend |
| Jason Luper | Elias Garcia | Richard B. Hasselkus |
| Paul Friedenberg | John Haag | Andrew Fu |
| Lisa Frantz | Alonzo Keys | |
13. The Radiation Safety Officer (RSO) for this license is **William Scott Claunch, R.Ph.**
14. Notwithstanding the requirements of 10 CFR 32.72(b)(2)(ii), the licensee may approve authorized nuclear pharmacists in accordance with application dated July 20, 2011.
15. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by NRC under 10 CFR 32.210 or by an Agreement State.
- B. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by NRC under 10 CFR 32.210 or by an Agreement State prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.

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- C. Sealed sources need not be tested if they are in storage and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
 - D. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 Becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 Becquerels) or more of removable contamination, a report shall be filed with the U. S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.
 - E. Tests for leakage and/or contamination shall be performed by the licensee or other persons specifically licensed by the Commission or an Agreement State to perform such services.
 - F. Records of leak test results shall be kept in units of microcuries and shall be maintained for three years.
- 16. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.
 - 17. The licensee shall conduct a physical inventory every six months, or at other intervals approved by NRC, to account for all sealed sources and/or devices received and possessed under the license.
 - 18. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
 - 19. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash provided:
 - A. Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate survey meter set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
 - B. A record of each disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

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20. Except for maintaining labeling as required by 10 CFR Part 20 or 71, the licensee shall obtain authorization from NRC before making any changes in the sealed source, device, or source-device combination that would alter the description or specifications as indicated in the respective Registration Certificates issued either by the Commission pursuant to 10 CFR 32.210 or by an Agreement State.
21. The licensee is authorized to retrieve, receive and dispose of radioactive waste from its customers, limited to radiopharmacy-supplied syringes and vials and their contents.
22. Notwithstanding the requirements of 10 CFR 32.72(c), the licensee may re-distribute alpha-, beta-, or photon-emitting radioactive drugs, which have been initially distributed by another radiopharmaceutical supplier licensed pursuant to 10 CFR 32.72, without verifying the radioactivity of the dosage. The licensee must not manipulate the dosage, including the packaging and label.
23. This license does not authorize distribution to persons exempt from licensing.
24. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U. S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated July 20, 2011; and,
- B. Letters dated December 18, 2006, February 8, 2007, July 25, 2011, December 7, 2011, January 30, 2012, May 3, 2012 (updated training program), August 16, 2012, October 5, 2012 (regarding the remodel of Sioux Falls, SD location), January 21, 2013 (with attachments), May 1, 2013, March 20, 2013 (with attachments), and July 3, 2013.

FOR THE U. S. NUCLEAR REGULATORY COMMISSION

Date

JAN 07 2015

By



Bryan A. Parker
Materials Licensing Branch
Region III

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590745



DATE

04/20/2016

NAME AND ADDRESS OF APPLICANT AND/OR LICENSEE

Mr. Dale J. Schippers, M.S.
Radiation Safety Officer
The Queen's Medical Center
1301 Punchbowl Street
Honolulu, HI 96813

LICENSE NUMBER

53-16533-02

MAIL CONTROL NUMBER

590745

LICENSING AND/OR TECHNICAL REVIEWER

JAB

This is to acknowledge the receipt of your:

☒ LETTER and/or☐ APPLICATION

DATED: 04/22/2016

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) 200-1140

✓ 4-26-16

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM WBL

Program Code: 02230
Status Code: Pending Amendment
Fee Category: 3E 7C
Exp. Date:
Fee Comments: CODE 23
Decom Fin Assur Req'd: N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: QUEEN'S MEDICAL CENTER, THE
Received Date: 04/22/2016
Docket Number: 3014522
Mail Control Number: 590745
License Number: 53-16533-02
Action Type: Amendment

2. FEE ATTACHED

Amount: _____

Check No.: _____

3. COMMENTS

Signed: _____

Date: _____

Jennifer Budge
4-26-16

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: _____