



APPLICATION FOR MATERIALS LICENSE

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to InfoCollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NE08-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW. *AMENDMENTS/RENEWALS THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NEW OR HIGHER FEE CATEGORY WILL REQUIRE A FEE.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

MATERIALS SAFETY LICENSING BRANCH
DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,

SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN,
SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,

SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

☐

A. NEW LICENSE

☒

B. AMENDMENT TO LICENSE NUMBER

25-01203-01

☐

C. RENEWAL OF LICENSE NUMBER

2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)

Department of Health and Human Services
National Institutes of Health, NIAID
Rocky Mountain Laboratories
903 South 4th Street

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Rocky Mountain Laboratories
903 South 4th Street
Hamilton, MT 59840

RECEIVED
JUN 20 2016
DNMS

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Barry Twardoski, Radiation Safety Officer

BUSINESS TELEPHONE NUMBER

(406) 363-9216

BUSINESS CELLULAR TELEPHONE NUMBER

(406) 381-2796

BUSINESS EMAIL ADDRESS

twardoskib@niaid.nih.gov

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

- a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

**12. LICENSE FEES (Fees required only for new applications, with few exceptions*)
(See 10 CFR 170 and Section 170.31)**

FEE CATEGORY

3E, 3L

**AMOUNT
ENCLOSED \$**

0.00

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

Joshua Kellar, RML Associate Director

SIGNATURE

DATE

6/13/16

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
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APPROVED BY

DATE

591133

ITEM 7: INDIVIDUALS RESPONSIBLE FOR THE RADIATION SAFETY PROGRAM

7.3 Radiation Safety Officer

Rocky Mountain Laboratories (RML) would like to appoint Mr. Aaron Bestor as the new Radiation Safety Officer responsible for overseeing the activities outlined in RML's Type A Broad Scope License. Mr. Bestor is to replace Mr. Barry Twardoski who has been the RSO at RML since 2008.

Mr. Bestor has worked as the Health Physicist assisting with RSO duties for the past two years at RML. Prior to his current position, Mr. Bestor worked as a Biological Research Technician at RML for 11 years where he was the section's Authorized User of radioisotopes since 2007, and has been a member of the RML Radiation Safety Committee since 2011. Mr. Bestor has a Bachelor's of Science degree in Biology and Chemistry, the included completion of courses in math, physics, chemistry and biology sufficient to understand the health protection standards, theories and practices required for working with and overseeing the use of radioisotopes.

Formal Training Courses:

- Radiation Safety Officer Training Course (40 hours of lecture and training), Dade Moeller Radiation Safety Training Academy, Gaithersburg, Maryland, May 2015.
- DOT Certification for the shipping of radioactive material, Dade Moeller Radiation Safety Training Academy, Gaithersburg, Maryland, May 2015.
- Liquid Scintillation Counting Theory and Techniques, Dade Moeller Radiation Safety Training Academy, Gaithersburg, Maryland, May 2015.
- RML, NIAID, Irradiator Training Course to qualify as an Authorized User of the Gamma Irradiators, August 2014.
- RML, NIAID, NIH Training Course for qualification as an Authorized User at RML (20 Hours of lecture and laboratory training), Sept. 2007.

Experience in Performing RSO Duties and Responsibilities.

Over the past two years as a Health Physicist at RML, Mr. Bestor has performed the following tasks under the current RSO:

1. Communication Skills

- Assists the RSO in conducting all required Radiation Safety training for general awareness for new RML employees; initial radiation safety training for laboratory use of radioisotopes; initial and annual refresher training for gamma irradiators users; radiation safety and security training for shipping and receiving personnel; and initial and annual refresher training for all individuals involved in the safety and security of category 1 and 2 materials.

- Maintains constant communication with all users to address any questions associated with the security, safety, use and disposal of small quality isotopes at RML.
 - Actively participated in discussions with the NRC representative during an inspection of activities and compliance with 10 CFR Part 37 requirements under RML's license, in February of 2016.
 - Assisted in the preparation, submission and addressing of NRC comments in renewing RML's Type A Broad Scope license in 2015.
 - Maintain regular communication with members of the NIH Radiation Safety branch in Bethesda, MD, to inform them of any changes to RML's program, discuss implementation of new NRC requirements, etc.
 - Actively participated in an internal audit of RML's radiation safety program conducted by members of the NIH Radiation Safety branch.
 - Assist the RSO in organizing and conducting Radiation Safety Committee meetings, drafting meeting minutes and organizing correspondence with RSC members.
2. Material Receipt, Accountability and Inventory Management
- Assist the RSO in approving radioisotope orders.
 - Conducts surveys of all incoming isotope shipments.
 - Maintains records of all isotopes on hand, on order or in waste storage.
 - Manages proper record keeping, inventory and disposal of radioactive waste with compliance to sewer disposal and incinerator stack effluent limits.
 - Ensures proper storage and security of isotopes and sealed sources.
 - Knowledge and experience in calculating radioactive decay for all radioactive materials and waste at RML.
3. Regulatory Knowledge
- Familiar with NRC regulations specific to RML's Type a Broad scope license, specifically those associated with safety, training, exposure limits and monitoring, emergency plans, inventory receipt and management, security, etc. associated with 10 CFR 19, 10 CFR 20, 10 CFR 30, 10 CFR 33, and 10 CFR 37.
 - Assisted in the preparation, submission and NRC comment responses associated with RML's 10 year NRC license renewal application, following the requirements and guidance of applicable NUREG documents.
 - Actively participated in discussions regarding RML's implementation of 10 CFR Part 37 requirements for security of Category 1 and 2 materials with NRC inspector.
 - Implemented the security system testing procedures for RML's sealed sources as per the requirements of 10 CFR Part 37.
 - Assists with review of background investigations and conducting the training requirements associated with granting access to the irradiators, as per the requirements of 10 CFR Part 37.

4. Instrument Use and Management

- Knowledgeable and regularly uses radiation detection, monitoring and measuring instruments including: portable survey meters with both gamma and pancake G-M detectors, liquid scintillation counters, ion chambers, room monitors and electronic dosimeters.
- Maintains the calibration schedule of all radiation detection equipment, and performs survey meter calibration tests using check sources prior to redistributing the meters for use.
- Assisted in the calibration and implementation of the gamma irradiator dosimetry system.
- Knowledge and understanding of survey meters and detectors that is required for the appropriate selection and use of the instruments utilized for detecting various energy levels of gamma and beta emitters.
-

5. Health and Safety

- Understands and implements the principals of shielding for selection of the appropriate shielding and PPE required for reducing radiation exposure.
- Knowledgeable in the calculation of internal and external dose calculation using the factors of time, distance and shielding.
- Assists with the execution of RML's personnel monitoring program, including dosimeter exchange, exposure notices, etc.
- Knowledgeable in the dose limitations associated with the public, occupational radiation exposure and pregnant/childbearing age women.
- Actively involved in achieving the primary objective of radiation safety; keeping personnel exposures to radiation ALARA.
- Regularly inspects and surveys laboratories for contamination, cleanliness, radioisotope security and overall compliance with required safety practices.
- Performs leak tests on instruments containing self-shielded sources of penetrating radiation.
- Assist with decommissioning of areas as required.
- Provide assistance and support when responding to any emergencies and supervise decontamination of any spills.

6. Security

- Implemented the testing plan for the irradiator room security systems.
- Conduct regular inspections of laboratories and waste storage areas to ensure isotopes are proper secured.
- Assist the RSO in reviewing access requests for the gamma irradiators. This includes determining the necessity for access of the individual, verifying the necessity for access with the individual's supervisor, initiating the background investigations to determine if the individual is Trustworthy & Reliable and providing irradiator security and safety training to the individuals.

- Providing initial and annual refresher training to all individuals involved in the security of Category 1 and 2 materials.
- Review weekly irradiator access logs to ensure only those individuals with valid access to irradiators have entered the rooms.
- Assist the RSO in compliance with all requirements associated with 10 CFR Part 37 for the security of category 1 and 2 materials.

The duties, responsibilities, and authority of the RML Radiation Safety Officer are as follows:

1. Supervise all health physics activities, including both personnel and environmental monitoring.
2. Furnish consulting services to personnel at all levels of responsibility on all aspects of radiation protection. In matters beyond the experience of the RSO, he/she will consult the Radiation Safety Officer at NIH, Bethesda, Maryland.
3. Maintain liaison with the Radiation Safety Branch in Bethesda and keep a current list of names and phone numbers of radiation physicists in Bethesda who may be called upon for advice.
4. Arrange for monitoring, safety checks and leak tests of instruments capable of producing penetrating radiation.
5. Supervise distribution and processing of personnel monitoring equipment (e.g. dosimeters). Perform and keep records of required bioassays.
6. Advise each worker annually of the worker's dose, as shown in records maintained by the licensee [10 CFR 19.13(b)].
7. Instruct personnel in the nature and properties of ionizing radiation and the proper procedures for the use of radioactive materials or supervise and arrange for such instruction by qualified specialists.
8. Supervise the lab records of storage and waste disposal; make periodic checks of the records kept by authorized users.
9. Maintain current inventory of all radioactive materials at RML, and ensure that possession limits given in the NRC license are not exceeded.
10. Maintain monthly monitoring and survey records of all lab areas using radioactive materials.
11. Receive all requests for acquisition of radioactive materials which comply with the current policies and procedures. Approve orders with reference to protocol number and inventory number assigned before purchase. Maintain a log of all approved requests. Designate an alternate member of the RML Radiation Committee to perform this function in the absence of the RSO.
12. Supervise receipt and delivery of all shipments of radioactive materials received at the institution; supervise packaging and shipping of all radioactive materials leaving the institution.
13. Maintain inventory and perform leak tests on all sealed sources at least once every six months, as required by license conditions, and keep the records of the results of such tests.
14. Supervise storage, decay program, current activity and disposal of radioactive waste.
15. Supervise decontamination in case of spills or other contaminating accidents.
16. Investigate incidents and respond to emergencies.

Application for Amendment to Type A Broad Scope License
Rocky Mountain Laboratories NIH/NIAID
License Number 25-01203-01

17. Submit the required reports to the NRC on any cases of overexposure to radiation or other reportable incidents.
18. Prepare and submit application for renewal of the NRC license when the expiration date approaches and applications for any desired amendments.
19. Review quarterly laboratory radiation inspections and provide follow-up as needed.
20. Supervise decommissioning procedures and reports and maintain all decommissioning records.
21. Ensure compliance with 10 CFR Part 37 for security of sealed sources.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Building 31 (7A/03)
31 Center Drive, MSC 2520
Bethesda, MD 20892-3207
Phone: (301) 496-9677
Fax: (301) 496-4409
Email: auchinclossh@niaid.nih.gov

MEMORANDUM

DATE: June 10, 2016

FROM: Hugh Auchincloss, M.D., Acting Scientific Director, DIR, NIAID

THROUGH: Joshua A. Kellar, RML Associate Director

SUBJECT: Appointment of RML RSO

TO: Mr. Aaron Bestor

As you are aware, RML is required to have a qualified RSO to oversee the use, monitoring, and disposal of radionuclides. The Nuclear Regulatory Commission (NRC) requirements for an RSO vary with the type of license and types of materials used. Under RML's Type A Broad Scope NRC License, the RSO should be qualified by training and experience to perform the duties required for radiation protection and be available to RML employees for advice and assistance on all radiological safety matters.

It is clear that you have the necessary qualifications for this position. To be specific, you have worked as the Assistant RSO for the past two years under the supervision of Barry Twardoski, who is the current RSO. During this time, you were tasked with completing all the health physicist responsibilities at RML required by RML's Type A Broad Scope License, conducting Radiation Safety Training for RML employees as required, and preparing RML's 10-year NRC License renewal application. Before that time, you worked as a biological research technician where you were the Authorized User of radionuclides for the Patricia Rosa lab since May of 2007, and have been a member of the RML Radiation Safety Committee since 2011. You have demonstrated an understanding of the RML Radiation Safety Program as well as the ability to communicate with radiation users at RML to meet the requirements associated with our NRC license.

Additional evidence of your qualifications is that you successfully completed the following: a 40-hour Radiation Safety Officer training course at the Radiation Safety Academy; an NIH Authorized User training course; multiple RML Radiation Safety in the Laboratory training courses; multiple RML Authorized Irradiator User training courses; and DOT Training for the Shipment of Radioactive materials.

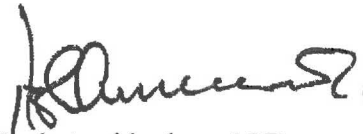
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Page Two
Aaron Bestor
June 10, 2016

After due consideration, I would like to appoint you to be the replacement for Mr. Twardoski as the RML RSO. I also request that you work with him to prepare the necessary paperwork and submit an amendment to the RML NRC License for this appointment. Given the clear evidence of your training and experience, it is fitting that you assume the lead role in this critical program at RML.

Thank you for your willingness to serve in this valuable position.

Sincerely,

A handwritten signature in dark ink, appearing to read "H. Auchincloss".

Hugh Auchincloss, M.D.
Acting Director, Division of Intramural
Research
National Institute of Allergy
and Infectious Diseases
National Institutes of Health

Accepted:

Delegation of Authority for Radiation Safety Officer

June 10, 2016

Memorandum To: All Employees

From: Associate Director, Office of Operations Management, Rocky Mountain Lab NIH/NIAID

Aaron Bestor has been appointed to take over the responsibilities of Radiation Safety Officer from Barry Twardoski, who has served as RSO for RML since 2008. Mr. Bestor is hereby delegated the authority and responsibility for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations for the security and use of byproduct material.

The Radiation Safety Officer has authority to immediately stop any operations involving the use of byproduct material in which health and safety may be compromised or may result in non-compliance with NRC requirements.

Sincerely,



Joshua Kellar

Associate Director, Office of Operations Management

Rocky Mountain Laboratories, NIH/NIAID

Insert
airbill
here

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ST 2
10:30
6263
A

ORIGIN ID:MSOA (406) 363-9324
CARLA DAY
ROCKY MOUNTAIN LABS
903 SOUTH FOURTH STREET

SHIP DATE: 17JUN16
ACTWGT: 1.00 LB
CAD: 102756387/NET3730

HAMILTON, MT 59840
UNITED STATES US

BILL THIRD PARTY

TO NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION
1600 E. LAMAR BOULEVARD

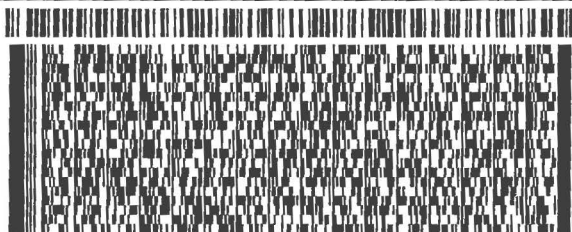
ARLINGTON TX 76011

(817) 860-8100
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PRIORITY OVERNIGHT

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76011
TX-US DFW



RECEIVED
JUN 20 2016

DNMS

or
cable

591133



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Mr. Barri R. Twardoski, Radiation Safety Officer
Department of Health and Human Services
National Institutes of Health, NIAID
Rocky Mountain Laboratories
903 South 4th Street
Hamilton, Montana 59840

Date

06/21/2016

License Number(s)

25-01203-01

Mail Control Number(s)

591133

Licensing and/or Technical Reviewer or Branch

CLH

This is to acknowledge receipt of your: ☒ Letter and/or ☐ Application Dated: 06/13/2016

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 complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>
Follow the instructions on the form for submission.

☐ The following administrative omissions have been identified:

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

✓ 6/21

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM WBL

Program Code: 03610
Status Code: Pending Amendment
Fee Category: 3E 3L
Exp. Date: 05/31/2015
Fee Comments: 3E ADDED 2/2/94
Decom Fin Assur Req: Y

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: Department of Health & Human Services
Received Date: 06/20/2016
Docket Number: 3005167
Mail Control Number: 591133
License Number: 25-01203-01
Action Type: Amendment

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: _____