ACCEPTANCE REVIEW MEMO

Licensee: Great Falls Clinic

License No.: 25-27721-01 **Docket No.:** 030-35944

Mail Control No.: 470521

Type of Action: Amend **Date of Requested Action:** 04-18-05

Reviewer Assigned: Jackie **Date Assigned to Reviewer:** 05-02-05

Reviewer(s) Who Performed Review: Torres - Walker

Response Received	Deficiencies Noted During Acceptance Review
JTC	1. Need to submit NRC Form 313A to document Dr. Ro's and Dr. Will's 100,200 ✓ 6/6/05 100 200+ 300 experience in 35.300.
	2. will resubmit Dr. Ro's credentials at a later time.
	3. will authorize Dr. Ro for 35.100 + 35.200
	4.

Reviewer's Initials: JTC **Date:** 5/27/05

Branch Chief's and/or SR. HP's Initials: AMG **Date:** 6/1/05

☐Yes ☐No Action - decommissioning notification should be issued within 30 days.

☐Yes ☐No Termination request < 90 days from date of expiration

☐Yes ☐No Action to be expedited

_____Medical emergency

_____Licensee in noncompliance (i.e. no RSO, location of use/storage not on license, radioactive material in possession not on license)

_____National Security

_____Other (_____)

Branch Chief's and/or Sr. HP's Initials: _____ **Date:** _____

SISP Review

☐Yes ☒No **Non-Publicly Available, Sensitive** if any item below is checked

_____Radionuclides, forms, and quantities

_____Location of RAM

_____Building drawings with locations of RAM

_____Security of RAM (locks, alarms, etc.)

_____SS&D Catalog information

_____Specifics of Emergency Plan (routes to and from RAM, response to security events, etc.)

_____Safeguards Information

Branch Chief's and/or Sr. HP's Initials: JTC **Date:** 5/2/05

Kari Cann, MS DABR
Radiation Safety Officer

406-455-2059 (p)
406-455-2071 (F)

MAY 2 7 2005

BENEFIS HEALTHCARE

Fax

To:	Judith Walker	**From:**	Kari Cann, MS RSO
Fax:	817-860-8263	**Pages:**	4
Phone:	817-860-8299	**Date:**	5/27/2005
Re:	Benefis Healthcare NRC License 25-12710-01		

☐ **Urgent** ☐ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

Hi Judith,

I have received notification from St Louis University the Dr. Ro does not have sufficient clinical experience for Part 300 type materials. We will obtain that experience here at Benefis and resubmit his credential at a later date.

Would you please pass this on to Jacqueline Cook regarding the Great Falls Clinic license number 25-27721-01? I left a voicemail for her on this subject today.

I would like to add Dr Carol Swartz, MD (aka Carol Swartz Milburn) to the Benefis Healthcare License (25-12710-01) as an authorized user for 10 CFR Part 35.400 materials. To that end, I am attaching NRC form 313a Part 1, a copy of her Board Certification in Therapeutic Radiology and evidence of continuing education in the last seven years.

Please contact me if there are any questions or concerns regarding this addition.

Thank you for you time in these matters,

Kari Cann

Kari Cann,MS DABR
Medical Physicist / RSO
Benefis Healthcare

Radiation Safety Officer

406-455-2059 (p)
406-455-2071 (F)

[redacted]

MAY 26 2005

Fax

To:	Jacqueline Cook	**From:**	Kari Cann, MS RSO
Fax:	817-860-8263	**Pages:**	5
Phone:	817-860-8132	**Date:**	5/26/2005
Re:	Great Falls Clinic License # 25-27721-01 docket # 030-35944 Control 470521		

☐ **Urgent** ☐ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

Hi Jackie,

I am attaching the NRC form 313 to document Dr Will's clinical experience for Part 300 materials.. I am still working with the folks at St Louis University to document clinical experience for Dr Ro and will have it to you within a week, I hope.

Kari

Kari

APPENDIX B

NRC FORM 313A (10-2002) U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2005

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT

PART I – TRAINING AND EXPERIENCE

Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulations.

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)

DR TYLER WILL, MD AUTHORIZED USER 10 CFR 35.300

2. For Physicians, Podiatrists, Dentists, Pharmacists – State or Territory Where Licensed

MONTANA MEDICAL LICENCE

3. CERTIFICATION

Specialty Board	Category	Month and Year Certified
AMERICAN BOARD OF RADIOLOGY	DIAGNOSTIC RADIOLOGY	JUNE 2002

Stop here when using Board Certification to meet 10 CFR Part 35 training and experience requirements.

4. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical Physicists)

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation			
Radiation Protection			
Mathematics Pertaining to the Use and Measurement of Radioactivity			
Radiation Biology	PREVIOUSLY SUBMITTED		
Chemistry of Byproduct Material for Medical Use			
OTHER			

NRC FORM 313A (10-2002) PRINTED ON RECYCLED PAPER PAGE 1

APPENDIX B

NRC FORM 313A (10-2002) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

5a. WORK EXPERIENCE WITH RADIATION

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and Clock Hours of Experience

PREVIOUSLY SUBMITTED

5b. SUPERVISED CLINICAL CASE EXPERIENCE

Radionuclide	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Materials License Number	Dates and Clock Hours of Experience
I-131	THYROID FUNCTION		DR JAMES HARRIS	BENEFIS	SEPT 2002
	OR HYPERTHYROIDISM	15+		HEALTHCARE LICENSE #	TO
	CARDIAC OR DYSFUNCTION			25-12710-01	PRESENT
					(MAY 2005)
I-131	THYROID CARCINOMA	5+	DR JAMES HARRIS	"	

NRC FORM 313A (10-2002) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

6. FORMAL TRAINING (applies to Medical Physicists and Therapy Physicians)

Degree, Area of Study or Residency Program	Name of Program and Location with Corresponding Materials License Numbers	Dates	Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.490)
N/A			

7. RADIATION SAFETY OFFICER – ONE-YEAR FULL-TIME TRAINING

☐ YES ☒ N/A Completed 1-year of full-time radiation safety experience (in areas identified in item 5a) under supervision of _____ the RSO for License No. _____.

8. MEDICAL PHYSICIST – ONE YEAR FULL-TIME TRAINING/WORK EXPERIENCE

☐ YES ☒ N/A Completed 1-year of full-time training in therapeutic radiological physics under the supervision of _____ who meets requirements for Authorized Medical Physicists; and

☐ YES ☒ N/A Completed 1-year of full-time work experience (for areas identified in item 5a) for _____ modality(ies) under the supervision of _____ who meets requirements for Authorized Medical Physicists for _____ modality(ies).

9. SUPERVISING INDIVIDUAL – IDENTIFICATION AND QUALIFICATIONS

The training and experience indicated above was obtained under the supervision of *(if more than one supervising individual is needed to meet requirements in 10 CFR 35, provide the following information for each)*:

A. Name of Supervisor: Dr James Harris

B. Supervisor is:
☒ Authorized User ☐ Authorized Medical Physicists
☐ Radiation Safety Officer ☐ Authorized Nuclear Pharmacists

C. Supervisor meets requirements of Part 35, Section(s) 390 for medical uses in Part 35, Section(s) 300.

D. Address: BENEFIS HEALTHCARE
1101 26TH ST SOUTH
GREAT FALLS MT 59405

E. Materials License Number: 25-12710-01

APPENDIX B

NRC FORM 313A (10-2002) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE AND PRECEPTOR STATEMENT (continued)

PART II – PRECEPTOR STATEMENT

Note: This part must be completed by the individual's preceptor. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. This part is not required to meet the training requirements in 10 CFR 35.590.

Item 10 must be completed for Nuclear Pharmacists meeting the requirements of 10 CFR Part 35, Subpart J. Preceptors do not have to complete items 11a, 11b, or the certifying statements for other individuals meeting the requirements of 10 CFR Part 35, Subpart J.

☐ YES ☒ N/A 10. The individual named in item 1 has satisfactorily completed the training requirements in 10 CFR 35.980 and is competent to independently operate a nuclear pharmacy.

☐ YES ☒ N/A 11a. The individual named in item 1 has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) _____.

☒ YES ☐ N/A 11b. The individual named in item 1. is competent to independently function as an authorized USER for PART 300 uses.

12. PRECEPTOR APPROVAL AND CERTIFICATION

☐ I certify the approval of item 10 and certify I am an Authorized Nuclear Pharmacist;

or

☐ I certify the approval of items 11a and 11b and certify I am an Authorized Nuclear Pharmacist;

or

☒ I certify the approval of items 11a and 11b, and I certify that I meet the requirements of 35.390 or equivalent Agreement State requirements to be a preceptor authorized USER for the following uses of byproduct material: 35.300

A. Address: GREAT FALLS CLINIC
1100 29 ST SOUTH
GREAT FALLS, MT 59405

B. Materials License Number: 25 27721 01

C. NAME OF PRECEPTOR (print clearly)	D. SIGNATURE – PRECEPTOR	E. DATE
JAMES HARRIS, MD	James Harris	5/19/05

GREAT FALLS CLINIC

GREAT FALLS CLINIC, LLP

GFC-Immediate Care
1220 Central Avenue
Great Falls, MT 59401
406-771-0000

GFC-West Oncology
400 13th Avenue South
Suite 203
Great Falls, MT 59405
406-727-4584

GFC-Northwest
1600 Division Road
Great Falls, MT 59404
406-268-1600

GFC-Marketplace
2012 14th Street Southwest
Great Falls, MT 59404
406-727-7171

GFC-Choteau
914 4th Street NW
Choteau, MT 59422
406-466-5255

GFC-Fairfield
324 Central Ave
Fairfield, MT 59436
406-467-2304

Helena Physicians' Clinic
3330 Ptarmigan Lane
Helena, MT 59602
406-442-3570

April 18, 2005

APR 2 8 2005

United States Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, Texas 76011-8064

SUBJECT: License amendment

To Whom It May Concern:

This letter is to request a license amendment for changes to the Authorized Users for the Great Falls Clinic, NRC License number 25-27721-01.

1. Please add the following individuals to the Authorized User list with the corresponding Material and Use authorization:

   George Ro, MD for material identified in 10 CFR 35.100, 35.200, 35.300,

   I have attached a copy of Dr. Ro's ABR certification in Diagnostic Radiology and a letter attesting to his training and qualification for 10 CFR 35.300.

   Tyler Will, MD for material identified in 10 CFR 35.300

   I have attached a copy of Dr. Will's ABR certification in Diagnostic Radiology and a letter attesting to his training and qualification for 10 CFR 35.300

2. Please remove the following individual from the Authorized users list:

   Peggy J Reep, MD
   Michel E Richards, MD

Thank you for your attention to this matter. Please contact Kari Cann, MS our Radiation Safety Officer at 406-455-2060 if you have any questions.

Sincerely,

Gregory D. Hagfors
Administrator/CEO

The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association,
the American Society for Therapeutic Radiology and Oncology, the Association of
University Radiologists, and American Association of Physicists in Medicine
Hereby certifies that

George Ro, MD

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of
The American Board of Radiology
On this eighth day of November, 2004
Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of

Diagnostic Radiology

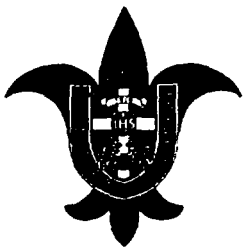
Steven A. Seibel, M.D.
President

Richard T. Hoppe M.D.
Secretary-Treasurer

P.P. Hattery M.D.
Executive Director

Certificate No. 51143

Valid through 2014



3635 Vista Ave. at Grand Blvd.
P.O. Box 15250
St. Louis, MO 63110-0250
Phone: 314-268-5780
FAX: 314-268-5116

SAINT LOUIS
UNIVERSITY

Health Sciences Center
School of Medicine

Department of Radiology

Michael K. Wolverson, M.D.
Professor and Chairman

April 8, 2005

Benefits Healthcare
Great Falls MT 59401

To Whom It May Concern:

I certify that Dr. George Ro has received the following training and experience at our institution, St. Louis University Hospital, under the supervision of an authorized user. Our radioactive material license number is 24-00196-07

The training satisfies all aspects of the following US Nuclear Regulatory Commission requirement:

§35.390 Training for use of unsealed byproduct material for which a written directive is required

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.300 to be a physician who--

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or (b)(1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience must include--

(i) Classroom and laboratory training in the following areas--

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in § 35.390(a), § 35.390(b), or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status. The work experience must involve--

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontaminatio procedures;

(F) Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(G) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status--

(1) Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131;

(2) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131 [2];

2 Experience with at least 3 cases in Category (G)(2) also satisfies the requirement in Category (G)(1).

(3) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; and/or

(4) Parenteral administration of any other radionuclide; and

(2) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a), § 35.390(b), or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status.

4-8-05

Signature of residency program director

Michael K. Wolverson, M.D.
Residency Program Director
Saint Louis University Hospital

The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association,
the American Society for Therapeutic Radiology and Oncology, the Association of
University Radiologists, and American Association of Physicists in Medicine
Hereby certifies that

Tyler L. Will, MD

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of
The American Board of Radiology
On this twelfth day of June, 2012
Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of

Diagnostic Radiology

THE AMERICAN BOARD OF RADIOLOGY
INCORPORATED IN THE DISTRICT OF COLUMBIA
1934

AMERICAN BOARD OF MEDICAL SPECIALTIES

R.P. Hatten, M.D.
President

Steven A. Leibel, M.D.
Secretary-Treasurer

M. [illegible], M.D.
Executive Director

Certificate No. 48845

Valid through 2012

21

I certify that Dr. Tyler Will has received the following training and experience at our institution, University of Michigan Health System, under the supervision of an authorized user. Our radioactive material license number is NRC 21-00215-04

The training satisfies all aspects of the following US Nuclear Regulatory Commission requirement:

§35.390 Training for use of unsealed byproduct material for which a written directive is required

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.300 to be a physician who--

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or (b)(1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience must include--

(i) Classroom and laboratory training in the following areas--

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in § 35.390(a), § 35.390(b), or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status. The work experience must involve--

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;

(F) Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(G) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status--

(1) Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131;

(2) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131

2 Experience with at least 3 cases in Category (G)(2) also satisfies the requirement in Category (G)(1).

(3) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; and/or

(4) Parenteral administration of any other radionuclide; and

(2) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a), § 35.390(b), or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status.

Jan 6 2004 Our residents as a part of the radiology training program receive training in all the done areas except G.

Barry Shulkin MD
Interim Chief, Nuclear Medicine

Signature of residency program director

Dr. Richard Cohen, MD
University of Michigan Health System
Department of Radiology
1500 East Medical Center Drive
Ann Arbor, Michigan 48109

I certify that Dr. Tyler Will has received the following training and experience at our institution, Benefis Healthcare, under the supervision of an authorized user. Our radioactive material license number is NRC 25-12710-01

The training satisfies all aspects of the following US Nuclear Regulatory Commission requirement:

§35.390 Training for use of unsealed byproduct material for which a written directive is required

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.300 to be a physician who--

(G) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status--

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(4) Parenteral administration of any other radionuclide; and

(2) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.390(a), § 35.390(b), or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in § 35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)(1), (2), (3), or ~~(4)~~) as the individual requesting authorized user status.

Dr. James Harris, MD
Benefis Healthcare
Great Falls, MT

JUN - 1 2005
DATE

This is to acknowledge the receipt of your letter/application dated 4/18/05, and to inform you that the initial processing, which includes an administrative review, has been performed.

☒ There were no administrative omissions. Your application will be assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card:

The action you requested is normally processed within 90 days.

☐ A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 470521.
When calling to inquire about this action, please refer to this mail control number.
You may call me at 817-860-8103.

Sincerely,

Debbie Hendricks

Licensing Assistant

NRC FORM 532 (RIV)
(9-2003)

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02200
Status Code: 0
Fee Category: 7C
Exp. Date: 20120331
Fee Comments: _____
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
Applicant/Licensee: GREAT FALLS CLINIC
Received Date: 20050428
Docket No: 3035944
Control No.: 470521
License No.: 25-27721-01
Action Type: Amendment

2. FEE ATTACHED
Amount: _____
Check No.: /

3. COMMENTS

Signed Colleen Brennahan
Date 4/29/05

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 _____