ACCEPTANCE REVIEW MEMO (ARM)

Licensee: Bonner General Hospital **License No.:** 11-27785-01

Docket No.: 030-36658 **Mail Control No.:** 471212

Type of Action: Amend **Date of Requested Action:** 12-26-06

Reviewer Assigned: **ARM reviewer(s):** Cook & Torres

Response	Deficiencies Noted During Acceptance Review
	[ ] Open ended possession limits. Limit possession. Submit inventory. [ ] Submit copies of most recent leak test results. [ ] Add - delete IC license condition. Add IC paragraph in cover letter. [ ] Split license from cover letter. Add SUNSI marking to license. [ ] Ask the licensee if they have any type-amount of EPAct Material.

Reviewer's Initials: _____ **Date:** _____

☐Yes ☐No Unrestricted release Group 2 or >: Transfer memo to FCDB within 10 days.

☐Yes ☐No Decommissioning notification should be completed within 30 days.

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

☐Yes ☐No Expedite (medical emergency, no RSO, location of use/storage not on license, RAM in possession not on license, other)

☐Yes ☐No TAR needed to complete action.

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

SUNSI Screening according to RIS 2005-31

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

General guidance:

_____RAM = or > than Category 3 (Table 1, RIS 2005-31), use Unity Rule
_____Exact location of RAM (whether = or > than Category 3 or not)
_____Design of structure and/or equipment (site specific)
_____Information on nearby facilities
_____Detailed design drawings and/or performance information
_____Emergency planning and/or fire protection systems

Specific guidance for medical, industrial and academic (above Category 3):

_____RAM quantities and inventory
_____Manufacturer's name and model number of sealed sources & devices
_____Site drawings with exact location of RAM, description of facility
_____RAM security program information (locks, alarms, etc.)
_____Emergency Plan specifics (routes to/from RAM, response to security events)
_____Vulnerability/security assessment/accident-safety analysis/risk assess
_____Mailing lists related to security response

Branch Chief's and/or Sr. HP's Initials: JAC **Date:** 1/11/07

Pre-Licensing Screening

Applicant Information: **Control No.** 471212

Name: Bonner General Hospital	Type of Request: Amend Program Code(s):
Location: ID	License No.: 11-27785-01 Docket No.: 030-36658

STEP 1–Radioactive Materials and Quantities Requested:

		Yes or No
Instructions for Step 1: **Complete Step 1 for all applications**. If all your responses in Step 1 are "No" then do not complete Step 2 (Screening Criteria). Sign and date the completed step-sheet and add it as the sensitive and non-publicly available OAR in ADAMS. If a "yes" response is indicated for any item in Step 1, also complete Step 2. If the type of use is subject to a Security Order or the requirements for increased controls, complete Step 3 (Item A or Item B) without delay.		
A.	The request is from a new applicant.	N
B.	NUREG-1556, Volume 20, Section 4.9 indicates a licensing site visit is needed for the requested type of use, e.g., (1) Type A broad scope license, (2) panoramic irradiator containing > 10000 curies, (3) manufacturers or distributors using unsealed radioactive material or significant quantities of sealed material, (4) radioactive waste brokers, (5) radioactive waste incinerators, (6) commercial nuclear laundries, and (7) any other application that in the judgement of the reviewer and cognizant supervisor involves complex technical issues, complex safety questions, or unprecedented issues that warrant a site visit.	N
C.	The applicant requested certain radionuclides and quantities that equal or exceed the Risk Significant Quantity (TBq) values in the table, below, that have been **"highlighted"** by the reviewer	N

Table of Risk Significant Quantities

(Category 2 Quantities, IAEA Safety Guide No. RS-G-1.9, Categorization of Radioactive Sources, August 2005)

Radionuclide	Risk Significant Quantity (TBq[1])	Risk Significant Quantity (Ci[1])	Radionuclide	Risk Significant Quantity (TBq[1])	Risk Significant Quantity (Ci[1])
Am-241	0.6	16	Pm-147	400	11,000
Am-241/Be	0.6	16	Pu-238	0.6	16
Cf-252	0.2	5.4	Pu-239/Be	0.6	16
Cm-244	0.5	14	Ra-226[2]	0.4	11
Co-60	0.3	8.1	Se-75	2	54
Cs-137	1	27	Sr-90 (Y-90)	10	270
Gd-153	10	270	Tm-170	200	5,400
Ir-192	0.8	22	Yb-169	3	81

[1] The primary values are TBq. The curie (Ci) values are for informational purposes only.

[2] The Atomic Energy Act, as amended by the Energy Policy Act of 2005, authorizes NRC to regulate Ra-226 and NRC is in the process of amending its regulations for discrete sources of Ra-226.

Calculations of the Total Activity or the Unity Rule are attached to document whether or not the screening criteria in Step 2 were also completed to evaluate the application. NOTE–If an amendment of an existing license is being requested, the calculations will include the previously authorized quantities for the radionuclide(s).	Yes , No, or Not Applicable (NA)
Total Activity–multiple activities are requested for a single radionuclide and the sum of the activities equals or exceeds the quantity of concern for the radionuclide	
Unity Rule--multiple radionuclides are requested and the sum of the ratios equals or exceeds unity, e.g.,[(total activity for radionuclide A) ÷ (risk significant quantity for radionuclide A)] + [(total activity for radionuclide B) ÷ (risk significant quantity for radionuclide B)] ≥ 1.0.	

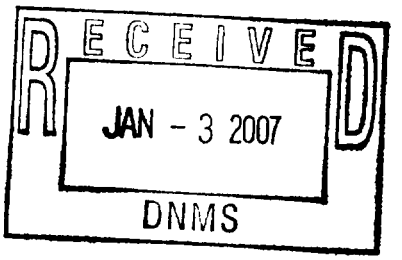
Signature and Date for Step 1:

4/11/07

License Reviewer and Date

Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Dr. Suite 400
Arlington, Tx. 76011-4005

12/26/2006



SUBJECT: LICENSE AMENDMENT

Please find enclosed the additional documentation requested in order to add Dr. Mark Weber as our RSO License No. 11-27785-01.

Sincerely, Tami Hicks C.N.M.T.

Tami Hicks, CNMT

Bonner General Hospital
520 North 3rd Avenue
Sandpoint, Id. 83864

IL 471212

NRC FORM 313A (04-2005) U.S. NUCLEAR REGULATORY COMMISSION

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION

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

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 regulation (10 CFR Part 35).

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

   MARK E WEBER, MD

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

   Idaho

3. CERTIFICATION

a. Provide a copy of the board certification. *(Stop here if applying under 10 CFR Part 35, Subpart J or 35.590(a); continue if applying under other subparts.)*

b. Provide documentation in appropriate items 4 through 10 of training or clinical case work required by 35.50(e); 35.51(c); 35.290(c)(1)(ii)(G) for AU seeking 35.200 authorization; 35.390(b)(1)(ii)(G); 35.396(d)(1) and 35.396(d)(2); 35.590(c); or 35.690(c).

c. Provide completed Part II Preceptor Attestation, Items 11a through 11d.

Stop here after completing items 3a, 3b, and 3c when using board certification to meet 10 CFR Part 35 training and experience requirements.

4. INDIVIDUALS IDENTIFIED ON A LICENSE OR PERMIT AS RADIATION SAFETY OFFICERS (RSO), AUTHORIZED USERS (AU), AUTHORIZED MEDICAL PHYSICISTS (AMP), OR AUTHORIZED NUCLEAR PHARMACISTS (ANP) SEEKING ADDITIONAL AUTHORIZATIONS

a. Provide a copy of the license or broadscope permit listing the current authorization **and** (b) or (c)

b. Complete items 6c (and 10 when training is provided by an RSO, AMP, ANP, or AU) and preceptor items 11b through 11d to meet requirements for: RSO in 35.50(c)(2) or 35.50(e); or AU in 35.290(c)(1)(ii)(G) or 35.390(b)(1)(ii)(G) or 35.590(c) or 35.690(c); or AMP under 35.51(c).

c. Complete items 5, 6a, 6b, 10, and Preceptor items 11a through 11d to meet AU requirements in 35.396(a).

5. DIDACTIC OR CLASSROOM AND LABORATORY TRAINING (optional for Medical

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			
Chemistry of Byproduct Material for Medical Use			
OTHER			

No. 471212

NRC FORM 313A (04-2005) U.S. NUCLEAR REGULATORY COMMISSION

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

6a. WORK OR PRACTICAL EXPERIENCE WITH RADIATION

Description of Experience	Name of Supervising Individual(s)	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience
DIAGNOSTIC RADIOLOGY RESIDENT UNIVERSITY of VIRGINIA July 1, 1989 - June 30 1993	CHARLES TEATES MD		Please refer to separate FORMS

6b. SUPERVISED CLINICAL CASE EXPERIENCE (describe experience elements in 6a)

Radionuclide	Type of Use	No. of Cases Involving Personal Participation	Name of Supervising Individual	Location and Corresponding Materials License Number	Dates and/or Clock Hours of Experience

PAGE 2

NRC FORM 313A (04-2005) U.S. NUCLEAR REGULATORY COMMISSION

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

6c. TRAINING FOR SECTIONS 35.50(e), 35.51(c), 35.590(c), or 35.690(c)

Training Element	Type of Training *	Location and Dates
N/A		

* Types of training may include supervised (complete item 10 for 35.50(e), 35.51(c), and 35.690(c)), didactic, or vendor training.

7. FORMAL TRAINING Physicians (for uses under 35.400 and 35.600) and Medical Physicists

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)
Diagnostic Radiology Residency	University of Virginia Charlottesville, VA 22908	July 1, 1989 – June 30, 1993	

8. RADIATION SAFETY OFFICER (RSO) -- ONE-YEAR FULL-TIME EXPERIENCE

☐ YES ☐ N/A Completed 1 year of full-time radiation safety experience (in areas identified in item 6a) under supervision of _____ the RSO for License No. _____.

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

☐ YES ☐ N/A Completed 1 year of full-time training (for areas identified in item 6a) in therapeutic *radiological physics* (35.961) or medical physics (35.51) under the supervision of _____

and

☐ YES ☐ N/A Completed 1 year of full-time work experience (at location providing radiation therapy services described and for topics identified in item 6a) for (specify use or device) _____ under the supervision of _____ who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51) (specify use or device) _____.

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NRC FORM 313A (04-2005) — U.S. NUCLEAR REGULATORY COMMISSION

MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

10. 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: Stephen J. Bartok, m.D.

B. Supervisor is:

- ☒ Authorized User
- ☐ Authorized Medical Physicist
- ☐ Radiation Safety Officer
- ☐ Authorized Nuclear Pharmacist

C. Supervisor meets requirements of Part 35, Section(s) 35.290.
for medical uses in Part 35, Section(s) 35.100 & 35.200.

D. Address

E. Materials License Number

PART II -- PRECEPTOR ATTESTATION

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 35.590 or Part 35, Subpart J (except 35.980).*

I attest the individual named in Item 1:

11a.
☒ has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) _____,
as documented in section(s) _____ of this form.

11b. Select one
☐ meets the requirements in ☐ 35.50(e), ☐ 35.51(c), ☐ 35.390(b)(1)(ii)(G), ☐ 35.690(c) for _____ types of use, as documented in section(s) _____ of this form.
☒ N/A

11c.
☐ has achieved a level of competency sufficient to operate a nuclear pharmacy (for 35.980); **or**
☒ has achieved a level of competency sufficient to function independently as an authorized User for 10 CFR 35.100 & 200 uses (or units); **or**
☐ has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee ; **or**
☒ N/A

11d.
☐ I am an Authorized Nuclear Pharmacist; **or** ☐ I am a Radiation Safety Officer; **or**
☒ I meet the requirements of 35.290 section(s) of 10 CFR Part 35
or equivalent Agreement State requirements to be a preceptor ☒ AU or ☐ AMP
for the following byproduct material uses (or units): 35.100 & 35.200

A. Address

B. Materials License Number

C. NAME OF PRECEPTOR *(print clearly)*	D. SIGNATURE -- PRECEPTOR	E. DATE
Stephen J. BARTOK, m.D.		

PAGE 4

NRC FORM 313M SUPPLEMENT A
(9-81)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Mark Weber, M.D.	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Radiology	Diplomate	June 1993

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES *(Hours)* C	SUPERVISED LABORATORY EXPERIENCE *(Hours)* D
a. RADIATION PHYSICS AND INSTRUMENTATION	University of Virginia July 1, 1989 - June 30, 1993	100	50
b. RADIATION PROTECTION	See Above	30	20
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	See Above	20	
d. RADIATION BIOLOGY	See Above	20	
e. RADIOPHARMACEUTICAL CHEMISTRY	See Above	30	10

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Tc-99m	30 mCi	UVa	1040 hours all areas	clinical
Mo-99	2000 mCi	UVa	see above	"
I-131	150 mCi	UVa	see above	"
In-111	5 mCi	UVa	see above	"
Ga-67	10 mCi	UVa	see above	"
Tl-201	3 mCi	UVa	see above	"
I-125	50 uCi	UVa	see above	"
Yb-169	500 uCi	UVa	see above	

NRC FORM 313M SUPPLEMENT B (9-81) U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

Mark Weber, M.D.

STREET ADDRESS

CITY | STATE | ZIP CODE

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION		
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING	3	
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	95	
OTHER	-		
Tc-99m	BRAIN IMAGING	11	
	CARDIAC IMAGING	760	
	THYROID IMAGING	94	
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING	18	
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING	45	
	LUNG IMAGING	130	
	BONE IMAGING	499	
OTHER	RENAL IMAGING	130	

RECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 *(Soluble)*	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 *(Colloidal)*	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA	4	
	TREATMENT OF HYPERTHYROIDISM	29	
Au-198	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR	60	
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS	45	
Other			
Tc-99m	Gastroesophageal Study	105	
Tc-99m	LeVeen Shunt Study	3	
Tc-99m	Cystogram	2	
Ga-67	Gallium Scan	45	
I-131	Adrenal Scan	11	
In-111	WBC Scan	5	
Cr-51	RBC volume	5	

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

July 1, 1989 - June 30, 1993 1040 hours, University of Virginia
Charlottesville, VA 22908

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
Charles D. Teates, M.D.

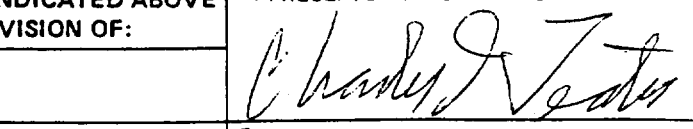
b. NAME OF INSTITUTION
University of Virginia Hospitals

c. MAILING ADDRESS
Box 486

d. CITY
Charlottesville, VA 22908

5. MATERIALS LICENSE NUMBER(S)

6. PRECEPTOR'S SIGNATURE



7. PRECEPTOR'S NAME *(Please type or print)*

Charles D. Teates, M.D.

8. DATE

February 12, 1993

NRC FORM 313M SUPPLEMENT 8
(9-81)

GPO 890-913

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

Mark Edward Weber, M.D.

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 ninth day of November, 1992

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

Lee F. Rogers M.D. Lester J. Peters Kenneth L. Goodspeed M.D.

In 471212

JAN 22 2007

DATE

This is to acknowledge the receipt of your letter/application dated 12-26-06, 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** 471212.
When calling to inquire about this action, please refer to this mail control number.
You may call me at 817-860-8103.

Sincerely,

Colleen Murnahan

Licensing Assistant

NRC FORM 532 (RIV)
(10-2006)

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02121
Status Code: 0
Fee Category: 7C
Exp. Date: 20141031
Fee Comments: _____
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: BONNER GENERAL HOSPITAL
   Received Date: 20070103
   Docket No: 3036658
   Control No.: 471212
   License No.: 11-27785-01
   Action Type: Amendment

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

3. COMMENTS

Signed Colleen Murnahan
Date 01-09-07

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 _____

BONNER GENERAL HOSPITAL
520 N. THIRD AVENUE
P.O. BOX 1448
SANDPOINT, IDAHO 83864-0877

ADDRESS SERVICE REQUESTED

11-27785-01
030-36658

Nuclear Regulatory Com.
Region IV
611 Ryan Plaza Dr., Suite 400
Arlington, TX. 76011-4005
ATTN: Jacqueline Cook

76011+4005-00 C001