



DEPARTMENT OF THE ARMY
WESTERN REGIONAL MEDICAL COMMAND
AND MADIGAN ARMY MEDICAL CENTER
TACOMA, WASHINGTON 98431-1100

September 3, 2008

RECEIVED

U.S. Nuclear Regulatory Commission, Region IV
Nuclear Materials Licensing Section
611 Ryan Plaza Drive, Suite 400
Arlington, Texas 76011-8064

SEP 15 2008

DNMS

Dear Sir or Madam:

Request that NRC License 46-02645-03 be amended with the following changes: Add Dr. Yang-En Kao as an Authorized User under 10 CFR 35.100, 35.200, and 35.300, Items 6.E thru 6.KK as outlined on our current license. His respective preceptor attestation is enclosed.

Point of contact for this action is Captain Joshua Sperry, Radiation Safety Officer, commercial phone (253) 968-4300.

Sincerely,

Ronald J. Place
Colonel, U.S. Army
Deputy Commander for Clinical Services
Chairman, Radiation Control Committee

Enclosure

1. NRC Form 313A (Dr. Yang-En Kao)
2. Preceptorship Statement and workload (Dr. Yang-En Kao)



**MEDICAL USE TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2008**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)

Yang-En Kao

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

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 Physicists)

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation	National Naval Medical Center 8901 Wisconsin Avenue Bethesda, MD 20889-5600	18	02/26/2007-03/09/2007
Radiation Protection	Same as above	16	Same as above
Mathematics Pertaining to the Use and Measurement of Radioactivity	Same as above	6	Same as above
Radiation Biology	Same as above	20	Same as above
Chemistry of Byproduct Material for Medical Use	Same as above	15	Same as above
OTHER NRC Regulations, Nuclear Incident Management	Same as above	5	Same as above

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
N/A			

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
N/A					

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 Number	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)

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

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

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

- ☐ YES 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 _____
- ☒ N/A who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51);

and

- ☐ YES 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) _____
- ☒ N/A under the supervision of _____ who is a medical physicist (35.961) or meets requirements for Authorized Medical Physicists (35.51) (specify use or device) _____

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 Part 35, provide the following information for each):

A. Name of Supervisor _____

B. Supervisor is:

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

C. Supervisor meets requirements of Part 35, Section(s) _____

for medical uses in Part 35, Section(s) _____

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 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) N/A 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 independently operate a nuclear pharmacy (for 35.980); **OR**☐ has achieved a level of competency sufficient to function independently as an authorized _____ for _____ 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 57,59,190,290,390,392,394 and 396 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 and 35.300

A. Address

National Naval Medical Center
8901 Wisconsin Avenue
Bethesda, MD 20889-5600

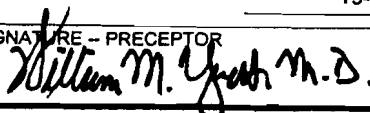
B. Materials License Number

19-00168-21NP

C. NAME OF PRECEPTOR (print clearly)

William M. Yudt, M.D.

D. SIGNATURE – PRECEPTOR



E. DATE

03/09/2007



DEPARTMENT OF THE ARMY
WALTER REED ARMY MEDICAL CENTER
WALTER REED HEALTH CARE SYSTEM
WASHINGTON, DC 20307-5001

REPLY TO
ATTENTION OF:

MEMORANDUM FOR RECORD

04 JUNE 08

SUBJECT: SUMMATIVE EVALUATION OF MAJ YANG-EN KAO, MD

MAJ Yang-En Kao, MD, served as a fellow in the National Capital Consortium Nuclear Medicine Fellowship Program from 01 JUL 07 TO 30 JUN 08. A final composite summary evaluation was prepared in June 2008 by reviewing the independent evaluations submitted by each full-time member of the faculty. The composite opinion of the faculty, with concurrence of the Program Director, is that MAJ Kao performed at the "outstanding" level in all of the following categories: patient care, medical knowledge, practice-based learning, interpersonal and communication skills, professionalism, and system-based learning.

Attached is a copy of MAJ Kao's final "Work History Statement" showing the number of each Nuclear Medicine study performed by Dr. Kao during his fellowship training, with additional logs of cardiac stress testing and radionuclide therapies. It is the judgment of the Program Director that Dr. Kao has attained proficiency in administering radioiodine therapies and cardiac stress testing.

Dr. Kao was generally regarded by the Nuclear Medicine staff as a well rounded fellow, exceptionally strong in every aspect of training, including patient care, procedures, teaching and research. His test scores and clinic performance place him at the top of his class.

The Program Director states unequivocally that Dr. Kao has demonstrated sufficient competence to enter practice without supervision as a nuclear medicine physician.

Sincerely,

Jennifer S. Jurgens, M.D.
LTC, MC, US Army
Director, Nuclear Medicine Fellowship
National Capital Consortium

No 4 7 1 9 5 3

PRECEPTOR STATEMENT

Statement 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'S PHYSICIAN'S NAME AND ADDRESS (PRINT OR TYPE)

FULL NAME
MAJ Yang-En Kao

STREET ADDRESS
6900 Georgia Ave. N.W.

CITY Washington D.C. **ZIP CODE** 20307-5001

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1. Supervised examination of patients to determine the suitability for radionuclide 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.

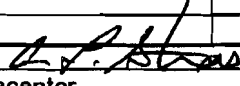
2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

NUCLIDE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION	COMMENTS (ADDITIONAL INFORMATION OR COMMENTS MAY BE SUBMITTED IN DUPLICATE ON SEPARATE SHEETS.) D
	DIAGNOSIS OF THYROID FUNCTION	52	<p style="text-align: center;">National Capital Consortium Quality Assurance Document 10 USC 1102 Improper Release Subject to Fines up to \$20,000</p>
I-131	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME	3	
OR	LIVER FUNCTION STUDIES		
I-125	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN-VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING		
P-32	EYE TUMOR LOCALIZATION		
SE-75	PANCREAS IMAGING		
YB-169	CISTERNOGRAPHY		
XE-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	55	
AEROSOL	PULMONARY FUNCTION STUDIES	1	
Tc-99m	BRAIN IMAGING	30	100% SPECT
	CARDIAC IMAGING	1889	
	THYROID IMAGING	54	
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING	632	Gated cardiac blood pool, 7% exercise
	PLACENTAL LOCALIZATION		
	LIVER AND SPLEEN IMAGING	41	10% SPECT
	LUNG IMAGING	63	
	BONE IMAGING	916	15% SPECT
OTHER Cr-51	RED CELL MASS / RBC SURVIVAL / SEQUESTRATION	3	

ADDENDUM TO CLINIC TRAINING AND EXPERIENCE
(Page 6, NRC-313m)

NUCLIDE	CONDITION DIAGNOSED/TREATED	NO. OF PERSONAL PARTICIPATION CASES	COMMENTS
99mTc	Cardiac Shunts	1	
	CEA		
	Cystogram (Retrograde)	13	
	Defecography	3	
	Esophageal Clearance	5	
	Deep Vein Thrombosis (Accutech)		
	Gastric Emptying	50	
	Gastric Reflux	1	
	GFR	1	
	G.I. Bleed	9	
	Hemangioma (RBC)	9	SPECT
	Hepatobiliary	97	
	Lymphoscintigraphy (HSA)	48	
	Meckels Imaging	3	
	Milk Aspiration	4	
	Myocardial Perfusion	1771	22% Drug Stress, SPECT
	Parathyroid	35	
	Peritoneal Shunts		
	Renal (Cortical)	37	50% SPECT
	Renal (Flow/Function)	65	40% Drug Intervention
	Scintomammography		
	Testicular		
	Tumor (Neotect, Mibi)		
	WBC (HMPAO) Infection		10% SPECT
67Ga	Infection/Tumor		65% SPECT
111In	WBC's Infection	34	10% SPECT
	CSF Flow	2	
	Oncoscint (Tumor)		
	Octreoscan (Endo Tumor)	4	
	Prostascint	3	
	Zevalin		
123I	Thyroid (Imaging)	2	
	Thyroid (Uptake)	2	
	MIBG Tumor	1	
	Thyroid (Imaging) N&C	17	
131I	Thyroid (Imaging) N&C	42	
	Thyroid (Uptake) Dosimetry	4	
	MIBG Tumor		
	NP59 Adrenal		
89Sr	Metastron		
201Tl	Myocardial (Stress/Rest)	890	30% Drug Stress, SPECT
	Whole Body		
	Brain	1	
153Sm	Quadramet	1	
57/58Co	Schillings Test		
18F	Tumor Localization	621	

Preceptor Statement for: MAJ Yang-En Kao


 Preceptor
 Nuclear Medicine
 Walter Reed Army Medical Center
 Washington D.C.

Preceptor Statement for: MAJ Yang-En Kao

PRECEPTOR (Continued)

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

NUCLIDE 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	THYROID TREATMENT GREATER THAN 33 mCi (1.22 GBq)	11	
	THYROID TREATMENT LESS THAN OR EQUAL TO 33 mCi (1.22 GBq)	14	
Au-198	INTRACAVITARY TREATMENT		
Pd-103	INTERSTITIAL TREATMENT		
Co-60 or	INTERSTITIAL TREATMENT		
Cs-137	INTRACAVITARY TREATMENT		
I-125	INTERSTITIAL TREATMENT		
Ir-192	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
	BRONCHIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
OTHER			
C-14	Urea Breath Test	13	
Y-90	Non-Hodgkins Lymphoma Treatment		

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIONUCLIDE TRAINING.
1 July 2007 – 30 June 2008

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

b. NAME OF SUPERVISOR (PRINT OR TYPE)

LTC Aaron L. Stack

b. NAME OF INSTITUTION

Walter Reed Army Medical Center

c. MAILING ADDRESS

6900 Georgia Ave. N.W.

d. CITY

Washington

e. STATE

D.C.

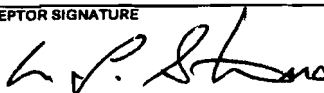
f. ZIP

20307-5001

5. MATERIALS LICENSE NUMBER(S) AND ISSUING AGENCY

08-01838-02

6. PRECEPTOR SIGNATURE



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

Aaron L. Stack

LTC MC

Chief, Nuclear Medicine Service

8. DATE

30 June 08

**¹³¹Iodine Thyroid Therapy Greater Than 33 mCi (1.22 gigabecquerels)
Nuclear Medicine Service
Preceptor Statement for: MAJ Yang-En Kao**

DTG	Dosage (mCi)	Preceptor
7-9-07	182	MAJ Derek Stocker
7-24-07	149.8	LTC Aaron Stack
7-30-07	251.7	LTC Jennifer Jurgens
11-5-07	161	MAJ Derek Stocker
11-26-07	193.6	LTC Sidney Hinds
12-4-07	236	LTC Aaron Stack
12-4-07	153	LTC Aaron Stack
1-14-08	160	LTC Sidney Hinds
3-10-08	161.2	LTC Sun Yong Kim
3-10-08	248	LTC Sun Yong Kim
5-5-08	253	LTC Aaron Stack

**¹³¹Iodine Thyroid Therapy Less Than or Equal to 33 mCi (1.22 gigabecquerels)
Nuclear Medicine Service**

DTG	Dosage (mCi)	Preceptor
7-24-07	15.66	LTC Aaron Stack
8-9-07	32.2	LTC Sidney Hinds
9-24-07	31.1	LTC Jennifer Jurgens
12-5-07	19.88	LTC Sidney Hinds
12-7-07	33	LTC Sun Yong Kim
12-14-07	15.7	LTC Aaron Stack
1-17-08	15.57	LTC Sun Yong Kim
1-25-08	15.24	LTC Aaron Stack
2-8-08	15.85	LTC Sun Yong Kim
2-12-08	16.03	LTC Sun Yong Kim
3-6-08	15.74	LTC Aaron Stack
3-18-08	32.1	LTC Aaron Stack
4-15-08	16.09	LTC Sun Yong Kim
5-29-08	14.95	LTC Sun Yong Kim

**Radionuclide Therapies (Other)
Nuclear Medicine Service**

DTG	Radionuclide Therapy and Dosage (mCi)	Preceptor
8-30-07	112.3 mCi Samarium	MAJ(P) Derek Stocker

30 Jun 2008
Date

Preceptor

AARON L. STACK
LTC, MC
Chief, Nuclear Medicine Service

No 4 7 1 9 5 3

ACCEPTANCE REVIEW MEMO (ARM)

Licensee: Army, Dept of (Madigan AMC)

License No.: 46-02645-03

Docket No.: 030-03368

Mail Control No.: 471953

Type of Action: Amend

Date of Requested Action: 09-03-08

Reviewer
Assigned:

ARM reviewer(s): Cook

Response	Deficiencies Noted During Acceptance Review
	<p>[] Open ended possession limits. Submit inventory. Limit possession.</p> <p>[] Submit copies of latest leak test results.</p> <p>[] Add IC L.C./Fingerprint LC, add SUNSI markings to license.</p> <p>[] Confirm with licensee if they have NARM material.</p>

Reviewer's Initials: _____

Date: _____

- ☐ Yes ☐ No Request for unrestricted release Group 2 or >. Consult with Bravo Branch.
- ☐ 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 HP's Initials: _____ Date: _____

SUNSI Screening according to RIS 2005-31

☐ Yes ☒ No Sensitive and Non-Publicly Available 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 [suite #, bldg. #, location different from mailing address] (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 HP's Initials:  Date: SEP 18 2008

9-19-08

DATE

This is to acknowledge the receipt of your letter/application dated 9-03-08, 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** 471953.
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

BETWEEN: : (FOR LFMS USE)
: INFORMATION FROM LTS
: -----
:
License Fee Management Branch, ARM : Program Code: 02120
and : Status Code: 0
Regional Licensing Sections : Fee Category: 7C 3M EX 2B
: Exp. Date: 20101031
: Fee Comments: NOT BROAD PER REGION V
: Decom Fin Assur Req'd: N
: ::::::::::::::::::::::::::::::::::::::

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: ARMY, DEPARTMENT OF THE
Received Date: 20080915
Docket No: 3003368
Control No.: 471953
License No.: 46-02645-03
Action Type: Amendment

2. FEE ATTACHED

Amount: _____
Check No.: /

3. COMMENTS

Signed Colleen Murnahan
Date 9-18-08

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 _____

Command
Madigan
Attn: MCHJ-PVR (Health Physics)
Tacoma, WA 98431-5000

U.S. Nuclear Regulatory Commission
Region IV
Nuclear Licensing Section
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011-8064

