Q-8



Danbury Hospital

March 10, 2006

Shirley Xu Nuclear Materials Safety Branch United States Nuclear Regulatory Commission, Region 1 475 Allendale Road King of Prussia, Pennsylvania 19406-1415

Re: NRC License No. 06-08544-01 Control # 138427

Dear Ms. Xu:

In response to your inquiry from 3/8/06 regarding our NRC license amendment proposal of 2/2/06:

- The area adjacent to the hot lab at the proposed Southbury, CT cardiology site is an exam room/ECHO room that is part of the cardiology facility. Routine area surveys will be performed in this area as per our usual protocols.
- 2. I am forwarding a copy of Dr. Mani's official ASNC certificate (she had received a copy since we sent the original proposal) along with preceptorship statements from Dr. Jonathan Alexander & myself who are both licensed users here at Danbury Hospital.
- 3. I have corrected the information (10 CFR 35 numbers) on Dr. Savino's paperwork to correspond with your current system.

Please inform me if you require any further information.

Sincerely,

William 2 John MD

William D. Johns, MD Radiation Safety Officer Danbury Hospital 24 Hospital Avenue Danbury, CT 06810

Tel: 203-797-7222 Fax: 203-739-6473

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WDJ;wdj 3/10/06

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NMSS/RGNI MATERIALS-032

24 Hospital Avenue • Danbury, Connecticut 06810 • Phone (203) 797-7000 • www.danhosp.org



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Danbury Hospital

February 2, 2006 (corrections February 8, 2006-WJ)

Licensing Assistant Section Nuclear Materials Safety Branch U. S. Nuclear Regulatory Commission, Region I 475 Allendale Road King of Prussia, PA 19406-1415

RE: NRC License No. 06-08544-01 (Danbury Hospital) Amendment Request

To Whom It May Concern:

I.

Enclosed you will find an application and supporting information for an amendment to the Danbury Hospital material license. We recently completed our 10-year renewal process. Included in this proposed amendment will be:

1. Addition of a satellite facility (owned and operated by Danbury Hospital) for nuclear cardiology diagnostic imaging located in Southbury, Connecticut. The address of the facility will be:

> Cardiovascular Diagnostic Center (Danbury Hospital) 22 Old Waterbury Road, Suite 106 Southbury, CT 06488 Tel: 203-262-4270

The facility will be staffed by Danbury Hospital employees and will include 1 gamma camera and other equipment required for operation. Tc-99m and TI-201 will be used for diagnostic imaging and other sealed sources will be required for instrument calibration, etc. We will have a hot lab and on-site radioactive waste storage. No therapeutic modalities using isotopes will be performed at this site. Diagrams of the planned facility and hot lab are enclosed.

The facility will be under the supervision of the Radiation Safety Officer (Dr. William Johns) and our medical physics staff at Danbury Hospital, with activities being overseen by the Radiation Safety Committee at Danbury Hospital. All hospital policies and procedures will be followed at the satellite facility for compliance with NRC and State of Connecticut regulations.

- 2. We would like to add 2 physicians to our NRC license:
 - a. Robert Savino, OD: Dr. Savino is Chief of Endocrinology at Danbury Hospital. He is board certified in Endocrinology and has completed an 80-hour course in radiation physics/nuclear

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endocrinology (certificate enclosed). He has been supervised here at Danbury Hospital in the administration of I-131 therapies to 10 patients with hyperthyroidism and 3 patients with thyroid cancer. He is applying for privileges under 10 CFR **35.392** (treatment of hyperthyroidism) and **35.394** (treatment of thyroid cancer). Preceptorship statements are also attached.

b. Susan Mani, MD: Dr. Mani is a staff Cardiologist here at Danbury Hospital. She is board certified in Cardiology and Nuclear Cardiology. Here certifications are enclosed. She is applying for privileges for Nuclear Cardiology diagnostic imaging under 10 CFR 35.100 and 35.200.

Please inform us if you require any further information. Inquiries may be directed to the Radiation Safety Officer (Dr. William Johns).

Sincerely,

Patricia O'Connor Senior Vice President, Operations Danbury Hospital 24 Hospital Avenue Danbury, CT 06810

WDJ;wdj 2/2/06



Danbury Hospital

January 19, 2006 (amended March 8, 2006- WJ)

Nuclear Materials Safety Branch United States Nuclear Regulatory Commission, Region 1 475 Allendale Road King of Prussia, Pennsylvania 19406-1415

Re: NRC License No. 06-08544-01

Subject: Addition of Robert Savino, D.O. to Hospital License

To Whom It May Concern:

We request the addition of Dr. Robert Savino to the Danbury Hospital NRC license as an authorized user for treatment of hyperthyroidism (**35.392**) and thyroid carcinoma (**35.394**). Dr. Savino is currently the Chief of Endocrinology here at the hospital. He completed his fellowship training in endocrinology in 1994 and coursework in radiological physics in 2003 (certificate attached).

He has completed 80 hours of classroom and laboratory training that includes radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, and radiation biology. Dr. Joseph Belsky who is currently a licensed user has supervised him in treatment of hyperthyroidism in 10 individuals here at Danbury Hospital. Drs. Gupta and Johns who are currently licensed users have also supervised him in treatment of thyroid cancer in 3 individuals here at Danbury Hospital. We certify that he has successfully completed training and is competent in the use of I-131 to treat both hyperthyroidism and thyroid cancer.

Sincerely,

Shiv Gupta, MD (Preceptor) Chief of Nuclear Medicine Chairman, Radiation Safety Committee, Danbury Hospital

William John 750

William Johns, MD (Preceptor) Nuclear Medicine Radiation Safety Officer, Danbury Hospital

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Joseph Belsky, MD (Preceptor) ' Endocrinology, Danbury Hospital

WDJ:wdj 1/19/06

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RC FORM 313A -2009 MEI	DICAL USE TRAINING		NCE AND PRECEPTOR	U.S. NUCLEAR REGULATO ATTESTATION (continu	
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Dosci	ription of Experience		Name of Supervising Individuel(s)	Location and Corresponding Materials License Number	Dates and/o Clock Hours of Experience
	··· ···				
	b. SUPERVISED CLIN	ICAL CASE EX	PERIENCE (describe ex	perience elements in 6	a)
Radionuclide	Type of Use	No. of Cases Involving Personal Perticipation	Name of Supervising Individual	Location and Corresponding Materials License Number	Dates and/ Clock Hours of Experience
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					10 hours
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NRC FORM \$13A (10-2006) MEDICAL USE TRAINING AND EXPERIENCE AND P	U.S. NUCLEAR REGULATORY COMMENT PRECEPTOR ATTESTATION (continued)
10. SUPERVISING INDIVIDUAL ~ IDENTIFIC	
The training and experience indicated above was obtained under the	
individual is needed to meet regulrements in 10 CFR Part 35, provid	de the following information for each) :
A. Name of Supervisor B. Supervisor is:	
William Johns, MD & Authorized Us	ser Authorized Medicei Physicist
Rediation Saf	fety Officer 🔲 Authorized Nuclear Pharmacist
C. Supervisor meets requirements of Part 35, Section(s)	35. 394 (cance Thirson).
for medical uses in Part 35, Section(s)	
D. Address	E. Materials License Number
24 Haraital Avenue	
Danbury Hospital 24 Hospital Avenue Danbury, CT 06810	06-08544-01
PART II PRECEPTOR A Note: This part must be completed by the individual's preceptor. I experience, obtain a separate preceptor statement from eac requirements in 35.590 or Part 35, Subpart J (except 35.981	If more than one preceptor is necessary to docume ch. This part is not required to meet training
l attast the individual named in item 1: Robert Savino	
11a.	_
has satisfactorily completed the requirements in Part 35,	
as documented in section(s) of this fo	iom.
meets the requirements in 35.50(e) 35.51(c) N/A types of use, as documented in section(e)	of this form.
11c.	
has achieved a level of competency sufficient to indepen	
has achieved a level of competency sufficient to function	n independently as an authorized / c. pacco uses (or units); OT
USC for <u>II3/</u>	
has achieved a level of radiation safety knowledge suffic	cient to Tupotion Independently as a Madieton Sele
Officer for a modical use licensee ; OF	
11d.	and a second
I am an Authorized Nuclear Pharmacist; Of Dr I am a	a Radiation Safety Officer; OF
I meet the requirements of	section(s) of 10 CFR Part 35
or equivalent Agreement State requirements to be a precept	tor AU or AMP
for the following byproduct material uses (or units):	131 Thereny (chance)
	B. Matoriala License Number
A. Address Dasbury Hospital	
24 Hospital Avenue	
Dasbury, CT 06810	06-08544-01
. NAME OF PRECEPTOR (print alwarity) D. SIGNATURE PRE	ECEPTOR E. DATE
William D, John MD William	Oghn mD 1/19/06

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IRC FORM 313A INEDICAL USE TRAINING AN	U.S. NUCLEAR REGULATORY COMBESSION ND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)
	NDIVIDUAL - IDENTIFICATION AND QUALIFICATIONS
The training and experience indicated abor ndividual is needed to meet requirements	ve was obtained under the supervision of (if more than one supervising In 10 CFR Part 35, provide the following information for each) :
A. Name of Supervisor	B. Supervisor is:
Shiv Gupta MD	Authorized User Authorized Medical Physicist
	Radiation Safety Officer Authorized Nuclear Pharmacau
•	(Part 35, Section(s) 35:394 [Lance Thermy].
for medical uses in Part 35, Sectio	E. Materials License Number
D. Address Danbury Hi 24 Hospita	al Avenue
Danbury,	CT 06810 06-08544-01
Note: This part must be completed by th experience, obtain a separate pre requirements in 35.590 or Part 35	ART II – PRECEPTOR ATTESTATION he individual's preceptor. If more than one preceptor is necessary to docume inceptor statement from each. This part is not required to most training i, Subpart J (except 35.980).
I attest the individual named in item 1:	Robert Savino DO
1.1a.	e requirements in Part 35, Section(s) and Paregraph(s)
as documented in section(6)	C of this form.
as documented in section(6)	C of this form.
as documented in section(c)	of this form. 35.50(e) []] 35.51(c) []] 35.390(b)(1)(ii)(G) []] 35.690(c) for n section(s) of this form.
as documented in section(e)	of this form. 35.50(e) 35.51(c) 35.390(b)(1)(ä)(G) 35.690(c) for n section(s) of this form.
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as documented in section(e) 11b. Select one meets the requirements in N/A types of use, as documented in 11c. has achieved a level of competi- has achieved a level of competi-	of this form. 35.50(e) 35.51(c) 35.390(b)(1)(ii)(G) 35.690(c) for n section(s) of this form. tency sufficient to independently operate a nuclear pharmacy (for 35.980); Of tency sufficient to function independently as an authorized
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as documented in section(e) 11b. Select one Image: the requirements in image: the re	or this form. 35.50(e) $35.51(c)$ $35.390(b)(1)(ii)(G)$ $35.690(c)$ for n section(s) of this form. tency sufficient to independently operate a nuclear pharmacy (for 35.980); Of tency sufficient to function independently as an authorized for $1-12$ CACC uses (or units); OF on safety knowledge sufficient to function independently as a Radiation Safety
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as documented in section(e) 11b. Select one Image: the requirements in Image: the re	35.50(e) 35.51(c) 35.390(b)(1)(ii)(G) 35.690(c) for
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NRC FORM 313A	U.S. NUCLEAR REGULATORY COM
(10-2005) MEDICAL USE TRAINING AND E	XPERIENCE AND PRECEPTOR ATTESTATION (continued)
10. SUPERVISING INDIV	IDUAL - IDENTIFICATION AND QUALIFICATIONS
The training and experience indicated above we individual is needed to meet requirements in 10	as obtained under the supervision of (if more than one supervising CFR Part 35, provide the following information for each) :
	. Supervisor is:
Joseph Belsky, MD	Authorized User Authorized Medical Physicist
	Radiation Safety Officer 🔲 Authorized Nuclear Pharmac
C. Supervisor meets requirements of Part	35, Section(s) 35.392 (Hyporthyro
for medical uses in Part 35, Section(s)	
D. Address	E. Materials License Number
Danbury Hospital 24 Hospital Aven Danbury, CT 06	48
Dachury (TT PE	PID 06-08544-0
Note: This part must be completed by the ind	II PRECEPTOR ATTESTATION lividual's preceptor. If more than one preceptor is necessary to doc or statement from each. This part is not required to meet training opart J (except 35.980).
I attest the individual named in item 1: $ m R_{o}$	but Savino, DO
has satisfactorily completed the requ	uirements in Part 35, Section(s) and Paragraph(s)
as documented in section(s)	
11b. Select one	
meets the requirements in 35.50	0(e) 35.51(c) 35.390(b)(1)(ii)(G) 35.690(c) for
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Officer for a medical use licensee ; (
□ N/A	
11d. I am an Authorized Nuclear Pharmacist	t; OF I am a Radiation Safety Officer; OF
I meet the requirements of 35 .	392 section(s) of 10 CFR Part 35
or equivalent Agreement State requiren	nents to be a preceptor 🛛 AU or 🔲 AMP
for the following byproduct material use	es (or units): I- 131 (Hyperthyroid R
A. Address	B. Materials License Number
Danbary Hospital 24 Hospital Avenue	
24 Hospital Avenue	
Drahua (T OGRIT	D. SIGNATURE PRECEPTOR X Judgell L, Belly Mul 1/19/04
Danbury, CT OGDIC	



Danbury Hospital

March 9, 2006

Nuclear Materials Safety Branch United States Nuclear Regulatory Commission, Region 1 475 Allendale Road King of Prussia, Pennsylvania 19406-1415

Re: NRC License No. 06-08544-01 Control #: 138427

Subject: Addition of Susan Mani, MD to Hospital License

To Whom It May Concern:

We request the addition of Dr. Susan Mani to the Danbury Hospital NRC license as an authorized user for diagnostic Nuclear Cardiology (35.100, 35.200). She completed her training in Nuclear Cardiology and is board certified by the American Society of Nuclear Cardiology.

She has been employed at Danbury Hospital since June 2005 and has been precepted here by Dr. Jonathan Alexander and Dr. William Johns. She is familiar with all procedures using isotopes in Nuclear Cardiology, as well as having demonstrated good knowledge regarding radiation safety procedures and isotope handling. We certify that she is competent to be place on our license.

Sincerely,

Jonathan Alexander, MD Director of Nuclear Cardiology

William Johns(/MD Nuclear Medicine/Radiation Safety Officer

WDJ⁻wdj 3/9/06



Susan Maní, M.D.

HAVING MET THE REQUIREMENTS PRESCRIBED BY THIS BOARD FOR PHYSICIANS RESIDING IN THE UNITED STATES AND HAVING SATISFACTORILY PASSED THE REQUIRED EXAMINATION,

IS HEREBY DESIGNATED

A DIPLOMATE CERTIFIED IN THE SUBSPECIALTY OF

NUCLEAR CARDIOLOGY

FOR THE PERIOD 2005 THROUGH 2015

CERTIFICATE # 4061 OCTOBER 23, 2005

TD:215 337 5269

MAR-10-2006 14:22 FROM:DANBURY HOSPITAL

2037396473

TO:215 337 5269

NRC FORM \$13A	U.S. NUCLEAR REGULATOR	Y COMMERCION		
(10-2005)			APPROVED BY EXPIRES: 10/31	OMB: NO. 3150-0120
AND PRECE	PTOR ATTESTATION		CAPIRES: 1913	
	PART I - TRAINING AND EXPER			
Note: Descriptions of training and ex criteria in the applicable regula	perience must contain sufficient det ation (10 CFR Part 35)	all to match the	training and e	xperience
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Susa	n Mani, MD -	Nucle	no ercd	intos-
2. For Physicians, Podiatrists, Dentists, Pt	narmacists - State or Territory Where Ll	censed		
ET				
	3. CERTIFICATION			
a. Provide a copy of the board cartification continue if applying under other sub- continue if applying under sub- continue if applying	ation. (Stop here If applying under 1 bparts.)	0 CFR Part 35,	Subpart J or 3	35.590(a);
b. Provide documentation in appropria 35.51(c); 35.290(c)(1)(ii)(G) for AU 35.590(c); or 35.690(c).	ite items 4 through 10 of training or seeking 35.200 authorization; 35.39	clinical case wo 0(b)(1)(ii)(G); 3	rk required by 5.396(d)(1) and	35.50(e); d 35.398(d)(2);
c. Provide completed Part II Preceptor	r Attestation, Items 11a through 11d			
Stop here after completing items 3a experience requirements.	i, 3b, and 3c when using board certh	fication to meet	10 CFR Part 3	35 training and
AUTHORIZED US AUTHORIZED NUCLEAR	ON A LICENSE OR PERMIT AS RA ERS (AU), AUTHORIZED MEDICA PHARMACISTS (ANP) SEEKING	L PHYSICISTS ADDITIONAL	(AMP), OR AUTHORIZATI	
a. Provide a copy of the license or bro				
 b. Complete items 6c (and 10 when the 11d to meet requirements for: RSO 35.590(c) or 35.690(c); or AMP und 	in 35.50(c)(2) or 35.50(e); or AU in			
c. Complete items 5, 6a, 6b, 10, and F	Preceptor items 11a through 11d to i	meet AU require	ements in 35.3	96(a).
5. DIDACTIC OR CLASSRO	DOM AND LABORATORY TRAININ	IG (optional fo	r Medical Phy	nsicists)
Description of Training	Location	Clock Ho	urs Dat	les of Training
Radiation Physics and Instrumentation	Board Cert	fied -		
Radiation Protection	American S	cicts	, or	
Mathematics Pertaining to the Use and Measurement of Radloactivity	Nuclear Ca	reho log	57	
Radiation Biology	Fello with po -	rainin	r Dona	<u>ــــــــــــــــــــــــــــــــــــ</u>
Chemistry of Byproduct Material for Medical Use				
OTHER				
NRC FORM 313A (10-2005)	PRINTED ON RECYCLED PAPER	<u></u>		PAGE 1

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ż	08. WON	CR OR PRACTIC	AL EXPERIENCE WIT	Location and	Dates and/o
Descr	ription of Experience		Name of Supervising	Corresponding	Clock
			Individual(s)	Materials License Number	Hours of Experience
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6	b. SUPERVISED CLI	and the second	PERIENCE (describe	experience elements in t	
adionuclide	Type of Use	No. of Cases Involving	Name of Supervising	Location and Corresponding	Dates and/or Clock
	i ypa or oad	Personal Participation	Individual	Materials License Number	Hours of Experience
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MAR-10-2006 14:23 FROM:DANBURY HOSPITAL 2037396473

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TD:215 337 5269

P.14/15

Susan Mari Mo	
IRC FORM 313A	U.S. NUCLEAR REGULATORY COMMISSIO
MEDICAL USE TRAINING AND EXPERIENCE AND PREC	
10. SUPERVISING INDIVIDUAL IDENTIFICATI	ion and qualifications
The training and experience indicated above was obtained under the sundividual is needed to meet requirements in 10 CFR Part 35, provide th	pervision of (If more than one supervising the following information for each) :
A. Name of Supervisor B. Supervisor is:	_
Jonathan Alexander DeAuthorized User	Authorized Medical Physicist
Radiation Safety (Officer 🔲 Authorized Nuclear Pharmacist
C. Supervisor meets requirements of Part 35, Section(s) $3 \bar{3}$	T.100 35,200
for medical uses in Part 35, Section(s)	290 .
D. Address Darbury Hospital	E. Materials License Number
D. Address Danbury Hospital 21 Hospital Avenue Danbury CT D6+12	06-085 44-01
	a Activity of the second
PART II PRECEPTOR ATTE Note: This part must be completed by the Individual's preceptor. If mu experience, obtain a separate preceptor statement from each. requirements in 35.590 or Part 36, Subpart J (except 35.980).	ore than one preceptor is necessary to docume
l attest the individual named in Item 1:	35-100
has satisfactorily completed the requirements in Part 35, Sec	ction(s) and Paragraph(s) 35.200
as documented in section(s)	

11b. Select one meets the requirements in 35.50(e) 35.51(c) 35.	390/b)(1)([])(G) 35 690/c) for
	of this form.
N/A types of use, as documented in section(s)	of this form.
N/A types of use, as documented in section(s)	of this form.
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NRC FORM 313A U.S. NUCLEAR REGULATORY COMMISSIO (10-2005) MEDICAL USE TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)
والشاع المحرج المركز المركز المركز المركز المركز المحرجي والمتشار ويتكاف فالمركز والمركز والمحرج والمح
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:
William John Authorized User Authorized Medical Physicist
Radiation Safety Officer 🔲 Authorized Nuclear Pharmecist
C. Supervisor meets requirements of Part 35, Section(s) 35,109, 35,200
for medical uses in Part 35, Section(s) 357, 293
D. Address Darbur, Hupiki E. Materials License Number
D. Address Darhu, Hup, KI E. Materials License Number 24 Holpital Averue
Danhory CT 0 (810 06-005 74-0)
PART II - PRECEPTOR ATTESTATION
Note: This part must be completed by the individual's preceptor. If more than one preceptor is necessary to documen 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:
has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) 35.100 35.2
has satisfactorily completed the requirements in Part 35, Section(s) and Paragraph(s) $0.7 \cdot 10^{5} \cdot 5^{7} \cdot 2^{7}$ as documented in section(s) $1/C$ of this form.
meets the requirements in 35.50(e) 35.51(c) 35.390(b)(1)(ii)(G) 35.690(c) for N/A types of use, as documented in section(s) of this form.
11c. has achieved a level of competency sufficient to independently operate a nuclear pharmacy (for 35.980); OF
has achieved a level of competency sufficient to function independently as an authorized U.S.C. for $3S.U.S.S.C.$ uses (or units); OF
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 A am a Radiation Safety Officer; OF
I meet the requirements of I v> 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): Nuclea Carlo logy all ushine lise
Dannung Hapitel
Dashury, 5706+13 06-080-44-01
C. NAME OF PRECEPTOR (print doorly) D. SKGNATURE - PRECEPTOR E. DATE
William, D. John, M) Wallen Storn 2 3/10/06