

PATIENT Safety
Starts WITH ME

Br. 1

September 19, 2006

U.S. Nuclear Regulatory Commission, Region I Office, Division of NMSS
Attn: Materials Licensing, Ms. Sandy Gabriel
475 Allendale Road
King of Prussia, PA 19406

2006 SEP 25 PM 2:00

RECEIVED
REGION I

Dear Ms. Gabriel (License No.: 45-00131-02) 03003298

We would like to resubmit our request for addition of Dr. G. Stephen Brown as an authorized user, for radioisotope therapies under 35.396, specifically parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required. Dr. Brown's supervised work experience includes 3 administrations of Y-90 Zevalin in 2006. Three separate letters of attestation are attached to document these cases, along with a group letter attesting to Br. Brown's performance of other related duties during these cases.

Dr. Brown has performed no other radioisotope therapies this year. Vendor training for the Zevalin therapies is attached.

Attached are several other documents related to Dr. Brown's previous work experience under several licenses during the period from 1969-1989. His board certification dated 1968 is also included.

For more information, please do not hesitate to contact me at (757) 388-3030.

Sincerely,



Sandy Wolff
Radiation Safety Officer
Sentara Hospitals



139457
NMSS/RGNI MATERIALS-002



Scriver Cancer Institute
800 Graham Drive
North Virginia Beach
VA 757 627 2832
www.sentara.com

September 11, 2006

U.S. Nuclear Regulatory Commission, Region I Office, Division of NMSS
Attn: Materials Licensing, Ms. Sandy Gabriel
475 Allendale Road
King of Prussia, PA 19406

Dear Ms. Gabriel (License No.: 45-00131-02)

We hereby confirm that Dr. G. Stephen Brown's work under our direction in 2006 included one administration of Y-90 Zevalin and the following associated tasks:

- Ordering, receiving, and unpacking radioactive materials safely & performing radiation surveys;
- Performing quality control procedures on instruments used to determine the activity of dosages;
- Performing checks for proper operation of survey meters;
- Calculating, measuring, and safely preparing patient dosages;
- Using administrative controls to prevent a medical event involving unsealed byproduct material;
- Practicing of procedures to safely contain spilled radioactive material;
- Simulating proper decontamination procedures; and
- Administering dosages of radioactive drugs to patients.

We further attest that Dr. Brown has satisfactorily completed the requirements of 10 CFR 35.595 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.396, i.e. parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required.

For more information, please do not hesitate to contact Sandy Wolfe, RSO, at (757) 388-3030.

Sincerely,

Christopher C. Sinesi, MD
Department of Radiation Oncology, SNGH

Michael Miller, MD
Department of Radiation Oncology, SCH

Scott Williams, MD
Radiation Oncology, SNGH

Sandy Wolfe, RSO
Sentara Hospitals

Wen-Yong Wang, AMP
Sentara Hospitals

September 11, 2006

U.S. Nuclear Regulatory Commission, Region I Office, Division of NMSS
Attn: Materials Licensing, Ms. Sandy Gabriel
475 Allendale Road
King of Prussia, PA 19406

Dear Ms. Gabriel (License No.: 45-00131-02)

(Unsigned
copy for
legibility)

We hereby confirm that Dr. G. Stephen Brown's work under our direction in 2006 included one administration of Y-90 Zevalin and the following associated tasks:

^{each}
Ordering, receiving, and unpacking radioactive materials safely & performing radiation surveys;
Performing quality control procedures on instruments used to determine the activity of dosages;
Performing checks for proper operation of survey meters;
Calculating, measuring, and safely preparing patient dosages;
Using administrative controls to prevent a medical event involving unsealed byproduct material;
Practicing of procedures to safely contain spilled radioactive material;
Simulating proper decontamination procedures; and
Administering dosages of radioactive drugs to patients.

We further attest that Dr. Brown has satisfactorily completed the requirements of 10 CFR 35.396 and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.396, i.e. parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required.

For more information, please do not hesitate to contact Sandy Wolff, RSO, at (757) 388-3030.

Sincerely,

Christopher C. Sinesi, MD
Department of Radiation Oncology, SNGH

Sandy Wolff, RSO
Sentara Hospitals

Michael Miller, MD
Department of Radiation Oncology, SCH

Wen-Jong Wang, AMP
Sentara Hospitals

Scott Williams, MD
Radiation Oncology, SNGH

June 16, 2006

U.S. Nuclear Regulatory Commission, Region I Office, Division of NMSS
Attn: Materials Licensing, Ms. Sandy Gabriel
475 Allendale Road
King of Prussia, PA 19406

To whom it may concern:

I hereby confirm that Dr. G. Stephen Brown's work under my direction in 2006 included one case of administration of Y-90 Zevalin to patients. For this case he was involved in the following tasks related to use of unsealed byproduct material: ordering, receiving, and unpacking radioactive materials and performing the required radiation surveys; performing quality control procedures on instruments used to determine the activity of dosages; performing checks for proper operation of survey meters; calculating, measuring, and safely preparing patient dosages; using administrative controls to prevent a medical event involving use of unsealed byproduct material; and using procedures to safely contain and decontaminate spilled byproduct material.

I further attest that Dr. Brown has satisfactorily completed the requirements in paragraph 10 CFR 35.396(d)(2) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.396.

For more information, please do not hesitate to contact Sandy Wolff, RSO, at (757) 388-3030.

Sincerely,



Michael Miller, DO
Department of Radiation Oncology
Sentara Careplex Hospital
NRC License 45-09087-01

June 16, 2006

U.S. Nuclear Regulatory Commission, Region I Office, Division of NMSS
Attn: Materials Licensing, Ms. Sandy Gabriel
475 Allendale Road
King of Prussia, PA 19406

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For more information, please do not hesitate to contact Sandy Wolff, RSO, at (757) 388-3030.

Sincerely,



Christopher Sinesi, MD
Department of Radiation Oncology
Sentara Norfolk General Hospital
NRC License 45-00131-02

June 19, 2006

U.S. Nuclear Regulatory Commission, Region I Office, Division of NMSS
Attn: Materials Licensing, Ms. Sandy Gabriel
475 Allendale Road
King of Prussia, PA 19406

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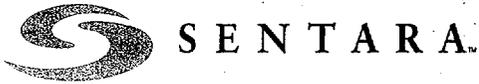
I further attest that Dr. Brown has satisfactorily completed the requirements in paragraph 10 CFR 35.396(d)(2) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.396.

For more information, please do not hesitate to contact Sandy Wolff, RSO, at (757) 388-3030.

Sincerely,



Scott Williams, MD
Department of Radiation Oncology
Sentara Norfolk General Hospital
NRC license 45-00131-02



LW
Sentara Norfolk General Hospital
600 Gresham Drive
Norfolk, VA 23507
www.sentara.com

June 19, 2006

U.S. Nuclear Regulatory Commission
Region I Office, Division of NMSS
Attn: Materials Licensing
475 Allendale Road
King of Prussia, PA 19406

RE: NRC license number 45-00131-02

To whom it may concern,

~~We have discontinued our IVBT program and returned all strontium-90 sources to the vendor as of May 23, 2006. Enclosed is confirmation of source receipt by Best Vascular. Please remove this modality and equipment from our NRC license.~~

We would like to request the addition of Dr. G. Stephen Brown as an authorized user, for radioisotope therapies under 35.396, specifically parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required. Dr. Brown's supervised work experience includes 3 administrations of Y-90 Zevalin in 2006. Three separate letters of attestation are attached to document these cases.

Attached are several documents related to Dr. Brown's previous work experience under several licenses during the period from 1969-1989. His board certification dated 1968 is also included.

For more information, please do not hesitate to contact our Radiation Safety Officer, Sandy Wolff, at (757) 388-3030.

Sincerely,

A handwritten signature in black ink that reads 'Bruce Holstien'.

Bruce Holstien
Senior Vice President
Administrator, Sentara Norfolk General Hospital

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Gerald Stephen Brown (ABMSUID - 175146)

Viewed: 12/19/2005 2:57:52 PM CST

DOB: 07/22/1938
Status: Alive

Certification

American Board of Radiology
Therapeutic Radiology - General

Active	Lifetime	Initial Certification	1968 -
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Education

1963 MD (Doctor of Medicine)

Location

Unknown



User Notice: It is up to the user to determine that the physician record obtained from this service is that of the physician you seek.

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Brenda L. Burrell

G. Stephen Brown, M.D., F.A.C.R.

Cancer Program Consultant
P.O. Box 280
St. Michaels, MD 21663
TEL 410-745-9194
FAX 410-745-9195

CELLULAR 410-924-4560
e-mail -browgs@aol.com

December 11, 2005

Academic Position Held since completion of residency

1969-1972	Instructor in Radiology, Univ of Hawaii, School of Medicine
1973-1977	Associate Professor of Radiology, Univ of Vermont School of Medicine
1977-1980	Associate Clinical Professor of Radiology, Univ of California, Irvine School of Medicine
1980-1984	Clinical Associate Professor of Radiology, Univ of Southern Calif, School of Medicine
1984-1996	Clinical Professor of Radiology, Univ of Southern Calif, School of Medicine
1996-2003	Professor of Radiation Oncology, Univ of Texas, M.D. Anderson Cancer Center

Clinical and Administrative Positions since completion of residency

ATTACHED	1968	Associate Attending Radiation Therapist, Medical Center Hospital of Vermont, Burlington, VT
	✓ 1969-72	Chief, Radiation Therapy Service and Chief, Nuclear Medicine Service, Tripler Army Medical Center, Honolulu, HI
	✓ 1972-1977	Director, Division of Radiation Therapy, Medical Center Hospital of Vermont, Burlington, VT
	✓ 1973-1977	Clinical Director, Vermont Regional Cancer Center, Burlington, VT
	✓ 1977-1990	Radiation Oncologist and co-owner, Radiation Oncology Medical Group of Southern Calif
	1990-1992	Consultant, Cancer Department, World Health Organization, Geneva, Switzerland
	1992-1993	Associate Director, Radiation Research Program, Division of Cancer Treatment, National Cancer Institute, Bethesda, MD
	1993-1996	Corporate Medical Director, Oncology Services Corp
	1996-2003	Medical Director for Radiation Oncology, M.D. Anderson Physicians Network, Houston, TX
	1996-1997	Medical Director and Interim President, M.D. Anderson Cancer Network, Tarrant County, Fort Worth, TX
ADMIN ONLY	2003	Locum Tenens, Georgetown Cancer Center, Georgetown, TX (3 months)
	2004	Locum Tenens, Maryland Regional Cancer Care, Waldorf, MD (16 months)
	2005	Locum Tenens, Peninsula Cancer Care Center, Salisbury, MD (Oct 2005 to present)

no unsealed isotope use



DEPARTMENT OF THE ARMY
UNITED STATES ARMY TRIPLER GENERAL HOSPITAL
APO SAN FRANCISCO 96438

TAGH-RA

8 April 1969

SUBJECT: Minutes of Radioisotope Committee

Commanding General
U. S. Army Tripler General Hospital
APO 96438

NRC License 53-00458-04

1. Under the provisions of USATGH Reg. No. 40-34 dated 25 Oct 67, a quarterly meeting of the Radioisotope Committee was convened on 8 April 1969 at 1330 hours in the office of the Chief of Radiology Service. LTC James J. DuBois, Chief, Radiology Service, Chairman, presided.

2. Members present:

LTC James J. DuBois, MC, Chief, Radiology Service, Chairman
COL O'Neill Barrett, Chief, Department of Medicine
MAJ Gerald S. Brown (for LTC Jerry M. Earl), Radioisotope
Clinic, Radiology Service
CPT James A. Roseboro, MSC, Radiation Protection Officer, Radiation
Physicist
CW3 James A. Moore, MSC, Recorder Without Vote

Members absent:

Chief, Pathology Service

3. Minutes. Minutes of the last meeting, 17 Jan 69, were read and approved.

4. Reports/Discussions.

a. The report of the Chief, Radioisotope Clinic, was received and no discrepancies in the operation of the Radioisotope Clinic existed, nor were there any deviations in the administration of radioisotopes. Inventory covering quantities of radioisotopes procured, used, disposed of during the period, and in storage at the end of the period (1 Jan 69 thru 31 Mar 69) was submitted (Inclosure #1). Reports of the procedures performed in the Radioisotope Clinic during this period were also submitted (Inclosure #2).

TAGH-RA
SUBJECT: Minutes of Radioisotope Committee

8 April 1969

b. The report of the Radiation Protection Officer (Inclosure #3) was received and no discrepancies were noted either in receipt, storage, handling or disposal of radioisotopes, and there were no deviations from procedures during the reporting period.

c. It was reported that the new byproduct material license has been received.

d. CPT Roseboro reported that he has checked into the possibility of doing leak testing locally and stated he has been unable to find a local source for activated charcoal. He will check into this further.

e. Notification has been received that the annual U. S. Army Environmental Hygiene Agency radiation protection survey of Tripler General Hospital will be conducted from 18-21 July 1969. MAJ James Roy will conduct the survey.

f. LTC John M. Hardman, MC, is replacing COL William C. Butz, MC, as Chief, Pathology Service, and as a member of this committee. A copy of his training and experience is attached to these minutes as Inclosure #4.

g. LTC Jerry M. Earl has been certified as a user of Selenium 75 in pancreatic scanning. This certification is attached as Inclosure #5. His training and experience in the use of Se-75 were submitted with the Quarterly Report in January.

★ h. MAJ Gerald S. Brown was certified as a user of radioisotopes. A copy of his certification, training and experience is attached hereto as Inclosure #6.

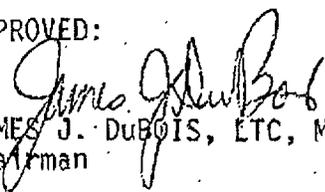
i. Training and experience gained by MAJ Henry M. Labiche, Jr., Pathology Service, during his rotation through the Radioisotope Clinic was submitted (Inclosure #7) and will be included as a permanent part of his 201 file.

j. Discussion was held as to the possibility of using ytterbium for brain scanning. This will be investigated further by CPT Roseboro and MAJ Brown.

5. There being no further business, the meeting was adjourned at 1400 hours.

6 Incl
as

APPROVED:


JAMES J. DuBOIS, ETC, MC
Chairman


JAMES A. MOORE
CW3, MSC
Recorder

June 6, 1977

Re: G. Stephen Brown, M.D.

To Whom It May Concern:

This is to certify that, pursuant to Condition 12, amendment 36 of U.S. Nuclear Regulatory Commission license number 44-10187-03; the above named individual was designated by the University of Vermont Radiological Safety Committee to use and to supervise the use of:

- (A) Cesium-137 and radium-226 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer.
- (B) Iodine-125 and radon-222 as seeds for interstitial treatment of cancer.
- (C) Strontium-90 sealed in an applicator for treatment of superficial eye conditions.
- (D) Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions.
- (E) Phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases.

John F. Harwood
Clerk, Radiological Safety Committee

FJH/ewa
Enc: Amendment 36, license number 44-10187-03

7-25-06
Sandy Gabriel
(NRC)
needs to
verify
this
document

RADIOACTIVE MATERIAL LICENSE

Pursuant to the California Code of Regulations, Division 1, Title 17, Chapter 5, Subchapter 4, Group 2, Licensing of Radioactive Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, use, possess, transfer, or dispose of radioactive material listed below, and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders of the Department of Health Services now or hereafter in effect and to any standard or specific condition specified in this license.

1. Licensee	Radiation Oncology Medical Group of Southern California	3. License No.	2833-30	Amendment No:	14
2. Address	11100 Warner Avenue #162 Fountain Valley, CA 92708	4. Expiration date	February 14, 1997		(3)
Attention:	Robert J. Woodhouse, M.D. Radiation Safety Officer	5. Inspection agency	Health Care Agency Orange County		

In response to the letter dated April 25, 1996, signed by Jacqueline Fakjian, Administrator, License Number 2833-30 is hereby amended in its entirety.

6. Nuclide	7. Form	8. Possession Limit
A. Strontium 90	A. Sealed Source	A. Total 55 mCi in one source.

9. Authorized Use

- A. Group 6  Ophthalmic treatments utilizing sealed or solid sources manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to Title 10, Code of Federal Regulations, Part 32.74, or a specific license issued by an agreement state pursuant to equivalent state regulations (except for sources manufactured prior to August 16, 1974).

LICENSE CONDITIONS

10. Radioactive material shall be used only at the following locations:

- (a) 1211 West La Palma, Suite 100, Anaheim, CA

11. This license is subject to an annual fee for sources of radioactive material authorized to be possessed at any one time as specified in Item 6, 7, 8 and 9 of this license. The annual fee for this license is required by and computed in accordance with Title 17, California Code of Regulations, Sections 30230-30232 and is also subject to an annual cost-of-living adjustment pursuant to Section 113 of the California Health and Safety Code.

12. The individuals named below are authorized the specific uses of radioactive material described in Items 6, 7, 8 and 9 of this license as follows:

- (a) Chahin M. Chahbazian, M.D. Group 6
-  (b) G. Stephen Brown, M.D. Group 6
- (c) Sriprayoon Prasasvinichai, M.D. Group 6
- (d) Donald C. Karon, M.D. Group 6
- (e) Robert J. Woodhouse, M.D. Group 6

This is to acknowledge the receipt of your letter/application dated

9/19/2006, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment 45-00131-02 There were no administrative omissions. Your application was 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

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 139457.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (R)
(6-98)

Sincerely,
Licensing Assistance Team Leader