

**CHRISTIANA CARE**
HEALTH SYSTEM**Helen F. Graham Cancer Center**

4701 Ogletown-Stanton Road
Newark, Delaware 19713
www.christianacare.org

302-623-4500 phone
800-811-8116 toll free
302-623-4554 fax

Nicholas J. Petrelli, MD, FACS
Bank of America Endowed
Medical Director

Patrick A. Grusenmeyer, ScD, FACHE
Vice President

Frank V. Beardell, MD
Medical Director
Bone Marrow Transplant

Joseph J. Bennett, MD
Surgical Oncology

Mark E. Borowsky, MD
Gynecologic Oncology

Theresa A. Gillis, MD
Medical Director
Oncology Rehabilitation/
Pain Management

Stephen S. Grubbs, MD
Chief, Medical Oncology
Principal Investigator
Community Clinical
Oncology Program

Michael Guarino, MD
Director, Pharmaceutical
Clinical Trials

Christopher Koprowski, MD
Chair, Radiation Oncology

D. Bruce Panasuk, MD
Chief, Thoracic Surgery

Randolph C. Ragland, Jr.
Senior Health Physicist
NRC Region I
475 Allendale Road
King of Prussia, PA 19426

Re: Mail Control No.: 139062

Dear Mr. Ragland:

At your request, we are responding by fax to your e-mail of August 1, 2006 (see Attachment 1).

1. We clarify and confirm that we are requesting that Jon F. Strasser, M.D. be added as an Authorized Medical User(AMU) for 35.400; Yttrium-90 Sirspheres; Iodine-125-labeled IOTREX for use in the GliaSite RTS System; and Iridium -192 in a remote afterloading brachytherapy device(HDR).
2. Christopher Koprowski, M.D., Chair, Department of Radiation Oncology at Christiana Care, attests to Dr. Strasser's competency in an attached letter (see Attachment 2).
3. a)Dr. Strasser shall receive specific vendor training prior to any independent clinical procedures for patient treatment using the Proxima Therapeutics' GliaSite RTS based on I-125 IOTREX liquid brachytherapy and Proxima's delivery system.

b)Dr. Strasser shall receive specific vendor training prior to any independent clinical procedures for patient treatment using the Sirspheres microsphere delivery system using Sirspheres' Yttrium-90 microspheres.

MS 16
L-2
07-12153-02
03001303

139062

NMSS/RONI MATERIALS-002

August 2, 2006

Randolph C. Ragland, Jr.

Page 2

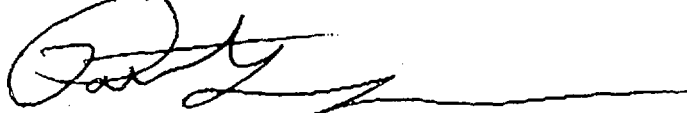
If you need further information or clarification please contact Dr.
Larry Simpson:

302-545-3870

LSimpson@ChristianaCare.org

He shall keep me fully-informed on progress in these matters.

Sincerely,

A handwritten signature in black ink, appearing to read 'Patrick A. Grusenmeyer', followed by a long horizontal line.

Patrick A. Grusenmeyer, ScD, FACHE
Vice President
Helen F. Graham Cancer Center

cc:

Larry D. Simpson, Ph.D., Director, Medical Physics
Joseph R. Solge, Jr., Radiation Safety Officer

Attachment 1-1

File: RaglandEmailResponse-20060801-Request for Additional Information.txt

From: Randolph Ragland [RCRI@nrc.gov]
Sent: Tuesday, August 01, 2006 6:26 PM
To: LSimpson@Christianacare.org
Subject: Request for Additional Information

Dr. Simpson,

NRC License No.: 07-12153-02
NRC Docket No.: 03001303
Mail Control No.: 139062

I reviewed your June 29, 2006 license amendment request and am requesting the following additional information. Please contact me at my number listed below if you have any questions. Also, please ensure that your response includes a management signature, and be sure to include Mail Control No. 139062 on all correspondence related to this issue.

1) Your amendment request letter dated June 29, 2006, requested an amendment to NRC License No. 07-12153-02, to add Jon Strasser, M.D. as an Authorized User under 35.400 [i.e., Manual Brachytherapy]. In our 8/1/2006, telephone conversation, you stated that you actually had intended to have Dr. Strasser added as an authorized user for the same materials and uses listed on your license (i.e., 35.400; Yttrium 90 SIRspheres; Iodine 125 for use in the GliaSite RTS System; Iridium 192 in a remote afterloading brachytherapy device).

Please confirm that you are requesting Jon F. Strasser, MD to be added as an authorized user for 35.400; Yttrium 90 SIRspheres; Iodine 125 for use in the GliaSite RTS System; Iridium 192 in a remote afterloading brachytherapy device.

2) We are requesting a more specific preceptor statement for Dr. Strasser. You can either obtain a more specific preceptor statement signed by Dr. Jay Harris, Brigham and Women's Hospital, or you could have one of the physicians who is currently authorized on Christiana Care Health Services license No. 07-12153-02 sign a preceptor statement for Dr. Strasser.

Option 1: In your July 22, 2005, amendment request, you provided an attestation statement for Jon Strasser, M.D. from Jay Harris, M.D. The attestation statement is considered vague because it states that Jon Strasser, M.D. has achieved a level of

1-2

File: RaglandEmailResponse-20060801-Request for Additional Information.txt

competency sufficient to function independent as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status.

In addition, although you provided in your June 29, 2006, amendment request documentation that Jay Harris, MD is listed on the Commonwealth of Massachusetts, Agreement Broad Scope License #44-0004, Permit #900, it was not clear that Dr. Harris was authorized for high dose rate remote afterloaders.

Please provide additional information that documents or confirms that Dr. Jay Harris is an Authorized User on Commonwealth of Massachusetts, Agreement BroadScope License #44-0004, Permit #900 and is authorized for 10 CFR 35.400 use and and Iridium 192 in a remote afterloading brachtherapy device, AND request Dr. Harris to re-submit a preceptor statement that specifically attests that Dr. Strasser has achieved a level of competency to function independently as an authorized user for 35.400 and Iridium 192 in a remote afterloading brachtherapy device.

OR

Option 2: Have a Physician that is a current authorized user on Christiana Care Health Services NRC License No. 07-12153-02 (e.g., Christopher Koprowski, M.D.) for the materials and uses for which Dr. Strasser is seeking authorization (e.g., 35.400; Yttrium 90 Sirspheres; Iodine 125 for use in the GliaSite RTS System; Iridium 192 in a remote afterloading brachtherapy device), review Dr. Strasser's qualifications, and sign and date a preceptor statement that attests that

"Dr. Strasser has achieved a level of competency to function independently as an authorized user for 35.400 and Iridium 192 in a remote afterloading brachtherapy device."

3) Please confirm that Dr. Strasser will receive vendor training in the use of microspheres and the microsphere delivery system prior to any independent clinical procedures using Yttrium-90 SIRspheres.

4) Please confirm that Dr. Strasser will receive vendor training in the use of Proxima Therapeutics' GliaSite RTS prior to any independent clinical procedures using I-125 Iotrex Liquid Brachytherapy Source in Proxima GliaSite Radiation Therapy

1-3

File: RaglandEmailResponse-20060801-Request for Additional Information.txt

System.

5) Please have a management representative sign the response, include Mail Control No. 139062, and fax your response to NRC Licensing Assistant Team at 610-337-5269.

Please contact me if you have any additional questions.

Regards,

Randolph C. Ragland, Jr.
NRC Region I
610-337-5083 (office)
610-337-5269 (fax)
610-310-7799 (cell phone)

Attachment 2

Mr Randolph Ragland
NRC Region I

August 2, 2006

Re: Jon Strasser

The purpose of this note is to attest that I have reviewed Dr Strasser's qualifications and Dr Strasser has achieved a level of competency necessary to function independently as an authorized user for 35.400 and Iridium 192 in a remote afterloading brachytherapy device.



Christopher Koprowski, MD, MBA
Chair, Department of Radiation Oncology
Helen F Graham Cancer Center
Christiana Care Health System

NRC License No. 07-12153-02

302 623 4800