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Yale
NewHaven
Health

March 16, 2018

License No.: 06-00819-03
Docket No.: 030-01244

U.S. Nuclear Regulatory Commission, Region I
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

SUBJECT: Yale New Haven Hospital Requests a License Amendment to Add the use of the Best Vascular, Inc., Beta-Cath™ Intravascular Brachytherapy (IVB) System

Gentlemen and women of the NRC,

Yale New Haven Hospital (YNHH) would like to amend NRC license 06-00819-03 to add the use of the Best Vascular, Inc., Beta-Cath™ Intravascular Brachytherapy (IVB) System. YNHH was previously authorized to use this system and recently dropped the authority from the license during our recent license renewal. However, clinical staff has expressed an interest in restarting the IVB program.

Although previously licensed to use the Beta-Cath™, YNHH will recommission the program in it's entirety, since the last clinical use of the system was over ten years ago.

Initially, all Authorized Users (AU), Authorized Medical Physicists (AMP) and Interventional Cardiologists/Radiologists affiliated with the program will complete vendor training in device operation, safety procedures and clinical use. New personnel added to the program after it's reinitiation, will be trained by an AU or AMP, as appropriate, authorized for the use of the same Beta-Cath™ IVB system. AU's and AMP's authorized for the program by the YNHH Radiation Safety Committee, will meet the training and experience requirements in 10 CFR 35.690, 10 CFR 35.51 or 10 CFR 35.57 (HDR, teletherapy and GSR units), as appropriate, in addition to the specific Beta-Cath™ training. Vendor training, or subsequently, on-site training by a Beth-Cath™ IVB approved AU or AMP, will include "hands-on" device operation, safety procedures, clinical use and treatment planning.

Radiation Safety Office
Radiological Physics
20 York St. – WWW 229
New Haven, CT 06510
Phone: (203) 688-2950
Fax: (203) 688-4135

RadiationSafetyGroup@ynhh.org

Clinical procedures will be conducted under the supervision of a Beth-Cath™ IVB approved AU who will consult with Interventional Cardiologist/Radiologist and AMP before initiating treatment. All procedures will be conducted with the Beth-Cath™ IVB approved AU or AMP physically present until the treatment is completed.

Written directives will be completed before treatment by the IVB AU, specifing treatment site, the radionuclide and dose.

The IVB AMP will perform an independent measurement of source output, before the first patient treatment, using a dosimetry system that meets the requirements of 10 CFR 35.630(a).

YNHH will develop, implement and maintain written emergency procedures for both stuck and detached sources, including the provision of appropriate emergency response equipment and any appropriate surgical procedures.

Patients receiving IVB treatment will be surveyed, along with the treatment catheter, immediately following source retraction or removal, to confirm complete retraction or recovery of all source(s), as specified by 10 CFR 35.404.

A dual syringe system will be used and an introducer sheath will also be used, unless it is contraindicated for an individual patient, for radiation safety purposes and to reduce the risk of a medical event.

If the AU wishes to perform "source stepping", YNHH will establish an appropriate procedure in writing.

The Beth-Cath™ IVB system will be kept in a locked Hot Lab during storage and will be accompanied by approved personnel, physically present at all times, when it is in transport or in use.

Maintenance and repair of the Beth-Cath™ IVB system will only be performed by the manufacturer or persons specifically licensed by the NRC or an Agreement State to perform such services and will be inspected and serviced at intervals recommended by the manufacturer.

Source separations during treatment will be evaluated as possible medical events.

The YNHH Radiation Safety Committee (RSC) reserves the authority to modify this program in the future, in response to updated NRC guidance or manufacturer's recommendations, under the following conditions:

(1) The revision is in compliance with the NRC regulations;

(2) The revision is based upon the NRC's current guidance for the Beth-Cath™ IVB System 35.1000 use, posted on the NRC web site;
(3) The revision has been reviewed and approved by the licensee's Radiation Safety Oficer (RSO) and management;
(4) The affected individuals are instructed on the revised program before the change is implemented;
(5) YNHH will retain a record of each change for five years; and
(6) The record will include a copy of the appropriate web site guidance, the old procedure, the effective date of the change, and the signature of the YNHH management that reviewed and approved the change.

If you have any further questions, please feel free to contact the Radiation Safety Officer at mike.bohan@yale.edu or (203) 688-2950.

Sincerely,

Michael J. Bohan
Radiation Safety Officer

Arthur P. Lemay, M.S., R.Ph.
Exec. Director, Smilow Cancer Hospital Network

cc: State of Connecticut - Dept. of Energy & Env. Protection, Rad. Control Unit
Marna P. Borgstrom, President, Chief Executive Officer

NRC FORM 532
(05-2016)

U.S. NUCLEAR REGULATORY COMMISSION

ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Michael J. Bohan
Radiation Safety Officer
Yale-New Haven Hospital
Radiological Physics - WWW 229
20 York Street
New Haven, Connecticut 06510

Date
March 23, 2018

License Number(s)
06-00819-03

Mail Control Number(s)
602673

Licensing and/or Technical Reviewer or Branch
Medical Branch

This is to acknowledge receipt of your: ☑ **Letter and/or** ☐ **Application** **Dated:** March 16, 2018

The initial processing, which included an administrative review, has been performed.

☑ **Amendment** ☐ **Termination** ☐ **New License** ☐ **Renewal**

☑ **There were no administrative omissions identified during our initial review.**

☐ **This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.**

☐ **Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf**

Follow the instructions on the form for submission.

☐ **The following administrative omissions have been identified:**

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
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