

March 30, 2020

License Reviewer
Materials Licensing Branch
US Nuclear Regulatory Agency – Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

RE: Materials License 21-08317-01, Munson Medical Center

Dear Reviewer,

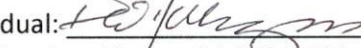
Neil Forster, M.D. is an authorized user on the Materials License. Please add to his Materials and Use 10 CFR 35.1000 (limited to strontium-90 in intravascular brachytherapy devices). Refer to included attestation from his supervising individuals for information regarding training and experience.

Sincerely,



Dennis Aurand, MS, DABR®
Diagnostic Medical Physicist
Radiation Safety Officer
daurand@mhc.net
phone: 231.392.8612

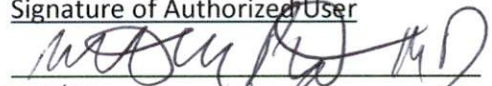
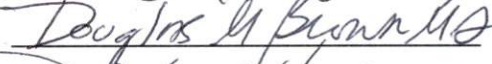

I attest that Neil Forster, M.D. has satisfactorily completed the 3 supervised cases using Strontium-90 as permitted by 10 CFR 35.1000 in a Best Vascular Inc. Model A1000 device. Training and experience have been satisfactorily completed and the individual is able to independently fulfill the radiation safety-related duties as an AU for the requested medical uses.

Supervising Individual:  David Heimburger, MD
Authorized User listed on License 21-08317-01

Hands-on training was received from the vendor (Best Medical) on January 11, 2018 and from Robert M. Prust, M.D. (an Authorized User) on March 15, 2019, which included the following items for correct device operation, safety procedures, and appropriate clinical use:

- Sterile technique requirements for the Beta-Cath™ system
- Priming of delivery catheter lumen with water before treatment
- Correctly confirming the vessel injury and length and delivery catheter location
- Proper connection of the delivery catheter to the transfer device
- Importance of keeping the hemostatic valve open for source delivery and retrieval
- Visually determining the presence or absence of the source train in the transfer device
- Sending the source train out of the transfer device into the catheter and to the vessel injury
- Identifying the source train location on fluoroscopy
- Proper timing of source train dwell within the vessel
- Appropriate pressure to apply to maintain the treatment position of the source train
- Process for switching syringes of water, if necessary
- Process for performing a "pullback" or "source stepping" in the case of a treatment area that is longer than may be acceptably treated by sending the source train to a single location
- Retrieval of the source train after the end of treatment
- Determining that the source train has returned to the transfer device
- Determining the appropriate parameters for treatment that are needed for the written directive
- Emergency procedures in case a source is not able to reach its destination in the patient or be returned to the transfer device, including:
 - o Keeping the delivery catheter and transfer device connected
 - o Ensuring that the delivery catheter is removed from the patient and placed in the "Bail-Out Box" to shield the source
 - o Radiation survey of the patient and area

Dr. Forster completed cases under the direct supervision of Authorized Users authorized for use of this 10 CFR 35.1000 intravascular brachytherapy device under our license (21-08317-01) on the following dates:

<u>Date</u>	<u>Supervising Authorized User</u>	<u>Signature of Authorized User</u>
March 15, 2019	Robert M. Prust, M.D.	
May 24, 2019	Doug Brown, M.D.	
November 11, 2019	David Keith Heimburger, M.D.	

Song, Taehoon

From: Gryglak, Magdalena
Sent: Monday, April 20, 2020 2:16 PM
To: Song, Taehoon; Pavon, Sandy
Cc: Tomczak, Tammy
Subject: FW: RE: Request to name Dr. Forster as an AU for 10 CFR 35.1000 (Sr-90 in IVB), NRC license no. 21-08317-01, Munson Medical Center
Attachments: 2020 March Forster IVBrachy amendment.pdf; NRC Attestation for Dr Forster 2020.pdf

Tae,
Please replace ML20092K002 with the attached. It is the same letter but with all signatures legible.

Thank you

MG

From: Aurand, Dennis <daurand@mhc.net>
Sent: Monday, April 20, 2020 10:36 AM
To: Gryglak, Magdalena <Magdalena.Gryglak@nrc.gov>
Subject: [External_Sender] RE: Request to name Dr. Forster as an AU for 10 CFR 35.1000 (Sr-90 in IVB), NRC license no. 21-08317-01, Munson Medical Center

See attached.

Dennis Aurand, MS, DABR® 
Radiation Safety Officer
Diagnostic Medical Physicist
Munson Medical Center
Traverse City, MI
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[Website](#) | [Maps](#)

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From: Gryglak, Magdalena [<mailto:Magdalena.Gryglak@nrc.gov>]
Sent: Monday, April 20, 2020 11:30 AM
To: Aurand, Dennis <daurand@mhc.net>
Subject: Request to name Dr. Forster as an AU for 10 CFR 35.1000 (Sr-90 in IVB), NRC license no. 21-08317-01, Munson Medical Center

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NEVER provide your login or password

Good morning Mr. Aurand,

I reviewed your request dated March 30, 2020 to name Dr. Forster as an AU for 10 CFR 35.1000 material. I have no follow up technical questions.

However, would you be able to send the original letter and the attestation form as a pdf file via email? Your request was faxed and the some of the signatures are not legible.

Thank you so much.

Magdalena R. Gryglak
U.S. NRC Region III
630-829-9875