

November 7, 2003

Mr. A. Carl Warner, M.S.
Warner Consulting
6002 Winthrop Avenue
Indianapolis, IN 46220-1942

SUBJECT: USE OF RADIATION ONCOLOGISTS DURING INTRAVASCULAR
BRACHYTHERAPY PROCEDURES

Dear Mr. Warner:

I am responding to your letter of October 16, 2003, addressed to Chairman Diaz, concerning the delay that you have experienced in receiving a response to the question that you submitted on August 15, 2003, via the U.S. Nuclear Regulatory Commission's (NRC) web site.

The absence of a timely response is a result of corruption of e-mail files in the Office of Nuclear Material Safety and Safeguards (NMSS), following an electrical power failure, that occurred at Headquarters, in Rockville, MD, on September 12, 2003. Your e-mail query was among those e-mails that staff is unable to view, pending restoration/recovery of the files. The recovery operation has been delayed several times, to ensure that the goal of nearly complete restoration is achieved. We apologize for the delay.

The question you asked was why can't a specially-trained cardiologist/physician, with the assistance of a specially-trained radiation physicist, deliver intravascular brachytherapy procedure treatments without the physical presence of a radiation oncologist/physician. The following addresses your query.

The question of which health professionals should comprise the team for the delivery of intravascular brachytherapy (IVB), and which type of physician should be in charge, was extensively considered by NRC and medical professional groups when the revised 10 CFR Part 35, "Medical Use of Byproduct Material," was under development.

For IVB medical usage licensing, current NRC web-site-available guidance, at <http://www.nrc.gov/materials/miau/miau-reg-initiatives/intravascular.html>, is as follows (example is for the Cordis Checkmate™ IVB system).

Authorized users should meet the training and experience requirements in either 10 CFR 35.490, "Training for use of manual brachytherapy sources," or until October 25, 2004, 10 CFR 35.940, "Training for use of brachytherapy sources."

The authorized user, interventional cardiologist/physician, and authorized medical physicist should receive the vendor training for use of the device.

Procedures should be conducted under the supervision of the authorized user, who would consult with the interventional cardiologist/physician and authorized medical physicist prior to initiating treatment. The procedures should be conducted in the physical presence of the authorized user or the authorized medical physicist

[emphasis added].

As is apparent from the above, NRC has already considered your question and revised its earlier licensing guidance. The previous guidance for IVB procedures called for the physical presence of the authorized user/physician (AU), the interventional cardiologist/physician, and the authorized medical physicist (AMP). Now, the guidance calls for IVB procedures to be conducted in the physical presence of the AU **or** the AMP, with the expectation that the interventional cardiologist/physician will always be present. A licensee that has a license condition requiring the physical presence of the AU **and** the AMP during IVB procedures can seek an amendment to modify its procedures to comport with the current web guidance. Moreover, such a licensee can also request authorization to modify its IVB procedures to comport with future adjustments to the web guidance without seeking an additional license amendment.

Information related to the question of what training should be required for the AU under whose supervision IVB procedures are conducted can be found in "Supplementary Information," Section III, "Summary of Public Comments and Responses to Comments," as published in the Federal Register on April 24, 2002. Specifically, refer to pages 20266 [Issue 1: "What is the appropriate level of training to require?"], at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=page+20249-20298, and 20320 [Issue 4: "Why are there no training requirements for endovascular brachytherapy in Subpart J?"], at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=page+20299-20348.

As noted above, training requirements for IVB AUs have not yet been codified, as the utilization remains developmental. In the future, current recommendations will be reevaluated, based on experience, and possibly revised.

If you have any further questions on this matter, please refer them to Ronald E. Zelac, Ph.D., Senior Health Physicist, Materials Safety and Inspection Branch (301/415-7635; rez@nrc.gov).

Sincerely,

Charles L. Miller, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

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/RA/

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