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Ms. Cathy Haney
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Ms. Haney:

Thank you very much for sharing your valuable time yesterday with Dr. Blitzer, Mr. Woods, and me to discuss training requirements regarding endovascular brachytherapy. Below I would like to provide you with a more formal, and hopefully more cogent, set of remarks as you prepare your notes for the Commissioners.

We in the radiation oncology community strongly advise against any present relaxation in training requirements with regards to endovascular brachytherapy for the following reasons:

1. It is internally inconsistent to argue for relaxation of training requirements based upon a "one anatomic site, one isotope" construct when a collaborative approach for many years has been policy in this country with regards to other anatomic sites of therapeutic administration.

As examples, the mutli-disciplinary approach between the radiation oncology and the urologic surgery and the neurosurgery communities, respectively, has yielded enviable records of efficacy and—more importantly, safety--in prostate permanent seed brachytherapy and Gamma Knife stereotactic radiosurgery. This cooperation also has led to several important technological advancements and has greatly improved our understanding of these techniques' radiobiologic mechanisms of action.

The "one anatomic site, one isotope" argument for relaxation of training requirements is further eroded as one recognizes that no single isotope—let alone one single type of emitter or delivery system—has emerged as the modality of choice for endovascular brachytherapy. Future data likely may suggest a role for a multitude of sources and delivery systems, as dictated by the clinical scenario. For example, a long, "shaggy" primary coronary arterial lesion may best be served by permanent placement of a beta-emitting Sr/Y-90 radioactive stent in conjunction with temporary high-dose rate Ir-192 brachytherapy; a markedly eccentric infra-inguinal arterial lesion by a liquid P32-filled balloon system; and a stenosed arteriovenous dialysis shunt by lower-dose rate Ir-192 alone.

2. It is also internally inconsistent to link the technical complexity of a given therapeutic radionuclide procedure with the requisite degree of training. The technical complexity, for example, in delivering a small administered activity of I-131 for benign thyroid disease is minimal. However, the breadth of knowledge required to fully understand the physical and biologic implications of this treatment is considerable. Imagine the counseling required when administering I-131 to a 20-year-old female comtemplating pregnancy and concerned about the long-term safety implications of treatment. It is this consideration which underlies the mandate that only appropriately trained endocrinologists and therapeutic radiologists/radiation oncologists (and not gastroenterologists or, for that matter, truck drivers!) be allowed to provide this service.

Based on this argument, I hold that radiation oncologists should participate fully in the informed consent process of any patient considering an endovascular brachytherapy procedure.

3. The argument that training requirements should be relaxed so that endovascular brachytherapy can be performed with less hindrance (ie, in a more timely or more widely available fashion) defies logic.

Endovascular brachytherapy is a very promising modality, but as with any new medical advance the potential for harm is greatest when a large number of inexperienced operators begin practicing an unfamiliar technique. The potential for harm is only magnified when training is cursory and oversight absent. This is precisely the situation that will ensue if radiation oncologists were excluded from the endovascular brachytherapy process. Instead of permitting for a lowering of standards, it is exactly in this context—a technique previously labelled as "high risk" by the FDA—that logic would insist upon the highest levels of training and familiarity with therapeutic radionuclide administration.

It also has been argued that maintaining current training requirements would inhibit access to care, as radiation oncologists would not be available to provide emergent services, especially in the setting of acute myocardial infarctions occurring in rural settings. This argument is seriously flawed. First, it would be most unusual for any medical center large and sophisticated enough to perform emergent "middle-of-the night" angioplasties to not have radiation oncology facilities. Secondly, the radiation oncologists on staff at these hospitals are required to follow the same guidelines regarding availability and call coverage as the other physician members of the hospital staff. We in the radiation oncology community routinely do treat patients with life-threatening illness at all hours of the day. Thirdly, it should be soundly noted that there is absolutely no evidence that endovascular brachytherapy is indicated in the setting of acute coronary syndromes. In fact, all human studies on the subject specifically exclude these patients. It is ridiculous to argue for a lessening of training requirements based on

the premise that patients with heart attacks will not be able to get prompt treatment when all investigations in the field have excluded these individuals!

Ms. Haney, I hope you will pass along these remarks to the Commissioners. Once again, thank you for meeting with us to listen to our concerns.

Very truly yours,

David A. Diamond, MD