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PROPOSED RULE PR 35
(62FR42219)

RE: REVISION OF 10 CFR PART 35

Dr. Donald A. Cool
U.S. Nuclear Regulatory Commission
11545 Rockville Pike
Rockville, MD 20852-2738

Dear Doctor Cool:

I would like to express my opinion regarding the proposed change in NRC training guidelines for the practice of teletherapy or brachytherapy.

Residency training in Radiation Oncology leading to certification by the American Board of Radiology, requires that a candidate spend at least 3 years and from this year onwards 4 years in active training which includes clinical teaching and didactic sessions in clinical oncology, Radiation Physics and Radiation Biology.

As Radiation Oncologists we routinely collaborate with a number of other specialists i.e., General Surgeons, Gastroenterologists, Urologists, etc. in the management of various cancers. In addition, we also treat a number of benign conditions i.e., keloids, heterotopic bone, hyperthyroidism, pterygium, hemangiomas, etc. I would like to emphasize at this point that unlike coronary brachytherapy the treatment of these benign conditions have been standardized after years of research and close clinical follow up. The question as to whether the radiation oncologist should be involved in the management of any one of these conditions has never risen in the past, so I wonder why such a question should be raised at this time with two experimental modalities like coronary brachytherapy and gamma knife radiosurgery. As you very well know, the present system has ensured that our patients receive the best quality treatment while the guidelines of radiation safety and protection have always been meticulously followed. I feel that the level of success thus far achieved comes from the sound understanding and close cooperation of the Radiation Oncologist, Physicist and Radiation Safety Officer. Any change in this system should be towards making the requirements more stringent to ensure better and safer use of radiation rather than diluting it by allowing non-Radiation Oncologists to perform brachytherapy procedures without the supervision of the Radiation Oncologist.

A few hours of lectures in Physics and Radiobiology will never give a non-Radiation Oncologist the expertise to independently use teletherapy or brachytherapy for the management of any benign or malignant disease. The field of Radiation Physics is very vast and constantly evolving, and even as Radiation Oncologists, it is very challenging to keep up with some if not all of these changes. Also, the invasion of Molecular Biology has given a new direction to Radiation Biology, and we are only beginning

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to understand some of the genetic mechanisms of radiation cell damage. A very important complication that we always consider in our patients is the long term risk of treatment induced cancer, especially when we use radiation to treat non-cancerous conditions. This is an area of intense research and agents with radioprotective effects are now beginning to be tested with the hope that such long term consequences could be reduced. Again, only carefully conducted clinical trials and long term follow up will give us answers to some of these very important questions. This being the case, the future practice of Radiation Oncology will see a lot of changes in teletherapy and brachytherapy that are guided by the results of these research endeavors that every Radiation Oncologist is a part of. I cannot see how a busy non-Radiation Oncologist would understand these issues and be able to keep up with or contribute to this learning process.

The practice of endovascular brachytherapy and gamma knife radiosurgery are relatively very new. There is not even a consensus on dose prescription or dose fractionation and knowledge of efficacy as well as complications is limited. In view of this and in light of the above discussion, I hope you would agree that changing the status quo towards dilution of training requirements for the clinician that uses teletherapy or brachytherapy will adversely impact patient care and impede the progress of clinical research.

Thank you for your consideration.

Sincerely,

Bharat B. Mittal, M.D.,
Assistant Professor & Chief
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BBM/dfr