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PROPOSED RULE PR 35
(62 F.R 42219)

OFFICE OF SECRETARY
RULFMAKINGS AND
ADJUDICATIONS STAFF

December 4, 1997

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

RE: Proposed changes to 10 CFR, Part 35

Dear Dr. Cool,

I am writing to recommend that when the NRC revises 10 CFR, Part 35, that there should be no changes in the training requirements for teletherapy or brachytherapy. The current requirements were carefully titrated over many years to maximize

patient safety and have served well in this regard.

Radiation safety depends on much more than specifying a radiation dose. Physicians who write radiation prescriptions at a minimum need to have a keen understanding of dose homogeneity, treatment volume, fractionation, dose rate, the tolerance of each individual organ and tissue to radiation, how medications affect radiation toxicity and efficacy, and the interactions between these factors. Gaining the knowledge necessary to safely prescribe radiation using brachytherapy requires vast experience. Resident physicians in radiation oncology training programs who are in their fourth year of training cannot prescribe these doses without attending physician oversight. Many physicians take fellowships in brachytherapy after completion of residency training in order to enhance their skill and experience in this area.

Authorized users of brachytherapy sources or teletherapy equipment should have at least three years of training in therapeutic radiology including at least 6,000 hours of direct clinical experience using radiation to treat patients. Specifically, these requirments should apply to the use of the Gamma-Knife and the use of gamma or beta sources for coronary artery brachytherapy. Both of these are high risk procedures for patients. Inappropriate prescriptions could easily be lethal or cause incapicitating morbidity. I should point out that despite the training requirements that are in place, accidents that injure patients sometimes occur anyway. In my opinion, the current guidelines minimize the risk of radiation damage to patients and

should be maintained.

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Flease call me if you would like to discuss my recommendations on this matter further or if you have any questions about my recommendation.

Sincerely yours,

Shiv R. Khandelwal, M.D.

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Medical Director