60



DOCKETED

## '98 JAN 12 P4:24

OFFICE OF SECRE AND RULEMAKINGS AND ADJUDICATIONS STAFF

PROPOSED RULE

(62FR42219)

Radiation Oncology Richard F. Evans, M.D., Inc. E. Wayne Torigoe, M.D., Inc. Francine Halberg, M.D. Lloyd Miyawaki, M.D., M.P.H. (415) 925-7326 FAX: (415) 925-7333

December 8, 1997

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

re: 10CFR Part 35

Dear Dr. Cool:

This letter is to emphasize the importance of current training requirements for brachytherapy and teletherapy. Radioactive sources showld definitely not be handled by physicians who do not have extensive training. In fact, the current training requirements have accomplished their mission. Patients have been protected. Using radiation safety requirements goes against the public's increasing concern about that very issue. The physician's involvement in radiation safety goes far beyond just prescribing a dose. Understanding how the sources are to be used, what a prescribed dose actually means, and the radiation safety issues both from a personnel standpoint and, more importantly, from the patient's standpoint, are crucally important.

It is inconceivable that training requirements for coronary artery brachytherapy should be any less than for brachytherapy used in the treatment of malignancies. In fact, in some situations the patients may have a much longer lifespan and therefore the risks from radiation injury are much greater. This applies whether a beta or a gamma source is used. Radiation to the heart must be considered a high-risk procedure. It would be ill-advised to lessen the training for uses of this equipment and technology to have less than the currently required 3 years of therapeutic radiology/radiation oncology.

In a similar vein, the training requirements for gamma knife radiosurgery have to be the same as that for all teletherapy. The treatment of brain parenchyma is similarly a very high risk procedure for the patient. Again, authorized users should have a minimum of 3 years in therapeutic radiology.

The board certification rendered by the American Board of Radiology certainly covers the necessary training. If other specialty boards are to be considered for credentialing users of these forms of radiation therapy, the standards have to be the same with respect to radiation therapy training. The ABR requires 6000 hours of direct clinical experience with radiation in order to establish competency. This requirement should not be lessened.

9801260084 971208 PDR PR 05 62FR42219 PDR



e Box 8010, San Raft 21 CA 94912-8010

(415) 925-7000

DSID

A Nonprofit Community Medical Center

DR. DONALD A. COOL December 8, 1997 page 2

Thank you so much for your consideration.

Yours sincerely,

Francine Halberg, M.D.

dc/12-9

.