(Attachment 2)

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January 7, 1991

The United States
Nuclear Regulatory Commission
Office of Nuclear Materials
Safety and Safeguards
Washington D.C., 20555

Dear Sir:

The purpose of this letter is to request that the USNRC review their restrictions on the use of Ir-192 and I-125 sources for brachytherapy purposes. The current standard use permitted by the USNRC, as found in the new subgroup G and in the old VI classification, permits the use of these isotopes for interstitial work only. The same section permits the use of Cs-137 for intracavitary, interstitial, and topical applications. In my opinion the division of brachytherapy into these three categories, namely intracavitary, interstitial, and topical, is not sufficient. Into what category should intraluminal applications be placed?

The restriction of I-125 seeds for interstitial work only does not reflect current practice in the U.S. As you are aware, the Cooperative Ocular Melanoma Study uses I-125 seeds contained in eye plaques for the treatment of ocular melanoma. Is such a plaque application an interstitial or topical procedure? Ir-192 is often used for an intraluminal procedure to treat recurrent carcinoma of the lung. When the source is placed into the appropriate location in the lung through a passage way through the nose, does that constitute an intracavitary procedure? However, when the same source is placed through a tracheostomy, which may be made exclusively for that purpose, does that constitute an interstitial procedure? As we are all aware, Ir-192 sources present the user with considerable flexibility in that they are able to adjust both the active length and the activity to meet a certain clinical situation. Such sources in the form of Ir-192 wire have been used for intracavitary applications for treatment of carcinoma of the cervix in France for several decades. Ir-192 seed ribbons have been used in the United States for treatment of carcinoma of the cervix using perineal templates for a number of years. However, it appears that it would be contrary to the USNRC regulations to use the same sources to treat the same condition if a GYN applicator is placed into the natural cavities of the body as opposed to needles placed interstitially.

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From the perspective of safety, Ir-192 is a less penetrating isotope which would result in a lower dose to the environs than Cs-137. The issues involved in the use of this isotope for intracavitary, mold, or intraluminal applications are no different when it's used for interstitial applications.

It is certainly true that individual institutions can apply for license amendments for special uses for these isotopes. In fact, I have recently requested that my institution do exactly that. However, in my opinion this is a unnecessary exercise and thus I'm requesting that USNRC review their reasons for such restrictions and clarify their vocabulary to include all brachytherapy procedures. Thank you very much for consideration of this request. I'll be happy to pro ide you additional information upon request.

Best Wishes,

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MG/kco