August 22, 2001

NOTE

FOR: FILE, NORDION THERASPHERES
NR-0220-D-113-S

FROM: John P. Jankovich
MSIB/IMNSS/NMSS

SUBJECT: LETTER FROM ROBERT M. HALLISEY
COMMONWEALTH OF MASSACHUSETTS

The staff responded to Mr. Hallisley's letter dated August 16, 2001, by telephone. Specifically, John Hickey, Chief, MSIB, Frederick Sturz, and Donna-Beth Howe called him on August 17, 2001. The NRC staff informed him that we consider the MDS Nordion Theraspheres brachytherapy sources, whose distribution is governed by the provisions of 10 CFR 32.74, "Manufacture and distribution of sources or devices containing byproduct material for medical use." Each microsphere is considered a brachytherapy source with the Y-90 sealed in the glass matrix. NRC included the Theraspheres in its sealed source and device registry (NRC Sealed Source and Device Registration Certificate No. NR-0220-D-113-S). Such a classification of the Theraspheres is consistent with FDA's approval of the Theraspheres as a medical device as well as with FDA's definition of a device in the US Food, Drug, and Cosmetic Act as Amended. The Theraspheres do not interact with the body chemically or physiologically; therefore, they are not a drug. Their function is to administer radiation to diseased tissue, similarly to other sources and devices as specified in 10 CFR 35.400.