

DCD

OCT 20 1989

St. Louis University
ATTN: Arthur Baue, M.D.
Vice President, Medical
Center
1402 South Grand Boulevard
St. Louis, MO 63104

License No. 24-00196-07

Gentlemen:

This refers to the telephone conversation on October 19, 1989, between Mr. Rodger Munday of your staff and Mr. Roy J. Caniano of my staff regarding the calculation error which affected a patient being treated at your facility on October 17, 1989 with an iridium-192 afterloading device.

Based on that conversation, it is our understanding, that to prevent a recurrence of this type of error, you will immediately:

1. Assure that at least two individuals review dose calculations for all high intensity iridium-192 afterloading implants prior to the initiation of treatments. The individuals will consist of a physicist, a dosimetrist and/or a radiotherapist. The review of the calculations will be documented and maintained.
2. Review your quality assurance procedures currently referenced in your license with regard to use of the afterloading device and provide to this office within 30 days, in the form of an amendment request, a revised quality assurance procedure that, at a minimum, will incorporate the procedures for review of dose calculations as stated in Item No. 1.
3. Review your procedures with regard to your other therapy programs to ensure that sufficient quality assurance procedures exist to preclude similar errors from occurring.

Issuance of this Confirmatory Action Letter does not preclude the issuance of an Order requiring implementation of the above commitments. If your understanding differs from that set forth above, please call this office by telephone (312) 790-5500.

Sincerely,

Original signed by
A. Bert Davis

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REG3 LIC30
24-00196-07 PDC

A. Bert Davis
Regional Administrator

See Attached Distribution

RIII

Caniano
10/2/89

RIII

Mallett
10/20/89

RIII

Martini
10/20/89

RIII

Grobe
10/20/89

RIII

Paparello
10/20/89

RIII

Davis
10/20

CONFIRMATORY ACTION LETTER

yes
10/20/89
1/0

St. Louis University

2

OCT 20 1989

Distribution:

cc: James Fletcher, M.D.,
St. Louis University
Medical Center
DCD/DCB (RIDS)

bcc: J. Clifford, OEDO
J. Lieberman, OE
P. Golberg, OGC
R. Bernero, NMSS
J. Glenn, NMSS