

December 27, 1993

Mr. W. L. Axelson, Director Division of Radiation Safety and Safeguards United States Nuclear Regulatory Commission Region III 801 Warrenville Rd. Lisle, IL 60532-4351

> RE: Docket No. 030-02101 License No. 21-11494-01

Dear Mr. Axelson:

The purpose of this correspondence is to acknowledge receipt of your Confirmatory Action Letter dated December 22, 1993.

The agreement to discontinue brachytherapy until such time as the Hospital develops and submits its Quality Management Program has been communicated to our radiation oncologist, Joel Nass, D.O. (copy enclosed).

I trust these actions are consistent with your directives.

Sincerely,

Robert A. Deputat

Vice President of Operations

RAD/jf

cc: Anthony R. Tersigni, Ed.D., FACHE

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December 22, 1993

Dr. Joel Nass 28595 Orchard Lake Road, Ste. 110 Farmington Hills, MI 48334

Dear Dr. Nass:

The Nuclear Regulatory Commission (NRC) conducted an extensive two day inspection visit on December 20 and 21, 1993. Several concerns were raised relative to our compliance to Commission requirements pertaining to established guidelines and protocols for safely handling isotopes used in brachytherapy. Conspicuous by its absence was the Quality Management Program required to have been filed with the NRC prior to January, 1992.

Subsequent to completion of the survey visit, I received a telephone call from Jack Grobe, Chief, Nuclear Material Safety Section 2 requesting that we immediately cease performing implant brachytherapy until such time as our Quality Management Program has been completed, approved by the Radiation Safety Committee and filed with the NRC. The purpose of this correspondence is to advise you that I have agreed to comply with his request.

The Hospital has been advised that further sanctions, potentially including civil penalties may be imposed. I will advise you of further details as they become available. Perhaps you, Dr. Porter and I should meet in the very near future to develop a strategy which will satisfy the regulations. Thank you in advance for your assistance in this regard.

Sincerely,

Robert A Debutat

Vice President of Operations

RAD: vam

cc. Dr. Feinman, Radiation Safety Director

Dr. Wolfe, Medical Director

Dr. Anthony R. Tersigni, President/Chief Executive Officer

Thomas Marsh, Radiology

Kathleen Gaffney, V.P. of Nursing