

30-01615 DCB

February 7, 1991

J. Paige Clousson and Associates
ATTN: J. Paige Clousson
Attorney
39 South LaSalle Street
Suite 707
Chicago, IL 60603

Gentlemen:

This is in response to your letters of January 8 and 9, 1991, regarding the Audit Report of the brachytherapy program at St. Mary Medical Centers in Hobart and Gary performed in accordance with the Commission's Order of April 27, 1990. We appreciate your advising us that Dr. Sarma agrees with the independent auditors' report. However, some of your other comments merit a more detailed response.

Several of your comments pertain to the review of documents by our inspectors and our physician-consultant. Your comment that the NRC inspectors relied solely on hospital records to the exclusion of records at the Diagnostic Outpatient Center (DOC) is incorrect. After initially reviewing the hospital records and concluding, in many cases, that they were inadequate for us to reach firm conclusions regarding whether medical misadministrations occurred, our inspectors went to the DOC on two occasions to obtain any additional documents and information Dr. Sarma could provide. Specifically, on April 5, 1990, Mr. King, a radiation specialist, went to the DOC and reviewed 10 files, but found nothing which provided additional information regarding the prescribed doses. Later that day, another radiation specialist, Mr. Mullauer, and his section chief, Mr. McCann, went to the DOC. They interviewed Dr. Sarma at the DOC who advised that there was unlikely to be anything new in his files regarding prescribed doses because it was often his practice to not reduce his prescriptions to writing. Dr. Sarma made his files available and Mr. McCann reviewed a sample of them. Mr. McCann found nothing that was useful in helping him determine a prescribed dose for the cases in question.

You also noted that the NRC physician-consultant did not review documents at the DOC. That is correct. However, as a medical professional, he reviewed whatever records he considered necessary to form the conclusions he reached.

We agree with you that the licensee's revised quality assurance plan should assure that there is a set of rules of record keeping between the hospital and the DOC. This plan should also assure a properly implemented brachytherapy program. It is also our view that if the previous version of the quality assurance plan had been implemented, these objectives would have been achieved in a more timely manner.

IE 07
11

With regard to your suggestions concerning our final report on the brachytherapy program, please be assured that the NRC staff members involved in these inspections were fully qualified to evaluate the regulatory aspects of the St. Mary Medical Centers' brachytherapy program and recognized the non-industrial nature of the program. NRC inspectors are trained to inspect a broad spectrum of NRC licensed medical programs. Different means are used to determine compliance with the requirements, including the review of licensee records, observation of licensee work practices, evaluation of the licensee's administrative and management controls, and appropriate use of NRC medical consultants. Our review of records, including those maintained at the DOC, was discussed above. In this case, we also used the services of a physician consultant as part of this evaluation.

Our purpose in this inspection was not to require any new pretreatment steps or inject ourselves into medical decisions, but rather to determine if sufficient information existed to determine that the radiation dose administered to the patients was administered in a safe, controlled manner in accordance with existing facility license conditions and NRC regulations and was that dose intended to be administered by the physician.

If you have any questions concerning these matters, please contact Mr. John A. Grobe of my staff at (708) 790-5512.

Sincerely,

Original signed by
A. Bert Davis

A. Bert Davis
Regional Administrator

cc w/ltrs dtd 01/08/81 &
01/09/91:
S. H. Pratt, Hall, Render,
Killian, Heath & Lyman
B. Kaminski, St. Mary
Medical Centers
DCD/DCB (RIDS)
Materials License
File Nos. 13-0359-02;03

bcc w/ltrs dtd 01/08/91 &
01/09/91:
J. Lieberman, OE
J. Goldberg, OGC
R. Bernero, NMSS
J. Mullauer, RIII

<i>WJH</i> RIII <i>yes</i> Grobe 02/7/91	<i>BB</i> RIIII Bertson/db 02/7/91	<i>yes</i> RIIII <i>yes</i> Northus 02/7/91	<i>by telephone</i> NMSS <i>for John Glenn</i> Glenn 02/7/91	<i>No legal collection</i> OGC <i>for LC by telephone</i> Chandler 02/7/91	RIIII <i>D</i> Paperiello 02/7/91	RIIII <i>D</i> Davis 02/7/91
--	---	---	--	--	--	---------------------------------------