

UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

In the Matter of	)	
	)	
ST. MARY MEDICAL CENTER -	)	Docket No. 030-31379-OM
HOBART	)	
ST. MARY MEDICAL CENTER -	)	Docket No. 030-01615-OM
GARY	)	
(Order Suspending Brachytherapy	)	ASLBP No. 90-612-04-OM
Activities and Modifying	)	EA No. 90-071
License)	)	

SETTLEMENT AGREEMENT

The United States Nuclear Regulatory Commission Staff (hereinafter "NRC Staff"), St. Mary Medical Center-Hobart and St. Mary Medical Center-Gary (hereinafter collectively referred to as "Licensees") and Koppolu P. Sarma, M.D. (hereinafter "Dr. Sarma") in comprehensive settlement of all issues raised in this proceeding hereby agree as follows:

1. That, on April 27, 1990, an Order Suspending Brachytherapy Activities and Modifying License (hereinafter "Order") was issued by the NRC. The Order, among other things, provided for the immediate suspension of certain portions of Licensees' licenses pertaining to brachytherapy treatments carried on at Licensees' facilities and required Licensees to "retain an independent medical consultant or organization to assist with the audit of all appropriate records and patient medical files of the brachytherapy department since program inception."

2. That, on May 17, 1990, Licensees filed an Answer in which certain allegations contained in the Order were admitted and certain allegations contained in the Order were denied because the Licensees were without knowledge or information sufficient to form a belief as to the veracity of those certain factual allegations. Nothing

contained in this Settlement Agreement shall be taken as an admission by Licensees, or Dr. Sarma, of any fact or conclusion not otherwise admitted in Licensees' Answer or in the Answer filed by Dr. Sarma.

3. That, in conjunction with their Answer, Licensees also filed a request for a hearing on the Order.

4. That, on May 17, 1990, Dr. Sarma submitted a petition to intervene, a request for a hearing on the Order, and an Answer, and that Dr. Sarma was admitted as an intervenor to the proceedings in this matter by Prehearing Conference Order of the Atomic Safety and Licensing Board dated June 26, 1990.

5. That, by letter dated September 28, 1990, Licensees nominated an audit group (hereinafter "Independent Auditor") and by letter dated November 7, 1990, Licensees submitted an Audit Plan, which includes a provision for submission of a written report to the NRC at the completion of the audit, pursuant to the terms of Item V.B of the Order, as last modified by the Regional Administrator, Region III, on October 30, 1990.

6. That the NRC Staff regards any written report of the audit provided to the NRC Staff as an agency record and, as such, the public availability of the report is as prescribed in 10 C.F.R. § 2.790 (Availability of Official Records) and 10 C.F.R. Part 9, Subpart A (Freedom of Information Act Regulations).

7. That, in accordance with the guidance regarding press releases in the NRC Enforcement Manual, in the event the NRC Staff decides to issue a press release concerning matters in this settlement agreement, such press release will not be issued until 24 hours after the Licensees and counsel for Dr. Sarma have been notified and

provided a copy of the press release that is substantively the same as the press release to be issued.

8. That, by this Settlement Agreement, the NRC Staff agrees that the conclusions, opinions and recommendations in the Independent Auditor's written report shall solely be the conclusions, opinions and recommendations of the Independent Auditor, and Dr. Sarma and Licensees agree that in the event that either Dr. Sarma or Licensees do not agree with the written report of the Independent Auditor, the party disagreeing with any of the conclusions, opinions or recommendations of the Independent Auditor will submit to the NRC Staff an explanation of the bases for such disagreement within thirty (30) days of the party's receipt of the Independent Auditor's written report.

9. That, by this Settlement Agreement, Licensees agree to timely make the required reports of any misadministration in compliance with 10 C.F.R. § 35.33 that the Licensees may discover as a result of the audit, as required in Item V.B. of the Order, and the NRC Staff agrees that, regarding misadministrations that may be discovered as a result of the audit, the time for making the notifications required in 10 C.F.R. § 35.33, or any other rule or regulation regarding misadministrations, shall be computed from delivery of the Independent Auditor's written report to the Licensees.

10. That, by this Settlement Agreement and in consideration of Licensees undertaking a comprehensive audit by the Independent Auditor of all appropriate brachytherapy records and patient medical files since program inception, the NRC Staff agrees that it will not assess civil penalties against Licensees or Dr. Sarma as a result of any nonwillful violations of any statute, rule or regulation involving the operation of the Licensees' brachytherapy program from its inception to the date of the issuance of the Order. Notwithstanding that the NRC Staff has not identified, as of the date of its

approval of the Audit Plan, any willful violations involving the operation of the Licensees' brachytherapy program, nothing in this condition shall be construed to prevent the NRC Staff from taking enforcement action as a result of any willful violations, as willful is defined in 10 C.F.R. Part 2, Appendix C, Section III, which may be identified as a result of the Licensees' audit or as a result of any subsequent investigation by the NRC Staff. Further, nothing in this condition shall be construed to prevent the NRC Staff from issuing a Notice of Violation without proposed civil penalty for any nonwillful violation of any rule or regulation involving the operation of the Licensees' brachytherapy program which may be identified as a result of the Licensees' audit or as a result of any inspection or investigation by the NRC Staff.

11. That, by this Settlement Agreement, the NRC Staff agrees that the remaining requirements of Item V.B. of the Order, to wit, the completion of the audit with submission of results to the NRC and notifications pursuant to 10 C.F.R. § 35.33, is met when the Independent Auditor's written report is in the hands of the NRC Staff and the items in Condition 9. of this Settlement Agreement are complete.

12. That, by this Settlement Agreement, Licensees agree that they will continue to comply with and will not challenge Item V.A of the Order.

13. That the NRC Staff, Licensees, and Dr. Sarma agree to file a joint motion with the Atomic Safety and Licensing Board ("Board") for an Order approving this Settlement Agreement and terminating this proceeding.

14. That this settlement agreement shall become effective upon approval by the Board and that in the event the Board does not approve this settlement agreement, it shall be null and void.

FOR THE NRC STAFF

By: Susan Chidakel Dated: 12/17/90  
Susan Chidakel  
Counsel for NRC Staff

By: Eugene Holler Dated: 12/17/90  
Eugene Holler  
Counsel for NRC Staff

ST. MARY MEDICAL CENTER-HOBART  
ST. MARY MEDICAL CENTER-GARY  
("LICENSEES")

By: Stephen W. Lyman Dated: 12/11/90  
Stephen W. Lyman

By: Steven H. Pratt Dated: 12/11/90  
Steven H. Pratt  
Attorneys for Licensees

KOPPOLU P. SARMA, M.D. ("INTERVENOR")

By: J. Paige Clousson Dated: 12/14/90  
J. Paige Clousson  
Attorney for Koppolu P. Sarma, M.D.

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NUCLEAR REGULATORY COMMISSION

DOCKETED  
USNRC

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OFFICE OF SECRETARY  
DOCKETING & SERVICE  
BRANCH

CERTIFICATE OF SERVICE

I hereby certify that copies of "JOINT MOTION OF PARTIES FOR APPROVAL OF SETTLEMENT AGREEMENT AND TERMINATION OF PROCEEDING" in the above-captioned proceeding have been served on the following by deposit in the United States mail, first class, or as indicated by an asterisk through deposit in the Nuclear Regulatory Commission's internal mail system, this 17th day of December, 1990:

Charles Bechhoefer, Chairman\*  
Administrative Judge  
Atomic Safety and Licensing Board  
Panel  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555

Dr. Walter H. Jordan  
Administrative Judge  
881 W. Outer Drive  
Oak Ridge, TN 37830

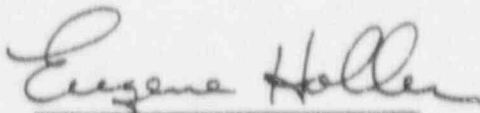
Office of the Secretary\*  
Attn: Docketing & Service Section  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555

Dr. Jerry R. Kline\*  
Administrative Judge  
Atomic Safety and Licensing  
Board Panel  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555

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Atomic Safety and Licensing  
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