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LBP-90-46

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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ATOMIC SAFETY AND LICENSING BOARD

Before Administrative Judges:

Charles Beenhoefer, Chairman
Dr. Walter H. Jordan
Dr. Jerry R. Kline

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In the Matter of

ST. MARY MEDICAL CENTER--
HOBART

Docket No. 030-31379-OM

ST. MARY MEDICAL CENTER--
GARY

Docket No. 030-01615-OM

(Order Suspending
Brachytherapy Activities
and Modifying License)

ASLBP No. 90-612-04-OM

EA No. 90-071

December 26, 1990

MEMORANDUM AND ORDER
(Order Approving Settlement Agreement)

This proceeding involves an immediately effective order, dated April 27, 1990,¹ modifying the byproduct materials licenses of St. Mary Medical Center--Hobart and Gary (hereinafter, Licensees) to (1) suspend brachytherapy activities under those licenses (subject to certain conditions) and (2) require an audit of past brachytherapy activities. Parties are the Licensees, the NRC Staff, and

¹The Order was published at 55 Fed. Reg. 19376 (May 9, 1990).

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Dr. Koppolu P. Sarma (Intervenor).² For further details, see our Memorandum and Order (Schedules for Filings and Prehearing Conference), dated May 30, 1990 (unpublished) and our Prehearing Conference Order, LBP-90-21, 31 NRC 589 (June 26, 1990).

At the prehearing conference, the Licensing Board granted the parties' joint motion to defer the proceedings for 30 days to accommodate ongoing settlement negotiations, with a report to be filed if settlement was not reached. Thereafter, based on status reports filed by the parties (at the Board's direction), the Board on several occasions granted the parties' further joint motions to extend the dates for deferral of proceedings. Memoranda and Orders dated July 24, 1990, August 23, 1990, October 3, 1990, and December 6, 1990 (all unpublished). The latest of these orders noted the parties' agreement that the Licensees were in compliance with the modification order and extended the deferral as long as the Licensees remained in compliance, retaining authority for the Board to resolve certain potential disputes arising out of the prescribed audit (which had been undertaken but not yet reported).³

²A Notice of Hearing and Prehearing Conference was issued on May 31, 1990 and published at 55 Fed. Reg. 23157 (June 6, 1990).

³We required a further report by January 14, 1991, if settlement was not reached by that date.

On December 17, 1990, the parties to this proceeding jointly filed a proposed settlement agreement. (A copy of this agreement is attached hereto.) The agreement apparently predates the receipt (or at least the evaluation) of the audit report. It leaves the modification order in effect, thus precluding brachytherapy activities at the hospital except as may be permitted by NRC under specified conditions (i.e., based on certifications to be provided to the Region III Administrator concerning certain aspects of the brachytherapy program).

The agreement further designates the violations thus far discovered to be non-willful and defines the scope of further enforcement activities arising from the audit. No civil penalties are to be imposed for past non-willful violations (such as misadministrations), although the Staff retains the right to impose other corrective actions based on audit findings. The agreement also establishes a time frame for the reporting to the NRC of any misadministrations uncovered by the audit.

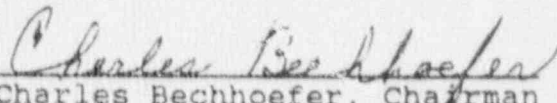
Our authority to approve the settlement of proceedings of this type stems from 10 C.F.R. § 2.203, which requires that any such settlement accord "due weight to the position of the staff" as well as the "public interest." The parties jointly express their belief that termination of this proceeding on the basis of the settlement agreement "is in the public interest." Inasmuch as the modification order

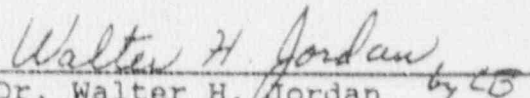
remains in effect as originally intended and the parties challenging the order no longer wish to do so, we agree with that evaluation, noting that, in our view, the settlement in fact accords "due weight to the position of the staff." Accordingly, the parties' joint motion is granted and, subject to the terms of the settlement agreement, this proceeding is hereby terminated.

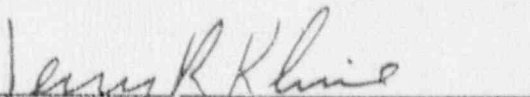
This order is subject to Commission review pursuant to 10 C.F.R. § 2.762. Absent any such review, this order shall become the final action of the Commission thirty (30) days from the date of its issuance. 10 C.F.R. § 2.760(a).

IT IS SO ORDERED.

THE ATOMIC SAFETY AND
LICENSING BOARD


Charles Bechhoefer, Chairman
ADMINISTRATIVE JUDGE


Dr. Walter H. Jordan
ADMINISTRATIVE JUDGE


Dr. Jerry R. Kline
ADMINISTRATIVE JUDGE

Bethesda, Maryland
December 26, 1990

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

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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 Settlement Manual, in the event the NRC Staff decides to issue a press release regarding matters in this settlement agreement, such press release will not be issued 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.

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of

ST. MARY MEDICAL CENTER - HOBART
AND BARY
(Byproduct Material License Nos.
13-03459-03 and 13-03459-02)

Docket No. (e) 20-31379/1615-0M

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing LB M&O (LBP-90-46) DTD 12/26 have been served upon the following persons by U.S. mail, first class, except as otherwise noted and in accordance with the requirements of 10 CFR Sec. 2.712.

Atomic Safety and Licensing Appeal
Board
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Administrative Judge
Charles Bechhoefer, Chairman
Atomic Safety and Licensing Board
U.S. Nuclear Regulatory Commission
Washington DC 20555

Administrative Judge
Walter H. Jordan
Atomic Safety and Licensing Board
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Administrative Judge
Jerry R. Kline
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U.S. Nuclear Regulatory Commission
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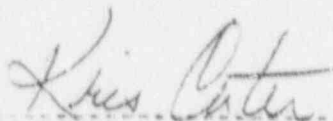
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A. Bert Davis
Regional Administrator, Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Dated at Rockville, Md. this
26 day of December 1990


Office of the Secretary of the Commission