NUCLEAR REGULATORY COMMISSION

In the Matter of Henry Ford Hospital Detroit, Michigan

Docket No. 030-00274 License No. 21-04109-08 EA 94-046

CONFIRMATORY ORDER RESCINDING CONFIRMATORY ORDER DATED JULY 17, 1984

I

Henry Ford Hospital (Licensee) is the holder of NRC License No. 21-04109-08 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 35. The license authorizes the Licensee to possess and use cobalt-60 for medical use as described in 10 CFR 35.600 in an AECL Theratron 780 teletherapy unit, and for irradiation of animals. The license was issued on August 2, 1957, was most recently amended in its entirety on February 14, 1994, and is due to expire on November 30, 1998.

H

As a result of a teletherapy misadministration which occurred in early 1984, the NRC issued a Confirmatory Order dated July 17, 1984, which ordered the Licensee to implement a Teletherapy Treatment Quality Assurance Program as described in Section II of the Order (EA 84-067). In accordance with 10 CFR 35.32(f)(2) the Licensee submitted a written quality management program to the NRC on January 23, 1992. In a letter dated April 8, 1993, the Licensee requested the NRC to rescind the 1984 Order for the following reasons: (1) all subsequent NRC inspections have found the Licensee to be in compliance with the 1984 Order; (2) no therapeutic misadministrations have occurred at Henry Ford Hospital since the 1984 Order was issued; and (3) regulatory

9403300009 940328 PDR ADDCK 03000274 C PDR changes in 10 CFR Part 35 pertaining to the Quality Management Program encompass all aspects of the 1984 Order.

III

In December 1993 the NRC's Division of Industrial and Medical Nuclear Safety completed a review of the licensee's 1992 Quality Management Program submittal. Subsequently, in a letter dated March 1, 1994, the NRC notified the Licensee that its Quality Management Program, as set forth in its letter dated January 23, 1992, appears to meet the requirements of 10 CFR 35.32. In addition, the NRC staff agrees with the Licensee that the actions required by the 1984 Order are superseded by current regulatory requirements.

I find that the Licensee's Quality Management Program encompasses the requirements of the Teletherapy Treatment Quality Assurance Program required by the 1984 Order. Therefore, the 1984 Order should be rescinded.

IV

Accordingly, pursuant to sections 81, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR Part 35, IT IS HEREBY ORDERED THAT THE CONFIRMATORY ORDER ISSUED TO THE LICENSEE ON JULY 17, 1984 (EA 84-067) IS RESCINDED.

Any person adversely affected by this Confirmatory Order, other than the Licensee, may request a hearing within 20 days of its issuance. Any request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Docketing and Service Section, Washington, D.C. 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351, and to the Licensee. If such a person requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order should be sustained.

In the absence of any request for hearing, the provisions specified in Section IV above shall be final 20 days from the date of this Order without further order or proceedings.

FOR THE NUCLEAR REGULATORY COMMISSION

James Lieberman, Director Office of Enforcement

Dated at Rockville, Maryland this 28 Taday of March 1994

## Henry Ford Hospital

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