

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of)	
)	Docket No. 030-32493
RADIATION ONCOLOGY CENTER)	License No. 29-28685-01
AT MARLTON)	EA 93-041
Marlton, New Jersey)	

CONFIRMATORY ORDER MODIFYING LICENSE
(EFFECTIVE IMMEDIATELY)

I

Radiation Oncology Center at Marlton (licensee) is the holder of NRC License No. 29-28685-01 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Parts 30 and 35. The license authorizes the licensee to possess iridium-192 sealed sources for use in an Omnitron International, Inc. Model 2000 high dose rate (HDR) after-loading brachytherapy unit (HDR) for the treatment of humans. The license initially was issued on January 17, 1992, and is due to expire on January 31, 1997.

II

NRC Region I staff conducted a routine safety inspection of the subject license on February 2 and 4, 1993. During this inspection, apparent violations of NRC requirements related to the implementation of the licensee's radiological safety program were identified. Of particular concern to the NRC was the lack of radiation safety program oversight by the Radiation Safety Officer (RSO) in discharging her licensed responsibilities and the lack of knowledge demonstrated by the RSO/Authorized User and her staff of the license conditions and the routine and emergency

operation of the HDR. The inspectors also determined that the iridium-192 source authorized under the NRC license was removed from the licensee's HDR unit by the manufacturer on February 2, 1993 and subsequently returned to the manufacturer for disposal on February 3, 1993.

III

As a result of concerns expressed by NRC Region I officials over the apparent violations, the licensee agreed to certain actions. By a confirmatory action letter (CAL) dated February 5, 1993, from Richard W. Cooper, II, Director, Division of Radiation Safety and Safeguards, NRC, Region I, to the licensee, the NRC confirmed that the licensee had agreed that:

1. It would not obtain any sources of radioactive material authorized under its license until specifically authorized in writing by the Director, Division of Radiation Safety and Safeguards, NRC, Region I.
2. By February 10, 1993, it would provide the NRC Region I office with a complete printout of the operational data stored in its Omnitron Model 2000 HDR computer memory, including error messages, and a written explanation for each individual code. In addition, by February 18, 1993, the licensee would submit to the NRC Region I office a report

that assessed, for each patient treatment that it had performed using the HDR, whether a misadministration had occurred. In making this determination, the licensee, as a minimum, would compare the HDR computer data with the written patient prescription and calculated doses.

3. It would take actions required by 10 CFR Part 35, including reporting and notification, if its review revealed that a misadministration had occurred.

The CAL provided that the issuance of the CAL did not preclude the issuance of an order formalizing the above commitments.

By letter dated February 9, 1993, the licensee reaffirmed its commitment not to receive any radioactive sources without authorization from Region I and submitted a printout of the operational data stored in its Omnitron Model 2000 HDR computer memory, including error messages, and a written explanation for each individual code. The licensee also stated that an audit of all treatments conducted at its facility would begin on February 12, 1993, and that the results of this audit, including any misadministrations identified, would be forwarded to the NRC. By letter dated February 12, 1993, the licensee submitted the results of the February 12, 1993 audit, concluding that they had

no misadministrations. Both submittals required by Item 2 of the CAL have been received and are under staff review. The licensee also satisfied Item 3.

I find that the licensee's commitment as set forth in Item 1 of the February 5, 1993 letter is still necessary and conclude that with adherence to this commitment, the public health and safety is reasonably assured. For the reasons described above, I have determined that the public health and safety require that the licensee's commitment as set forth in Item 1 of the February 5, 1993 CAL be confirmed by this Order. Pursuant to 10 CFR 2.202, I have also determined that the public health and safety require that this Order be immediately effective. The licensee consented to the issuance of this Confirmatory Order during a March 5, 1993 telephone call between Mr. Richard Cooper and Ms. Pamela Henderson of the NRC Region I Office and Dr. Horowitz, Radiation Safety Officer, acting on behalf of the licensee.

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 Parts 30 and 35, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT LICENSE NO. 29-28685-01 IS MODIFIED AS FOLLOWS:

Pending further action by the NRC: (1) any NRC-licensed material possessed by the licensee shall be placed and maintained in a locked, stored, and shielded condition; and (2) the licensee may not receive any NRC-licensed material. All other requirements of the license continue in force.

The Regional Administrator, Region I, may relax or rescind, in writing, the above condition upon a showing by the licensee of good cause.

V

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 I, 475 Allendale Road, King of Prussia, PA 19406, 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.

Pursuant to 10 CFR 2.202(c)(2)(i), 57 Fed. Reg. 20194 (May 12, 1992), any person other than the licensee adversely affected by this Order, may, in addition to demanding a hearing, at the time the hearing request is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error.

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. AN

ANSWER OR A REQUEST FOR HEARING SHALL NOT STAY THE IMMEDIATE
EFFECTIVENESS OF THIS ORDER.

FOR THE NUCLEAR REGULATORY COMMISSION


Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards,
and Operations Support

Dated at Rockville, Maryland
this 9th day of March 1993

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Radiation Oncology Center
at Marlton

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