UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. 030-31765
	)	License No. 37-28540-01
	)	
DR. DAVID E. CUNNINGHAM	)	Docket No. 030-03151
	)	License No. 37-11866-01
Indiana, Pennsylvania	)	
	)	Docket No. 030-00472
	)	License No. 37-02385-01
	)	
	)	Docket No. 030-33297
	)	
	)	EA 94-007

DEMAND FOR INFORMATION

I

Dr. David E. Cunningham is named as an authorized user and medical physicist in Condition 12 on Byproduct License No. 37-11866-01 issued to Lancaster General Hospital by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Parts 30 and 35. That license authorizes use of byproduct material under 10 CFR Parts 35.100, 35.200, 35.300, 35.400, 35.500; use of cesium-137 for calibrations of instruments; and use of iridium-192 in a high dose rate remote (HDR) afterloader. Dr. Cunningham also is named as the teletherapy physicist on Byproduct License No. 37-02385-01 issued to Carlisle Hospital by the Commission pursuant to 10 CFR Parts 30 and 35. That license authorizes the use of cobalt-60 in accordance with 10 CFR 35.600. Additionally, Dr. Cunningham is named as the medical physicist on an application for a license pursuant to 10 CFR Parts 30 and 35 filed on August 19, 1993 by Capital Area R. T. Associates, Oakwood Center Radiation Oncology. The application seeks

authority to use byproduct material in an HDR afterloader for the interstitial intercavitary treatment of carcinoma.

II

Between August 3, 1990 and April 2, 1993, Dr. Cunningham was named as the Radiation Safety Officer (RSO) on Byproduct License No. 37-28540-01 (License) issued to Oncology Services Corporation by the NRC pursuant to 10 CFR Parts 30 and 35. The License authorizes possession and use of iridium-192 in brachytherapy remote afterloaders for the treatment of humans at several specified facilities located within the Commonwealth of Pennsylvania in accordance with the conditions specified therein.

As the RSO for License No. 37-28540-01, Dr. Cunningham was responsible for radiological safety oversight at six facilities owned and operated by Oncology Services Corporation, including its Indiana Regional Cancer Center in Indiana, Pennsylvania. In November 1992, a treatment with an HDR afterloader resulted in a patient being exposed to significant levels of radiation, and numerous members of the public being exposed to unnecessary radiation. At the time of the incident, Dr. Cunningham was the RSO for those six Oncology Services Corporation facilities. His failure to provide sufficient RSO oversight and support of licensed activities at those facilities contributed to the November 1992 event. Based in part on this event, the License

was suspended on January 20, 1993, by an Order Suspending License (Effective Immediately). In accordance with the conditions of that Order, the suspension has been relaxed partially several times for good cause shown.

Additionally, in June and July 1993 during the NRC investigation into the November 1992 incident, it came to the NRC's attention that on or about April 23, 1991, Dr. Cunningham directed an unauthorized removal of licensed material, an iridium-192 source in a brachytherapy remote afterloader, from an authorized location inside an Oncology Services Corporation facility, the Greater Harrisburg Cancer Center, to an unauthorized location outside that facility, and subsequently performed an unauthorized activity with this source (an experiment), in violation of License Condition 15 and 10 CFR §§ 30.34(c) and 35.13(e).

Based on the above, the NRC has serious concerns regarding Dr. Cunningham's performance of, and his continued involvement in, NRC-licensed activities, and whether Dr. Cunningham can be relied upon to comply with or to assure compliance with NRC requirements. Therefore, further information is needed to determine whether the Commission can have reasonable assurance that in the future Dr. Cunningham will conduct licensed activities in accordance with the Commission's requirements, and that the health and safety of the public will be protected.

III

Accordingly, pursuant to sections 161c, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.204, as well as 10 CFR 30.32(b), in order for the Commission to determine whether to grant or deny the application of Oakwood Center Radiation Oncology, and whether enforcement action should be taken to ensure compliance with NRC regulatory requirements, Dr. David E. Cunningham is required to submit to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, within 30 days of the date of this Demand for Information, the following information, in writing and under oath or affirmation:

A. Identify each institution, including its location, at which Dr. Cunningham engages in NRC licensed activities. For each institution, identify the duties performed and the number of hours spent in these activities at each location;

B. Explain the circumstances concerning the experiment conducted by Dr. Cunningham as described above, including who authorized it and why the NRC should not conclude that it was not an authorized activity under License No. 37-28540-01 issued to Oncology Services Corporation;

C. Explain why NRC should conclude that Dr. Cunningham properly exercised responsibility as the radiation safety officer for License No. 37-28540-01 issued to Oncology Services Corporation. The explanation should address the reason for each of the conditions described below:

1. Licensee personnel at the Indiana Regional Cancer Center, as well as the Exton and Lehighton facilities had not received training in the radiation hazards associated with the operation of a high dose rate afterloader; licensee personnel at the Indiana Regional Cancer Center and the Exton facility had not received training in the licensee's written quality management program; ancillary personnel, technologists, and authorized users at the Indiana, Exton, and Lehighton facilities were not trained on the licensee's policies and procedures; technologists were not adequately trained in the operational characteristics of the Omnitron-2000 high dose rate afterloader including safety interlocks, error messages generated by the afterloader and displayed on the unit monitor, and radiological emergency procedures.

2. The failure of Dr. Cunningham to establish and implement written policy and procedures for using byproduct material safely, in that, as of December 3, 1992, the procedures were in a draft form and were not distributed to the staff;

3. The failure of Dr. Cunningham to establish and implement written policy and procedures for taking emergency action if control of byproduct material was lost.

4. The failure of Dr. Cunningham to implement procedures at the Indiana Regional Cancer Center for checking survey instruments and the high dose rate afterloader treatment room door interlock.

5. Dr. Cunningham did not ensure housekeeping personnel at the Indiana Regional Cancer Center were denied access to the keys to the treatment room nor were they restricted, thereby allowing work in the vicinity of the high dose rate afterloader and the source container containing the 3.7 curie iridium-192 source by individuals not trained in radiation safety.

6. Dr. Cunningham did not provide training for device operators at the Indiana Regional Cancer Center, the Exton Cancer Center, and Mahoning Valley Cancer Center that included emergency training where the device operator demonstrated emergency routine competence during a "dry run" emergency as required by License Condition 17, Amendment 3, August 19, 1992.

7. Dr. Cunningham did not ensure that licensee personnel at the Indiana Regional Cancer Center routinely check their survey meter with a dedicated check source on

days when the instrument was used.

8. On or about April 21, 1991, Dr. Cunningham changed the area where byproduct material is used for high dose rate afterloader calibration procedures from the shielded therapy room at the Indiana Regional Cancer Center to an area outside the treatment room and outside of the building, and, as of that date, the licensee had not applied for or received a license amendment authorizing the change.

9. Dr. Cunningham did not ensure that the transport of licensed material outside the confines of your plant or the delivery of licensed material to a carrier for transport complies with the applicable regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Part 170-189, as evidenced by the shipment of 3.7 curies of iridium-192 on December 1, 1992 without a closure device on the package, no surveys on the package, external surface radiation levels in excess of 200 mrem per hour, and no "Radioactive" placard.

10. Dr. Cunningham allowed licensee personnel to operate in violation of license conditions, in that on many occasions, licensee personnel at the Indiana Regional Cancer Center unplugged the power supply to the primalert monitor when it was in the alarm mode which would disable the monitor; was not in close contact

with all users and workers in order to develop as low as reasonably achievable (ALARA) procedures for working with radioactive material; on November 16, 1992, during a patient treatment at the Indiana Regional Cancer Center, attending personnel did not remain in the control area and re-entered the treatment room while the room radiation detector did not indicate that a "safe" condition prevails; daily checks of all interlocks were not performed and logged at the Indiana Regional Cancer Center; on November 16, 1992, licensee personnel at the Indiana Regional Cancer Center entered the treatment room without a portable survey meter or audible dosimeter after they assumed that the room monitor had failed; on November 16, 1992, at the Indiana Regional Cancer Center, the room radiation monitor had failed and the treatment was not terminated until the monitor was replaced or repaired.

11. Dr. Cunningham did not ensure consistent application of surveys to assure compliance with that part of 10 CFR 20.101 that limits the radiation exposure to the whole body.

D. State why, in light of the facts set forth above, the NRC should have confidence that Dr. Cunningham can and will safely perform licensed activities in accordance with NRC requirements. In addition, in light of the facts set forth

above, state why the NRC should have confidence in Dr. Cunningham's ability to perform licensed activities in each of his current and proposed positions involving licensed activities.

E. State why, in light of the facts set forth above, the NRC should not deny the Capital Area R. T. Associates, Oakwood Center Radiation Oncology license application and issue Orders to NRC licensees, by whom Dr. Cunningham is employed or for whom he otherwise performs licensed activities, prohibiting Dr. Cunningham from performing NRC licensed activities under those licenses; and if the Capital Area R.T. Associates, Oakwood Center Radiation Oncology license application should not be denied, and if such Orders should not be issued, why the NRC should have confidence that Dr. Cunningham will comply with all Commission requirements.

Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the above address, and to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

After reviewing the response, the NRC will determine whether further action is necessary to ensure compliance with regulatory requirements.

FOR THE NUCLEAR REGULATORY COMMISSION

James Lieberman, Director
Office of Enforcement

Dated at Rockville, Maryland
this 11th day of March 1994