UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of		
	)	
	)	
Dr. Gary D. Kao	)	IA-09-035
	)	

DEMAND FOR INFORMATION

I

Dr. Gary Kao has performed duties as an authorized user at the Veterans Affairs Medical Center in Philadelphia, Pennsylvania (VAMC Philadelphia). The Department of Veterans Affairs holds a Master Materials License (MML) Number 03-23853-01VA issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 35. The VAMC Philadelphia is a medical broad scope permittee authorized by the MML to use a variety of byproduct materials for diagnostic and therapeutic purposes. The therapeutic treatments include brachytherapy iodine-125 used for permanent prostate implants. Dr. Kao was an approved authorized user for brachytherapy iodine-125 used for permanent prostate implants under the permit.

II

On May 16, 2008, the NRC received information that on May 5, 2008, a potential medical event (as defined in 10 CFR 35.3045) occurred at the VAMC Philadelphia and this event report was followed by numerous others. It was determined that 57 patients, who were prescribed permanent prostate implant brachytherapy using iodine-125 seeds, received an administrated dose less than 80 percent of the prescribed dose. In addition, 35 more patients received doses

in excess of 50 rem to an organ or tissue other than the treatment site from misplaced implanted seeds.

In addition, during the period from December 2006 through November 2007, post-treatment dose verification was not performed for 16 patients due to computer system interface problems. Even after the computer interface problems were resolved, post-treatment plans were not completed for seven patients until December 2007.

Based on the initial inspection and investigation conducted by NRC of the 92 reported medical events, you were the authorized user during 88 of these medical events. Therefore, the NRC is demanding the following information:

A. are you currently participating, or planning to participate, in any activities using byproduct material, including but not limited to brachytherapy activities, at any other NRC or Agreement State licensed facilities;
B. if the answer to A above is yes, then provide the name of the license holder(s), the NRC or Agreement State license number, and the date of the activity;
C. should you decide to perform any activity using byproduct material subsequent to this DFI, inform the NRC 72 hours prior to engaging in this activity.

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 Code of Federal Regulations (CFR) section 2.204 and 10 CFR Part 35, the NRC seeks the above information in order to determine whether additional regulatory action should be taken to ensure adequate protection of public health and safety. No later than **12:00 p.m. (noon), Eastern time, May 28, 2009**, you must submit a written answer to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission,

Washington, DC 20555-0001. Your answer must be submitted under oath or affirmation, and it must provide the following information:

A. are you currently participating, or planning to participate, in any activities using byproduct material, including but not limited to brachytherapy activities, at any other NRC or Agreement State licensed facilities;
B. if the answer to A above is yes, then provide the name of the license holder(s), the NRC or Agreement State license number, and the date of the activity;
C. should you decide to perform any activity using byproduct material subsequent to this DFI, inform the NRC 72 hours prior to engaging in this activity.

Upon review of your answer, or if no answer is filed, the Commission may institute a proceeding pursuant to 10 CFR 2.202 or take such other action as may be necessary to ensure adequate protection of public health and safety. Your response to this Demand for Information will be considered before a decision is made in this matter. However, if no answer is filed, we will proceed on the basis of available information.

The response to items A & B of this Demand for Information should be submitted to the NRC no later than **12:00 p.m. (noon), Eastern time, May 28, 2009**. Please fax your response to the Director, Office of Enforcement at (301) 415-3431 and a copy to the Region III Regional Administrator at (630) 810-4377.

Your response to item C of this Demand for Information should be submitted to the Director, Office of Enforcement and the Region III Regional Administrator, by fax, as described above, with a confirmation phone call to the Office of Enforcement at (301) 415-2741 and Region III at (630) 810-4370.

FOR THE NUCLEAR REGULATORY COMMISSION

/RA/
Cynthia A. Carpenter, Director
Office of Enforcement

Dated this 26th day of May 2009