

February 23, 2011

IA-09-035

Dr. Gary Kao  
c/o Jack L. Gruenstein, Esq.  
Marshall, Dennehey, Warner, Coleman & Goggin  
1845 Walnut Street  
Philadelphia, PA 19103-4797

SUBJECT: ORDER PROHIBITING INVOLVEMENT IN NRC-LICENSED ACTIVITIES

Dear Dr. Kao:

The enclosed Order Prohibiting Involvement in U.S. Nuclear Regulatory Commission (NRC) Licensed Activities is being issued to you as a result of the NRC staff's conclusions based on the results of NRC inspections at the Philadelphia Veterans Affairs (VA) Medical Center and review of your responses to two Demands for Information.

On May 26, 2009, the NRC issued a Demand for Information to you in order to receive a written list of your current and planned participation in any activities using byproduct material and confirmation that you would inform the NRC 72 hours prior to engaging in any activity using byproduct material. The Demand for Information was issued because the NRC determined that you were the authorized user responsible for a significant number of medical events reported by the Department of Veterans Affairs to the NRC beginning in May 2008. Those events involved prostate brachytherapy treatments at the Philadelphia VA Medical Center from February 2002 through June 2008. All the events met the regulatory definition of a medical event and therefore needed to be reported whether or not they were eventually determined to be clinically significant.

On May 28, 2009, you responded to the Demand for Information, stating that you were not participating, or planning to participate, in any activities using byproduct material, including but not limited to brachytherapy activities, at any NRC or Agreement State licensed facilities and that you agreed to notify the NRC 72 hours prior to participating in any activities using byproduct material.

On March 17, 2010, the NRC issued a Notice of Violation with a \$227,500 proposed civil penalty to the VA. The Notice of Violation included two Severity Level II violations and three Severity Level III violations assessed a civil penalty, and one Severity Level II violation and two Severity Level IV violations not assessed a civil penalty. The VA provided the NRC with its response to the Notice of Violation and proposed civil penalty, dated April 8, 2010, and forwarded payment of the civil penalty provided in a follow-up letter, dated April 13, 2010.

On May 24, 2010, the NRC issued a second Demand for Information to you to receive an update and additional information about your activities. Specifically, the NRC needed information about the actions you had taken since May 2008, and the actions that you planned to take in the future, that would provide the NRC reasonable assurance that you could safely use radioactive material in accordance with NRC requirements.

In your June 1, 2010, reply to the second Demand for Information you indicated that: (1) you were not designated as an authorized user on any NRC or Agreement State license or on any permit; (2) your responses to the May 26, 2009, Demand for Information still applied; (3) you had not taken, and did not plan to take, any actions to ensure that, should you engage in activities involving the use of byproduct material, including but not limited to brachytherapy implant treatments, such activities would be performed safely and in accordance with the written directive; (4) you had not taken, and did not plan to take, any actions to ensure that you understood the NRC definition of a medical event; and (5) you had not taken, and did not plan to take, any actions to ensure that you understood the steps needed to identify and report medical events. You closed by stating that you were not currently engaged in the administration of brachytherapy treatment and had no plans to become so engaged in the future. In addition, prior to performing any brachytherapy treatment, you stated that you would take all necessary and appropriate steps to ensure that you were current on all applicable requirements of the NRC.

The NRC noted that you voluntarily stopped performing brachytherapy treatments and that you committed to take all necessary and appropriate steps to ensure that you would be current on all applicable requirements should you perform brachytherapy treatments in the future. However, your response lacked specificity as to the steps you considered necessary and appropriate.

The NRC does not routinely issue significant enforcement action to individuals who violate NRC requirements. However, this action is necessary to provide the NRC with reasonable assurance that the protection of public health and safety will not be compromised by your involvement in NRC-licensed activities until you provide the NRC with sufficient information relative to the corrective actions you have taken to address your part in the violations identified at the Philadelphia VA Medical Center (EA-09-038, ML100710692). Specifically, the Order prohibits your involvement in any NRC-licensed activity until rescinded by the NRC, contingent upon your completing specialized training, demonstrating the ability to correctly identify and report medical events, and providing other documentation to the NRC supporting your completion of the requirements specified in the enclosed Order. This Order will be effective 20 days after it is published in the *Federal Register*.

In accordance with 10 CFR 2.202, you are required to provide an answer to this Order within 20 days of its publication in the *Federal Register*. Failure to comply with the provisions of this Order may result in further civil enforcement action. Pursuant to Section 223 of the Atomic Energy Act of 1954, as amended, any person who willfully violates, attempts to violate, or conspires to violate, any provision of this Order shall be subject to criminal prosecution as set forth in that section. Violation of this Order may also subject you to civil monetary penalty.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your answer to the Order will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. Previous correspondence, such as the second Demand for Information and your response, will also be made public as of the date of this Order. The NRC also includes

G. Kao

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significant enforcement actions on its Web site at (<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>). In addition, this letter will be maintained by the Office of Enforcement in an NRC Privacy Act system of records, NRC-3, "Enforcement Actions Against Individuals." The NRC-3 system notice, which provides detailed information about this system of records, can be accessed from the NRC Web site at <http://www.nrc.gov/reading-rm/foia/privacy-systems.html>.

Questions concerning the enclosed Order should be addressed to the Director of the Division of Nuclear Materials Safety, NRC Region III, Lisle, IL, who can be reached at 630-829-9800.

Sincerely,

*/RA/*

Roy P. Zimmerman, Director  
Office of Enforcement

Enclosure: As Stated

cc w/enclosure: State of Pennsylvania

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Roy P. Zimmerman, Director  
Office of Enforcement

Enclosure: As Stated

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Letter to G. Kao from R. Zimmerman dated February 23, 2011

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