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2443 Warrenville Road
Lisle IL 60532
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Contacts:
Viktoria Mitlyng 630-829-9662
Prema Chandrathil 630-829-9663

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E-Mail: opa3@nrc.gov
Web site: www.nrc.gov

NRC ISSUES ORDERS TO TWO INDIVIDUALS INVOLVED IN 2002-2008 MEDICAL ERRORS AT VA MEDICAL CENTER IN PHILADELPHIA

The Nuclear Regulatory Commission has issued an order that bars a former Veterans Administration (VA) physician from engaging in NRC-regulated activities unless he undergoes certain training and meets other requirements spelled out by the agency. The order involving Dr. Gary Kao, who previously worked at the Veterans Affairs Medical Center in Philadelphia (VA Philadelphia), takes effect 20 days after its issuance.

At the same time, the NRC has issued a separate order requiring a medical physicist who worked at the same facility to notify the agency if he accepts employment in that capacity involving NRC-regulated activities. Gregory Desobry must carry out such notification within 20 days of beginning such work.

The orders are the latest actions taken by the NRC in response to an unprecedented number of medical errors identified at VA Philadelphia. The errors involved the incorrect placement of iodine-125 seeds in patients to treat prostate cancer. Out of 116 such brachytherapy procedures performed at the facility between 2002 and 2008, the VA reported that 97 were carried out incorrectly. On March 17, the NRC issued a $227,500 fine against the Department of Veterans Affairs for violations of agency regulations associated with the errors.

Multiple NRC reviews determined that Kao was the physician involved in 91 of the 97 incorrect procedures.

Previously, two Demands for Information (DFIs) were issued to Kao by the NRC regarding his actions, both taken and planned. Despite a commitment by Kao in response to the second DFI to take all "necessary and appropriate" steps to ensure his adherence to all applicable requirements during any future brachytherapy treatments, the NRC considers the order necessary until Kao takes corrective actions to ensure he can safely use radioactive material in accordance with NRC requirements.

"We are taking this action to protect the public by ensuring that before Dr. Kao works in NRC-licensed areas again he proves to the NRC he has addressed his part in the violations at the Philadelphia VA Medical Center," said Roy Zimmerman, Director of the NRC's Office of Enforcement.

The order prohibits Kao's involvement in any NRC-licensed activity, including prostate brachytherapy, until, and unless, he does the following: (1) completes specialized training regarding medical events and the importance of reporting non-compliances and identifying associated corrective

actions; (2) documents successful demonstration of the ability to correctly identify and report medical events; and (3) documents his understanding of the definition of a medical event, his roles and responsibilities regarding written directives, the steps necessary to identify and report medical events to the NRC and the process he would follow to identify corrective actions if he was involved in the future with a non-compliance with NRC requirements.

Meanwhile, the NRC's order to Desobry, who served as the medical physicist for the vast majority of the medical events, states that the agency wants the opportunity to inspect his future involvement in similar NRC-licensed activities to "verify your understanding of medical events, the role and responsibility of the medical physicist regarding medical events, and the steps needed to identify and report such events to the NRC."

The NRC's response to the VA Philadelphia medical errors included the assignment of a special team of inspectors to conduct in-depth inspections of how so many treatments could have been executed incorrectly. In addition, the NRC hired an independent medical consultant to assess the impact of medical errors on patients. After reviewing data of 39 patients, the consultant concluded that several patients experienced symptoms that could be related to the medical errors in their treatment, such as inflammation and damage to the lower parts of the colon, rectal bleeding and recurrence of cancer. The NRC concluded that a widespread programmatic breakdown had occurred at the facility.

VA Philadelphia subsequently implemented numerous corrective actions, including the suspension of the prostate cancer treatment program at the center. The VA Philadelphia brachytherapy program remains suspended.

The NRC orders are available in the agency's ADAMS electronic document system under Accession Numbers ML103410384, ML103410390 to Kao and ML103410282 and ML103410284 to Desobry.

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