

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of
Dr. Gary Kao

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IA-09-035

ORDER PROHIBITING INVOLVEMENT IN
NRC-LICENSED ACTIVITIES

I

Dr. Gary Kao has performed duties as an authorized user at the Philadelphia Veterans Affairs Medical Center in Philadelphia, Pennsylvania (PVAMC). The Department of Veterans Affairs (VA) holds a Master Materials License (MML) Number 03-23853-01VA issued by the U.S. Nuclear Regulatory Commission (NRC or Commission) pursuant to Title 10 of the Code of Federal Regulations (10 CFR) Part 30. The PVAMC 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.

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 PVAMC; this event report was followed by numerous others. By October 2009, the VA had reported to the NRC that 97 medical events involving prostate brachytherapy occurred at the PVAMC from February 2002 through June 2008. The NRC determined that Dr. Kao was the authorized physician during 91 of the 97 reported medical events.

In addition, during the period from December 2006 through November 2007, post-treatment dose verification, required pursuant to 10 CFR 35.41(b)(2), was not performed for at least 16 patients under Dr. Kao's purview 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.

In response to the reported medical events, the VA National Health Physics Program (NHPP) conducted onsite inspections at the PVAMC on May 28 and 29, 2008, and June 24 and 25, 2008. The VA NHPP issued an inspection report on October 16, 2008, documenting violations of NRC requirements. The NHPP concluded that, for medical events occurring between February 25, 2002, and May 5, 2008, Dr. Kao was aware of the D90 (dose to 90 percent of the prostate volume) doses and, in some cases, of the seeds being implanted outside the prostate. The NHPP determined that Dr. Kao had adequate clinical and technical

knowledge of the patient circumstances surrounding the medical events. However, the NHPP concluded that Dr. Kao did not report these circumstances to the Radiation Safety Officer to evaluate as possible medical events. The NRC considered this a missed opportunity to correct the issue, allowing further medical events to occur.

On July 17, 2008, the PVAMC Director convened an Administrative Board of Investigation (ABI) to review the brachytherapy program. The ABI submitted the results of its investigation in a memorandum to the PVAMC Director on September 4, 2008. The ABI report concluded that Dr. Kao was aware of the poor and inconsistent results from the brachytherapy treatments, but chose not to alert senior management or the Radiation Safety Committee. Additionally, the ABI report stated that Dr. Kao chose not to stop the program when problems were identified relating to post-treatment monitoring and evaluation because of data transmission issues from the radiology department. The ABI report also noted that Dr. Kao failed to take corrective action for those cases found to have low D90s or when the computerized tomography to treatment planning system network problem made post implant evaluations impossible.

The NRC also responded to the medical events being reported by conducting onsite inspections at the PVAMC on various dates from July 23, 2008, to October 16, 2009. The results of the NRC inspections were documented in NRC Special Inspection Report 030-34325/2008-029(DNMS), dated March 30, 2009, and NRC Reactive Inspection Report 030-34325/2009-001(DNMS), dated November 17, 2009. While the NRC inspection reports did not focus on the roles of individuals and their contributions to the issues at the PVAMC, the NRC recognized that Dr. Kao was the

authorized user for almost all the reported medical events. The NRC identified that contributing factors to the medical events included a lack of a safety culture where safety concerns went unreported, and a non-rigorous and informal assessment of patient doses existed which did not demonstrate a commitment to improve performance. The NRC identified eight apparent violations of NRC requirements.

The NRC discussed these violations with the VA at a Predecisional Enforcement Conference conducted on December 17, 2009. In a letter dated January 14, 2010, the VA accepted the violations, including the root or basic causes identified by the VA and the NRC.

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.

The information gathered through the multiple review processes outlined above called into question whether the NRC had reasonable assurance that Dr. Kao would perform his duties as an authorized user in accordance with NRC regulations and the Atomic Energy Act. As a result, on May 26, 2009, the NRC issued a Demand for Information (DFI) to Dr. Kao. This DFI was limited in scope to information about whether Dr. Kao was currently performing any

activities using byproduct materials, if so, where, and, if not, requiring Dr. Kao to notify the NRC 72 hours before performing any such activities. In his May 28, 2009, response, Dr. Kao indicated that he was not then participating in any activities using byproduct materials, including but not limited to brachytherapy activities, at any NRC or Agreement State licensed facilities and that he would inform the NRC 72 hours prior to participating in any such activities.

On May 24, 2010, the NRC issued a second DFI to Dr. Kao, to provide an update to Dr. Kao's previous responses, and provide additional information about actions Dr. Kao had taken, or planned to take, to: (1) ensure that, should he engage in activities involving the use of byproduct material, including but not limited to brachytherapy implant treatments, such activities would be performed safely and, specifically, that such activities would be in accordance with the written directive; (2) ensure that he fully understood NRC's definition of a medical event and the steps that he needed to take to identify and report medical events; and (3) to describe any additional information that would provide the NRC with reasonable assurance about his involvement in NRC-regulated activities.

Dr. Kao responded to the NRC's second DFI on June 1, 2010. His reply indicated that he was not designated as an authorized user on any NRC or Agreement State license or any permit and was not currently involved in any activities involving byproduct material. The reply also indicated that Dr. Kao had not taken and did not plan to take any actions at this time to ensure that any future activities would be performed safely and in accordance with a written directive. The reply did not provide any information that indicated that Dr. Kao had taken any actions to

gain understanding of the NRC's definition of a medical event or to ensure that Dr. Kao would identify and report medical events. Finally, Dr. Kao indicated that he was not currently engaged in the administration of brachytherapy treatment and had no plans to become so engaged in the future. Dr. Kao attested that, prior to performing any brachytherapy treatment, he would take all necessary and appropriate steps to ensure that he was current on all applicable NRC requirements.

III

Based on Dr. Kao's performance at the PVAMC and his responses to the aforementioned DFI's, as set forth in Section II of this Order, the NRC lacks reasonable assurance until Dr. Kao takes the appropriate corrective actions and can demonstrate his knowledge of the safe use of radioactive material to protect health or to minimize the danger to life or property in compliance with the Commission's requirements. Therefore, the public health, safety and interest require that Dr. Kao be prohibited from any involvement in NRC-licensed activities until he can provide the NRC with reasonable assurance that he can safely use radioactive material in accordance with NRC requirements, and that he can correctly identify and report medical events.

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 150.20, IT IS HEREBY ORDERED THAT:

1. Beginning on the effective date of this Order, Dr. Kao is prohibited from engaging in NRC-licensed activities. NRC-licensed activities are those activities that are conducted pursuant to a specific or general license issued by the NRC, including, but not limited to, those activities of Agreement State licensees conducted pursuant to the authority granted by 10 CFR 150.20.

2. If, after issuance but prior to the effective date of this Order, Dr. Kao has performed NRC-licensed activities for another person or organization as an employee or contractor, he shall provide written notification to the Director of the NRC Office of Enforcement, with a copy to the Region III Regional Administrator, of the name, address and telephone number of that person or organization, and provide a copy of this Order to that person or organization. The notifications required by this paragraph, if applicable, shall be accomplished within 5 days of the effective date of this Order.

3. If, after issuance but prior to the effective date of this Order, Dr. Kao has performed activities licensed by an Agreement State, then Dr. Kao shall (1) provide a copy of the Order to the person or organization by whom he was employed or contracted within 5 days of the effective date of this Order, and (2) provide written notification to the Director of the NRC Office of Enforcement, with a copy to the Region III Regional Administrator, within 5 days of the effective date of this Order. If, after the effective date of this Order, Dr. Kao accepts an offer of employment, enters a contract to perform work, or otherwise plans to perform activities licensed by an Agreement State, Dr. Kao shall

- (1) provide a copy of this Order to the person or organization by whom he will be employed or contracted, within 5 days of any such offer, contract, or plan, and
- (2) provide written notification to the Director of the NRC Office of Enforcement, with a copy to the Region III Regional Administrator, within 5 days of any such offer, contract, or plan.

- 4. At any time after the effective date of this Order, Dr. Kao may file a written request with the Director of the NRC Office of Enforcement that the Order be rescinded, such that he could resume, for example, the activities of an authorized user for medical administrations, based upon the satisfactory completion of all of the following conditions:
 - a. In addition to the training and qualification requirements set forth in NRC regulations applicable to the use of byproduct material, Dr. Kao shall provide documentation showing that he has successfully completed specialized training regarding (1) the definition of a medical event contained in NRC regulations, how to identify a medical event, and the requirements for proper reporting of a medical event, with particular emphasis on medical events arising out of prostate brachytherapy treatments, but not limited to such treatments; and (2) the importance of reporting non-compliances and identifying appropriate corrective actions under the NRC Enforcement Policy. Such documentation shall include training dates, course syllabi, and instructor qualifications;
 - b. Dr. Kao shall provide documentation showing that he has successfully demonstrated, under the supervision of a trained and qualified authorized user

competent in the identification and reporting of medical events, the ability to correctly identify and report medical events in accordance with NRC regulations, including (but not limited to) medical events resulting from prostate brachytherapy. This paragraph does not permit Dr. Kao to use byproduct material, act as an authorized user, or otherwise engage in NRC-licensed activities. Such documentation shall include an attestation by the authorized user under whom Dr. Kao performed regarding the methodology (e.g., observation, examination, use of biologically equivalent human phantoms) used to demonstrate Dr. Kao's competence; and

- c. Dr. Kao shall provide to the Director of the NRC Office of Enforcement, with a copy to the Region III Regional Administrator, a written document describing in detail his understanding of: (1) the 10 CFR Part 35 definition of a medical event; (2) his role and responsibility regarding performing activities in accordance with a written directive; (3) the steps necessary to identify and report medical events to the NRC and (4) the process he would follow to identify the corrective actions that would be necessary if he were to be involved with a noncompliance of NRC regulations in the future, including (but not limited to) a medical event resulting from prostate brachytherapy.

5. If Dr. Kao seeks rescission of this Order under Paragraph IV.4, the information required by Paragraph IV.4 shall be provided to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region III, 2443 Warrenville Road, Suite 210, Lisle IL 60532.

6. This Order shall be effective 20 days following its publication in the *Federal Register* and shall remain in effect until the conditions specified above have been met and the Director of Office of Enforcement determines in writing that the Order is rescinded.

The Director, OE, may, in writing, relax or rescind any of the above conditions upon demonstration by Dr. Kao of good cause.

v

In accordance with 10 CFR 2.202, Dr. Gary Kao must, and any other person adversely affected by this Order may, submit an answer to this Order within 20 days of its publication in the *Federal Register*. Dr. Kao's answer must be submitted under oath and affirmation. In addition, Dr. Kao and any other person adversely affected by this Order may request a hearing on this Order within 20 days of its publication in the *Federal Register*. Where good cause is shown, consideration will be given to extending the time to answer or request a hearing. A request for extension of time must be directed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, and include a statement of good cause for the extension.

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the

submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC E-Filing rule (72 FR 49139, August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by e-mail at hearing.docket@nrc.gov, or by telephone at (301) 415-1677, to request (1) a digital ID certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals/apply-certificates.html>. System requirements for accessing the E-Submittal server are detailed in NRC's "Guidance for Electronic Submission," which is available on the agency's public Web site at <http://www.nrc.gov/site-help/e->

[submittals.html](#). Participants may attempt to use other software not listed on the web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, web-based submission form. In order to serve documents through the Electronic Information Exchange (EIE), users will be required to install a web browser plug-in from the NRC web site. Further information on the web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public web site at <http://www.nrc.gov/site-help/e-submittals.html>.

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The E-Filing system also distributes an e-mail notice that provides access to the document to the NRC Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the

documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the agency's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the "Contact Us" link located on the NRC web site at <http://www.nrc.gov/site-help/e-submittals.html>, by e-mail at MSHD.Resource@nrc.gov, or by a toll-free call at (866) 672-7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) first class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the

provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in NRC's electronic hearing docket, which is available to the public at http://ehd.nrc.gov/EHD_Proceeding/home.asp, unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

If a person other than Dr. Kao requests a hearing, that person shall set forth with particularity the manner in which his/her interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.309(d).

If a hearing is requested by a licensee or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearings. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained. In the absence of any request for hearing, or written approval of an extension of time

in which to request a hearing, the provisions specified in Section IV above shall be final 20 days from the date this Order is published in the *Federal Register* without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section IV shall be final when the extension expires if a hearing request has not been received.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

/RA/

Roy P. Zimmerman, Director
Office of Enforcement

Dated this 23rd day of February 2011