[7590-01-P]

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of Gregory Desobry, Ph.D.	)))))	IA-10-010

ORDER REQUIRING NOTIFICATION OF INVOLVEMENT
IN NRC-LICENSED ACTIVITIES

[NRC-2011-0047]

I

Mr. Gregory Desobry previously performed duties as a medical physicist 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 which was authorized by the MML to use a variety of byproduct materials for diagnostic and therapeutic purposes. The therapeutic treatments included brachytherapy iodine-125 used for permanent prostate implants. Mr. Desobry's role included assuring the safe use of radioactive materials for patients, including performance of a post-treatment determination of the actual radiation treatment administered to the patient in order that the actual treatment parameters could be verified with the intended treatment identified in the

written directive. Mr. Desobry was involved with the vast majority of the 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 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. In addition, during the period from December 2006 through November 2007, post-treatment dose verification was not performed for at least 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.

In response to the reported medical events, the VA National Health Physics Program (NHPP) conducted onsite inspections at the PVAMC on May 28 through 29, 2008, and from June 24 through 25, 2008, and issued an inspection report with violations of NRC requirements, dated October 16, 2008. The NHPP concluded that, for medical events occurring between February 25, 2002, and May 5, 2008, Mr. Desobry was aware of the D90 doses (the minimum dose received by 90 percent of the prostate volume) and, in some cases, of the seeds being implanted outside the prostate. However, Mr. Desobry did not report these circumstances to the RSO to evaluate as possible medical events. The NRC considered this a missed opportunity to correct the issue, allowing further medical events to occur. The NHPP also concluded that Mr. Desobry had adequate clinical and technical knowledge of the patient circumstances surrounding the medical events. Finally, the NHPP concluded that the lack of evaluations by

Mr. Desobry and his failure to raise this issue to higher-level management was contrary to patient safety and demonstrated a lack of a safety conscious work environment.

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 No. 030-34325/2008-029(DNMS), dated March 30, 2009, and NRC Reactive Inspection Report No. 030-34325/2009-001(DNMS), dated November 17, 2009. The NRC determined that Mr. Desobry was the primary medical physicist at the PVAMC for brachytherapy implants and participated in the majority of treatments that subsequently resulted in reported medical events. Also, Mr. Desobry was the primary medical physicist during the period when post treatment dose verifications were not performed due to computer interface problems. The NRC inspection reports documented eight apparent violations of NRC requirements and noted that the VA's internal Administrative Board of Investigation concluded that there was a lack of a safety culture at the PVAMC where Mr. Desobry, among others, accepted a substandard approach to brachytherapy treatments, which resulted in poor implant techniques, a patient dose assessment process that lacked rigor and formality, a failure to communicate concerns with the implants, a misperception that safety checks were performed by other team members, and an overall system that did not demonstrate a commitment to safety.

The NRC discussed these violations with the VA in 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.

During interviews conducted by the NRC's Office of Investigations (OI), Mr. Desobry acknowledged being involved in over 90 percent of the brachytherapy procedures conducted at the PVAMC. Mr. Desobry also informed the NRC OI that he had never received training as to what constituted a medical event and was unaware of the reporting requirements of a medical event.

Notwithstanding Mr. Desobry's training as a Medical Physicist, with board certification by the American Board of Radiology in 1989 and subsequent practice in the field of Medical Physics, Mr. Desobry's actions at the PVAMC, as they contributed to these medical events, called into question whether Mr. Desobry would work to assure that radioactive materials are used safely for patients, adequately understands the applicable NRC regulations, and would perform future activities in accordance with applicable NRC requirements and the Atomic Energy Act. Therefore, on May 24, 2010, the NRC issued a Demand for Information (DFI) to Mr. Desobry. This DFI required Mr. Desobry to provide information about actions he had taken, or planned to take, to ensure that Mr. Desobry fully understood: (1) the 10 CFR Part 35 definition of a medical event; and (2) his role and responsibilities pertaining to his duties as a medical physicist and the steps necessary to identify and report medical events to the NRC. The NRC further required

information about the names and locations of the facilities where Mr. Desobry worked as a medical physicist. Finally, the NRC required information about any other additional actions not already mentioned that would provide the NRC with reasonable assurance about Mr. Desobry's involvement in NRC-licensed activities.

Mr. Desobry responded to the DFI on June 28, 2010. His reply indicated that he was not currently employed as a medical physicist, but had been employed at the Capital Health System – Mercer Campus, in Trenton, New Jersey, from January 2008 until December 2009; Capital Health System was affiliated with the University of Pennsylvania Health System during that time frame. Mr. Desobry indicated that while at Capital Health System under the supervision of the Head of the Department of Radiation Oncology, he worked with the Radiation Safety Officer and with radiation oncology physicians to examine that institution's definition of a medical event, which Mr. Desobry indicated reinforced his understanding (and corrected any prior misunderstanding) of the 10 CFR Part 35 definition of a medical event; his role and responsibility regarding medical events; and the steps needed to be taken to identify and report medical events to the NRC. Mr. Desobry indicated that he was dedicated to regulatory compliance and patient safety and stated that, in the event that he should ever be hired to work again as a medical physicist, he would request training in this area at an appropriate and accredited institution.

III

Based on Mr. Desobry's response to the May 24, 2010, DFI, the NRC recognizes that Mr. Desobry has taken steps to improve his understanding of how to safely use radioactive material in treatment of patients. Mr. Desobry worked with the Radiation Safety Officer and with

radiation oncology physicians at the Capital Health System facility to correct and reinforce Mr. Desobry's understanding of the 10 CFR Part 35 definition of a medical event, his role and responsibility regarding medical events, and the steps needed to be taken to identify and report medical events to the NRC. However, since Mr. Desobry was involved in a large number of reported medical events at PVAMC, the NRC has concluded that it needs the opportunity to inspect Mr. Desobry's involvement in future similar NRC-licensed activities to assess the efficacy of Mr. Desobry's actions to improve his understanding of the 10 CFR Part 35 definition of a medical event, his role and responsibility regarding medical events, and the steps needed to be taken to identify and report medical events to the NRC, in the event that he accepts a position as a medical physicist in the future. This action will provide NRC the opportunity to confirm that reasonable assurance exists that licensed activities can be conducted in compliance with the Commission's requirements and that the health and safety of the public will be protected.

Therefore, the public health, safety and interest require that Mr. Desobry notify the NRC within 20 days of accepting a position as a medical physicist.

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. If Mr. Desobry accepts, or has accepted since the time of his response to the DFI, dated May 24, 2010, a medical physicist position involving the use of byproduct materials in either NRC jurisdiction or in an Agreement State, he shall inform the NRC within 20 days

of acceptance of an employment offer or within 20 days of this Order, whichever comes later. This notification is a one-time requirement and no further notification is required for any subsequent acceptance of an employment offer. This notification 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, Lisle IL 60532. The notification shall include the name, address, and telephone number of the employer or the entity where he is or will be employed as a medical physicist.

2. This Order shall be effective 20 days following its publication in the Federal Register and shall remain in effect until the conditions of Item 1 have been met.

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

V

In accordance with 10 CFR 2.202, Mr. Gregory Desobry 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. Mr. Desobry's answer must be submitted under oath and affirmation. In addition, Mr. Desobry 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://ehd1.nrc.gov/EHD*, 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 Mr. Desobry, Ph.D., 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