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# Hospital Enforcement: NRC Suspends Operations and Proposes Second Largest Fine Ever Against a Medical Facility

### March 19, 2010

The Nuclear Regulatory Commission (NRC) has proposed fining the Department of Veterans Affairs (DVA) \$227,500 for causing 97 veterans to receive incorrect radiation doses for prostate cancer at the Veterans Affairs Medical Center in Philadelphia, during treatment there from 2002 to 2008. This is the second largest fine ever proposed by the NRC against a medical facility and one of the highest for any NRC materials licensee. The DVA has 30 days to either pay or challenge the proposed fine and, in the interim, the prostate cancer treatment program will remain suspended and cannot be restarted without informing the NRC.

As discussed in Morgan Lewis's February 5, 2010 LawFlash, "Rising Regulatory and Congressional Scrutiny of Facilities Using Radiation-Emitting Devices," the NRC, among other federal and state agencies, has oversight authority for medical radiation through licensing, inspection, and enforcement action programs. The NRC had previously directed DVA hospitals to undertake corrective actions as a result of multiple excessive exposures. Prior to Wednesday however, the NRC had not decided whether to take enforcement action and potentially, propose a fine.

The principal violation cited by the NRC involves the DVA's failure to develop, implement, and maintain written procedures to ensure correct medical radiation treatment implementation. Other violations include ordering and implanting incorrect radiation doses into a patient, inadequate training on NRC-required reportability requirements, and the failure to timely report medical safety events to the NRC. The NRC cited a systematic lack of "safety culture" as the underlying cause for these violations.

The NRC continues its inspections of medical facilities, including inspections of non-DVA hospitals. Based on the size of this fine and the scope of the violations, we anticipate more regulatory scrutiny from the NRC of medical facilities' compliance with applicable safety requirements.

Morgan Lewis's Nuclear Energy Practice has experience in both NRC and state regulatory matters, including representing and advising hospitals, universities, and other medical facilities in connection with the medical use of radioactive materials.

This Morgan Lewis LawFlash is available at <a href="http://www.morganlewis.com/pubs/XPLF">http://www.morganlewis.com/pubs/XPLF</a> RadiationEmittingDevices LF 05feb10.pdf.

Morgan Lewis's FDA and Healthcare Practice also regularly represents clients in FDA regulatory matters. Whether you are a hospital, other user facility, or device manufacturer, our attorneys can provide advice and assistance with your reporting obligations. We stand ready to help your organization reduce both its regulatory and liability exposure, particularly in this time of increased regulatory oversight of facilities using radiation-emitting devices. Morgan Lewis's Litigation Practice also has experience in device liability litigation, and works with companies to reduce their liability exposure.

If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact any of the following Morgan Lewis attorneys:

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