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Rising Regulatory and Congressional Scrutiny of Facilities Using Radiation-Emitting Devices

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The *New York Times* recently published a series of articles that highlighted medical issues associated with excessive or incorrect radiation exposures in therapeutic applications. The articles suggest that, in many cases, the events occurred due to inadequate staffing and training, user failure to follow or properly implement device quality assurance plans and procedures, and/or software issues. In our experience, these are not unusual problems and happen with some frequency in many different types of radiation-licensed activities. In fact, this issue has garnered congressional scrutiny as evidenced by plans by the U.S. House of Representatives' Subcommittee on Health, Employment, Labor, and Pensions to hold a hearing on February 10 titled "Medical Radiation: An Overview of the Issues."

The Nuclear Regulatory Commission (NRC) and various state radiation control agencies oversee medical uses of radioactive materials and devices through licensing, inspection, and enforcement programs. The NRC and these agencies issue medical use licenses to medical facilities and authorized physician users, and develop guidance and regulations for use by licensees. The NRC maintains a committee of medical experts to obtain advice about the use of radioactive materials in medicine.

Problems similar to those reported in the *New York Times* articles have occurred at Veterans Affairs (VA) hospitals. In May 2008, the NRC received notification that a patient at a VA hospital in Philadelphia, Pennsylvania, was given an incorrect dosage of radiation while undergoing treatment for prostate cancer. The NRC immediately conducted an in-depth inspection at the hospital and identified eight apparent violations. These violations included, for instance, a lack of procedures to ensure that each cancer radiation treatment was delivered as prescribed, inadequate reporting requirements, and a failure to provide complete and accurate written reports. The NRC held a predecisional enforcement conference (PEC) on December 17, 2009. The NRC's decision on whether to take enforcement action remains pending.

In addition to VA hospitals, the NRC continues its inspection efforts at other medical institutions. For example, on January 21, 2010, the NRC announced that it had entered into an agreement with a nuclear medicine practice, Beta Gamma Nuclear Radiology (BGNR), through the NRC's Alternative Dispute Resolution (ADR) process. BGNR allegedly submitted falsified information to the NRC concerning its failure to prepare written directives or orders prior to the administration of nuclear medicine treatments. Under the agreement, BGNR agreed to pay a $5,000 fine and implement corrective actions related to radiation safety. We anticipate more regulatory scrutiny from the NRC of medical facilities' compliance with applicable safety requirements.

Morgan Lewis's Nuclear Energy Practice is the largest in the nation. Our experience in both NRC and state regulatory matters includes the representation of hospitals, universities, and other medical institutions in connection with the medical use of radioactive materials. The attorneys in our Nuclear Energy Practice may be able to assist you in preventing or addressing compliance issues in order to avoid the types of situations discussed in the *New York Times* articles. The following are just some of the areas where the Nuclear Energy Practice may be able to provide assistance:

- Training in NRC and state regulatory requirements
- Performance of compliance reviews of procedures and quality assurance controls, along with recommendations on how to establish an independent framework of oversight consistent with the regulations
- Development of a strong "safety culture," with attributes that include: conservative decision-making, a safety-over-production concept, and strict procedural adherence
- Event response: Identifying the underlying causes of a problem, ensuring corrective actions are adequate in scope and properly focused on the causes, and ensuring effective interactions with the regulatory agencies
- Enforcement advice: Assistance in responding to, and mitigating to the extent possible, regulatory enforcement actions
- Alternative Dispute Resolution (ADR): Assistance in representing clients that seek to resolve issues with the NRC through the ADR process
- Congressional action: Monitor congressional and regulatory agency developments. For instance, the U.S. House of Representatives recently proposed a bill (currently referred to committee), titled the "Veterans' Health and Radiation Safety Act," that seeks to enhance the training and oversight of individuals administering radioactive treatment to veterans

Government oversight in this area is not limited to the NRC and states. Even before the recent series of *New York Times* articles, the Food and Drug Administration (FDA) began investigating hundreds of cases of possible radiation overexposure from computed tomography (CT) imaging scans at hospitals in California and possibly Alabama. The latest *New York Times* reports likely will lead to a broader FDA investigation of facilities using radiation-emitting medical devices. Possibly triggered in part by these recent news articles, internal FDA reorganizational efforts already are under way that could lead to increased regulatory scrutiny of radiation-emitting medical devices and related reporting requirements.

FDA's focus will be on whether the unintended exposures are being caused by device user error or a problem with the equipment, as well as on compliance with adverse event reporting requirements. Hospitals and other user facilities are subject to FDA adverse event reporting regulations, which require the reporting of any device-related deaths to FDA and of any device-related serious injuries to the device manufacturers (Medical Device Reports, or MDRs). Manufacturers in turn must submit MDRs to FDA for death and serious injury reports received from the user facilities, and accidental radiation occurrence reports for events not reported in an MDR. The recent news articles suggest that hospitals and other user facilities may be underreporting these events and, thus, FDA is expected to closely review their compliance with device reporting requirements.

Morgan Lewis's FDA/Healthcare Practice regularly represents clients in FDA regulatory matters. Whether you are a hospital, other user facility, or device manufacturer, the attorneys in our FDA/Healthcare Practice can advise you on, and assist you with, your reporting obligations, to help

reduce both your regulatory and liability exposure, as FDA and other governmental agencies increase their regulatory oversight of facilities using radiation-emitting devices.

For further information about the topics discussed in this LawFlash, please contact any of the following Morgan Lewis attorneys:

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