



Inspections of Medical Licensees Demonstrate Non-Compliance with NRC Regulations

I. Introduction

Recent events have demonstrated a frequent disconnect between Nuclear Regulatory Commission (“NRC”) regulations and hospital practice in the execution of medical procedures utilizing radiological materials. Over the past five years, NRC investigations have revealed that certain NRC regulations have not been routinely met by medical facilities and practitioners. Although there has not always been a correlation with patient safety, the NRC will respond with increased regulatory scrutiny. Suffice it to say, the NRC seeks a level of strict regulatory and procedural compliance that is typical in the nuclear power industry, but is not always typical in academic or medical institutions. This presents a clear challenge for institutional Radiation Safety Officers and oversight committees tasked with maintaining a broad scope license for nuclear materials.

II. Regulatory Framework

Pursuant to 10 C.F.R. § 35, the NRC has the authority to license the medical use of radioactive materials in diagnosis and therapy. The NRC shares this authority with states pursuant to the agency’s Agreement State Program.¹ As defined by NRC regulations, medical use is the intentional internal or external administration of byproduct material or the radiation from byproduct material to patients under the supervision of an authorized user.² An authorized user is any physician, dentist, or podiatrist who meets the regulatory requirements.³ In part, NRC regulations mandate certain written directives, training procedures, and physical presence and reporting requirements for licensed facilities engaging in the medical use of radioactive material.⁴

III. NRC Inspections Demonstrate Non-Compliance with NRC Regulations

- A. **UPMC** - In Spring 2007, an NRC investigation determined that the University of Pittsburgh Medical Center Gamma Knife facility (“UPMC”) violated the terms of its Byproduct Material License in its execution of gamma stereotactic radiosurgery (“GSR” or “Gamma Knife”), which is used to treat brain tumors and other abnormalities. Contrary to the terms of UPMC’s license, a GSR was conducted without the continuous physical presence of an authorized medical physicist, where the NRC construed physical presence to be at the console, rather than in the medical suite. Further, the NRC’s investigation revealed that, over a 10-month period, simultaneous GSR treatments were being conducted in separate

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¹ The Atomic Energy Act provides the statutory basis under which the NRC relinquishes to states certain portions of its regulatory authority to license and regulate medical byproduct materials. See 42 USC § 2021(b).

² 10 C.F.R. 10 § 35.2.

³ Id.

⁴ See 10 C.F.R. Part 35.

suites when there was only one authorized medical physicist present. While disputed by the licensee, the NRC characterized the licensee's practice as one of careless disregard of the physical presence requirement.

The NRC investigation also revealed that a UMPC neurosurgeon had initiated a GSM treatment without an authorized user present, or without having had the authorized user sign a written directive. This alleged violation highlighted a disconnect between NRC regulations and medical practice. The neurosurgeon was the medical team lead, but was not an authorized user under the NRC license. NRC regulations assign that responsibility to the radiation oncologist. The UPMC matter was ultimately resolved through a mediation followed by a settlement agreement in which the hospital agreed that a noncompliance had occurred and committed to remedial measures to improve the compliance of its GSR treatment procedures and practices.

- B. DVA Kentucky** - In September 2007, a routine NRC inspection revealed that a Radiation Safety Officer at the Department of Veterans Affairs Center in Lexington, K.y. ("DVA Kentucky") had failed to implement DVA Kentucky's radiation safety program in accordance with NRC regulations. The NRC identified several apparent violations, including the failure of the Radiation Safety Officer to: 1) conduct periodic meetings of the radiation committee; 2) perform annual reviews of the licensee's nuclear medicine program; and 3) complete required training. The NRC subsequently issued a confirmatory order requiring the Radiation Safety Officer to perform certain remedial activities. The order illustrates the NRC's need to rely on Radiation Safety Officers, who are assigned responsibility for performing key safety functions, and stresses the need for Radiation Safety Officers to take their responsibilities seriously.
- C. VA Philadelphia** - In May 2008, the Veterans Affairs Medical Center in Philadelphia ("VA Philadelphia") notified the NRC of a prostate cancer procedure in which the patient received a radioactive dose more than 20 percent lower than prescribed. The treatment, brachytherapy, was intended to implant 125 iodine seeds into the patient's prostate in order to create a "radioactive cloud" that would conform to and treat the disease. A subsequent investigation revealed an additional 91 medical events at VA Philadelphia— 57 events where the dose delivered to the prostate was less than prescribed and 35 involving an unintended dose to an organ or tissue. Virtually none of the substandard

implants were reported to the NRC or Veterans Affairs regulator (the National Health Physics Program). Thus, according to the NRC, errors went uninvestigated for months and sometimes years, during which many patients were unaware of their flawed treatment.

The NRC investigation identified six violations of NRC regulations. The violations included the failure of VA Philadelphia to: 1) develop adequate written procedures to ensure prostate seed implant procedures are performed in accordance with NRC regulations; 2) develop procedures to ensure practitioners follow those written procedures; 3) train supervised individuals to identify and report medical events to regulators; 4) train unsupervised individuals in the same; 5) record patients' total dose in written directives; and 6) follow reporting requirements.

In follow up to the events at VA Philadelphia, the NRC and the National Health Physics Program are conducting inspections at all 13 Veterans Affairs hospitals currently authorized to perform prostate cancer treatments and the National Health Physics Program is developing and implementing standardized procedures for prostate cancer treatments at all such hospitals. Any prostrate cancer treatment program found to exhibit a 20 percent or greater rate of treatments being identified as medical events will be suspended. Five programs at Veterans Affairs hospitals, including the program at VA Philadelphia, have been suspended to date.

- D. Gamma Knife Center** - Most recently, the NRC announced on July 28, 2009 that it is conducting a special inspection at Gamma Knife Center of the Pacific in Honolulu ("Gamma Knife Center"). Weeks earlier, a patient being treated for brain cancer received a larger than prescribed dose of gamma radiation. The NRC plans to review the circumstances related to the incident, develop a chronology of events, assess the licensee's investigation, and evaluate the adequacy of the licensee's remedial measures. The NRC is expected to issue its report in early September 2009.

IV. Lessons Learned

These events highlight failures on the part of all parties involved. The medical licensees apparently failed to strictly follow the terms of their licenses. The regulators, including the Agreement States and the NRC, failed to exercise oversight or set expectations. Inspections were limited and did not catch licensee errors.

For medical licensees, there are several lessons to be learned. Improvements can be made in two spheres. First, licensees should follow the tenants of good medical practice, including peer review, to reduce medical errors and increase quality of care. Second, the recent events reinforce the importance of strict compliance with NRC or state regulations. Medicine is an ever-changing and constantly developing field in which critical decisions are often necessarily made on the spot in response to a patient's evolving needs. As such, there appears to be an institutional reluctance among some medical licensees to accept the need to establish and follow procedures to ensure that their practitioners function within NRC regulations when performing medical procedures that utilize

radioactive materials. However, the regulators perceive that this failure places patients at medical risk, and therefore expect a culture of strict compliance. Therefore, compliance problems may put facilities at risk of losing their byproduct materials licenses. It is also important for licensees to recognize that NRC regulations are designed to promote patient health and safety, and that following the regulations is consistent with providing quality medical care.

Moving forward, we recommend that medical licensees evaluate their current programs and adopt remedial measures to ensure that they are in compliance with NRC or Agreement State regulations.

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