U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

Fact Sheet

Office of Public Affairs
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Risks Associated with Medical Events

Members of the public often associate a "medical event" involving certain radioactive materials with injury to the patient. However, the Nuclear Regulatory Commission uses this term to highlight potential problems in a medical facility's use of radioactive materials in diagnosis, treatment or research. An event does not necessarily indicate harm to the patient.

NRC regulations are designed to assure the proper use of radioactive materials in medical diagnosis, treatment and research to assure the safety of patients, medical workers and the public, and to protect the environment.

Medical use of radioactive materials falls broadly into two categories: diagnostic and therapeutic procedures. Most diagnostic procedures using radioactive materials, such as those used in nuclear medicine, involve the use of relatively small amounts of radioactive materials to facilitate imaging of certain organs to help physicians locate and identify tumors, size anomalies, or other physiological or functional organ problems.

Therapeutic uses of radioactive materials include teletherapy, brachytherapy, Gamma Knife® radiosurgery, and therapeutic nuclear medicine. The purpose of all four is to kill cancerous tissue, reduce the size of a tumor, or reduce pain. Radioactive materials are also used in research tests involving administration to humans.

What is a "medical event"?

For all medical uses of NRC-licensed radioactive materials, a "medical event" occurs if ***BOTH*** of the following criteria are met:

(1) One or more of the following representative incidents occur:

- the dose[1] administered to a patient differs from the prescribed dose by at least 20 percent, either too high or too low
- the wrong radioactive drug is administered
- the radioactive drug is administered by the wrong route
- the dose is administered to the wrong individual
- the patient receives a dose to a part of the body other than the intended

[1] The word "dose" refers to administered total radiation dose or radioactive drug dosage.

treatment site that exceeds by 50 percent or more the dose expected by proper administration of the prescription

- a sealed source used in the treatment leaks;

AND

(2) The difference between the dose administered and the prescribed dose exceeds one of the reporting limits contained in the NRC's regulations at 10 CFR 35.3045, which correspond to the annual occupational dose limits at 10 CFR 20.1201.

A "medical event" does not necessarily result in harm to the patient.

The NRC requires licensees to report a medical event because it indicates that the licensee had technical or quality assurance problems in administering the physician's prescription. A dose error of 20 percent or more may indicate treatment delivery problems in the medical facility's operations that need correcting. However, there is no scientific basis to conclude that such an error necessarily results in harm to the patient.

Actual harm to a patient, whether injury (from overexposure) or inadequate treatment (due to underexposure) must be determined through a separate analysis done by the physician. In severe events (for example, rare occurrences when the dose error is well over 20 percent too high or too low), an independent medical consultant will assess the patient's risk of harm.

A "medical event" indicates potential problems in a medical facility's use of radioactive materials. It does not necessarily result in harm to the patient.

For more information:

NRC regulations on medical uses of radioactive material, Title 10 Code of Federal Regulations Part 35
http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/

Reporting requirements for medical events, 10 CFR 35.3045
http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-3045.html

NRC's annual dose limits, 10 CFR 20.1201
http://www.nrc.gov/reading-rm/doc-collections/cfr/part020/part020-1201.html

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