U.S. Medical Event Reporting Criteria

Medical Radiation Safety Team

Office of Federal and State Materials and Environmental Management Programs

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

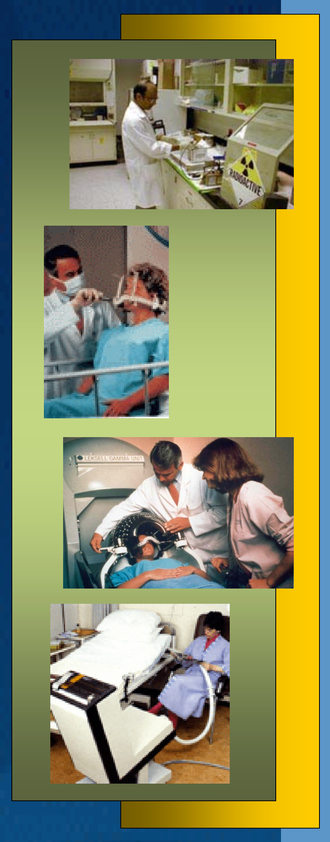
NRC Mission

License and regulate the Nation's civilian use of byproduct, source, and special nuclear materials to ensure adequate protection of public health and safety, promote the common defense and security, and protect the environment.

Medical Event

NRC's term 'medical event' conveys that the byproduct material or radiation from byproduct material was not administered as prescribed by the authorized physician.

Medical Use Policy Statement



- NRC regulates the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public.
- NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public.
- NRC will, when justified by the risk to patients, regulate the radiation safety of patients, primarily to assure the use of radionuclides is in accordance with the physician's directions.
- NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety.

Reporting Medical Events

NRC Requires Medical Events to be Reported When:

1. A dose differs from the prescribed dose by more than:
   - 0.05 Sv effective dose equivalent,
   - 0.5 Sv to an organ or tissue, or
   - 0.5 Sv shallow dose equivalent to the skin

AND

Total dose delivered differs from the prescribed dose by 20% or more or fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50% or more.

2. A dose exceeds:
   - 0.05 Sv effective dose equivalent,
   - 0.5 Sv to an organ or tissue, or
   - 0.5 Sv shallow dose equivalent to the skin

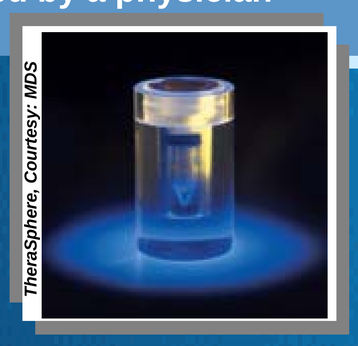
from any of the following:

- Wrong drug
- Wrong route of administration
- Wrong individual
- Wrong mode of delivery
- Leaking source

3. A dose to the skin or organ or tissue other than the treatment site exceeds by 0.5 Sv and 50% or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside of the treatment site)

NRC Does Not Require Reporting When:

An event that meets the criteria above resulted from patient intervention unless that patient intervention resulted in unintended permanent functional damage to an organ or a physiological system as determined by a physician



TheraSphere, Courtesy: MDS

Notification Requirements

Licensees are Required to:

- Telephone NRC's Operation Center no later than the next calendar day after discovery of the medical event
- Notify referring physician and the individual who is the subject of the medical event no later than 24 hours after discovery of the medical event
- Provide an annotated report to the referring physician no later than 15 days after discovery of the medical event
- Provide a written report to the NRC within 15 days after discovery of the medical event

Perfexion, Courtesy: Elekta

NRC's Regulatory Authority

- NRC regulates byproduct material, to include radioactive drugs for medical use.
- NRC does not regulate radiation electronic emitting devices including radiation therapy accelerators. These devices are regulated by the individual States.
- NRC's medical use regulations cover manual brachytherapy, remote afterloader units, teletherapy units and gamma stereotactic radiosurgery units.

Public Awareness

Medical events are made available to the public so other users can be made aware of generic problems that result in medical events and so patient can make timely decision regarding remedial and prospective health care.

Report to U.S. Congress

NRC provides a report annually to the U.S. Congress of events which NRC considers significant from the standpoint of public health and safety.