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

Fact Sheet

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Medical Use of Radioactive Materials

The purpose of NRC regulation of the medical use of radioactive material is to prevent needless radiation exposures of both patients and medical workers while not interfering with treatment established by the physician.

Background

The Nuclear Regulatory Commission's mandate to protect public health and safety and the environment includes regulation of the medical use of radioactive material in the fields of nuclear medicine, radiation therapy, and research.

Medical use of radioactive materials falls broadly into two categories: diagnostic and therapeutic procedures. About one-third of all patients admitted to hospitals are diagnosed or treated using radiation or radioactive materials. This branch of medicine is called nuclear medicine, and the radioactive materials are called radiopharmaceuticals.

For most diagnostic nuclear medicine procedures, a small amount of radioactive material is administered, either by injection, inhalation or oral administration. The radiopharmaceutical collects in the organ or area being evaluated, where it emits photons. These photons can be detected by a device known as a gamma camera. The gamma camera produces images that provide information about the organ function and composition, and help physicians locate and identify tumors, size anomalies, or other physiological or functional organ problems. Two examples of nuclear medicine procedures are the use of technetium-99m in the diagnosis of bone, heart or other organ problems and radioactive iodine in the imaging of the thyroid gland.

Therapeutic uses of radioactive materials include teletherapy, brachytherapy, and therapeutic nuclear medicine. The purpose of all three is to kill cancerous tissue, reduce the size of a tumor, or reduce pain.

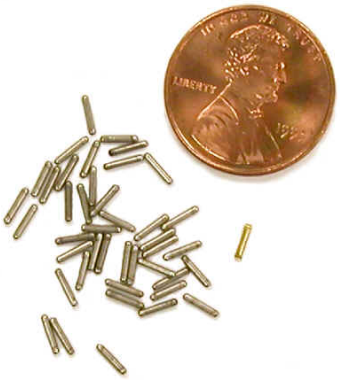
Gamma Knife® (Courtesy: Elekta)

- In **teletherapy,** an intense beam of radiation from a powerful source external to the patient is focused on the cancerous tissue. An example of teletherapy is the use of a device called the Gamma Knife®, which focuses radiation from numerous cobalt-60 sources

to a specific location deep within brain tissue.

- In **brachytherapy**, one or more lower-activity radioactive sources are placed close to, or within, cancerous tissue, such as in the breast, prostate, or cervix. Brachytherapy sources include sealed "seeds" injected or surgically implanted, then removed after the prescribed dose is received by the patient. Intravascular brachytherapy systems use small sources that are placed into arteries using catheters.

- In **therapeutic nuclear medicine**, high dosages of radioactive materials are injected into, or ingested by, the patient. One example is the use of radioactive iodine to destroy or shrink a diseased thyroid.



Brachytherapy Seeds
(Courtesy: Oak Ridge Associated Universities)

Regulatory authority over the medical use of radioactive material and other sources of ionizing radiation (such as x-ray machines) is shared among several government agencies at the federal, state, and local levels. Radioactive material is regulated by either the NRC or an Agreement State (one of 35 states that have entered into an agreement with the NRC to regulate the use of certain radioactive materials). Agreement States issue licenses and currently regulate approximately 6,000 medical-use licensees, such as university medical centers, hospitals, clinics, and physicians in private practice.

The NRC regulates the medical use of radioactive material in the 15 non-Agreement States, the District of Columbia, Puerto Rico, and various territories of the United States, totaling approximately 1,500 medical-use licensees. The NRC maintains jurisdiction nationwide in matters regarding the common defense and security of nuclear materials, such as enhanced security measures.

The Food and Drug Administration (FDA) oversees approval of radiation-producing machines and radiopharmaceuticals for safety and efficacy; however, it does not regulate the use of the devices and radiopharmaceuticals that it approves. Radiation-producing machines, such as x-ray machines and linear accelerators that do not produce radioactive material, are regulated by the states.

Discussion

The NRC and its predecessor, the Atomic Energy Commission, have regulated the medical use of radioactive materials since 1946. These regulations are currently laid out in Title 10 of the Code of Federal Regulations, Part 35. The purpose of these regulations is to prevent needless radiation exposures of both patients and medical workers while not interfering with treatment established by the physician. This is the basis of the Medical Use Policy Statement, published in the *Federal Register* on August 3, 2000. The Policy indicates that the NRC will:

1. continue to regulate the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public;

2. not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public;

3. when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of the radionuclides is in accordance with the physician's directions; and

4. in developing a specific regulatory approach, consider industry and professional standards that define acceptable approaches for achieving radiation safety.

Regulation

The NRC oversees medical use of radioactive materials through licensing, inspection, investigation, and enforcement programs. The NRC issues licenses to facilities, approves individuals authorized to administer radioactive materials, and develops appropriate regulations and guidance for use by licensees.

The NRC maintains the Advisory Committee on the Medical Uses of Isotopes (ACMUI), a committee of medical experts to obtain advice in the use of radioactive materials in medicine. The ACMUI meets twice a year to be briefed by, and provide advice to, the NRC staff on current initiatives in medical uses of radioactive materials. The committee consists of health care professionals from various disciplines in the areas of diagnostic and therapeutic medical use of radioactive materials. Members include a nuclear cardiologist, a nuclear medicine physician, two radiation oncologists, an Agreement State representative, a nuclear pharmacist, a therapy medical physicist, a medical physicist in nuclear medicine, a patients' rights advocate, a health care administrator, an FDA representative, and a radiation safety officer.

Memorandum of Understanding between NRC and FDA

On December 12, 2002, an earlier Memorandum of Understanding between FDA and NRC was renewed for an indefinite time. It clarifies the respective roles of each agency in regulating the safe use of radiopharmaceuticals and sealed sources, or devices containing radioactive material. As a result, NRC and FDA have established liaison officers and identified key management and technical personnel for coordinating responses to emergencies or specific events of mutual interest. They have conducted joint inspections of medical events involving device failures and human or computer-generated errors. Additionally, senior management meetings between the two agencies are conducted annually.

Major Regulatory Changes

In recent years, the NRC has implemented several changes to the way it regulates the medical uses of radioactive materials.

1. On October 24, 2002, revisions to the regulations on medical uses of radioactive material became effective. The revisions focus on those procedures that pose the highest risk and those requirements that are essential for protecting patient safety.

2. On March 30, 2005, the training and validation requirements for doctors authorized to use radioactive materials in 10 CFR Part 35 were amended. This rule also revised the regulations for recognition of specialty boards.

3. On October 1, 2007, NRC implemented expanded authority over radioactive material to include discrete sources of radium-226, accelerator-produced radioactive materials, and discrete sources of naturally occurring radioactive material, as required by the Energy Policy Act of 2005. This change placed radioactive materials produced in accelerators under the regulatory jurisdiction of the NRC (or its Agreement States).

More information on medical uses of radioactive materials can be found on NRC's Web site at: http://www.nrc.gov/materials/miau/med-use.html.

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