Backgrounder

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Medical Use of Radioactive Materials

Background

The Nuclear Regulatory Commission's mandate to protect public health and safety and the environment includes regulation of the medical use of radioactive (byproduct) 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. 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. Two examples of nuclear medicine procedures are the use of technetium-99m in the diagnosis of bone, heart or other organs and radioactive iodine in the imaging of the thyroid gland. The radioactive materials typically are injected into the patient and allow physicians to locate and identify tumors, size anomalies, or other physiological or functional organ problems.

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.

- In **teletherapy,** an intense beam of radiation, from a high-activity source external to the patient, is focused on the tissue. An example of teletherapy is the use of a device called the Gamma Knife, which uses a collimating helmet to focus 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.

The radioactive materials used in medical applications are either byproduct material (nuclear material produced in a reactor), accelerator produced nuclear material, or radiation-producing machines such as x-ray machines.

Regulatory authority over the use of byproduct materials and other sources of ionizing radiation in medicine is shared among several government agencies at the federal, state, and local levels. Byproduct material is regulated by either the NRC or by 33 states, known as Agreement States (these are states that have entered into an agreement with the NRC to regulate the use of byproduct material). The 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 maintains jurisdiction in matters regarding the common defense and security of nuclear materials, such as enhanced security measures. The NRC regulates the medical use of byproduct material in 17 non-Agreement States, the District of Columbia, the Commonwealth of Puerto Rico, and various territories of the United States, totaling approximately 1,500 medical-use licensees.

The Food and Drug Administration (FDA) oversees approval of radiation-producing machines and radiopharmaceuticals. Radiation-producing machines such as x-ray machines and accelerator produced radioisotopes 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. The NRC regulates medical uses of radioactive material under Part 35, "Medical Use of Byproduct Material" in Title 10 of the Code of Federal Regulations. The purpose of NRC regulation of the medical use of byproduct material is to prevent needless radiation exposures of both patients and medical workers while not interfering with treatment protocols 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.

The NRC oversees medical use of radioactive materials through licensing, inspection, investigation, and enforcement programs. The NRC issues licenses to facilities, authorizes physician users, 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 byproduct materials in medicine. The ACMUI meets twice each year to be briefed by, and provide advice to, the NRC staff on current initiatives in medical use of radioactive materials. The committee consists of physicians specializing in all areas of diagnostic and therapeutic medical use of byproduct materials. Members include a nuclear cardiologist, a nuclear medicine physician, two radiation oncologists, an Agreement State representative, an interventional cardiologist, a nuclear pharmacist, a medical physicist, a patient advocate, a health care administrator, 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 period. It clarifies the respective roles of each agency in regulating the safe use of radiopharmaceutical and sealed sources, or devices containing byproduct 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 will be conducted annually.

Regulatory Changes

On October 24, 2002, revisions to the regulations on medical uses of byproduct material (Title 10 of the Code of Federal Regulations, Part 35: Medical Use of Byproduct Material) became effective. The revisions focus on those procedures that pose the highest risk and on those requirements that are essential for protecting patient safety.

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

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