

U.S. NRC

U.S. Nuclear Regulatory Commission

Role of NRC and Other Agencies in Regulating the Medical Use of Nuclear Materials

Regulatory authority over the medical use of ionizing radiation is shared among several Federal, state, and local government agencies. NRC (or the responsible [Agreement State](#)) has regulatory authority over the possession and use of byproduct, source, or special nuclear material in medicine. Byproduct material is used in some calibration sources, radioactive drugs, bone mineral analyzers, portable fluoroscopic imaging devices, brachytherapy sources and devices, gamma stereotactical surgery devices, and teletherapy units used in medicine. Source material is used for radiation shielding and counterweights in medical devices. A few cardiac pacemakers are still powered by special nuclear material batteries.

With the exception of the use of 1 microcurie carbon-14 urea radioactive drug capsules for in vivo diagnostic use in humans, all internal or external administrations of byproduct material or the radiation therefrom to human patients or human research subjects must be done in accordance with a medical use license (or authorization) issued pursuant to NRC's regulations in [10 CFR Part 35](#), "Medical Use." NRC licenses the medical use of byproduct materials in diagnostic devices in the practices of dentistry and podiatry. The medical use of plutonium in nuclear powered pacemakers is licensed pursuant to [10 CFR Part 70](#).

NRC (or the responsible [Agreement State](#)) also regulates the manufacture and distribution of these products (see [Medical Products Distribution Licensee Toolkit](#)). The Food and Drug Administration oversees the good practices in the manufacturing of radiopharmaceuticals, medical devices, and radiation-producing x-ray machines and accelerators. The states regulate the practices of medicine and pharmacy and administer programs associated with radiation-producing x-ray machines and accelerators.

NRC oversees medical uses of nuclear material through licensing, inspection, and enforcement programs. NRC issues medical use licenses to medical facilities and authorized physician users, develops guidance and regulations for use by licensees, and maintains a committee of medical experts to obtain advice about the use of byproduct materials in medicine. The [Advisory Committee on the Medical Uses of Isotopes](#) (ACMUI), comprised of physicians, scientists, and other health care professionals, meets twice a year to be briefed by, and provide advice to, the NRC staff on current initiatives in the medical uses of radioactive materials.

Types of Medical Use Regulated by NRC and Agreement States

Diagnostic medical use

Use of nuclear materials in radioactive uptake, dilution, excretion, imaging, or localization diagnostic clinical or research procedures. The metabolic or physiological properties of radiolabeled drugs are used to obtain medical information, and the radiation produced from sealed sources are used in diagnostic devices to image body parts or determine tissue density. Diagnostic medical use includes the use of certain portable imaging devices in dentistry and podiatry, as well as bone mineral analysis devices in podiatry.

Therapeutic medical use

Use of nuclear materials to deliver palliative (pain relieving) or therapeutic doses of radiation to specific tissues or body areas. Although most therapeutic uses of radiation involve the treatment of cancer, therapeutic doses may also be used to treat benign conditions such as the use of intravascular brachytherapy radiation to treat clogged blood vessels (restenosis).

Medical research use

Research involving human subjects using byproduct materials may only be performed if the licensee has a 10 CFR Part 35 medical use authorization. There are a wide variety of research uses of nuclear materials in human subjects. They include the use of nuclear materials in well-established nuclear medicine procedures to monitor a human research subject's response to a nonradioactive drug or device treatment as well as clinical trials to determine the safety or effectiveness of new radioactive drugs and devices. The particular medical research use must conform with the requirements in 10 CFR Part 35 and the possession and medical use authorizations in the license.

Certain in vitro diagnostic tests

Some medical facilities or private physicians may only have regulated material in the form of prepackaged in vitro diagnostic test kits. These facilities and physicians do not have "medical use" licenses because these materials are not regulated pursuant to 10 CFR Part 35. The amount of regulated materials used in this form of in vitro diagnostic testing determines whether its use is authorized by a specific license issued pursuant to 10 CFR Part 30 or a general license pursuant to 10 CFR Part 31.11. See the [General License Uses](#) page for those materials generally licensed pursuant to 10 CFR 31.11.