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Naturally Occurring and Accelerator-Produced Radioactive Materials - 1987 Review

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ABSTRACT

From time to time, the issue as to whether the U.S. Nuclear Regulatory Commission (NRC) should seek legislative authority to regulate naturally occurring and accelerator-produced radioactive materials (NARM) is raised. Because NARM exists in the environment, in homes, in workplaces, in medical institutions, and in consumer products, the issue of Federal controls over NARM is very old and very complex. This report presents a review of NARM sources and uses as well as incidents and problems associated with those materials. A review of previous congressional and Federal agency actions on radiation protection matters, in general, and on NARM, in particular, is provided to develop an understanding of existing Federal regulatory activity in ionizing radiation and in control of NARM. In addition, State controls over NARM are reviewed. Eight questions are examined in terms of whether the NRC should seek legislative authority to regulate NARM. The assessment of these questions serves as the basis for developing and evaluating five options. The evaluation of those options leads to two recommendations.

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EXECUTIVE SUMMARY

From time to time the issue as to whether the U.S. Nuclear Regulatory Commission (NRC) should seek legislative authority to regulate naturally occurring and accelerator-produced radioactive materials (NARM) is raised. NARM is in the environment, in homes, in medical institutions, in consumer products, and in industrial applications. Congress has never seen fit to expand Atomic Energy Commission (AEC)/NRC jurisdiction into the NARM arena, apparently because other agencies already have jurisdiction and because the States have the primary responsibility for protecting the public health and safety. Thus, NRC's responsibilities and activities have remained linked to the neutron chain reaction.

In deciding whether NRC should seek legislative authority over NARM, it is important to understand what NARM encompasses, how it is used, how the NARM risks compare to other related risks, previous congressional and Federal agency actions on radiation protection matters, and what the States are now doing to regulate NARM.

Defining the universe of NARM is extremely important because naturally occurring radioactive materials are ubiquitous. Radon-222 and radium-226 are significant sources of radiation to which the public is exposed. Radium can be unintentionally concentrated through routine operations such as phosphate mining and purifying drinking water. Radium use in medical institutions, in industrial applications, and in consumer products appears to be diminishing. Thousands of cyclotrons produce NARM and NARM wastes in medical, industrial, and research applications. Eight radionuclides important to the medical community are produced exclusively by cyclotrons. These are: carbon-11; nitrogen-13; oxygen-15; cobalt-57; gallium-67; indium-111; iodine-123; and thallium-201. Two other important radionuclides produced through cyclotrons or nuclear reactors are fluorine-18 and strontium-87. Most of these isotopes have half-lives in the order of minutes to hours.

The quantities and concentrations of NARM form a continuum in the human world, and the potential hazards of NARM form a continuum, ranging from background to potentially significant ones, in all facets of life. Thus, any effort to control the risks from NARM calls for an integrated control program to ensure that the dominant hazards are appropriately addressed, without undue attention to the lesser hazards. However, incidents and problems involving NARM do not always reflect a consistent and significant actual hazard associated with NARM. To be sure, there have been significant incidents involving contamination of facilities, loss of materials, and inadvertent introduction of radium into commerce, but significant exposures of the public to discrete sources of radium rarely occur, based on available data. One particular problem with NARM is proper disposal of discrete radium sources, primarily radium needles. Meager information exists on the hazards associated with cyclotron-produced radiopharmaceuticals, probably mainly because of their relatively infrequent use. Apparently, about 1 percent of the total misadministrations of diagnostic radiopharmaceuticals involves cyclotron-produced radionuclides.

Congress has already vested jurisdiction over NARM in the Environmental Protection Agency, the Consumer Product Safety Commission, the Department of Health and Human Services, and the Department of Labor. In addition, the Departments of Agriculture, Commerce, Energy, Housing and Urban Development, the Interior, State, and Transportation and the U.S. Postal Service and the Interstate Commerce Commission have possible or actual interests in exposures to or commerce in NARM.

There has never been an explicit decision on the Federal role versus the State role in protecting the public from exposures to ionizing radiation, except that set out in Section 274 of the Atomic Energy Act of 1954, as amended. Federal agencies exercise discretion regarding the degree to which they implement their authorities to control exposures to ionizing radiation. Furthermore, congressional mandates to the above agencies vary so greatly that it is not clear whether the worst and most controllable exposures are being addressed without undue attention to lesser ones. As a consequence of all of the above, Federal controls over ionizing radiation, in general, and over NARM, in particular, are fragmented and uneven.

All 29 Agreement States regulate and control discrete sources of NARM in the same way they do Atomic Energy Act materials. Of the 21 non-Agreement States, only 4 have a NARM licensing program. Of the remainder, 2 States have voluntary or partial licensing programs, and 14 States have registration programs, leaving 1 State, Montana, with nothing. With regard to NARM inspections, all 29 Agreement States inspect NARM, as do 14 non-Agreement States, whereas 4 States conduct partial inspections and 5 States conduct no inspections. A comparison of the 1977-versus-1987 level of activity indicates that the States are increasing the amount of attention they give to NARM. Nonetheless, on August 26, 1987, the Conference of Radiation Control Program Directors (CRCPD) once again urged that the NRC seek legislative authority to regulate NARM.

An analysis of the sources and uses of NARM, the incidents and problems with it, and the current jurisdictions and activities of other Federal agencies and the States, led to the following eight questions, which help to clarify the issue as to whether the NRC should seek regulatory authority over NARM:

(1) Is there a national problem with NARM?
(2) Are there currently integrated Federal controls over NARM?
(3) Would NRC regulation of NARM overlap other Federal agencies' programs?
(4) Are the States' controls over NARM adequate?
(5) Is NARM a Federal, State, or professional responsibility?
(6) Would Congress consider the NRC responsible for controlling NARM hazards?
(7) What are the resource implications?
(8) Would NRC responsibility for NARM regulation change the nature of NRC?

An assessment of these eight questions served as the basis for developing the following five options, regarding possible NRC involvement with NARM:

(1) status quo, but continue to encourage the CRCPD efforts on NARM regulations

(2) seek legislative authority over NARM

(3) seek authority to regulate radium disposal

(4) seek authority to regulate cyclotron-produced radionuclides for medical use only

(5) refer the issue of NARM regulation to the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC)

The evaluation of those options and given that many Federal agencies already have jurisdiction over NARM and that the States are increasing their regulation of NARM, leads to the conclusion the unregulated NARM risks are not rising to a level that would suggest they should be the next target of congressional legislation. A forthcoming EPA regulation will address radium disposal. NRC can facilitate that regulation by specifying acceptable and unacceptable concentrations of radium for disposal at low-level waste sites. Finally, NRC regulation of NARM in hospitals would divert limited hospital resources to a lesser problem (NARM) at the expense of greater problems in hospitals.

Two recommendations evolve from this review:

(1) Refer the issue of NARM regulation to CIRRPC for the purposes of developing an integrated policy and agency assignments on NARM, in particular, and ionizing radiation, in general, in those situations where one agency's jurisdiction overlaps that of another (e.g., in the Federal regulatory programs dealing with health care activities).

(2) Inform the Governors of those States not within the CRCPD-recognized NARM licensing States that NRC is not going to seek legislative authority to regulate NARM because such regulation is a responsibility of the States and because other Federal agencies already have jurisdiction over most facets of NARM hazards. Further, urge those Governors to take the necessary actions and to assign appropriate resources to become such recognized States.

Although not directly within the scope of this assignment, it should be noted that information gathered during the conduct of this study suggests that, because of the varying congressional mandates of the numerous agencies having jurisdiction over ionizing radiation, because of the varying and conflicting priorities and programs among those agencies, and because there has never been an explicit and consistent determination of the Federal role versus the State role in protecting the public from exposures to ionizing radiation, there is a need for better integration of the numerous Federal programs governing exposures to ionizing radiation.

ACRONYMS AND INITIALISMS

AEA	Atomic Energy Act
AEC	Atomic Energy Commission
ANPR	advance notice of proposed rulemaking
BRH	Bureau of Radiological Health
CFR	Code of Federal Regulations
CIRRPC	Committee on Interagency Radiation Research and Policy Coordination
CPSC	Consumer Product Safety Commission
CRCPD	Conference of Radiation Control Program Directors
DOE	Department of Energy
EDO	Executive Director for Operations
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FR	Federal Register
FTE	full-time equivalents
FY	fiscal year
GAO	General Accounting Office
HEW	Health, Education, and Welfare, Department of
HHS	Health and Human Services, Department of
HUD	Housing and Urban Development, Department of
IAEA	International Atomic Energy Agency
IEEE	Institute of Electrical and Electronics Engineers
LLW	low-level waste
Mev	million electron volts
NARM	naturally occurring and accelerator-produced radioactive materials
NCRP	National Council of Radiation Protection and Measurements
NGA	National Governor's Association
NIH	National Institutes of Health
NIOSH	National Institute of Occupational Safety and Health
NORM	naturally occurring radioactive materials
NPR	notice of proposed rulemaking
NRC	U.S. Nuclear Regulatory Commission
NYT	New York Times
OSHA	Occupational Safety and Health Administration
OSTP	Office of Science and Technology Policy
OTA	Office of Technology Assessment

PET	positron emission tomography
PNL	Pacific Northwest Laboratory
RPC	Radiation Policy Council, United States
SNM	Society of Nuclear Medicine
TSCA	Toxic Substances Control Act
USP	United States Pharmacopeial

1 INTRODUCTION

NARM refers to the collective body of naturally occurring and accelerator-produced radioactive materials. NARM is in the environment, in homes, in medical institutions, in consumer products, and in industrial applications. NARM is one of the more significant sources of radiation exposure to the public. Thus, on the premise that it is prudent to have an orderly Federal program to control harmful radiation exposures, NARM regulation is more an issue of regulating exposures to ionizing radiation than one of regulating certain radioactive materials. A rational Federal program to control risks would first seek to address the worst and most controllable exposures to ionizing radiation; to do otherwise would mean that the total amount of harm being prevented would be less than that which could be prevented, given a constant application of resources. (See "Risk Assessment in the Federal Government: Managing the Process," National Research Council, National Academy Press, Washington, DC, 1983.)

Federal control over NARM is a very old and complex issue. It resurfaces every few years, occasionally in the context of whether there is sufficient rationale to consider having the U.S. Nuclear Regulatory Commission (NRC) regulate all but that small portion of nuclear medicine that involves radium and accelerator-produced radioactive materials. The direct and short answer to why the Federal government has not taken overall jurisdiction of NARM is history.

It has long been recognized that there is a fundamental Federal, State, and professional responsibility for protecting the public from exposure to ionizing radiation. The issue of governmental controls over exposures to NARM is not whether the Federal government should create an authority to establish such controls, but, rather, whether the Federal government should preempt the authority that the States already have. A preeminent purpose of the Federal government, in the creation of an organized community bound by common rules, is to promote the general welfare. Because the nation's resources are limited, the Federal government must direct its resources toward the actions that will produce the greatest reductions in risks to the public health and safety. If the risks of the same type (e.g., risks of cancer from exposure to ionizing radiation) are to be regarded as comparable regardless of the route through which people are exposed to them, then there should be an integrated approach to controlling exposures of people to such risks.

About 18 Federal agencies currently have an uneven and fragmented role in programs governing exposures to ionizing radiation. Although the responsibilities of the Federal government and State governments have shifted somewhat over time, there has been no explicit decision on what the Federal role is--or should be--in protecting the public from exposures to ionizing radiation. For example, is it--or should it be--a function of the Federal government to ensure that exposures of the public be as low as reasonably achievable? Inasmuch, assuming a general Federal role, at what exposure level does the Federal government believe exposures are below concern? Furthermore, there has been no explicit definition of the Federal role versus the State role on protecting the public from ionizing radiation, except that set out in Section 274 of the Atomic Energy Act of 1954, as amended. Because there is no generally applicable policy on

the Federal role in regulating exposures of the public to ionizing radiation and because there is no generally applicable Federal definition of de minimis exposures, there appears to be no precise rationale for bracketing the universe of NARM for possible regulation by the NRC. Depending on any selected bracketing of the definition, as will be illustrated later, other Federal agencies may be involved.

In deciding whether the NRC should seek legislative authority over NARM, it is important to understand what NARM encompasses, how it is used and misused, how the risks associated with NARM compare to other related risks, and what is now being done about those risks.

In the medical field, there are higher risks associated with other sources of ionizing radiation than those that are apparent with accelerator-produced radioactive materials. Congressional interests with respect to the quality of health care and problems in the health care delivery programs, including those involving ionizing radiation, are much more important and fundamental than those represented by a small percent of a nuclear medicine institution. Even so, Congress appears to be moving rather slowly on addressing these more important problems. Thus, the issue of whether there should be additional Federal controls over NARM is an issue of defining Congress' next target for reducing exposures of the public to ionizing radiation. (See, for example, "The Environmental Protection Agency Needs Congressional Guidance and Support to Guard the Public in a Period of Radiation Proliferation," General Accounting Office (GAO) Report CED-78-27, Washington, DC, January 1978; "Unnecessary Exposure to Radiation from Medical and Dental X-rays," U.S. House of Representatives Committee Print 96-52, Washington, DC, August 1980; "Nationwide Evaluation of X-ray Trends," Department of Health and Human Services (HHS) PB 84-189281, Washington, DC, April 1984; "Medical Technology and Costs of the Medicare Program," Office of Technology Assessment (OTA)-H-227, Washington, DC, July 1984; "Federal Policies and the Medical Devices Industry," OTA-H-230, Washington, DC, October 1984; P.L. 99-660 and Legislative History on Health Programs; "Medical Devices: Early Warning of Problems is Hampered by Severe Underreporting," GAO/PEMD-87-1, GAA, Washington, DC, December 1986.)

2 DEFINITION OF NARM

The definition of the universe of NARM for possible Federal regulatory jurisdiction is extremely important because naturally occurring radioactive materials are everywhere in the environment. Natural radiation and naturally occurring radioactive materials are the dominant sources of human radiation exposure. (See "Ionizing Radiation Exposure of the Population of the United States," National Council of Radiation Protection and Measurements (NCRP) Report No. 93, Bethesda, MD, November 1987.) Naturally occurring radionuclides that represent a significant source of human radiation exposure include carbon-14, potassium-40, polonium-210, radon-222, and radium-226. Some of these radionuclides, particularly radium-226, can be unintentionally concentrated through routine operations such as purifying drinking water (resins used to bring drinking water into compliance with the Environmental Protection Agency standards remove and concentrate radium-226 on the resins) and transmission of oil and gas through pipelines (scale on the inside of the pipes trap and concentrate radium-226).

The book, Radionuclides Production (CRC Press, Boca Raton, FL, Vol. II, F. Helus Ed., 1983), identifies 24 specific radionuclides that the biological and medical fields use most often. Of these, 14 are produced exclusively in nuclear reactors (thus, byproduct material), 8 are produced exclusively in cyclotrons (carbon-11, nitrogen-13, oxygen-15, cobalt-57, gallium-67, indium-111, iodine-123, and thallium-201), and 2 are produced by either means (fluorine-18 and strontium-87). There are many other cyclotron-produced radioisotopes being used in the medical, research, and development fields. Most of the cyclotron-produced radionuclides have relatively short half-lives, in the order of minutes to hours; thus, they typically decay onsite or are disposed of with byproduct low-level wastes. Cobalt-57, with a half-life of 271 days, is an exception. In addition, there are some longer-lived gamma ray emitters, produced through accelerators, which are used in agricultural tracer studies (e.g., sodium-22 and manganese-52 with half-lives of 2.6 years and 312 days, respectively). Another major exception with respect to the half-lives of accelerator-produced radionuclides derives from accelerator targets and components. For example, from 1976 to 1986, the average annual amount of radioactive waste shipped from the Fermi National Accelerator Laboratory was 7,700 cubic feet per year. This volume of low-level waste is about as much as that generated by a large power reactor. (See Department of Energy (DOE) memorandum from L. E. Temple to Prospective Proposers on the Superconducting Super Collider, dated August 3, 1987.)

There is another issue that frequently surfaces in the context of NARM and that has a bearing on the issue of whether risks of the same type are to be considered comparable, regardless of the route of exposure, that is, the similarity of cobalt-60 teletherapy units and X-ray devices. Both machines are used in radiation therapy, but X-ray devices are replacing cobalt-60 units because the linear accelerators are more versatile. (See "Trends in Radiation Therapy Demographics - 1974 to 1983," J. J. Diamond et al., Int. J. Radiation Oncology Biol. Phys., Vol. 12, pp. 1673, 1674, Pergamon Press, New York, NY, 1986.)

NRC regulates the possession and use of cobalt-60, whereas the Food and Drug Administration (FDA) regulates the manufacture and assembly of medical devices, including X-ray devices and cobalt-60 teletherapy devices, but not the use. Albeit, FDA has recommended that quality assurance programs be developed at user facilities (21 CFR 1000.55), but this is not a requirement. Thus, the cobalt-60 and X-ray devices can stand side by side and the use of cobalt-60 devices is subject to Federal requirements (including the reporting of misadministrations) whereas the use of X-ray devices is not. This is a dichotomy equal to that of NRC regulating byproduct material used in nuclear medicine and not regulating NARM used in nuclear medicine. However, X-ray teletherapy units are not strictly within the definition of NARM. Nonetheless, this dichotomy has surfaced as an example of the importance of having a clear logic on any extension of the scope of Federal controls over NARM beyond that which already exists.

3 SOURCES AND USES OF NARM

3.1 Radium

First discovered in 1898, radium has been used longer than any other radioactive material. As an alpha- and gamma-emitter with a half-life of about 1600 years, and as a bone-seeker, radium is one of the most hazardous radionuclides

to human beings. Until around the 1930's, radium was considered almost magical as a cure for cancer and other ailments. As a radioluminous material, radium constituted the first application of radioactive materials in consumer products, including dials for aircraft instruments, religious articles, pull chains for electric lights, and knobs for chamber pot covers. Approximately 60 known deaths resulted from the use of radium in luminizing compounds. Before the dangers of radium came to be appreciated, an unknown fraction of the total production also was used in quack medicine, resulting in additional cases of radium-induced bone cancers. For example, compresses used for miscellaneous aches and pains contained 0.1 mg of radium-226. (See Environmental Radioactivity, Third Edition, pp. 4 and 234, Merril Eisenbud, Academic Press, San Diego, CA, 1987.)

As an investment in the 1920's and 1930's, radium was hoarded until cheaper, substitute sources of ionizing radiation became available after the Manhattan Project. Doctors and others who bought radium when the price was high were reluctant to let it go at a small fraction of the purchase price, so some stored it in safe-deposit boxes and in attics. (See "Lost Radium...Killer at Large," Popular Mechanics, Hearst Magazines, New York, NY, February 1966.)

The total amount of radium produced worldwide by the time production ceased in about the 1950's was little more than 3000 grams. (See Radionuclides Production, Vol. I, p. 2, F. Helus, Ed., CRC Press, Boca Raton, FL, 1983.) Of this amount, according to the only extensive national survey of radium use, undertaken in 1968, approximately 1300 grams (curies) of radium were sold in the United States. About 550 grams of radium were apparently sold as a luminous compound for such items as watches, clocks, and aircraft dials; another 320 grams of radium were sold to the medical community; and 260 grams were sold for other applications. In 1968, there were 152 grams under leases for medical and other uses. Although fraught with uncertainties, in 1968 it appeared that almost all major users of radium had been located. Not known are the possessors of small, but potentially hazardous, quantities of radium. (See "State and Federal Control of Health Hazards from Radioactive Materials Other than Materials Regulated Under the Atomic Energy Act of 1954," pp. xi, 29, 43, and 44, FDA 72-8001, FDA, Washington, DC, June 1971.)

Off and on from 1964 through 1982, FDA and the Environmental Protection Agency (EPA) carried out a program to collect and dispose of radium sources that were no longer needed. In the summer of 1983, all of the radium collected during the program, 145 grams, was transferred to Hanford, Washington. (See "NORM-EPA's Point of View," F. L. Galpin and S. T. Windham, Conference of Radiation Control Program Directors Meeting on May 21, 1987.)

The medical uses of radium generally involve brachytherapy treatments, but most observers believe such use is declining. Industrial uses include soil density gauges, well logging, calibration standards, and radiography. Residential uses of radium involve smoke detectors, and clocks and watches that are illuminated with radium. The estimated 550 grams of radium in luminous compounds are so dispersed that it is unlikely there could ever be an accounting for that source. Radium, in conjunction with berryllium, becomes a neutron source with applications in activation analyses. Most observers believe this use of radium is being replaced by americium.

Four companies have been identified as marketing radium or radium-containing devices. The Thomas Register lists only one company marketing radium; based on an informal contact with people in that company, they indicate that there is

little interest in radium and that companies are moving away from radium. Their total sales over the last year were between 0.5 and 1.0 curie of radium (i.e., about one-half to one gram of radium). Most of the sources sold are in the few millicurie range, usually for level measurement gauges. Some standard solutions, containing either 0.5 microcurie or 5 microcuries of radium, for calibrating instruments are sold each year. The company obtains its radium through imports from its parent company in the United Kingdom. One company in Wisconsin has been identified as still offering radium in its soil-density gauges, but it may change to another radionuclide for economic reasons. Another company in New York distributes lightning rods containing up to 80 microcuries of radium. Still another company owns 140 grams of radium; most of which is housed in its facility in New York City. Since 1983, the State of New York has banned all commercial operations at the site. (See "Queens Radium Supplier is Faulted on Safety," New York Times (NYT), New York City, NY, October 4, 1987.)

EPA has identified 70 specific waste streams containing NARM and has grouped these into 10 general categories, based on similarities in source type, waste form, and/or waste processing. EPA emphasizes that there are two very different types of NARM wastes. First, there are discrete sources of higher radioactive concentrations, such as radium needles used in medical practices, or radium-contaminated drinking water cleanup resins that have radioactivity characteristics similar to much of the byproduct low-level wastes. Second, there are lower activity, diffuse sources such as residuals from mining and extraction industries and from burning ignite coal. The latter are produced on the order of hundreds of millions of tons per year. (See "Low-Level and NARM Radioactive Wastes, Background Information Documents," EPA 520/1-87-012, EPA, Washington, DC, August 1987.)

With regard to the diffuse sources of NARM, the following radium-226 concentrations have been measured in mineral ores: phosphate ores, from 3 to 50 picocuries per gram; titanium metal ores, from 12 to 15 picocuries per gram; zirconium ores, 13 picocuries per gram; and alumina ores, 7.4 picocuries per gram. Depending on the processing technique used to extract the mineral, radium enhancement factors of perhaps 80 may occur in going from ore to waste, resulting in radium concentrations ranging from 100 to 2000 picocuries per gram. (See "NORM in Mineral Processing," D. W. Hendricks, given at Conference of Radiation Control Program Directors Meeting of May 21, 1987.)

Building materials for homes and offices can contain potentially significant concentrations of radium, including red-mud brick (7.6 picocuries per gram), fly ash (5.7 picocuries per gram), some tuff (6.5 picocuries per gram), some concrete (35 picocuries per gram), and phosphogypsum (17 picocuries per gram). (See "NORM: Is it NORMal or abNORMAL?" E.D. Bailey, Eighteenth Annual National Conference on Radiation Control, May 20, 1986.)

For comparative purposes, the EPA standards for remedial actions at inactive uranium processing sites call for cleaning up the mill tailings if the radium concentration is greater than 5 picocuries per gram within the top 15 centimeters of the surface or if the radium concentration is greater than 15 picocuries per gram in any 15-centimeter layer below the surface. (See Federal Register, 48 FR 592, January 5, 1983.) EPA has analyzed the wastes from 17 uranium mines to determine their radium concentration and found that 14 of the waste piles had at least one sample measuring 20 picocuries radium per gram or more. (See

"Report to Congress: Wastes from the Extractions and Beneficiation of Metallic Ores, Phosphate Rock, Asbestos, Overburden from Uranium Mining, and Oil Shale," EPA/530-SW-85-033, pp. 4-31, EPA, Washington, DC, December 1985.)

Some food products concentrate naturally occurring radioisotopes. For example, Brazil nuts can contain up to 3 picocuries radium per gram whereas legumes, leafy vegetables, fruits, and nuts can contain between 3 and 6 picocuries potassium-40 per gram. (See "CRC Handbook of Environmental Radiation," A. W. Klement, Jr., Ed., CRC Press, Boca Raton, FL, 1983.) Drinking water can also contain high concentrations of radium-226, leaving some to state that "nature often violates Federal radiation standards." (See letters to the Editor, NYT, New York City, NY, December 3, 1987.)

3.2 Other Naturally Occurring Radioisotopes

Exposures of the public to naturally occurring radon constitute 55 percent (200 millirem per year) of the average total dose the U.S. population receives in a year. Radon doses to the public are over twice that of the combined man-made sources of radiation exposures through medical X-rays, nuclear medicine, and consumer products and may cause thousands of deaths each year. (See "Ionizing Radiation Exposure of the Population of the United States," NCRP Report No. 93, Bethesda, MD, November 1987, and NYT, New York City, NY, November 20, 1987.)

Polonium-210 is believed to enter tobacco by ingrowth of lead-210 deposited on tobacco leaves from the atmosphere. In addition, dietary habits that tend to favor broad-leaf vegetables or other foods subject to surface deposition may influence the polonium-210 content of tissues. Of the two pathways, smoking is by far the more significant. However, it is very difficult to estimate the effective dose equivalent resulting from tobacco use. One such estimate is 1300 millirem for the average smoker. (See Environmental Radioactivity, Third Edition, p. 148, Merril Eisenbud, Academic Press, San Diego, CA, 1987; and "Ionizing Radiation Exposure of the Population of the United States," NCRP Report No. 93, NCRP, Bethesda, MD, November 1987.)

And finally, for completeness, it is worth noting that polonium-210 is used in products as a static eliminator. However, rather than separate polonium-210 as a naturally occurring radionuclide, the industrial sector obtains it through neutron irradiation of bismuth-210, thus making possession and use of polonium-210 subject to the provisions of the Atomic Energy Act of 1954.

3.3 Accelerator-Produced Radioactive Materials

Some 40 cyclotrons have been installed in the United States. Generally, the machines bombard enriched stable isotopes with particles to produce over 40 different radioisotopes for the practice of medicine and for research and development purposes. In addition, the Los Alamos Meson Physics Facility and the Brookhaven National Laboratory produce important radionuclides for medical applications, including beryllium-7, copper-67, strontium-82, and xenon-127. (See letter from Kenneth B. Halliday, CTI Group, Inc., Knoxville, TN, to J. Austin, NRC, dated November 10, 1987; Separated Isotopes: Vital Tools for Science and Medicine, National Academy Press, Washington, DC, 1982; and J. Nucl. Med., Society of Nucl. Med., New York, NY, Vol. 28 [9], pp. 1371-1382, September 1987.)

Heavy ion accelerators are used in the industrial sector as ion implanters, primarily to modify the properties of materials. There are nearly 3000 of these machines installed in semiconductor fabrication plants. One of the potential hazards associated with these machines is exposure to ionizing radiation. Electrons are created by the interaction of positive ions with component parts of the implanter, which in turn produce X-rays upon decelerating. Resulting dose rates can be 0.5 millirem per hour. The extent to which these machines present a NARM waste stream has not been determined. (See "Design of Accelerators for Ion Implantation," B. O. Pedersen, Nucl. Instr. and Methods in Physics Res., B24/25, pp. 776-782, North Holland Publ. Co., Amsterdam, Netherlands, 1987; and "Radiation Protection Considerations of Ion Implantation Systems," C. J. Maletskos and P. R. Hanley, Institute of Electrical and Electronics Engineers (IEEE) Trans. on Nucl. Science, Vol. NS-30, No. 2, pp. 1592-1596, IEEE, New York, NY, April 1983.)

Electron accelerators are used in radiation therapy. For those machines that operate above 10 million electron volts (Mev), neutrons can be produced through the electroproduction reaction, resulting in additional doses to patients and to operating personnel from direct exposure both to neutrons and to the resulting residual radioactivity (i.e., NARM). (See "Neutron Contamination from Medical Electron Accelerators," NCRP Report No. 79, Bethesda, MD, November 1, 1984.)

Neutron generators fuse deuterium and tritium to yield a 14-Mev neutron and an alpha particle. The machines are useful for preparing short-lived radionuclides only, through (n, p), (n, 2n) and (n, He) reactions. Over 50 radionuclides can be produced this way, with the more important medically useful radionuclides being fluorine-18, bromine-80, and mercury-199m. The costs of the generators are comparable to the costs of cyclotrons. (See "Radionuclides Production," Vol. II, pp. 153-160, F. Helus, Ed., CRC Press, Boca Raton, FL, 1983.)

Neutron generator machines also are used for neutron therapeutic treatment of cancer. Although there are probably no more than about 25 such active facilities, there is one estimate that as many as one-third of the yearly cancer deaths in this country could be helped by neutron therapy. The neutron generators also have been used for years for neutron activation analysis, using the conventional Cockcroft-Walton accelerators. In addition, accelerator well-logging devices, employing the T(d,n)He reaction, are used for activation analysis of boreholes, to give indications of the type of formations. (See "Industrial and Medical Applications of Accelerators with Energies Less Than 20 Mev," J. L. Duggan, IEEE Trans. Nucl. Science, Vol. NS-30, No. 4, pp. 3039-3043, IEEE, New York, NY, August 1983.)

One significant source of cyclotron- or accelerator-produced radioisotopes is the Department of Energy, which compiles annually, its production and distribution activities. (See, for example, "List of DOE Radioisotope Customers with Summary of Radioisotope Shipments, FY 1985," D. A. Baker, Pacific Northwest Laboratory Report PNL-5948, Richland, WA, August 1986.) A comparison of DOE FY 1985 records on customers in non-Agreement States with NRC headquarters and regional files on licensees revealed that all recipients of DOE radioisotopes, whether materials covered by the Atomic Energy Act or NARM, were holders of NRC byproduct licenses.

Foreign countries export radioisotopes to this country, with Canada, Belgium, and Switzerland being the major exporters. Although Switzerland generates

accelerator/cyclotron-produced radioisotopes, it only exports them to neighboring countries because of the short half-lives of the isotopes. (See letter from H. P. Hertiz, Embassy of Switzerland to J. H. Austin, NRC, dated November 19, 1987.) Although Canada exports radium in very small quantities to the United States for use in instrument calibration, information on the quantities is not readily available. The extent to which Canada exports cyclotron-produced radioisotopes has not been determined. However, the Atomic Energy Control Board of Canada has issued licenses to authorize exports to the United States of cobalt-57, gallium-65, indium-111, iodine-123, and thallium-201. (See letters from T. D. McGee, Canadian Embassy, to J. H. Austin, NRC, dated December 14 and 29, 1987.) It also could not be determined whether Belgium exports NARM to the United States, although its situation is probably similar to Switzerland's.

Radioisotopes, both those covered by the Atomic Energy Act and NARM, are used extensively in the medical field to diagnose ailments and to treat cancers. New and emerging uses of radioisotopes include modalities, such as positron emission tomography (PET) and monoclonal antibodies. (See, for example, Nuclear Medicine Technology and Techniques, D. R. Bernier et al., Eds., C. V. Mosky Company, St. Louis, MO, 1981; "Radiation Protection and New Medical Diagnostic Approaches," NCRP Proceedings No. 4, Bethesda, MD., April 6-7, 1982; and CRC Handbook of Radiobiology, K. N. Prasad, Ed., CRC Press, Boca Raton, FL, 1984; "Scientific Highlights: 'Slices of Life,'" H. N. Wagner, J. Nucl. Med. Vol. 28 [8], pp. 1235-1245, Soc. of Nuclear Med., New York, NY, August 1987; and "Diagnosis and Treatment of Metastatic Tumors with Radiolabeled Monoclonal Antibodies: Experience with Lymphoma, Melanoma, and Colon Cancers," S. M. Larson, National Institutes of Health (NIH), Bethesda, MD, E. P. Pendergrass, New Horizons Lecture, 1986.)

PET involves the injection of a beam of charged particles from a cyclotron into a "black box" containing the stable target, which in turn becomes the activated chemical for quick injection into the patient who is being diagnosed for a medical problem. The black box amounts to a hot chemistry laboratory. The entire system is rather complex and must work together accurately to be successful. The FDA is currently considering whether the system is a medical device (and subject to the provisions of the Medical Device Amendments Act) or a drug (and subject to the provisions of the Pure Food and Drugs Act, as amended) or neither. (See "Transcript of Radiopharmaceutical Drugs Advisory Committee," FDA, 5600 Fishers Lane, Rockville, MD, public meeting on November 16, 1987.)

Should NRC regulate this aspect of NARM, it may be that the entire system (the cyclotron, the "black box" and the patient) would have to be regulated, because the success of the PET diagnostic procedure depends on the entire system working together successfully. Worth noting is the fact that the radiolabeled chemicals are produced, used, and generally decay at the site, raising the question as to whether interstate commerce is involved in this modality.

3.4 Trends

The trends and uses of nuclear medicine in the United States have been surveyed for the years 1972 through 1982. The results indicate that, while the nuclear medicine procedures changed markedly in type over the decade, the overall frequency of examination doubled to 32 per 1000 population. The growth was a result of a markedly increased frequency of, for example, bone, liver, lung, and cardiovascular imagery. Such a trend may portend increased use of NARM.

(See "Trends and Utilization of Nuclear Medicine in the United States," F. A. Mettler et al., J. Nucl. Med., Vol. 26 [2], pp. 201-205, Soc. of Nuclear Med., New York, NY, 1985.)

3.5 Discussion

As evident from the above, sources and uses of NARM are ubiquitous. NARM is in the environment (and of interest to EPA); in homes (and of interest to EPA and the Department of Housing and Urban Development); in consumer products (and of possible interest to the Consumer Product Safety Commission), in industrial applications (and of interest to the Department of Health and Human Services (HHS) and the Department of Labor); and in medical institutions (and of interest to the HHS). The Departments of Agriculture, Commerce, Energy, the Interior, State, and Transportation and the U.S. Postal Service and the Interstate Commerce Commission also have possible or actual interests in exposures to or commerce in NARM.

The quantities and concentrations of NARM form a continuum in the human world, and thus the potential hazards of NARM form a continuum, ranging from background to potentially significant ones, in all facets of life. Thus, to the extent that there is a need for centralized controls over those hazards, there is a need for an integrated control program to ensure that the dominant hazards are appropriately addressed without undue attention to the lesser hazards.

4 PROBLEMS AND INCIDENTS WITH NARM

4.1 Radium and Radon

Incidents involving radium have occurred since the earliest days of radium use, including losses, thefts, contamination from ruptured sources, and overexposures of individuals. The total number and severity of such occurrences cannot be determined since the Federal government has never had the authority to control radium possession and use and there is no government requirement to report radium incidents.

The potential acute hazard associated with radium sources is well known. A milligram (millicurie) of radium can expose a person in close proximity to about 100 millirems in an hour. The sources in therapeutic medical applications range from 1 to 50 milligrams, with concomitant exposures of 100 to 5000 millirems per hour. Industrial sources may be as large as several hundred milligrams.

From 1963 through about 1968, the Bureau of Radiological Health (BRH) of the Public Health Service collected, analyzed, and disseminated radium-incident information for the purposes of determining the extent and causes of radium incidents and to devise preventive measures. BRH also assimilated reports of earlier incidents, as reported in literature, for example, The New York Times. Altogether, BRH collected information on 415 incidents that took place since 1905. BRH found that the apparent rate of occurrence of radium incidents increased almost continuously up to the early 1960's and then stabilized at about 20 to 30 incident reports annually. Sixty-five percent of the reported radium incidents involved losses of the source, with virtually all of them occurring at medical facilities. Of those sources eventually recovered, over half were found in the conventional trash system, generally at the municipal

disposal site or sanitary landfill. (See "A Review of Radium Incidents in the United States of America," J. C. Villforth et al., International Atomic Energy Agency, Vienna, Austria, IAEA-SM-119/26, pp. 389-398, 1969.)

No single organization or agency has compiled radium incidents since around 1969. In 1975, the Conference of Radiation Control Program Directors (CRCPD or the Conference) established Task Force No. 7, Natural Radioactivity Contaminated Problems, to, among other reasons, define the currently known or suspected sources of materials containing possibly hazardous amounts of naturally occurring radioactive materials (NORM) and to recommend priorities for control programs to address such problems. (The Conference is comprised of Radiation Control Directors from all States and territories and was incorporated in 1968.) Its last report was printed in 1981 and listed an extensive array of radiation pathways from incidental NORM use. In that report, the Conference recommended soil contamination guidelines for cleanup or control of selected radionuclides. The concentration above which removal or controls would be mandatory for radium-226 bearing residuals was 6 picocuries per gram. (See "Natural Radioactivity Contamination Problems," Report No. 2, Conference of Radiation Control Program Directors, August 1981.)

The NRC 1977 task force that examined the regulation of NARM summarized NARM incidents in the following manner:

> The available information indicates that radium is the NARM isotope which is most often identified in reports of incidents. However, the available information is incomplete. Present available information does not permit an overall assessment of the possible or actual impact or threat to the public health and safety. It is known that available data represents an underreporting but the degree is unknown. (See "Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials," D. A. Nussbaumer et al., NUREG-0301, July 1977.)

That NRC task force report was updated in 1984, wherein the authors stated that since 1977 "there continue to be numerous NARM incidents. The number of incidents reported to State agencies involving NARM (both medical and industrial users) range from 30 to 50 per year." That update also noted that in 1981, numerous radioactive contaminated gold items were discovered in the Northeastern States, apparently from inadvertently recycling gold seeds containing radon-222 that had been used in radiation therapy. (See "Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials: An Update," L. A. Bolling et al., NUREG-0976, October 1984.)

NARM is inadvertently introduced into commerce in other ways. For example, in November 1984, a radiation alarm was triggered as a truckload of scrap steel was entering a processor's facility in Pennsylvania. The source of radiation was later identified as a static eliminator bar that contained radium-226. (See letter to H. Cutler, Institute of Scrap Iron and Steel, from V. Miller, NRC, dated August 12, 1987.)

In a more recent event in September 1987, samples of contaminated aluminum dross were found to contain radium-226, producing radiation levels of 0.4 to 0.5 millirem per hour at the surface of the rail cars containing the dross. The dross material in the two box cars was later found to contain 2000 picocuries radium-226

per gram. (See letter to J. Snyder, United Technology, from J. A. Hind, NRC, dated September 24, 1987.)

The primary national interest in radon is currently focused on indoor radon exposures in certain eastern areas of the United States, such as Pennsylvania and New Jersey, where radon levels in houses are found to exceed levels used by the Federal Government to clean up misused uranium mill tailings. As previously mentioned, inhalation of naturally occurring radon results in a significant contribution to the average radiation dose to the population of the United States. The hazard is so great that the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC) has selected radon as one of the major national ionizing-radiation issues and is urging an accelerated research program as well as a national indoor radon survey. (See "CIRRPC Third Annual Report," Office of Science and Technology Policy, Executive Office of the President, Washington, DC, June 30, 1987.)

4.2 NARM in General

On October 22, 1987, the CRCPD requested all State radiation control programs to describe, by November 31, 1987, NARM incidents during the past 5 years. As of December 7, 1987, nine Agreement States, eight non-Agreement States, and one territory had responded, listing a total of about 91 NARM incidents. Thirteen of these States and the one territory reported between one and four incidents over the 5-year period (for a total of 21 incidents); the remaining four States reported a total of 70 incidents. The incidents range from false alarms (e.g., after investigation, no actual involvement of radioactive material was found), to lost sources, to radium sources appearing from "out of nowhere," to actual exposures and contamination problems. However, for most of the incidents, exposures or contamination problems were not reported. The dominant radioisotope identified in the incidents was radium. There were five significant occurrences of radium-contaminated facilities, requiring State intervention and involving radium as a luminous paint. Three States reported 26 incidents of lost cobalt-57 sources--almost always in the microcurie range--whereas a few other States reported an occasional loss. The State with the most of these incidents (12) deemed the quantities so small that they did not present an environmental or public health hazard. One State reported concrete wall materials had substantial radiation activity because of the use of an accelerator so that the facility could not be cleared as an uncontrolled area; parts of the accelerator, such as targets and turning magnets, also showed activity. One State emphasized a problem with NARM in the oil and gas industries. The pipes used in production wells accumulate deposits (scales) that must be periodically removed. The scales trap radium, thus making the deposits a source of highly contaminated waste. That State, recognizing that other States have had the same experience and recognizing that the scales are similar to byproduct wastes, believes that there is a national issue here, which needs to be addressed by Congress and the Federal Government. (See letters and enclosures from C. M. Hardin, Executive Secretary of CRCPD, to J. H. Austin, NRC, one dated November 25, and two dated December 7, 1987.)

The Conference points out additional problems with NARM:

> Non-uniform regulation of NARM sources and devices has caused considerable problems for Agreement States in their issuance of specific licenses for the use of such sources and/or devices when

manufactured in a non-Agreement State. Since most non-Agreement States do not license the manufacture of such sources and devices, there is no mechanism to reciprocally recognize the manufacture of such. Consequently, the Agreement States for NARM sources and devices, must either license each and every source and/or device, or issue a license on the good faith that the manufacturer will apply acceptable quality control in the manufacture of all sources and devices on the production line. (See attachment to letter from C. M. Hardin, Executive Secretary, CRCPD, to J. H. Austin, dated November 25, 1987.)

Informal contacts with manufacturers of radiopharmaceuticals containing cyclotron-produced radioisotopes indicate similar difficulties in marketing such materials in a non-uniform regulatory environment.

The United States Pharmacopeial (USP) convention has since 1820 established national standards of strength, quality, and purity of medicinal products, and its expertise has been recognized in congressional legislation since as early as 1848. More recently, the Medical Device Amendments of 1976 recognized the articles of USP concerning medical devices. Since 1980, USP has operated for the FDA the voluntary Problem Reporting Program for radiation therapy devices. From January 1, 1980, to June 1987, USP received 28 reports on problems with brachytherapy devices; five problems related to apparently housing or intending to house radium and the rest involved byproduct material. (It should be noted that the actual problems with the devices did not necessarily involve the radioactive material.) In the same timeframe, there were 88 problems reported involving cobalt-60 teletherapy units and 113 problems involving linear accelerators. (See "Problem Reporting Program for Radiation Therapy Devices, Summary of Reports Received," National Center for Devices and Radiological Health, periodic reports from January 1980 through June 1987, FDA, Washington, DC.)

Misadministrations to patients of cyclotron-produced radioactive materials are not required to be reported to the NRC. However, if a patient is supposed to receive cyclotron-produced material, but actually receives byproduct material, then the licensee is required to report the misadventure to the NRC as a misadministration of byproduct material. (See 45 FR 31704, May 14, 1980.) Such reports give an indication, albeit incomplete, of the degree of problems in handling cyclotron-produced materials. From January 1981 through December 1986, the NRC received 2298 reports of misadministrations of diagnostic radioisotopes, generally from licensees in non-Agreement States. (Agreement States did not require, until recently, reporting of misadministrations.) Of these reported misadministrations, 1 report involved cobalt-57, 14 reports involved gallium-67, 12 reports involved iodine-123, 14 reports involved thallium-201, and none involved xenon-127. These five isotopes represent the bulk of the use of accelerator-produced radioisotopes. For all of these cases, the patients were prescribed the indicated accelerator-produced radioisotope, but actually received a byproduct isotope, usually technetium-99m or another iodine isotope. Thus the apparent rate of misadministration reports involving NARM is about 1 percent of the total number of reports. (See memorandum from S. Pettijohn to J. H. Austin, NRC, dated December 22, 1987.)

Misadministrations of byproduct radioisotopes in medical diagnostic procedures are estimated to occur at a rate of about one in 10,000 procedures. (See "NRC

Reports on Misadministrations and Unannounced Safety Inspections," N. L. McElroy, J. Nucl. Med. 27, pp. 1102-1107, Soc. of Nuclear Med., New York, NY, July 1986.)

To the extent that the above five radioisotopes reflect the set of applications of cyclotron-produced radioisotopes, it appears that misadministrations of NARM in diagnostic procedures occur at a rate of about one in one million procedures. It is noteworthy that the NRC definition of misadministration does not necessarily mean any adverse reaction within the patient.

The Society of Nuclear Medicine (SNM) and the FDA monitor adverse reactions to radiopharmaceuticals, with the FDA also monitoring conventional pharmaceuticals. Over the 9 years encompassing 1976 through 1984, SNM received 356 adverse-reaction reports. Of these, about 70 percent of the adverse reactions involved compounds labeled with technetium-99m and about 5 percent involved compounds labeled with iodine-131, both being byproduct radioisotopes. Radiopharmaceuticals labeled with gallium-67, indium-111, or thallium-201 (all cyclotron-produced isotopes), each accounted for about another 5 percent of the reported adverse reactions. (See Essentials of Nuclear Medicine Science, pp. 310-311, W. B. Hladik, Williams & Wilkins Co., Baltimore, MD, 1986.)

From 1979 through 1987, the FDA received--through its Spontaneous Reporting System--1239 communications from domestic sources reporting adverse reactions associated with patient exposures to radiopharmaceuticals. (Adverse reactions are essentially any unfavorable experience a patient has in association with using an FDA-approved pharmaceutical or biological product.) Of these, 746 were reports of "no drug effect," presumably related to lack of imaging and 52 reports were classified as serious. A serious classification denotes the patient outcome was death, permanent disability, inpatient care (or prolonged hospitalization if the individual was hospitalized when the reaction occurred); a report of cancer or a congenital anomaly; or an adverse reaction occurring after a drug overdose. These 52 serious reactions included 17 deaths over the 9-year period with all of them apparently associated with radiopharmaceuticals labeled with technetium-99m. Of the remaining 35 reports of serious adverse reactions, one of them involved gallium-67 and two involved indium-111 as the radionuclides in the drugs. It is important to understand that although a serious adverse reaction report may be prepared in association with the use of a drug, that report does not necessarily imply causality. (See letter from J. B. Arrowsmith, MD, FDA to J. H. Austin, NRC, dated December 15, 1987.)

4.3 Discussion

The above collection of incidents and problems involving NARM does not always reflect a consistent and significant actual hazard associated with NARM. To be sure, there have been real problems with contamination of facilities, with the loss of the materials, and with the inadvertent introduction of radium into commerce, but significant exposures of the public to discrete sources of radium rarely occur, based on available data. Some do involve interstate commerce. However, the information supplied to the CRCPD in its survey of late 1987 suggests that actual inadvertent exposures of people to radium or contamination problems are very infrequent events.

The real and known problem with NARM is the disposal of discrete radium sources. Radium is not suitable for disposal in sanitary landfills because of its hazardous properties, some of which are similar to plutonium. Radium is an alpha and a

gamma emitter, has a higher specific activity than plutonium, has a 1600-year half-life, is soluble, is a bone seeker, and has a radioactive daughter that is a gas. EPA has reported that a survey of the States by the Conference indicates that State regulatory agencies know of at least 400 radium sources requiring disposal, whereas a preliminary survey by a DOE contractor shows over 500 high-activity commercial sources requiring disposal. (See "Low-Level and NARM Radioactive Wastes, Background Information Document," pp. 3-34, EPA 520/1-87-012, August 1987)

The Barnwell low-level waste facility will not accept radium. The Hanford facility will only accept discrete radium sources that are packaged with a total activity of less than 100 nanocuries per gram, precluding disposal of many radium sources. The Beatty facility will accept radium only in specially constructed sealed containers. The cost for packaging can range up to $2000 for one radium needle. (See Preliminary Draft "Economic Impact Analysis of Proposed Standards for Disposal of Low-Level Radioactive Waste," Putman, Hayes & Bartlett, Inc., for EPA Contract No. 68-01-7033, pp. 6-21, Washington, DC, May 11, 1987.)

The State of Michigan legislature is considering a bill that would make Michigan the host State for a low-level-waste disposal facility for the Midwest Compact. One of the bills passed by the Michigan Senate on October 8, 1987, would define low-level waste as given in 10 CFR 61.55 and explicitly excludes NARM wastes. However, that Bill mandates a study of whether NARM should be included in the definition of low-level waste. (See bill to amend Act No. 368 of the Public Acts of 1978, entitled, as amended, "Public Health Code," substitute for Senate Bill No. 65, Michigan Senate, October 8, 1987.)

There is incomplete information on the hazards associated with cyclotron-produced radiopharmaceuticals. It appears that their misadministration rate is about 1 percent of total misadministrations. However, serious adverse reactions associated with the use of radiopharmaceuticals seem to be far more significant than the "misadministrations" of them.

5 THE FEDERAL GOVERNMENT AND NARM

As indicated previously, numerous Federal agencies have possible or actual interests in or jurisdiction over NARM. A review of past congressional actions on radiation protection matters in general, and on NARM in particular, is important to a fuller understanding of Federal regulatory activity in ionizing radiation. It also would be useful in deciding whether and where any additional Federal authority over NARM might be vested. Such a review is the purpose of this section.

5.1 Pre-Atomic Energy Act

As first recognized, ionizing radiation was in the form of X-rays and emanations from radioactive materials, primarily radium. In the first few decades of the twentieth century, uses and applications of ionizing radiation sources were primarily in the hands of physicians or researchers. When physiological effec of radiation began to manifest themselves, in terms of eye injuries and eryth , the user community quickly set about to develop protection standards. By 192 the privately funded national organization called the Advisory Committee on X-ray

and Radium Protection had been formed to establish national protection standards. That organization evolved into what is now called the National Council on Radiation Protection and Measurements (NCRP). In that timeframe, there was little or no Federal involvement in developing safeguards against ionizing radiation, notwithstanding the known harms and deaths to workers in the field. (See Radiation Protection Standards, L. S. Taylor, CRC Press, Boca Raton, FL, 1971.)

In a major study for the U.S. Senate in 1977, regarding the history of Federal regulation, the Regulatory Reform Study Group of the Committee on Governmental Affairs observed:

> First, protecting citizens from harm and injury constitutes a fundamental concern of government, a major premise for creation of an organized community bound by common rules. To "promote the general welfare" is a preeminent purpose of the Federal government, ranked only after justice and security in the preamble of the Constitution.
>
> Yet the general welfare clause aside, there is no express provision of the Constitution for Federal jurisdiction over health and safety. Rather it is an implied power, emanating from specific or enumerated constitutional responsibilities. Once a subject falls within an enumerated power, the Federal ability to legislate over that activity is complete and comprehensive. For example, the Constitution in express terms grants to Congress the power to regulate interstate commerce; and that necessarily involves considerations of public welfare in commerce between the states. The comprehensive potential of Federal health and safety regulation, pursuant to that authority, is suggested by the scope of the interstate commerce clause, as sketched by Mr. Chief Justice Marshall in 1824:
>
>> It is the power to regulate; that is, to prescribe the rule by which commerce is to be governed. This power, like all others vested in Congress, is complete in itself, may be exercised to its utmost extent, and acknowledges no limitations, other than are prescribed in the Constitution.
>
> Federal legislation to protect the worker, the consumer and the environment rests upon that firm constitutional basis. (Footnotes removed.)
>
> * * *
>
> Congress was slow to exercise its power in health and safety matters. "Vertical regulation" characterized much of that legislation; that is, regulatory action directed at a specific hazard, or a certain occupation, or a particular concern--all too often with little consideration of the overall situation. Comprehensive Federal regulation of a "horizontal" nature--that is, regulation directed across-the-board at the variety of hazards or industries--is largely a development of the past 15 years or so. Previously the power was not necessarily denied; rather, the

potential went only partially realized. (See Study of Federal Regulation, Vol. V, pp. 308, 309, Committee on Governmental Affairs, United States Senate, December, 1977.)

Thus, before the Atomic Energy Act, Congress left to the States and private organizations the development of radiation protection standards for workers, consumers, the public, and the environment.

A notable exception to this came in 1936, when the attention of the transportation authorities was forcefully drawn to the fact that radioactive substances and undeveloped photographic films were incompatible if shipped together. This led to the first Federal dictates, through the Postmaster General, governing ionizing radiation:

> Radium, thorium or any other radioactive substance or any materials containing radioactive substance such as powders, containing radium or thorium, liquids containing radium emanation, radium salts, radioactive minerals, or any radioactive material whatever, not permitted in the mails. (See "Physical, Biological, and Administrative Problems Associated with the Transportation of Radioactive Substances," R. D. Evans, National Academy of Sciences, Washington, DC, 1951.)

Thus, the first Federal excursion into the field of ionizing radiation came from economic considerations.

The Manhattan Project led to shipments of increasing amounts of radioactive materials and the need to protect transport workers. Shipping packages relied on massive lead shielding for radiation protection during shipments of radioisotopes from the Oak Ridge Tennessee Manhattan Project facility, at that time, to hospitals and universities. Recognizing the need to minimize cargo weight and space without compromising safety and under instructions from Congress in 1946, the Interstate Commerce Commission developed regulations governing transport of radioactive substances that took into account both safety of transport workers and economics. (See "The Regulatory and Institutional Outlook on Meeting the Challenge of the Future," J. G. Davis, Seventh Int'l. Sym. on Packaging and Transportation of Radioactive Materials, CONF-830528, Vol. 1, p. 22, New Orleans, LA, May 15-20, 1983.)

5.2 The Atomic Energy Act of 1946, as Amended Through 1959

The nuclear enterprise is unique in U.S. history on two accounts. First, the technology was created, owned, and monopolized by the Federal Government in the national security arena. Second, the Congress recognized from the beginning that this technology was inherently dangerous and required carefully monitored development. Unlike other sectors of private enterprise where the Government awaits problems to develop before stepping in, the Congress mandated that the nuclear industry would be regulated from the outset. (See Controlling the Atom: The Beginnings of Nuclear Regulation 1946-1962, G. T. Mazuzan and J. S. Walker; University of California Press, Berkeley, CA 1984.)

In creating the Atomic Energy Commission (AEC) in 1946 through the Atomic Energy Act (AEA) and in encouraging widespread private development and use of nuclear technology through amendments to the AEA in 1954, the Congress mandated a very narrow framework of Federal regulation (i.e., directed to fissionable materials, to source materials from which fissionable materials could be obtained, and to radioactive material yielded in, or made, radioactive by exposure to the fission process). At the same time, Congress directed that such regulation would be very deep (i.e., possession, use, owning, acquiring, delivering, or transferring such materials would be regulated). This was in contrast to many other regulatory mandates that are very broad (i.e., directed across-the-board at a particular hazard, such as FDA regulating devices emitting ionizing radiation), but are shallow (i.e., directed to the regulation of the manufacturer, but not the user).

Naturally occurring radioactive materials--other than source materials--such as radium were deliberately left outside the scope of the AEA. Also excluded were the materials that were fissionable, but could not sustain a chain reaction (e.g., actinium-227). The AEA did not address any health and safety problems that might be posed by the radioactive materials because these were considered manageable and relatively insignificant. There appeared to be no urgent need and, from the standpoint of the common defense and national security, no basis for Federal regulation of NARM. (See "Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials," D. A. Nussbaumer et al., NUREG-0301, July 1977, and "Anomalies of Nuclear Criticality," E. D. Clayton, PNL-SA-4868, Rev. 5, p. 89, Richland, Washington, June 1979.)

In 1959, a new section was added to the AEA to authorize the AEC to enter into agreements with the Governor of any State under which the Commission would relinquish, and the State would assume, regulatory authority over byproduct and source materials and special nuclear material in small quantities. (See P.L. 86-373.)

In doing so, Congress stated:

> First, the bill has been redrafted by the Joint Committee to make it clear that it does not attempt to regulate materials which the AEC does not now regulate under the Atomic Energy Act of 1954. Such other sources such as X-ray machines and radium also present substantial radiation hazards, but have been for many years the responsibility of the States, the Public Health Service, or other agencies. (See Senate Report No. 870, accompanying P. L. 86-373, September 1, 1959.)

5.3 Federal Radiation Council, 1959-1961

Through Public Law 86-373, the Federal Radiation Council was formed in 1959 to provide a Federal policy on human radiation exposure. A major function of the Council was to "advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States." The President approved and caused to be published in the Federal Register on May 18, 1960, the Council's first recommendations for the guidance of Federal agencies in the conduct of their radiation protection activities. Those guides, while significant in their time,

were incomplete. They did not apply to radiation exposure resulting from natural background or purposeful exposure of patients by practitioners of the healing arts. The Council set as a guide for the individual in the population, an annual whole-body dose of 500 millirems, recognizing that "there can be no single permissible or acceptable level of exposure without regard to the reason for permitting the exposure." Those guides were advisory and the Council left it to the individual agencies to decide how and whether they would implement them. Each agency was allowed to decide its own policy on Federal-versus-State responsibility for protecting the public from exposures to ionizing radiation. (See FR May 18, 1960, p. 4402-3.)

In the Council's second report, it made recommendations for the guidance of Federal agencies in activities designed to limit exposures of the public from radioactive materials deposited in the body as a result of their occurrence in the environment. Radium-226 was among the radionuclides for which graded scales of actions were recommended. Again, it was left to each agency to decide how or whether to implement the guidance, and there was no guidance on Federal-versus-State roles. (See FR September 26, 1961.)

5.4 The Radiation Control for Health and Safety Act of 1968

In 1968, Congress declared that the public health and safety required protection from the dangers of electronically produced radiation through passage of the Radiation Control for Health and Safety Act. Among other things, that Act directed the Secretary of the Department of Health, Education, and Welfare (HEW) to conduct a "study of present State and Federal control of health hazards from electronic product radiation and other types of ionizing radiation, which study shall include, but not be limited to (a) control of health hazards from radioactive materials other than materials regulated under the Atomic Energy Act of 1954; (b) any gaps and inconsistencies in present controls; ... (d) measures to assure consistent and effective control of the aforementioned health hazards." (See Sec. 357 of P.L. 90-602.)

The legislative history indicates that Congress believed that such a program on reducing unnecessary exposures to ionizing radiation could "best be effectuated through the Department of Health, Education, and Welfare - the Federal agency with primary responsibility for the protection of the public health." (See Senate Report No. 1432, accompanying P.L. 90-602, July 17, 1968.)

HEW's study of the health hazards of NARM was sent to Congress in 1971. HEW concluded:

> Responsibility for the control of all non-Federal use of radium and accelerator-produced radionuclides resides in the States. While some States have adequately met these responsibilities, many have not developed and enforced effective control programs. Not only have there been ineffective controls at the State level, but there may also be ineffective control at the Federal level, since no single Federal agency has been charged with the responsibility for developing uniform effective controls over all Federal use of the materials. (See "State and Federal Control of Health Hazards from Radioactive Materials Other Than Materials Regulated Under the Atomic Energy Act of 1954," G. L. Pettigrew et al., FDA 72-8001, Washington, DC, p. 63, 1971.)

The assessment led to an HEW staff legislative proposal for a radioactive materials control act that addressed all sources of radioactive materials not covered by the AEA. The proposal was forwarded to the HEW Office of the Assistant Secretary for legislation, but no further action was taken. (See "Activities and Accomplishments of the Bureau of Radiological Health in Controlling Radioactivity in Consumer Products," P. Paras and A. C. Tapert, in "Health Physics Aspects of Radioactivity in Consumer Products," NUREG/CP-0001, p. 55, 1978.)

5.5 The Consumer Product Safety Act of 1972

Through Public Law 92-573 of 1972, Congress consolidated the consumer health and safety mandates at the Federal level within the newly created Consumer Product Safety Commission (CPSC). In 1973, FDA's Product Safety Bureau and its functions under the Hazardous Substances Act were transferred to the CPSC. Since radium is a naturally occurring radioactive material not subject to regulation under the AEA, CPSC acquired jurisdiction over radium in consumer products. In July 1973, the FDA's Bureau of Radiological Health formally submitted a request for action to the CPSC to regulate radium in consumer products. Although acknowledging jurisdiction, the CPSC voted in May 1975 to deny the request for such regulation on the grounds that the "marginal nature of the hazard posed to consumers" made the action "unwarranted." The Bureau persisted and expressed disappointment at the CPSC decision, noting that in 1975 there were an estimated 500,000 clocks and some 350,000 smoke detectors containing radium in homes. CPSC staff apparently reviewed the matter, but again concluded that the "level of risk does not merit a separate commission action on the radioactive hazards alone" in these consumer products. (See Study on Federal Regulation, Vol. V, p. 335, Committee on Government Affairs, U.S. Senate, December 1977.)

5.6 The National Institute for Occupational Safety and Health Study of 1976

Under Public Law 91-596, the Occupational Safety and Health Act of 1970, the Occupational Safety and Health Administration (OSHA) has responsibility for user compliance with radiation standards for sources not regulated by the NRC (formerly AEC). Inspection of facilities containing such sources (e.g., radium and accelerators) was not a high priority. In 1976, HEW's National Institute for Occupational Safety and Health (NIOSH) commissioned a study of the potential hazards of these sources to radiation workers. The data for that evaluation were obtained from the records of five Agreement States, five non-Agreement States, and the files of a commercial dosimetry service. That study concluded:

> This study did not uncover any extraordinary occupational hazards from the use of industrial x-ray machines, accelerators, or radium sources. Most of the States surveyed appear to be controlling these sources, with no significant differences noted between NRC Agreement and non-Agreement States. In comparing the data collected from this study with NRC data, the effectiveness of the State programs in regulating these sources appears comparable to that of the NRC in regulating radioactive materials. (See "Evaluation of Occupational Hazards from Industrial Radiation: A Survey of Selected States," S. C. Cohen et al., HEW Contract No. 210-75-0071, December 1976.)

5.7 The 1977 NRC Task Force Review

(1) Initial Review

Following an October 1974 meeting, the Agreement States developed several requests and recommendations for NRC (then AEC) action, including:

> The States recommend that the AEC, or its successor agency, move immediately to bring accelerator-produced and naturally occurring radioactive material under its jurisdiction.

On May 8, 1975, the Executive Committee of CRCPD met with the NRC Commissioners. One of the points discussed at the meeting was later summarized by the Conference in a May 20, 1975 letter to then-Commissioner Richard T. Kennedy:

> There is concern on the part of several States regarding the need for Federal control of radioactive material not being regulated by Agreement States or the NRC. Most Agreement States have included naturally occurring and accelerator-produced radioactive material under the same regulatory control as materials coming under the Atomic Energy Act when these agreements were signed. However, since there are 25 non-Agreement States, there is a definite gap existing in the proper control of these non-Agreement materials. Therefore, we strongly urge the NRC to consider taking appropriate actions to place this type material under the same control as is now applied to materials falling under the Atomic Energy Act.

In response, the NRC established a task force composed of representatives from all relevant offices to review the matter of regulation of NARM. Resource persons representing Agreement and non-Agreement States and Federal agencies also participated. The task force conclusions included:

> The regulation of naturally occurring and accelerator-produced radioactive material (NARM) is fragmented, non-uniform and incomplete at both the Federal and State level. Yet, these radioactive materials are widely used--excluding those who would be exempt from licensing, about 30 percent of all users of radioactive materials use NARM. There are an estimated 6,000 users of NARM at present. The use of accelerator-produced radioisotopes, particularly in medicine, is growing rapidly.
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> * * *
>
> Because of the fragmented and non-uniform controls over radium and other NARM, information on the impact of the use of NARM on public health and safety is fragmentary. Thus, it is difficult to know, in an overall sense, whether proper protection is being provided to workers and the public. A number of the incidents involving NARM and other data, however, which have come to the attention of public health authorities give definite indications of unnecessary and possibly excessive radiation exposure of workers and the public.

The task force had one major recommendation:

> The Task Force recommends that the NRC seek legislative authority to regulate naturally occurring and accelerator-produced radioactive materials for the reason that these materials present significant radiation exposure potential and present controls are fragmentary and non-uniform at both the State and Federal level.

(See "Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials," D. A. Nussbaumer et al., NUREG-0301, July 1977.)

(2) Response to the 1977 Review

The Commission approved publication of the task force report (NUREG-0301) for public comment. The report was given wide distribution. A total of 25 comments was received, with 21 of the respondents expressing varying degrees of support for the task force recommendation. These included all of the six States and five of the seven Federal agencies that commented. EPA commented that it had adequate existing authority to regulate NARM, thus opposing the recommendation. FDA's Bureau of Radiological Health commented:

> As a long-range goal, it appears logical to include all radioactive material under the authority of one agency with the intent of having one national, uniformly applied program to control user radiation safety and to set performance standards for products and devices, regardless of the origin of the radioactive material.

The FDA comments went on to say that "the report fails to note, however, that when specific actions were proposed at the Federal level, it was not possible to show that the use of NARM represents sufficient hazard to the public to warrant action when compared to other agency priorities."

Importantly, FDA stated that "the FDA has authority to regulate medical radiation sources under the Medical Device Amendments of 1976 (Public Law 94-295, 90 Stat. 539-583) of the Federal Food, Drug, and Cosmetic Act. This authority would include medical radiation sources containing NARM." Finally, FDA suggested deferring action until the voluntary FDA/State effort to control NARM had been implemented and its effectiveness had been evaluated.

On the basis of its analysis of the comments, the NRC staff repeated its recommendation to draft a bill that would give NRC regulatory jurisdiction over NARM. The Commission took no action on the staff recommendation (SECY-78-211), but asked the staff to resubmit it for reconsideration after addressing questions about the magnitude of NARM overexposure, the compatibility of the proposed NRC regulatory authority with other agencies, and other issues.

(See SECY-78-211 and its enclosures, "Final Recommendations of the Task Force on Regulation of NARM," April 14, 1978; and memorandum dated June 30, 1978 from S. J. Chilk to Lee V. Gossick, regarding the SECY paper.)

(3) Resolution of the 1977 Review

The NRC staff responded to the Commission directive on December 18, 1978, in SECY-78-667, without a staff consensus on what actions should be taken. The NRC Executive Director for Operations (EDO) highlighted four major issues that needed to be considered:

- the risk to the public health and safety (the available data appeared insufficient)
- the scope and cost of regulatory control (The NARM boundaries were thought to be broader than that suggested by the task force and the resource requirements may be far in excess of the estimated seven full-time equivalents.)
- whether there is a regulatory conflict with other Federal agencies
- the NRC's role in radiation protection

Responding in a May 10, 1979, letter to the EDO, the Commission directed the staff to forward the findings of the task force to interested parties with a letter indicating that:

> ...NRC believes that this source of radiation exposure should be uniformly regulated and should urge that the matter be addressed promptly. It should note that, while NRC could logically regulate NARM--given legislative authority--NRC is not pursuing that authority because it believes that such efforts should be integrated into the larger effort to properly allocate Federal responsibilities for radiation protection.

Ultimately, the issue of whether the Federal Government should regulate NARM was referred to the U.S. Radiation Policy Council. This will be elaborated on later.

5.8 The Interagency Task Force on the Health Effects of Ionizing Radiation - 1979

An Interagency Task Force on the Health Effects of Ionizing Radiation was established in 1978 to carry out a Presidential directive to formulate a national program to, among other objectives, reduce adverse radiation exposures. NRC was represented on the task force. The task force issued its report in June 1979, observing that virtually everyone agreed that "the Federal government should enhance its institutional capacity to develop clear and consistent policies on radiation matters." It, too, found gaps and inconsistencies in the controls over ionizing radiation, including NARM, and made a number of recommendations for reducing overall exposures to ionizing radiation. Significantly, the task force recommended establishing an Interagency Federal Radiation Council that would be assigned numerous functions, including consideration of basic issues of policy relating to radiation protection, as well as an evaluation of the overall direction and effectiveness of Federal activities in this regard. (See "Report of the Interagency Task Force on the Health Effects of Ionizing Radiation," June 1979.)

5.9 The United States Radiation Policy Council from 1980 to 1982

The President's response to the above report was to create, through Executive Order 12194, the United States Radiation Policy Council (RPC), in 1980, for the purpose of coordinating the formulation and implementation of Federal policies relating to radiation protection. In that year, the RPC adopted as a preliminary agenda, nine broad policy issues that would be examined during 1981 through 1983. Those issues included the roles and responsibilities of Federal agencies, radiation exposure reduction, and Federal/State relationships. The RPC noted a perplexing number of Federal agencies involved with ionizing radiation. This resulted in a maze of functions and responsibilities within the Federal establishment that appeared to fragment Federal radiation protection efforts, create undue administrative difficulties for those being regulated, and bewilder the public. RPC also observed that the States have a major responsibility in radiation protection. The role of the Federal Government vis-a-vis the States was to be examined in the policy issue on the Federal/State relationship, particularly as it had a bearing on NARM. However, RPC did not complete this task before its demise in about 1982. (See "Progress Report and Preliminary 1981-83 Agenda," United States Radiation Policy Council, RPC-80-001, Washington, DC, September 1980.)

5.10 The Consumer-Patient Radiation Health and Safety Act of 1981

Through the Consumer-Patient Radiation Health and Safety Act of 1981 (Public Law 97-35), the Congress directed the Secretary of the Department of Human and Health Services (HHS) to promulgate standards for the accreditation of educational programs to train personnel to perform radiological procedures and for the certification of such individuals. On July 12, 1983, HHS issued a notice of proposed rulemaking (NPR) that would establish standards for five occupations: radiographers, dental hygienists, dental assistants, radiation therapy technologists, and nuclear medicine technologists. In this NPR, there was no distinction made between NARM and materials covered by the AEA. The standards are intended to assist those States that desire to regulate the education and practice of personnel in the field of radiology. HHS observed that "while the standards were developed by the Department, the Act preserves the traditional prerogatives of States in the approval of education programs and in regulation of personnel." The rule was made final on December 11, 1985, essentially as proposed. At the end of 1986, 16 States licensed radiographers; 12 States licensed radiation therapy technologists; and 7 States licensed nuclear medicine technologists. (See Report to Congress, "Compliance by the States with the Consumer-Patient Radiation Health and Safety Act of 1981: Annual Report for 1986," HHS, Washington, DC, September 10, 1986.)

5.11 Committee on Interagency Radiation Research and Policy Coordination from 1984

The RPC appeared unable to significantly improve Federal policy coordination. In view of this continuing need, Senator John Glenn introduced legislation in 1982 that would create a Federal Council on Radiation Protection. The Administration's position was that legislation was not necessary. In May 1984, the Administration created the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC) under the Office of Science and Technology Policy (OSTP) for the purposes of, among other things, coordinating radiation matters between agencies and advising OSTP on issues involving Federal radiation policy.

At the first meeting of CIRRPC on May 25, 1984, each of the then 15 member agencies, including NRC, was requested to respond to a questionnaire for identification of current issues of concern to each agency. The 34 specific issues identified were condensed into 10 major national issues dealing with ionizing radiation. NARM was not on the list, but radon was. (See "CIRRPC Report on Identification of Federal Radiation Issues," OSTP, Washington, DC, March 1986.)

5.12 The Low-Level Radioactive Waste Policy Amendments Act of 1985

The NRC sought legislative authority over NARM wastes during the time that Congress was enacting the Low-Level Radioactive Waste Policy Amendments Act of 1985 (P. L. 99-240). In commenting on H.R. 1083 of the 99th Congress, the Commission noted that neither Section 3(a) on State responsibilities nor 3(b) on Federal responsibilities specified responsibility for the disposal of NARM wastes. The Commission went on to say that without clear statutory direction identifying the responsibility for disposing of these wastes, neither NRC, the Agreement States, nor waste generators would be able to ensure that all NARM wastes would eventually be accepted for disposal. The Commission proposed conforming language for NARM disposal authority, but to no avail. (See letter from N. J. Palladino, Chairman, NRC, to the Honorable M. K. Udall, Chairman, Committee on Interior and Insular Affairs, U.S. House of Representatives, dated June 4, 1985.)

In early versions of what became the Act, Congress considered requiring the Department of Energy to prepare a report on "orphan wastes." Such a report would have included a study of NARM. The NARM issue was specifically debated in the Senate Subcommittee on Energy Research and Development, Committee on Energy and Natural Resources, without final resolution. The Act did not assign responsibilities for NARM wastes either to the States or to the Federal government. The final language in the Act did not require any Federal agency to study the NARM issue. Although not explicit in the legislative history, it appears that the provision for a study of NARM vis-a-vis low-level waste (LLW) was dropped because the magnitude of the issue appeared almost unbounded. (See "The Low-Level Waste Handbook: A User's Guide to the Low-Level Radioactive Waste Policy Amendments Act of 1985," pp. 17-23, H. Brown, National Governor's Association, Washington, DC, November 1986; and letter from J. W. Vaughan, Jr., DOE, to C. M. Hardin, CRCPD, dated July 22, 1986.)

5.13 Advance Notice of Proposed Rulemaking - Definition of High-Level Waste in 1987

An advance notice of proposed rulemaking (ANPR) was published in the Federal Register for comment, announcing the Commission's intent to modify the definition of high-level radioactive waste. (See 52 FR 5992-6001, February 27, 1987.) The ANPR solicited public comment on the following question:

> When the Commission carries out its analyses to identify "other highly radioactive material that...requires permanent isolation," should NARM be included in the analyses?

Some 21 commentors addressed this question. Generally, the commentors favored inclusion of NARM in the analyses, with most observing that materials of like hazards should be disposed of in similar fashions.

5.14 U.S. Environmental Protection Agency Activities, 1984-Present

In 1984, State representatives and others indicated to the EPA that the exclusion of NARM from EPA's LLW standards was the most serious deficiency in its program. They expressed to EPA concern that NARM wastes present a radioactive waste disposal problem with a great potential for harm, without existing Federal direction or means of ensuring consistent interstate control. Since then, EPA has been developing a proposed rule that would include NARM in its LLW standard, under the authority vested in EPA through the Toxic Substances Control Act (TSCA) of 1976. The TSCA authorizes EPA to prohibit, restrict, or regulate the manufacture, processing, distribution in commerce, use or disposal of any substance that presents "an unreasonable risk of injury to health or the environment." (See EPA memorandum from F. L. Galpin to R. J. Guimond dated June 6, 1986.)

The recent approach EPA has been taking on the rulemaking is that the regulations would be limited to only higher activity, low-volume NARM wastes. Apparently there will be a minimum concentration of about 2 nanocuries per gram; wastes below this value would not be deemed LLW. The regulations would require the disposal of NARM wastes (greater than 2 nanocuries per gram) in licensed LLW facilities in a manner similar to comparable AEA wastes. One major issue in this effort is how to enforce the standards. An option under consideration is to include provision for the States to assume the inspection and enforcement functions of the regulations. (See "Inclusion of NARM in the EPA LLW Standard," M. S. Bandrowski et al., Presented at the Eighth Annual DOE LLW Management Forum, Denver, CO, September 22-26, 1986.) However, another option under active consideration is to look to the NRC for inspecting and enforcing the NARM disposal regulations--of course, NRC does not presently have authority to do so.

With regard to the lower limit concentration of 2000 picocuries radium-226 per gram, as the possible definition of LLW, EPA has established standards for protection against uranium mill tailings that call for cleaning up of the mill tailings if the radium concentration is greater than 5 picocuries per gram within the top 15 centimeters of the surface. (See 48 FR 592, January 5, 1983.)

With regard to radon in dwellings, a science panel consisting of CIRRPC members, chaired by the Department of Labor, has issued a report "Radon Protection and Health Effects," which contains a number of recommendations. Among these recommendations are accelerating research on the health risks from indoor radon and performing a national indoor radon survey. (See CIRRPC Third Annual Report, OSTP, Washington, DC, June 30, 1987.) EPA has assumed a major role in this Federal program of sufficient magnitude and importance to create a Division in the Office of Radiation Programs devoted solely to the radon problem. Of course, EPA, the Department of Interior, and other agencies have interests in radon as it exists in mines, caves, and elsewhere.

5.15 The United States Pharmacopeial Convention

As previously mentioned, the United States Pharmacopeial (UPS) Convention has since 1820 established national standards of strength, quality, and purity of medicinal products, together with the standards for their production, dispensation, and use. Both Congress and the States recognize the USP as an "official compendium." In addition, the Medical Device Amendments Act of 1976 recognized

that the articles in the USP may constitute devices under the terms of the Act. As part of its activities, USP prepares monographs for radiopharmaceuticals, including cyclotron-produced isotopes, such as cyanocabalamin (cobalt-57) oral solutions, gallium-67 citrate injections, sodium iodide-123 capsules, and thallous (Tl-201) chloride injections. Thus, national standards have been and are being developed governing the production and use of radiopharmaceuticals containing cyclotron-produced radionuclides. (See The United States Pharmacopeia, Twenty-first Rev. and its supplements, USP Convention, 12601 Twinbrook Parkway, Rockville, MD.)

5.16 U.S. Nuclear Regulatory Commission

Although Congress has never explicitly authorized the NRC to regulate NARM (with the one special exception of radium in uranium mill tailings only), the Commission's regulations do address NARM in several places. For example, Title 10, Code of Federal Regulations, Part 20 (10 CFR 20) specifies the standards for protection against radiation; § 20.101(a) states that no "individual in a restricted area [is] to receive in any period of one calendar quarter from radioactive material and other sources of radiation, a total occupational dose in excess of" the specified standards. That is, occupational doses from radium and/or X-ray machines must be added to the doses from NRC-licensed materials in determining compliance. Similar language appears in § 20.105(a) regarding permissible levels of radiation in unrestricted areas. With regard to permissible concentrations of radionuclides in effluents released to unrestricted areas, 10 CFR 20, Appendix B, limits licensee releases of radium to the air or in the water effluents. Furthermore, § 20.203(e) requires that licensee areas or rooms containing radioactive materials "in an amount exceeding 10 times the quantity of such material specified in Appendix C" shall be posted with the radiation caution symbol, among other requirements. A quantity of 0.01 microcurie of radium-226 is listed in 10 CFR 20, Appendix C. Finally, the packaging and transportation of radium is governed by 10 CFR 71. Thus, NRC can, to a degree, control licensee activities involving NARM, but individuals who are not licensees and possess NARM would not be controlled by NRC regulations.

Nothing in NRC's regulations prohibits disposal of NARM in NRC-licensed LLW sites. The Agency's authority is sufficient to dictate whatever controls are necessary over certain hazardous chemical and waste forms to ensure that the safety of the site is not compromised. License conditions and/or regulatory guidelines might be employed that specify the concentrations and forms of NARM that may and may not be disposed of in an NRC-licensed LLW site.

5.17 Discussion

The above indicates that, in general, the States have the primary jurisdiction over the health and safety of the public. The issue of governmental controls over exposure to NARM is not whether the Federal government should create an authority to establish such controls, but is really a matter of whether the Federal government should preempt the authority the States already have. The interstate commerce clause of the Constitution provides for Federal preemption of such State responsibilities to "promote the general welfare." The Congress exercised this power in creating the Atomic Energy Commission to regulate fissionable material, source material, and byproduct materials.

The above review of congressional actions supports a conclusion that over the years, Congress has consciously chosen not to broaden the AEC/NRC reach into the NARM arena, leaving it to the States or other Federal agencies. In fact, in 1968, Congress looked to the HEW, as the Federal agency with primary responsibility for protecting the public health and safety, when it mandated an examination of the regulatory controls over NARM. In creating the OSHA in 1970, Congress mandated Federal controls over NARM in the workplace through OSHA, provided that the jurisdiction the FDA had over devices emitting radiation remained with FDA. In creating the Consumer Product Safety Commission, in 1972, Congress vested Federal control over NARM in consumer products with that Commission, again provided that the FDA retain its existing authorities. In the Medical Device Amendments of 1976, Congress vested with the FDA the authority to regulate medical radiation sources, including those containing NARM. The EPA has the authority to regulate NARM in the environment. And, in 1976, Congress authorized EPA to regulate essentially all aspects of any hazardous substance to the public or to the environment. Thus, there currently exists Federal authority to control exposures to NARM in the environment, in consumer products, in the workplace, in homes, and in the medical field. However, there is no uniform and consistent Federal policy on the degree to which the Federal agencies will exercise their authorities to control exposures. As a consequence, Federal controls are fragmented and uneven. In fact, this is true for exposures to ionizing radiation in general. Finally, the United States Pharmacopeial Convention, recognized as an expert organization by Congress and the States, has developed and continues to develop, national standards governing the production and use of, among other items, radiopharmaceuticals containing cyclotron-produced radioisotopes.

There has never been an explicit decision on the Federal role versus State role in protecting the public from exposures to ionizing radiation, except that set out in Section 274 of the Atomic Energy Act of 1954, as amended. Furthermore, the mandates that Congress has given to agencies vary so greatly that it is not clear that the worst and most controllable exposures are being addressed without undue attention to lesser ones.

6 THE STATES AND NARM

State radiation control programs began developing in the 1950's and 1960's. In about 1968, a group of program directors began realizing that the States were developing differing regulations, primarily dealing with X-ray sources, and that each State was trying individually to cope with common concerns. State authorities agreed that mutual benefits would accrue through exchanges of information, which eventually led to the 1970 incorporation of the Conference of Radiation Control Program Directors (CRCPD), comprised of all 50 States, the territories, and some large municipal agencies. Among the purposes of this Conference, one is to "foster uniformity of radiation control laws and regulations."

In its 1971 report to Congress on the State and Federal controls over NARM, HEW observed:

> The only non-AEC controlled radioactive materials of commercial or health consideration are radium and its daughter products, and accelerator-produced radionuclides. The production of radium in

the United States was stimulated in the early 1900's when the U.S. Bureau of Mines undertook with private industry the development of a refining process to extract radium from carnotite ore. Unlike the development of atomic energy by the Manhattan project some 30 years later, there was little recognition of the hazards of exposure to radium and radiation protection controls were not instituted by the Federal government. The regulation and control of radium and accelerator-produced materials has been a part of the traditional State function of protecting the health of the public. (See "HEW Report FDA 72-8001, p. 5, HEW, Washington, DC, June 1971.)

In 1974, as previously mentioned, the Agreement States urged the AEC/NRC to seek legislative authority over NARM, as did the CRCPD in 1975. Also in 1975, the States formed a task force, composed of CRCPD representatives as well as representatives from NRC, EPA, and FDA, to develop a set of NARM guides as part of a nationwide system for the uniform evaluation and control of products containing NARM. Those NARM guides were first published in 1977 and included suggested State regulations. The States, through the CRCPD, indicated their support of the NARM guide program. (See letter from J. P. Hile, HEW, to Secretary of the Commission, NRC, dated September 22, 1977.)

In 1977, all of the then 25 Agreement States and 5 non-Agreement States had licensing programs covering NARM users. The Agreement States' programs for regulating NARM were deemed comparable to their programs for regulating materials covered by the AEA under agreements with NRC. However, there were seven States that exercised no regulatory control over NARM users, whereas the remaining States had control programs of varying scope. (See "Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials," D. A. Nussbaumer et al., NUREG-0301, July 1977.)

At the end of 1987, all 29 Agreement States regulated and controlled NARM in the same way they do those materials covered by the AEA. Of the 21 non-Agreement States, only 4 have a NARM licensing program. Of the remainder, 2 States have voluntary or partial licensing programs, and 14 States have registration programs, leaving 1 State, Montana, with nothing. With regard to NARM inspections, all 29 Agreement States inspect NARM, as do 14 non-Agreement States, whereas 4 States conduct partial inspections and 5 States conduct no inspections. (See "Position Paper on NRC Regulatory Control of NARM," CRCPD, August 24, 1987 revision; and "Profile of State and Local Radiation Control Programs in the United States for Fiscal Year 1985," CRCPD Publication 87-3, 1987.) Comparing the 1977-versus-1987 level of activity indicates that the States are increasing the amount of attention to NARM.

Because there was no mechanism to recognize those States that had a comprehensive program for the regulation and control of NARM, the CRCPD, in 1983, instituted a procedure to recognize such State programs. To be a CRCPD-recognized NARM licensing State, a State must specifically request recognition and must meet the CRCPD criteria, which are basically the criteria used by the NRC to evaluate an Agreement State. To date a total of 10 States (all Agreement States) are CRCPD-recognized NARM licensing States. (See "CRCPD Recognition of Licensing States for Regulation and Control of NARM," CRCPD LS-1, Rev. of April 28, 1987, CRCPD, and private communication from C. M. Hardin, Executive Secretary of CRCPD on December 15, 1987.)

In FY 1985, the States expended a total of 1037 full-time equivalents (FTE) positions to support their radiation programs, with about 180 of these positions applied to radioactive materials. The number of FTE positions for individual State radiation programs ranged from 1.6 in Alaska to 125 in Illinois. The employees filling these 180 FTE positions oversaw about 15,000 materials licensees, and inspected over 6200 of their facilities. (See "Profile," CRCPD Publication 87-3, 1987.)

The CRCPD has been active in facilitating disposal of discrete radium sources. They have worked with the U.S. Department of Transportation (DOT) in obtaining an exemption from its regulations. That exemption authorizes the use of specially sealed DOT specification 2R containers in concrete-filled drums for one-time transport for disposal of not more than 500 millicuries of radium-226 in normal or special form, without each shipper keeping a package test performance certification file. This exemption is estimated to reduce the costs of packaging by an order of magnitude. CRCPD also has prepared directions for packaging and has worked with the State of Nevada to ease disposal of radium sources at the Beatty waste disposal site. (See U.S. Department of Transportation issuance USDOT-E 9488 (First Rev.), Washington, DC, April 13, 1987; and letter with attachments from C. M. Hardin, CRCPD, to All Program Directors, regarding the CRCPD Radium Disposal Project, February 27, 1987.)

The CRCPD attaches some urgency to this program:

> Since NARM is not addressed in the Low-Level Waste Policy Amendments Act and is not included under the definition of low-level waste in any of the Compacts, this may be the last opportunity to dispose of radium sealed sources in a reasonable manner. (See Hardin letter of February 27, 1987.)

The CRCPD also has been developing a suggested regulation for disposal of naturally occurring radioactive materials (NORM). These efforts grew from requests by private companies to respective States to use phosphate fertilizer tails and slag and coal ash in road and railroad bases, in concrete, and in cinder blocks. The States expressed concerns about such uses since the NORM "content/concentrations far exceed those that can be considered de minimis, and exceed the levels proposed by the EPA for inactive uranium mill cleanup and those adopted by the NRC for active uranium recovery facilities." Radium is the primary radionuclide of concern. The States observed that many of the proposed uses of these wastes involved products or commodities that were to be introduced into interstate commerce, thus warranting uniform regulation. (See CRCPD issuance "Rationale: Part N," SSRCR, Draft 5, undated.)

Draft 5 of this proposed regulation calls for a three-tier approach to regulating NORM. The first tier would exempt, from any requirements, disposal of radium at a concentration of less than 5 picocuries per gram, i.e., below regulatory concern. For concentrations above this level, but below levels requiring a specific license, a general license would be issued to, among other things, use and dispose of NORM. However, that general license would not authorize the manufacture or distribution of products containing, among other materials, radium in concentrations greater than 5 picocuries per gram. With regard to the disposal of NORM wastes, the proposed regulation stipulates that:

> Each person subject to the general license in N.10 shall manage and dispose of wastes containing NORM in accordance with the applicable requirements of the U.S. Environmental Protection Agency for disposal of such wastes [or in a manner equivalent to the requirements for uranium and thorium byproduct materials in 40 CFR 192 or shall transfer wastes for disposal to a land disposal facility licensed by the U.S. Nuclear Regulatory Commission or an Agreement State pursuant to 10 CFR 61 or equivalent regulations].

As mentioned above, EPA is considering a regulatory definition of low-level waste (LLW) as a material containing, for example, radium at a concentration above 2000 picocuries per gram. Thus, there appears to be emerging significant differences between Federal and State definitions of LLW and, possibly, what constitutes radiation levels "below regulatory concern." (See CRCPD issuance "Part N: Regulation and Licensing of Naturally Occurring Radioactive Materials [NORM]," Draft 5, undated.)

In September 1981, the National Governor's Association (NGA) undertook a comprehensive review of the NRC's Agreement State Program. The NGA report on that effort was published in January 1983 and contained the following recommendation:

> The Atomic Energy Act should be amended to authorize the regulation of radioactive materials not presently affected by the act, that is, naturally occurring and accelerator-produced radioactive material (NARM).

Since such legislation would broaden the scope of the Agreement State functions, that recommendation is not entirely consistent with the NGA finding that:

> The necessity of meeting NRC review criteria sometimes directs state resources towards those areas on which they will be judged by NRC and away from what states consider more pressing problems.

The NGA has taken no formal action on the above recommendation. (See "The Agreement State Program: A State Perspective," H. Brown, NGA, Washington, DC, January 1983.)

On August 26, 1987, the CRCPD once again urged that the NRC seek legislative authority to regulate NARM:

> The Conference strongly urges the Nuclear Regulatory Commission to begin the appropriate actions necessary to regulate this hazardous radioactive material in the states which are not currently regulating NARM. It is our belief that because (1) there is no single federal agency where uniform guidance on NARM is provided and that (2) in some States there is no control of NARM, the resulting potential for public health exposure and environmental contamination presents an intolerable situation. We believe a uniform regulatory program operated by the NRC is the best solution. The details of our rationale for NRC control of NARM is clearly described in our position paper. (See letter from T. R. Strong, Chairman, CRCPD, to H. R. Denton, NRC, dated August 26, 1987.)

7 THE ISSUES REGARDING NRC AND NARM

The foregoing establishes that NARM is pervasive in the environment and all facets of life. However, no clear picture emerges on the risks to society given the presence of NARM, with the possible exception of radon. Many Federal agencies already have been granted, through the Congress, jurisdiction over nearly all aspects of the NARM hazards. Finally, the foregoing establishes that the level of State regulation of NARM is increasing.

This section presents an assessment of the eight questions listed below, to serve as the basis for developing options for the NRC to consider regarding NARM.

(1) Is there a national problem with NARM?
(2) Are there currently integrated Federal controls over NARM?
(3) Would NRC regulation of NARM overlap other Federal agencies' programs?
(4) Are the State controls over NARM adequate?
(5) Is NARM a Federal, State, or professional responsibility?
(6) Would Congress consider NRC responsible for controlling NARM hazards?
(7) What are the resource implications?
(8) Would NRC responsibility for NARM change the nature of NRC?

7.1 Is There a National Problem with NARM?

The collection of incidents involving NARM, discussed in Section 4, does not give a clear picture as to the degree of hazards associated with NARM. At issue is whether those past problems are of sufficient magnitude to warrant Federal intervention in a general way. Many, if not most, observers believe incidents involving radium are declining in part because of increased awareness of its hazards, in part because of the availability of replacement radionuclides, and in part because of the actions by many States, by the CRCPD and by the EPA and FDA in rounding up existing radium sources and in discouraging continued use of radium. Nonetheless, the Conference concludes that there "is the potential for radiation exposure and/or contamination from the misuse of these sources and devices. The misuse, including improper storage, of NARM sources and devices may represent a very significant public health problem." (See the attachment to a letter from C. M. Hardin, Executive Secretary, CRCPD, to J. H. Austin, NRC, dated November 25, 1987.)

The most significant national problem with NARM is radon in dwellings. As already stated, radon constitutes the population's chief exposure to radiation. Such exposures are over twice that of all man-made sources such as medical X-rays, nuclear medicine procedures, and consumer products. EPA and other Federal agencies and the States already have substantial programs under way for radon monitoring and for promoting remedial action where elevated levels of radon are found in residences.

The next most significant national problem with NARM concerns radium, but there are two aspects to it. First, there is the national problem with how to dispose of the discrete radium sources that were scattered throughout the country largely during the 1920's through the 1950's, without any central control. Radium in a concentrated form is not suitable for disposal in sanitary landfills, because its hazards are equivalent to or greater than the low-level radioactive wastes that the NRC requires to be disposed of in a site licensed under the Atomic

Energy Act provisions. According to the CRCPD, no State Compact formed under the provisions of the Low-Level Waste Policy Act incorporates radium into its definitions of waste that the Compact will accept. The Beatty LLW site in Nevada is accepting radium for now. The EPA has jurisdiction over the disposal of radium and is developing regulations governing such disposal, but there is an issue as to which authority will enforce the regulations. Candidates are EPA, the States, and the NRC. There appears to be nothing in NRC's regulations that would prohibit disposal of radium in NRC-licensed LLW sites. Further, NRC could facilitate EPA's forthcoming regulations by establishing license conditions and/or regulatory guidance (1) to preclude disposal of certain large concentrations of radium and low concentration, high-volume sources in LLW sites for safety and environmental reasons and (2) to avoid filling up licensed burial grounds with low activity materials just as it precludes disposal of certain hazardous chemical and waste forms. By such specific exclusions, the NRC regulates what is suitable and unsuitable for LLW sites--radium could be one such specification. However, since the NRC does not address radium disposal at LLW sites and since State Compacts are patterning their regulations after NRC's, radium is continuing to be an orphan waste by not being incorporated into the State laws governing LLW sites. Radium disposal is an area for possible NRC involvement and is included in the options section of this paper.

The second aspect of radium has to do with diffuse sources such as residuals from mineral extraction industries. The concern is twofold: (1) whether the wastes need to be cleaned up and (2) whether those waste streams can be used in construction materials, such as wall boards, bricks, and roadways. On the cleaning concern, EPA already has jurisdiction, and on the waste-stream-use concern, other Federal agencies such as CPSC, DOL, Department of Housing and Urban Development (HUD), or DOT have or could have jurisdiction. Thus, there appears to be no role for NRC on this aspect of radium.

There may be an emerging problem involving possible differences between Federal agencies' and States' regulatory definitions of what constitutes LLW and what constitutes radiation levels that are "below regulatory concern." A national consensus on these definitions appears warranted.

There does not seem to be a significant problem with radium in the workplace. The NIOSH study of 1976 (described in Section 5.6) supports this observation. Further, OSHA maintains a data bank on its inspections. From FY 1973 through mid-FY 1987, there were a total of 24 serious violations of its radiation regulations in the health services industry, a major location of radium. On the basis of an NRC audit of serious violations in the health services industry and in other industries cited by OSHA, the violations found generally involved X-ray machines (e.g., not posting the regulations or not wearing radiation film badges) or in a few cases byproduct material. None of the OSHA field offices that the NRC has contacted could identify problems involving radium, although some recalled hearing of problems. (See letters from J. A. Kalalinas, Director, Office of Management Data Systems, OSHA, to J. H. Austin, NRC, dated October 5, 1987 and November 4, 1987.)

Polonium-210 in cigarettes causes significant radiation doses to the lung and represents a major national problem. However, for this and other reasons, the CPSC and HHS have substantial efforts targeted to this consumer product, so there is no need for NRC to become involved.

The other naturally occurring radioactive materials appear to have no major national problems associated with them.

Accelerators/cyclotrons are used extensively in industry. Although data on safety or environmental problems are sparse, what data are available support a conclusion that the machines are generally not causing health, safety, or environmental problems rising to a level warranting congressional action.

A growing application of cyclotrons is within medical departments, where short-lived radioisotopes are generated for performing diagnostic procedures. Most, if not all, observers believe these materials are treated in the same manner as byproduct materials. Misadministrations of NARM in diagnostic procedures appear to be approximately 1 percent of the total misadministrations. This does not mean any actual harm to the patient occurred; to the contrary, available data suggest there is a very low likelihood of a diagnostic misadministration causing harm. Thus, in terms of health and safety, there appears to be no significant national problem with cyclotron-produced radioisotopes. Notwithstanding this, the option of NRC seeking legislative authority over such materials will be considered below because of the apparent logical inconsistency of NRC not regulating that aspect of nuclear medicine.

Based on an estimated number of clinical procedures performed in diagnostic imaging (20 million per year) and the estimated misadministration rate (1 in 10,000) and an estimated misadministrated dose of 100 mrem, there would be, statistically, about 0.01 cancer death per year resulting from diagnostic misadministrations. NARM misadministrations might be associated with, statistically, 0.0001 cancer death per year. This is in contrast with an average of about two deaths per year, actuarially, associated with the use of technetium-labeled radiopharmaceuticals. Again, the association does not necessarily imply causality, but the latter would much more appear to warrant further study than the former. FDA indicates it is examining those reports, since FDA approves the safety and efficacy of drugs, including radiopharmaceuticals. (NRC rules governing use of radiopharmaceuticals are tied to FDA approvals. See 10 CFR 35.100, 35.200, and 35.300.) Although there have been a few serious adverse reactions reported over the past 9 years in association with the use of cyclotron-produced radiopharmaceuticals, none of the reports listed death as the outcome.

Another measure of the relative hazards in the medical field is the number of injuries and illnesses contracted by hospital personnel and reported to OSHA that involve disability for some period of time. The Bureau of Labor Statistics compiles such data from the 18 States participating in their Supplementary Data System Program. For 1983, there were a total of 40,370 reported cases of employee disability occurring in hospitals for all categories of the nature of injuries or illnesses. Among the categories that DOL identifies as being the nature of the injury or illness are radiation effects, non-ionizing radiation, microwave, X-rays, and radioisotopes. Within the 40,370 cases, there were four injuries or illnesses reported in association with radiation efforts, or 0.01 percent of the cases; three reported in association with non-ionizing radiations, also 0.01 percent of the cases; and no reports in the other subcategories identified above. This suggests that radiation in hospitals is far from a significant contributor to hospital employee hazards. (See transmittal note and enclosures from W. W. Cloe, DOL, to J. Austin, dated September 16, 1987.)

A comparison of nuclear medicine misadministrations and prescribed general drug misadministrations in U.S. hospitals on an annual basis reveals that general drugs are misadministered in 15 percent of the prescriptions, whereas nuclear medicine misadventures occur in 0.01 percent of the cases. (See "One Year's Experience With Misadministration Reporting," L. A. Roche, Society of Nuclear Medicine (SNM) Newsline, New York, NY, March 1982.)

The above are some examples to illustrate the need to have an integrated Federal program for controlling risks and the fact that NARM in hospitals is not a dominant risk.

7.2 Are There Currently Integrated Federal Controls over NARM?

NARM is an important source of radiation exposures of the public. There are other significant sources of radiation exposure. Thus, on the premise that it is prudent to have an orderly Federal program on controlling harmful radiation exposures, the NARM issue is less one of regulating certain radioactive materials and more an issue of regulating exposures to ionizing radiation. A rational Federal program on controlling risks would seek to address the worst and most controllable exposures first; to do otherwise would mean that the total amount of harm being prevented would be less than that which could be prevented.

On the issue of whether there currently exist integrated Federal controls over NARM, the answer is no. This also is true for Federal controls of exposures to ionizing radiation in general. Congress has amply vested jurisdiction over NARM hazards in agencies other than the NRC. However, the mandates to those agencies and the priorities established within the agencies have resulted in fragmented and uneven regulation of NARM.

There exists integrated guidance to Federal agencies on controlling radiation exposures of the public through the Federal Radiation Council recommendations of 1960 and 1961. However, because of the great variation in the Congressional mandates to the agencies, because of the variation in the ways the agencies have implemented that guidance, and because there is no uniform policy on the Federal roles versus State roles, there exists a need for a coordinated Federal approach to regulating NARM vis-a-vis other ionizing radiation hazards. Such coordination is a logical function of the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC). Thus, an option for NRC is to refer the matter of additional Federal regulation of NARM to CIRRPC for appropriate coordination and priority setting.

7.3 Would NRC Regulation of NARM Overlap Other Federal Agencies' Programs?

As previously indicated, Congress has already granted to other Federal agencies authority to control exposures to NARM in the environment, in consumer products, in the workplace, in homes, and in the medical field. Thus, any NRC regulation of NARM would overlap other Federal agencies' jurisdiction. With regard to the programs being implemented by those other agencies, generally NARM seems to be a low priority, relative to their other programs. However, few Federal regulatory agencies other than the NRC, if any, regulate an activity as thoroughly as NRC does when it regulates the possession, use, transfer, ownership, disposal, and so forth of byproduct materials. Thus, if NRC were to regulate NARM, there would be much more vertical regulation of those materials than occurs now.

There are many Federal agencies and private organizations that have jurisdiction over--or interest in--the quality of health care delivery programs. NRC is but one among the many; however, because of its congressional mandate, NRC regulates not only possession of nuclear medicines, but also the uses. Other Federal agencies avoid, either through policies or through their mandates, regulating the providers of health care. For example, the HHS has promulgated standards for the accreditation of radiology education programs and for the certification of individuals in the field of radiology, such as nuclear medicine and radiation therapy technologists. In doing so, HHS observes: "While the standards were developed by the Department, the [Consumer-Patient Radiation Health and Safety] Act preserves the traditional prerogatives of States in the approval of education programs and in regulation of personnel." Further, Congress and the States recognize the United States Pharmacopeial (USP) Convention as the expert organization for establishing national standards for the production, packaging, labeling, and use of pharmaceuticals, including radiopharmaceuticals. USP is an unbiased and private organization of experts that constantly revises and adds to its standards, as the situation warrants--a process that is easier and probably better than formal rulemakings. HHS relies on USP standards. Since USP has developed and continues to develop standards governing radiopharmaceuticals containing cyclotron-produced radioisotopes, NRC's regulation of those products would overlap USP and HHS activities.

There is overlap and conflict between HHS' and NRC's policies and programs as they deal with health care programs, raising the question as to whether NRC is over-regulating nuclear medicine programs at the expense of other health care programs. There exists a need to examine the issue of whether or not, or the extent to which NRC's regulation of nuclear medicine institutions is consistent with or in conflict with other Federal agencies' regulation of the medical profession. The NRC should determine the extent to which its regulatory activities detract from quality of care in conventional medical programs, through possible misappropriation of resources, by directing attention to areas where the result is not optimum. Such an examination would be beneficial in advance of any NRC decision to seek additional legislative authority to regulate NARM.

7.4 Are the States' Controls over NARM Adequate?

The States' radiation control programs are well matured now, compared to the programs of 1974, the year when the Agreement States first urged the AEC/NRC to seek legislative authority over NARM. The Conference of Radiation Control Program Directors (CRCPD) has prepared, with the assistance of NRC, EPA, and FDA, a set of NARM guides as part of a nationwide system for uniform regulation of NARM. As stated previously, the Conference recently instituted a procedure to recognize certain State programs--CRCPD-Recognized NARM licensing State--as a way of encouraging and recognizing those States that have implemented comprehensive control programs for NARM. A State must specifically request such recognition and must meet the CRCPD criteria. To date, 10 States (all Agreement States) have been so recognized.

At this time, all 29 Agreement States regulate and control NARM in the same way they do materials covered by the AEA. Of the 21 non-Agreement States, only 4 have a NARM licensing program. Of the remainder, 2 States have voluntary or partial licensing programs, and 14 States have registration programs, leaving only 1 State, Montana, with nothing. With regard to NARM inspections, all 29 Agreement States inspect NARM users as do 14 non-Agreement States, whereas 4

States conduct partial inspection and 5 States conduct no inspection. Comparing this level of activity with that of 1977, it appears that the States are increasing the amount of attention to NARM.

The States' response to the October CRCPD request for a listing of all NARM incidents over the past 5 years does not support a conclusion that the States' controls over NARM are inadequate.

The Conference is actively pursuing a NARM disposal program and heightening awareness of the need to properly dispose of radium. There appears to be emerging differing views between the States and Federal agencies regarding the definitions of what constitutes LLW and radiation exposures "below regulatory concern." Additional coordination is needed in this regard.

An option for the NRC is to prepare a policy statement fully supporting the CRCPD recognition of licensing States for regulation and control of NARM. An alternative, or addition to this, is for the Commission to write to the Governors of those States that do not regulate NARM. The purposes of such a letter would be (1) to inform those States that, although CRCPD has again urged NRC to regulate NARM, the Commission has chosen not to seek such authority, but believes the States should adopt the CRCPD-suggested regulations for NARM and (2) to urge the States to become a CRCPD-recognized NARM licensing State.

7.5 Is NARM a Federal, State, or Professional Responsibility?

With regard to radium disposal, neither the Federal government nor the States have assumed responsibility. Discrete radium sources are an orphan waste. Although EPA is working on a regulation addressing NARM disposal, enforcement of that regulation remains open. NRC is a candidate; thus, an option is for the NRC to seek legislative authority limited to enforcing the forthcoming EPA regulation, assuming there is no way the NRC could do that under its existing authorities. This will be discussed later under options.

With regard to Federal/State/Professional responsibilities over NARM use in the medical field, there is a real and fundamental issue. NRC appears unique in the Federal government in the scope of its regulation of byproduct materials. Other Federal agencies generally recognize the historic State prerogatives of regulating personnel in the medical field. Any NRC regulation of NARM would further preempt these traditional State responsibilities. With regard to professional responsibilities in the medical field, in a pleading to the FDA, one physician observed:

> The responsibility for the final drug product quality rests on the shoulders of the pharmacists and physicians who put their professional competence on the line when they prepare these compounds for human use. It doesn't matter whether they use a cyclotron, an automated synthesis machine, a centrifuge, or chromatography equipment.

* * *

> The consequences of carelessness are lawsuits against the institution and malpractice charges against the pharmacist and physician. These are strong deterrents to sloppiness. They are all that is needed.
>
> (See letter from C. S. Marcus, Ph.D., M.D. Harbor-UCLA Medical Center, Torrance, CA, to R. Temple, MD, FDA, dated July 20, 1987.)

That letter also recognizes the role of the States in assigning responsibilities to the pharmacists and physicians: "This is entirely within the bounds of laws set out by the various States regarding the practice of pharmacy and the practice of medicine."

Thus, an option for NRC is the status quo.

7.6 Would Congress Consider the NRC Responsible for Controlling NARM Hazards?

Congress has consistently looked to entities other than the NRC for the generalized functions of protecting the public health and safety. Historically, Congress recognizes that the States have the primary responsibility for ensuring such protection. Generally, when a societal problem involving interstate commerce arises, Congress can and does enact legislation preempting such State functions and establishes, to some degree, Federal jurisdiction over the problem to promote the general welfare. In the case of NARM hazards, in particular, Congress has historically refused to broaden the regulatory functions of the AEC/NRC. Rather, to the extent that Congress has found a need to address NARM hazards, it has delegated such functions to, for example, EPA, CPSC, DOL, HHS, and others. Furthermore, Congress, as well as other Federal agencies, other than the NRC, has explicitly recognized the State role in this regard. Ample regulatory authority has already been given to other Federal agencies to control any NARM hazards; there exists only the matter of whether the NARM hazards rise above other hazards to warrant increased regulatory oversight. At least implicitly, the other Federal agencies appear to say the NARM hazards do not. Thus, the burden would fall on NRC to establish that other agencies are not properly performing their responsibilities--if the NRC were to seek legislative authority to regulate NARM more than it is regulated now.

7.7 What Are the Resource Implications?

The resource implications of NRC regulating NARM range from inconsequential to enormous, depending on how broad such regulation would be. This is because the quantities and concentration of NARM form a continuum in the human world and because the potential hazards form a continuum ranging from background to potentially significant ones in all facets of life. Should NRC seek to regulate only the disposal of discrete sources of radium, the resource implications would likely amount to less than five FTE positions per year since such regulation would represent a small addition to this Agency's LLW activities. However, should NRC seek jurisdiction over diffuse sources of radium, the resource implications would jump by multiples, perhaps orders of magnitude, because of the ubiquitous nature of radium.

Likewise, should NRC seek legislative authority over accelerator-produced radioactive materials, the resource implications would be substantial, probably tens of FTE positions because there are thousands of accelerators/cyclotrons in

use. Large resources would be required because the machines must function as intended and must be properly maintained to minimize doses to employees and to minimize the generation of NARM wastes. Thus, the NRC would probably have to regulate not only the materials activated by the machines, but the devices themselves. Even if NRC were to try to carefully bracket the definition of NARM to only that produced in nuclear medicine institutions, the agency would probably have to regulate the patients, the practitioners, the materials, and the cyclotrons as well because all must work together properly for there to be success. Although NRC has no precise formula for predicting necessary resources to do this, it judges that regulation of such a narrow definition of NARM would require around 10 FTE positions to maintain the program. Substantially more FTE positions would be required to establish the program. It would probably involve research, rule development, and the hiring and training of staff to deal with cyclotron technology--expending perhaps several tens of FTE positions per year and $1 million per year for 5 years. But, the resource implications might not stop there. With a limited expansion of NRC regulatory reach into these kinds of devices, comes the potential for further expansion into other sources of exposures to ionizing radiation and concomitant resource implications.

For perspective, the entire existing NRC materials licensing and inspection programs expend 85 to 90 FTE positions per year and $1 to $2 million. (See memorandum from R. B. Loach, Division of Budget and Analysis, NRC, to J. H. Austin, NMSS, NRC, dated January 21, 1988.)

7.8 Would NRC Responsibility for NARM Regulation Change the Nature of NRC?

The regulatory authority of AEC/NRC has been relatively stable for several decades. All of NRC activities and responsibilities have a link to the neutron chain reaction, with a large amount of its resources directed to preventing accidents that could result in very large consequences. Seeking jurisdiction over NARM would be an unprecedented extension of NRC's activities into the realm of generalized concerns over exposures to ionizing radiation, a province heretofore the domain of other Federal agencies and the States. NRC would likely have to regulate the operation of cyclotrons/accelerators, the extraction industries that generate NARM wastes, water purification plants that concentrate radium, and others. Even if NRC were to seek a limited jurisdiction over certain aspects of NARM, such a departure from the historic role of AEC/NRC opens the potential for further expansion of responsibilities at a later date.

As previously indicated, the positron emission tomography (PET) procedure involves cyclotron-produced radioisotopes with half-lives in the order of minutes to hours. The radioisotopes are created on site, used on site for diagnostic purposes, and decay on site. Thus, those radioisotopes are not in interstate commerce. FDA has yet to decide whether the system is a medical device, or a drug, or neither. If FDA ultimately decides not to regulate the PET procedure, and NRC decides to regulate cyclotron-produced radioisotopes, then NRC will have to rule on the safety and efficacy of the PET modality in order to circumvent the provisions of 10 CFR 35.100 and 35.200, which require FDA acceptance or approval of diagnostic radiopharmaceuticals.

8 OPTIONS

On the basis of the analysis of the issues identified above, the NRC sees five options regarding its possible involvement with NARM:

(1) status quo, but continue to encourage the CRCPD efforts on NARM regulation

(2) seek legislative authority over NARM

(3) seek regulatory authority over radium disposal

(4) seek regulatory authority over cyclotron-produced radionuclides for medical use only

(5) refer the issue of NARM regulation to CIRRPC

Each is evaluated below.

8.1 Status Quo

Selecting the status quo option would recognize that many other Federal agencies already have jurisdiction over NARM as it exists in the environment, in homes, in the work place, in consumer products, and in medical institutions. This option also recognizes that there is no major national problem with NARM that is going unaddressed and that the States are increasingly exercising their traditional prerogatives to protect the public health and safety. Further, maintaining the status quo preserves the historic function of the NRC of only regulating activities that have a link with the neutron chain reaction and avoids the potential of the NRC becoming involved in generalized regulation of ionizing radiation. Finally, the status quo option has no resource impact.

On the other hand, this option might result in radium continuing to be an orphan waste and could continue the existing uncertainty over whether radium can or should be disposed of in LLW sites. Further, maintaining the status quo could leave the impression that the NRC does not support the significant efforts of the States to better control the radiation hazards associated with NARM.

Also on the negative side, the status quo would mean that in non-Agreement States manufacturers of NARM sources who are not required to apply acceptable quality control procedures, may ship such sources to individuals in non-Agreement States without checking to see if such individuals are properly qualified to handle radioisotopes. Furthermore, some States (e.g., Texas and Colorado) will not authorize receipt of NARM that is manufactured in a State that does not regulate NARM, in part, because of the lack of assurance that appropriate quality control procedures were used. Some State representatives believe this problem, which is largely economic, may grow.

Finally, the status quo option does not ensure consistent Federal and State definitions of NARM low-level wastes and NARM concentrations "below regulatory concern."

8.2 Seek Legislative Authority over NARM

Should the NRC seek and obtain legislative authority over NARM, there would be an advantage of one single Federal agency having jurisdiction over all radioactive materials, with centralized and uniform regulation of their hazards. No longer would there exist gaps in and uneven regulation of similar risks associated with radioactive materials. Nuclear medicine institutions would be totally regulated, except in the use of X-ray devices.

On the other hand, this option seeks to correct what appears to be a non-problem, when one compares the NARM hazards with other greater hazards in, for example, hospitals. NRC jurisdiction over NARM would duplicate existing responsibilities of many other Federal agencies, and because the NRC's congressional mandate is to regulate very deeply, there would be enormous resource ramifications. The nature of the NRC would fundamentally change. The burden would be on NRC to convince Congress that the Federal agencies already having jurisdiction over NARM are not doing an adequate job. This option would ignore the many ongoing and substantial programs to control and improve the quality of care in the medical field including those of individual States, HHS, the Joint Commission on Accreditation of Healthcare Organizations, the USP, and the numerous Associations and Societies representing the health care practitioners. Standards, guides, selection criteria, and peer review groups are all being used and further developed and expanded to ensure quality in health care delivery programs.

Finally, this option would divert Federal resources from greater hazards.

8.3 Seek Legislative Authority over Radium Disposal

EPA is currently developing regulations for radium disposal, and one of its options is to look to the NRC for enforcement of them. Since discrete radium sources are now an orphan waste, there would be a definite benefit in ensuring that this very hazardous material is properly disposed of. NRC- and Agreement-State-licensed LLW sites are suitable locations for discrete radium sources, but not diffuse sources. Thus, any legislation would have to bracket the authority to cover only discrete sources. This option would further ensure that hazards of similar kinds are treated similarly. If NRC does not have authorization to regulate radium disposal, then it could not cite those individuals who improperly dispose of radium. The NRC does not believe the resource implications of this option are significant because radium disposal would be a small addition to its ongoing activities on LLW.

On the negative side, because NRC's mandate is to regulate possession, use, transfer, or ownership of byproduct materials, its regulation of radium disposal might entail regulation of the generators of discrete sources of radium (e.g., water purification plants). As mentioned previously, the NRC could, through license conditions and/or regulatory guidance, specify the quantities, concentrations, and forms of radium that are and are not suitable for LLW sites, just as it specifies chemical disposal for safety reasons. This argues against seeking legislative authority, but would leave unaddressed the record of enforcement action against those that dispose of discrete radium sources in, for example, sanitary landfills.

8.4 Seek Legislative Authority over Cyclotron-Produced Radionuclides for Medical Use Only

This option removes the inconsistency of NRC regulating all of the radioisotopes in nuclear medicine institutions except for the cyclotron-produced ones. (If NRC seeks such legislative authority, it may as well request authority over radium in nuclear medicine institutions.) This option would provide for uniform regulation of cyclotron-produced radiopharmaceuticals, removing the competitive disadvantage to manufacturers who are located in States that do not regulate NARM. Although not necessarily an advantage, seeking such authority would allow NRC to regulate materials that may cause, statistically, 0.0001 death per year. Finally, this option would better ensure that all radionuclides in nuclear medicine institutions are uniformly treated.

On the negative side, regulating the cyclotron-produced materials would require hiring and training individuals schooled and trained in cyclotrons. The NRC may have to judge the safety and efficacy of the PET modality, if FDA does not. This option would remove the link between NRC responsibilities and the neutron chain reaction and replace it with a link to generalized concerns over ionizing radiation. The nature of NRC would change. As with the second option, this option ignores the ongoing and substantial programs to control and improve the quality of care in the medical field; those programs involve Federal, State, local, and private organizations. Ten FTE positions may be needed to maintain the program. If these materials result in a statistical 0.0001 death per year, that translates to about $10 billion per life saved, assuming that NRC regulation would change the incidence of misadministrations to any significant degree. This option could duplicate the jurisdiction FDA already has over these materials, and NRC would have to establish why FDA is not doing an adequate job. Finally, the United State Pharmacopeial Convention, recognized as an expert organization by Congress and the States, has developed and continues to develop national standards governing the production and use of, among other items, radiopharmaceuticals containing cyclotron-produced radioisotopes. The NRC would have to establish why that program is not adequate.

8.5 Refer the Issue of NARM Regulation to CIRRPC

The Committee on Interagency Radiation Research and Policy Coordination was created to coordinate radiation matters between agencies and to advise the Office of Science and Technology Policy on issues involving Federal radiation policy. NARM cuts across existing jurisdiction of other agencies. There is a need for an integrated control program over ionizing radiation, in general, and over NARM, in particular, to ensure that the dominant hazards are appropriately addressed without undue attention to the lesser hazards. Thus, CIRRPC is the logical entity to resolve the NARM issue. In fact, in 1979, the Commission referred the NARM issue to the predecessor of CIRRPC, but action was never completed.

The only negative side of this option would be that NARM might become lost in CIRRPC because of higher priority issues, but that would say something about the NARM hazards.

8.6 Discussion

The evaluation of the above options and given that many Federal agencies already have jurisdiction over NARM and that States are increasing their regulation of

NARM, leads to the conclusion that the unregulated NARM risks are not rising to a level that would suggest they should be the next target of congressional legislation. Radium disposal is the subject of a forthcoming EPA regulation, and NRC can facilitate that regulation by specifying acceptable and unacceptable concentrations of radium for disposal at LLW sites. There are many more important problems in hospitals than those associated with NARM. NRC regulation of NARM in hospitals would divert the limited resources of the hospitals to the lesser problem (NARM) at the expense of the greater problems. There is a need for an integrated approach to controlling exposures to ionizing radiation, in general, and to NARM, in particular; however, NRC is not the agency to do that integrating.

The States are increasing their regulation of NARM. The NRC has worked with the States in the past and should continue with such assistance and support.

The conflicting ways in which the NRC and HHS regulate medical applications of ionizing radiation raises the question as to whether the NRC is over-regulating nuclear medicine programs at the expense of other health care programs. Examination of this issue would be beneficial in advance of any NRC decision to seek additional legislative authority to regulate NARM.

9 RECOMMENDATIONS

The NRC has the following two recommendations:

(1) Refer the issue of NARM regulation to CIRRPC for the purposes of developing an integrated policy and agency assignments on NARM, in particular, and ionizing radiation, in general, in those situations where one agency's jurisdiction overlaps that of another (e.g., in the Federal regulatory programs dealing with health care activities).

(2) Inform the Governors of those States not within the CRCPD-recognized NARM licensing States that NRC is not going to seek legislative authority to regulate NARM because such regulation is a responsibility of the States and because other Federal agencies already have jurisdiction over most facets of NARM hazards. Further, urge those Governors to take the necessary actions and to assign appropriate resources to become such recognized States.

Although not directly within the scope of this assignment, it should be noted that information gathered during the conduct of this study suggests that the depth to which NRC regulates nuclear medicine is inconsistent with Federal regulation of medicine in general. There is a need for better integration within the Federal government to ensure that the dominant hazards associated with medical practice are being appropriately addressed without paying undue attention to lesser hazards associated with nuclear medicine. Furthermore because of the varying congressional mandates of the numerous agencies ha jurisdiction over ionizing radiation, because of the varying and conflict priorities and programs among those agencies, and because there has never been an explicit and consistent determination of the Federal role versus the State role in protecting the public from exposures to ionizing radiation, there is a need for better integration of the numerous Federal programs governing exposures to ionizing radiation.

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13. ABSTRACT (200 words or less)

From time to time, the issue as to whether the U.S. Nuclear Regulatory Commission (NRC) should seek legislative authority to regulate naturally occurring and accelerator-produced radioactive materials (NARM) is raised. Because NARM exists in the environment, in homes, in workplaces, in medical institutions, and in consumer products, the issue of Federal controls over NARM is very old and very complex. This report presents a review of NARM sources and uses as well as incidents and problems associated with those materials. A review of previous congressional and Federal agency actions on radiation protection matters, in general, and on NARM, in particular, is provided to develop an understanding of existing Federal regulatory activity in ionizing radiation and in control of NARM. In addition, State controls over NARM are reviewed. Eight questions are examined in terms of whether the NRC should seek legislative authority to regulate NARM. The assessment of these questions serves as the basis for developing and evaluating five options. The evaluation of those options leads to two recommendations.

14. DOCUMENT ANALYSIS - a. KEYWORDS/DESCRIPTORS
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Attachment 1; Table 1 - Four Classifications of Radioactive Material [1]							
1. Primordial Radioisotopes (abundance) (decay mode)	**Half-Life (yrs)**	**Source Material**	**Fertile**	**SNM**	**Mill Tailings [11.e(2)]**	**NORM**	**Notes**; e.g., Use of Material
U-238 Decay Series (99.27%) long-lived isotopes:							
U-238 (α) (Th-234; 24 days, β)	4.47×10^{9}	Yes	Yes		Yes	Yes	Radiation shield; Penetrator
U-234 (α)	2.46×10^{5}	Yes			Yes	Yes	
Th-230 (thorium) (α)	7.54×10^{4}				Yes	Yes	
Ra-226 (radium) (α) (Radon-222; 3.8 days, α)	1.6×10^{3}				Yes	Yes	
Pb-210 (lead) (β) (Bi-210; 5 days, β)	22.3				Yes	Yes	
Po-210 (polonium) (α)	138 days					Yes	Static eliminator
Pb-206 (lead)	Stable						
U-235 Decay Series (0.7%) Daughters no significant dose	7.1×10^{8}	Yes		Yes	Yes	Yes	Becomes SNM if enriched
Th-232 Decay Series long-lived isotopes:							
Th-232 (thorium) (α) (100%)	1.405×10^{10}	Yes	Yes		Yes	Yes	Th-Mg Alloy; Welding
Ra-228 (radium) (β)	5.75				Yes	Yes	
Th-228 (thorium) (α) (Ra-224; 3.66 days, α)	1.91				Yes	Yes	
Pb-208 (lead)	Stable						

1. Primordial Radioisotopes, continued (decay mode)	**Half Life (yrs)**	**Source Material**	**Fertile**	**SNM**	**Mill Tailings [11.e(2)]**	**NORM**	**Notes**; e.g., Use of Material
K-40 (potassium) (β decay) (0.0117%)	1.28×10^{9}					Yes	major internal body burden
V-50 (vanadium) (electron capture) (0.25%)	1.4×10^{17}					Yes	
Rb-87 (rubidium) (β) (28%)	4.75×10^{10}					Yes	earth mantle heat flux
In-115 (indium) (β) (95.71%)	4.41×10^{14}					Yes	
Te-123 (tellurium) (e) (0.91%)	1.0×10^{13}					Yes	
La-138 (lanthanum) (e & β) (.09%)	1.05×10^{11}					Yes	
Ce-142 (cerium) (β) (11%)	5.0×10^{16}					Yes	
Nd-144 (neodymium) (α)(24%)	2.29×10^{15}					Yes	
Sm-147 (samarium) (α) (15%)	1.06×10^{11}					Yes	
Sm-148 (α) (11%)	7×10^{15}					Yes	
Sm-149 (α) (14%)	2.0×10^{15}					Yes	
Gd-152 (gadolinium) (α)(0.2%)	1.08×10^{14}					Yes	
Hf-174 (hafnium) (α) (0.16%)	2.0×10^{15}					Yes	
Lu-176 (lutetium) (β) (2.6%)	3.78×10^{10}					Yes	meteorite dating
Os-186 (osmium) (α) (1.58%)	2.0×10^{15}					Yes	
Re-187 (rhenium) (β) (62.6%)	4.35×10^{10}					Yes	
Pt-190 (platinum) (α) (0.01%)	6.5×10^{11}					Yes	
Pb-204 (lead) (α) (1.4%)	1.4×10^{17}					Yes	
Pa-231 (protactinium) (α)	3.27×10^{4}					Yes	

1. Primordial Radioisotopes, decay chain missing from the earth due to short half-lives	**Half Life (yrs)**	**Source Material**	**Fertile**	**SNM**	**Mill Tailings [11.e(2)]**	**NORM**	**Notes**; e.g., Use of Material
Am-241 (americium) (α)	432.2						
Np-237 (neptunium) (α)	2.14×10^{6}						
U-233 (uranium) (α)	1.59×10^{5}						
Th-229 (thorium) (α)	7880						
Ra-225 (radium) (β) (Ac-225)	15 days						
Rn-221 (radon) (α)	25 minutes						
Rn-217 (α)	0.54 millisecond						
Po-213 (polonium) (α)	4.2 μ second						
Bi-209 (bismuth) (stable)	$> 2 \times 10^{18}$						

2. Cosmic-Ray-Induced Radioisotopes (decay mode)	**Half Life (yrs)**	**Source Material**	**Fertile**	**SNM**	**Mill Tailings [11.e(2)]**	**NORM**	**Notes**; e.g., Use of Material
H-3 (tritium) (β)	12.33					Yes	thickness gauge
Be-7 (beryllium) (e capture)	53 days					Yes	
Be-10 (β)	1.51×10^6					Yes	
C-14 (carbon) (β)	5.73×10^3					Yes	thickness gauge, tracer, determination of age
Na-22 (sodium) (e)	2.6					Yes	
Si-32 (silicon) (β)	172					Yes	
P-32 (phosphorus) (β)	14 days					Yes	
P-33 (β)	25 days					Yes	
S-35 (sulfur) (β)	87 days					Yes	
Cl-36 (chlorine) (β)	3.01×10^5					Yes	thickness gauge
Cl-39 (β)	55 minutes					Yes	

3a. Reactor-Produced Radioisotopes; Activation Products Used in Medicine (decay mode)	**Half Life (yrs)**	**Source Material**	**Fertile**	**SNM**	**Mill Tailings [11.e(2)]**	**NORM**	**Notes**; e.g., Use of Material
C-14 (carbon) (β)	5.73×10^3						urea halobacter pylori test
P-32 (phosphorus) (β)	14 days						medical procedures, inter-vascular brachytherapy
Co-60 (cobalt) (β)	5.27						teletherapy, brachytherapy, interstitial and intracavitary cancer therapy
Sr-89 (strontium) (β)	50.5 Days						palliative treatment
Sr-90 (β)	28.8						brachytherapy, treatment of superficial eye conditions
Y-90 (yttrium) (β)	64.1 hours						micro-sphere brachytherapy
Tc-99m (technetium) (IT, γ)	6 hours						imaging
Pd-103 (palladium) (e)	17 days						brachytherapy, interstitial cancer therapy
I-125 (iodine) (e)	59.4 days						brachytherapy, interstitial cancer therapy
I-131 (β)	8.02 days						hyperthyroidism, thyroid cancer
Xe-133 (xenon) (β)	5.2 days						lung studies
Cs-137 (cesium) (β)	30.1						brachytherapy, interstitial and intracavitary cancer therapy
Ir-192 (iridium) (β)	73.8 days						brachytherapy, interstitial cancer therapy
Au-198 (gold) (β)	2.7 days						brachytherapy, interstitial cancer therapy

3b. Reactor-Produced Radioisotopes; (% remaining 20 years post irradiation)	**Half Life (yrs)**	**Source Material**	**Fertile**	**SNM**	**Mill Tailings [11.e(2)]**	**NORM**	**Notes**; e.g., Use of Material
H-3 (tritium) (β) (0.09%)	12.33						tracer
Co-60 (cobalt) (β, γ) (0.23%)	5.27						density gauge, γ radiography
Ni-63 (nickel) (β) (0.13%)	100.1						thickness gauge
Kr-85 (krypton) (β) (0.83%)	10.8						
Sr-90 (strontium) (β) (14.65%)	28.8						
Y-90 (yttrium) (β) (14.65%)	64.1 hours						
Sb-125 (antimony) (β) (0.04%)	2.76						
Cs-134 (cesium) (β) (0.08%)	2.06						
Cs-137 (β) (23.15%)	30.1						
Ba-137m (barium) (γ) (21.90%)	2.5 minutes						
Pm-147(promethium)(β)(0.18%)	2.62						
Sm-151 (samarium) (β) (0.12%)	90.0						
Eu-154 (europium) (β) (0.84%)	8.59						
Eu-155 (β) (0.17%)	4.76						
Pu-238 (plutonium) (α) (1.26%)	87.7						
Pu-239 (α) (0.12%)	2.41×10^4			Yes			
Pu-240 (α) (0.18%)	6.56×10^3						
Pu-241 (β) (19.25%)	14.35			Yes			
Am-241 (americium) (α)(1.08%)	432.2						x-ray fluorescence analysis
Cm-244(curium) (α) (0.96%)	18.1						

4. Accelerator-Produced Radioisotopes (decay mode)	**Half Life (yrs)**	**Source Material**	**Fertile**	**SNM**	**Mill Tailings [11.e(2)]**	**ARM**	**Notes**; e.g., Use of Material
C-11 (carbon) (positron)	20 minutes					Yes	lung uptake & metabolism, prostrate tumor localization, positron tomography
N-13 (nitrogen) (positron)	10 minutes					Yes	pancreatic scan, brain scan, positron tomography
O-15 (oxygen) (positron)	2 minutes					Yes	brain scan, shunt detection, positron tomography
F-18 (fluorine) (positron)	110 minutes					Yes	bone uptake, brain scan, chemotherapy, metabolism, positron tomography
Na-22 (sodium) (positron)	2.60					Yes	extra-cellular water
Mg-28 (magnesium) (β)	20.9 hours					Yes	
P-32 (phosphorus) (β)	14 days					Yes	medical procedures
P-33 (β)	25 days					Yes	palliative treatment
Ar-37 (argon) (e)	35 days					Yes	total calcium measurement
K-43 (potassium) (β)	22 hours					Yes	myocardial imaging
Sc-49 (scandium) (β)	57 minutes					Yes	
Mn-52 (manganese) (e)	5.6 days					Yes	
Fe-52 (iron) (positron)	8.3 hours					Yes	
Co-56 (cobalt) (e)	77.3 days					Yes	tumor localization
Co-57 (e)	272 days					Yes	vitamin B-12 measurement, tumor imaging calibration, x-ray fluorescence analysis, simulated tumors

4. Accelerator-Produced Radioisotopes, continued	**Half Life (yrs)**	**Source Material**	**Fertile**	**SNM**	**Mill Tailings [11.e(2)]**	**ARM**	**Notes**; e.g., Use of Material
Co-58 (cobalt) (e)	71 days					Yes	intestinal absorption studies
Cu-62 (copper) (positron)	9.7 minutes					Yes	radiopharmaceuticals
Cu-67 (β)	61.8 hours					Yes	studies of Wilson's disease
Ga-67 (gallium) (e)	3.26 days					Yes	lung scan, bowel scan, parotid gland uptake (Sjogren's syndrome), cardiac scanning
Ga-68 (e)	68 minutes					Yes	brain scan, positron emission tomography for cerebral hemo-dynamics
As-74 (arsenic) (e)	18 days					Yes	brain tumor localization
Br-77 (bromine) (e)	57 hours					Yes	
Kr-77 (krypton) (positron)	74 minutes					Yes	brain scan, positron tomography
Rb-81 (rubidium) (e)	4.6 hours					Yes	myocardial imaging
Rb-82 (positron)	1.3 minutes					Yes	imaging, positron tomography
Rb-84 (e)	33 days					Yes	radiopharmaceuticals
Sr-87m (strontium) (isomeric transition)	2.8 hours					Yes	bone scan, index of bone growth
Y-87 (yttrium) (e)	80 hours					Yes	parent of Sr-87m
Tc-97m (technetium) (IT)	91 days					Yes	imaging
Pd-103 (palladium) (e)	17 days						brachytherapy, interstitial cancer therapy
In-111 (indium) (e)	2.8 days					Yes	cisternography, tomography, tagged platelets, tagged lymphocytes

4. Accelerator-Produced Radioisotopes, continued	**Half Life (yrs)**	**Source Material**	**Fertile**	**SNM**	**Mill Tailings [11.e(2)]**	**ARM**	**Notes**; e.g., Use of Material
I-123 (iodine) (e)	13 hours					Yes	thyroid studies, imaging, labeled fibrinogen for in-vivo identification of thrombophlebitis
I-125 (e)	59 days					Yes	bone mineral analysis, interstitial treatment of cancer, uptake studies
Xe-127 (xenon) (e)	36 days					Yes	cardiac studies, blood-flow studies, pulmonary function studies
Cs-129 (cesium) (e)	32 hours					Yes	myocardial imaging
Cs-131 (e)	9.7 days					Yes	thyroid scanning
Dy-157 (dysprosium) (e)	8 hours					Yes	bone tumor localization
Ir-190 (iridium) (e)	11.8 days					Yes	
Au-195 (gold) (e)	186 days					Yes	
Hg-197 (mercury) (e)	64 hours					Yes	brain and kidney scanning
Tl-199 (thallium) (e)	7.4 hours					Yes	cardiac scanning
Tl-201 (e)	73 hours					Yes	cardiac scanning
Pb-203 (lead) (e)	52 hours					Yes	detection of malignant melanoma
Bi-204 (bismuth) (e)	11 hours					Yes	soft tissue scanning
Bi-206 (e)	6.24 days					Yes	soft tissue scanning

[1]Data from online data base, Table of the Nuclides, linked to web site for Brookhaven National Laboratory at http://www.dne.bnl.gov/CoN/index.html