NUREG-0301

REGULATION OF NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

A Task Force Review

Office of Nuclear Material Safety and Safeguards
U. S. Nuclear Regulatory Commission

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Manuscript Completed: June 1977
Date Published: July 1977

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This document is a report of an NRC Task Force. The results, opinions, conclusions and recommendations expressed in this report are those of the Task Force and do not necessarily express the positions of NRC or other Federal or State agencies.

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TASK FORCE

FOR THE

MATTER OF REVIEW OF REGULATION OF NATURALLY OCCURRING

AND

ACCELERATOR PRODUCED RADIOACTIVE MATERIALS

HISTORY AND PURPOSE OF TASK FORCE

Following the October 1974 meeting of the Agreement States in Bethesda, Maryland, the Agreement States developed several requests and recommendations for NRC (then AEC) action, one of which was the following:

> "The States recommend that the AEC, or it's successor agency, move immediately to bring accelerator-produced and naturally occurring radioactive material under it's jurisdiction" (Appendix A).

On May 8, 1975, the Executive Committee of the Conference of Radiation Control Program Directors (CRCPD) met with the Commissioners. One of the points discussed at the meeting was later summarized by the Conference in a letter to Commissioner 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" (Appendix B).

In response to these requests, in January, 1976, NRC established a task force to review the matter of regulation of these materials. Representatives from SP, IE, NMSS, ELD and SD were appointed. Resource persons representing Agreement and non-Agreement States and Federal agencies also participated. This report is the product of that Task Force review.

TASK FORCE PARTICIPANTS

Members of the Task Force were:

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EXECUTIVE SUMMARY

Conclusions

1. 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% 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.

2. One NARM radioisotope - ^{226}Ra - is one of the most hazardous of radioactive materials. ^{226}Ra is used by about 1/5 of all radioactive material users. Also, there are about 85,000 medical treatments using ^{226}Ra each year.

3. All of the 25 Agreement States and 5 non-Agreement States have licensing programs covering NARM users. The Agreement States' programs for regulating NARM are comparable to their programs for regulating byproduct, source and special nuclear materials under agreements with NRC. But there are 7 States who exercise no regulatory control over NARM users, and the remaining States have control programs which are variable in scope. There are no national, uniformly applied programs to regulate the design, fabrication and quality of sources and devices containing NARM or consumer products containing NARM which are distributed in interstate commerce.

4. Naturally occurring radioactive material (except source material) associated with the nuclear fuel cycle is only partially subject to NRC regulation, i.e., when it is associated with source or special nuclear material being used under an active NRC license.

5. 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.

6. Although outside the scope of this study, data and evidence gathered in support of this study showed that the regulatory control for radiation safety for accelerators (which can be used to produce NARM) may also be fragmented and incomplete.

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.

SCOPE OF WORK

The primary objective was to assess the need for, and feasibility of, the Federal government regulating naturally occurring and accelerator-produced radioactive materials. The task force examined the existing State and Federal programs concerning these materials and attempted to assess their effectiveness. The examination included the existing rules and regulations, the sources and uses of materials (including wastes), and the number and frequency of incidents involving these materials. With regard to feasibility, an assessment was made of the public policy and legal questions with regard to whether the Federal government can and should regulate these materials. With respect to Federal government involvement, the task force considered recommendations for new or improved NRC actions for regulating the various sources and uses of the materials (including radium associated with mineral industry tailings). Finally, the task force considered the value/impact of these recommendations and developed estimates of NRC resources which may be required to carry out the recommendations.

SOURCES AND USES OF NATURALLY OCCURRING AND ACCELERATOR PRODUCED RADIOACTIVE MATERIAL

Sources

All radioactive materials, for purposes of this study, were divided into two groups, namely, one group that is subject to the regulation at this time by the Nuclear Regulatory Commission (NRC) and a second group over which the NRC presently does not exercise jurisdiction. The first group consists of byproduct material, source material and special nuclear material as defined in the Atomic Energy Act.* This group was not of direct interest to this study except that it was used as a reference point in consideration of the second group. The second group is referred to in this study as naturally occurring and accelerator-produced radioactive material (NARM). This group includes the following subgroups:

1. Primordial and cosmic ray induced radionuclides, and
2. Radioactive materials produced as a result of nuclear interactions in accelerators.

*The Atomic Energy Act of 1954, as amended (68 Stat. 919), Sections 11.e, z and aa.

Examples of primordial radionuclides and major cosmic ray activated radionuclides are shown in Tables 1 and 2.* It should be noted that uranium and thorium, although primordial radionuclides, were not included in this study as primordial radionuclides since these are defined in the Atomic Energy Act as "source material" and are subject to NRC regulation (when certain criteria are met). However, some of the decay daughters in the uranium and thorium series are included in the listing of primordial radionuclides since they are not defined as "source material". Certain isotopes occur as primordial or cosmic ray radionuclides, but also are produced in reactors. When they are produced in a reactor, they meet the definition of byproduct material. Examples are ^{210}Pb, ^{210}Po and ^{3}H.

Naturally Occurring Radioactive Materials

Naturally occurring radioactive materials exist in soil, rocks, air, and water.[1] Generally speaking, unless removed from their places in nature, or processed for some type of use, they are not considered to be a threat to the public health and safety. The following is a partial listing of current uses in which these materials can contribute to the population dose and may adversely affect the public health and safety: [2,3,4,5]

1. Drinking waters having concentrations of ^{226}Ra and daughters, in excess of established standards,
2. Rn in natural gas,
3. Rn in caves,
4. Agricultural gypsums (^{226}Ra),
5. Construction materials (brick, concrete blocks and aggregate, fossil fuel flyash products, gypsum wall boards, etc.),
6. Tobacco and other agricultural products (^{210}Po),
7. Mining and milling tailings (including U, Th and phosphate industries),
8. Fossil fuels (^{226}Ra),

*Tables are found on pp 52 to 62.

9. Smoke detectors (^{226}Ra),
10. Lightning rods (^{226}Ra),
11. Static eliminators (^{226}Ra, ^{210}Po),
12. Radioluminous sources (^{226}Ra) (wrist watches, clocks, compasses, instrument dials, etc.),
13. Industrial gages (^{226}Ra),
14. Vacuum tubes (^{226}Ra),
15. Vacuum gages (^{226}Ra),
16. Ion Generators (^{226}Ra),
17. Well logging devices (^{226}Ra),
18. Calibration and check sources (^{226}Ra, Ra D,E,F),
19. Educational materials (^{226}Ra, Rn D,E,F, ^{210}Po), and
20. Medical sources (^{226}Ra, ^{222}Rn, Ra D,E,F).

In addition to this partial listing, past activities have resulted in the distribution of a wide spectrum of consumer products, most using radium as the radiation source. These consumer products include radioluminous devices and devices to inject radioactivity into water.[5,6] Manufacturing activities associated with the radium production and utilization industries have resulted in contaminated buildings, structures and sites which have required remedial action.[7]

Uranium Mill Tailings

Radiological problems associated with certain mining and milling activities have been recognized and, in some cases, remedial action has been indicated as necessary to protect the public health and safety.[8,9,10]

Although the processing of uranium ore which contains .05% uranium (by weight) or greater is subject to NRC regulation, radium and other radionuclides in the uranium decay series are not subject to NRC regulation as licensed material. However, NRC does require uranium and thorium mill licensees to control radium and its daughters associated with licensed activities. These requirements include stabilization of tailings piles and their isolation from wind and water and are designed to control release of radium, radon and other radionuclides.

In the past, materials taken from uranium mill tailings piles were not recognized as potentially hazardous and were not adequately regulated. As a result, tailings have been used in a variety of construction activities, e.g., roads, homes, schools, and public buildings. Exposures of the public to radiation have resulted and in some cases, remedial action became necessary. For example, in Colorado, a study of locations where tailings were used in construction showed 170 locations where remedial action was suggested or indicated because of excessive radon levels.[10] The matter of uranium mills including tailings management is the subject of an Environmental Impact Statement being prepared by NRC.

It has been estimated that there are 2.5×10^7 tons of uranium mill tailings in "inactive" piles, containing 14,000 curies of radium. Additional tailings contain 58,000 curies of radium in "active" piles at 16 operating mills in the United States. Projections of the demand for uranium ore have been prepared for the generic environmental impact statement on mixed oxide fuels (GESMO). These projections are dependent upon a number of assumptions including whether or not there will be recycling of irradiated fuel for the recovery of uranium and plutonium. If it is assumed that uranium and plutonium are recycled, and using other GESMO assumptions, it can be projected that the number of tons of ore produced from mines will increase from 6.6 million in 1975 to 113.1 million in the year 2000. The number of mills producing 1,050 tons of U_3O_8 per year will increase from 10 in 1975 to 77 in the year 2000. If there is no recycling, the projected values would be increased for the year 2000 to 160 million tons of ore from mines and to 109 mills, each producing 1,050 tons of U_3O_8 per year.

In May, 1975, the National Resources Defense Council, Inc. filed a petition for rule making with the NRC. The petitioners requested the NRC to issue regulations that would require uranium mill operators licensed by NRC or by Agreement States to post a performance bond to cover stabilization and ultimate disposal of tailings.[11] The petitioners also requested the NRC to issue or renew no mill licenses while a programmatic environmental impact statement which they requested on the regulation of uranium mills was being prepared. The NRC is preparing a generic environmental impact

statement (GEIS) on uranium mills including management of uranium mill tailings. NRC is working with individual States in which licensed mills are located to develop performance bond arrangements to cover management of tailings following termination of NRC licensed activities. NRC and Agreement States are incorporating a condition into uranium mill licenses specifying that the licenses may be subject to modification as a result of the GEIS. EPA, under the authority of the Resource Conservation and Recovery Act of 1976, will draft regulations concerning management of mill tailings.

Other Industry Tailings and Products

Studies have been conducted by EPA on the radiological aspects of the phosphate industry in Florida.[9,12,13] The results suggest a potential may exist for problems similar to those resulting from uses of uranium mill tailings, e.g. EPA reported that about one third of the houses located on land reclaimed following the mining of uranium bearing phosphate deposits have levels of radon sufficiently high to warrant consideration of remedial action.[9] Concern has also been expressed by EPA over the potential radiological impact of uses of products and residues from the phosphate industry, such as agricultural fertilizer and aggregates.[2,12] Data obtained by EPA indicates occupational exposures in the phosphate industry do not exceed guidelines for the general population, but EPA has recommended more studies are needed to better define the problem.[13]

Limits for acceptable levels of naturally occurring radioactivity incidentally present in articles or products from the phosphate industry have not been established in the United States. NRC does not exert control over processing and refining of ores, or possession of chemical mixtures, compounds, solutions or alloys in which source material is by weight, less than 0.05% of the mixture, compound, solution or alloy.*

Radium

Radium, one of the nuclides in the uranium decay series is the principal naturally occurring radioisotope in use today. The characteristics of radium have led to its wide use in a large number of medical, industrial and military applications, and in consumer items (Tables 3 and 4).

*10 CFR 40.13 (a) and (b).

Between 1912 and 1961, nearly 2,000 gm. (i.e. about 2,000 Ci) of radium have been processed in, or imported into, the United States.[14]* Of this amount, 712 grams were imported during 1951-61. Approximately 3,600 persons are known to regulatory agencies to possess radium sources.[15] These include 1,800 medical users and 1,300 industrial users. These figures do not include owners of consumer type products presently in the public domain. It is believed that the numbers of users of radium have decreased in recent years as other alternative isotopes have become available. But, in the absence of national data, (or a national regulatory program controlling its distribution and use) the change is difficult to quantify. Radium salts are no longer manufactured in the United States. However, at least 36 U.S. companies manufacture or distribute radium sources or devices containing radium which could be subject to regulation by the States.[5] This figure includes 3 companies which manufacture smoke detectors containing radium for distribution to persons exempt from State licensing or other regulation.** Lastly, at least 5 companies received radium luminous powder in 1976 from a U.S. supplier, presumably for radium luminous paint applications.

There is no national regulatory program to require radium source and device manufacturers and distributors to comply with accepted standards for fabrication, testing, quality control and distribution of radium and radon sources used in consumer products, medicine and in industry. A voluntary control effort has been fostered by FDA's Bureau of Radiological Health in cooperation with the States.[5] However, the adequacy of this program is strongly influenced by the efforts of individual State regulatory programs. Seven States have neither a licensing nor a registration program for radium.[15]

*This figure applies only to sources, or devices containing radium or into which radium has been deliberately incorporated. It does not include products incidentally contaminated with radium, e.g. phosphate or other ores.

**The manufacture of such devices, however, is an activity that would be subject to licensing and to regulation.

Despite competent licensing and regulatory efforts by Agreement States and some non-Agreement States to control the users of radium who are subject to licensing or registration, there is not always assurance that products containing radium sources, including consumer products, will be manufactured and distributed in conformance with quality control and shipping practices comparable to those which are imposed by NRC upon its licensed manufacturers and distributors.

As an example, one might review the documentation NRC requires to support an application for distribution of ^{241}Am sources contained in smoke detectors to persons exempt from licensing.[16] Among other things the data must include evaluation of doses that might be received from external radiation and the potential for exposure to airborne ^{241}Am resulting from fires. Hazards from storage of large quantities of such detectors also must be evaluated. These evaluations are done in compliance with the requirements of 10 CFR 32.26 and 32.27.

Equivalent Federal regulations do not exist which require similar evaluation for smoke detectors using NARM and comparable evaluations have not been made for all currently available smoke detectors containing NARM. Guidelines for the States for such evaluations are being prepared by the Conference of Radiation Control Program Directors (CRCPD) and the Suggested State Regulations are to be revised to conform with the guidelines.

As another example, the application of byproduct material to timepieces (as the activating agent for self-luminosity) for distribution to persons exempt from licensing requires a specific license from NRC or an Agreement State and compliance with certain requirements for manufacturing and quality control.* Further, NRC (i.e., Federal) authorization is needed to distribute such devices to persons exempt from licensing.** An NRC license is required to import such devices.+ There are no requirements for a Federal license to distribute timepieces containing radium nor is a Federal license required to import timepieces containing radium. Of five companies reported to have received radium luminous compounds in 1976, one is located in an Agreement State, three are in States which conduct radium licensing programs and one is located in a State with no licensing program. Product and quality control standards equivalent to

*10 CFR 30.15 and 32.14.
**10 CFR 150.15 (a) (6).
+10 CFR 36.31

those of the NRC have not been uniformly applied to these companies. Although the States can control distribution within their borders, the States cannot control distribution of radium in interstate commerce or importation of radium into the U.S.

Health and safety problems associated with radium users have been significant. As an example, a Wisconsin study of 39 medical radium facilities found radiation levels in uncontrolled areas up to 100 mR per hour.[17] In 4 facilities, workers in unrestricted areas may have received more than 500 mrem in a year.[17]

Initial surveys of medical users in 8 States* disclosed between 13% to 53% of the facilities surveyed possessed sources which were leaking or were contaminated.[18] The relatively high percentages of medical facilities initially found to have leaking or contaminated sources (13% to 53%) is a significant finding. FDA pointed out that these sources are used for superficial and intracavitary treatment. The inadvisability of using leaking sources is obvious. The threat of contamination of the medical facility is equally unacceptable.[18]

Leak-test requirements imposed by Agreement States and many other States can serve to alleviate this problem by assuring timely identification of leaking sources. Nonetheless, leaking radium sources continue to be a problem. Data reported by Agreement State licensees to the Agreement States for the 18 month period, January 1, 1975 to June 30, 1976 disclosed that of 23 reports of leaking sources, 9 (39%) involved radium and five of these were medical sources.[19] The ages of the 9 leaking sources were unknown in 6 cases and ranged from 10 to over 21 years for 3 cases.**

Older sealed radium sources present special safety problems. Some were fitted only with friction plugs without threads.[14] Inadequate drying of the radium salts prior to encapsulation leads to residual water which is disassociated into oxygen and hydrogen gases by the radiation. The

*Alabama, Georgia, Indiana, Kansas, Kentucky, Minnesota, New York and Pennsylvania.

**A search was made of NRC records, available on computer, for comparable data. The results of the data search were inconclusive - the computer program has not been structured to permit outputting of data in a form suitable for the purpose of using it as a comparison base for this study.

resultant pressures can reach several hundred atmospheres and lead to rupture, especially in a friction fitted capsule.[14] New medical radium sources use improved sealing techniques and are reportedly doubly encapsulated. However, there are singly encapsulated sources with threaded ends which are soldered that are still in possession of medical users. An early FDA report stated that examinations of over 970 sources containing 45.4 Ci of radium disposed through the joint EPA-BRH radium disposal project (many of which were disposed of because they were discovered to be leaking) disclosed corrosion and failure of encapsulation threads and brazed areas.[18]

As noted earlier, there is no national regulatory program which requires present radium source and device manufacturers to comply with fabrication, testing and quality control standards, that is, a pre-market clearance program. Few of the radium sources in use today in medicine have been subjected to the same kind of an evaluation by a regulatory agency to assure adequate design and integrity as are made by NRC and the Agreement States of sealed sources containing byproduct, source or special nuclear materials.[5,20,21]

Accelerator-Produced Radioisotopes

The availability and use of accelerator-produced radioisotopes has increased rapidly in recent years. Particularly rapid growth in the use of accelerator-produced radionuclides has taken place in medicine for purposes of tumor localization, organ scanning or imaging, tomography, cisternography, and heart shunt detection (Table 5).

James Blackburn, from Illinois, a non-Agreement State which licenses NARM, provided the following observations to the Task Force on the proliferation of ^{57}Co sources:

> "With the increased use of production accelerators, large numbers of Cobalt 57 sources have entered the market place. These sources include a multitude of items including marker sources, radioactive rulers, flexible markers, flexible rulers, orientation indicators, etc., all designed to assist the physician to outline the organ of interest, mark the anatomical landmarks, provide a scale for organ size

*This project accumulated 2,350 sources during the period 1974-76, most of which were medical sources. Total radium in storage, as of April, 1977, is over 92.5 grams.

> determination and provide orientation of images on the film. Although these sources are relatively low in activity, (less than 1 mCi) many of them are designed to be taped directly to the patient's skin during the medical procedure. These sources are marketed by a variety of firms using private labeling. A recent search for the manufacturer of a particular source revealed that the source had been labeled and sold by a minimum of 3 different firms. Each time the source was sold it changed regulatory jurisdiction. This entire sequence occurred before any competent regulatory agency had even documented the existence of such a source. Without pre-marketing evaluation and clearance, the entire regulatory program governing the distribution of radioactive sources becomes marginal".

Typically, accelerator-produced radioisotopes are short-lived (months, days or less) and many are so short-lived they must be produced on-site. In such cases, the radiation safety problems associated with accelerators are additional health physics considerations.[22] Such problems can range from activation of accelerator components (i.e. production of NARM) to prevention of inadvertent, potentially lethal exposures to radiation during operation.

The matter of accelerator radiation safety, other than that associated with NARM production, is outside the scope of this study. Nonetheless, the question arises that if the regulatory control of the production of accelerator produced radioisotopes is incomplete, is the regulatory control over other radiation safety aspects of accelerators adequate? At a recent public meeting on the regulation of nuclear medicine by NRC, a distributor of sources for teletherapy units made the following observation concerning one possible consequence of the differences in the regulation of accelerators compared to ^{60}Co teletherapy units:

> "It is our observation, and I believe you will find it widely shared, that our society has become so highly regulated that regulatory considerations have come to play an important part in decisionmaking.
>
> "Particularly, in matters where the decision is for a choice among near equals, in the field of radiation therapy. There is little, if any, known clinical differences between the use of photons emitted by cobalt-60, and the use of photons produced by four MeV and six MeV electron accelerators.

"To some extent the outcome of competition between these two techniques is already influenced by differences in regulatory status deriving not from any substantive differences in hazard to either user or patient, but rather from the fact that photons emitted by cobalt-60 sources fall within the scope of the Atomic Energy Act, and photons produced by electron accelerators do not.

"We do not want to overstate this position, and without doubt, there are other more consequential nonclinical factors that affect the competition between these two systems that are outside the scope of this hearing.

"Nevertheless, at current levels of NRC regulatory involvement, there exist delays, inconveniences and disadvantages that are substantive.

"Furthermore, we believe that increased regulatory involvement for cobalt users that are not applied simultaneously and equally to accelerator users, would simply induce many responsible users to abandon cobalt therapy in favor of a clinically equal, less regulated alternative.

"I would like to analyze for you this thesis in the context of the considerations outlined in the notice of this hearing.

"The physician in exercising his right and his duty to apply his best professional judgment in the practice of medicine would be compelled to choose the least regulated alternative, if for no other reason than to have more time available to devote to the patient-oriented demands of his practice.

"In the absence of a major change in regulatory technique, we doubt very much that on balance, patients would receive more competent medical care and protection against exposure, as a result of increased regulatory involvement.

"More skilled and responsible practitioners who demonstrate satisfactory performance will either have their productive effort reduced by the time demands of additional regulation or will convert their practice to a less regulated mode.

"We seriously question that the restriction of choice that would result will be balanced by whatever improvements are made in the practice of those that would still come under the increased regulatory involvement.

"The NRC responsibility to regulate so as to protect the public health and safety would be compromised in two ways.

"In these times of soaring hospital costs, the use of cobalt-60 therapy, the less expensive of two substantially equal alternatives, would be discouraged.

"And as previously noted, we believe that any further imbalance in the relative degree of regulation of alternative techniques would result in a flight from the more highly-regulated to the less-regulated method.

"With regard to the possible involvement of other regulatory bodies or peer groups, it appears to us that any regulatory program that is to command respect should provide equal or at least comparable regulation of different methods involving comparable hazards.

"If, by law, the NRC is able only to regulate one of two competing alternatives, then we think its responsibilities to the patients and to the public would best be met if it cooperated with those agencies that have broader authority in the field of use, so that competing alternatives receive more or less uniform regulation.

"I think that what is required for cooperation is really not something that needs legislation.

"We think that the various agencies who are involved in the regulation of the medical practice have the authority to achieve uniformity promptly, if they have the will and the administrative ability.

"In any event, we believe that the dichotomy of the regulations, two available alternatives for producing and using one to two MeV photons can be and should be properly resolved and until such regulation is effected, any increase in the regulation of one alternative would be counterproductive."23

States which have followed the format of the Suggested State Regulations for Control of Radiation have specific regulatory requirements for accelerators.[24] In FY 1975, 14 percent of the accelerators reported by the States were inspected by the States.[15] Such data, however, does not reflect accelerators at Federal facilities and does not adjust for possible differences in the depth and qualities of the regulatory efforts. FDA is expected to develop performance standards and guidelines concerning medical applications of accelerators.

Scope of NARM Use

Some perspective for the scope of the use of NARM was gained in a study on "Non-SNM/Source Material" shipments.[25] The information was obtained from questionnaires completed by 1,334 NRC and Agreement State licensees and ERDA contractors in 1975. The total number of packages of these materials shipped in 1975 approached 1.1 million. Of these, about 14% were NARM shipments. About 25% of the different radionuclides involved were NARM. However, NARM constituted only 0.06% of the total curies shipped.

About two/thirds of the NARM shipments were made by five suppliers including one who conducts operations at seven locations in six States. For these five suppliers, NARM shipments constituted about 20% of their shipments. About 16% of the NARM was intended for research purposes and 84% was intended for medical purposes. The other sources of NARM are university cyclotrons and imports, mainly from Holland and South Africa. It should be pointed out that with respect to radium, a major domestic supplier did not choose to participate in this study and the data does not reflect its activities. It has been estimated that this company originated between 3000 to 4000 shipments involving radium (all forms) and radon in 1976.

The annual sales of fire detectors containing radium was estimated in a 1971 FDA report to be 10,000 per year.[18] However, partial data for 1976 indicated 2 companies manufactured 200,000 units. Complete updated data including imports are not available. In comparison, annual sales of fire detectors containing byproduct material averaged 820,000 per year during the period 1970-75. However, it is interesting that 9 companies currently listed as distributors and manufacturers of radium fire detectors were not included in the 1971 report and apparently are new distributors, again suggesting an expanding market.[5,18]

The FDA report estimated 3 million timepieces containing radium were sold in 1975. It is believed that this volume has decreased significantly since, but no hard data is available.

The annual whole body dose rate in the United States from all sources (natural and artificial) was estimated by the BEIR Committee to be, in 1970, 37,400,000 person-rem per year.[26] Moghissi has estimated the population doses from radium and tritiated luminous timepieces to be 2500 and 3600 person-rem/year respectively, or about 0.01%.[27]

The contribution to the population dose from radium luminous timepieces is small, but the dose to individuals wearing or having contact with them can be considerable.

Average values of radium content in ordinary wrist watches have been reported from 0.014 μCi to 0.36 μCi with a maximum observed value of 4.5 μCi.[28] The following annual radiation doses have been reported as received by critical organs from a wrist watch containing 0.15 μCi of ^{226}Ra:[18]

Organ	Estimated Annual Dose (mRem)
Skin of the Wrist	4,800
Lens of the Eye	110
Blood-Forming Tissue	30
Gonads	10

For comparisons, natural background in the U.S. contributes an average dose to the gonads of 80 to 100 mrem per year and the mean average bone marrow dose to adults from diagnostic radiology in the U.S. in 1970 is estimated to have been 103 mrad.[29]

The results of a survey by Oak Ridge National Laboratory of luminescent clocks in 48 Tennessee households suggested that 1 out of every 3 households has a clock which emits penetrating radiation (i.e., gamma rays from radium) and that these clocks are responsible for a 10 percent increase in the gamma ray background to 5 percent of the population.[30]

These data do not suggest a clear answer to the question of whether a need exists for a Federal regulatory program to control the distribution of radium luminous timepieces. In 1975, it was reported that there are nearly three times as many tritium luminous timepieces as there are radium luminous timepieces.[27] They contribute only slightly more to the population dose than radium timepieces.[27] Nonetheless, the

distribution (including import) of tritium luminous watches is controlled by the Federal government (through licensing by NRC) and the distribution of radium luminous timepieces is not.

As noted earlier, at least 36 companies are listed as U.S. manufacturers or distributors of radium sources and devices which are considered to be subject to State licensing or registration.[5,24] An additional 21 companies are engaged in the manufacture and distribution of consumer items containing radium.[5]

The FDA report indicated that licensable radium users possessed 330 Ci contained in 50,000 to 55,000 sources used in medicine at 2,300 facilities.[18] These facilities provided 85,000 medical treatments annually. Non-medical applications accounted for 150 Ci at 1,900 facilities.[18*]

There are about 19,000 NRC and Agreement State licenses authorizing possession and use of byproduct, source, and special nuclear material.[19] Data from Agreement States suggest persons who only use NARM constitute another 5% or 1000 licensable users.[31] The total of licensable users of byproduct, source, special nuclear, and NARM is then about 20,000. There are about 3,600 persons reported by FDA to possess or use radium who are licensed or would be subject to State licensing requirements similar to those applied to byproduct, source and special nuclear material users.[15,24] Radium users, therefore, constitute about 18% of users subject to licensing, a significant portion.** As previously shown, the health and safety problems with these users have been significant.

*The total, 4,200 facilities appears to be at variance with the previous cited figure of 3,600. However, the 3,600 represents persons identified by States in an annual survey (1975) as subject to State regulation. The 4,200 is the total identified in a special survey of the States conducted in 1969.

**The actual number of radium users may be somewhat higher since the FDA data is restricted to persons subject to State regulation. The use by Federal agencies is not included. See pp. 33-34.

About 25% of Agreement State licenses authorize NARM in addition to byproduct, source and special nuclear materials.* Another 5% are for NARM only.[31] Thus, of the approximately 20,000 persons who are or could be subject to license requirements in the U.S., an estimated 30% use NARM.

Some additional insight on the scope of NARM use, and the problems associated with its use, was provided to the Task Force by David Lacker, Administrator of the Texas Radiation Control Program:

> "Radium has been a regulated material in Texas since March 1, 1963. I have reviewed our incident/accident files since March 1, 1970 and in that period we have had a total of 56 reported incidents involving radium sources or contamination. Almost half of these incidents involved the loss of radium sources by licensees. (25 reported lost sources.) Of these in only eleven instances were the sources found or returned to the licensee. In 5 /cases/ medical sources were presumed to have been buried in sanitary land fills at a depth which prevented location. The fate of the others is still unknown.
>
> "We have had seventeen reported leaking radium sources with eleven of these revealing contamination of storage areas and in two cases, office areas.
>
> "There were three radium sources found in different locations beside one highway ranging from 10 to 40 millicuries for which no owners have been located.
>
> "In performing environmental sampling in the last eight months, we have located three areas with significant radium contamination. The source of this contamination is now under investigation but it is possible that it came from oil field pipe cleaning operations.
>
> "We have one case reported and investigated relating to an individual who purchased a watch repairman's tools and supplies which contained a dial paint repair kit. He used the radium paint in his home to make costume jewelry which glowed in the dark. Fortunately for that individual, he only made one application of the radium before learning that it could be dangerous and called us. There was minimal contamination in his home.

*This figure was furnished to the Task Force by the Office of State Programs, NRC. For certain types of licenses, the percentage of NARM use is much higher, for example, most of the medical licensees who perform imaging studies possess ^{57}Co "flood" sources.

"These incidents represent to me a serious potential hazard since they occurred in a regulating State. What happens in those areas of the country where there are essentially no regulations requiring the usual radiation safety precautions?

"We have also been made aware of four incidents in non-Agreement States where ^{57}Cobalt sources used in x-ray fluorescent analyzer's were ruptured and contamination resulted. Although there was no regulatory requirement for reporting, the supplier learned of these when new sources were ordered and the contamination was properly cleaned up and the sources disposed of as radioactive waste.

"It seems to me that we must recognize that NARM, particularly radium, in the non-regulatory States probably is in much wider use than in States with regulatory programs. The reporting of incidents such as the areas I have cited is not required therefore we must assume that the potential for serious injury is greater in that contamination and other exposure could go on for extended periods of time".

One consequence of the lack of a national, uniformly applied control program for NARM is that information on its use and on the problems associated with its use is fragmentary. However, the information that is available - especially from States actively engaged in the regulation of NARM - definitely indicate that the use of NARM, both in articles subject to licensing and in consumer products, constitutes a significant part of radioactive materials usage in the United States, in terms of numbers of users, numbers of consumer product articles, and the potential for radiation exposure of users and other persons in contact with NARM sources.

Other Issues

Currently operating commercial low-level radwaste burial sites accept NARM for disposal. The need to continue to provide for disposal of NARM wastes at these sites must be considered in the development of a national policy for low-level waste disposal. The Resource Conservation and Recovery Act of 1976 (P.L. 94-580) which deals with solid waste disposal only excludes source, byproduct and special nuclear materials but NARM is included.

EPA, in cooperation with FDA, operates a radium disposal facility at the Eastern Environmental Radiation Facility in Alabama. Its current capability is limited by a lack of adequate numbers of shipping containers. States have reported waiting for up to six months for an opportunity to dispose of radium. For persons and States disposing radium, however, this endeavor provides a simple and inexpensive means of removing surplus radium sources from the public sector.

"Excess sites" (former AEC licensed or ERDA facilities released for unrestricted use) are currently being reexamined by ERDA and NRC in cooperation with the States to reevaluate any potential health and safety hazards that may result from residual radioactivity at these sites. Some of these sites contain NARM such as the former Vitro facility in Cannonsburg, Pennsylvania.

There is evidence indicating that there are many radium sources currently in the possession of members of the public which are not known to regulatory authorities and would be subject to licensing. They range from radium activated luminous devices to medical sources possessed by widows of physicians. Several of the latter have been discovered in bank safe deposit vaults. In the past, these sources have been located by State regulatory agencies through publicity efforts, contacts with State and local medical and other professional societies, personal contacts and, when available, review of old sales and transfer records of radium manufacturers and distributors.

INCIDENTS INVOLVING NARM

For purposes of discussion, incidents are considered to be unplanned events usually involving the loss or theft of sources, contamination, or overexposures.

FDA/Bureau of Radiological Health Data

The Bureau of Radiological Health has reported data on radium incidents which occurred from 1966 to 1969. (Table 6). Although this is the best source of information available, it should be noted that the information was obtained through voluntary participation of State radiological health

programs. In turn, the information submitted by each of the State programs is influenced, in large part, by the quality of the program and the intensity of their effort to learn of, and investigate, incidents involving NARM. An annual average of 29 radium incidents was reported. The majority of these involved loss of material. Because of the uncertainties in these data, it is believed that the extent of the problem may be significantly underestimated.

U.S. Department of Transportation Data

The U.S. Department of Transportation (DOT) is currently preparing a report on radioactive material incidents. Preliminary information collected for this report indicates that, of 32,000 reports of incidents during the period 1971 to 1975 which involved the transportation of hazardous materials, 144 (0.45%) included or involved radioactive material. Of these, less than one half were classified by DOT as having a potential for release of contents. Most of these cases involved packages containing radiopharmaceuticals which had been run over by vehicles and actual release of the radioactive materials was not verified in all cases. Although data is not readily available, few of these cases are believed to have involved NARM.

The actual hazard to the public resulting from the transportation of radioactive materials is considered by DOT to be small, especially relative to the hazards resulting from transportation of other hazardous materials.[32] According to DOT, most of their concern was over companies which lease radium to physicians on a short-term (case rental) basis.* According to DOT information, these companies are involved in about 8,000 to 10,000 shipments per year. DOT stated that they received only one report per year regarding lost radium needles or radium contamination.**

*In March, 1977, one of these companies ceased its case rental of radium brachytherapy sources. Two companies are known to remain, a large one located in New York City and a much smaller concern located in California.

**Most radium transportation incidents are handled by State authorities without DOT assistance.

Interagency Radiological Assistance Plan

ERDA serves as contact for the Interagency Radiological Assistance Plan (IRAP). Although the IRAP team identifies levels and hazards, they do not always identify the radioactive material involved in their team reports.

Consumer Products Safety Commission

The Consumer Products Safety Commission indicated they have no information regarding NARM incidents.

EPA

The Environmental Protection Agency indicated that they have no specific information on NARM incidents.

U.S. Department of Defense

The United States Air Force, Army and Navy were contacted. No information on NARM incidents was available.

NRC-State Agreements Program

The State Agreements Program of NRC receives reports of incidents from Agreement States. Reports for the years 1974 and 1975 were reviewed (Table 7). The data appears to be consistent with the numbers and types of incidents reported by the Bureau of Radiological Health for the late 1960's (Table 6).

Non-Agreement States

Information on incidents involving NARM in non-Agreement States is only available from the Bureau of Radiological Health program described above. There are no national information collecting centers or inventories to which information on NARM incidents is required to be reported.

Summary - NARM Incidents

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.

AGREEMENT AND NON-AGREEMENT STATE PROGRAMS AND RESOURCES COMMITTED TO THE REGULATION OF NARM

Agreement State Programs

Agreement States currently are responsible for 10,800 licenses.[19] Of these, about 5% or about 540 are NARM only licenses.[31] However, about 25% of Agreement State licenses authorize both Agreement material and NARM.* The Agreement States do not normally differentiate between the two in their regulatory activities.**

As a result, it is difficult to establish a dollar value for administering the portion of a regulatory program for NARM. Estimates of costs can be made, however. The expenditures for regulatory programs for NARM were requested by the Task Force from individual Agreement States and were reported to be from $650 per year to $12,000. These estimates do not include the costs to States responsible for regulation of uranium and phosphate mining and milling industries. Some estimates for the costs for the regulation of uranium and phosphate industries were $30,000 annually on compliance and surveillance activities for the regulation of uranium mining and milling operations in one State and $218,000 was allocated in one year for a special study of the NARM hazards associated with the phosphate mining industry in another State. It is not possible to estimate the annual costs for regulating the phosphate mining industry until studies of its impact have been completed, the results analyzed, and the needs for regulation established.

It is apparent that, for Agreement States, the costs of including a regulatory program for NARM (excluding mills and mill tailings and phosphate mining industry) are relatively small compared to the cost of establishing a regulatory program for Agreement materials. As an example, a large Agreement State spent approximately $42,000 in FY 1976 on all NARM activities. This represented 13.5% of their total radioactive material control expenditures for FY 1976 and 7.5% of their total radiation control budget. For a small State program, the added cost for NARM

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*See Footnote, P. 20.

**An exception to this exists in three Agreement States which apply OSHA standards and enforcement practices to non-Agreement material licensees.

control is also relatively small, in one case, 4.5% of their radioactive material budget was for NARM.

The Agreement States reported that the major problems encountered in regulating NARM relate to the lack of nationally uniform regulations and the failure by States to evaluate NARM sources, for example, by utilizing available draft guidelines on NARM which would provide quality assurance for sources and devices manufactured in any State in the United States and for imported sources and devices.

The States could refuse to issue a license to an applicant proposing to use unevaluated sources. In general, they have not done so because such action taken by an individual State would not be effective in limiting their use and such action could be construed as discriminatory, especially in the practice of medicine. As it now stands, the States can impose and inspect quality control programs only over those sources and devices which are manufactured within their jurisdiction. Items which are manufactured in States where such a program is not carried out, or which are imported, are generally of unknown quality although some exceptions exist where the Bureau of Radiological Health (FDA), as a result of a request, has evaluated the device or source and distributed an evaluation report. Not all of these evaluations, however, are subject to inspections to confirm manufacturing practices because not all States have a viable regulatory program for NARM. The Bureau of Radiological Health only participates when requested by a State and only in States which have authority to perform such inspections.

A significant regulatory problem relates to the fact that radium sources have been distributed in the United States since the beginning of this century without effective regulatory controls over their manufacture, distribution or use. States having aggressive regulatory programs for NARM have been successful in locating and regulating many of these sources which are subject to their jurisdiction. These States found a significant number of these radium sources to be leaking.[18] In some cases, resulting contamination presented hazards to public health and safety and

decontamination was required. It has been the experience of Agreement States that when radium is regulated in the same manner as other radioactive materials, some radium users will switch to byproduct materials or relinquish possession of the sources.

The uranium industry presents another problem since their tailings contain concentrated levels of naturally occurring materials, principally radium and its daughters, which must be adequately controlled. In the absence of direct Federal control of NARM as licensed material, after milling licensesare terminated the States have been forced to develop their own procedures for controlling hazards from inactive tailings. Regulatory requirements and practices of the States for controlling inactive tailings have not been uniform. At the present time, Agreement State control of active uranium mill tailings is confined to 4 States. As a result of the passage of the Resource Conservation and Recovery Act of 1976, EPA will draft regulations concerning management of such tailings. With rising prices for uranium and development of new technologies for extracting uranium from lower grade ores, including uranium as a byproduct from phosphate minerals, involvement of additional Agreement States is likely. Commercial contracts have been announced for the extraction of uranium from phosphates in two Agreement States.[33] Such extraction should now be considered a part of the nuclear fuel cycle.

Notwithstanding the utilization of phosphates as a source of uranium, the radiological impact of the phosphate mining and milling industry* has not been fully assessed at this writing but it is under study. It is clear that the phosphate industry could impact upon the environment in a manner similar to that of the older and traditional uranium industry and could require additional regulatory attention.

*Nearly all present domestic phosphate mining occurs in Florida, North Carolina, Tennessee, Idaho and Montana. All of these States except Montana are Agreement States.

In summary, the Agreement States' programs for NARM are integrated with the regulatory program for Agreement materials. The problems that do exist are related to the fact that NARM is not uniformly regulated in all States and is not adequately regulated at the Federal level. As a result, there does not exist a full reciprocal exchange of information and control over manufacture, distribution, use, and import of NARM. It is the Agreement States' position that all radioactive materials present potential public and occupational health and safety hazards and they believe that, in the absence of uniform State control, Federal regulation is needed (Appendices A and B). This would insure adequate protection to all citizens from unnecessary exposure to radioactive material without regard to its source or origin.

Non-Agreement State Programs

The Task Force requested information from the 28 non-Agreement States programs (25 States and 3 territories) on their programs for controlling NARM. Thirteen of these agencies responded (Table 8). The regulatory efforts of these 13 States can be categorized as follows:

1. States with Licensing Programs - Four non-Agreement States indicated that they are presently licensing the use of NARM using regulations they stated are "compatible" with the Council of State Government's Suggested State regulations. (No attempt was made by the Task Force to assess the degree of compatibility). The estimated budgets for NARM ranged from $60 to $646 per license with a weighted mean of $302 per license. /In comparison, in FY 1976, Agreement State expenditures for all licensed materials ranged from $158 to $418 per license and the weighted mean was $273 per license.[31] The NRC's recommended guideline is $200 to $350 per license/.[34]

2. States With Legislation Authorizing Regulatory Programs But No License Program - Five States indicated that, although appropriate legislation has been passed, they do not, at this time, extend more than minimum amounts of effort on NARM control. Each of these States identified "insufficient

funds" as the restraint which kept them from engaging in this activity. One of these States has promulgated regulations which provide for licensing but has not implemented the regulations because of a lack of financial resources.

3. States With No Legislation, No Regulations or No Programs - Four of the States who responded indicated that they have not received legislative authority to enable them to implement a radiation control program for NARM.

Information available from other sources indicates that of the 24 non-Agreement States and territories not licensing NARM, 17 conduct registration programs (i.e., require persons possessing NARM to register with the State) and 7 have neither a licensing nor registration program.[15*]

REGULATORY FUNCTIONS OF FEDERAL AGENCIES

Department of Health, Education & Welfare

The Department of Health, Education and Welfare (HEW) is involved in both regulatory and indirect control programs. Within HEW's Food and Drug Administration (FDA), the Bureau of Drugs approves New Drug Applications for radiopharmaceuticals and applications for use of investigative new drugs. Without such approval, manufacturers cannot commercially distribute radiopharmaceuticals or release them for investigative use. The Bureau of Foods has the authority to set tolerances on the presence of radioactive material in foods and requires premarketing clearance of radiation sources used in food processing. The Bureau of Medical Devices and Diagnostic Products has purview over medical devices and *in vitro* diagnostic products which utilize radioactive material. The Bureau of Biologics currently licenses hepatitis associated antigens, whereas all other radiobiologicals used as diagnostic agents are under the authority of the Bureau of Drugs.

The Bureau of Medical Devices and Diagnostic Products, through recent legislative action (Pub. L. 94-295, 90 Stat. 539-583) has the authority to classify an item as requiring premarketing clearance based on performance

*The seven States are Alaska, Delaware, Iowa, Rhode Island, Utah, Vermont and Wyoming.

review, as subject to specified standards of safety and performance, or as exempt from standards or preclearance. The Bureau has stated it has not established any requirements under the act for devices of the kind covered by the State radiation program requirements that have been developed under the Atomic Energy Act, and accordingly, State requirements are not preempted at this time.[35] This position, however, is not entirely clear with respect to medical devices using NARM (principally ^{226}Ra, ^{222}Rn and ^{57}Co) in non-Agreement States where no formal mechanism exists to certify the adequacy of State radiation program requirements.

The FDA's Bureau of Radiological Health (BRH) issues guidelines on the safe use and disposal of radioactive products, participates in the development of standards, and acts jointly with the NRC and the Council of State Governments to produce model regulations in the form of Suggested State Regulations for the Control of Radiation. In addition, as noted earlier, this Bureau conducts a voluntary, cooperative program with the States to evaluate the safety of products containing NARM sources according to guidelines paralleling those utilized by the NRC for evaluating sources containing byproduct material. Recently, a joint BRH-EPA-NRC-State Task Force developed regulatory guides for NARM. Unused and defective radium sources are collected for disposal through a joint program of the Bureau and the Environmental Protection Agency (EPA).

Other agencies of HEW which can have an impact on the use of radioactive material are the Social Security Administration (SSA) and the Center for Disease Control (CDC). The Bureau of Health Insurance of the SSA approves payment under Medicare and Medicaid programs to about four hundred private certified laboratories for diagnostic procedures which include radioactive bioassays. Certification is provided by the CDC, or its State contractors, based on standards for qualifications of personnel, and evaluation of proficiency testing and quality control programs. The Bureau of Quality Assurance of the SSA sets standards for Radiology and Nuclear Medicine facilities as minimum criteria for eligibility to participate in the Federal Health Care for the Aged (Medicare) program.

The National Institutes of Health (NIH) support research and develop health care guidelines which may recommend continuance or cessation of use of specific radionuclide procedures. The National Institute of Occupational Safety and Health (NIOSH) has a program for testing and certification of devices and equipment used in industry and makes recommendations to the Occupational Safety and Health Administration (OSHA) of the Department of Labor and to other Federal agencies. NIOSH also develops criteria for substances used in the work-place as guidelines for future regulations.

Consumer Products Safety Commission

The Consumer Products Safety Commission (CPSC) has regulatory authority to require appropriate brands and labeling of articles containing radioactive substances if determined to be sufficiently hazardous to warrant control. Their jurisdiction is limited to products introduced or delivered for introduction into interstate commerce. The CPSC is excluded from regulating materials regulated by the NRC. CPSC has not, to date, determined that any NARM article is sufficiently hazardous to warrant control. The CPSC has decided not to take action pertaining to radioactive materials in consumer products generically although it may still regulate radioactive materials on a case-by-case basis.[2]

Environmental Protection Agency

Under authorities from the Public Health Service Act, and the Atomic Energy Act, transferred to the Agency, EPA can 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; establish generally applicable environmental standards for the protection of the general environment from radioactive material; and conduct research and provide technical assistance to States.

The Federal Water Pollution Control Act, as amended, authorizes EPA to establish National Effluent Limitations Guides for various industries to control discharge of pollutants including NARM. The Act also authorizes

the Agency to issue discharge permits for facilities limiting pollutant releases including NARM. The Agency must also develop water quality criteria. The Clean Air Act authorizes EPA to establish national emission standards for hazardous air pollutants.

The Ocean Dumping Act prohibits the dumping of high-level radioactive waste in the ocean. A permit is required from the Agency in order to dump other radioactive materials including NARM in the ocean.

The Safe Drinking Water Act requires EPA to establish regulations for the maximum contaminant levels of radioactivity allowed in public drinking water supplies. Enforcement of these regulations is by the States, or EPA should a State fail to act.

The Resource Conservation and Recovery Act of 1976 (P.L. 94-580) requires the Administrator to identify hazardous wastes and establish standards and a permit system for generators, transporters, users, storage, and disposal of hazardous waste. The Toxic Substances Control Act allows the Administrator to prescribe requirements on the manufacturing, processing, distribution, use, or disposal of chemical substances or mixtures which present an unreasonable risk of injury to health or the environment. EPA will be required to develop regulations under these Acts to control NARM.

EPA operates a radium disposal project at its Eastern Environmental Radiation Facility in cooperation with the Bureau of Radiological Health.

EPA has drafted a proposed bill to enable EPA to directly regulate naturally occurring radioactive materials. NRC, along with other Federal agencies provided comments to the Office of Management and Budget. The bill would apparently coordinate and extend in some circumstances direct EPA regulatory control over radiation hazards occurring *in situ*, e.g. radon in caves, or geographical areas having naturally occurring high external radiation levels. The bill would also coordinate and extend direct EPA control over the use, storage and disposal of naturally occurring radioactive materials, including authority to evaluate and approve products containing these materials. The EPA bill is being redrafted at the present time.

Department of Labor

Within the Department of Labor the Occupational Safety and Health Administration (OSHA) has a program to assure safety during employment in a work-place. OSHA has promulgated standards and set regulations concerning exposure to ionizing radiation.* Persons operating under NRC or Agreement State licenses and in compliance with applicable requirements are deemed to be in compliance with respect to materials subject to NRC regulation or NRC-State Agreements. Policies have been established in cooperation with NRC for handling the regulation of persons using both Agreement and NARM sources.[36] States can receive financial support from OSHA to conduct occupational radiation protection programs on behalf of OSHA relative to x-ray and NARM use.

The jurisdiction of OSHA does not extend to working conditions of employees covered by statutory authority of other Federal agencies who are actively exercising such authority. However, by Executive Order, Federal agencies are required to meet OSHA standards for their own employees. For military personnel, the Department of Defense has a policy of adhering to OSHA standards.

Nuclear Regulatory Commission

The NRC does not regulate accelerator produced radioactive materials nor naturally occurring radioactive material other than thorium and uranium pursuant to 10 CFR 40. NRC does require uranium mill licensees to control NARM in the course of their licensed activities. The NRC exerts influence on the control of NARM through the promulgation of standards and guidelines, participation in the development of model legislation for the States, and licensing and inspection of facilities which utilize NARM in addition to licensed byproduct, source and special nuclear materials. Through its Agreement State program, it has encouraged States to develop regulatory programs for NARM comparable with those for Agreement materials. However, NRC cannot insist upon State action with respect to NARM as a matter of compatability or adequacy of the State program.

Federal agencies, except for ERDA and certain activities of the Department of Defense, are subject to the requirements of the Atomic Energy

*29 CFR 1910.96.

Act and the U.S. Nuclear Regulatory Commission, including requirements for a license. Federal agencies are not subject to State requirements.* Consequently, while NRC approval may be required (i.e. a license) prior to a Federal agency obtaining byproduct, source or special nuclear materials, there are no similar restrictions placed upon Federal agencies when they obtain NARM.

One consequence of this is that there is very little information available on the extent of use of NARM by the Federal government. Government surplus channels were identified in 1964 as an inadequately controlled source of radioactive materials entering the consumer market.[37]

Energy Research and Development Administration

ERDA directly, or through contract, controls about 1/4 of the accelerator facilities in the United States including most of the largest units. Radioactive material is synthesized both as an incidental product of high energy particle research and directly for use in medical and other research programs but is not normally available for commercial purposes. ERDA has responsibility for the safety of personnel and conduct of operations at ERDA and contractor facilities. ERDA and its prime contractors are exempted by statute from NRC licensing except in certain limited instances. Radiation safety control is achieved through contract requirements. ERDA inspects and enforces compliance at its facilities and contractor sites in accordance with OSHA standards under agreement with that agency. ERDA has recently considered asking the States to assist in the regulation of their accelerators.

The agency also actively participates in standards development.

Department of Transportation and U.S. Postal Service

The transport of radioactive material is governed by the regulations of the Department of Transportation (DOT) and the U.S. Postal Service (USPS). DOT encompasses the Federal Highways, Railroad and Aviation Authorities and the Coast Guard, all of whom are responsible for the enforcement of packaging and labeling requirements and the prescribed degree of control

*Some individual Federal facilities have requested State agencies to review their radiation safety programs as a means of obtaining an independent audit. Such action is voluntary, however.

to be exercised by carriers in interstate commerce. The USPS has promulgated regulations on packaging, labeling and maximum allowable activity. Parcels not meeting these requirements are non-mailable.

Customs Service

The Customs Service of the Department of Treasury may, at the request of other Federal agencies, act to control the import of products containing radioactive materials not in conformity with Federal regulations.

Federal Trade Commission

Intermittent control over the use of radioactive material has been exercized by the Federal Trade Commission (FTC). As an example, the FTC prohibited the interstate advertising of alleged beneficial health effects resulting from intake of air and water containing radon.

National Bureau of Standards

The National Bureau of Standards (NBS), Department of Commerce, provides reference standards for radioactive materials, calibration and evaluation services, and technical expertise in the development of standards.

Department of Interior

The Mining Enforcement and Safety Administrator (MESA) has established radon daughter exposure limits in mine facilities based upon Federal guidelines established for that purpose by EPA.

Other Federal Agencies

The Department of Defense, the Veterans Administration, and the General Services Administration are able, through procurement specifications, to influence the design and quality of major lines of products containing radioactive material. These agencies also set requirements for use and disposal of sources by their facilities. The Army recently reported that procurement of radium activated phosphors is now forbidden.[2]

National Council on Radiation Protection and Measurements

The National Council on Radiation Protection and Measurements (NCRP) is not a Federal agency but has been chartered by Congress to collect, analyze, develop and disseminate information and recommendations about protection against radiation, and radiation measurements, quantities and

units, particularly those concerned with radiation protection. The Council does not have regulatory authority but its recommendations do serve as the basis for nearly all Federal and State regulations on radiation protection and for the evaluation of radiation hazards.

Federal Regulation of NARM-Present Status

Authority to regulate NARM by the Federal government is fragmented among many departments and commissions and agencies each having some limited authority. The jurisdictions of these agencies overlap in some areas and leave gaps in others. Existing authorities have not been uniformly exercised.

The regulatory picture for NARM is one of disarray, especially when compared to the regulation of byproduct, source and special nuclear materials. Users of the latter materials are generally excluded from regulation by Federal agencies other than NRC with respect to radiation safety. However, users of byproduct, source and special nuclear materials who also use NARM can find themselves subject to regulation by additional, and frequently more than one, Federal agencies. The following example serves to illustrate this:

Type of Radioactive Material	Activity	Federal Agency Having Primary Jurisdiction
Byproduct, Source and Special Nuclear Materials	Occupational Exposure.....	NRC
	Effluents to Air and Water.....	NRC
	Distribution of Consumer Products..	NRC
	Solid Waste Disposal.....	NRC
NARM	Occupational Exposure.....	OSHA
	Effluents to Air and Water.....	EPA
	Distribution of Consumer Products..	CPSC
	Solid Waste Disposal.....	EPA

Excluding fissile materials, these divisions of regulatory authority do not seem to be related to any system of differentiation based upon the hazards from NARM and from NRC licensed materials.

NRC (AEC) LEGISLATIVE HISTORY AS TO WHY NRC DOES NOT NOW REGULATE NARM

The reasons why NRC does not regulate naturally occurring and accelerator-produced radioactive materials today may be traced back to the origins of the NRC's predecessor agency, the United States Atomic Energy Commission. In enacting the Atomic Energy Act of 1946 and establishing the U.S. Atomic Energy Commission as the government agency solely responsible for the production and the use of fissionable material, Congress responded to the urgent and serious public concerns for the peace and security of the Nation which followed the development and military use of the atomic bomb. These concerns recognized the necessity and the importance of subjecting all aspects of the nuclear fission process to tight control. At the same time, Congress was equally concerned that this control, which included exclusive government ownership of fissionable material, not become all-pervasive and that basic freedoms not be threatened.* In an effort to reconcile these conflicting concerns, the provisions of the Atomic Energy Act of 1946 were kept sharply and narrowly focused on fissionable materials, on source materials from which fissionable materials could be obtained, and on radioactive material yielded in or made radioactive by exposure to the fission process.

Naturally occurring radioactive materials (other than source materials), such as radium, which could not be used in the nuclear fission process were deliberately left outside the reach of the Act. Also excluded were the materials which were fissionable but in which a self-sustaining nuclear reaction could not be maintained. In contrast to the overwhelming peril of the atomic bomb, any health and safety problems which these materials might cause were considered manageable and relatively insignificant. Given

*See Senate debate on bill which became the Atomic Energy Act of 1946, June 1, 1946, Congressional Record, pp. 6082, 6086, and explanation of bill by Senator McMahon, Congressional Record June 1, 1946, pp. 6094-6098. See also House debate, July 17, 1946, Congressional Record, pp. 9268-9269.

the state of the art -- at that time comparatively few uses of radioactive materials had been developed and supplies of radioactive materials were limited (the available radium had been distributed and seldom moved in interstate commerce and significant quantities of man-made radioactive materials were not as yet available) -- there appeared to be no urgent need and, from the standpoint of the common defense and security, no basis for federal regulation of these materials.

Section 5 of the Atomic Energy Act of 1946 provided for the control of fissionable, source and byproduct materials. Byproduct material was defined in subsection 5(c)(1) as:

> "...any radioactive material (except fissionable material) yielded in or made radioactive by exposure to the radiation incident to the processes of producing or utilizing fissionable materials."*

Subsection 5 (c)(2) authorized the Commission to distribute byproduct materials with or without charge:

> "...to applicants seeking such materials for research or development activity, medical therapy, industrial uses, or such other useful applications as may be developed. In distributing such materials, the Commission shall give preference to applicants proposing to use such materials in the conduct of research and development activity or medical therapy. The Commission shall not distribute any byproduct materials to any applicant, and shall recall any distributed material from any applicant, who is not equipped to observe or who fails to observe such safety standards to protect health as may be established by the Commission or who uses such materials in violation of law or regulation of the Commission or in a manner other than as disclosed in the application therefor."

*Section 5 (a)(1) of the 1946 Act defined "fissionable material" as "plutonium, uranium enriched in the isotope 235, any other material which the Commission determines to be capable of releasing substantial quantities of energy through nuclear chain reaction of the material, or any material artificially enriched by any of the foregoing; but does not include source materials, as defined in section 5 (b)(1)."
Section 5 (b)(1) defined "source material" as "uranium, thorium, or any other material which is determined by the Commission, with the approval of the President, to be peculiarly essential to the production of fissionable materials; but includes ores only if they contain one or more of the foregoing materials in such concentration as the Commission may by regulation determine from time to time."

Section 12 (a)(2) gave the Commission broad authority to:

> "...establish by regulation or order such standards and instructions to govern the possession and use of fissionable and byproduct materials as the Commission may deem necessary or desirable to protect health or to minimize danger from explosions and other hazards to life and property;..."

Although the 1946 Act authorized the Commission to regulate byproduct material from the standpoint of radiological health and safety, it did not establish a licensing system. In lieu of licenses, the Commission issued authorizations for radioactive material procurement to persons able to comply with the requisite regulatory requirements applicable to byproduct material. These authorizations were also used by the Commission to allocate byproduct material, then in short supply, in a manner which would best serve the overall purposes of the Act.

By 1954 the advances in nuclear medicine and technology had reached the point where participation by private industry in developing peaceful uses of atomic energy was considered both feasible and necessary. In order to encourage this development and to facilitate the team work between industry and government which Congress regarded as essential to optimum progress towards the goal of peacetime nuclear power, Congress undertook a major revision of the law. The Atomic Energy Act of 1954 was enacted to provide a legal framework within which government and industry could work together effectively. That Act authorized the Atomic Energy Commission (AEC) to license private industry to possess and use, but not to own,* special nuclear material and to own, construct and operate reactors designed to produce and utilize such material. At the same time, the Commission retained its continuing responsibilities for the development and promotion of the industrial and commercial uses of atomic energy.

Except for substituting the term "special nuclear material" for the term "fissionable material",** the Atomic Energy Act of 1954 made little

*In 1964, the Atomic Energy Act of 1954 was further amended to end the requirement for exclusive government ownership of special nuclear material and to permit such material, subject to licensing requirements, to be privately owned. (Pub. L. 88-489, 78 Stat. 602)

**This change extended Commission control to materials essential to the process of nuclear fusion. Prior to this change, the Commission was only authorized to control materials essential to the process of nuclear fission.

substantive change in the definition of byproduct material contained in the 1946 Act.* The Commission's prior authority to distribute byproduct material was modified by the grant of additional authority to issue byproduct material licenses. Section 81 of the 1954 Act authorized the Commission to exempt certain classes of byproduct materials from licensing requirements after first finding that:

> "...the exemption of such classes and quantities of material or such kinds of uses or users will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public."

The Commission's authority to promulgate standards and regulations governing the possession and use of byproduct material was retained and ownership of byproduct materials by private persons continued to be permitted. The 1954 Act made no change in the Commission's regulatory authority over source, byproduct and special nuclear (formerly fissionable) materials.**

On September 23, 1959, a new section was added to the Atomic Energy Act of 1954 which provided for cooperation with the States (Public Law 86-273, 42 U.S.C. 2021). Among other things, the Commission was authorized to enter into agreements with the Governor of any State providing for relinquishing to the State the regulatory authority of the Commission with respect to byproduct and source materials and special nuclear material in quantities not sufficient to form a critical mass. On March 26, 1962, Kentucky became the first "Agreement State". Since then, the Commission has entered into similar agreements with 24 additional States. A list of the Agreement States follows:

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*Section 11e of the Atomic Energy Act of 1954 defines "byproduct material" as "...any radioactive materials (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material."

**Section 161b of the Atomic Energy Act of 1954 authorizes the Commission to "establish by rule, regulation, or order, such standards and instructions to govern the possession and use of special nuclear material, source material, and byproduct material as the Commission may deem necessary or desirable to promote the common defense and security or to protect health or to minimize danger to life or property;..."

State	Became an Agreement State On
Kentucky	March 26, 1962
Mississippi	July 1, 1962
California	September 1, 1962
New York	October 15, 1962
Texas	March 1, 1963
Arkansas	July 1, 1963
Florida	July 1, 1964
North Carolina	August 1, 1964
Kansas	January 1, 1965
Oregon	July 1, 1965
Tennessee	September 1, 1965
New Hampshire	May 16, 1966
Alabama	October 1, 1966
Nebraska	October 1, 1966
Washington	December 31, 1966
Louisiana	May 1, 1967
Arizona	May 15, 1967
Colorado	February 1, 1968
Idaho	October 1, 1968
North Dakota	September 1, 1969
South Carolina	September 15, 1969
Georgia	December 15, 1969
Maryland	January 1, 1971
Nevada	July 1, 1972
New Mexico	May 1, 1974

The provisions of the Atomic Energy Act of 1954 relating to byproduct material remained unchanged until 1974 when Congress amended Section 81 to make clear that persons licensed by Agreement States under Section 274 of the Act stood on the same footing as AEC licensees with respect to the distribution of byproduct material (Public Law 93-377, 88 Stat. 475).

On January 19, 1975, in accordance with the Energy Reorganization Act of 1974, the U.S. Nuclear Regulatory Commission assumed the licensing and related regulatory functions vested in the former U.S. Atomic Energy Commission by the provisions of the Atomic Energy Act of 1954, as amended. These functions included the authority to license and regulate among other things (not NARM), the manufacture, production, transfer, possession, use, import and export of byproduct material.

In summary, in 1946, Congress focused its concern on the overwhelming peril of the atomic bomb and the problems related to control of material associated with the fission process. (The use of accelerators to produce

radioactive materials was relatively insignificant.) NARM was excluded from the Atomic Energy Act and has remained excluded. In the succeeding three decades, a need to regulate NARM in various activities has become recognized. Since the Atomic Energy Act excluded these materials, authority for Federal regulation of these materials has been included in various legislation affecting other Federal agencies. Administration of these authorities has been assigned by Congress to agencies responsible for such things as employee health and safety (OSHA), discharges to streams and solid wastes (EPA), etc.

The exclusion of NARM from the 1946 Act has profoundly influenced the course of legislative action with respect to the Federal control of NARM and has led to two systems for regulating radioactive materials in the United States. The hazards from NARM are not uniquely different from those from NRC regulated materials (except fissile material) and, therefore, there is no health and safety basis for regulating these groups of materials differently.

CONCLUSIONS, RECOMMENDATIONS AND PUBLIC POLICY ISSUES

Conclusions

The NCRP identifies 5 categories of radiation exposure of the public:

1. Medical,
2. Industrial,
3. Production of Nuclear Power (Nuclear Fuel Cycle),
4. Consumer Products,
5. Natural Background.

A sixth category, often identified separately from any of the others is transportation. Current regulatory authorities and gaps for the control of NARM in these categories can be summarized as follows:

(1) Medical Sources (Brachytherapy, tumor localization, organ scanning and imaging, in-vitro tests, markers, etc.) - Some, but not all States regulate the users and the manufacturers of medical NARM sources for purposes of radiation protection. A voluntary, cooperative Federal/State program is in effect for manufacturing and quality control standards. FDA has authority to regulate these sources under the Medical Device Amendments of 1976 (Public Law 94-295, 90 Stat. 539-583), however, implementing regulations with respect to specific devices have not yet been adopted. There is no Federal program requiring pre-market approval of NARM radioactive medical sources or requiring the sources to conform with specified manufacturing and quality control standards. Occupational hazards to employees from the use of NARM medical sources are subject to OSHA regulations.

(2) Industrial Sources (gauging, ionization sources, calibration and check sources) - Some, but not all States regulate the manufacturers and users of industrial NARM sources. Only a voluntary, cooperative Federal/State program exists for establishing nationally applicable manufacturing and

quality control standards. Occupational hazards to employees from the use of NARM industrial sources are subject to OSHA regulations.

(3) Fuel Cycle (Radium and daughters, primarily in association with mining and milling of source material ores) - The Mining Enforcement and Safety Administration and the States exercise control over mining of source materials. NARM encountered in activities which are part of, or in support of, the fuel cycle licensed by NRC and Agreement States (primarily as the contaminant in mill tailings) must be controlled by the licensee. However, NRC does not exercise any control over the NARM as licensed material. Hence, after termination of an NRC license, NRC control over NARM ends. Agreement States do exercise direct control in such cases but their regulation and control of the NARM in inactive tailings piles after termination of an NRC license varies. Under the Solid Waste Act and Toxic Substances Act, EPA will be required to develop regulations to control these materials.

(4) Consumer Products (radioactive luminous timepieces, radon in drinking water and natural gas, ionization smoke detectors, agricultural gypsums, aggregates, building blocks, and wallboard manufactured from phosphates, etc.) - No Federal authority has been exercised to establish limits for permissible NARM radioactivity in manufactured consumer products or to impose standards and conditions for their manufacture and distribution. The Consumer Products Safety Commission has declined to proceed with regulations pertaining to radioactive materials in consumer products, although it may take action on a case-by-case basis. Many, but not all States, license and regulate some manufacturers and distributors of products into which NARM is deliberately introduced or incorporated. States have not uniformly regulated the manufacture of products which may be contaminated by NARM, e.g. phosphate industry byproducts. There is no

existing Federal program for requiring pre-marketing approval for importation of consumer products containing or contaminated with NARM. EPA has established radioactivity standards for drinking waters. The new Toxic Substances Control Act provides the EPA with authority to control manufacture, use, and disposal of toxic substances which may provide effective control over certain consumer products once regulations are developed. EPA is asking Congress for broader authority to regulate in this category.

(5) Background NARM (high terrestial radiation, radon in caves) - Limited authorities exist in Federal agencies to exercise controls over this source.

(6) Transportation - Adequate Federal authority exists through DOT and USPS. Intra-State transportation (excluding air transport and military) is subject to State regulation. NARM is a small part of the radioactive materials transportation picture. Incidents resulting from the transportation of all radioactive materials are not a significant problem.

Radium users alone constitute 18% of all radioactive material users subject to licensing. Health and safety control of these users has been a serious, continuing problem to State regulatory agencies.

Radium sources are frequently found to leak. Most radium sources have not been subjected to a regulatory evaluation equivalent to NRC practices for assessing source integrity design.

Radium and daughters in the tailings of uranium mills constitute a continuing regulatory problem especially since NRC control ends with termination of the NRC license. EPA intends to develop regulations in this area.

The use of accelerator-produced radioisotopes has grown rapidly.

There is no regulatory assurance that all NARM sources, devices and consumer products currently in use, or being distributed today, meet

minimum manufacturing and quality control standards or limits for NARM contamination. States actively engaged in regulating NARM have expressed special concern over the lack of uniformly applied standards governing the manufacture and distribution of NARM devices.

Whether or not radioactive material is subject to adequate regulatory control seems to be not related to the hazards of the radioactive material but, whether or not it is material defined in the Atomic Energy Act, as amended, and therefore subject to licensing and regulation by NRC. There is existing regulatory authority to control NARM under the Consumer Product Safety Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, and the Medical Device Amendments of 1976. However, these authorities have not been exercised uniformly. The situation is confusing, especially to persons who, as a result of handling both NARM and NRC regulated materials find themselves subject to, and required to know and comply with, many different sets of regulations.

One result of the fragmented and non-uniform regulation of NARM is that it is difficult to develop information which can be definitive in describing the extent and kinds of problems experienced in using NARM. However, the available information strongly indicates that workers and the public are being exposed to unnecessary, and possibly excessive, levels of radiation from NARM. In this regard, most of the regulatory experience over NARM comes from the States. The concern of the States has been that the potential problems from inadequate regulation of NARM are sufficiently serious to have resulted in State requests to NRC to fill the regulatory gaps.

Recommendations

There is no apparent justification for continuing the regulation of radioactive material in this confusing and probably wasteful manner. State regulatory efforts should be encouraged to develop in those States having no programs. However, if no State program is put into effect, the Federal government should act to assure that workers and the public in these States are provided the same protection from unnecessary or excessive exposure from NARM as is provided in other States. It is recommended that the existing

NRC-Agreement State regulatory pattern be expanded to fill the gaps in a manner which would be consistent with Section 274 of the Atomic Energy Act, as amended, (Cooperation with States). Such an approach has the advantage of building upon existing pools of regulatory expertise and experience, an efficient solution in terms of utilization of personnel resources which also serves to simplify a presently confusing, fragmented regulatory picture. The licensing approach used by NRC is an effective regulatory tool and should be applied to manufacturers, distributors and users of NARM sources and devices along the same lines currently applied by NRC to byproduct, source and special nuclear materials.

However, when existing State NARM licensing efforts are found to be adequate and compatible with existing Agreement material licensing practices, provisions should be made in Section 274 of the Act to recognize those State programs and NRC authority discontinued in those States. In these cases, NRC review of Agreement State programs currently conducted with respect to byproduct, source, and special nuclear materials should be expanded to include NARM.

With respect to new or improved NRC actions, it is recommended that the Commission seek legislative authority to:

A. License and regulate NARM as follows:*

1. In any activity that is part of, or in support of, the nuclear fuel cycle regulated by NRC.
2. In any activity where: (a) NARM is manufactured (e.g. production of accelerator radioisotopes, the separation of radium and radium daughters, and radon generators); (b) NARM is incorporated into sources or devices subject to licensing; or (c) NARM is used in the same manner as radioactive materials subject to NRC regulation.

*One possible mechanism to accomplish this would be to amend the definition of "Byproduct Material" to include NARM.

3. In any activity where NARM is introduced into products intended for distribution to persons exempt from licensing.*
4. In any activity involving the management of NARM wastes which result from licensed activities.

B. Extend authority under Section 274 of the Atomic Energy Act to relinquish authority to regulate NARM (except control of the distribution of NARM to persons exempt from licensing) to Agreement States and to other States having existing regulatory programs for NARM which are determined to be adequate and to be compatible.

Adequate provision should also be made to encourage proper disposition of unwanted NARM sources. Towards this end, the Federal radium disposal project should be continued and expanded.

The results of the joint NRC-ERDA reexamination of excess sites may dictate a need for Federal support if additional clean-up of these sites is needed. Standards applicable to such sites may need to be developed.

A modest program to publicize the need for removing previously manufactured and distributed radium sources from the public domain is recommended. An effort should also be mounted to review existing records of past sales and transfers of radium to identify recipients of licensable medical and industrial sources who may still possess the sources unknown to regulatory authorities.

Public Policy Issues

It is believed that public reaction to NRC taking the actions recommended would be favorable since the proposed actions would serve to promote the public health and safety.

Conversion by many radium users to other isotopes, particularly in medicine, will probably occur, but this would be consistent with numerous recommendations already issued by Federal, State and medical groups.

*It is intended that this include only activities where the introduction of NARM is deliberate and has as a purpose the utilization of its radioactive properties.

The States look to the NRC as a lead agency in the regulation of nuclear energy and radioactivity and have specifically requested NRC to regulate NARM. The essential public policy question to be addressed is the matter of how much Federal control is needed. Regulatory efforts by Agreement States and certain other States have been adequate in those areas where States have traditionally regulated and have exercised their authority to act. There is no reason to discontinue State authority in these areas.

All radioactive material used in the nuclear fuel cycle, or otherwise utilized for its radioactive properties, in the United States, would be subject to uniform regulatory control to protect the public health and safety.

In licensed activities which are part of, or in support of, the nuclear fuel cycle, NARM would be subject to direct regulation by the NRC as licensed material, including tailings from uranium mill sites. This should enable improved regulatory management of mill tailings and minimize the adverse impact upon the environment and the public health and safety from tailings from active and inactive mills.

All users of NARM, including manufacturers and distributors, would be subject to the same requirements as NRC and Agreement State licensees. This will have positive impact upon the health and safety in 1600 facilities where NARM is used but where the NARM is not subject to licensing. About 1300 of these users are presently licensed by NRC for use of byproduct, source, and special nuclear materials. In many of these cases, the existing radiation safety procedures developed for the NRC licensed program also cover the use of NARM. The impact of complying with additional license requirements for NARM should be minimal for these users.

The remaining 300 users would be newly subject to license requirements (and to fees). Based upon the experiences of many States, the initial contacts with these users will likely disclose many significant hazardous conditions. The impact of the NRC regulatory process upon these users should be positive by causing corrections to be made since these users will be subject to more stringent regulations requiring development of adequate, documented radiation safety programs for using NARM.

The establishment and enforcement of Federal regulatory standards for the design and fabrication of NARM sources should eventually lead to a significant reduction in the numbers of sources which leak and can potentially contaminate persons and property.

All NARM deliberately incorporated into products to utilize, directly or indirectly, its radioactive properties and which is intended for distribution to the public as exempt items, or imported into the U.S., would be subject to the same requirements as are currently applied by NRC. A national pre-marketing approval would, in effect, be required for the distribution of consumer products into which NARM has been deliberately introduced. None is required now.

The extension of NRC control over management of NARM wastes resulting from licensed activities should clarify Federal responsibilities over radioactive wastes by providing a uniform regulatory program for all radioactive wastes generated as a result of licensed activities.

Overall, the impact upon States would be positive. State programs for licensing for NARM would be recognized by the Federal government and Federal authority relinquished. In other States, development of regulatory programs for NARM would be encouraged. State cooperation and participation in development of standards and regulations for NARM would be enhanced. The regulation of abandoned uranium mill tailings by NRC in non-Agreement States will be a positive impact. A slight negative impact will be felt by those States having certain contracts with OSHA in that funding for coverage of NARM users would probably be lost.

NRC's responsibilities in certain areas, e.g. mill tailings management will be clarified. The cost impact upon NRC is difficult to estimate because the number and mix of radium licensees cannot be accurately determined. New annual costs are estimated to be between $150,000 to $300,000. This estimate primarily reflects the costs of administering licensing and compliance programs for new (i.e. NARM only) licenses. Professional staff requirements would increase by at least 4 person-years. However, additional one-time costs will probably be incurred as the result of non-routine tasks such as the need to develop new standards applicable to

"exempt" devices containing NARM, evaluation of sealed sources and devices using NARM, initial licensing and compliance actions, and initial assessments of State NARM regulatory programs.

The recommendations do not cover activities where NARM, or more particularly, naturally occurring radioactive material, is encountered *in-situ*, is incidentally present in mineral industry activities outside of the fuel cycle, or is an incidental contaminant in consumer products (i.e., has not been deliberately introduced or reconcentrated in a product for the purpose of utilizing its radioactive properties). NRC involvement in these areas was not specifically requested by the States.

The recommendations for NRC action will be consistent with NRC's recognized role as a lead Federal agency in the control of hazards from radioactive materials.

Table 1

Primordial Radionuclides

Nuclide	Half-life (Years)	Primary Mode of Decay
^{40}K	1.3×10^{9}	Beta
^{50}V	6×10^{16}	Electron Capture
^{87}Rb	4.7×10^{10}	Beta
^{115}In	6×10^{14}	Beta
^{138}La	1.1×10^{11}	Beta
^{142}Ce	5×10^{16}	Alpha
^{144}Nd	5×10^{15}	Alpha
^{147}Sm	1.06×10^{11}	Alpha
^{148}Sm	1.2×10^{14}	Alpha
^{149}Sm	1×10^{15}	Alpha
^{152}Gd	1.1×10^{14}	Alpha
^{174}Hf	4.3×10^{15}	Alpha
^{176}Lu	3.6×10^{10}	Beta
^{187}Re	7×10^{10}	Beta
^{190}Pt	7×10^{11}	Alpha
^{192}Pt	1×10^{15}	Alpha
^{204}Pb	1.4×10^{17}	Alpha
^{235}U decay series	-	-
^{238}U decay series	-	-
^{232}Th decay series	-	-

Table 2

Major Cosmic Ray-Induced Radionuclides

Nuclide	Half-Life	Primary Mode of Decay
^{3}H (T)	12.26 yrs	Beta
^{7}Be	53 days	Electron Capture
^{10}Be	2.7×10^{6} yrs	Beta
^{14}C	5760 yrs	Beta
^{22}Na	2.58 yrs	Beta
^{32}Si	280 yrs	Beta
^{32}P	14.3 days	Beta
^{33}P	25 days	Beta
^{35}S	86.7 days	Beta
^{36}Cl	3×10^{5} yrs	Beta
^{39}Cl	.55 min	Beta

Table 3

Civilian Uses of Radium
(Including Radon and RaDEF)

Item	Typical Activity
Medical Sources	
Needles, Capsules & Tubes	0.1 to 100 mCi
Plaques	5 to 25 mCi
Nasopharangeal Applicators	50 mCi
Radium DEF Eye Applicators	No data
Radon Seeds	0.1 to 5 mCi
Industrial Sources	
Level, Thickness and Density Gauges	0.1 to 10 mCi
Gamma Well Logging	10 to 50 mCi
Ra-Be Neutron Well Logging	300 to 600 mCi
Soil Moisture and Density Gauges	3 to 5 mCi
Radiography	up to 150 mCi
Ionization Sources, Static Eliminators (Ra)	3 µCi to 3 mCi
Calibration, Check & Compensating Sources	1 pCi to 1 Ci
Gamma & Neutron Sources for Research	1 pCi to 1 Ci
Gas Chromatograph Sources and Dew Point Meter Sources	6.25 to 100 µCi 22.5 to 100 µCi
Consumer Items	
Self-luminous Products (excluding Diver's Watches and Depth Gauges)	0.01 to 5 µCi
Smoke Detectors	0.05 to 40 µCi
Electron Tubes	0.001 to 6 µCi
Educational Sources (Cloud Chambers, Spinthariscopes)	1 pCi to 50 µCi

Table 4

Military Uses of Radium

Item	Typical Activity μCi
Alidades, Pelorus	15
Calibration sources	10^{-3} to 10^{3}
Circuit Breakers	60
Compass, Rose	1000
Compass, Divers, Wrist	15
Compass, Unmounted	15
Compass, Lensatic	15
Direction Finder	15
Distress Markers	No data
Electron Tubes, Glow Lamps, Spark Gap Tubes	10^{-3} to 6
Fuse Setter	No data
Generator Gauges	2.5
Indicator, Fuel Gage	No data
Indicator, Battery	0.5
Indicator, Air speed	1 to 15
Indicator, Tachometer, Speedometer	1 to 15
Indicator, Manifold Pressure	.009
Indicator, Oil Pressure	1 to 15
Indicator, Water Pressure	0.8
Indicator, Suction	1 to 15
Indicator, Altimeter	1 to 15
Indicator, Temperature	15
Indicator, Turn and Bank	15
Indicator, Azimuth	3.7
Indicator, Vertical	0.002
Indicator, Rate of Climb	0.027
Indicator, Directional Gyro	0.026
Instrument Dials, Voltmeter	0.08
Instrument Dials, Ammeter	0.35

Table 4 (Cont'd)

Item	Typical Activity μCi
Instrument Dials, Galvanometer	1
Instrument Dials, Audio Level	0.7
Luminous Markers	7
Oxygen Pressure Reducer	No data
Phone Jack Boxes	No data
Switches, Push Button	0.37
Switches, Toggle	0.37
Switches, Barrel	0.37
Switches, Rotary	0.37
Tensiometers	No data
Timepieces, Wrist Watches	15
Timepieces, Marine Clock	10
Timepieces, Chronometer	15
Timepieces, Interval Timer	6
Transit	15

Table 5

Selected Accelerator-Produced Radionuclides
(including some examples of uses)

Nuclide	Half-Life	Primary Mode of Decay	Uses
^{11}C	20.4 minutes	Positron	Lung Uptake & Metabolism, Prostrate tumor localization, Pancreas visualization
^{13}N	10.0 minutes	Positron	Pancreatic scanning, Brain scanning
^{15}O	123 seconds	Positron	Brain scanning, left-right shunt detection
^{18}F	109 minutes	Positron	Uptake in normal and abnormal bone, brain function scan, cancer chemotherapy
^{22}Na	2.62 years	Positron	Extra-cellular water
^{28}Mg	21.2 hours	Beta	Parent of ^{28}Al
^{28}Al	2.31 minutes	Beta	
^{33}P	24.4 days	Beta	Palliative treatment for osseous neoplasms
^{37}Ar	35.1 days	Electron Capture	Total Body calcium determination
^{43}K	22.4 hours	Beta	Myocardial imaging
^{49}Sc	57.5 minutes	Beta	
^{52}Mn	5.60 days	Electron Capture	
^{52m}Mn	21.1 minutes	Positron	
^{52}Fe	8.2 hours	Positron	Parent of ^{52m}Mn
^{56}Co	77.3 days	Electron Capture	Tumor localization
^{57}Co	270 days	Electron Capture	Vitamin B-12, tumor imaging calibration sources, anatomical (scanning) makers, Mossbaüer studies, X-ray fluorescence lead analyzers, simulated tumors in phantoms.

Table 5 (Cont'd)

Nuclide	Half-Life	Primary Mode of Decay	Uses
^{58}Co	71.3 days	Electron Capture	Intestinal absorption studies
^{62}Cu	9.76 minutes	Positron	Radiopharmaceuticals
^{67}Cu	58.5 hours	Beta	Studies of Wilson's Disease
^{62}Zn	9.13 hours	Electron Capture	Parent of ^{62}Cu
^{66}Ga	9.45 hours	Positron	
^{67}Ga	77.9 hours	Electron Capture	Lung scan, Bowel scan, Parotid gland uptake (Sjogren's syndrome)
^{68}Ga	68.3 minutes	Positron	Brain scan, Positron emission tomography for cerebral hemodynamics
^{68}Ge	275 days	Electron Capture	Parent of ^{68}Ga
^{73}As	80.3 days	Electron Capture	
^{74}As	17.9 days	Electron Capture	Brain Tumor localization
^{73}Se	7.1 hours	Positron	
^{77}Br	57 hours	Electron Capture	
^{77}Kr	1.19 hours	Positron	Brain Scan, Positron tomography
^{81m}Kr	13 seconds	Isomeric Transition	Lung ventilation studies, imaging
^{81}Rb	4.7 hours	Electron Capture	Myocardial imaging
^{82}Rb	1.25 minutes	Positron	Imaging
^{84}Rb	33 days	Electron Capture	Radiopharmaceuticals
^{82}Sr	25 days	Electron Capture	Parent of ^{82}Rb
^{87m}Sr	2.83 hours	Isomeric Transition	Bone scanning, Index of bone growth
^{87}Y	80 hours	Electron Capture	Parent of ^{87m}Sr

Table 5 (Cont'd)

Nuclide	Half-Life	Primary Mode of Decay	Uses
^{97m}Tc	91 days	Isomeric Transition	
^{111}In	2.81 days	Electron Capture	Cisternography, Tomography, Tagged Platelets & Lymphocytes
^{123}I	13.3 hours	Electron Capture	Thyroid studies, Imaging, Labelled fibrinogen for in-vivo identification of thrombophlebitis
^{124}I	4.15 days	Electron Capture	
^{125}I	60.2 days	Electron Capture	Bone mineral analysis, Interstitial treatment of cancer, Uptake studies
^{126}I	12.8 days	Electron Capture	
^{127}Xe	36.4 days	Electron Capture	Cardiac studies, Bloodflow studies, Pulmonary function studies
^{129}Cs	32.1 hours	Positron	Myocardial imaging
^{131}Cs	9.70 days	Electron Capture	Thyroid scanning
^{145}Pm*	5.98 hours	Beta	Bone mineralization studies
^{157}Dy	8.1 hours	Electron Capture	Bone tumor localization
^{190m}Os	9.9 minutes	Isomeric Transition	
^{190}Ir	11 days	Electron Capture	
$^{190m1}Ir$	1.2 hours	Isomeric Transition	
$^{190m2}Ir$	3.2 hours	Electron Capture	Parent of ^{190m}Os
^{193m}Pt	11.9 days	Isomeric Transition	Tumor Scanning
^{195}Au	183 days	Electron Capture	
^{195m}Au	30.6 seconds	Isomeric Transition	

*Also produced as a fission product.

Table 5 (Cont'd)

Nuclide	Half-Life	Primary Mode of Decay	Uses
^{197}Hg	65 hours	Electron Capture	Brain and kidney scanning
^{199}Tl	7.4 hours	Electron Capture	Cardiac scanning
^{201}Tl	74 hours	Electron Capture	Cardiac scanning
^{203}Pb	52.1 hours	Electron Capture	Detection of malignant melonoma
^{204}Bi	11.2 hours	Electron Capture	Soft tissue scanning
^{206}Bi	6.24 days	Electron Capture	Soft tissue scanning
^{207}Bi	30.2 years	Electron Capture	

Table 6

Reported Radium Incidents in United States 1966-1969

Type of Incident	Number	Average Rate Per Year
Loss	63	15.8
Theft	6	1.5
Contamination	19	4.8
Overexposure	4	1.0
Other	23	5.8
Total	115	29.0

Table 7

NARM Incidents in Agreement States, 1974-1975

	Number		Average Rate Per Year		
Type of Incident	Radium	Accelerator Isotopes	Radium	Accelerator Isotopes	Year Total NARM
Loss	19	13	9.5	1.5	11.0
Theft, Unauthorized Disposal	1	0	0.5	0	0.5
Contamination	2	3	1	1.5	2.5
Overexposure	2	0	1	0	1.0
Other	2	1	1	0.5	1.5
Total	26	17	13	3.5	16.5

Table 8

Non-Agreement States

State or Territory	Enabling Legislation[a]	Comprehensive Regulations[a]	Presently Licensing NARM[a]	Number of NARM Uses[b]	Responded to NARM Task Force Request for Information
Alaska				No Program	No
Connecticut				28	No
Delaware	Yes	No	No	17	Yes
District of Columbia				20	No
Hawaii				3	No
Illinois	Yes	Yes	Yes	121	Yes
Indiana				72	No
Iowa	No	No	No	20	Yes
Maine	Yes	No	No	19	Yes
Massachusetts	No	No	No	166	Yes
Michigan	Yes	Yes	No	135	Yes
Minnesota				33	No
Missouri				24	No
Montana				27	No
New Jersey	Yes	Yes	Yes	150	Yes
Ohio	No	No	No	196	Yes
Oklahoma	Yes	No	No	50	Yes
Pennsylvania	Yes	Yes	Yes	300	Yes
Rhode Island				48	No
South Dakota	Yes	No	No	24	Yes
Utah				No Program	No
Vermont				7	No
Virginia	Yes	Yes	Yes	50	Yes
West Virginia				50	No
Wisconsin				84	No
Wyoming	No	No	No	22	Yes
Puerto Rico				5	No

Notes: [a]Information recorded only for those States responding to NARM Task Force Inquiry.

[b]For States not responding to NARM Task Force Inquiry, data was obtained from Report of State and Local Radiological Health Programs, Fiscal Year 1975, DHEW Publication (FDA) 76-8005.

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APPENDIX A

Texas State Department of Health

AUSTIN, TEXAS 78756

October 16, 1974

Mr. G. Wayne Kerr, Chief
Agreements & Export Branch
Directorate of Licensing
U. S. Atomic Energy Commission
Washington, D. C. 20545

Dear Wayne:

At the Annual Meeting of the Agreement States, October 8-11, 1974, the State caucus held on October 9, made the following requests and recommendations of the A.E.C.

1. The States appreciate the Agreement and Export Branch's expressed interest in providing additional training for state regulatory personnel. The States request that the Agreement and Export Branch continue close coordination with the Government Liason Division in establishing priorities for training programs in order that the priorities established by the National Conference of Radiation Control Program Directors receive due consideration.

   The Texas Radiation Control Branch is currently developing an Oil Well Logging Course in cooperation with the Region VI training committee. The States request that the A.E.C. consider funding state attendees to that course and possibly others that may be developed to meet specific regulatory needs.

2. The States request that the A.E.C. reevaluate Generally Licensed Devices used in measuring levels, density and thickness with the intent to determine if the devices currently being distributed continue to meet radiation safety criteria which allow them to be eligible for general licensed distribution. The evaluation should include a determination that the devices continue to meet essential safety criteria throughout their useful life.

The States will provide the A.E.C. a list of observed circumstances which indicate that the requested evaluation may show that these devices may not be eligible for continued distribution for generally licensed use. The list will be sent to you by Aubrey Godwin, 1975 Chairman, in 60 days.

3. The States request that the A.E.C. consider changing 10 CFR 30.204 to allow land burial of small quantities of radioactive material by specific request only. (Similar to the current rule for specific approval of incineration.)

4. The States request the A.E.C. to investigate the possibility of providing the States with uniform soil contamination limits.

5. The States request that the A.E.C. provide descriptive Sealed Source and Device sheets for devices distributed under the terms of General Licensing. The States will provide similar sheets for devices distributed under their licensure.

6. The States request that the A.E.C. consider reestablishing notifications of shipments of large quantities of radioactive materials and quantities of S.N.M. sufficient to form a critical mass thru state jurisdictions.

7. The States recommend strongly that the A.E.C., or it's successor agency, move immediately to bring accelerator produced and naturally occurring radioactive material under it's jurisdiction.

The States also suggested that the A.E.C. should examine the possible impact of the Act creating a new agency upon agreements now in effect with the U. S. A.E.C.

The States expressed appreciation for the positive action of Mr. Brown of the Government Liason Division in committing funds to permit interaction of the States in emergency response planning.

I enclosing a copy of Dr. Paul Numerof's "shotgun" letter to state team personnel. The States feel that the establishment of an ization such as this may tend to dilute the proper routes for cation of incidents and accidents.

I want to express our appreciation to you and Don Nussbaumer in particular and the rest of the A.E.C. staff in general for a productive meeting with a minimum of controversy. We recognize that your problems and ours are many and varied and we look forward to working with you as we attempt to improve radiation safety practices in mutual areas of concern.

Yours truly,

David K. Lacker
Chairman, Agreement States
1974 Meeting

Encl.

APPENDIX B

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CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS

May 20, 1975

Richard T. Kennedy
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555

Dear Commissioner Kennedy:

On behalf of the Conference of Radiation Control Program Directors, I want to thank you for giving members of our Executive Committee the opportunity to meet with you and discuss the activities of our Conference. I feel that the meeting was very fruitful in that we were able to learn of some of your concepts relating to state activities, and we hope we were able to provide you information as to the Conference's relationship with the Nuclear Regulatory Commission.

As indicated during our visit, the Conference of Radiation Control Program Directors represents the radiation control programs of each of the fifty states, the District of Columbia, certain metropolitan agencies, the Virgin Islands, and Puerto Rico. The Conference, therefore, not only represents those states which have signed agreements with the Nuclear Regulatory Commission but all radiation control programs. On the attached document I have listed the objectives of this Conference and the task forces which have been active during the past year. In addition to these task forces, the Conference also performs its work through workshop activities at its annual meeting. Also attached is a listing of these specific workshops which were conducted at our last annual meeting. Proceedings of this annual meeting will be published, and we will provide you with a copy when the proceedings are available.

I would like to list some of the points which were discussed with you during our meeting.

1. The Agreement States have expressed concern regarding the organizational location of the Agreements and Exports Branch within the NRC. Prior to the reorganization of the AEC in May of 1972, the Agreement States communicated with the Division of State and Licensee Relations. Organizationally, this Division was only two levels below the Commission. It was felt by the Agreement States that this Division was able to express the concerns of the Agreement States to the Commission. It was also felt that the Division of State and Licensee Relations was involved in policy development for the Commission. Currently, the Agreement States communicate with the Agreements and Exports Branch within the Division of Materials and Fuel Cycle Facility Licensing. Several states have expressed concern that after the reorganization of May 3, 1972, of the AEC and the last reorganization of January 19, 1975, the communication point with the NRC is at such a

CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS

level in the organization that these concerns may not reach top management.

2. In light of the concern as expressed in item no. 1 above, another point discussed during our meeting was the consideration of the establishment of an advisory group to the Commission representing the states. Such an advisory group could not only express the concerns and interests of the Agreement States but, additionally, could inform the Commission of other state activities and concerns in matters dealing with environmental monitoring of nuclear facilities, emergency response planning and capabilities, and other topics of state concern. If such a group would be appropriate, the Executive Committee of the Conference could serve in this capacity.

3. Another suggestion for consideration regarding improved communications from states to the NRC would be the establishment of a regional position in each of the NRC regional offices whereby direct communication with states and the regional office could occur. Both the FDA and the EPA have such positions and have found these regional contacts with states to be very productive.

4. 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.

Again, let me thank you for giving us the opportunity to meet with you. We hope this is one of several opportunities that we will have to periodically meet with the Commission.

Yours very truly,

Charles M. Hardin
Past-Chairman

CMH:co

Attachments

BIBLIOGRAPHIC DATA SHEET	1. Report No. NUREG-0301	2.	3. Recipient's Accession No.
4. Title and Subtitle Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials - A Task Force Review			5. Report Date June 1977 6.
7. Author(s) Donald A. Nussbaumer, et al.			8. Performing Organization Rept. No.
9. Performing Organization Name and Address U.S. Nuclear Regulatory Commission Office of Nuclear Material Safety and Safeguards Washington, D.C. 20555			10. Project/Task/Work Unit No. 11. Contract/Grant No.
12. Sponsoring Organization Name and Address Same as Item 9.			13. Type of Report & Period Covered Task Force Report 14.

15. Supplementary Notes

16. Abstracts

In response to requests from the States, an NRC Task Force reviewed the regulation of naturally occurring and accelerator-produced radioactive material (NARM). The Task Force concluded that the regulation of NARM is fragmented, non-uniform and incomplete at both Federal and State levels. NARM is widely used. Excluding those who would be exempt from licensing, about 30% of all users of radioactive materials use NARM, about 6,000 persons. The use of accelerator-produced radioisotopes is growing rapidly. One NARM radioisotope, ^{226}Ra, is used by about 1/5 of all radioactive material users. It is also one of the most hazardous of radioactive materials. Because of the fragmented and non-uniform controls over NARM, it is difficult to know in an overall sense whether proper protection is being provided to workers and the public. However, reports of incidents involving NARM and other data indicate unnecessary, and possibly excessive exposure of workers and the public is occurring. The Task Force recommends NRC seek legislative authority to regulate naturally occurring and accelerator-produced radioactive materials.

17b. Identifiers/Open-Ended Terms

17c. COSATI Field/Group

18. Availability Statement	19. Security Class (This Report)	21. No. of Pages
Release Unlimited	20. Security Class (This Page)	22. Price