POLICY ISSUE
INFORMATION

March 29, 2001 SECY-01-0057

FOR: The Commissioners

FROM: William D. Travers
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SUBJECT: PARTIAL RESPONSE TO SRM COMEXM-00-0002 - "EXPANSION OF NRC STATUTORY AUTHORITY OVER MEDICAL USE OF NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIAL (NARM)"

PURPOSE:

To provide the Commission with a response to the request in the second paragraph of Staff Requirements Memorandum COMEXM-00-0002, dated December 5, 2000, by identifying potential areas in which the U.S. Nuclear Regulatory Commission's (NRC) jurisdiction might be adjusted.

BACKGROUND:

The first paragraph of COMEXM-00-0002 approved the drafting of two potential legislative proposals by the Office of the General Counsel (OGC), in coordination with the staff. The first proposal would extend NRC's statutory authority in the Atomic Energy Act to regulate radioactive material to include accelerator-produced material when used for medical purposes. The second proposal would extend NRC's statutory authority to regulate radioactive material to include accelerator-produced material in all applications, but would not include other sources of ionizing radiation such as "machine-produced" radiation (e.g., linear accelerators, x-ray units).

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In the second paragraph of COMEXM-00-0002, the Commission made the following request.

> The staff, in consultation with OGC, should also identify other areas in which NRC's jurisdiction might appropriately be adjusted so as to ensure radioactive materials and other sources of ionizing radiation presenting similar risks are treated similarly (e.g., technologically-enhanced naturally-occurring material). This is not meant to be a resource-intensive effort. The Commission simply wants the potential areas identified so that it can decide whether to draft legislation and enter a consultation process with the States and other Federal agencies similar to that for the accelerator-produced material described in paragraph one.

DISCUSSION:

Radioactive materials and other sources of ionizing radiation can be divided into five classifications.

- Reactor-produced radioisotopes
- Accelerator-produced radioisotopes
- Primordial radioisotopes
- Cosmic-ray-induced radioisotopes
- Machines that produce ionizing radiation

As an introduction to the general subject area and for completeness, Table 1 [Att. 1] provides background information on the four classifications of radioactive material: primordial radioisotopes; cosmic-ray-induced radioisotopes; reactor-produced radioisotopes; and accelerator-produced radioisotopes. This paper will not discuss in any detail the reactor-produced radioisotopes, over which NRC currently has statutory authority, or accelerator-produced radioisotopes, which will be the subject of the response to the first paragraph of COMEXM-00-0002, due later this year. Naturally occurring radioactive material (NORM) includes both primordial and cosmic-ray-induced radioisotopes.

Primordial Radioisotopes. The first classification in Table 1, "Primordial Radioisotopes," includes those isotopes that have been present on earth since the earliest days of the planet, and begins with the decay series for U-238 and Th-232. The radioisotopes in the U-238 and Th-232 decay series are NORM if undisturbed in nature, but after human intervention can become source or byproduct material, over which NRC currently has jurisdiction. The NORM radioisotopes are not currently under NRC authority. On page 2 of Table 1, the remaining primordial radioisotopes are identified. The most notable is K-40, which is a major source of our internal body burden and accounts for 11 percent of the average background radiation to the public [Att. 2, p. 3]. The estimated annual effective dose equivalent from internally deposited radioisotopes (e.g., K-40, Po-210) is 0.40 mSv (40 mrem), while the annual effective dose equivalent from terrestrial radioisotopes is 0.28 mSv (28 mrem) [Ref. 1, p. 58].

Cosmic-Ray-Induced Radioisotopes. The second classification includes cosmic-ray-induced radioisotopes, which are identified in Table 1 on page 4. Since these radioisotopes are induced by widely dispersed, random interactions with cosmic radiation, they are not amenable to regulatory control [Att. 3, p. 7]. The most important cosmic-ray-induced radioisotope is C-14 [Att.

2, p. 6]. The estimated annual effective dose equivalent to the body from the primary cosmic-ray-induced radioisotopes (i.e., H-3, Be-7, C-14, and Na-22) is just over 10 μSv/yr (1 mrem), with essentially the entire dose arising from C-14 [Att. 2, pp. 6-7]. This dose could be compared to the estimated annual effective dose equivalent of 0.27 mSv (27 mrem) received directly by a U.S. resident from cosmic radiation from beyond the earth [Ref.1, p. 58].

TENORM. Technologically enhanced naturally occurring radioactive material (TENORM) is defined to be material whose radioactivity has been increased or concentrated as a result of human intervention. TENORM is a subset of NORM. The Environmental Protection Agency (EPA), in EPA 402-R-00-01 dated June 2000, reported that the amount of TENORM produced annually in the U.S. may be in excess of $1x10^9$ tons. For comparison, the annual amount of low-level waste produced for disposal under the Low-Level Radioactive Waste Policy Amendments Act is less than $1x10^5$ tons.

The majority of TENORM is produced by eight industrial sectors [Att. 2, pp. 24-25]:

- Uranium mining overburden;
- Phosphate waste;
- Phosphate fertilizers;
- Coal ash;
- Oil and gas scale and sludge;
- Water treatment;
- Metal mining and processing (including rare earths and other metals); and
- Geothermal energy production wastes.

In Table 2 [Att. 4], the staff identifies several TENORM waste streams that produce very large quantities of relatively low specific radioactivity. For each waste stream, Table 2 presents the estimated quantity produced each year and the contained concentrations of radioactivity from uranium, thorium, and radium. The more notable waste streams are uranium overburden, phosphate, coal ash, and mineral processing. Table 3 [Att. 5] identifies the occurrence and concentrations of NORM in natural rocks and soil. Tables 2 and 3 allow a comparison between TENORM and NORM concentrations of radioactivity.

At the Federal level, a number of agencies assert authority over some aspect of TENORM. EPA has asserted authority to regulate TENORM based on several statutes, including the Clean Air Act; Uranium Mill Tailings Radiation Control Act; Comprehensive Environmental Response, Compensation, and Liability Act; and Toxic Substances Control Act [Att. 6, p. 7]. Other Federal agencies, such as the Departments of Labor, and Health and Human Services, also have an interest under legislation specific to them. However, although EPA has issued relevant guidance documents, according to Egidi and Carter [Att. 2, p. 56] and the Committee on Evaluation of EPA Guidelines for Exposure to Naturally Occurring Radioactive Materials [Ref.1, p. 246], there are currently no Federal regulations that specifically control TENORM.

States have general regulatory authority to protect the health and safety of their population, and TENORM is one area in which States have asserted such authority. The Conference of Radiation Control Program Directors (CRCPD), a nonprofit professional organization, whose primary membership is made up of individuals in State and local government who regulate the use of radiation sources, has developed model regulations for control and disposal of

TENORM for State use. Even though many States consider TENORM to be regulated by their general rules on radiation, some States have specific regulations on the subject. Eleven States currently have regulations specifically for TENORM - [Att. 2, p. 57; Ref.1, p. 197]. Eight States are considering TENORM regulations - [Att. 2, p. 57].

Machines that Produce Ionizing Radiation. In this section the staff will present a brief overview of some of the machines that produce ionizing radiation, based on readily available information, without conducting a resource-intensive effort. Machines that produce ionizing radiation, include x-ray units, betatrons, cyclotrons, linear accelerators, microtrons, heavy-ion accelerators, neutron generators, and electrostatic accelerators. In Table 4 [Att. 7], the staff identifies various types of particle accelerators. Based on data from the CRCPD, there are at least 650,000 x-ray machines in current use across the country.

Electron accelerators such as betatrons, linear accelerators, and microtrons are used for either electron or x-ray therapy. These machines typically accelerate electrons at energies ranging from 10 to 50 MeV [Ref. 2, pp. 1-4]. There are probably between 3000 and 4000 medical linear accelerators in use across the country. For electron accelerators that operate above 10 MeV, neutrons can be produced through the photonuclear reaction, resulting in additional doses to patients and operating personnel from direct exposure both to neutrons and the resulting residual radioactivity [Ref. 2].

Cyclotrons are used to bombard enriched stable isotopes with particles to produce a variety of different radioisotopes used in medicine or research. Cyclotrons are also used to produce the radioisotopes necessary for positron emission tomography (PET). There are more than 50 PET Centers in operation in the United States. PET involves the injection of a beam of charged particles from a cyclotron into a “black box” containing the stable target, which in turn becomes the activated radioisotope for quick injection into the patient. The black box amounts to a hot chemistry laboratory. The entire system is rather complex and must work together to be successful. Moreover, the PET system is only possible because of close coupling of a cyclotron machine whose radiation produces a relatively short-lived radioisotope and a patient waiting for the diagnostic procedure. If NRC were to regulate PET, it may be that the entire system would have to be controlled [Att. 8, p. 8].

Heavy-ion accelerators are used by industry as ion implanters, primarily to modify the properties of materials. In 1987 there were 3000 heavy-ion accelerators being used in semiconductor fabrication plants. Electrons are created by the interaction of positive ions with component parts of the implanter, which in turn produce x-rays upon decelerating. Resulting dose rates can be 0.5 mrem per hour [Att. 8, p. 7].

Neutron generators are used for preparing short-lived radioisotopes. Over 50 radioisotopes can be produced this way, with the more important medically useful radioisotopes being fluorine-18, bromine-80, and mercury-199m. Neutron generators are also used for neutron therapeutic treatment of cancer. They also have been used for neutron activation analysis, using the conventional Cockcroft-Walton accelerators. In addition, accelerator well-logging devices are used for activation analysis of boreholes, to indicate the type of formations [Att. 8, p. 7].

CONCLUSION:

Consistent with the Commission's direction to identify potential areas, the staff has not attempted to re-analyze the situation, or make recommendations at this time. Moreover, SECY Papers from April and December 1978, March 1988, and September 1992 have made recommendations to the Commission on whether to extend NRC's statutory authority. Attachment 9 provides a short synopsis of the staff's earlier efforts. The staff notes that the information in this paper may be useful to both the Interagency Jurisdictional Working Group on Evaluating the Regulation of Low Concentrations of Uranium and Thorium, that is responding to the Staff Requirements Memorandum for SECY-99-259, and the National Materials Working Group. Moreover, in accordance with COMEXM-00-0002, the Office of the General Counsel, in consultation with the staff, will separately address the Commission's direction regarding accelerator-produced radioactive materials used in medicine and other applications.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper.

/RA/

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References:
1. "Evaluation of Guidelines for Exposures to Technologically Enhanced Naturally Occurring Radioactive Materials," National Academy Press, Washington, DC 1999
2. NCRP Report No. 79, issued November 1, 1984
3. McGraw-Hill "Encyclopedia of Science and Technology," Volume 13, 8th Edition, p. 130

Attachments:
1. Table 1 - "Four Classifications of Radioactive Material"
2. NORM and TENORM Producers, Users, and Proposed Regulations by P. Egidi and C. Hull
3. The Regulation of NORM from a Nuclear Decommissioner's Viewpoint, by Shankar Menon
4. Table 2 - "Sources, Quantities, and Concentrations of TENORM"
5. Table 3 - "Occurrence and Concentrations of NORM"
6. Regulatory Initiatives for Control and Release of TENORM by P. Egidi
7. Table 4 - "Particle Accelerators"
8. NUREG-1310, published March 1988
9. "Staff's Earlier Work from the Periods 1976-'78; 1984; 1987-'88; and 1992"

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

1. Primordial Radioisotopes, continued (decay mode)	**Half Life (yrs)**	**Source Material**	**Fertile**	**SNM**	**Mill Tailings [11.e(2)]**	**NORM**	**Notes**; e.g., Use of Material
K-40 (potassium) (β decay) (0.0117%)	$1.28x10^{9}$					Yes	major internal body burden
V-50 (vanadium) (electron capture) (0.25%)	$1.4x10^{17}$					Yes	
Rb-87 (rubidium) (β) (28%)	$4.75x10^{10}$					Yes	earth mantle heat flux
In-115 (indium) (β) (95.71%)	$4.41x10^{14}$					Yes	
Te-123 (tellurium) (e) (0.91%)	$1.0x10^{13}$					Yes	
La-138 (lanthanum) (e & β) (.09%)	$1.05x10^{11}$					Yes	
Ce-142 (cerium) (β) (11%)	$5.0x10^{16}$					Yes	
Nd-144 (neodymium) (α)(24%)	$2.29x10^{15}$					Yes	
Sm-147 (samarium) (α) (15%)	$1.06x10^{11}$					Yes	
Sm-148 (α) (11%)	$7x10^{15}$					Yes	
Sm-149 (α) (14%)	$2.0x10^{15}$					Yes	
Gd-152 (gadolinium) (α)(0.2%)	$1.08x10^{14}$					Yes	
Hf-174 (hafnium) (α) (0.16%)	$2.0x10^{15}$					Yes	
Lu-176 (lutetium) (β) (2.6%)	$3.78x10^{10}$					Yes	meteorite dating
Os-186 (osmium) (α) (1.58%)	$2.0x10^{15}$					Yes	
Re-187 (rhenium) (β) (62.6%)	$4.35x10^{10}$					Yes	
Pt-190 (platinum) (α) (0.01%)	$6.5x10^{11}$					Yes	
Pb-204 (lead) (α) (1.4%)	$1.4x10^{17}$					Yes	
Pa-231 (protactinium) (α)	$3.27x10^{4}$					Yes	

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

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

3a. Reactor-Produced Radioisotopes; Activation Products Used in Medicine (decay mode)	**Half Life (yrs)**	**Source Material**	**Fertile**	**SNM**	**Mill Tailings [11.e(2)]**	**NORM**	**Notes**; e.g., Use of Material
C-14 (carbon) (β)	$5.73x10^3$						urea halobacter pylori test
P-32 (phosphorus) (β)	14 days						medical procedures, inter-vascular brachytherapy
Co-60 (cobalt) (β)	5.27						teletherapy, brachytherapy, interstitial and intracavitary cancer therapy
Sr-89 (strontium) (β)	50.5 Days						palliative treatment
Sr-90 (β)	28.8						brachytherapy, treatment of superficial eye conditions
Y-90 (yttrium) (β)	64.1 hours						micro-sphere brachytherapy
Tc-99m (technetium) (IT, γ)	6 hours						imaging
Pd-103 (palladium) (e)	17 days						brachytherapy, interstitial cancer therapy
I-125 (iodine) (e)	59.4 days						brachytherapy, interstitial cancer therapy
I-131 (β)	8.02 days						hyperthyroidism, thyroid cancer
Xe-133 (xenon) (β)	5.2 days						lung studies
Cs-137 (cesium) (β)	30.1						brachytherapy, interstitial and intracavitary cancer therapy
Ir-192 (iridium) (β)	73.8 days						brachytherapy, interstitial cancer therapy
Au-198 (gold) (β)	2.7 days						brachytherapy, interstitial cancer therapy

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

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

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

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

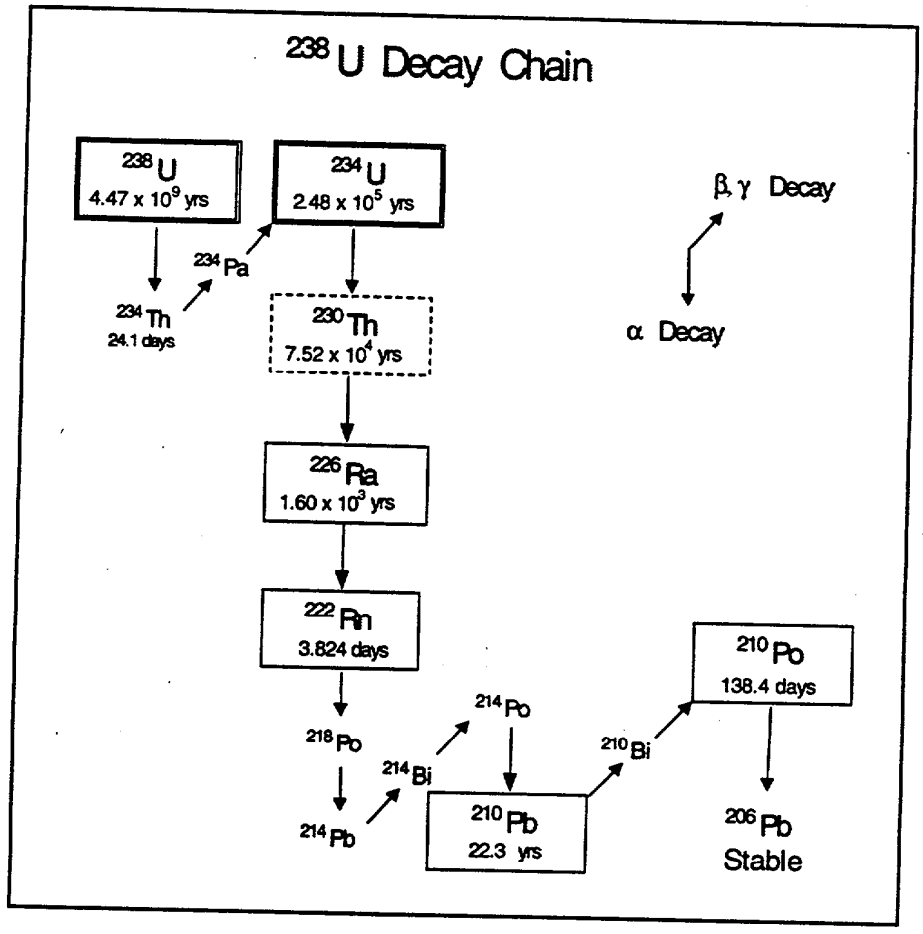
[1]Data from online data base, Table of the Nuclides, linked to web site for Brookhaven National Laboratory at http://www.dne.bnl.gov/CoN/index.html

V

NORM and TENORM

(Naturally Occurring and Technologically Enhanced Naturally Occurring Radioactive Material)

Producers, Users, and Proposed Regulations



PEP Course 1.A Notes

Health Physics Society 1999 *(32nd)* Midyear Meeting
Albuquerque, New Mexico
24 January 1999

Notes Prepared by:

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NORM and TENORM

(Naturally Occurring and Technologically Enhanced Naturally Occurring Radioactive Material)

Producers, Users, and Proposed Regulations

PEP Course 1.A Notes

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INTRODUCTION

Naturally Occurring Radioactive Material (NORM) is everywhere. We are exposed to it every day. However this is not unusual; it is, as the terminology expresses, natural. Actually, NORM is one of the primary reasons that Earth remains habitable. NORM is the source of the Earth's heat flux, drives the movements of the planet's tectonic plates, and so plays a major rôle in the evolution of life on Earth. NORM is an integral part of the planet, our bodies, the food we eat, air we breathe, the places where we live and work, and within products we use. We are also bathed in a sea of natural radiation coming from the sun and deep space. Terrestrial life has evolved with this natural radiation and radioactivity. Conversely, processing of some natural resources concentrates naturally occurring radionuclides to a degree that they may pose risks to humans and the environment. These and other activities, such as flying at high altitudes, increase exposures to radioisotopes beyond limits that occurred naturally.

This session focuses on Technologically Enhanced (TE) NORM. All degrees of TENORM exist, but our concerns are typically with components of large-volume, low specific radioactivity industrial waste streams. These include minerals mining, transport, beneficiation and chemical processing of ores, production of phosphate fertilizers, extraction and purification of trace elements, manufacture of some metals, water treatment and purification, use of TENORM-bearing by-products, as well as oil and gas and other energy production. The majority of radionuclides in TENORM are found in the uranium and thorium decay chains. Radium (^{226}Ra) and its decay products (*e.g.*, radon – ^{222}Rn) are quite often used to characterize the redistribution of TENORM that results from human activities. A synopsis of these large volume streams of TENORM will be presented, as shall a brief review other natural radionuclides, *e.g.* potassium and rubidium isotopes, and other such minor sources that primarily contribute to background doses.

TENORM is found in various concentrations in a variety of forms (physical and chemical matrices) such as scrap metal, sludges, slags, fluids, scales in storage tanks and piping, chemical residues, processing fluids, surface and groundwaters, and mine tailings. TENORM has also been found in industries that were not thought to be subject to radioactive contamination. The levels

of and sources of radioactivity in TENORM vary significantly in various forms. Although TENORM is prevalent in industrialized societies, it is emphasized that few industrial processes actually concentrate NORM. Neither the Atomic Energy Act nor any other U.S. Federal regulations address TENORM. Control and regulation of TENORM is inconsistent from industry-to-industry and between states, provinces, and nations.

So when is TENORM a problem? Where is it a problem? This depends on who is presenting and organizing the data and discussion, when it is presented, and where. One is likely to receive somewhat differing views on exactly the same topic from, for instance, the phosphate industry *versus* that of state/provincial or federal regulators. The authors do not wish to contribute to conflicting views on TENORM regulatory issues; our main objective is to present unbiased facts relating to NORM and TENORM. These session notes are organized to begin with a brief review of background radioactivity followed by a discussion of the geological framework, mobility, and variability of these radionuclides. A review of some of the industrial sectors affected by TENORM is then given. An overview of proposed guidelines and regulatory aspects of TENORM concludes these notes.

Ceiling Tiles Hat
U – Radon
Pellets.

BACKGROUND RADIOACTIVITY

There are two generic definitions for background radioactivity:

1) Radioactivity that is the result of naturally occurring concentrations of radionuclides that represent ambient conditions present in the environment that are *in no way influenced by human activity*, or
2) Concentrations of radionuclides from *anthropogenic sources originating from non-site sources* (Gesell and Prichard, 1975). An example is global fallout.

Components of Background Radioactivity

The following discussion is drawn largely from NCRP 94. Four major components constitute "background sources" of radiation:

- Human Produced
- Terrestrial
- Cosmogenic
- Cosmic

Most TENORM is associated with terrestrial sources, but the other types may interfere with measuring levels of TENORM. **Fig. 1** shows the background sources to the U.S. population.

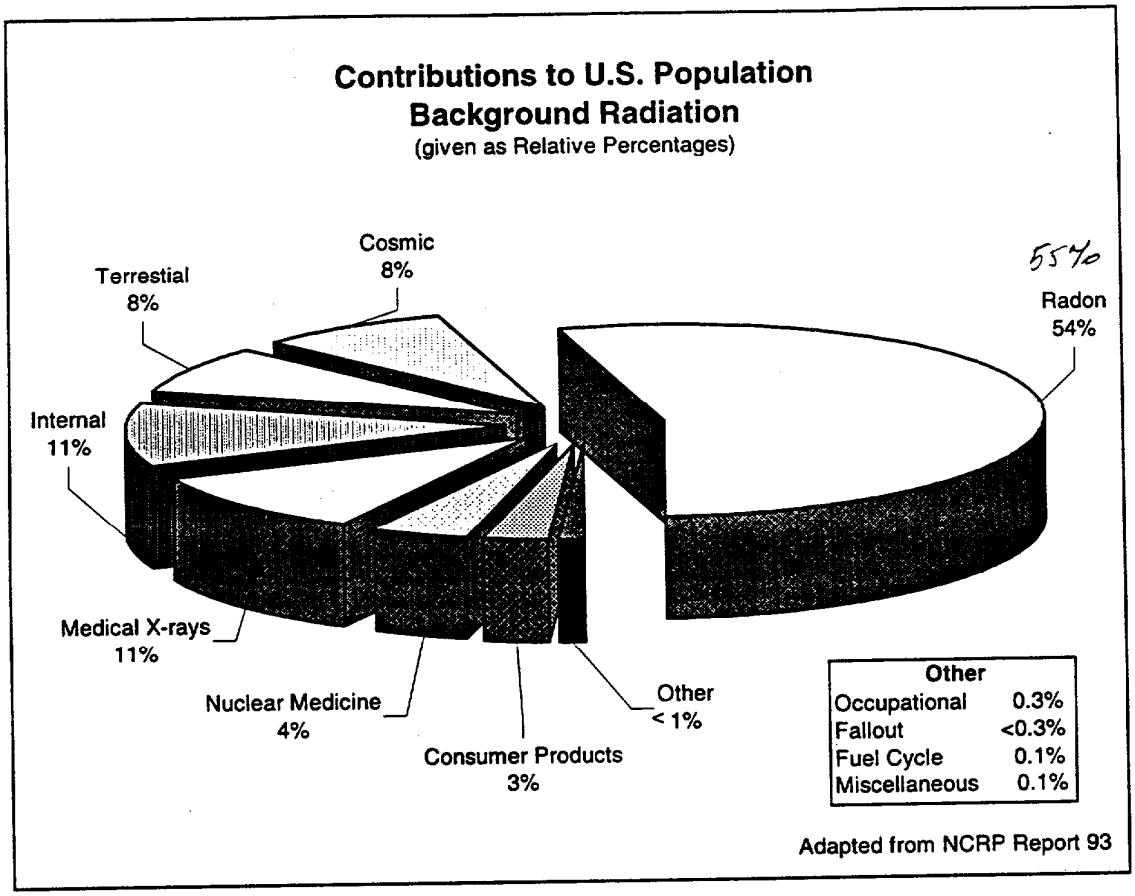


Figure 1. Sources of Background Radiation to the Public

Human Produced (Anthropogenic) Sources of Radioactivity

Anthropogenic sources of radiation are often considered as a component of the background. Why is this; it is not logical or intuitive? This likely occurred since these types of human produced sources are ubiquitous throughout the environment as opposed to being locally distributed. Activities that have contributed to the dispersion of radionuclides in the environment include:

- Nuclear weapons tests and use
- Nuclear accidents (Chernobyl) and incidents
- Nuclear reactors (for this discussion, ^{14}C and Tritium)

Most anthropogenic radionuclides are short-lived, but some have intermediate half-lives of a few years and worthy of note. These intermediate half-lived nuclides are listed in **Table 1**.

Table 1. Examples of Half-Lives for Some Anthropogenic Radionuclides

Radionuclides of Interest	Half-Life ($t_{1/2}$)
^{137}Cs	30.2 y
^{90}Sr	28.1 y
^{85}Kr	10.73 y

Also, the global inventory of ^{14}C and ^{3}H has been increased from human activities, and it is sometimes necessary to measure these globally distributed radionuclides separately and to distinguish them from locally produced sources. In addition Pu isotopes were released in fallout.

The variability of anthropogenic sources of radiation and radioactivity relates directly to the population distribution and level of technology found in different areas around the world. Deposition in an area depends upon wind and precipitation patterns (NRC 1994).

Cosmic Radiation

This type of background refers to both the *primary* energetic particles of extraterrestrial origin that strike the earth's atmosphere and to the *secondary* particles generated by their interaction with the atmosphere.

Primary radiation itself consists of two components, designated as ***galactic*** or ***solar*** depending on origin.

Primary particles are attenuated in upper atmosphere. Reactions take place and generate secondary particles. The cosmic radiation field at ground altitude (0 to 3 km) consists almost entirely of secondary particles whose origins are almost exclusively galactic.

Annual external dose rates from cosmic rays depend slightly on latitude and strongly on altitude (**Table 2**). The latitude effect is due to the charged-particle nature of the primary cosmic rays. When they come near the earth, its magnetic field tends to deflect the rays away from the equator and toward the poles (Gollnick 1988).

Table 2. Altitude Dependence of Cosmic Ray Dose
(Dose equivalent; does not include the neutron component).

Altitude, m (ft)	Dose Rate, $\mu Sv\ yr^{-1}$ ($mrem\ yr^{-1}$)	Example
Sea level	~270 (31)	Los Angeles
1,525 (5,000)	~478 (55)	Denver
3,050 (10,000)	~1,190 (137)	Leadville, Colo.
9,140 (30,000)	~16,530 (1900)	Normal jetliner
15,240 (50,000)	~76,125 (8750)	Concorde
24,340 (80,000)	~106,140 (12,200)	Spy plane

Adapted from Gollnick 1988.

Cosmogenic Radiation

Cosmogenic radionuclides arise from the collision of highly energetic cosmic ray particles with stable elements in the atmosphere and in the ground. The entire geosphere, the atmosphere, and all parts of the earth that directly exchange material with the atmosphere contain cosmogenic radionuclides. The major production of cosmogenic radionuclides results from the interaction of cosmic rays with atmospheric gases.

The outermost layer of the Earth's crust is another area where reactions with cosmic rays occur. However, the rate at which they occur is several times smaller than the atmospheric component because most of the cosmic rays are attenuated in the atmosphere. The result is that the contribution to background dose is minimal.

The most important cosmogenically produced radionuclide is ^{14}C. However, many others, such as ^{3}H, ^{22}Na, and ^{7}Be, occur. Carbon-14 produced in the atmosphere is quickly oxidized to CO_2. The equilibrium concentrations of ^{14}C in the atmosphere are controlled primarily by the exchange of CO_2 between the atmosphere and the ocean. The oceans are the major sinks for removal of ^{14}C from the atmosphere.

Most of the other cosmogenically produced radionuclides in the atmosphere are oxidized and become attached to aerosol particles. These particles, or geoaerosols, act as condensation nuclei for the formation of cloud droplets and eventually coagulate to form precipitation. About 10 to 20% of cosmogenically produced radionuclides are removed from the atmosphere by dry deposition on the earth's surface.

Concentrations of cosmogenic radionuclides vary in the atmosphere with time and location. Variations are day-to-day, seasonal, longitudinal, and sunspot-cycle related. The concentrations of some cosmogenic radionuclides, such as ^{3}H, ^{14}C, ^{22}Na, and ^{37}Ar, have increased during nuclear tests. Reactors also generate ^{14}C that eventually will be distributed in the atmosphere, but is estimated to be two orders of magnitude lower than the natural concentration.

The total effective dose equivalent rate to the body produced by the primary cosmogenic radionuclides is just over 10 μSv (1 mrem yr^{-1}), with essentially the entire dose arising from ^{14}C.

Terrestrial Radiation

The final component of background comes from radionuclides found on Earth. Several dozen naturally occurring radionuclides have half-lives of at least the same order of magnitude as the estimated age of the earth (4.5×10^9 y), and are assumed to represent a primordial inventory. These primordial radionuclides are also what we are most concerned with in the TENORM issue.

The primordials are usually divided into two groups:

- Those that occur singly (non-series) and decay directly to a stable nuclide
- Those radionuclides that occur in decay chains (series) and decay to a stable isotope of lead through a sequence of radionuclides of wide-ranging half-lives.

Non-Decay Series Radionuclides

Two primary non-decay series radionuclides contribute to background dose, Potassium-40 (^{40}K) and Rubidium-87 (^{87}Rb). Potassium-40 is a beta (87.3%) and gamma (10.67%) emitter and contributes to both internal and external doses. It exists as a constant fraction of stable potassium (0.0117%). Potassium-40 behaves chemically as does stable potassium. It is ubiquitous at the Earth's surface and is concentrated in felsic igneous rocks and their weathering products. Potassium-40 is also concentrated in flowering plant buds, in cereal grains, and mesostems of many plants. Potassium-40 is also present in most organisms; for instance human sweat contains ^{40}K. This is one reason why gamma spectrometrists take care not to touch detectors or sample containers – an elevated background for the ^{40}K photopeak may result. The ^{40}K contribution to

external dose is variable, depending on its concentration in rocks and soil. Average concentration is about 0.6 Bq g^{-1} (17 pCi g^{-1}) in crustal rock. Potassium-40 is found in TENORM, particularly building materials (bricks, cinder blocks). It may be necessary to determine background fractions separately from total concentrations. Potassium is metabolically regulated by the body and is not controlled by intake.

Rubidium-87 is a pure beta emitter and is found in crustal rock in concentrations of about 0.07 Bq g^{-1} (2 pCi g^{-1}). It is not an external hazard and is rarely considered in dose calculations. However, ^{87}Rb is quite important in the generation of heat in the mantle and crust of the Earth.

The remainder of the non-series radionuclides has combinations of half-lives, isotopic abundance, and elemental abundance such that they have negligibly small specific activities and are not significant in background calculations.

Decay Series Radionuclides

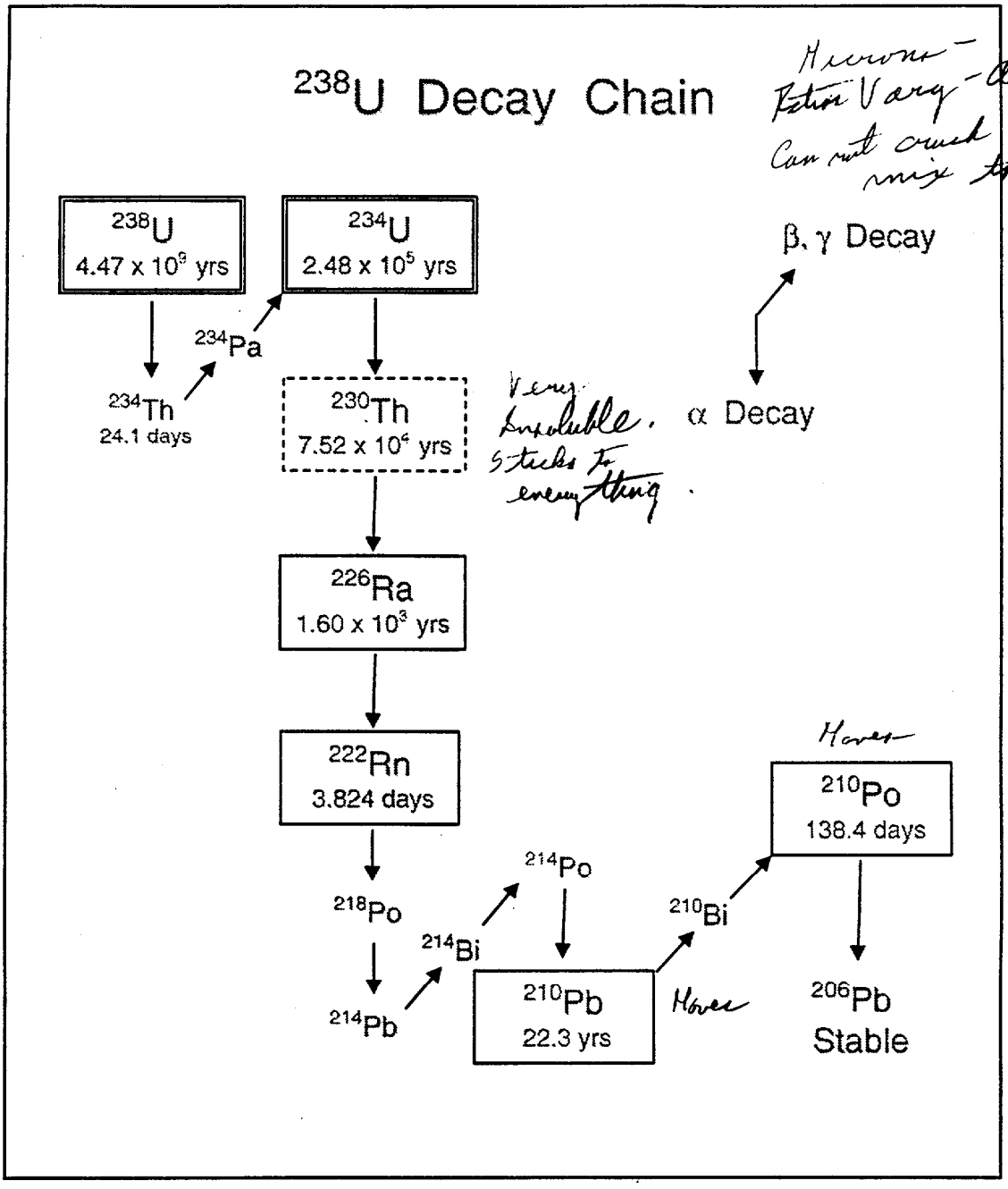
There are three naturally occurring decay series, headed by the radionuclides ^{238}U, ^{235}U, and ^{232}Th. These series are commonly called the uranium series, the actinium series, and the thorium series respectively. **Table 3A** lists components of the uranium and thorium series. **Table 3B** lists a few of the non-series radionuclides. Generally, the actinium series does not play a significant rôle in industrial TENORM due to its very low presence (one-sixth of ^{238}U) in the natural environment.

If not subjected to chemical or physical separation, each of these series attains a state of secular radioactive equilibrium. Technological enhancement of NORM as well as natural physical and chemical reactions often interfere with this balance. Crustal concentrations of the heads of the three series are extremely small (parts *per* million); the short-lived decay progeny are present in such exceedingly minute concentrations that their behavior does not always follow chemical (mass action) controls. There will be further discussion about this later.

Table 3A. Principal Natural Radionuclide Decay Series

Nuclide	Symbol	Half-Life ($t_{1/2}$)	Major Radiations
Uranium-238	(^{238}U)	4.47 billion years	alpha, x–rays
Thorium-234	(^{234}Th)	24.1 days	beta, gamma, x–rays
Protactinium-234m	(^{234m}Pa)	1.17 minutes	beta, gamma
Uranium-234	(^{234}U)	248,000 years	alpha, x–rays
Thorium-230	(^{230}Th)	77,000 years	alpha, x–rays
Radium-226	(^{226}Ra)	1600 years	alpha, gamma
Radon-222	(^{222}Rn)	3.83 days	alpha
Polonium-218	(^{218}Po)	3.05 minutes	alpha
Lead-214	(^{214}Pb)	26.8 minutes	beta, gamma, x–rays
Bismuth-214	(^{214}Bi)	19.7 minutes	beta, gamma
Polonium-214	(^{214}Po)	164 microseconds	alpha
Lead-210	(^{210}Pb)	22.3 years	beta, gamma, x–rays
Bismuth-210	(^{210}Bi)	5.01 days	beta
Polonium-210	(^{210}Po)	138 days	alpha
Lead-206	(^{206}Pb)	stable	
Thorium-232	**(^{232}Th)**	14.1 billion years	alpha, x–rays
Radium-228	(^{228}Ra)	5.75 years	beta
Actinium-228	(^{228}Ac)	6.13 hours	beta, gamma, x–rays
Thorium-228	(^{228}Th)	1.91 years	alpha, gamma, x–rays
Radium-224	(^{224}Ra)	3.66 days	alpha, gamma
Radon-220	(^{220}Rn)	55.6 seconds	alpha
Polonium-216	(^{216}Po)	0.15 seconds	alpha
Lead-212	(^{212}Pb)	10.64 hours	beta, gamma, x–rays
Bismuth-212	(^{212}Bi)	60.6 minutes	alpha, beta, gamma, x–rays
Polonium-212	(^{212}Po)	0.305 microseconds	alpha
Thallium-208	(^{208}Tl)	3.07 minutes	beta, gamma
Lead-208	(^{208}Pb)	stable	

^{87}Rb – Drives mantle heat flux.



From Hull (1996a,b; 1997)

Figure 2. A Simplified Decay Scheme of the Uranium Decay Series

Table 3B. Principal Natural Radionuclide in Non-Decay Series - ^{40}K and ^{87}Rb

Nuclide	Symbol	Half-Life ($t_{1/2}$)	Major Radiations
Potassium-40	(^{40}K)	1.28 billion years	beta, gamma
Argon-40	(^{40}Ar)	stable	
Calcium-40	(^{40}Ca)	stable	
Rubidium-87	(^{87}Rb)	47 billion years	beta
Strontium-87	(^{87}Sr)	stable	

Source: NRC (1994a)

GEOLOGY OF NORM

Igneous Rocks

The original sources of uranium-series, thorium-series, actinium-series, potassium and rubidium radioactivity in the terrestrial environment are the earth's crust and mantle (**Table 4**).

Table 4. Crustal Concentrations of Terrestrial Radionuclides

Rock Type	Uranium (U)	Thorium(Th)	Potassium (K)	Rubidium (Rb)
Mafic (Dark Colored)	0.5 to 1 ppm	3 to 4 ppm	0.8%	40 ppm
Salic (Light Colored)	3 ppm	17 ppm	4%	170 to 200 ppm

Source: NCRP 94.

As molten magma cools, silicate minerals crystallize (magmatic differentiation). In the early stages of cooling, the silicates tend to be mafic (those that contain proportionately more iron

and magnesium), and deficient in aluminum, silicon, sodium, and potassium. As cooling and differentiation progress, the salic (containing mostly silicon-aluminum) igneous rocks as formed. **Fig. 3** shows a generalization of the process, known as Bowen's Reaction Series (Montgomery 1990). Neither uranium nor thorium "fits" into the crystalline structures of the major silicate minerals so they are excluded by the solid phases and concentrated in the fluid phase of the magma. In addition, they are present in such small quantities as to have little tendency to form minerals in which they would be essential components. The result of this relationship is that the remainder of the magma cools to form varied minor mineral which contain relatively elevated concentrations of uranium, thorium and other minor and trace elements. The last crystallizing silicates contain most of the potassium and rubidium.

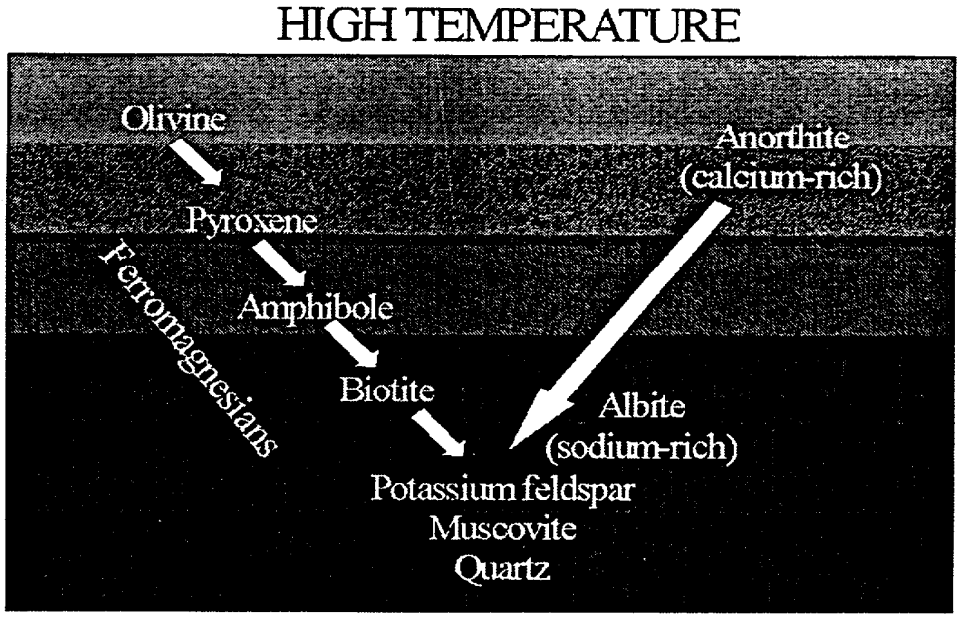


Figure 3. Bowen's Reaction Series

Weathering of Igneous Rocks

Mechanical (physical) and chemical processes break rock down into soil. Weathering plays a key role in this process. Where mechanical processes dominate the breakdown, the separation usually occurs along mineral boundaries that lead to a separation of the major silicates

from the minor ones containing the thorium and uranium. These minor minerals include zircon and monazite. They are stable and resistant to chemical decay and are often found as small individual grains.

Where chemical (or biological) action predominates, the thorium- and uranium-bearing minor minerals can give up their radionuclides to layers of cations in clay minerals. When the host rocks erode, the clay minerals containing with the adsorbed series radionuclides tend to be separated from the major minerals.

Therefore, if igneous rock is broken down to individual grains, the products end up as:

- Sands of the major mineral (depleted of the radionuclides),
- Fine-grained clay minerals (slightly enriched in the radionuclides), and
- Relatively small quantities of resistant, dense grains of the minor minerals containing most of the series radionuclides.
- The potassium and rubidium are removed in solution.

Sedimentary Rocks

Although they comprise only a small part of the earth's crust by volume, sedimentary rocks cover about 85% of the land area of the continental U.S. Therefore, much of the surface soil is derived from sedimentary rock. Sedimentation processes naturally sort the products of weathering and develop several major sedimentary rock types of significantly differing radionuclide concentrations. The major types are:

- Shales
- Sandstones
- Carbonate rocks

As with the igneous rocks, thorium and uranium tend to be minor or disseminated. The radionuclides may become mobile or be deposited by migration of water or oil. Some organic complexes, notable humic acids, create mobile complexes of uranium.

Uranium and other minor and trace elements have an affinity for crude oil. They are probably residues of consolidated organic and marine deposits. Petroleum is often assumed to have migrated to a position of minimum hydraulic potential in a reservoir rock, which may or may not be derived from the same source deposits as the petroleum.

Shales

Shales normally contain at least 35% clay minerals, and a significant fraction contains potassium as an essential constituent. Shales can adsorb the series radionuclides. The radionuclides may also be present bound to organic matter in minor minerals or as precipitates or coprecipitates in the cementing material that binds the rock.

Sandstones

Sandstones are usually made of grains that are primarily quartz, but may contain some potassium-containing feldspars. Those sandstones that contain more than 25% feldspar are called arkoses, and the chief feldspars are those containing potassium. On the whole, sandstones are low in both the series and non-series radionuclides. However, many deposits of uranium are found at the boundary of different layers of sandstones.

Carbonate Rocks

Carbonate rocks are limestones or dolomites derived by chemical precipitation from water or by the buildup of shells, bones, and teeth of organisms. Although the carbonate minerals themselves are relatively free of radionuclides with the exception of U, the intergranular spaces may contain elements found in the seawater from which they were deposited. Potassium is very soluble and does not stay in the deposited matter. Thorium is depleted in seawater and is not metabolized by marine organisms. Therefore, potassium and thorium are usually of low

concentrations in carbonate rocks, but uranium may be present because it may be fixed by reducing conditions in decaying organic matter where the rocks are deposited. Uranium also is chemically speciated as uranyl carbonate aqueous complexes.

Uranium can replace calcium or be adsorbed in the principal phosphate minerals. U is associated with phosphates, as will be discussed in more detail in a following section.

Metamorphic Rocks

The characteristics of metamorphic rocks are based on those of the parent rock in many instances. However, fluids involved in metamorphic processes are often enriched in "eutectic compositions" and these often contain elevated concentrations of U and other NORM. Significant fractionation of decay-series radionuclides can occur during metamorphic events as radioelements are re-distributed in fluids and partial melting zones.

Soils

Radioactivity in soils results from the rock from which it is derived. It is often:

- Diminished by leaching of water,
- Diluted by increased porosity and by added water and organic matter, and
- Augmented by sorption and precipitation of radionuclides from incoming water.

It is the top 0.25 m of soil that contributes significantly to background dose. **Table 5A** is a summary of concentrations of long-lived radionuclides in major rock types and soil. **Table 5B** is a compilation of data for U and Th in accessory mineral phases. Background concentrations of radionuclides in soil vary because of many factors. Soil may have been produced from the weathered top layer of still-intact bedrock below or transported laterally from the same rock unit or type some distance away. Some methods of transport are:

Table 5A. Concentrations of Long-Lived Radionuclides in Major Rock Types and Soils.

Rock Type	Potassium-40 ^{40}K		Rubidium-87 ^{87}Rb		Thorium-232 ^{232}Th		Uranium-238 ^{238}U	
	Percent total K	Bq kg^{-1}	ppm of Total Rb	Bq kg^{-1}	ppm	Bq kg^{-1}	ppm	Bq kg^{-1}
Igneous Rocks								
Basalts - Average	0.8	300	40	30	3-4	10-15	0.5-1	7-10
Mafic Basalts	0.3 - 1.1	7-400	10-50	1-40	1.6, 2.7	7, 10	0.5, 0.9	7-10
Rhyolites	4.5	>1000	170-200	150-180	16, 20	60, 80	3.9, 4.7	50, 60
Granite - Average	>4	>1200	170-200	150-180	17	70	3	40
Sedimentary Rocks								
Shales - Sandstones	2.7	800	120	110	12	50	3.7	40
Quartz Sandstones	<1	<300	<40	<40	<2	<8	<1	<10
Silty Sandstones	2	400	90	80	3-6	10-25	2-3	40
Arkoses	2-3	600-900	80-120	80	2	<8	1-2	10-25
Beach Sands (unconsolidated)	<1	300	40	40	6	25	3	40
Carbonate Rocks	0.3	70	10	8	2	8	2	25
Upper Continental Crust (Lithosphere)	2.8	850	112	100	10.7	44	2.8	36
Soils	1.5	400	65	50	9	37	1.8	66

Source: NCRP 1994

Table 5B. Concentrations of U and Th in Accessory Minerals.

Accesory Mineral Phases	Total Uranium (ppm)	Total Thorium (ppm)	Th/U
Allanite {accessory	30-700	500-5000	5-10
{pegmatitic	?-100	1000-20000	High
Apatite {accessory	5-150	20-150	1
{coarse aggregate	10-50(?)	50-250(?)	1-5
Epidote	20-50	50-500	2-6
Ilmenite	1-50	-	-
Magnetite (and other opaques)	1-30	0.3-20	
Monazite	500-3000	25000-200000	25-50
Sphene	100-700	100-600	1-2
Zenotime	500-35000	Low	Low
Zircon {accessory	300-3000	100-2500	0.2-1
{pegmatitic	100-6000	50-4000	1

Adapted from Ivanovich and Harmon (1982)

- Natural phenomena such as earthquakes, volcanoes, glaciers and changes in soil composition from flooding.

- Water is the dominant transporting medium. Glacier-derived deposits are common in the Great Lakes area, New England, and Alaska. Outwash erosion products from mountains may produce a soil surface that is more radioactive than the underlying bedrock.

- Wind can be a significant factor, particularly in the Southwest United States.

Mobilization and Redeposition of NORM

(Largely taken from the CRCPD E-4 Committee Report on NORM Contamination and D&D - CRCPD 1994a).

In addition to the geological weathering of rock and soil, NORM concentrations and exposure rates vary because of physical and chemical processes, both natural and anthropogenic. If mobilized, the NORM radioisotopes are available for transport. When radionuclides are dissolved in groundwater, the isotopes tend to travel with the water until redeposition takes place. Airflow serves to transport fine particulates, combustion or volatilization products. Radon, a noble gas, moves in the vapor phase. Radon emanation coefficients will vary depending on the matrix; vitrified products will release less radon than a sandy matrix. We will discuss radon emanation in the sections pertaining to industrial sectors.

Mobilization by human activity can be intentional or unintentional. Two examples are:

1) Uranium extraction by *in situ* leaching maximizes solubility of uranium.

2) Unintentional mobilization occurs when the element is desirable for its non-radiological properties. Vanadium and uranium were originally mined for their non-radiological properties. Usually, however, the TENORM isotope is mobilized along with other minerals of interest.

Generally, redeposition of NORM involves the same factors as mobilization. Changes in any of the parameters of a stream of material may result in reduced mobility and subsequent redeposition. These processes may also take place preferentially; concentrations of specific minerals may occur. Examples include chlorination of metallic ores as one step in metal production mobilizes radium, which accompanies uranium in the ore. The high solubility of $RaCl_2$ relative to other species leads to extraction of radium wherever the parent mineral is exposed to chloride ions. Production of brine or brine-contaminated oil includes dissolved radium as well, since the brine contains chloride ions.

- Low solubility of alkaline earth SO_4^{2-} (sulfate) species is also a factor in redeposition of NORM. Movement of sulfuric acid solutions through piping in mineral extraction processes is known to cause precipitation of scale containing high concentrations of radium. Production of water containing sulfate-bearing solutions can also cause precipitation of pipe scale containing elevated concentrations of uranium.

- Groundwater chemistry may change as the water reaches the surface or as it passes through different strata and the dissolved minerals form at the surface. Changes in pH, oxidation state, or chemical equilibrium may result in precipitation of dissolved minerals. This mechanism accounts for the existence of many ore bodies. Addition of alum and softening chemicals in drinking water treatment plants similarly precipitates radium with the other minerals. Uncontrolled discharges from tailings may contain radionuclides (as well as other heavy metals).

- Oxidation-reduction potential can affect solubility. Variation in oxidation state affects solubility since the formation of many chemical complexes depends strongly on oxidation state. For example, water exposed to sulfur-bearing minerals generally exhibits reducing potential, which may alter the oxidation state of other minerals in contact with the water.

- Adsorption depends on the substrate and the specific species in question. Clays are known to adsorb some chemical species preferentially over others; passage of groundwater through a layer of clay may strip out NORM species that would otherwise travel with the water. Adsorption of radon on activated charcoal is an equilibrium process. Desorption can occur if the ambient radon concentration drops; saturation can prevent further radon removal.

- Ion exchange is used to control water chemistry, typically to remove contaminants, soften potable water, or remove radium. Ion exchange does not cause mobilization of radionuclides, but once mobilized in water, any subsequent treatment by ion exchange has clear potential for reconcentration.

- Temperature-dependent variations in solubility result in increased concentrations of radionuclides, together with other elements in geothermal waters. Thermal processes can mobilize radionuclides. Any high-temperature process such as furnaces, kilns, roasters, calcination, and smelting can volatilize lead and polonium. Combustion of coal or lignite volatilizes some isotopes (thorium, uranium, radium, and bismuth). Subsequent redeposition may occur in process equipment, in pollution control equipment, or in the environment. Minerals dissolved in naturally occurring geothermal waters typically plate out as the temperature drops. Deposits of scale containing substantial concentrations of radionuclides may result.

- As the water comes to the surface and the partial vapor pressure drops, radon dissolved in water partitions into the air. In open air, dilution, convection, and diffusion minimize increases in concentration, but in caves or buildings, higher concentrations of radon and its progeny may result. Brines exhibit similar behavior. Oil mixed with brine brings radium with it; as the chemical and physical conditions change in the pipe string and at the well head, the radium precipitates with other minerals and forms scale inside the piping.

- Mechanical reduction in particle size enhances the potential for mobilization of material, such as erosion, movement of alluvial or glacial particles, bulldozers, mining, and construction. In addition, radionuclide concentrations can increase when part of the matrix is removed, leaving radionuclides behind in increased concentrations in the residue. Extraction of phosphate from ore leaves uranium behind in filter cake; bauxite ore contains aluminum, which is extracted leaving "red mud" containing uranium. Coal combustion leaves uranium in ash and slag.

- Suspended materials settle out of material streams as the velocity decreases. Fines settle out where the current is slowest, with successively coarser material settling out in the faster sections. Such gravimetric separation may result in deposits of zircon or monazite sands. Airborne particles exhibit similar behavior, with the coarser material settling closest to the source.

VARIABILITY OF BACKGROUND RADIATION

Background radiation varies over a range of concentrations and exposure rates from a variety of causes. The magnitude of variation can be significant over a short distance and also can vary in the same place from time-to-time. The background variance can result from natural as well as human activities. Understanding the characteristics of background radioactivity, and the wide range of background values encountered in the field is beneficial when designing and conducting surveys. This is especially important because some of the current regulatory exclusion limits are set at an activity or exposure rate above background (EPA 1980). Proposed clean-up guidance is essentially indistinguishable from background (NRC 1997). Variation due to geology, chemical and physical mobility and deposition, temporal, and human affects should all be considered.

TEMPORAL VARIABILITY OF BACKGROUNDS

Temporal changes in background radioactivity range occur over a wide range of timeframes; hours to days, months to years, and centuries or more. Short and medium term

changes in background have been measured (Maiello 1997). There are changes in background from terrestrial and cosmic sources that can be summarized as follows (NUREG-1501):

- Cyclic changes on a daily basis are due to changes in radon concentrations in air, which are dependent on the atmosphere (**Fig. 4**). Early mornings are typically calm, so radon escaping from the ground stays near the surface causing radon levels to rise. During the day, the sun warms the ground and air near it rises, generating a mixing effect that sends the radon (and its progeny) to higher levels in the atmosphere, thus lowering the radon level.

- Diurnal Variation Dose rates rise gradually as soil dries out. Water shields the radiation coming from the NORM in the ground, and dilutes the concentrations of NORM in the soil. After rainfall, the background values drop.

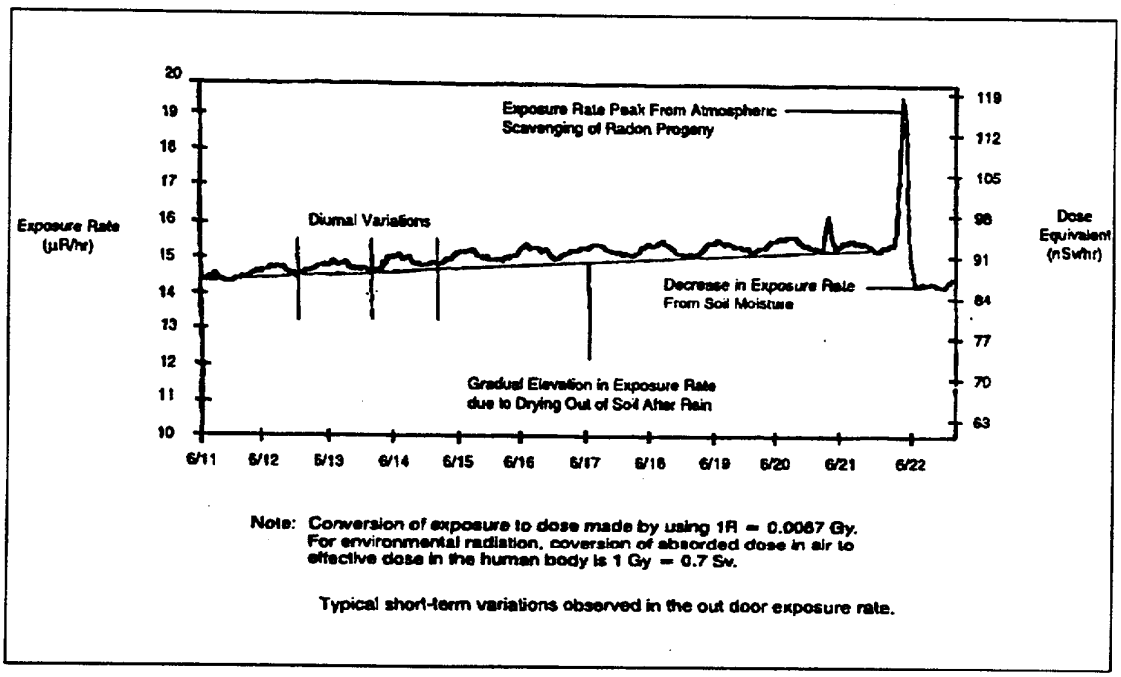


Figure 4. Diurnal Variation of Radon Emanation.

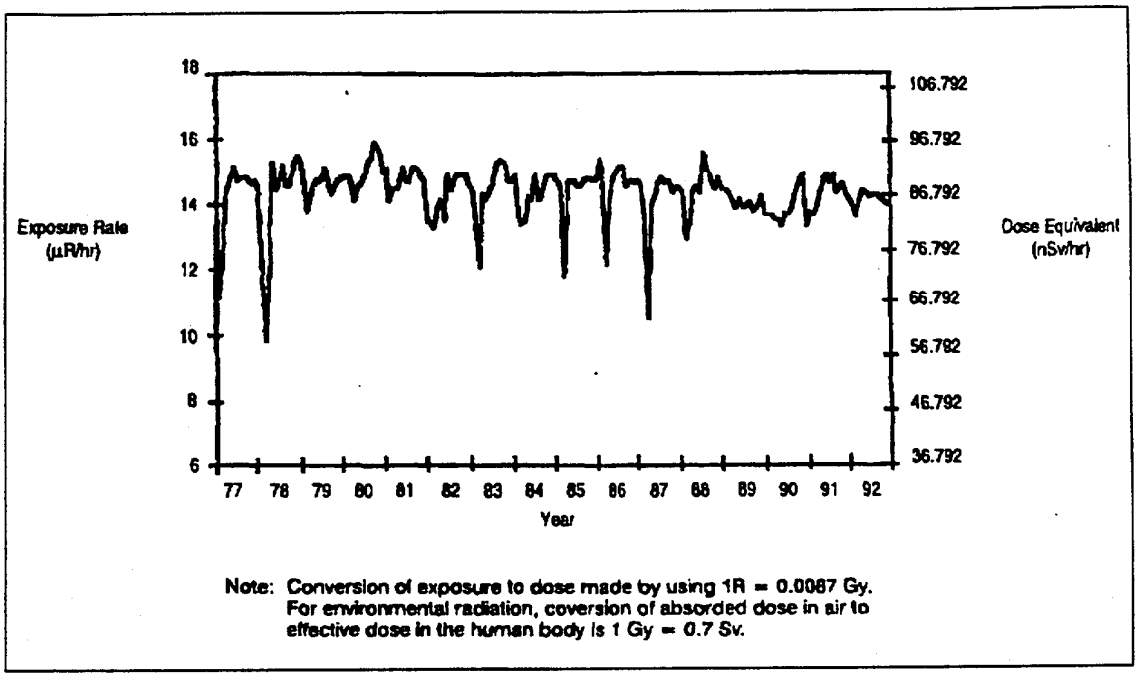


Figure 5. Shielding effect of snow cover on exposure rates and dose equivalence.

- Rainfall scours radon and its progeny from the atmosphere, causing radiation levels to rise at ground level. Some larger storms may double the gamma exposure rate for a short period of time.

- The shielding effect of snow is substantial (**Fig. 5**). Shielding is dependent on the water equivalent of the snow because a heavy wet snow is more effective at shielding than a dry snow.

- Daily and longer term variations in background are due mostly to changes in soil moisture content and snow cover. Winter months trend to lower radiation levels because of higher soil moisture and summer months trend toward higher levels because of lower soil moisture. Seasonal effects actually average out over the course of a year (**Fig. 6**).

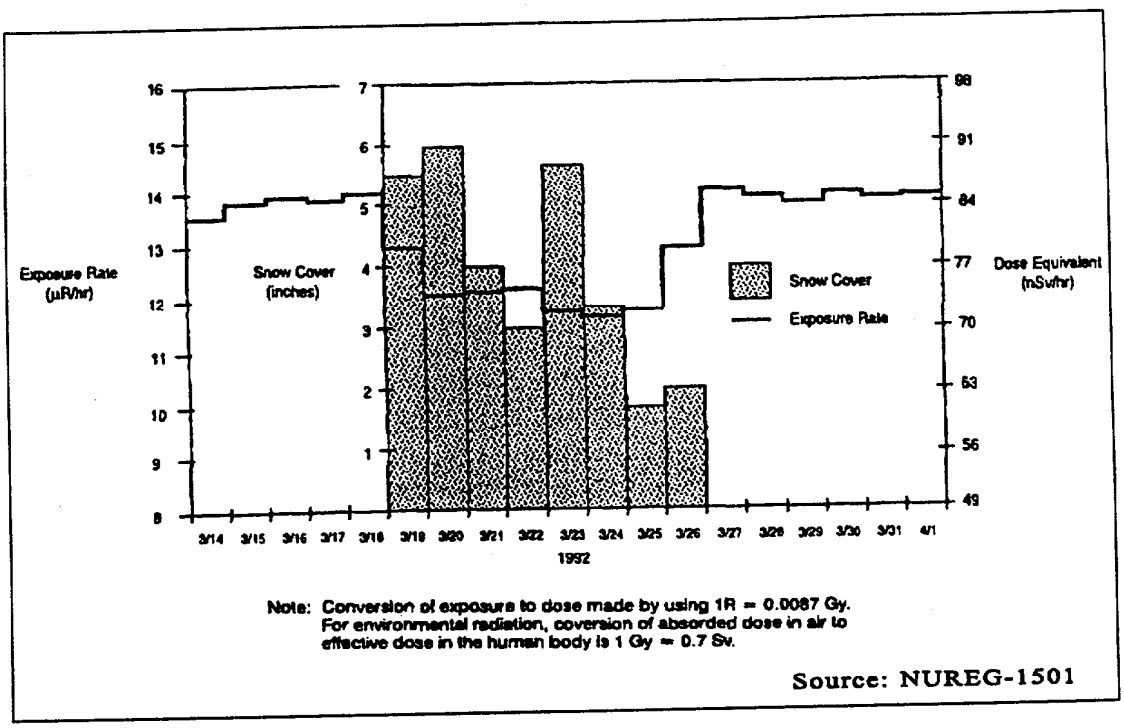


Figure 6. Daily and Longer Term Variations in Background Radiation. These variations are primarily due to changes in soil moisture content and snow cover.

- Anthropogenic activities also affect background values. According to NUREG 1501 (NRC 1994a), about two-thirds of the background gamma dose comes from NORM contained in the top 15 cm of soil out to at distance of 6 meters from where a person stands. Therefore, ground coverings, (e.g., asphalt, concrete) may decrease the gamma exposure rate. Conversely, building materials may contribute to dose. The magnitude of change depends on the amount of material involved, and relative radionuclide concentrations in the old and new situations.

- Background increases have been related to nuclear accidents and weapons tests.

- Cosmic ray variations tend to be small and result from changes in barometric pressure. With a high pressure system, there is a larger mass of air to provide a shielding effect, as compared to a low pressure system, which has less air mass and less shielding.

- Cosmogenic radionuclide production varies according to changes in the cosmic ray intensity. A more active sun produces changes in the solar wind and magnetic field, which oppose the cosmic rays coming from outside the solar system.

- Seasonal changes also occur in the deposition of cosmogenic radionuclides on the ground. Deposition is greater during the spring months when air in the stratosphere mixes with air in the troposphere. As mixing occurs, cosmogenic material fluxes to the surface usually increase with higher precipitation rates.

INDUSTRIAL SECTORS WITH TENORM

Data in this section are taken primarily from EPA (1993).

The majority of TENORM issues center on waste from industrial processes. Most of the wastes that are discussed are produced in very large volumes, but are of relatively low specific radioactivity. While some wastes are disposed of, others are put to commercial uses. The improper disposal, re-use, and recycling of diffuse TENORM has led to circumstances resulting in contamination events and unnecessary public exposures. Disposal in piles or stacks can lead to groundwater contamination and to airborne releases of radioactive particulates and radon. Improper use and/or disposal, such as for soil conditioning or fill around homes, can lead to buildup of radon gas in homes, direct exposure to individuals, and contamination of soil and of the crops growing in the soil. Reuse of TENORM- contaminated materials, such as in concrete aggregate, can lead to increased radiation risks to members of the public in a variety of ways.

This overview is not comprehensive. It is representative of the types of industries that have TENORM. The summaries presented in EPA 1993 were extracted from studies that were conducted to characterize the presence of radioactivity, industry practices, and waste and materials. It should be noted that quality data are not available for many of these industries, and some sectors are not overly willing to share data. Therefore, the data presented in **Table 6** are often extrapolated and best estimates. The main radionuclides investigated in the uranium series

in industrial TENORM situations are ^{238}U, ^{234}U, ^{230}Th, ^{226}Ra, and ^{222}Rn (and progeny). In the thorium series, we look at ^{232}Th, ^{228}Ra, and ^{220}Rn (and progeny). In addition, ^{40}K should be characterized. Radium-226 is used here to show the relative activity and volume among the TENORM sectors. In assessing dose and risks, all radionuclides need to be considered. Eight industrial sectors will be examined:

- Uranium mining overburden
- Phosphate waste
- Phosphate fertilizers
- Coal ash
- Oil and gas scale and sludge
- Water treatment
- Metal mining and processing (including Rare Earths and Other Metals)
- Geothermal energy production wastes.

Uranium Overburden and Mine Spoils

Unlike ore (source material) and mill tailings (byproduct material), uranium overburden is not regulated by the Atomic Energy Act (AEA 1954) or the Uranium Mill Tailings Remedial Action (UMTRA) program (EPA 1980), and therefore is considered TENORM.

The uranium mining industry began in the 1940s primarily for the purpose of producing uranium ore for use in weapons and soon after for nuclear fuel fabrication. The majority of the mines are located in the west, mainly in Utah, Colorado, Wyoming, Arizona, South Dakota, New Mexico, and Texas. Mining of uranium ores by surface and underground methods produces large amounts of bulk material, including overburden, low-grade ore, and mining spoils. Surface mining produces the bulk of the spoils.

Table 6. Estimated TENORM Annual Production Rates and Average ^{226}Ra Specific Activities

Material/Waste Stream	Production Rate (metric tons *per* year)	Average ^{226}Ra Concentration, Bq g-1 ($\rho Ci\ g^{-1}$)
Uranium overburden	3.8E+07	0.92 (25)
Phosphate waste		
- Phosphogypsum	4.8E+07	1.2 (33)
- Slag	1.6E+06	1.29 (35)
Phosphate fertilizers*	4.8E+06	0 .31 (8.3)
Coal ash	6.1E+07	0.14 (3.7)
- Fly ash	4.4E+07	0.14 (3.9)
- Bottom ash and slag	1.7E+07	0.11 (3.1)
Oil and gas scale and sludge	2.6E+06	3.33 (90)
Water treatment	3.0E+06	0.59 (16)
- Sludges	2.6E+06	0 .59 (16)
- Radium selective resins	4.0E+04	1295 (35,000)
Metal mining and processing	1.0E+09	0.18 (5)
- Rare Earths	2.1E+03	33.3 (900)
- Zirconium, hafnium, titanium, and tin	4.70E+05	1.59 (43)
- Large volume industries (e.g., copper, iron)	1.0E+09	0.18 (5)
Geothermal energy production wastes	5.4E+04	4.9 (132)

Adapted from EPA (1993) and Hull (1996, 1997)

*Phosphate fertilizers shown above in **Table 6** are not wastes, but are included in this tabulation due to their widespread use; especially in North America.

Overburden, which overlies the ore deposit, contains limited amounts of natural uranium and its progeny; average ^{226}Ra concentrations are .92 Bq g^{-1} (25 ρCi g^{-1}) (**Table 7**).

Table 7. Radionuclide concentrations of Environmentally Significant Radionuclides in Uranium Mining Overburden

Radionuclide	Concentration Bq g^{-1} (ρCi g^{-1})
^{238}U	0.92 (25)
^{234}U	0.92 (25)
^{230}Th	0.92 (25)
^{226}Ra	0.92 (25)
^{210}Pb	0.66 (18)
^{210}Po	0.66 (18)
^{235}U	0.048 (1.3)
^{231}Pa	0.048 (1.3)
^{227}Ac	0.048 (1.3)
^{232}Th	0.037 (1.0)
^{228}Ra	0.037 (1.0)
^{228}Th	0.037 (1.0)

Source: EPA (1993)

Mining spoils include low-grade ore and other materials excavated during the mining process. Low-grade ore contains significant amounts of uranium, but usually not enough to make milling economically attractive. The concentrations of ^{226}Ra at the interface of overburden and low-grade ore boundaries vary from about 0.1 to ~10 Bq g^{-1} (three to several hundred ρCi g^{-1}).

The estimated total volume of mine waste produced is about 4 billion metric tonnes (MT), almost 90% of this within the last 20 years by surface mining. Although demand has fallen off, the deposits that were recently mined are of lower quality and harder to access; therefore, the amount of waste *per* volume of ore generated has increased significantly. As of 1988, there were 3.1 billion MT of unreclaimed overburden in the United States. Uranium mining and milling in America had virtually ceased due to market forces. However, there is now some renewed interest in mining and milling of uranium because stockpiles are low and the price of uranium is rising.

Most uranium overburden is piled and stabilized where it is mined. Uranium overburden has few uses. It is typically used for backfilling mined out areas and for constructing site roads. Mine reclamation will utilize overburden as the practice is implemented. Only about 4% of the mines have been reclaimed. ORNL has found overburden and mine muck used as road aggregate in Colorado (Rice 1995).

Most areas where uranium mining has occurred are remote and arid. These areas are starting to become more populated, and chances for exposures to populations are increasing. A good example of this phenomena is Moab, Utah. The population of Moab was stagnant and actually decreasing during the 1970s and early 1980s. The population of Moab has increased dramatically in recent years with the advent of recreational activities like mountain biking and river rafting. Not only is the population increasing, but tourism in the back country is increasing. The possibility of exposure to TENORM is a concern because numerous uranium mines are located in eastern Utah. These abandoned mines have spoils piles that may not be under any control, and can be accessible. Old mining roads into the back country are used by the recreationists.

Radon concentrations are reduced by escape through diffusion and advection at varying rates. The amount of ^{210}Po and ^{210}Pb are also reduced by the amount of radon lost. If a radon emanation coefficient of 0.3 is used (sandstone matrix), the ^{210}Po and ^{210}Pb concentrations are 0.7 times that of ^{226}Ra or about 0.66 Bq g^{-1} (18 ρCi g^{-1}). Radon rates were not given because its release rate from the surface of the overburden was determined from the ^{226}Ra concentration.

Phosphate Industry Wastes

Phosphate rock extraction is the fifth largest mining industry in the United States in terms of quantity of material mined. Domestic production from these open pit mines was 38 million metric tonnes (MT) in 1988. Florida produces about 80% of domestic capacity, with North Carolina and Tennessee generating 10% and Idaho, Utah, Montana and Wyoming the balance. Phosphate rock is processed to produce phosphoric acid and elemental phosphorus. These are then combined with other chemicals to produce phosphate fertilizers, detergents, animal feeds, other food products, and phosphorous chemicals. The production of fertilizers accounts for over 90% of the phosphate rock demand in the United States.

Phosphate ore contains one-third quartz sands, one-third clay minerals, and one-third phosphate particles. Uranium in phosphate ores ranges in concentration from 20 to 300 ppm (0.26 to 3.7 Bq g^{-1}) (7 to 100 ρCi g^{-1}). Thorium is present in background amounts, ~1 to 5 ppm (3.7 to 22.2 mBq) (0.1 to 0.6 ρCi g^{-1}). When the phosphate particles are separated from the bulk ore (beneficiated), two types of wastes are produced: phosphatic clay tailings and sand tailings (**Fig.7**). The clay slimes contain 48% of the radionuclides in the host ore, the sand tailings contain 10%, and the remaining 42% are carried by the phosphate rock. Florida clay slime contains about 1.67 Bq g^{-1} (45 ρCi g^{-1}) ^{226}Ra.

Phosphogypsum is the principal waste by-product generated during the phosphoric acid production process (wet process), and phosphate slag is the principal waste by-product generated from the production of elemental phosphorous (thermal process). It is estimated that there have been over 8.2 billion MT (9.1 billion short tons) of phosphogypsum generated globally between 1910 and 1991. Impurities contained in the phosphogypsum and phosphate slag include uranium and thorium and their progeny (**Table 8**). These can become concentrated in the waste by-products.

Phosphatic clay tailings
Sand Tailings
Phosphogypsum

Clay Slimes 50%
Sand Tailings 10%.

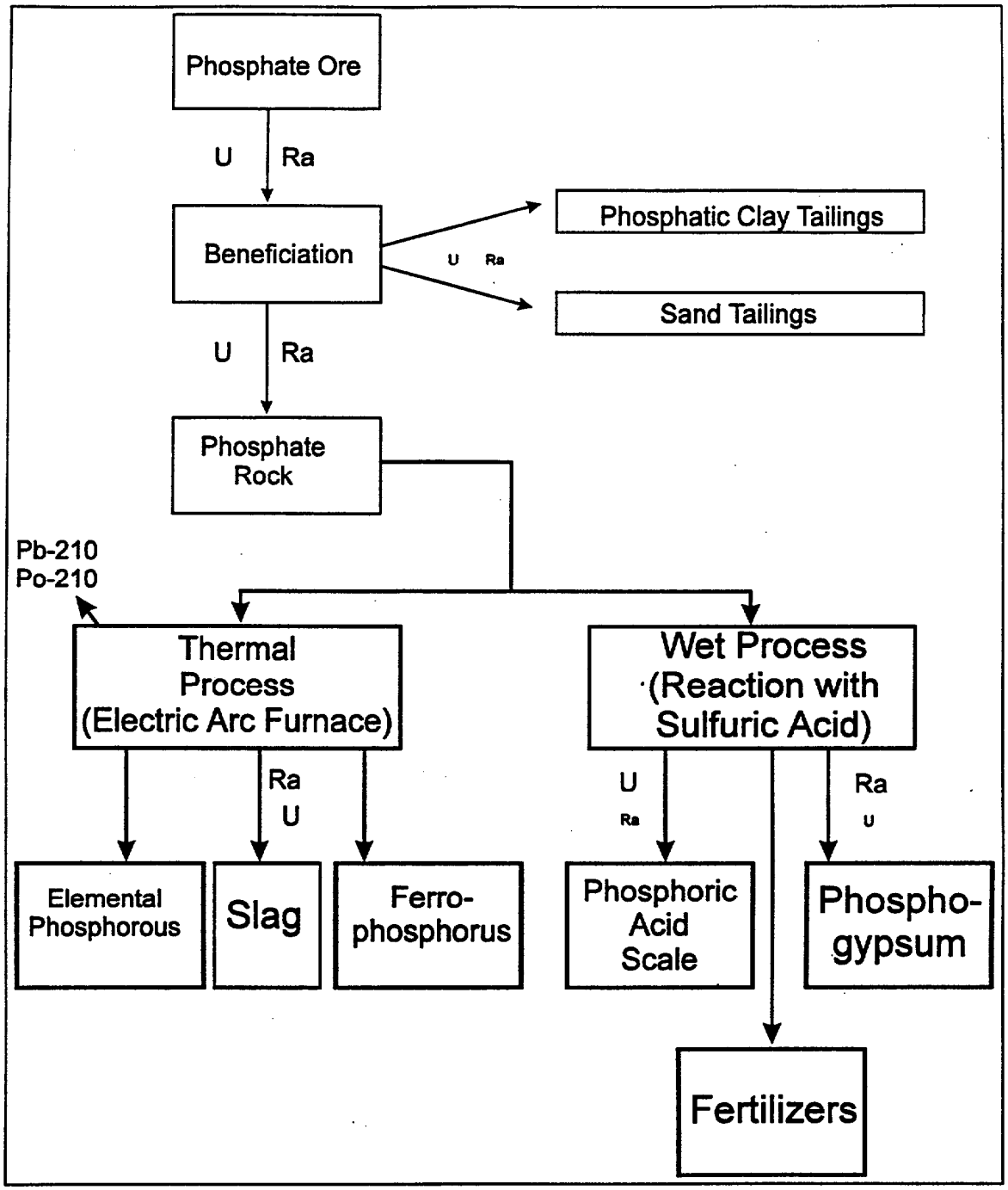


Figure 7. Schematic Production Flow Diagrams of the Thermal and Wet Processes for Manufacture of Phosphate Fertilizers.

Table 8. Radionuclide Concentrations in Phosphogypsum

Radionuclide	Concentration, Bq g-1 (ρCi g^{-1})
^{238}U	0.22 (6.0)
^{234}U	0.23 (6.2)
^{230}Th	0.48 (13)
^{226}Ra	1.22 (33)
^{210}Pb	0.96 (26)
^{210}Po	0.96 (26)
^{235}U	0.01 (0.30)
^{231}Pa	0.01(0.30)
^{227}Ac	0.01 (0.30)
^{232}Th	0.009 (0.27)
^{228}Ra	0.009 (0.27)
^{228}Th	0.052 (1.4)

Source: EPA (1993) and Hull (1996a,b; 1997)

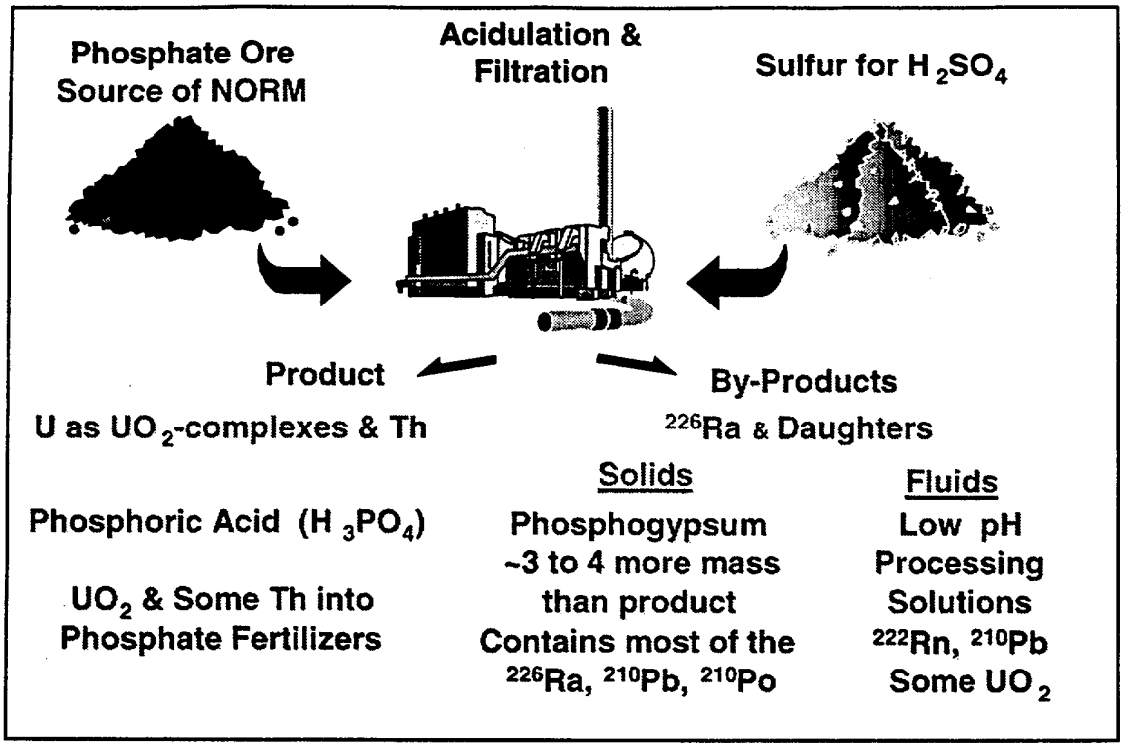


Figure 8. A Generalized Flow-Chart of the "Wet Process" Production of Phosphoric Acid from Phosphate Ore Rock.

A schematic diagram of the "wet-process" of phosphoric acid production and the fractionation of TENORM in this process is shown in **Fig. 8**. The sulfur is usually processed into sulfuric acid at the fertilizer production facility. The sulfuric acid, water, and ore are reacted under controlled conditions to maximize the production of phosphoric acid. The phosphoric acid is filtered through large, woven polypropylene filter screens under a partial vacuum to separate the majority of solid, by-product phosphogypsum (PG). The phosphoric acid is pumped to storage tanks and again filtered prior to reaction with liquid ammonium to produce diammonium phosphate fertilizers. These fertilizers contain almost all the uranium and most the thorium from the ore rocks.

About 85% of the ^{226}Ra follows the phosphogypsum, while about 86 % of the uranium and 70% of the thorium are found in the phosphoric acid. Typical radium concentrations in Florida

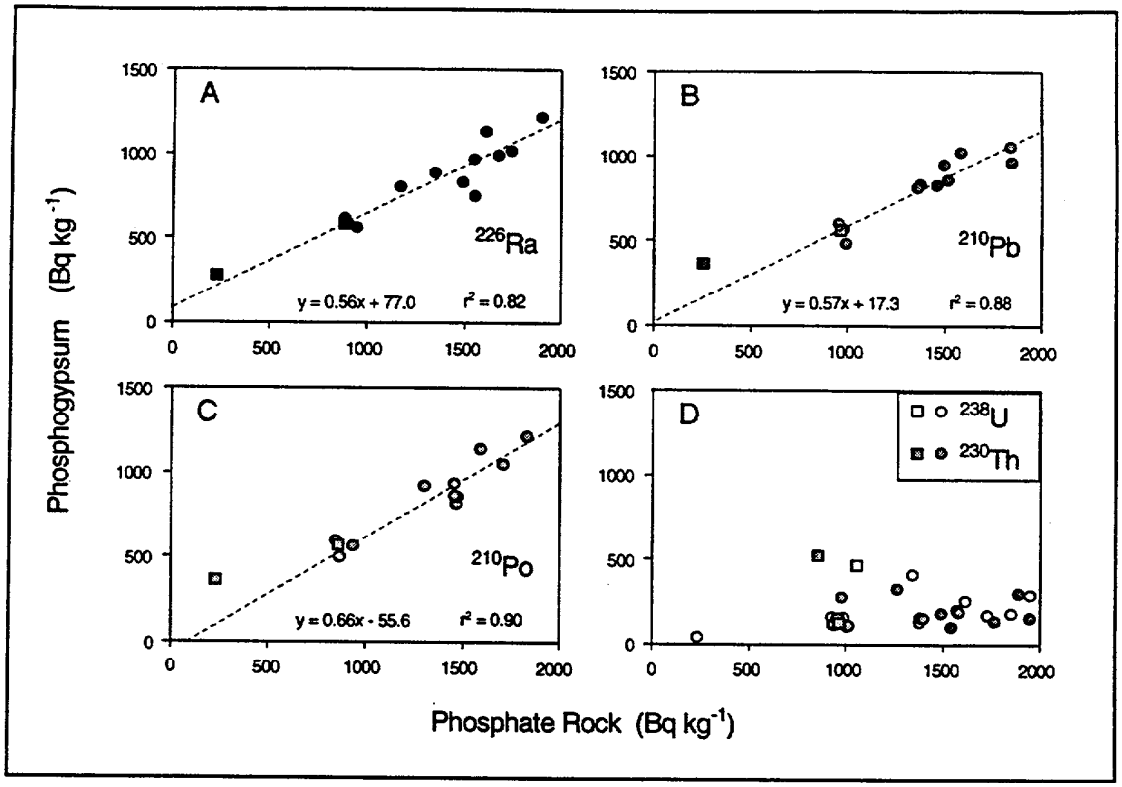


Figure 9. Cross-Plots of the Fractionation Of ^{238}U, ^{230}Th, ^{226}Ra, ^{210}Pb, and ^{210}Po from Phosphate Ore to the Corresponding Phosphogypsum By-Product.

phosphogypsum stacks fall within a range of 0.41 to 1.3 Bq g^{-1} (11 to 35 pCi g^{-1}), with progeny also in that range. About 88% to 92% of the radium (^{226}Ra) and lead (^{210}Pb) are fractionated to the phosphogypsum.

During the wet process, there is selective separation and concentration of radionuclides. Cross-plots of radionuclides in the phosphate ore rock being acidulated (plotted on the abscissa) at the time the corresponding phosphogypsum samples (ordinate) were collected as shown in **Fig. 9**. These plots illustrate the fractionation and re-distribution of radionuclides of interest during the processing of phosphate rock into phosphoric acid in Florida. Virtually all of the polonium (^{210}Po) is also included in the phosphogypsum. The slopes of the best-fit, regressed lines for these ore rock - phosphogypsum pairs is not 1 due to the stoichiometry of the reaction; about 1.7 grams

of phosphogypsum are produced for each gram of phosphate rock. It is easily discerned from this graph most of the U and Th are ending up in the phosphoric acid and processing solutions.

Phosphate production wastes, primarily phosphogypsum, is stored in large stacks which are commonly referred to as "gyp-stacks." The solid by-project PG is slurried with processing solutions and discharged onto the adjacent gyp-stack.. These stacks are huge and often cover 4 to 12 km^2 with an average height of 35 m. The slurries "de-water" and huge volumes of PG accumulate in storage "stacks" that cover a number of square kilometers at each fertilizer plant. Each facility may have one or more stacks that range from 2 to 300 hectares and range in height from 3 to 60 meters. Much of the stack is covered with low pH (2.5 or less), very high ionic strength solutions in ponds and ditches.

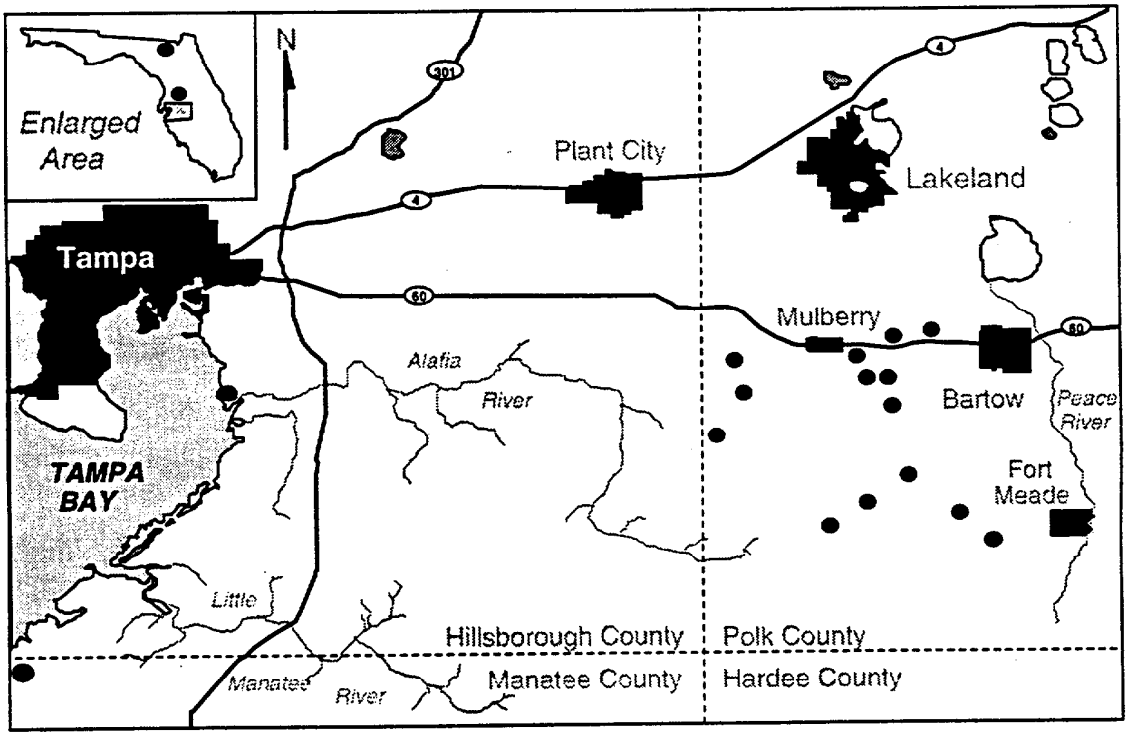


Figure 10. Phosphogypsum storage stacks in Florida (gyp-stacks). Most stacks are not lined to prevent contamination of the groundwater aquifers with high ionic strength, low pH solutions that contain TENORM.

Within Florida alone there are over 20 active and inactive gyp-stacks (phosphogypsum is no longer being deposited on inactive stacks). The locations of these gyp-stacks in Florida are shown in **Fig. 10**. Within the next two years storage of this water-soluble, radioactive waste shall exceed $1x10^9$ tons. Most of these "gyp-stacks" have been deposited directly on the land surface without any liners or other physical to reduce the flux of high ionic strength and radionuclide-bearing solutions into groundwater reservoirs. One of the larger of these "gyp-stacks" recently "fell-into" the Floridan Aquifer system. The acidic solutions emanating from these stacks dissolved the underlying carbonate rocks. Thousands of tons of this material was introduced into one of the largest fresh water aquifer systems in North America just upgradient of Tampa, Florida.

Radon flux rates from phosphogypsum stacks vary widely, due to the radium concentration in the parent rock, the emanation fraction, and other factors. Average fluxes have been reported to vary from 0.063 to 0.44 Bq $m^{-2}s^{-1}$ (1.7 to 12 ρCi m^{-2} s^{-1}), with a mean value of 0.25 Bq $m^{-2}s^{-1}$ (6.8 ρCi m^{-2} s^{-1}). The radon emanation coefficient for phosphogypsum is estimated at a value of 0.2.

Gamma radiation exposure rates from phosphogypsum stacks have been measured around ~0.287 μSv hr^{-1} (33 μR hr^{-1})[1]. Radiation surveys conducted in areas where large volumes of phosphate ores are stockpiled have yielded gamma exposure rates ranging from ~0.174 to 0.87 μSv hr^{-1} (20 to 100 μR hr^{-1}), with an average of ~0.522 μSv hr^{-1} (60 μR hr^{-1}).

Some phosphogypsum is used for agricultural and construction purposes. EPA has ruled that "Phosphogypsum intended for agricultural use must have a certified average concentration of ^{226}Ra of no greater than 10 ρCi g^{-1}" (EPA 1992). However, virtually no phosphogypsum has specific activities of ^{226}Ra in this low range; the great majority averages 20 to 35 ρCi g^{-1} (Hull, 1997).

[1] Conversion from exposure to dose made by using 1R=0.0087 Gy. A quality factor of 1.0 is used to convert from Gy to Sv.

In contrast to the "wet-process," during the thermal process vitrification yields slag, a material that contains the non- volatile radionuclides. This slag has been found to contain uranium and thorium concentrations in the range of 0.74 to 1.85 Bq g^{-1} (20 to 50 ρCi g^{-1}) and ^{226}Ra concentrations in the range of 0.15 to 1.5 Bq g^{-1} (4 to 40 ρCi g^{-1}) (**Table 9**). Because of the high temperatures, some radionuclides are vaporized during the process. As much as 95% of the ^{210}Pb and ^{210}Po have been measured in stack releases. Eventually, these isotopes decay and grow back into equilibrium with the ^{226}Ra.

Table 9. Radionuclide Concentrations in Phosphate Slag

Radionuclide	Concentration Bq g-1 (ρCi g^{-1})
^{238}U	0.92 (25)
^{234}U	0.88 (24)
^{230}Th	1.19 (32)
^{226}Ra	1.26 (35)
^{210}Pb	1.26 (35)
^{210}Po	1.26 (35)
^{235}U	0.05 (1.3)
^{231}Pa	0.05 (1.3)
^{227}Ac	0.05 (1.3)
^{232}Th	0.03 (0.77)
^{228}Ra	0.03 (0.77)
^{228}Th	0.03 (0.77)

Source: EPA (1993)

The total slag inventory in the United States in 1991 is estimated at 224 to 424 million MT (247 to 467 million short tons). The radon emanation coefficient for slag is estimated to be very low because of the vitrified matrix. A value of 0.01 was assumed for the referenced report.

Radon flux measurements conducted on Idaho slag indicate that very little radon escapes the vitrified slag matrix. An average radon flux rate of 0.02 Bq $m^{-2}sec^{-1}$ (0.5 ρCi m^{-2} sec^{-1}) is estimated for a typical phosphate slag pile. For comparison, measurements taken on two phosphate ore samples revealed radon fluxes of 2.11 and 2.37 Bq $m^{-2}sec^{-1}$ (57 and 64 ρCi m^{-2} sec^{-1}); radon fluxes from native soil samples ranged from 0.063 to 0.63 Bq $m^{-2}sec^{-1}$ (1.7 to 17 ρCi m^{-2} sec^{-1}).

Gamma radiation exposure rates of ~0.87 μSv hr^{-1} (100 μR hr^{-1}) have been measured on slag piles. Phosphate slag has been used as aggregate in making roads, streets, pavements, residential structures, concrete aggregate, railroad ballast, and buildings. Radiation surveys conducted in Montana and Idaho where slag has been used in construction materials and to pave streets have yielded measurements of ~0.565 μSv hr^{-1} (65 μR hr^{-1}) in homes and ~0.435 μSv hr^{-1} (50 μR hr^{-1}) on streets that utilized slag.

Phosphate Fertilizers and Potash

Phosphate fertilizers are one of the end products from the phosphate industry just discussed. Phosphate and potassium are also found in multiple-nutrient fertilizers, which are available in different blends of nitrogen (N), phosphorous (P), and potassium (K).

Potash is another material used as a fertilizer that contains natural radioactivity, primarily ^{40}K. Potash is composed principally of the salts of potassium, of which potassium chloride and potassium sulfate are the major components.

Phosphate fertilizers are produced by mixing phosphoric acid directly with phosphate rock. Ammonia and potassium salts are also added to produce a variety of fertilizers. Mined from sylvinite ore or produced by solar evaporation, potash can be used directly as a fertilizer without extensive chemical conversion. The continued widespread use of phosphate fertilizers may eventually result in a measurable increase in background radiation levels.

Radionuclide concentrations vary with the type of fertilizer and production process, with average concentrations ranging from 0.18 to 0.74 Bq g^{-1} (5 to 20 ρCi g^{-1}) for ^{226}Ra, 0.74 to 2.22 Bq g^{-1} (20 to 60 ρCi g^{-1}) for uranium, and 0.037 to 0.18 Bq g^{-1} (1 to 5 ρCi g^{-1}) for thorium (**Table 10**). The activity of ^{40}K in potash depends of the quantity of potassium present, which is normally expressed as equivalent mass of K_2O. The equivalent concentration of ^{40}K in potash is about 25.75 Bq g^{-1} (696 ρCi g^{-1}) K_2O. Since marketable potash contains about 60% K_2O, the concentration of ^{40}K in the final product calculates to approximately 15.5 Bq g^{-1} (420 ρCi g^{-1}).

Radon fluxes for phosphate fertilizers in soil are expected to be similar to those for unfertilized soils. A typical flux for a fertilized soil is approximately 0.037 Bq m^{-2} (1.0 ρCi m^{-2}) *per* ρCi g^{-1} of ^{226}Ra. The external gamma radiation attributable to fertilizer materials is only about 0.25% of that from unfertilized soil.

Table 10. Radionuclide Concentrations in the Average Phosphatic Fertilizer

Radionuclide	Phosphate Fertilizer	Potash
	Concentration, Bq g-1 (ρCi g^{-1})	
^{40}K	-	25.75 (696)
^{238}U	2.04 (55)	-
^{234}U	2.07 (56)	-
^{230}Th	1.96 (53)	-
^{226}Ra	0.31 (8.3)	-
^{210}Pb	0.22 (5.8)	-
^{210}Po	0.22 (5.8)	-

^{235}U	0.096 (2.6)	-
^{231}Pa	0.096 (2.6)	-
^{227}Ac	0.096 (2.6)	-
^{232}Th	0.037 (1.0)	-
^{228}Ra	0.037 (1.0)	-
^{228}Th	0.037 (1.0)	-

Source: (EPA 1993)

Coal Ash

There are over 1,300 coal-fired boilers operated by electric utilities and nearly 60,000 industrial boilers in the United States Electric utilities consume the most coal, currently at about 700 million MT (771 million short tons) *per* year. Domestic coal production has increased, as well as imports, while exports have remained relatively stable. In 1990, 61.6 million MT (67.9 million short tons) of ash and slag were generated, with another 17.2 million MT (18.9 million short tons) of sludges. Coal consumption generates large amounts of coal ash that requires proper management and disposal, either at the point of use or elsewhere in ash impoundment facilities. Since coal contains naturally occurring uranium and thorium, large quantities of coal ash may present a potential radiological risk to exposed individuals. The degree of risk will depend on the physical and radiological properties of the ash and on how the ash is disposed of or used.

The radioactivity of coal can vary over two orders of magnitude depending on the type of coal and the region from which it is mined. The concentrations of ^{238}U and ^{232}Th in coal average about 0.022 and 0.018 Bq g^{-1} (0.6 and 0.5 pCi g^{-1}), respectively. The concentrations of the radionuclides in ash will also vary (**Table 11**). They tend to be enriched in ash compared to coal.

Electrical utility boilers generate ash at a rate of about 10% of the original volumes of coal. Over 95% of the ash is retained. Bottom ash and slag make up about 20% and fly ash makes up the other 75%. Fly ash is formed when flue gases entrain (to draw after oneself) ash.

Fly ash is very fine. The remainder of the ash that is too heavy to go off with the gas settles to the bottom of the boiler to become bottom ash.

Ash also typically contains silicon, aluminum, iron and calcium. Liquid slag is produced when the ash melts under intense heat. Treatment of stack exhausts also results in the generation of flue gas desulfurization sludges. About 17 million MT (18.75 million short tons) were produced in 1990.

Table 11. Typical Average Radionuclide Concentrations for Coal Ash

Radionuclide	Concentration, Bq g-1 (ρCi g^{-1})
^{238}U	0.12 (3.3)
^{234}U	0.12 (3.3)
^{230}Th	0.085 (2.3)
^{226}Ra	0.14 (3.7)
^{210}Pb	0.25 (6.8)
^{210}Po	0.26 (7.0)
^{235}U	0.0037 (0.1)
^{231}Pa	0.0059 (0.16)
^{227}Ac	0.0059 (0.16)
^{232}Th	0.077 (2.1)
^{228}Ra	0.066 (1.8)
^{228}Th	0.19 (3.2)

Source: EPA (1993)

The radon emanation coefficient for ash is low because the ash is vitrified. A factor of 0.02 can be used to compare to other coefficients. Radon flux is also low, estimated at 0.018 Bq $m^{-2}sec^{-1}$ (0.5 ρCi m^{-2} sec^{-1}).

About 70 to 80% of the coal ash generated is disposed of in landfills or ponds. There are about 300 off-site coal-ash landfills and surface impoundments. A typical ash disposal landfill may be anywhere from 30 to 60 hectares. It is estimated there are 305 off-site coal-ash landfills and surface impoundments and that there are about 900 on-site disposal facilities. Fly ash, bottom ash, and boiler slags are used as substitutes in cement and concrete, as structural fills, for snow and ice control, and as blasting grits. The potential impact of long-term accumulation of by-products in the biosphere should be considered (Gabbard 1993).

Coal ash is used as an additive in concrete, cement, and roofing materials, land reclamation, paint and undercoatings, and various products and as a structural fill for road construction. About 30% of ash is reused. There is concern that fly ash may become regulated in the future, which would discourage reuse.

Oil and Gas Production Scale and Sludge

The rate of production of domestic crude oil is closely tied to the international price of crude and to fluctuations that depend on world-wide political and economic conditions. Production for the month of November 1995 was estimated at 6.5 million barrels *per* day (API 1996). Production in 1970 was approximately 9.6 million barrels *per* day. It is estimated that about 25 thousand MT (27.5 thousand short tons) of TENORM scale and 230 thousand MT (253.5 thousand short tons) of TENORM sludge are generated from domestic production each year, based on 1989 figures.

Radioactivity in oil and gas production and processing equipment is of natural origin and is now known to be widespread, occurring throughout the world. Estimates suggest that up to

30% of domestic oil and gas wells may produce some elevated TENORM contamination. The geographic areas with the highest recorded measurements were northern Texas and the gulf coast crescent from southern Louisiana and Mississippi to the Florida panhandle. Very low levels of TENORM radioactivity were noted in California, Utah, Wyoming, Colorado, and northern Kansas fields.

Uranium and thorium compounds are mostly insoluble and as oil and gas are brought to the surface, remain in the underground reservoir. As the natural pressure within the bearing formation falls, formation water present in the reservoir will also be extracted with the oil and gas. Some radium and radium daughter compounds are slightly soluble in water and may become mobilized when this production water is brought to the surface. The precipitate consists principally of barium sulfate ($BaSO_4$), calcium sulfate ($CaSO_4$), and calcium carbonate ($CaCO_3$). Because the chemistry of radium is similar to that of barium and calcium (all are Group IIA elements), radium may also precipitate to form complex sulfates and carbonates.

The amount of TENORM material from a producing field generally increases as the amount of water pumped from the formation increases. Since radium concentrations in the original formation are highly variable, the concentrations that precipitate out in sludges and as scale on internal surfaces of oil and gas production and processing equipment are also variable. This scale in these chemical matrices is relatively insoluble and may vary in thickness from a few millimeters to more than an inch. Scale deposits in production equipment may at times become so thick to completely block the flow in pipes as large as 10.1 cm (4 in.) in diameter.

Radium-226 in scales generally has higher specific activities than ^{228}Ra. Typically, ^{226}Ra in scale is in equilibrium with its progeny, but ^{228}Ra is not. The nominal activity appears to be about three times greater for ^{226}Ra than for ^{228}Ra (**Table 12**).

Table 12. Average Radionuclide Concentrations in Oil and Gas Scale

Radionuclide	Concentration, Bq g (ρCi g^{-1})
^{226}Ra	13.3 (360)
^{210}Pb	13.3 (360)
^{210}Po	13.3 (360)
^{228}Ra	4.44 (120)
^{228}Th	4.44 (120)

Source: EPA (1993)

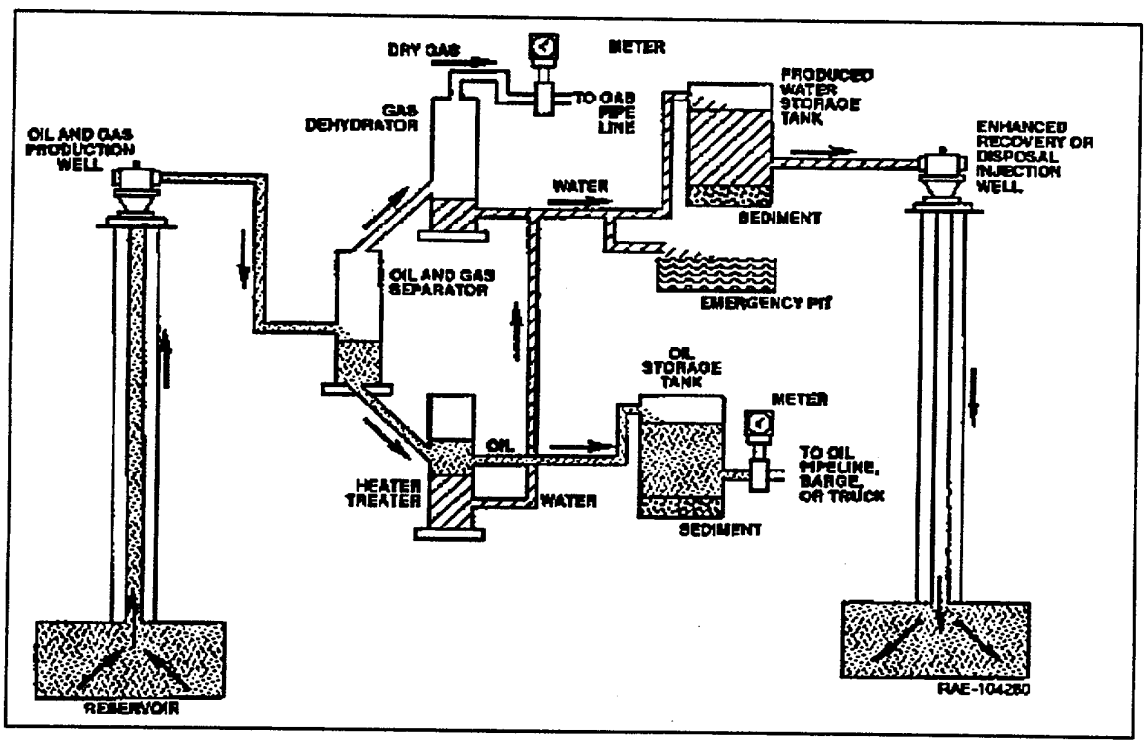


Figure 11. Schematic of Oil and Gas Processing Equipment.

The oil and gas production stream passes through a separator where the oil, gas, and water are divided into separate streams based on their different fluid densities (**Fig. 11**). Most of the solids removed in the separator accumulate there. The product may also be treated using a heater/treater to separate oil from produced water and sludge. The produced water flows from the separators into storage tanks and is often injected into disposal or recovery wells. Scales are usually found in piping and tubing, including oil flow lines, water lines, injection and production well tubing, manifold piping and small-diameter valves, meters, screens, and filters. The highest concentrations of TENORM occurred in wellhead piping and production piping near the wellhead. Concentrations of radium in scale deposited in production tubing near wellheads can range up to tens of thousands of picocuries *per* gram. The concentration of radium deposited in separators is about a factor of ten less than that found in wellhead systems. There is a further reduction of up to an order of magnitude in the radium concentration in heater/treaters. The activities in granular deposits found in separators range from one to about one thousand picocuries *per* gram. The largest volumes of scale have been found in the water lines associated with separators, heater/treaters, and gas dehydrators.

TENORM radionuclides may also accumulate in gas plant equipment from ^{222}Rn decay products, even though the gas is removed from its ^{226}Ra parent. Rn-222 concentrates in the liquid petroleum gas (LPG) fraction during processing. Gas plant deposits differ from oil production scales, typically consisting of radon decay products plated out on the interior surfaces of pipes, valves, and other gas plant equipment. The only significant radionuclides remaining in gas plant equipment are ^{210}Po and ^{210}Pb.

Radon flux rates from scale are hard to determine. Several factors, such as particle size, thickness of the deposit, and the presence of oil and other material may reduce radon flux rates. Since much of the waste is internal to components, it may be challenging to characterize net radon flux. A 0.05 radon emanation coefficient has been assumed for the referenced report (EPA, 1993).

Exposure rates vary widely depending on geographic location and the type of equipment. Median exposure rates were measured for water handling equipment in the ~0.261 to 0.348 $\mu Sv\ hr^{-1}$ (30 to 40 $\mu R\ hr^{-1}$) range. Gas processing equipment with the highest levels include reflux

pumps, propane pumps, and tanks and lines. Median exposure rates were reported to be in the ~0.348 to 0.609 μSv hr^{-1} (30 to 70 μR hr^{-1}) range. For both oil and gas processing equipment, a few measurements were observed to be in excess of ~8.7 μSv hr^{-1} (1 mR hr^{-1}).

The origin of TENORM-contaminated sludge is similar to that of scale. As the produced water is subjected to changes in temperature and pressure, dissolved solids may precipitate out of solution and deposit sludge within the oil production system. These deposits are generally in the form of oily, loose material. Sludge often contains silica compounds, but may also contain significant amounts of barium. Some of the solids in the original product stream are removed in the separator and accumulate there as sludge. As the stream is further treated using heater/treaters to separate oil from water, sludge is also separated and allowed to accumulate. The largest volumes of sludge settle out of the production stream and remain in the oil stock and water storage tanks. Radionuclide concentrations in sludge vary from background levels to several hundred picocuries *per* gram, with the highest concentrations in the separator and collection areas near the separator (drains, *etc.*) (**Table 13**). The levels deposited in heater/treaters and in sludge holding tanks are about a factor of 10 less than those found in the separator. TENORM concentrations in sludge deposits in heater/treaters and tanks are generally around 2.78 Bq g^{-1} (75 ρCi g^{-1}).

Table 13. Average Radionuclide Concentrations in Sludge

Radionuclide	Concentration, Bq g^{-1} (ρCi g^{-1})
^{226}Ra	2.07 (56)
^{210}Pb	2.07 (56)
^{210}Po	2.07 (56)
^{228}Ra	0.7 (19)
^{228}Th	0.7 (19)

Source: EPA (1993)

Radon flux from sludge is also hard to characterize for several reasons. The presence of oil or other petroleum products associated with the sludge may reduce radon flux rates. The presence and concentration of ^{226}Ra will govern radon flux and diffusion properties from sludge. A radon emanation coefficient of 0.22 was assumed for the referenced report (EPA 1993).

Oil field tubulars and equipment are now surveyed for the presence of radioactivity, and contaminated equipment is either held in storage or sent to a commercial decontamination facility. Tank sludges are also surveyed for radioactivity, dewatered, and held in storage pending disposal.

In some states and provinces, production water from oil and gas industry is disposed down hole. In addition, well injection for slurried material at limited concentrations has been permitted for oil field TENORM. Some oil field scale is stored in drums. The industry disposes of scale and sludge wastes removed from production equipment and also discards contaminated components. There are instances where TENORM waste is disposed of off-shore, under license from the United States Mineral Management Service.

Waste Water Treatment Sludge

Since water for domestic use comes from streams, lakes, reservoirs, and aquifers, it contains varying amounts of naturally occurring radioactivity. Radionuclides are leached into ground or surface water when water comes in contact with uranium- and thorium- bearing geologic media. The predominant radionuclides found in water include radium, uranium, and radon, as well as their progeny.

Water treatment includes passing the water through various types of filters and devices that rely on physical and chemical processes to remove impurities and organisms. If water containing radionuclides is treated by such systems, it is possible to generate radioactive wastes even if the treatment system was not originally intended to remove radioactivity. Such wastes include filter sludges, ion-exchange resins, granular activated carbon, and water from filter backwash.

Of the over 60,000 public water supply systems, it was estimated that about 700 of them treat water containing elevated NORM radionuclide concentrations. The areas suspected of having the most systems with elevated radionuclide concentrations are the North Central Region, the Piedmont and Coastal Plain Provinces, and portions of Arizona, New Mexico, Texas, Mississippi, Florida, and Massachusetts.

It is estimated that approximately 260,000 MT (287,000 short tons) of water treatment sludge containing elevated levels of TENORM, including spent resins and charcoal, are generated annually (**Table 14**).

Three technologies are likely to produce the TENORM waste because they generate sludge and are known to remove radioactivity from water. They are lime softening, greensand filtration, and ion-exchange and activated charcoal.

- Lime softening is used on larger systems to soften water by the addition of calcium hydroxide, which raises the pH causing calcium and magnesium in the water to precipitate. The precipitate, along with the suspended solids, is removed by sedimentation and filtration. Eighty to 90 % of the radium in the water is also trapped in the sludge.

- Greensand is made of grains of glauconite often mingled with clay or sand and may also contain natural algae. These large sand bed filtration systems remove nearly 60% of radium found in the water.

- Ion-exchange resins are used to soften water. Cation exchange removes about 95% of the radium. Anion exchange removes about 95% of the uranium. These resins are usually back- washed for reuse. The backwash water is typically discharged or back-washed to another column for further treatment. Radionuclide content eventually builds up in the resin after prolonged use. Activated charcoal is often used in conjunction with ion-exchange systems to

remove organics and gases, including radon. Over 95% of the radon, with smaller amounts of uranium and radium can be removed.

Table 14. Average Radionuclide Concentrations in Water Treatment Sludge

Radionuclide	Influent Water, Bq/L (pCi/L) (above normal concentrations)	Sludge, Bq g-1 (pCi g-1)
^{238}U	0.074 (2.0)	0.15 (4.0)
^{234}U	0.074 (2.0)	0.15 (4.0)
^{230}Th	0.0037 (0.1)	0.0074 (0.2)
^{226}Ra	0.30 (8.0)	0.59 (16.0)
^{210}Pb	0.18 (4.8)	0.41 (11.0)
^{210}Po	0.18 (4.8)	0.41 (11.0)
^{235}U	0.00052 (0.014)	0.0011 (0.03)
^{231}Pa	0.00052 (0.014)	0.0011 (0.03)
^{227}Ac	0.00052 (0.014)	0.0011 (0.03)
^{232}Th	0.0037 (0.1)	0.0074 (0.2)
^{228}Ra	0.37 (10.0)	0.74 (20.0) [0.59 (16)][a]
^{228}Th	0.0037 (0.1)	0.0074 (0.2) [0.33 (9.0)][a]

[a] For ^{228}Ra and ^{228}Th, the values shown in brackets are concentrations after two years of decay and ingrowth. Adapted from EPA (1993).

Ion-exchange resins generate waste at higher concentrations of those found in sludges but in much smaller quantities. Field data indicate that radium concentrations between 11.8 to 129.5 Bq L^{-1} (320 to 3,500 ρCi L^{-1}) occur in the column rinse and brine. Radium buildup in cation-exchange resins has been observed to average about 0.33 Bq g^{-1} (9 ρCi g^{-1}), with peak concentrations ranging from 0.92 to 1.48 Bq g^{-1} (25 to 40 ρCi g^{-1}).

Selective sorbants specifically designed to remove radium from water are particularly effective, with wastes retaining concentrations of ^{226}Ra averaging 1.48 kBq g^{-1} (40,000 ρCi g^{-1}) and up to 4.07 kBq g^{-1} (110,000 ρCi g^{-1}). This material is considered discrete NARM, > 74 Bq g^{-1} (> 2 nCi g^{-1}), and should be treated as low-level waste.

The concentration of radionuclides in water treatment sludge will depend on:

- The amount of naturally occurring radioactivity and radionuclide concentrations in the water supply
- Radionuclide removal efficiency for the system, and
- The amount of sludge produced *per* unit volume of water processed.

Water treatment sludges are placed in lagoons and may include lime sludge, back flush water, spent ion-exchange media, and sand filter elements. Disposal in lagoons results in the accumulation of radium in bottom sediments that may have to be dredged and disposed of properly. Sludge is also disposed of in sanitary landfills, discharged to sewers, injected in deep wells, or spread on agricultural soils, while the decanted water is recycled.

Radon fluxes from disposed sludges are assumed to be near those of typical soils. Radiation exposure rates from sludges are expected to be near those of ambient background levels. Exposure rates from spent resins and charcoal beds, however, would be much higher.

Exposure levels as high as several mR hr^{-1} have been observed on charcoal and resin beds. An average of ~0.748 μSv hr^{-1} (86 μR hr^{-1}) was adopted for the referenced report.

Metal Mining and Processing Waste

The mining and processing of ores for the production of metals generates large quantities of residual bulk solid and liquid wastes. Because the minerals of value make up only a small fraction of the ore, most of this bulk material has no direct use. It is estimated that the mining and processing of ores and minerals, other than uranium and phosphate, has resulted in the production of more than 40 billion MT (44 billion short tons) of mine waste and tailings from 1910 to 1981.

The metals extraction industry typically generates about 1.5 billion MT (1.65 billion short tons) of waste *per* year, including about 1.0 billion MT (1.1 billion short tons) of waste rock and overburden, 0.40 billion MT (0.44 billion short tons) of ore tailings, and less than 0.10 billion MT (0.11 billion short tons) of smelter slag. Depending on the original ores and processing methods, some of these wastes contain elevated concentrations of TENORM (**Table 15**).

It is generally believed by geologists that the level of NORM found in ores depends more on the geologic formation or region rather than on the particular type of mineral being mined. These ores often contain many different minerals, and the radionuclide content of one type of ore or mining operation or its wastes will not be representative of other mines or waste types. For some ores, the refining process may yield a waste process that may contain higher radionuclide concentrations when compared to the original ore. It has been reported that some of the more uncommon metals have highly radioactive waste products. Also, some processes associated with metal extraction appear to concentrate certain radionuclides and enhance their mobility.

Most of the metal mining waste is stored on-site or near the point of generation, in tailings ponds or used to construct dams, dikes, and embankments. About two-thirds is mine waste, and one-third is tailings. Metal mining processing wastes have only been reused in a limited number of applications, typically for backfilling mined out areas and for construction and road building near the mines. Some mineral processing wastes have been used to make wallboard and concrete.

Some of the mining wastes are stored in stockpiles that are reprocessed several times to extract additional minerals. NRC staff published guidance on September 22, 1995 (NRC 1995); allowing for certain feedstocks containing uranium and thorium to be processed by licensed uranium mills. This will allow the wastes to be disposed of in the uranium mill tailings pile. There are several restrictions on the feedstock.

Table 15. Metal and Mining Industries Known or Believed to Involve TENORM

Bauxite	Lead	Thorium
Beryllium	Molybdenum	Tin
Columbium	Nickel	Uranium
Copper	Rare Earths (Lanthanides)	Titanium
Gold	Silver	Zinc
Iron	Tantalum	Zirconium

Source: EPA (1993)

Rare Earths

The rare earth elements, sometimes called lanthanides, are a group of 15 chemical elements with atomic numbers 57 through 71. Yttrium, which has an atomic number of 39, is also included because it occurs with other rare earth elements and has similar chemical properties. The special properties of the rare earth elements are why they are used in catalysts, ceramics, refractory and metallurgical processes, magnets, *etc.* They are also used in low-temperature superconductor technology, which may increase their demand in the future. The United States is the world's leading producer of rare earth elements. Rare earth oxides include bastnasite, monazite, and xenotime.

Bastnasite (also spelled bastnaesite) can contain up to 75% rare earth oxides, including up to 0.1% ThO_2. Monazite can contain about 60% rare earth oxides, including 4 to 10% ThO_2. Uranium may also occur in monazite at 0.1 to 0.5% U_3O_8. Thorium can be removed from monazite ores by several methods, resulting in thorium residue wastes. Xenotime can contain elevated levels of thorium and uranium. The ThO_2 and U_3O_8 components from the rare earth metals appear in the waste products. Although some of these wastes have been treated as low-level waste and disposed of properly, some of the TENORM-contaminated wastes remain at the processing sites.

The annual generation rate of waste is assumed to be 20,800 MT (22,900 short tons) *per* year containing 6% TENORM with relative activities of 144 Bq g^{-1} (3,900 ρCi g^{-1}) for thorium and 666 Bq g^{-1} (18,000 ρCi g^{-1}) uranium. These values are considerably higher that the NRC's 0.05% for source material.

The radon flux rate from rare earth oxide waste piles depends on many factors, such as the radium concentration in the wastes, moisture content, porosity, and depth of the pile. The radon emanation coefficient for these wastes is estimated at 0.3.

Radiation exposure rates associated with these wastes can range from near background to several μSv hr^{-1} (several hundred μR hr^{-1}) for monazite wastes. Depending on the source, radiation levels may differ because many of the decay products may no longer be in secular equilibrium with uranium and thorium. A total external radiation exposure rate from thorium and uranium can be up to ~122 μSv hr^{-1} (14 mR hr^{-1}).

Other Metals

Zirconium, hafnium, titanium, and tin generate approximately 470,000 MT (518,000 short tons) of waste a year with an average ^{226}Ra concentration of 1.59 Bq g^{-1} (43 ρCi g^{-1}). Much of the ore from which titanium is obtained originates in sands that also contain monazite. Ores can contain concentrations of uranium and thorium in the range of 0.18 to 0.74 Bq g^{-1} (5 to 20 ρCi

g^{-1}). Total radium in sludge from titanium process streams had concentrations as high as 2.85 Bq g^{-1} (77 ρCi g^{-1}). Some ZrO_2 concentrates from South Africa are used in a process that chlorinates the sands and converts the zirconium to tetrachloride.

Measurements indicate that ^{226}Ra concentrations in this ore are about 7.4 Bq g^{-1} (200 ρCi g^{-1}). Direct chlorination of zircon puts the radium into the highly soluble radium chloride chemical form, which can yield high leachate concentrations in liquid waste streams. Values of 1665 Bq L^{-1} (45,000 ρCi L^{-1}) of ^{226}Ra were detected in water samples at one plant. The high solubility and mobility of radium chloride could pose a potential threat to the environment.

Amang is a general term for the by-products obtained when tin tailings are processed into concentrated ores. It includes minerals such as monazite, zircon, ilmenite, rutile, and garnet. Radium-226 and ^{232}Th activities in amang have been reported to range from 15.91 to 17.76 Bq g^{-1} (430 to 480 ρCi g^{-1}) and 42.9 to 326.7 Bq g^{-1} (1,160 to 8,830 ρCi g^{-1}) respectively. Tailings from these ores may have a significant potential to cause elevated radiation exposures.

Measurements made at a tin smelter showed ^{238}U concentrations up to 1.59 Bq g^{-1} (43 ρCi g^{-1}) and ^{232}Th concentrations up to 0.7 Bq g^{-1} (19 ρCi g^{-1}). Gamma survey measurements at a tin smelter showed radiation levels in slag storage areas ranging from ~0.087 to 4.35 μSv hr^{-1} (10 μR hr^{-1} to 500 μR hr^{-1}), with average levels less than ~0.522 μSv hr^{-1} (60 μR hr^{-1}). The large industries, including copper and iron, generate over 1.0 billion MT (1.1 billion short tons) of waste *per* year, with an average ^{226}Ra concentration of 0.18 Bq g^{-1} (5 ρCi g^{-1}).

Geothermal Energy Production Waste

Geothermal energy in the United States is utilized only in a few places, mostly in California. Solid wastes originating from the treatment of spent brines contain TENORM. Hot, saline fluids from geothermal reservoirs may have a dissolved solids content approaching 30% by weight. The average ^{226}Ra concentration in this waste is estimated at 4.88 Bq g^{-1} (132 ρCi g^{-1}), with waste generation estimated at 54,000 MT (59,500 short tons).

REGULATION, CONTROL, AND MANAGEMENT OF TENORM

Federal Regulation of TENORM

EPA and other Federal and State agencies are responsible for regulating public exposures to NORM that are not licensed by NRC. State authority is derived from the Constitution, by which the States have primary responsibility for the health and safety of the public. EPA, State, and NRC programs do not treat the radiological risks from NORM consistently. NRC licensees generally are required to meet more restrictive conditions than are possessors and users of other NORM. There are no significant differences in the radiological risks of these materials, although radon and some discrete radium sources have a higher radiological hazard than uranium and thorium (NRC, 1996).

The definition of source material found in the Atomic Energy Act (AEA 1954) is based on the early safeguards concerns for material that could be used to ultimately make reactor fuel or nuclear weapons. When the definition was written, Congress considered that source materials needed to be placed under regulatory control on the basis of promoting common defense and national security. The health and safety impacts from NORM other than source material were considered to be manageable, to be relatively insignificant, and to have no basis for regulation from the standpoint on the common defense and national security (NRC, 1996).

The hazards posed by mill tailings (by-product materials) were incompletely recognized in the uranium industry's early years, and, while the AEA of 1954 instituted licensing of mill operators, tailings remained free of controls (EPA 1980). Byproduct material under the Act limited control to tailings "produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content" (AEA, 1954). Therefore, other tailings (vanadium, radium, *etc.*) are not regulated by the AEA, and are considered TENORM.

In 1965, it was discovered by the Public Health Service (PHS) and the Colorado Department of Health that uranium mill tailings were being hauled from the mill site and used

for construction purposes in around habitable structures (CDH, 1989). Regulations were promulgated to effect cleanup for Grand Junction based on PHS recommendations, known as the Grand Junction Remedial Action Criteria, found at 10 CFR 712 (AEC, 1972). These regulations were designed to mitigate radon in structures from uranium mill tailings. In 1978, the Uranium Mill Tailings Radiation Control Act (UMTRCA)was passed to address the mill sites themselves, as well as disposal of the tailings. The regulations supporting UMTRCA are found at 40 CFR 192 (EPA, 1980) (**Table 16**). These regulations are the basis for the current regulations for NORM the States have adopted, along with surface contamination release limits found in NUREG 1.86 (NRC, 1974).

Table 16. 40 CFR 192 Standards

Soil, ^{226}Ra averaged over 100 m^2, shall not exceed background by more than:	5 ρCi g^{-1} ^{226}Ra averaged over the first 15 cm of soil below the surface 15 ρCi g^{-1} ^{226}Ra averaged over 15 cm thick layers of soil more than 15 cm below the surface
Habitable buildings:	Annual average radon decay product concentration (including background) not to exceed 0.02 WL. In any case, not to exceed 0.03 WL Level of gamma radiation shall not exceed the background level by more than 20 microroentgens *per* hour.

There are a number of issues to be considered when adopting the 40 CFR 192 values to TENORM:

- The limits were promulgated when radiation protection guidance policies in place at that time limited exposures to the public to ~5 mSv yr^{-1} (500 mrem yr^{-1}) whole body with limiting factors to critical organs. The proposed RPG is for an upper limit of ~1.0 mSv yr^{-1} (100 mrem yr^{-1}) from all sources (60 CFR 49296).

- The risks from low levels of radiation are assumed to be proportional to dose, that is, they are based on the linear no-threshold model. There is considerable debate over the validity of this theory (Patterson, 1997).

- The limits in 40 CFR 192 were calculated using radon emanation values for sandy material. Many TENORM wastes have very low radon emanation fractions (slag).

- The indoor gamma exposure rate criteria of ~0.174 mSv hr^{-1} (20 mR hr^{-1}) above background was designed to allow some limited flexibility in the methods chosen to reduce indoor radon decay product concentrations, not to meet a certain dose limit. In fact, based on 75% occupancy, the standard would allow gamma radiation doses from the tailings of about ~1.13 mSv yr^{-1} (130 mrad yr^{-1}) (EPA, 1980).

Currently there are no federal regulations specifically controlling TENORM. EPA was going to consider TENORM in proposing 40 CFR 196, but that rule was withdrawn at the request of DOE. It is unlikely that TENORM would be in a final rule due to pressure from industry.

Def - Not AEA

States Regulation of TENORM

Many states consider TENORM to be regulated by their general rules on radiation. Other States believe that TENORM should have specific regulations. The Conference of Radiation Control Program Directors (CRCPD) has developed templates for States to use in drafting regulations for control and disposal of TENORM. The previous drafts were based on the 40 CFR 192 radium in soil values with exemptions, methods for licensing, protection of workers and general population, and disposal. The draft regulations have gone through many iterations. Eight states currently have regulations pertaining to TENORM, most of them based on the CRCPD template. The States are listed in **Table 17**. CRCPD has established a blue ribbon panel to work more efficiently and effectively to finalize the Part N suggested state regulations for the control of TENORM. The panel released a new draft of the proposed State regulations in February 1997, the comment period ends June 30, 1997 (HPS 1997). A review of the new draft follows.

Table 17. States with TENORM regulations

New Mexico	South Carolina	Mississippi
Arkansas	Louisiana	Texas
Ohio	Georgia	Oregon

Other states currently considering TENORM regulations are listed in **Table 18.**

Table 18. States considering TENORM regulations

Alabama	Alaska		Connecticut	Florida
Illinois	Michigan	New Jersey	Oklahoma	Colorado?

CRCPD Suggested State Regulations for Control of Radiation (Part N)

Some features of the current draft are:

- A new definition of what TENORM is: "naturally occurring materials not regulated under the AEA whose radionuclide concentrations have been increased by or as a result of human practices. TENORM does not include the natural radioactivity of rocks or soils, or background radiation, but instead refers to materials whose radioactivity is technologically enhanced by controllable practices (or by past human practices)".

- The limits in the standard are dose-based. The implementing State is to determine what fraction of 100 mrem yr^{-1} TEDE (excluding natural background) to the reasonably maximally exposed individual is allowed from TENORM.

- Exemption limit of 5 ρCi g^{-1} ^{226}Ra or ^{228}Ra,

- Surface contamination guidelines follows NUREG 1.86 (NRC 1974),

- Excludes indoor radon from TEDE calculations,

- States are given a flexibility for implementing Part N consistent with their respective, unique circumstances,

- Safety criteria for products containing TENORM,

- Quality control, labeling and reports of transfer of TENORM,

- Implementation Guidance will be developed that will address issues such as determination of background, survey methods, *etc.*

HPS/ANSI Standard for NORM - Guide for Control and Release of NORM

In addition to the CRCPD efforts, the HPS has a working group that is developing an ANSI standard for control and release of NORM (HPS, 1997a). The working group is comprised of representatives of industry and government. The standard is still in draft form, consensus has not been reached on all issues, however, some basic themes of the standard can be discussed (Dehmel, 1997):

- Primary exposure limit of 1 mSv (100 mrem) yr^{-1}. TEDE, above background to average member of critical group exposed under realistic conditions, does not include radon,
- Limit to be calculated over 1,000 years,
- Allows for institutional or engineered controls,
- Provisional limit for infrequent exposures to RME of 5 mSv (500 mrem) yr^{-1} during remediation of facilities contaminated by past practices,
- Surface guidelines adopted from draft ANSI N13.12, July 1996 draft,
- Outdoor radon limited to 20 $\rho Ci\ sec^{-1}\ m^{-2}$, averaged over the entire area of the disposal unit, waste or material pile, or impoundment,
- Indoor radon limited to 4 $\rho Ci\ L^{-1}$ in areas that are occupied or occupiable,
- Dose limits for products or materials containing NORM.

GUIDANCE DOCUMENTS FOR TENORM

In addition to the CRCPD template for State regulations, some guidelines for the control, disposal, and release of TENORM are:

- *Guidelines for the Handling of NORM in Western Canada* (WCNC, 1995),
- Implementation manual for Management of NORM in Louisiana (LDEQ, 1990).
- Texas also has published regulatory guides on conducting close-out surveys of open land areas and requesting release for unrestrictive use (BRC, 1990).
- *Management of NORM in Oil and Gas Production.* (API, 1993) by the American Petroleum Institute.
- *Radiation Protection in the Mineral Extraction Industry.* NCRP Report No. 118.

RECYCLING AND DISPOSAL OF TENORM

Reuse of contaminated scrap metal is an industry unto itself and is the topic of much discussion. Scrap dealers and smelting facilities have detected the presence of radioactivity, including TENORM, in numerous shipments of scrap metals by the use of radiation detectors at their facilities. More sensitive and rugged detector systems are currently in development for metal recycling facilities and similar facilities. These should help to protect these industries from accidental recycling radioactive materials such as TENORM and anthropogenic sources.

Envirocare of Utah owns a licensed facility for commercial TENORM disposal located in Clive, Utah. The licensing of this facility follows criteria similar to those pertaining to uranium mill tailings disposal.

The U.S. Ecology low-level waste facility at Hanford, Washington will accept some TENORM wastes, but with restrictions. Extra packaging, waste form, and design requirements may result in lower radon releases and waste leach rates. This option would be limited by cost and volume restrictions.

Newpark Environmental TENORM Processing Facility of Port Arthur, Texas accepts TENORM wastes for processing for injection into deep wells.

Campbell Wells Corporation of Lafayette, Louisiana accepts TENORM and NOW for treatment and disposal.

Efforts have been made to convince NRC to allow disposal of TENORM wastes in 11e.(2) disposal cells. NRC staff published a notice in the Federal Register on September 22, 1995, stating that "Radioactive material not regulated under the AEA shall not be authorized for disposal in an 11e.(2) byproduct material impoundment" (NRC 1995).

EXAMPLES OF TENORM EXPOSURES

There have been a number of cases where the improper disposal of TENORM wastes has resulted in increased levels of direct radiation exposure to individuals. A few examples include:

- In Montclair, New Jersey, radium-contaminated soil caused elevated gamma exposure rate levels. This project is now a CERCLA site; cleanup is under way (EPA 1990).

- In Polk County, Florida surface soils have been removed during grading at construction site to expose and redistribute low-grade phosphate ores. Houses and condomenia have been built directly on these deposits. No studies of ^{222}Rn fluxes in the structures built at these sites are known to have been carried out. Typical radon fluxes in re-worked surface deposits near this site are quite elevated; sometimes by an order of magnitude or more than local backgrounds.

- Elemental phosphate slag used to construct roads in Pocatello, Idaho, has resulted in a doubling of the radiation levels in some areas. Phosphate ore tailings have also been used as aggregates on dirt roads in some counties in Florida. No studies have directly addressed the increased exposure to the public due to this activity.

- In Mississippi, recycled pipes that are contaminated with radium scales have been used to construct playground equipment and are used in welding classes. Both activities have resulted in unnecessary exposures.

- A phosphate fertilizer facility in Louisiana discharged thousands of tons a day of phosphogypsum and phosphate processing effluents directly into the Mississippi River. This practice ceased in the mid-1980's. Similar types of discharges in Spain have been found to significantly increase ^{226}Ra, ^{210}Pb, and U isotopes in rivers downstream of phosphate processing facilities.

- Vanadium and radium tailings have been used in construction materials and have contaminated soil and groundwater.

- In the past, pipe scale residue was left on the ground at pipe cleaning yards or washed into ponds or drainage basins. Surveys showed that some locations exhibited external radiation levels above 2 mR hr^{-1} and ^{226}Ra concentrations above 1,000 $\rho Ci\ g^{-1}$.

- Oil field sludges often were dumped into waste pits. Both burn and brine waste pits have been used for disposal of sludges and production water residues. This past practice may lead to ground and surface water contamination. In addition, direct radiation exposures may have occurred to individuals working or living near the disposal pits.

- Relatively elevated concentrations of ^{226}Ra were used for decades to produce luminous dials on instruments in aircraft, military equipment, on watches, *etc.*

In addition to these specific examples, numerous incidents occur each year in metal recycling. Scrap metals containing elevated TENORM as well as radiation sources are inadvertently combusted and smelted. These examples represent a very small fraction of events that result in elevated exposures, either through ignorance or neglect, to TENORM that the public is subjected to on a regular basis.

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APPENDIX A

TERMS AND DEFINITIONS

NORM and TENORM
Producers, Users, and Proposed Regulations

HPS PEP Course 1.A

24 January 1999

APPENDIX A

TERMS AND DEFINITIONS

Atomic Energy Act Definitions (42 USC 1954): Source material: Sec.11(z) " . . . means (1) uranium, thorium, or any other material which is determined by the Commission pursuant to the provisions of section 61 [42 U.S.C. 2091] to be source material; or (2) ores containing one or more of the foregoing materials, in such concentrations as the Commission may by regulation determine from time to time" (0.05% by weight).

Special nuclear material: Sec.11(aa) " . . . means (1) plutonium, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the Commission, pursuant to the provisions of section 51 [42 U.S.C. 2071], determines to be special nuclear material, but does not include source material; or (2) any material artificially enriched by any of the foregoing, but does not include source material."

By-product material: Sec.11(e) " . . . means (1) any radioactive material (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, and (2) the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content."

NARM: Naturally Occurring and Accelerator Produced Material. Any radioactive material that can be considered naturally occurring and is not source, special nuclear, or by-product material or that is produced in a charged particle accelerator (DOE 1988).

NORM: Naturally Occurring Radioactive Material, NORM is considered a subset of NARM. NORM is basically defined by exclusion. This has caused regulatory problems because NORM is not specifically regulated by the AEA. Definitions vary between agencies and all have exemptions.

HPS (1997a): "...means any radionuclides or radioactivity disturbed by man-made activities or technologically-enhanced state, which may result in a relative increase in radiation exposures and risks to the public above background radiation levels.

Technologically enhanced: "...means that the physical and chemical properties have been altered and radionuclide concentrations have been increased by human practices, such that there exists a potential for:

1) Exposures to individuals or populations
2) Environmental redistribution and contamination
3) Increased environmental mobility
4) Incorporation of radioactivity in products and construction materials
5) Recycling or re-use of contaminated material or equipment
6) Improper disposal or use of disposal methods that could result in unnecessary exposures to individuals and populations or environmental contamination

Technologically Enhanced Naturally Occurring Radioactive Material: CRCPD (1997): "...means naturally occurring materials not regulated under the AEA whose radionuclide concentrations have been increased by or as a result of human practices. TENORM does not include the natural radioactivity of rocks or soils, or background radiation, but instead refers to materials whose radioactivity is

technologically enhanced by controllable practices (or by past human practices).

Technologically Enhanced Naturally Occurring Radioactive Material: (cont'd.)

Gesell and Prichard (1975) define technological enhancement as: "...exposures to truly natural sources of radiation (*i.e.*, naturally occurring isotopes and cosmic radiation) which would not occur without (or would be increased by) some technological activity not expressly designed to produce radiation."

There are two methods to consider under their definition:

1) Bringing the receptor to the source; *e.g.*, inadvertent or deliberate proximity to a radiation source, air or space travel

2) Bringing the source to the receptor:
   - Industrial processes
   - Consumer products
   - Indoor radon

Risk – Modeling – Bounding – Relatively Easy
- Realistic – Very Hard
- Outcome Curve.

State: One Lower 500 mrem/yr – Practical 2 mrem/hr 100 mrem/7 consid
100 mrem/yr –
- ICRP 30 mrem/yr w/ Constraint
- EPA 15 mrem/yr Limit

1 pCi/gm U – Ra ~ 20 mrem/yr Bremen Mobile

5 pCi/gm Ra ~ 75 mrem/yr. Area

Max → Configure over life.

Can not regulate TENORM at the level begging to regulate AEA material

Iceland – High Radon – Geothermal Water.

Commission
- Exempt 40.13(a) 500 ppm
- Amer Min A – Mill Tailing – In-Situ
- Proposed Rule – Decon – U/Th for – 5 pCi/gm Ra Benchmark
  ↳ Practical Std.
- Interface TENORM – AEA State.

Yes – Yellowstone – Ra Cl
- Reduced Systems.

The Regulation of NORM from a Nuclear Decommissioner's Viewpoint

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ABSTRACT

Radiation protection and the management of radioactive material have hitherto been concerned mainly with artificial nuclides arising within the nuclear fuel cycle. In the last few years, there has been an increasing awareness of naturally occurring radioactive material (NORM) and the enhancement of its concentration in various non-nuclear industrial processes. This technologically enhanced NORM is of the same activity levels as low level waste and is very similar to the candidate material for exemption and clearance in the nuclear industry, but occurs in quantities that are huge in comparison.

Nuclear decommissioning projects are characterised by the large volumes of very low activity level materials arising. So the regulatory treatment of much larger volumes of material with similar radiological characteristics in the non-nuclear industries is being viewed with the greatest interest by the nuclear industry.

This paper gives an overview of the quantities of NORM arising both in Europe and the United States. An evaluation of the radiological impact of NORM in the Nordic countries is presented. Finally a comparison is made between some of the regulatory approaches being considered for NORM and the current regulatory treatment of very low level material in the nuclear industry.

INTRODUCTION

The management of the large volumes of contaminated materials arising from the decommissioning of nuclear facilities represents one of the most substantial cost fractions of such projects. Consequently, the minimisation of the volumes that have to be disposed of as radioactive waste is a high priority goal for decommissioners. Much of the redundant material is at very low levels of activity and is valuable for recycling, thus conserving natural resources and protecting the environment. The recycling of such material (or its reuse or disposal), without radiological restrictions, is seen as a significant means of achieving the aim of waste minimisation.

In the last few years, there has been an increasing awareness of naturally occurring radioactive material (NORM and the enhancement of its concentration in various non-nuclear industrial processes. This technologically enhanced NORM is of the same activity levels as the low level redundant material arising from the decommissioning of nuclear facilities, but occurs in quantities that are huge in comparison.

Many national and international organisations have put forward (or are working on) proposals, recommendations or directives regarding the activity levels at which material could be exempted or released from radiological regulation. Lately such discussions have also covered NORM. As the radiological characteristics of technologically enhanced NORM are very similar to those of candidate material for recycling from the nuclear industry, nuclear decommissioners are very interested in the regulatory treatment of such material.

This paper will focus on the quantities of NORM arising in the USA and in Europe, the collective dose impact of NORM on the population and on a comparison between the proposed regulatory treatment of NORM and radiologically similar material from the nuclear industry.

QUANTITIES OF NORM ARISING

The quantities of candidate material assumed in various studies on recycling from the nuclear industry have been

- 10000 t of steel per year arising from decommissioning projects in European studies [1],
- 50000 t of steel per year in the OECD Nuclear Energy Agency's Task Group on Recycling and Reuse study [2].

In comparison, the quantities of technologically enhanced NORM arising in the USA are huge, as illustrated in Table I, which shows the volumes and radioactivity of such material arising annually in the United States [3, 4]. More or less comparable quantities of NORM arise in Europe, with similar concentrations of radioactivity, as shown in Table II [5].

TABLE 1 Sources, Volumes and Concentrations of Naturally Occurring Radioactive Materials [3]*

Waste Stream	Production Rate per Yr.	Total U Bq/kg	Total Th Bq/kg	Total Ra Bq/kg
Phosphate	5.0×10^{10} kg	bkgd - 3000	bkgd - 1800	400 - 3700000
Phosphogypsum	4.8×10^{10} kg	bkgd - 500	bkgd - 500	900 - 1700
Slag	1.5×10^{9} kg	800 - 3000	700 - 1800	400 - 2100
Scale	4.5×10^{6} kg	**	**	1100 - 3700000
Coal Ash	6.1×10^{10} kg	100 - 600	30 - 300	100 - 1200
Fly Ash	4.4×10^{10} kg	**	**	**
Bottom Ash	1.7×10^{10} kg	**	**	**
Petroleum Production	2.6×10^{8} kg	**	**	bkgd - 3700000
Scale	2.5×10^{7} kg	**	**	bkgd - 3700000
Sludge	2.3×10^{8} kg	**	**	bkgd - 3700
Petroleum Processing	**	**	**	***
Refineries	**	**	**	> 4000
Petrochem Plants	**	**	**	> 4000
Gas Plants	**	**	**	***
Water Treatment	3.0×10^{8} kg	**	**	100 - 1500000
Sludges	2.6×10^{8} kg	**	**	100 - 1200
Resins	4.0×10^{7} kg	**	**	300 - 1500000
Mineral Processing	1.0×10^{12} kg	6 - 129000	8 - 900000	< 200 - 129000
Rare Earths	2.1×10^{7} kg	26000 - 129000	9000 - 900000	13000 - 129000
Zr, Hf, Ti, Sn	4.7×10^{8} kg	6 - 3200	8 - 660000	300 - 18000
Alumina	2.8×10^{9} kg	400 - 600	500 - 1200	300 - 500
Cu and Fe	1.0×10^{12} kg	< 400	< 400	< 200
Geothermal Waste	5.4×10^{7} kg	**	**	400 - 16000
Paper Mills	**	**	**	> 3700

* Derived partially from US EPA, 1993 [4]

** Data not available

*** Lead-210 and Polonium-210

Table II:1 NORM and Technologically Enhanced NORM [5]

PROCESS **i) Feed materials** **ii) Product** **iii) By-product/Waste**	**SCALE OF OPERATION**	**PROMINENT RADIONUCLIDES**	**TYPICAL ACTIVITY CONCENTRATIONS (Bq/kg) AND ENHANCEMENT**	**RADIOLOGICAL IMPACT** **(O)ccupational** **(P)ublic**
Power production from coal: i) Coal. ii) Energy production. iii) Coal ash (bulk and aerosol), sludges.	World-wide usage. iii) 30 Mt/a coal ash in the EU.	i) U 238 and Th 232 + d's. iii) As feed material but more volatile components (Pb 210 and Po 210) follow airborne pathways.	i) 20 Bq/kg for each of U 238 and Th 232, both with d's in equilibrium. iii) Factor 10 enhancement for U 238 and Th 232, perhaps a factor 100 for volatiles: Pb 210, Po 210.	(O) Active dust exposure: Pb 210 and Po 210, ~µSv/a. (P) Negligible dose from power plant, but poorly disposed ash can contaminate foodchain, 10's µSv/a.
Phosphate ore processing and use: i) Phosphate rock. ii) Phosphoric acid, fertiliser. iii) Slag, slurry, off-gas.	i) 126 Mt/a (world). ii) 4 Mt/a phosphate fertiliser in EU.	i) U 238 and Th 232 +d's. ii) Up to 50 % enhancement, especially Ra 226 in fertilisers. iii) Ra 226, Pb 210, Po 210.	i) 100's - 1000's Bq/kg in ore. ii) 100's - 1000's Bq/kg in fertiliser. iii) 5000 Bq/kg Ra 226 in phosphogypsum.	(O) 5 µSv/a for plant workers and 100's µSv/a for transport and storage workers. (P) 2 µSv/a from fertilisers, up to several mSv/a doses from certain marine pathways otherwise only µSv/a doses from alternate pathways.
Recycling waste in building materials: i) By-products/wastes. ii) Bricks, concrete, cement... iii) Slag, scales, gases, used products.	i) Process wastes recycled whenever possible: coal ash, phosphogypsum, slag... ii) Only lower activity materials used in inhabited structures. iii) Further recycling possible.	U 238 and Th 232 + d's as from process wastes. ii) Rn 222 + d's accumulation in buildings, otherwise external exposures from gamma emitting nuclides.	ii) 50 - 100 Bq/kg U 238 / Th 232 / Ra 226.	(O) 100's µSv/a from dusty operations. (P) Up to 500 mSv/a from close association with active buildings and roads. Rn + d's build-up in unventilated buildings
Rare earths and zirconium: i) Rare earth and zirconium ores. ii) Refined ores, glazes, polish, refractories. iii) Solid waste, aerosols, used products.	i) 0.7 Mt/a of zirconium ore (world), 30 kt/a rare earths in EU. ii) Milling and processing of Zr operations on 1 y in EU.	U 238 and Th 232 + d's.	100's - 1000's Bq/kg for both ores, products and wastes.	(O) Minimal µSv/a doses due to protective measures. (P) Little impact noted.

Table II:2 NORM and Technologically Enhanced NORM [5]

PROCESS i) Feed materials ii) Product iii) By-product/Waste	SCALE OF OPERATION	PROMINENT RADIONUCLIDES	TYPICAL ACTIVITY CONCENTRATIONS (Bq/kg) AND ENHANCEMENT	RADIOLOGICAL IMPACT (O)ccupational (P)ublic
Metal smelting: i) Metal ores (Sn, Nb, Pb, Bi, Fe...). ii) Metals / alloys (steels). iii) Slags, scales, aerosols and gases.	130 Mt/a crude steel in EU. Niobium steel production much smaller.	ii) Pb 210 and Po 210 in tin smelting. iii) U 238 and Th 232 in slag, Pb 210 and Po 210 in dusts.	i) 500 - 100 Bq/kg in ores. iii) Various waste products 10^2 10^5 Bq/kg. 10 000's Bq/kg U 238 and Th 232 in niobium steel ore, product and waste.	(O) Fractions of mSv/a from tin smelting and low doses from steel production. Niobium steel production: 4 mSv/a with protective measures. (P) 10's µSv/a from various exposure pathways.
Storage and use of copper mining tailings: i) Copper ore. ii) Copper. iii) Rock, slags, sludge, roast product.	Exploitation of high activity tailings previously occurred in Eastern Germany.	i) U 238 and Th 232 + d's in ores. iii) Ra 226, Pb 210 and Po 210 progeny in solid and sludge wastes. Pb 210 and Po 210 in airborne waste streams	iii) Slags: 1000 Bq/kg Ra 226. some sludges and furnace wastes have up to 20 000 Bq/kg Pb 210 and Po 210.	(O) Nil - industry closed. (P) Local waste piles: dose rates of 100's - 1000's µSv/h.
Oil and gas production: i) Natural oil and gas reservoirs. ii) Purified oil and gas. iii) Sludge, scale.	i) Largely North Sea regions. ii) 140 Mt/a oil in EU, 2×10^{11} m³/a gas in EU. iii) 10 000/m³ of active waste before treatment from EU oil and gas industries.	i) U 238 and Th 232 0 d's. ii) Natural gas has radon content. iii) Ra 226, Pb 210 and Po 210 in scales and sludges.	ii) 300 Bq/m³ Rn 222 on average in natural gas. iii) 10^5 Bq/kg each in sludges and up to several times this in scales.	(O) 1-2 mSv/a from working with or in the vicinity of scales and sludges. (P) Little contact between the public and the industries.
Other minor processes: i) Various. ii) Chemicals, water usages, glass... iii) Various.	Generally small scale operations with limited public contact. Water use in treatment plants and spas. Chemical industry scale in not recorded.	Various: U 238 and Th 232 + progeny. Water: radon plus progeny can be significant.	Little known about the radionuclide involvement in the chemical industry. Perhaps as much as 10^5 Bq/kg Ra 226 in mineral waters.	(O) Tend to be localised doses to parts of the body. Perhaps several mSv/a from Rn 0 d's to those workers in spas. (P) 10's µSv/a from radon in water supplies.

RADIOLOGICAL IMPACT OF NORM

A characteristic of NORM is that, because of their wide distribution from many sources, they give rise to relatively large collective radiological doses to the public in comparison to those caused by the nuclear industry. This is vividly illustrated in a study, made in 1990 [6] by the radiation protection authorities from the five Nordic countries, on the annual collective dose to their populations from natural radioactive sources, including some NORM-related ones. The respective contributions of the various sources were compared with the collective dose taken by the Nordic populations during the first year after the Chernobyl accident as well as with the annual collective dose from the operation of the 16 nuclear reactors in Sweden and Finland, with the following results:

Table III **Annual collective dose to population in Nordic Countries from natural radioactive sources, Chernobyl and operation of 16 nuclear power plants**

Source	Collective Dose Person-Sv/a
Radon in dwellings	65 000
Artificial fertiliser	50
Energy production (Thermal, non-nuclear)	80
Radioactivity in own body	8 100
Ground, building materials, etc	11 600
Cosmic radiation	7 100
Chernobyl accident (First year)	6 000
Normal operation of nuclear reactors in Sweden and Finland	20

On closer examination of the study report, the comparative impact of some of the NORM-related industries are, in fact, even more significant than shown.

The 20 person-Sv/year from the operation of the nuclear reactors is mostly occupational doses to the operating personnel. The total collective dose to the general public from plant emissions is less than 1 person-Sv/year.

The annual 50 person-Sv dose shown in the figure coming from artificial fertiliser covers only the internal doses taken by the Nordic public, through ingestion of food produced on the

fertilised soil. The external doses have not been included. The figure does not either cover the use of the by-product, gypsum, as a building material. Even a modest use of gypsum in homes could lead to an annual collective dose of about 100 person-Sv.

The figure of 80 personSv/year due to energy production from coal (mainly in Denmark) and from peat (mainly in Finland) refers only to radioactive emissions from the power plants. Not shown are the effects of the use of some of the fly ash in concrete, which increases the external gamma radiation in buildings and is likely to dominate the total dose from the use of coal and peat. The report mentions that most of the bottom ash ends up on municipal tips but does not attempt to estimate the radiological impact.

The Nordic study thus shows that the collective dose from the operation of the 16 nuclear plants is 1 person-Sv, while the use of artificial fertiliser and the operation of coal and peat for energy production causes two to three orders of magnitude higher collective population doses.

CURRENT REGULATORY APPROACHES

In connection with regulation of radioactivity, the following words are conventionally in use to denote specific conditions:

- **Exclusion** covers activity sources not amenable to control, such as K-40 in the human body, cosmic radiation, etc.,
- **Exemption** denotes radioactive materials which never enter the regulatory regime because it is considered that they give rise to low risks, and control would be a waste of societal resources,
- **Clearance** refers to material that has earlier been regulated but is released from regulatory control.

It is to be noted that, in principle, both "exempted" and "cleared" materials have, at the same activity levels, the same radiological impact on human beings.

In the nuclear industry, exemption and clearance are based on the IAEA Safety Series 89 [7], which prescribes

- a maximum individual dose/practice of about 10 μSv/year,
- a maximum collective dose/practice of 1 person-Sv/year,

to determine whether the material can be cleared from regulatory control or other options should be examined. The IAEA TECDOC 855 [8] was issued on these bases in January 1996 on an interim basis and will be revised after about three years to react to comments received and to experience gained in its application. This document presents recommended nuclide specific clearance levels for solid materials.

The EC recommendations for clearance levels for recycling of metals [1] were also based on the Safety Series 89 criteria.

To a large extent, the radiation protection regulators have been focusing on the nuclear fuel cycle with little attention given to the technological concentration of radioactivity in the

NORM industries. Consequently, the current regulatory management of NORM is very inconsistent with that of similar material arising in the nuclear industry.

Examples:

- Current level for clearance of material from the nuclear industry in Sweden is 0.5 Bq/g, while current exemption level for non-nuclear industries (by European Commission Directive 84/467/Euratom of 1984) is 100 Bq/g (or 500 Bq/g for "solid natural material").
- Exemption level for oil and gas industry NORM wastes [9]:
  - In the Netherlands, 100 Bq/g,
  - In Germany, 500 Bq/g.
- For subsurface road stabilisation in Germany:
  - Clearance level for concrete from a nuclear plant was 0.5 Bq/g,
  - Exemption level for slag from melting of scrap from the oil and gas industry was 65 Bq/g (to be diluted by a factor 4)

The EC came out with a new Directive in May 1996, with revised basic safety standards (BSS) for the radiation protection of both workers and the general public [10]. The Directive covers radioactivity in both nuclear and non-nuclear industries and will have to be ratified by member states within 4 years, i.e. by May 2000. In the BSS, industries are divided into "practices" (where radionuclides are, or have been processed in view of their fissile or fertile properties) and "work activities" (where the presence of radioactivity is incidental). Broadly speaking, "practices" refer to the nuclear industries, while "work activities" to the non-nuclear ones, i.e. industries like oil and gas or phosphate industries. The table of exemption values in the new EC-BSS covers only practices. The exemption values for work activities are not explicitly given. It seems clear, from the presentations at the NORM II meeting in November 1998, that the exemption values for material from non-nuclear industries can be based on a criterium of 1 mSv/year individual dose to the public, which is a factor of 100 greater than that for similar material from the nuclear industry [12].

In the United States, a draft set of regulations for technologically enhanced NORM (TENORM) was given out in February 1997 by the Conference of Radiation Control Program Directors (CRCPD). The CRCPD is an organisation primarily consisting of directors and technical staff from state and local radiation control programs and functions as the common forum for state, local and federal regulatory agencies to address NORM-related health and safety issues. Several states have already regulations in place to meet their specific individual needs. There is, however, no uniformity in these regulations. One of the main aims of CRCPD is working towards uniformity in regulations governing radiation [11].

SUMMING UP

The recycling and reuse of material arising from the decommissioning of nuclear facilities can very significantly affect the volume that would have to be disposed of as radioactive waste. Internationally accepted radioactivity clearance levels for such material are a necessary requirement for utilising this alternative advantageously.

Various national and international bodies have issued interim or draft recommendation on exemption and clearance levels. Recent discussions have also covered the management of

radioactivity in "non-nuclear" industries, where naturally occurring radioactivity is technologically enhanced to levels similar to those in low level redundant material arising from the decommissioning of nuclear facilities. The quantities of such technologically enhanced NORM are much larger than the candidate material for recycling from the nuclear industry.

The current approach as to the radiological regulation of technologically enhanced NORM seems to differ greatly from the stringent regulation of similar material in the nuclear industry. There is a great need for imposing consistency on the regulatory treatment of radioactive material, irrespective of the industry it arises in.

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Attachment 4; Table 2 - Sources, Quantities, and Concentrations of TENORM [Att. 2,3]				
Source Waste Stream	Quantity/Yr (kg)	U Concentration (Bq/kg)	Th Concentration (Bq/kg)	Ra Concentration (Bq/kg)
Uranium overburden	$3.8x10^{10}$	$1.8x10^{3}$	990	920
Phosphate:	$5.0x10^{10}$	bkgd - $3.0x10^{3}$	bkgd - $1.8x10^{3}$	400 - $3.7x10^{6}$
Phosphogypsum	$4.8x10^{10}$	bkgd - 500	bkgd - 500	900 - $1.7x10^{3}$
Slag	$1.5x10^{9}$	800 - $3.0x10^{3}$	700 - $1.8x10^{3}$	400 - $2.1x10^{3}$
Scale	$4.5x10^{6}$	❊	❊	$1.1x10^{3}$ - $3.7x10^{6}$
Phosphate fertilizers	$4.8x10^{9}$	740 - $2.2x10^{3}$	37 - 180	180 - 740
Coal Ash:	$6.1x10^{10}$	100 - 600	30 - 300	100 - $1.2x10^{3}$
Fly Ash	$4.4x10^{10}$	❊	❊	❊
Bottom Ash	$1.7x10^{10}$	❊	❊	❊
Petroleum Production:	$2.6x10^{8}$	❊	❊	bkgd - $3.7x10^{6}$
Scale	$2.5x10^{7}$	❊	❊	bkgd - $3.7x10^{6}$
Sludge	$2.3x10^{8}$	❊	❊	bkgd - $3.7x10^{3}$
Petroleum Processing:	❊	❊	❊	Pb-210 & Po-210
Refineries	❊	❊	❊	>$4.0x10^{3}$
Petrochemicals	❊	❊	❊	> $4.0x10^{3}$
Gas Plants	❊	❊	❊	Pb-210 & Po-210
Water Treatment:	$3.0x10^{8}$	❊	❊	100 - $1.5x10^{6}$
Sludge	$2.6x10^{8}$	❊	❊	100 - $1.2x10^{3}$
Resins	$4.0x10^{7}$	❊	❊	300 - $1.5x10^{6}$
Mineral Processing:	$1.0x10^{12}$	6 - $1.3x10^{5}$	8 - $9.0x10^{5}$	< 200 - $1.3x10^{5}$
Rare Earths	$2.1x10^{7}$	$2.6x10^{4}$-$1.3x10^{5}$	$9.0x10^{3}$ - $9.0x10^{5}$	$1.3x10^{4}$ - $1.3x10^{5}$
Zr, Hf, Ti, Sn	$4.7x10^{8}$	6 - $3.2x10^{3}$	8 - $6.6x10^{5}$	300 - $1.8x10^{4}$
Alumina	$2.8x10^{9}$	400 - 600	500 - $1.2x10^{3}$	300 - 500
Cu & Fe	$1.0x10^{12}$	< 400	< 400	< 200
Geothermal Waste	$5.4x10^{7}$	❊	❊	400 - $1.6x10^{4}$
Paper Mills	❊	❊	❊	> $3.7x10^{3}$

❊ means data are not available

1 Bq = 27 pCi; 1 kBq = 27 nCi; 1 Mbq = 27 μCi; 1 μCi = 37 kBq; 1 mCi = 37 Mbq; 1 Ci = 37 Gbq

Attachment 5; Table 3 - Occurrence and Concentrations of NORM [Ref.1]						
Material	K-40		Th- 232		U-238	
	% of total K	Bq/kg	ppm	Bq/kg	ppm	Bq/kg
Igneous Rock:						
Basalt (crustal)	0.8	300	3-4	10-15	0.5-1	7-10
Mafic	1.1	300	2.7	10	0.9	10
Salic	4.5	1400	20	80	4.7	60
Granite (crustal)	› 4	› 1000	17	70	3	40
Sedimentary rocks						
Shale	2.7	800	12	50	3.7	40
Sandstones						
Clean quartz	‹ 1	‹ 300	‹ 2	‹ 8	‹ 1	‹ 10
Dirty quartz	2	400	3-6	10-25	2-3	40
Arkose	2-3	600-900	2	‹ 8	1-2	10-25
Beach sands	‹ 1	‹ 300	6	25	3	40
Carbonate rocks	0.3	70	2	8	2	25
All rocks	0.3-4.5	70-1400	2-20	7-80	0.5-4.7	7-60
Continental crust	2.8	850	10.7	44	2.8	36
Soil	1.5	400	9	37	1.8	22

Regulatory Initiatives for Control and Release of Technologically Enhanced Naturally-Occurring Radioactive Material

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ABSTRACT

Current drafts of proposed standards and suggested State regulations for control and release of technologically-enhanced naturally-occurring radioactive material (TENORM), and standards for release of volumetrically-contaminated material in the United States (U.S.) are reviewed. These are compared to the recommendations of the International Atomic Energy Association (IAEA) Safety Series and the European Commission (EC) proposals.

Past regulatory efforts with respect to TENORM in the U.S. dealt primarily with oil-field related wastes. Currently, nine states (AK, GA, LA, MS, NM, OH, OR, SC, TX) have specific regulations pertaining to TENORM, mostly based on uranium mill tailings cleanup criteria. The new U.S. proposals are dose- or risk-based, as are the IAEA and EC recommendations, and are grounded in the linear no threshold hypothesis (LNT). TENORM wastes involve extremely large volumes, particularly scrap metal and mine wastes. Costs to control and dispose of these wastes can be considerable.

The current debate over the validity of LNT at low doses and low dose rates is particularly germane to this discussion. Most standards setting organizations and regulatory agencies base their recommendations on the LNT. The U.S. Environmental Protection Agency has released a draft Federal Guidance Report that recommends calculating health risks from low-level exposure to radionuclides based on the LNT. However, some scientific and professional organizations are openly questioning the validity of LNT and its basis for regulations, practices, and costs to society in general. It is not clear at this time how a non-linear regulatory scheme would be implemented.

INTRODUCTION

It has been known for years that naturally occurring radioactive material (NORM) may be concentrated during processing of natural resources (thus becoming technologically enhanced NORM or TENORM). Little attention was paid to the potential consequences of low concentrations of TENORM in waste streams. Industries have been identified as having TENORM contamination and waste problems, include the oil and gas industry, water treatment plants, sewer treatment plants, the phosphogypsum industry, hard rock mining waste and coal ash, scrap metal, and geothermal energy generation (1). Today TENORM is an international problem - not only do individual countries' industries grapple with it, increased globalization of business has led to cross-border transport of TENORM contaminated items and equipment. There is also commercial international trade of TENORM, in addition, there is also a growing black market dealing in TENORM. Radioactively contaminated scrap metal (including TENORM) has been found on an increasing basis at border crossings and scrap yards in Europe (2).

Several regulatory initiatives are being undertaken in the United States with respect to diffuse sources of TENORM. The Health Physics Society NORM Working Group is preparing a standard for submission to the American National Standards Institute (ANSI) (3). The proposed U.S. standards are dose-based, and are set according to the current radiation protection guidance (RPG) for past activities, and the proposed RPG for current and future activities (with exceptions). The Council of Radiation Control Program Directors (CRCPD) is developing suggested regulations for States to use when developing their rules (4). The new CRCPD proposal also changes the basis for its suggested regulations from concentration-based standards to dose-based. The Environmental Protection Agency (EPA) has proposed changes to the RPG (5), which could impact TENORM regulations. The proposed RPG adopts the recommendations of ICRP 60 (6), and would recommend regulation of sources as well as limits to individuals. The U.S. Nuclear Regulatory Commission (USNRC) is considering a recycling/release standard that may influence NORM standards setting in the U.S. The USNRC has also changed its policy on alternate feedstocks and disposal of waste in uranium mill tailings disposal sites (7). Canada is

considering adopting regulations for NORM based on a current Canadian guidance document (8). Initiatives to update existing regulations are also being undertaken in Europe as part of the European Union efforts (9).

A review of the evolution of International, Federal and State regulations, guidance, and standards-setting organizations lays the groundwork for the current initiatives. An abbreviated listing of regulations, standards, and guides pertaining to TENORM are presented in Table 1.

ICRP

The primary document outlining the system of radiation protection being adopted world-wide is the International Commission on Radiation Protection (ICRP) Publication 60 (6). This document outlines the system to regulation of sources as well as individuals. It is based on general principles with respect to practices: justification, optimization of protection, and limitation (individual dose limits). The concept of intervention (distinct from other practices) is based on general principles that: the intervention should do more good than harm; and the form, scale, and duration of the intervention should be optimized. For the public, an annual limit on effective dose of 1 mSv (100 mrem), with a subsidiary limit in some years, provided the average over five years does not exceed 5 mSv (500 mrem). It also recommends treatment of potential exposures, e.g., practices which may lead to interventions. ICRP 65 addresses indoor radon, both for the public and in occupational settings, and gives recommendations for practices and interventions (10). Buckley, et.al., (9) identifies provisions ICRP 60 has that are of particular relevance to current initiatives in the U.S. and for the EU countries:

- The drawing of clear distinction between the twin concepts of "practices" and "interventions";
- The more explicit treatment of intervention, and the development of the intervention principles;
- Introduction of lower dose limits, coupled with a five year dose limitation period for the adult worker limit;
- Concept of dose constraints as an elaboration of the principle of optimisation; and
- The need to bring natural radiation into the system in situations where there is a basis for exercising control.

IAEA

The International Atomic Energy Agency (IAEA) published standards based on the recommendations of the ICRP and other organizations. The Euratom treaty of 1957 prescribes that uniform basic safety standards (BSS) shall be prescribed. The first Directive was issued in 1959, and was revised over the years. The current revision to the Basic Safety Series was issued as *Principles for Exemption of Radiation Sources and Practices from Radiological Control,* Safety Series 89 (11). A draft revision, *International basic safety standards for protection against ionising radiation and the safety of radiation sources* was published in 1994. It introduces the distinction between practices and intervention and the concepts of dose constraint and potential exposure. There are two basic criteria that can determine whether or not a practice can be a candidate for exemption from the BSS: a) individual risks must be sufficiently low as not to warrant regulatory concern; and b) radiation protection, including the cost of regulatory control, must be optimized. The guide states that an individual effective dose of 10 - 100 μSv (1 to 10 mrem) per year would result in insignificant risks. Based on the possibility of multiple exposure from several exempted practices, the guidance recommends an annual *de minimis* dose of 10 μSv (1 mrem). The proposed HPS/ANSI 13.12 recommendations have some similarities to the Safety Series 89 limits (1). The EC issued a similar council directive in 1996. Current revisions to the EC BSS are due by May 2000. Additional BSS documents have been published that give measurable quantities to the dose limits in Safety Series 89 (12).

European Commission

The European Commission (EC) laid out its BSS for radiation protection (13). It is similar in many ways to the IAEA BSS. But the EC BSS distinguishes between "practices" of the nuclear industry, and "work activities" where radioactivity is incidental, but can lead to significant exposure of workers or the public. The EC BSS list of exemption values covers only practices (14). The most relevant directive recommends exposure limits and exemptions from various sources of radioactivity, including NORM, and authorizes specific practices without any regulatory controls. It endorses ALARA, including provisions for justification, optimization, and dose limitations for specific practices.

Table I. Current regulations, standards, and guides pertaining to TENORM.

Regulation/Standard /Guidance	Statute, Guide, or Standard	Standard	Application
Radiation Protection Guide for Federal Agencies, May 1960, September 1961. Radiation Protection Guidance to Federal Agencies for Occupational Exposure, January 1987.	RPG	The RPG is 0.5 rem/year each to the whole body and bone marrow, and 5 rem in 30 years to the gonads. Additional RPGs at comparable levels are specified for exposure to the thyroid and bone (1.5 rem/year). In addition, doses should be "as low as reasonably achievable(ALARA) and advised that control should be applied to keep doses below the RPG. Doses to workers limited to 5 rem/year, 1.5 R per quarter.	Provides a general framework for radiation protection and general principles of radiation control based on the annual intake of radioactive materials. Provides recommendations for population groups. Provides general principles, and specifies the numerical primary guides for limiting worker exposure.
Proposed Radiation Protection Guidance for Exposure of the General Public -	EPA	Dose limit to members of the public 1 mSv (100 mrem), from all combined sources of radioactivity. Allows an annual dose of 5 mSv (500 mrem) for special and temporary circumstances involving infrequent radiation exposures. Requires that the RPG be expressed in terms of a single weighted sum of doses to organs, and the separate RPGs for individual organs be deleted; The RPG limiting the average genetic dose to members of the U.S. population to 5 rems in 30 years and the annual whole body dose to 500 mrem dose equivalent be replaced by a single RPG of 1 mSv (1 mrem) effective dose equivalent received by or committed in a single year to any individual from all sources combined; Doses from individual sources be limited to a fraction of the RPG; and increased emphasis be given to ALARA, within the RPG.	Replaces old RPGs Adopts ICRP 60 methodology
40 CFR 192 -	UMTRCA	Concentration of ^{226}Ra in land averaged over any area of 100 square meters	Cleanup criteria for uranium and

Regulation/Standard /Guidance	Statute, Guide, or Standard	Standard	Application
Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings, as amended by EPA on 1/11/95 - Groundwater Standards for Remedial Actions at Inactive Uranium Processing Sites.		shall not exceed background by more than (1) 5 pCi/g, averaged over the first 15 cm of soil below the surface and (2) 15 pCi/g, averaged over any 15 cm thick layers, thereafter. 20 $pCi/m^2/sec^{-1}$ of ^{222}Rn flux; 500 yrs longevity for tailings piles. 20 uR/h indoors above ambient background radiation exposure rate. For thorium, limits are the same as radium, thoron the same as radon. Groundwater: 5 pCi/L (^{226}Ra and Ra), 30 pCi/L (^{234}U and ^{238}U) and 15 pCi/L gross alpha, excluding radon and uranium.	thorium mill tailings. Used by DOE in DOE Order 5400.5, FUSRAP/SFMP criteria CRCPD Part N template used limits for exemption Used as basis for many State regulations Used by EPA in CERCLA cleanups under certain conditions
40 CFR 300 National Contingency Plan	CERCLA	Risk - based standard in the range of 10^{-4} to 10^{-6}.	Establishes goals for selecting remediation goals at NPL sites. Radionuclides are hazardous substances under CERCLA, it has been applied to TENORM sites. EPA has issued guidance establishing cleanup levels on risk over dose.
ICRP 60 - Recommendations of the ICRP	ICRP	Primary annual guidance for members of the public - 1 mSv (100 mrem) for continual exposures. 5 mSv (500 mrem) for infrequent exposures.	Basis for general regulations on radiation protection Advocates: Justification, Optimization, and Limitation
NCRP 116	NCRP	Primary annual guidance for members of the public - 1 mSv (100 mrem) for continual exposures. 5 mSv (500 mrem) for infrequent exposures. 10 μSv (1 mrem) as a negligible dose.	Basis for general regulations on radiation protection for Federal States.

Regulation/Standard /Guidance	Statute, Guide, or Standard	Standard	Application
			Advocates: Justification, Optimization, and Limitation
Council Directive 96/29	Euratom	maximum annual dose limit of 1 mSv (100 mrem) to the public, provision for higher doses in a single year, provided average over 5 consecutive years does not exceed 1 mSv per year (100 mrem). specific practices may be exempted if the resulting annual dose in less than 10 μSv (1 mrem) and the collective effective dose in any one year does not exceed 1 man-Sv (100 person rem). 1 μSv/hr (0.1 mrem/h) at a distance of 0.1 meter from any material or items containing radioactive materials in excess of the above limits, provided that materials are contained in the form of a sealed source and that conditions for their disposal have been identified.	Follows ICRP 60 methodology Basis for EC member countries' radiological protection standards. Must be implemented by 2000 Directive includes provisions for alternate criteria, through dose assessments, for demonstrating when a practice or exemption is at its optimum, but exceeds the basic criteria. Clearance levels and dose constraints are recommended Dose limits for workers
HPS/ANSI N13.12	HPS	Primary dose limits of 100 μSv (10 mrem), TEDE to average member of critical group. Secondary screening limits for unconditional clearance: 0.1 Bq/g or Bq/cm^2 for Group I (includes radium and thorium decay series) 1.0 Bq/g or Bq/cm^2 for Group II (includes uranium decay series) Reduced by a factor of 10 for soil	Proposed criteria for release of surface and volume contaminated equipment. Replaces Reg Guide 1.86 Submitted for balloting

NCRP

The National Council on Radiation Protection and Measurements periodically updates its recommendations, including those germane to this discussion. NCRP published its Report 91 in 1988 (15) and was based on risk estimates given in ICRP 26 (16). NCRP Report 116 (17) was published to update the previous estimates and adopts the recommendations of ICRP 60 in general terms. For purposes of TENORM, the recommendations are similar. NCRP 116 is considered in the HPS/NORM working group recommendations (3). A committee has been formed to examine the linear dose response model (18), and will be discussed later.

NATIONAL RESEARCH COUNCIL

The National Research Council (NRC), an arm of the National Academy of Sciences, conducts research on the Biological Effects of Ionizing Radiation (BEIR). NRC also evaluated the current guidelines for TENORM, and will be discussed later.

BEIR V

BEIR V addressed health effects and risks due to low levels of radiation (19). The report concludes that the carcinogenic effectiveness of low LET radiation is generally reduced at low doses and low dose rates. In comparing protracted versus acute exposures, protracted exposures are expected to reduce lifetime risks by a factor of about two for the same dose of low LET radiation. Due to the amount of new data available since the publication of BEIR V, a new committee is in process of evaluating the effects of low LET radiation. This BEIR VII report is due about three years after commencement, and will examine the dose-response relationship at low doses and low dose rates.

BEIR VI

BEIR VI, based on an earlier report, focused on risk factors associated with the inhalation of radon gas and radon gas decay products (20). The report updated a previous report (21) and concluded (abbreviated): a) that reducing indoor radon concentrations below the EPA guideline of 148 Bq/m^3 (4 pCi/L) could prevent approximately about one-third of the radon related lung cancer cases in the U.S.; b) and that lung cancer cases could be prevented most effectively by limiting smoking; c) a single alpha particle traversal in a cell can result in mutation and transformation. There has been criticism of the methodologies used in this report, particularly the use of LNT as the basis for risk assessment, and failure to use residential domestic radon studies as a basis for setting the lower bound of heath risks to zero.

FEDERAL REGULATION OF NORM

In the U.S., as elsewhere, NORM and TENORM has often been defined by what it is not, rather than what it is. It has been defined by exclusion: it is not low level waste, nor is it source, special nuclear, or byproduct material under Atomic Energy Act. The definition of source material found in the Atomic Energy Act (22) is based on the early safeguards concerns for material that could be used to ultimately make reactor fuel or nuclear weapons. When the definition was written, Congress considered that source materials needed to be placed under regulatory control on the basis of promoting common defense and national security. The health and safety impacts from NORM other than source material were considered to be manageable, to be relatively insignificant, and to have no basis for regulation from the standpoint on the common defense and national security (23). The hazards posed by uranium mill tailings (byproduct material) were incompletely recognized in the uranium industry's early years, and, while the AEA of 1954 instituted licensing of mill operators, tailings remained free of controls. Byproduct material under the Act limited control to tailings "produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content" (22). Therefore, other tailings (vanadium, radium, etc.) as well as other NORM bearing wastes are not regulated by the AEA, and are considered TENORM.

EPA and other Federal and State agencies are responsible for regulating public exposures to NORM that are not licensed by USNRC. These exposures are set based on the recommendation of standards setting organizations, i.e., IAEA and NCRP. State authority is derived from the Constitution, by which the States have primary responsibility for the health and safety of the public. EPA, State, and USNRC programs do not treat the radiological risks from TENORM consistently. USNRC licensees generally are required to meet more restrictive conditions than are possessors and users of other NORM. There are no significant differences in the radiological risks of these

materials, although radon and some discrete radium sources have a higher radiological hazard than uranium and thorium (23).

Federal Radiation Protection Guidance

"The purpose of the RPG is to provide a common framework to help ensure that the regulation of exposure to ionizing radiation is carried out by Federal agencies in a consistent and adequately protective manner." (24). The current basis for radiation protection in the U.S. dates back to the RPG of 1960 and 1961. New Federal guidance issued in 1987 replaced those portions of the 1960 and 1961 guidance that applied to protection of workers.

The RPG is 0.5 rem/year each to the whole body and bone marrow, and 5 rem in 30 years to the gonads. Additional RPGs at comparable levels are specified for exposure to the thyroid and bone (1.5 rem/year). In addition, doses should be "as low as reasonably achievable (ALARA) and advised that control should be applied to keep doses below the RPG, but that surveillance alone was sufficient for levels up to 10% of the RPG (25). It should be noted here that the RPG for the gonads was based on limiting the incremental rate of mutation in the entire genetic pool of the U.S. population. The incremental level of mutation deemed unacceptable was on the order of a few percent (24).

Richardson (25) classified problems with the old RPGs into three categories: 1) methodological problems - the approach used organ-specific limits and failed to address future commitments of dose from the intake of radionuclides; 2) the guidance focuses on exposure of the individual and does not provide adequate insight on how to deal with the regulation of sources; and 3) the permitted individual risk level is now considered to be far too high. These same arguments can be applied to the TENORM issue and are considered in the proposed standards.

Proposed RPG

In 1994, EPA proposed new RPGs replacing the 1960s vintage guidance. The guidance would reduce the dose limit to members of the public from 5 mSv (500 mrem) to 1 mSv (100 mrem), from all combined sources of radioactivity. It allows an annual dose of 5 mSv (500 mrem) for special and temporary circumstances involving infrequent radiation exposures. It requires that the RPG be expressed in terms of a single weighted sum of doses to organs, and the separate RPGs for individual organs be deleted; the RPG limiting the average genetic dose to members of the U.S. population to 5 rems in 30 years and the annual whole body dose to 500 mrem dose equivalent be replaced by a single RPG of 1 mSv (1 mrem) effective dose equivalent received by or committed in a single year to any individual from all sources combined; doses from individual sources be limited to a fraction of the RPG; and increased emphasis be given to ALARA, within the RPG (24).

Uranium Mill Tailings

In 1965, it was discovered by the Public Health Service (PHS) and the Colorado Department of Health that uranium mill tailings were being hauled from the mill site located at Grand Junction and used for construction purposes in around habitable structures (26). Regulations were promulgated to effect cleanup for Grand Junction based on PHS recommendations, known as the Grand Junction Remedial Action Criteria (10 CFR 712. [27]). These regulations were designed to mitigate radon in structures from uranium mill tailings. In 1978, the Uranium Mill Tailings Radiation Control Act (UMTRCA) was passed to address the mill sites themselves, as well as disposal of the tailings. The regulations supporting UMTRCA are found at 40 CFR 192 (28). Final groundwater standards were promulgated in 1995 and are consistent with USNRC values found in 10 CFR 40 (29).

The UMTRCA regulations have been used as the basis for the current regulations for NORM the States have adopted, along with surface contamination release limits found in REG Guide 1.86 (30).

Other EPA Regulations

EPA has authority to protect the public health and environment from adverse affects of exposure to ionizing radiation. The authority to regulate TENORM is derived from several statutes, including the AEA; the Clean Air Act (CAA); UMTRCA (as mentioned); The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA); and the Toxic Substances Control Act (TSCA). The Resource Conservation and Recovery Act (RCRA) and the Solid Waste Disposal Act (SWDA) explicitly exclude source, byproduct, and special nuclear material (by definition), but they do not explicitly exclude NORM/TENORM. TSCA includes a subchapter on

Indoor Radon Abatement, which was written with residential NORM (i.e. Rn) in mind (1).

CERCLA

EPA considered regulating TENORM in the first discussion draft of 40 CFR 196, but that rule was withdrawn (31). It is unlikely that TENORM would be in a final rule. In practice, CERCLA is used for radioactive materials that: 1) were not subject to regulations before the passage of the AEA, 2) are presently unregulated (radioactive material that was never licensed or registered and they should have been), or 3) are outside the capabilities of regulators (lack of funding, staffing or capability to resolve the issue) (32). CERCLA has been used at sites with byproduct material (33). EPA has recently issued guidance documents on implementing cleanup levels under CERCLA that are risk-based to a reasonably, maximally exposed individual. Superfund issued a directive *Use of Soil Cleanup Criteria in 40 CFR 192 as Remediation Goals for CERCLA Sites* that clarifies when the UMTRCA standards can be used (32,34). This is important to TENORM sites because many of the wastes are similar to uranium mill tailings in that they have ^{226}Ra as a principle contaminant.

USNRC

As mentioned earlier, USNRC regulates source, byproduct and special nuclear material under authority of the AEA. Byproduct material under USNRC control, i.e. Title II UMTRCA sites are regulated at 10 CFR 40. The criteria for soil are the same as UMTRCA. Thirty States have entered into agreements with USNRC and have assumed jurisdiction over the use of byproduct material. The USNRC does not license TENORM, although many States believe they have authority over TENORM in their general rules on radiation. Prior to the implementation of the revised 10 CFR 20 in 1996, the 1981 Branch Technical Position (BTP) addressed four options for disposal of uranium and thorium wastes (35). Recent changes in USNRC policy on feedstocks for uranium mills has led to a series of reprossessing of industrial waste streams from non UMTRA sites to recover uranium. The wastes from these reprocessed materials are being disposed of in UMTRA disposal cells.

DOE

DOE regulates source, byproduct, and special nuclear material through its directive system. Under DOE Order 5400.5, exposures to members of the general public are limited to an annual dose of 1 mSv (100 mrem) from all pathways, and all sources. DOE has generic cleanup limits for radium and thorium based on the 40 CFR 192 criteria, with clarification on ingrowth, equilibrium, and hot spots (36). Authorized limits for other radionuclides are derived on a case-by-case basis. DOE Order 5400.5 has been proposed to be codified at 10 CFR 834, but has yet to be promulgated (37). DOE manages its waste through DOE Order 5820.2A (38). It treats NORM that is commingled with regulated wastes as low level waste. NORM that is not commingled is exempt.

The Formerly Utilized Sites Remedial Action Project (FUSRAP) addresses the cleanup of former DOE facilities that had been previously released. Oversight of this program was transferred from DOE to the Army Corps of Engineer (COE) by Congress in 1997. Guidelines issued under the FUSRAP program are essentially the same as those found in DOE Order 5400.5 (36).

States

Many states consider TENORM to be regulated by their general rules on radiation. Other States believe that TENORM should have specific regulations. The Conference of Radiation Control Program Directors (CRCPD) has developed templates for States to use in drafting regulations for control and disposal of TENORM. The previous drafts were based on the 40 CFR 192 radium in soil values with exemptions, methods for licensing, protection of workers and general population, and disposal. The draft regulations have gone through much iteration. Nine states currently have regulations pertaining to TENORM, most of them based on the CRCPD template (AK, GA, LA, MS, NM, OH, OR, SC, TX). In addition to the soil criteria, some of the States also allow for clearance based on exposure rate. Michigan has promulgated regulations allowing disposal of up to 50 pCi/g ^{226}Ra to be disposed of in a Type 2 Municipal Landfill (39).

There are some things that need to be considered when adopting the 40 CFR 192 values to TENORM: 1) The limits are based on the current RPG, exposures to the public allowed are now considered by most regulatory agencies to be too high. The proposed RPG is for an upper limit of ~1.0 mSv/year (100 mrem/y) from all sources (24), 2) The risks from low levels of radiation are assumed to be proportional to dose, that is, they are based on the LNT model.

There is considerable debate over the continued use of this theory in setting radiation protection standards (40), 3) The limits in 40 CFR 192 were calculated using radon emanation values for sandy material (~30%). Many TENORM wastes have very low radon emanation fractions. An example is slag, which has emanation fractions of <1% (41). Gamma radiation is the limiting factor for those wastes. Some States have a higher limit for low emanation wastes, typically 30 pCi/g ^{226}Ra, 4) The indoor gamma exposure rate criteria of ~0.174 uSv/h (20 uR/h) above background was designed to allow some limited flexibility in the methods chosen to reduce indoor radon decay product concentrations, not to meet a certain dose limit. In fact, based on 75% occupancy, the standard would allow gamma radiation doses from the tailings of about ~1.13 mSv/year (130 mrad/year) (28), and 5) The subsurface standard 555 Bq/g (15 pCi/g), is not a health-based standard, but instead is a instrumentation-based standard. It is not clear if the 555 Bq/g standard will survive.

CRCPD

CRCPD has established a blue ribbon panel to work more efficiently and effectively to finalize the Part N suggested state regulations for the possession, use, transfer, and disposal of TENORM. The panel released a draft of the proposed State regulations in February 1997, held public meetings on the draft, and issued a revised draft in September 1998 (4). Stakeholder meetings have been held with industry and State representatives, numerous issues are still under consideration. A review of the current draft follows.

Some features of the current draft are:

- A new definition of what TENORM is: "naturally occurring radionuclides whoses concentrations are increased by or as a result of past or present human practices. TENORM does not include background radiation or the natural radioactivity of rocks or soils. TENORM does not include uranium or thorium in "source material" as defined in the AEA and US NRC regulations."
- The limits in the standard are dose-based. The implementing State is to determine what fraction of 100 mrem/y total effective dose equivalent (TEDE) (excluding natural background) to the reasonably maximally exposed individual is allowed from TENORM.
- Exemption limit of 5 pCi/g ^{226}Ra or ^{228}Ra,
- Surface contamination guidelines follow REGGUIDE 1.86,
- Excludes indoor radon from TEDE calculations,
- States are given flexibility for implementing Part N consistent with their respective, unique circumstances,
- Safety criteria for products containing TENORM,
- Quality control, labeling and reports of transfer of TENORM,
- Implementation Guidance will be developed that will address issues such as determination of background, survey methods, etc.

It is not clear at this time why the current draft does not address: 1) liquid media (other than brief reference to CWA/SDWA for disposal), 2) intervention by States (CERCLA would need to be invoked), or 3) why Part N does not address radioactivity of material in its natural state that has been relocated (bringing subsurface NORM to the surface). Clearly, exposures to the public can occur from these activities.

HPS/ANSI Standard for NORM - Guide for Control and Release of NORM

In addition to the CRCPD efforts, the HPS has a working group that is developing an American National Standards Institute (ANSI) standard for control and release of NORM (3). The working group is comprised of representatives of industry and government. The standard is still in draft form, some basic themes of the standard can be discussed (42):

- Primary exposure limit of 1 mSv (100 mrem)/year. TEDE, above background to average member of critical group exposed under realistic conditions, does not include radon,
- Constraint of 0.25 mSv (25 mrem) per year above background from any single source of radioactivity,
- Sites with groundwater pathways use MCL for ^{226}Ra and ^{228}Ra at the point of use,
- Limit to be calculated over 1,000 years,
- Allows for institutional or engineered controls,

- Provisional limit for infrequent exposures to Reasonably Maximally Exposed Individual of 5 mSv (500 mrem)/yr during remediation of facilities contaminated by past practices,
- Surface guidelines adopted from draft ANSI N13.12, July 1996 draft,
- Outdoor radon limited to 20 pCi/s m^2, averaged over the entire area of the disposal unit, waste or material pile, or impoundment,
- Indoor radon limited to 4 pCi/L in areas that are occupied or occupiable,
- Dose limits for products or materials containing NORM.

HPS/ANSI N13.12

The HPS has also submitted a draft American National Standards Institute (ANSI) standard, *Surface and Volume Radioactivity Standards for Unconditional Clearance* (43) for review. The draft standard replaces Reg. Guide 1.86, which was instrumentation-based, not risk-based, and therefore may not be protective of public health. It adopts the effective dose definitions of NCRP 116 (17), which is compatible with ICRP 60 (6). It lists a primary dose criteria of 100 μSv/y (10 mrem/y), above background to an average individual in a critical group for the unconditional clearance of materials from regulatory control. It provides screening levels for surface and volume contaminated material and equipment, and clearance screening levels for soil. Current BSS clearance values are based on 10 μSv/y (1mrem/y).

NAS Report

Recently, the National Academy of Sciences (NAS) issued a report through the NRC evaluating guidelines for exposures to TENORM materials (43). The committee was tasked to address: 1) whether the differences in the guidelines for TENORM developed by EPA and other organizations are based upon scientific and technical information, or on policy decisions related to risk management, 2) if the guidelines developed by EPA and other organizations differ in their scientific and technical basis, what the relative merits of the different scientific and technical assumptions are, and 3) whether there is relevant and appropriate scientific information that has not been used in the development of contemporary risk analysis for NORM.

Findings of the committee are briefly summarized:

- The differences between EPA guidelines for TENORM and similar guidelines developed by other organizations are not based on scientific and technical information.
- The differences in the guidelines for TENORM developed by EPA and other organizations are based essentially on differences in policy judgements for risk management.
- There should be no difference between NORM and other radioactive materials with regard to suitable approaches to estimating doses and risks related to external or internal exposure.
- Transferability of standards developed for a specific class of TENORM waste is limited by the extent that the physical and chemical properties of the TENORM in issue, as well as projected exposure pathways, are substantially similar to those considered for uranium mill tailings.

Dose Response Relationship

The basis for current radiological standards are based on the LNT. The concept of using LNT as a philosophy of radiation protection has been recognized as conservative, but prudent because of all the uncertainty with extrapolating from high doses and dose rates to low doses and dose rates. There is also discussion in the literature as to the accuracy of the dosimetry, particularly for neutrons, with respect to the Hiroshima bomb. If so, significant changes to the dose-response relationship may be needed. There are also current studies that attribute more significance to dose rate than before. There are differing positions with respect to LNT, but three basic categories can be given for this paper: a) those who believe LNT is excessively stringent and result in increased financial costs; b) those who believe the standards are appropriately conservative; and c) those who believe that more stringent standards are needed (45).

TENORM regulations based on LNT may cost industry billions of dollars to implement, therefore, it is prudent to evaluate the applicability of LNT. Conversely, everyone is exposed to NORM, and proposed clearance levels will allow TENORM into commerce. More prudent practices (or interventions) may be needed to protect public health if LNT underestimates risk.

Dose- or risk-based standards also have a weakness in that the scenarios and parameters chosen for modeling the exposures can vary widely, and yield large differences in allowable residual source terms while still reaching the same "limit."

The answers to the question of dose response to low-level radiation will probably come from the field of biology and not physics. Current modeling methods are inconclusive, and most existing experimental and epidemiological data on the effects of low-LET radiation are extrapolated from observations at doses far above those in which the average cell is struck by no more than one radiation track. Based on direct experimental observations involving alpha particle microbeam experiments and theoretical considerations, it is concluded that cellular traversal by a single radiation track of any type of ionizing radiation has a finite probability of depositing enough energy in a critical macromolecular target, such as DNA, to injure, but not necessarily kill the cell in question (1). There are also new concerns about genomic instability due to alpha particle interactions with DNA (46).

The public has been told that there is no safe level of radiation based on LNT. Industry is concerned because of the tremendous costs involved in managing low levels of radioactive materials. The NCRP has commissioned a study of LNT, the draft report concludes that "For radiation protection purposes, therefore, pending further clarification of the relevant dose-response relationships, the weight of evidence causes the Council to conclude at this time that the risk from radiation increases monotonically with the dose, in the low dose range above natural background radiation levels" (1). A conference was held in 1997 to explore various approaches for bringing together scientific information, policy judgements, and legislative needs related to the control of health risks from low-level radiation exposures (45).

CONCLUSION

Despite the lack of leadership at the Federal level for regulations of TENORM, current recommendations for regulations (and lack thereof) in the U.S. for control of TENORM are being revised. These current revisions are more consistent with international guidance than previous recommendations. The revised standards will probably be based on some fraction of 1mSv/y (100 mrem/y) TEDE to an individual from all sources combined, with ALARA. Screening levels for clearance of surfaces and volumetric contamination may be available, although at this time it is not clear if the levels will be consistent with international recommendations. Indoor radon will be addressed separately, based on ICRP 65 or EPA current guidance. The proposed standards assume LNT, although there is significant pressure from industry and professional organizations to abandon LNT. Risk- or dose-based standards could effectively allow for higher concentrations of radionuclides to remain in the environment, depending on scenarios used in modeling. Environmental groups and other professional organizations are concerned that new information coming from the biological sciences showing that high-LET radiation (alpha particles) are more dangerous than previously thought, and therefore, the standards should be tighter for high-LET nuclides.

Other aspects: political, pragmatic, and economic will also drive the final implementation of the proposed standards. EPA has the authority to regulate TENORM, but seems reluctant to do so. A proposed scrap metal rule was abandoned in favor of USNRC rulemaking on clearance and recycling. Incidents involving the discovery of contaminated scrap metal, including TENORM, are increasing. This is leading to a necessity for a consistent international policy sooner rather than later. Industry is reluctant to see more regulations be promulgated. States will ultimately be the regulators, but with potential for inconsistency which can lead to difficulties in commerce. Although a direction has been taken, it is not clear where it will end. The next generation of guidance may very well be based on microdosimetry.

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Attachment 7; Table 4 - Particle Accelerators [Ref. 3]		
Accelerator Type	Particle Accelerated	Energy Level
Electrostatic Accelerators:		
Tandetron	p, d, α, & heavy ions	to 3 MV
Cockcroft-Walton	p, d, α, , e, & heavy ions	to 4 MV
Dynamitron	p, d, α, , e, & heavy ions	to 4 MV
Tandem Van de Graaff	p, d, α, , e, & heavy ions	to 20 MV
Tandem pelletron	p, d, α, , e, & heavy ions	to 26 MV
Vivitron	p, d, α, , e, & heavy ions	to 35 MV
Time-Varying Field Accelerators:		
Microtron	e^-	to 200 MeV
Sector or isochronous cyclotron	p, d, & α heavy ions	to 590 MeV (p) to 90 MeV/amu
Superconducting cyclotron	heavy ions	200 MeV/amu
Synchrotron (weak focusing)	p, e heavy ions	1-6 Ge (p) 2 GeV/amu
Alternating-gradient synchrotron	p, e^+ heavy ions; mass 12-197 heavy ions; mass 12-208	10-900 GeV (p) 11.4 GeV/amu 160 GeV/amu
Linear Accelerators:		
Heavy ion linear accelerator	p, d, α, & heavy ions	to 30 MeV/amu
Linear accelerator	p	50-800 MeV
CEBAF recirculating superconducting linear accelerator	e^-	0.5-4 GeV
Electron linear accelerator	e^+, e^-	6 MeV - 50 GeV
Colliding-Beam Storage Rings:		
Electron storage ring	e^+, e^-	0.3-100 GeV (CM)
Proton storage ring	pp	14 TeV (CM)
Proton-antiproton storage ring collider	(pp^{-1})	1.8TeV (CM)

Note:

p = proton; d = deuterium; α = alpha particle; e^- = electron; e^+ = positron;
amu = atomic mass unit;
pp = two proton beams; (pp^{-1}) = proton & antiproton beam; CM = center of mass

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Naturally Occurring and Accelerator-Produced Radioactive Materials - 1987 Review

U.S. Nuclear Regulatory Commission

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NUREG-1310

Naturally Occurring and Accelerator-Produced Radioactive Materials - 1987 Review

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ABSTRACT

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

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EXECUTIVE SUMMARY

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

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

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

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

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

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

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

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

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

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

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

(2) seek legislative authority over NARM

(3) seek authority to regulate radium disposal

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

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

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

Two recommendations evolve from this review:

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

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

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

ACRONYMS AND INITIALISMS

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

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

1 INTRODUCTION

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

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

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

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

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

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

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

2 DEFINITION OF NARM

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

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

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

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

3 SOURCES AND USES OF NARM

3.1 Radium

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3.2 Other Naturally Occurring Radioisotopes

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

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

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

3.3 Accelerator-Produced Radioactive Materials

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

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

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

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

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

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

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

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

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

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

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

3.4 Trends

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

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

3.5 Discussion

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

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

4 PROBLEMS AND INCIDENTS WITH NARM

4.1 Radium and Radon

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

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

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

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

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

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

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

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

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

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

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

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

4.2 NARM in General

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

The Conference points out additional problems with NARM:

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

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

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

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

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

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

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

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

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

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

4.3 Discussion

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

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

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

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

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

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

5 THE FEDERAL GOVERNMENT AND NARM

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

5.1 Pre-Atomic Energy Act

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In doing so, Congress stated:

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

5.3 Federal Radiation Council, 1959-1961

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

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

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

5.4 The Radiation Control for Health and Safety Act of 1968

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

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

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

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

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

5.5 The Consumer Product Safety Act of 1972

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

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

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

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

5.7 The 1977 NRC Task Force Review

(1) Initial Review

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

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

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

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

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

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

The task force had one major recommendation:

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

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

(2) Response to the 1977 Review

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

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

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

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

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

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

(3) Resolution of the 1977 Review

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

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

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

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

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

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

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

5.9 The United States Radiation Policy Council from 1980 to 1982

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

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

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

5.11 Committee on Interagency Radiation Research and Policy Coordination from 1984

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5.15 The United States Pharmacopeial Convention

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

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

5.16 U.S. Nuclear Regulatory Commission

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

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

5.17 Discussion

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

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

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

6 THE STATES AND NARM

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

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

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

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

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

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

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

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

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

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

The CRCPD attaches some urgency to this program:

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

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

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

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

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

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

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

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

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

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

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

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

7 THE ISSUES REGARDING NRC AND NARM

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

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

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

7.1 Is There a National Problem with NARM?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7.2 Are There Currently Integrated Federal Controls over NARM?

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

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

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

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

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

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

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

7.4 Are the States' Controls over NARM Adequate?

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

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

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

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

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

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

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

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

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

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

* * *

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

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

Thus, an option for NRC is the status quo.

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

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

7.7 What Are the Resource Implications?

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

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

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

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

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

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

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

8 OPTIONS

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

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

(2) seek legislative authority over NARM

(3) seek regulatory authority over radium disposal

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

(5) refer the issue of NARM regulation to CIRRPC

Each is evaluated below.

8.1 Status Quo

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

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

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

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

8.2 Seek Legislative Authority over NARM

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

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

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

8.3 Seek Legislative Authority over Radium Disposal

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

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

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

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

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

8.5 Refer the Issue of NARM Regulation to CIRRPC

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

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

8.6 Discussion

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

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

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

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

9 RECOMMENDATIONS

The NRC has the following two recommendations:

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

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

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

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U.S. NUCLEAR REGULATORY COMMISSION

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

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ATTACHMENT 9

STAFF'S EARLIER WORK FROM THE PERIODS 1976-'78; 1984; 1987-'88; and 1992

In January 1976, in response to requests from the 25 Agreement States, NRC established a Task Force to review the question of whether to bring Naturally Occurring and Accelerator- Produced Radioactive Material (NARM) under NRC's jurisdiction. The Task Force recommended [Encl. 1] that the Commission seek legislative authority to:

A. License and regulate NARM in any activity:

- That is part of, or in support of, the nuclear fuel cycle regulated by NRC;
- Where: (a) NARM is manufactured; (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;
- Where NARM is introduced into products intended for distribution to persons exempt from licensing; and
- Involving the management of NARM wastes that result from licensed activities.

B. Extend authority under Section 274 of the Atomic Energy Act to relinquish authority to regulate NARM to Agreement States and other States having existing regulatory programs for NARM that are determined to be adequate to protect the public and compatible with NRC's program.

The Task Force identified several Federal agencies with some statutory authority over NARM.

- Food and Drug Administration of the Department of Health, Education, and Welfare
- Consumer Product Safety Commission
- U.S. Environmental Protection Agency
- Occupational Safety and Health Administration of the Department of Labor
- Energy Research and Development Administration
- Department of Transportation
- U.S. Postal Service
- Customs Service
- Federal Trade Commission
- National Bureau of Standards
- Department of Interior
- Department of Defense

The Task Force recommended that NRC seek legislative authority to regulate NARM because these materials present significant radiation exposure potential and current controls are fragmentary and non-uniform at both State and Federal levels. Task Force recommendations were presented to the Commission in SECY-78-211 [Encl. 2] in April 1978. The Commission did not take any action, and asked the staff to resubmit the paper for reconsideration after addressing questions about the magnitude of NARM over-exposures, compatibility of the proposed NRC regulatory authority with other agencies, and other issues. In December 1978, staff responded to these questions with SECY-78-667 [Encl. 3], which also contained several conflicting positions. On the one hand, staff continued to recommend that NRC seek legislative authority over NARM.

On the other hand, the Director of the Office of Nuclear Material Safety and Safeguards recommended that NRC:

- Forward the Task Force findings to the Congress, Federal agencies, and State Governors;
- Offer to assist others in developing model control programs; and
- Review NARM control programs after several years to determine further appropriate NRC action.

Moreover, the Executive Director for Operations stated that there are three major issues to be considered in determining what action should be taken:

- Risk to public health and safety;
- Scope and cost of regulatory control; and
- Federal regulatory conflict and NRC's role.

In October 1984 the staff published NUREG-0976 [Encl. 4], entitled "Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials - An Update." This report presented a review of the status of use and regulation of NARM. For State regulation of NARM, the staff reported that in the 27 Agreement States NARM was regulated in the same manner as byproduct, source, and special nuclear material. In the 23 non-Agreement States, 5 States had NARM licensing programs, 2 States had voluntary or partial licensing programs, and 16 States had at least an initial registration requirement. All Agreement States and 14 non-Agreement States inspected NARM users. Four non-Agreement States conducted partial inspections, while five States did not inspect NARM users. The report concluded that the then currently fragmentary control of NARM leads to licensee confusion and a real potential for excessive radiation exposure to workers and the public.

In March 1988 the staff published NUREG-1310, entitled "Naturally Occurring and Accelerator-Produced Radioactive Materials - 1987 Review." This report presented a review of NARM sources and uses as well as incidents and problems associated with those materials. A review of previous Congressional and Federal agency actions on radiation protection matters, in general, and on NARM, in particular, was provided to develop an understanding of existing Federal regulatory activity in ionizing radiation and in control on NARM. In addition, State controls over NARM were reviewed. Specific questions were examined in terms of whether NRC should seek legislative authority to regulate NARM. The assessment of these questions served as the basis for developing and evaluating several options. The evaluation of the options led to two recommendations. This report was the basis for a subsequent SECY Paper.

In SECY-88-64 [Encl. 5] in March 1988, the staff presented recommendations to the Commission on the issue of whether NRC should seek legislative authority to regulate NARM. This paper noted that the quantities and concentrations of NARM form a continuum in the human world, and the potential hazards of NARM form a continuum ranging from background to potentially significant ones in all facets of life. Thus, any effort to control the risks from NARM calls for an integrated control program to ensure that the dominant hazards are appropriately addressed, without undue attention to the lesser hazards. This paper also reported that Congress had already vested jurisdiction over NARM in the Environmental Protection Agency; Consumer Product Safety Commission; Department of Health and Human Services; and Department of Labor. Moreover, for State regulation of NARM, the paper reported that the 29 Agreement States regulated discrete sources of NARM in the same manner as Atomic Energy Act material. In the 21 non-Agreement

States, 4 States had NARM licensing programs, 2 States had voluntary or partial licensing programs, and 14 States had registration programs, leaving 1 State, Montana, with nothing. All Agreement States and 14 non-Agreement States inspected NARM users. Four non-Agreement States conducted partial inspections, where as five States did not inspect NARM users. To clarify the issue of whether NRC should regulate NARM, the staff presented eight questions.

- Is there a national problem with NARM?
- Are there currently integrated Federal controls over NARM?
- Would NRC regulation of NARM overlap other Federal agencies' programs?
- Are the States' controls over NARM adequate?
- Is NARM a Federal, State, or professional responsibility?
- Would Congress consider NRC responsible for controlling NARM hazards?
- What are the resource implications?
- Would NRC responsibility for NARM regulation change the nature of NRC?

This SECY Paper concluded with two recommendations.

- Refer the issue of NARM regulation to the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC), for the purposes of developing an integrated policy and agency assignments on NARM, in particular, and ionizing radiation, in general, in those situations where agency jurisdictions overlap (e.g., Federal regulatory programs involving health care activities).
- Inform the Governors of the States not within the "Conference of Radiation Control Program Directors (CRCPD) Recognized NARM Licensing States" program that NRC is not seeking legislative authority to regulate NARM because such regulation is a responsibility of the States, and because other Federal agencies already have jurisdiction over most facets of NARM hazards; urge those Governors to take the necessary actions and to assign appropriate resources to become recognized NARM Licensing States.

In the Staff Requirements Memorandum for SECY-88-64, dated July 20, 1988, the Commission approved letters to the President's Science Advisor (who was the chair of the Federal Coordinating Council for Science, Engineering, and Technology that administratively created CIRRPC), and CRCPD. These letters referred the issue of Federal regulation of NARM to CIRRPC.

In SECY-92-325 [Encl. 6] in September 1992, the staff reevaluated and reported to the Commission on the public health and safety significance of discrete sources of NARM, and evaluated whether legislation extending NRC's jurisdiction to include NARM was necessary or desirable. This paper concluded that:

- The Commission should not seek legislative authority to extend its jurisdiction over the regulation of discrete NARM;
- Further NRC efforts related to discrete NARM should focus on assisting EPA in its efforts to apply the Toxic Substances Control Act to NARM and be conducted pursuant to the NRC-EPA Memorandum of Understanding dated March 16, 1992; and
- The NRC should inform the CRCPD, by letter, that the Commission will not seek legislative authority to regulate NARM, and indicate Commission support of the ongoing CRCPD program.

In the Staff Requirements Memorandum for SECY-92-235, dated October 15, 1992, the Commission did not object to the staff position to not seek legislative authority over NARM,

instructed the staff to so inform CRCPD by letter, and asked the staff to assist EPA in their efforts to address NARM under the Toxic Substances Control Act.

In September 1996 in Direction-Setting Issue 7 [Encl. 7], the staff identified options for the Commission's consideration for whether to continue to regulate or to revise its oversight of the medical uses of nuclear byproduct materials. The issue paper discussed five options.

- Expand NRC's regulatory responsibility to include x-ray, accelerators, and NARM.
- Continue the ongoing program, with improvements.
- Decrease oversight of low-risk activities with continued emphasis of high-risk activities.
- Discontinue regulation of all medical activities, except sealed sources and devices.
- Discontinue the materials program.

At that time, the Commission favored a combination of the second and third options. But in implementing the third option, the Commission wanted to use a risk-informed performance-based approach.

To summarize the staff's earlier work, SECY Papers from April and December 1978, March 1988, and September 1992 have made recommendations to the Commission on whether to extend NRC's statutory authority. On each occasion the result has been that the Commission did not seek to expand its statutory authority to include NARM.

Enclosures:

1. NUREG-0301, "Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials - A Task Force Review," published July 1977
2. SECY-78-211, "Final Recommendations of the Task Force on Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials," April 1978
3. SECY-78-667, "NRC Action on NARM Task Force Recommendation," December 1978
4. NUREG-0976, "Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials - An Update," published October 1984
5. SECY-88-64, "Naturally Occurring and Accelerator-Produced Radioactive Materials," March 1988
6. SECY-92-325, "Characterization of Discrete NARM and Evaluation of the Need to Seek Legislation Extending NRC Authority to Discrete NARM," September 1992
7. Strategic Assessment Issue Paper, Direction-Setting Issue 7 - Materials/Medical Oversight, September 1996

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

Available from
National Technical Information Service
Springfield, Virginia 22161
Price: Printed Copy $5.00; Microfiche $3.00

The price of this document for requesters outside of the North American Continent can be obtained from the National Technical Information Service.

NUREG-0301

REGULATION OF NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

A Task Force Review

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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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REPORT OF THE

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:

Donald A. Nussbaumer, Office of Nuclear Material Safety & Safeguards, Chairman,

Joel O. Lubenau, Office of State Programs, Coordinator,

Walter S. Cool, Office of Standards Development,

L. J. Cunningham, Office of Inspection & Enforcement,

Jane R. Mapes, Office of the Executive Legal Director,

Sheldon A. Schwartz, Office of State Programs, and

Donovan A. Smith, Office of Standards Development.

In addition, the following persons served as resource persons to the Task Force:

For the Agreement States,

David K. Lacker, Administrator,
Radiation Control Branch,
Texas State Department of Health,
Austin, Texas 78756.

Representing the views of the Non-Agreement States,

James Blackburn,
Illinois Department of Public Health,
Division of Radiological Health,
535 West Jefferson Street,
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Also serving as Resource Persons,

Richard J. Guimond,
Office of Radiation Programs,
U.S. Environmental Protection Agency,
Washington, D. C. 20460, and

Allan C. Tapert and
Donald L. Thompson,
FDA, Bureau of Radiological Health,
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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

[illegible], M.D., M.P.H.
COMMISSIONER OF HEALTH

[illegible], M.D., Dr. P.H.
CITY COMMISSIONER

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

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 5, 1972, of the AEC and the last reorganization of January 19, 1975, the communication point with the NRC is at such a

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

April 14, 1978 SECY-78-211

COMMISSIONER ACTION

For: The Commissioners

From: Lee V. Gossick
Executive Director for Operations

Subject: FINAL RECOMMENDATIONS OF THE TASK FORCE ON REGULATION OF NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS (NARM)

Purpose: To inform the Commission of the Public Comments on NUREG-0301 and the Task Force's recommendations to the Commission for seeking legislative authority to regulate NARM and to request approval to draft such legislation.

Category: This paper covers a major policy matter.

Issue: Whether NRC should regulate naturally occurring and accelerator-produced radioactive materials.

Discussion: BACKGROUND

NRC was requested by the Agreement States and by the Conference of Radiation Control Program Directors to look into the matter of regulating naturally occurring and accelerator-produced radioactive materials. On March 4, 1976, the Commission approved formation of an internal task force to review this matter (SECY-76-28).

The task force includes representatives from SP, ELD, IE and SD. The Chairman is Donald A. Nussbaumer of NMSS. Technical coordination is being provided by Joel O. Lubenau, SP. In addition, the Conference, the Agreement States, FDA's Bureau of Radiological Health, and EPA provided resource persons to the task force.

Contacts:
Donald A. Nussbaumer, NMSS
427-4130
and
Joel O. Lubenau, SP
[redacted]7767

Discussion: (continued)

An Information Report (SECY-77-155) was sent to the Commissioners following preparation of a draft task force report. In June, 1977, the Commission approved publication of the task force report for public comment (SECY-77-155A). The report was published in July, 1977 (NUREG-0301) and a Federal Register notice was published and a news release was issued announcing its availability and inviting public comment for a sixty-day period (Appendix A). The report was given wide distribution. Copies were sent to the following addressees with a request for comments:

56-State and Territorial Health Officers (Appendix B);

55-State and local Radiation Control Program Directors (Appendix C);

22-Federal Agencies identified in the report as having an interest, or potential interest, in regulating these materials, (Appendix D); and

72-Presidents of firms which are manufacturers and distributors of products containing NARM (Appendix E).

Copies were also sent to the Southern and Western Interstate Nuclear Boards and to the National Council on Radiation Protection and Measurements under a cover letter requesting comment. Copies of the news release and Federal Register notice were sent to professional societies. In all, over 200 persons representing Government, industry and professional groups were individually contacted.

The task force found that naturally occurring and accelerator-produced radioactive materials (NARM) 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. One NARM isotope, radium-226, is one of the most hazardous of radioactive materials. It is used by about 20% of all radioactive material users. About 85,000 medical treatments using radium occur each year.

The task force also found that the regulation of NARM is fragmented, non-uniform and incomplete at both Federal and State levels.

Discussion: (continued) As a result of its findings, the task force recommended the following:

"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.

"3. In any activity where NARM is introduced into products intended for distribution to persons exempt from licensing. (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.)

"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."

---

* e.g., sealed sources such as gauging devices, radiography sources, oil well logging sources and devices, etc.

** Radioactive materials used in normal form or loose form as, for example, in medical diagnosis.

Discussion: (continued)

SUMMARY OF PUBLIC COMMENTS

The comment period expired September 19, 1977. Twenty-five (25) comments were received. A detailed analysis of the comments is presented in Appendix F. Twenty-one (21) respondents expressed varying degrees of support for the task force recommendation. These included all of the 6 States and 5 of the 7 Federal Agencies who commented. Two respondents provided comments but took no position on the recommendation. One response received from industry (Westinghouse) and one received from a Federal Agency (EPA) opposed the recommendation. EPA commented that it has adequate existing authority to regulate NARM.

FDA's Bureau of Radiological Health supported the recommendation in principle but suggested deferring action until a voluntary FDA-State effort to control NARM has been implemented and its effectiveness has been evaluated.

No responses were received from the 15 other Federal Agencies contacted including the Occupational Health and Safety Administration or the Consumer Product Safety Commission.

Comments which qualified the support of the recommendation were received from 13 of the 21 who supported it. The most frequent of these expressed concern over the need for adequate numbers of NRC staff to handle the regulation of NARM. Three (3) comments were received which stated the data in the report does not support the recommendation. (Two of these were from commentors opposing the recommendation [Westinghouse and EPA] and the third from FDA.) (The problem here is a paucity of data due to fragmentary regulation among Federal and state agencies.) Two Federal Agencies (MESA and CDC-NIOSH) felt clarification was needed on the regulatory role of NRC with respect to mines.

Two of the comments supporting the recommendation were received from NCRP and NBS. NCRP supported efforts to obtain authority for NRC to regulate accelerator-produced radioactive material but reserved an endorsement of the recommendation as applied to naturally

Discussion: (continued) occurring radioactive materials until there was further clarification of the roles of NCRP, EPA, NRC and other interested parties. NBS fully supported the recommendation of the task force and noted the proposed authority was exactly the same as NBS proposed when it commented to OMB on EPA's proposed bill to regulate naturally occurring radioactive materials, in early 1977.

The Department of Energy supports the recommendation.

The staff took note of State comments on an NRC task force study concerning the Agreement States Program. A draft report was published in August, 1977 as NUREG-0299 (SECY-77-437). One conclusion of that draft report was that only one other NRC study (on low-level radwaste management [SECY-77-489]) might impact upon Agreement States. In their comments on the draft report, Kentucky and Colorado sharply disagreed and identified the NARM study as another which would impact upon States. As a result of these comments, the Final Task Force Report on the Agreement States Program (NUREG-0388, SECY-77-621) included an endorsement of the recommendation of the NARM task force that NRC seek authority to regulate these materials.

The NARM task force noted that the NARM study interfaces, in part, with the uranium milling GEIS, particularly control of mill tailings. The Commission has approved a staff proposal to draft proposed legislation to give NRC authority to regulate naturally occurring radioactive materials associated with mill tailings in non-Agreement States (SECY-77-303A). Such legislation, in principle, would be consistent with the NARM task force recommendation as it affected mill tailings.

STAFF CONSIDERATION OF THE TASK FORCE RECOMMENDATION

In considering the task force recommendation, the staff analyzed the findings in NUREG-0301, the public comments, and other information contained in Appendix G. The staff evaluation of the recommendation and other options available to the Commission is presented in Appendix H. The staff's conclusions, based upon this evaluation, are summarized as follows:

Discussion:

-- Full implementation of Federal controls is needed to fill significant regulatory gaps in the control of NARM and protect the public health and safety.

-- Legislative clarification of Federal regulatory responsibilities with respect to NARM is necessary.

-- The need for some NRC authority over NARM (in mill tailings) has already been established and recognized by the Commission.

-- Federal control of NARM can most easily be accomplished by folding such materials into the existing NRC regulatory programs for byproduct, source and special nuclear materials, including the Agreement State program.

-- In light of comments received, assertion by NRC of regulation of NARM, would not be objected to by other Federal Agencies, with the likely exception of EPA. (See Appendix F, Analysis of Public Comments on NUREG 0301.)

-- The impact upon NRC to implement the recommendation of NUREG-0301 will be relatively modest: An additional 7 person-years of professional effort will be needed to handle the additional routine workload. The dollar cost would be about $500,000 (Appendix I).

It should be noted that the Senate Committee on Governmental Affairs recently completed a study on Federal Regulation and published a report in December, 1977. With respect to radiation matters, the report stated that "Radiation safety is marked by too many agencies administering too many laws, adopted in a piecemeal approach." The report quotes liberally from the NARM Task Force report in discussing NARM. The report recommends that EPA be given authority to take over as lead agency in radiation protection matters. The NRC staff was contacted by the Committee staff during preparation of its report concerning the general issue of NARM and, specifically, the disposition by the Commission of the NARM Task Force recommendation. The staff believes a Commission position on this issue should be established in the near future.

Recommendations: The staff recommends that the Commission approve:

1. Preparation by the staff of a draft bill giving NRC regulatory jurisdiction over NARM.

2. Transmittal of letters (substantially as shown in Appendix K) to the appropriate Congressional Committees informing them of the decision.

3. Transmittal of letters (substantially as shown in Appendix J) to State and Territorial Health Officers, Radiation Control Program Directors, Federal Agencies, and manufacturers and distributors of NARM informing them of decision.

Coordination: The Office of the Executive Legal Director has no legal objections to the contents of this paper or the proposed letters. ELD notes and OPE concurs in the following: Any legislation designed to reduce duplication and overlap in regulatory authority over NARM and vest additional regulatory authority in NRC would deprive EPA of some of its existing authority. Given the impact which extension of NRC jurisdiction to include NARM would have on the jurisdiction of other agencies, consideration might be given by the Commission to a more comprehensive reorganization of existing radiation protection authorities. Whether NRC efforts along these lines are confined to NARM or are more ambitious, some controversy will likely result. To the extent the recommendation would apply to uranium mill tailings, OPE does not concur. OPE comments are responded to in Enclosure L.

The Offices of State Programs, Nuclear Material Safety and Safeguards, Inspection and Enforcement, and Standards Development concur in this paper. OGC has no comments.

Lee V. Gossick
Executive Director for Operations

Enclosures:
See next page

Enclosures:
Appendix A - Federal Register notice, NUREG-0301
B - D.A. Nussbaumer July 1977 ltr to State and Territorial Health Officers Regarding NUREG-0301
C - G. W. Kerr July 1977 ltr to All Agreement and non-Agreement States Regarding NUREG-0301
D - D.A. Nussbaumer July 1977 ltr to Federal Agencies Regarding NUREG-0301
E - D.A. Nussbaumer July 1977 ltr to Presidents of NARM Manufacturing and Distributing Firms
F - Analysis of Public Comments on NUREG-0301
G - Information Considered by the Staff Subsequent to NUREG-0301
H - Evaluation of Options
I - Estimation of NRC Resources Needed
J - Letters to State and Territorial Health Officers, Radiation Control Program Directors, Federal Agencies and NARM Manufacturers and Distributors
K - Letters to Congressional Committees
L - OPE Comments and Response

Commissioners' comments should be provided directly to the Office of the Secretary by close of business Monday, May 1, 1978.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT April 21, 1978, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional time for analytical review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

This paper is tentatively scheduled for a briefing at an Open Meeting during the Week of April 24, 1978. Please refer to the appropriate Weekly Commission Schedule, when published, for a specific date and time.

DISTRIBUTION
Commissioners
Commission Staff Offices
Exec Dir for Operations
Secretariat

APPENDIX A

FEDERAL REGISTER NOTICE, NUREG-0301

NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

Task Force Report

A Nuclear Regulatory Commission Task Force has completed a review of the matter of regulation of naturally occurring and accelerator-produced radioactive materials. These materials are not presently regulated by NRC because they do not come within the scope of the definitions of nuclear materials in the Atomic Energy Act. The scope of the study, as prescribed for the Task Force, was limited to review of Federal and State regulation of naturally occurring and accelerator-produced radioactive materials. Sources of ionizing radiation involving radiation-producing equipment, such as X-ray machines, were not included in the study.

The conclusions and recommendations of the Task Force are as follows:

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 ⅓ 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.

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.

The Commission believes that opportunity for public comment should be afforded before the Commission reaches any decision on the Task Force recommendations. All interested persons who desire to submit written comments on the report and its recommendations should send them by September 19, 1977, to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch.

Copies of the complete report are available for inspection and copying at the Commission's Public Document Room at 1717 H Street NW., Washington, D.C., and at the Commission's local Public Document Rooms. Copies of the comments received in response to this notice will be placed in the Commission's Public Document Room in Washington, as received. Single copies of the report may be obtained without charge, to the extent of supply, by writing to the Division of Document Control, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Copies of the report NUREG-0301 will be available for sale at the National Technical Information Service, Springfield, Va. 22161.

Dated at Washington, D.C., this 8th day of July 1977.

For the Nuclear Regulatory Commission.

SAMUEL J. CHILK,
Secretary of the Commission.

[FR Doc.77-21030 Filed 7-20-77;8:45 am]

APPENDIX A

APPENDIX B

D.A. Nussbaumer July 1977 ltr to State and Territorial Health Officers Regarding NUREG-0301

7/8/77

Ira L. Myers, M.D., State Health Officer
State Department of Public Health
State Office Building
Montgomery, AL 36104

Dear Dr. Myers:

A U.S. Nuclear Regulatory Commission (NRC) Task Force has recently completed a study on the regulation for health and safety of naturally occurring and accelerator-produced radioactive materials. These materials are not now regulated by NRC. NRC was requested by the States to seek authority to regulate these materials.

The Task Force recommended NRC should seek such authority. The Commission, recognizing the need for input from potentially affected persons and organizations, including State Agencies, as part of its deliberative process is making the report available for public review and comment. A Federal Register notice will be published concerning this action.

A copy of the Task Force report is enclosed. I am bringing it to your attention because the States' present regulatory role with respect to these materials could be affected if the recommended action is undertaken. A copy of this report has also been sent to the head of the radiological health program in your Agency.

Should you have any comments, please send them to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Should you have any questions on this matter that you would wish to discuss, please contact me or Joel Lubenau, Office of State Programs.

Sincerely,

D. A. Nussbaumer, Assistant Director
for Material Safety and Licensing
Office of Nuclear Material Safety
and Safeguards

APPENDIX B

APPENDIX C

G.W. Kerr July 1977 ltr to All Agreement and Non-Agreement States Regarding NUREG-0301

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

JUL 15 1977

Ref: SA/JOL

All Agreement States and Non-Agreement States

NRC TASK FORCE ON THE REGULATION OF NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

I have attached a copy of an NRC Task Force report on the above subject. We are also sending copies to each State Health Officer (or equivalent).

NRC was requested by the Agreement States in 1974 and by the Conference of Radiation Control Program Directors in 1975 to bring naturally occurring and accelerator-produced radioactive materials under its jurisdiction. In response to these requests, NRC, in January 1976, established a task force to review the matter of regulation of these materials. Resource persons from the Agreement States, non-Agreement States, FDA Bureau of Radiological Health and EPA, also participated.

The Task Force recommended NRC should seek legislative authority to regulate these materials.

Because of the recognized need to properly interface with other Federal and State agencies on this matter, NRC is making the report available to government agencies and to the public for comment.

A Federal Register notice announcing availability of the report and requesting public review and comment will be published shortly. We would appreciate receiving a copy of any comments you may file concerning the report.

G. Wayne Kerr, Assistant Director
for State Agreements Program
Office of State Programs

Enclosures:
As stated

APPENDIX C

APPENDIX D

D.A. Nussbaumer July 1977 ltr to Federal Agencies Regarding NUREG-0301

JUL 29 1977

Eula Bingham, Ph.D.
Assistant Secretary for Occupational
Safety & Health
Department of Labor
Third Street & Constitution Avenue, N.W.
Washington, D.C. 20210

Dear Dr. Bingham:

A U.S. Nuclear Regulatory Commission (NRC) Task Force has recently completed a study on the regulation for health and safety of naturally occurring and accelerator-produced radioactive materials. The NRC does not have legislative authority to regulate these materials. NRC was requested by the States to seek authority to regulate these materials.

The Task Force recommended NRC should seek such authority. The Commission, recognizing the need for input from potentially affected persons and organizations, including Federal Agencies, is making the report available for public review and comment. A Federal Register notice was published on July 14, 1977 concerning this action.

A copy of the Task Force report is enclosed. I am bringing it to your attention because your Agency was identified by the Task Force as an Agency having some regulatory interest, directly or indirectly, in this matter.

Should you have any comments, please send them to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch.

Sincerely,

D. A. Nussbaumer, Assistant Director
for Material Safety and Licensing
Office of Nuclear Material Safety
and Safeguards

APPENDIX D

ADDRESSEE LIST

David H. Link, Acting Director
Bureau of Medical Devices &
Diagnostic Products
Food & Drug Administration
5600 Fishers Lane
Rockville, MD 20852

Eula Bingham, Ph.D.
Assistant Secretary for Occupational
Safety & Health
Department of Labor
Third Street & Constitution Avenue, N.W.
Washington, D.C. 20210

Allan I. Roberts
Director of Office of Hazardous
Material Operations
Department of Transportation
400 Seventh Street, S.W.
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Leonard Lehman
Assistant Commissioner, Regulations
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U.S. Customs Service
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John D. Clare, M.D.
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Hugh F. McKenna, Acting Associate
Commissioner for Program Operations
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5600 Fishers Lane
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William C. Watson, Jr.
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1600 Clifton Road, N.E.
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Barbara Ludden
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Washington, D.C. 20207

Edward V. Dorrey
Senior Assistant Postmaster General,
Operations
U.S. Postal Service
Washington, D.C. 20260

J. Thomas Rosch, Director
Bureau of Consumer Protection
Federal Trade Commission
Washington, D.C. 20580

James M. Day, Administrator
Mining Enforcement & Safety Administration
Department of the Interior
Washington D.C. 20240

L. L. Mitchell, Acting Executive Director
Federal Supply Service
General Services Administration
Washington, D.C. 20406

James R. Cowan, M.D.
Assistant Secretary of Defense
(Health & Environment)
Department of Defense
The Pentagon
Washington, D.C. 20301

Warren K. Sinclair, President
National Council on Radiation
Protection & Measurements
7910 Woodmont Avenue
Bethesda, MD 20014

John C. Villeforth, Director
Bureau of Radiological Health (HFX-1)
Food & Drug Administration
5600 Fishers Lane
Rockville, MD 20852

William D. Rowe, Ph.D., Deputy
Assistant Administrator for
Radiation Programs
U.S. Environmental Protection Agency
401 M Street, S.W
Washington, D.C. 20460

James E. Leiss, Ph.D., Director
Center for Radiation Research
National Bureau of Standards
Washington, D.C. 20234

James L. Liverman, Assistant
Administrator
Energy Research and Development
Administration
20 Massachusetts Avenue, N.W.
Washington, D.C. 20545

Rauer H. Meyer, Director
Office of Export Administration
Department of Commerce
Washington, D.C. 20230

APPENDIX E

D.A. Nussbaumer July 1977 ltr to Presidents of
NARM Manufacturing and Distributing Firm

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

JUL 20 1977

Dear Sir:

A U.S. Nuclear Regulatory Commission (NRC) Task Force has recently completed a study on the regulation for health and safety of naturally occurring and accelerator-produced radioactive materials. These materials are not now regulated by NRC. NRC was requested by the States to seek authority to regulate these materials.

The Task Force recommended NRC should seek such authority. The Commissioners, recognizing the need for input from potentially affected persons and organizations as part of its deliberative process is making the report available for public review and comment. A Federal Register notice will be published concerning this action.

A copy of the Task Force report is enclosed. I am bringing it to your attention because your organization may be a distributor or manufacturer of these materials or devices containing these materials, and therefore has a potential interest in this matter.

Should you have any comments for the public record please send them to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch.

Sincerely,

D. A. Nussbaumer

D. A. Nussbaumer, Assistant Director
for Material Safety and Licensing
Office of Nuclear Material Safety
and Safeguards

Enclosure:
As Stated

APPENDIX E

Varian Associates
Vacuum Division
121 Hartwell Avenue
Lexington, Massachusetts 02173

Nuclear Associates
35 Urban Avenue
Westbury, New York 11590

Picker Corporation
595 Minor Road
Cleveland, Ohio 44143

Fisher Scientific Company
7722 Fenton Street
Silver Spring, Maryland 20910

General Electric
Medical Systems
4855 Electric Avenue
Milwaukee, Wisconsin 53219

Stratitrol Corporation
1030 West Ellsworth Avenue
Denver, Colorado 80323

Alnor Instrument Company
7301 North Caldwell Avenue
Niles, Illinois 60648

Minneapolis-Honeywell
Regulator Company
Minnesota Research Center
10701 Lyndale Avenue South
Bloomington, Minnesota 55420

Lustrolite Cleveland Corporation
(Presently Brilliant Electric Signs, Inc.)
1151 Main Avenue
Cleveland, Ohio 44113

New England Nuclear Corporation
549 Albany Street
Boston, Massachusetts 02118

Entronic Corporation
4348 Riverline Drive
Earth City, MO 63045

Coastal Radiation Services, Inc.
4117 Rhoda Drive
Baton Rouge, Louisiana 70816

Mine Safety Appliances Company
201 North Braddock Avenue
Pittsburgh, Pennsylvania 15208

Cenco Instruments Corporation
2600 South Kostner
Chicago, Illinois 60623

BRK Electronics, Inc.
525 Rathbone Avenue
Aurora, Illinois 60538

Atomic Products Corporation
P.O. Box 657
Center Moriches, New York 11934

Clinical Assays, Inc.
237 Binner Street
Cambridge, Massachusetts 02141

International Chemical and Nuclear
Corporation
2727 Campus Drive
Irvine, California 92664

Interex Corporation
3 Strathmore Road
Natick, Massachusetts 01760

Hochiki America, Corporation
21804 Belshire Avenue
Hawaiian Gardens, CA 90716

John U. Hidalgo
1209 Lair Avenue
Metairie, Louisiana 70003

3M Company
Minnesota Minning and Manufacturing
3M Center Street
St. Paul, Minnesota 55119

E.R. Squibb And Sons, Inc.
P.O.Box 4000
Princeton, New Jersey 08540

Fire Alert
Division of Walter Kidde
and Co., Inc.
Wheatridge, CO 80033

Vigor, Bergeon Bestfit
B. Jadow & Sons Inc.
53 W. 23rd Street
New York, New York 10010

Victoreen Instrument Company
10101 Woodland Avenue
Cleveland, Ohio 44104

Soiltest, Inc.
2205 Lee Street
Evanston, Illinois 60202

United Engineers
Automation Division of Black,
Sivalls and Bryson, Inc.
7455 East 46th Street
Tulsa, Oklahoma 74145

Glowall Corporation
Easton and Dansville Road
Willow Grove, Pennsylvania 19090

Gerald A. Leifchild
1409 West Helman Avenue
Alhambra, California 91803

Isotope Products Labs
1800 North Keystone Street
Burbank, California 91504

Radiation Detection Co.
162 Wolfe Road
Mountain View, California 94088

Kay Ray, Inc.
516 West Campus Drive
Arlington Heights, Illinois 60004

Unitec, Inc.
305 Kansas Avenue
Brewster, Kansas 67732

Campbell Pacific Nuclear Corporation
124 Buchanan Circle
Pacheco, Calfornia 94553

Environmental Sciences
2722 Campus Drive
Irvine, Calfornia 92664

Valtron, Inc.
2 Colorow Drive
P.O. Box 324
Morrison, Colorado 80465

American BioMedical
Bionuclear Division
7777 Forest Lane
Houston, Texas 75230

Columbia Scientific
Industries Corporation
P.O. box 9908
Austin, Texas 78766

Universal Security Instruments, Inc.
2829 Potee Street
Baltimore, Maryland 21225

U.S. Nuclear Corporation
a Division of International Chemical
and Nuclear Corporation
801 North Lake Street
Burbank, California 91503

Louis Ried, Jr.
195 Panwnew Drive
Boulder, Colorado 80303

Security Engineering Co., Inc.
4432 Woodlark Center
Clemen, North Carolina 27012

Notifier Corporation
3700 North 56th Street
Lincoln, Nebraska 68504

Amersham/Searle Corporation
2636 South Clearbrook Drive
Arlington Heights, Illinois 60005

Health Physics Associates Ltd.
2356 Skokie Valley Road
Highland Park, Illinois 60035

Searle/Anaitic
2000 Nuclear Drive
Des Plaines, Illinois 60018

Austin Science Associates, Inc.
5902 West Dee Caves Road
Austin, Texas 78746

Gulf Nuclear Inc.
P.O. Box 5866
Houston, Texas 77058

Mettler Instrument Corporation
Princeton Road
Heightstown, New Jersey 08542

C-E Invalco
1350 Lewisville Road
Tulsa, Oklahoma 74145

Sargent-Welch Scientific Company
7300 Linder Avenue
Skokie, Illinois 60076

Radiation Materials Co., Inc.
124 Calvary Street
Waltham, Massachusetts 02154

Source Production & Equipment Company
625 Oxley Street
Kenner, Louisiana 70062

Stock Equipment Company
731 Hanna Building
Cleveland, Ohio 44115

Dr. J.Goldstein
Medi-Physics
5801 Christie Ave.
Emoryville, Ca. 94708

Parckard Instrument, Co., Inc.
2200 Warrenville Road
Downers Grove, Illinois 60515

Tracor, Inc.
7500 Traco Lane
Austin, Texas 78721

Texas Nuclear Corporation
P.O. Box 9267
Austin, Texas 78766

Gearhart-Owen Industries, Inc.
1100 Everman Road
Fort Worth, Texas 76101

Gammatron, Inc.
Nuclear Sources and Services
5707 Etheridge Road
Houston, Texas 77017

Troxler Electronic Laboratories, Inc.
P.O. Box 12057
Cornwallis Road
Research Triangle Park, North Carolina
27709

Abbott Laboratories
1400 Sheridan Road
North Chicago, Illinois 60064

Nuclear Research & Development Co.
Nuclear Instruments and Accessories
P.O. Box 1261
Berkley, Michigan 48072

American Nuclear Products
1232 East Commercial
Springfield, Missouri 65803

Scientific Products
1430 Waukegan Road
McGaw Park, Illinois 60085

Princeton Gamma-Tech, Inc.
Box 641
Princeton, New Jersey 08540

Internetics, Inc.
2275 Southwest Temple
Salt Lake City, Utah 84119

Dynamics, Inc.
2125 Ivy Square
Charlottesville, Virginia 22903

Radium Chemical Company
161 East 42nd Street
New York, New York 10017

Ranger Electronics Corporation
P.O. Box 863
Alva, Oklahoma 73717

Seaman Nuclear Corporation
3846 West Wisconsin Avenue
Milwaukee, Wisconsin 53208

APPENDIX F

Analysis of Public Comments on NUREG-0301

APPENDIX F

ANALYSIS OF PUBLIC COMMENTS ON NUREG-0301

In July, 1977, NUREG-0301, "Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials" was published. A Federal Register notice requesting public review and comment was printed July 21, 1977. Two hundred persons in State and Federal Government, private industry and other sectors were contacted individually. In response, the following correspondence was received (PR-Misc [42 FR 37458]):

Respondent	Abbreviation	Docket No.
Robert Alan Parker	RAP	1
Virginia Department of Health	Va.	2
Campbell Pacific Nuclear	CPN	3
Oregon Department of Human Resources	Ore.	4
Rio Algom Corporation	RAC	5
U.S. Department of Interior Mining Enforcement & Safety Administration	MESA	6
U.S. General Services Administration	GSA	7
U.S. Environmental Protection Agency	EPA	8
Amersham Corporation	AC	9
U.S. Department of Health, Education and Welfare, Center for Disease Control, National Institute for Occupational Health & Safety	CDC-NIOSH	10
American College of Nuclear Physicians	ACNP	11
Arkansas Department of Health	Ark.	12
New England Nuclear	NEN	13

Respondent	Abbreviation	Docket No.
National Council on Radiation Protection and Measurements	NCRP	14
U.S. Department of Health, Education, & Welfare, Food & Drug Administration	FDA	15
Westinghouse Electric Corporation	W	16
New York State Energy Office	NY	17
American Iron & Steel Institute	AISI	18
U.S. Department of Commerce, National Bureau of Standards	NBS	19
Dielman Consultants, Inc.	DCI	20
University of Minnesota	UMinn	*
Colorado Department of Health (2 letters)	Colo.	*
Southern Interstate Nuclear Board	SINB	*
Illinois Department of Public Health	Ill.	*
U.S. Department of Energy	DOE	**

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* Comments were not addressed to Secretary of Commission, Attention: Docketing and Service Branch. Records Facility Branch, ADM were furnished copies and requested to handle as responses to PR-Misc. (42 FR 37458).

** Comment received two months after expiration of comment period. Copy was furnished to the NRC PDR.

Detailed analysis of the comments follow below. A summary of the comments appears in Table F-1. The commentor's abbreviations in parenthesis refer to responses which best represent the particular comment.

Support of the task force recommendation was expressed by 84% (21 of 25) of the comments received. Eight (8) expressed unreserved support (NBS, NY). Thirteen (13) others expressed varying degrees of qualification of the support. The most frequently expressed qualification concerned the need to provide NRC with adequate staff to handle the regulation of NARM (AC). Two respondents opposed the recommendation (EPA, W). Two respondents provided comments but took no position (CDC-NIOSH, UMinn).

State Comments

Six (6) states commented. All supported the recommendation but two states raised questions which concerned how NRC would recognize state programs (Va.and N.Y.) and the NRC staffing required to handle NARM (Ill.). One state noted minor technical errors in the report (Colo.).

Federal Agency Comments

Twenty-two (22) Federal Agencies, other than NRC, were identified in the report as having possible regulatory interests in NARM and were contacted by letter from the task force chairman (see Appendix D). Seven (7) responded. GSA and NBS fully supported the recommendation. NBS noted that the recommendation was identical to NBS's comments to OMB regarding EPA's proposed bill to regulate naturally occurring radioactive materials (see below, concerning EPA's comments).

The Department of Interior's Mining and Enforcement and Safety Administration (MESA) endorsed the recommendation but requested clarification of NRC regulatory role over mines. This need for clarification was expressed by CDC-NIOSH.

FDA stated that, "As a long range goal, it appears logical to include all radioactive material under the authority of one agency with the intent of having one national, uniformly applied program to control user radiation safety and to set performance standards

for products and devices, regardless of the origin of the radioactive material." FDA also stated, "As a long term goal, Federal regulatory control should be sought for imported NARM items, exempt NARM items and all NARM items manufactured and used in non-licensing States." FDA, however, believes a voluntary FDA-State cooperative program currently under development should be completed and time given to implement and evaluate this collaborative approach.* (FDA's letter is attached to this Appendix as Attachment 1.)

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* The FDA-State program involves a voluntary, cooperative effort by the states to regulate NARM. The Suggested State Regulations for Radiation Protection provide the regulatory model. "NARM Guides" have been developed which provide regulatory guidance to the states, and also provide assistance to manufacturers, assemblers and distributors with regard to radiation safety aspects for NARM sources and products. These documents have been developed as a result of cooperative efforts involving the states, FDA, NRC, and EPA. NRC has concurred in the Suggested State Regulations (they provide the basis for developing Agreement State regulations) and in the NARM guides (these are comparable to existing NRC regulatory practices for by-product, source and special nuclear materials).

This program has been an invaluable interim asset to those States which have chosen to establish regulatory, and in particular licensing, programs for NARM. The Bureau of Radiological Health and the participating States deserve commendation for undertaking and supporting this program. Despite some significant inherent deficiencies, as noted below, it has served as a technical information clearing house on NARM sources. Much of the work already accomplished can be directly applied in a more formalized regulatory program.

The system, however, already is subject to weakness that prevents it from providing an adequate regulatory basis for controlling NARM. NUREG-0301 reported that seven states have neither a licensing nor registration program for NARM and no comments were received differing with this view (including from these 7 states). There are no incentives identified in the FDA program which would cause development of even minimal regulatory programs in these states or to maintain adequate programs in other states. One State - New York - because of budget constraints for several years has not evaluated NARM sealed sources and devices. New York does perform such evaluations for radioactive materials covered by the Section 274 Agreement with the State in fulfillment of that Agreement. (NARM is not covered by current Section 274 Agreements.) The absence of such evaluations by New York is significant. Radium Chemical Co., New York, is a major U.S. supplier of sealed radium and radon sources for medical, industrial and research users and still supplies radium luminous compounds. (Footnote continues on next page).

The Department of Energy (DOE) supported the recommendation, noting that such action would lead to a single regulatory agency responsible for all radioactive material and this would be consistent with the International Atomic Energy Agency (IAEA) model regulatory code developed in conjunction with the World Health Organization (WHO) which treats all radioactive materials. DOE also noted the need for NRC to properly plan for disposal of radium wastes.

One Federal Agency did not take a position on the recommendation (CDC-NIOSH).

The U. S. Environmental Protection Agency opposed the recommendation (EPA). EPA stated, "...we believe there is available within EPA the necessary authorities to provide radiation protection from naturally-occurring radionuclides. Currently we are developing an overall plan and rationale to draw those authorities administered by EPA into a consistent program of uniform regulations which preclude the need for further regulation." With respect to uranium mill tailings, EPA noted it was meeting with NRC to assure adequate public health protection with proper regard to the roles of each Agency and that the recommendation, as applied to mill tailings, would duplicate EPA authorities under the Resource Conservation and Recovery Act and Clean Air Act Amendments. EPA also expressed the view that Congress has purposefully intended that NRC's mission be limited to "fission related facilities, materials and by-products." (EPA's letter is attached to this Appendix as Attachment 2.)**

The staff noted that the voluntary FDA-State program does not address two areas that need Federal - not State - action for effective control: Importing of NARM and surplusing and other supplying of NARM by Federal Agencies.

Lastly, the staff does not believe that effective control over NARM used in consumer products will be obtained through a voluntary Federal-State program having the deficiencies just cited.

**As noted in NUREG-0301, EPA proposed a bill to directly regulate naturally occurring radioactive materials. The EPA comment contained no reference to its proposed bill, and, on the surface, stands in apparent contradiction to EPA's action early in 1977 when it proposed legislation to provide additional authority for itself over naturally occurring radioactive materials. The EPA comment also did not specifically speak to accelerator-produced radioactive materials.

The staff examined the statutes identified in the EPA comments and has concluded that EPA's statement that, "Existing law... provides EPA with a variety of authorities to control NARM in environmental media, wastes, effluents, emissions, and as a toxic material in products..." is essentially correct. (Summaries of the staff review of these statutes are attached to this Appendix as Attachment 3.)

The task force, in its report, did not find that these various authorities had been effectively implemented. This view is consistent with a General Accounting Office report concerning EPA's radiation protection program, dated January 20, 1978. * (The GAO summary of its report is attached as Attachment 4.)

Even if EPA were effectively implementing its authorities -- and it is not -- the task force pointed out in its report that the regulation of some radioactive materials under the Atomic Energy Act, as amended, and other materials under other statutes is a division of Federal regulatory authority that is unrelated to hazard. Rather, it is the result of Congressional concerns in 1946 and the immediately following years to narrowly focus on the perils of the atomic bomb and the problems related to control of material associated with the fission process. NARM was excluded from the Atomic Energy Act. In the succeeding years, a need for regulating NARM in various activities became recognized. Since the Atomic Energy Act excluded NARM, authority for Federal regulation of these materials has been included in various legislation affecting other Federal agencies including EPA.

It can be reasonably argued that such division of authority, in addition to being subject to unequal levels of effort to implement them, also entail inefficiencies that result from the need to create and maintain qualified staff and programs in each of the affected agencies.

Thus, the question of seeking authority for NRC to regulate NARM, requires not only consideration of whether there is existing, adequate Federal authority to regulate these materials, but also consideration of the questions of whether or not other Federal agencies are adequately carrying out their existing responsibilities in this area and what Federal approach represents the best in economies and efficiency.

Assuming this to be an appropriate framework in which to analyze the EPA comment, simple existence of regulatory authorities for other agencies is not sufficient reason to dismiss further consideration of the task force recommendation.

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* Contrary to the recommendation in this paper, the GAO report, which focuses on EPA's responsibilities, recommended that this deficiency be remedied by strengthening EPA's authority and resources for controlling environmental exposure to radiation.

Weight must also be given to the fact that States did not make a general request of the Federal Government to act, nor did the States approach any other Federal agency. Rather, this agency was specifically named and asked to extend its authority over NARM.

Logically, the NRC is the most appropriate Federal agency to regulate NARM since it presently regulates radioactive materials other than NARM (which present similar radiation protection problems) and already has in place the organizational structure, regulations and licensing and inspection procedures necessary to conduct a regulatory program over NARM. In addition, it has the authority to transfer its regulatory responsibilities to the States when it finds the States have established regulatory programs that are adequate and compatible with those of the NRC.

No responses were received from the other 15 Federal agencies, including the Occupational Safety and Health Administration and the Consumer Product Safety Commission.

NARM Manufacturers and Distributors

Seventy-two (72) manufacturers and distributors of NARM were contacted and asked to comment on NUREG-0301 (see Appendix E). Most of these were identified from a reference manual of NARM sources and devices maintained by FDA's Bureau of Radiological Health.*

Three (3) provided comments and all supported the recommendation. One comment stated, "There has long been a program of sales pressure on consumers to buy the radium devices because it is '...so safe it doesn't even require a license'... Such equipment was, in fact, usually higher in external radiation than comparable Byproduct Material devices and with questionable internal safety features." (CPN).

Other Industrial

Three (3) responses were received from other members of the industrial sector. Two (2) supported the recommendation including a uranium mine and mill operator (RAC).

One respondent opposed the recommendation (W) stating, in part, "In the absence of regulation, conscientious users will remain conscientious; despite the presence of regulations, careless users will continue to find ways to cause problems... We question whether any small incremental improvements in the control of NARM brought about by NRC regulation will offset the costs of instituting across-the-board regulatory machinery in one-half of the nation."

* Uranium mine and mill operators were not included.

Professional Societies

One professional society responded and concurred with the recommendation (ACNP).

Other

NCRP supported the recommendation to the extent that it applied to accelerator-produced radioactive materials but withheld endorsement as it applied to naturally-occurring radioactive materials. NCRP felt additional clarification of roles of the different regulatory agencies in regulating these materials was needed.

The Southern Interstate Nuclear Board (SINB) and the American Iron and Steel Institute (AISI) expressed support.

Support was expressed by a private citizen (RAP).

Comments were received from one respondent concerning radium, uranium and thorium-230 in coal and requesting sponsorship of studies in this area (UMinn). No views were expressed on the recommendation. (NMSS has sent a reply referring his request to EPA and OSHA.)

Table F-1

Summary of
Analysis of Public Comments on NUREG-0301

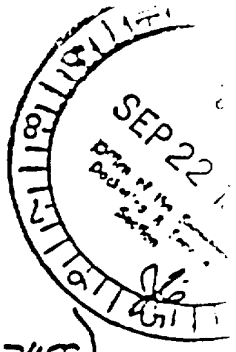
Recommendation that NRC Seek Regulatory
Authority over NARM

Respondent	No. Responses	Full Agreement	Qualified Support or Agreement w/Comment	Disagree	No Position
Federal Agencies	7	2	3	1	1
State Agencies	6	3	3	0	0
NARM Manufacturers & Distributors	3	1	2	0	0
Other Industrial	3	1	1	1	0
Professional Society	1	0	1	0	0
NCRP	1	0	1	0	0
Other	4	1	2	0	1
Totals	25	8	13	2	2
			21		

APPENDIX 1

Attachment 1

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857



Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

(15) PROPOSED RULE FR-Misc (42FR37458)

Attention: Docketing and Service Branch

Gentlemen:

In response to the Federal Register notice of July 21, 1977 (42 FR 37458), we offer our comments on the report, "Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials--A Task Force Review."

In April 1977, our Bureau of Radiological Health (BRH) commented on an earlier draft of this report which did not include the conclusions and recommendation of the Executive Summary contained on pages 3-4 of the final report. Therefore, we have limited our response mainly to general comments because our specific comments have already been considered by the Task Force.

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

In pursuing the goal of obtaining Federal legislative authority to regulate naturally occurring and accelerator-produced radioactive materials, it is suggested that consideration be given to the following:

1. Upon the recommendation of Workshop No. 7 of the Seventh Annual National Conference on Radiation Control in 1975, the Executive Committee of the conference appointed Task Force No. 1:

   "To develop the criteria needed to perform an adequate evaluation of devices, sealed sources, foils, dials, and matrices which contain naturally occurring or accelerator-produced radioactive material (NARM) and factors regarding their interstate distribution. By means of these criteria to provide a mechanism for State-Federal control of the manufacture and distribution of subject sources and products not covered under the Atomic Energy Act."

   This Task Force is composed of State personnel representing the Conference of Radiation Control Program Directors (CRCPD) and representatives of the Nuclear Regulatory Commission, the Environmental Protection Agency, and the Bureau of Radiological Health, FDA. The Task Force has met several times over the past two years and has developed a set of NARM Guides as part of a nationwide system for the uniform evaluation and control of products containing NARM (which includes the Radioactive Materials Reference Manual and the Suggested State Regulations for Control of [illegible]

cooperative efforts of the States and the Federal Government. The NARM Guides will also provide assistance to manufacturers, assemblers, and distributors regarding radiation safety aspects for NARM sources and products. Uniform application of the NARM Guides by radiation control agencies will serve to promote radiological safety in the manufacture, assembly, and distribution of NARM sources and products.

It is important that this voluntary NARM program which has received a great many man-hours of effort in its development by members of the CRCPD, NRC, EPA, and ERH be supported by the participating groups and given sufficient opportunity to function now that work on the NARM Guides has been completed. The NARM Guides were not available in 1974 when the Agreement States recommended Federal legislation governing naturally occurring and accelerator-produced radioactive material. The States through the CRCPD have now indicated their support of the NARM Guide program.

As a long-term goal, Federal regulatory control should be sought for imported NARM items, exempt NARM items, and all NARM items manufactured and used in non-licensing States. However, the process of seeking legislative authority for Federal control of NARM at this time should not detract from continued development of the voluntary State-Federal cooperative NARM program. The voluntary NARM program should be compatible, to the extent possible, with the Federal NARM control program which is to be developed in the future. Therefore, supporting and strengthening the voluntary NARM program at this time should contribute toward development of the Federal NARM control program as a long-range goal.

2. Although the Task Force report reflects considerable effort and provides a useful overview of the current status of agency responsibilities and limitations in the control of NARM material, it appears that there is a lack of sufficient current data to justify and serve as the basis for requiring a new initiative of Federal legislative authority to establish a regulatory control program. Much of the data in NUREG-0301 was taken from an FDA report (FDA 72-8001) published in 1971 and based on a study now almost ten years old. Considerable portions of this latter report were based on initial surveys of users made by State agencies during the 1950's and 1960's when State radiation control programs were just developing.

   The report points out that various Federal Agencies have authority for control over various aspects of the use of NARM and correctly notes that these agencies have not instituted specific controls. The report fails to note, however, that when specific actions were

proposed at the Federal level, it was not possible to show that the use of NARM represents sufficient hazard to the public to warrant action when compared to other agency priorities.

The Task Force report provides a basis for a further study on the comparative effectiveness and costs of a Federal licensing program versus a voluntary State-Federal program to assure the health and safety of the public in the use of the radioactive materials. The Task Force report provides no data on actual radiation hazards or injuries due to NARM, by-product, source, or special nuclear materials upon which to make a comparative hazard analysis. A further study would evaluate the effectiveness of the voluntary Federal-State NARM program. The Food and Drug Administration would be interested in participating in such a study, which should be accomplished with the support of all interested Federal Agencies as well as the CRCPD.

3. As indicated in the report, the FDA has authority to regulate medical radiation sources under the Medical Device Amendments of 1976 (Public Law 94-295, 90 Stat 539-583) of the Federal Food, Drug, and Cosmetic Act. This authority would include medical radiation sources containing NARM. BRH is the lead Bureau in FDA dealing with manufacturers of the following types of medical devices: (a) all medical devices which are electronic products subject to the Radiation Control for Health and Safety Act (x-ray machines, medical lasers, microwave and acoustic devices); (b) medical devices other than electronic devices subject to the Radiation Control for Health and Safety Act of 1968 but which emit ionizing radiation essential to their intended function (cobalt-60, teletherapy, brachytherapy sources, etc.); and (c) accessories or components of products falling under categories (a) or (b) which may influence the quantity, quality, or direction of the radiation emitted or produced (x-ray film, screens, image receptors, film processors, nuclear medicine scanners, etc.). We believe the second paragraph on page 30 of the NRC Task Force report may give the impression that BRH is only involved with voluntary recommendations in this area, whereas they are responsible for a regulatory program under the authority of the Medical Device Amendments for the types of medical devices indicated above.

Under (1) of Conclusions on page 43 of the report, the impression may be given that FDA does not have authority for pre-market approval of NARM radioactive medical sources under the Medical Device Amendments of 1976. The statement should be clarified by deleting the following sentence: "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." The classification of medical devices is actively under development by FDA as is the promulgation of regulations on "good manufacturing prac-

tice." The FDA classification program involves a systematic examination of the risk of injury and will provide a reasonable basis for the decision on requiring Federal pre-market approval.

At the top of page 30 discussing regulatory functions of the Department of Health, Education, and Welfare, the impression is given that only the regulations of Agreement State programs may be exempted from preemption at this time. The proposed rule regarding exemption from preemption under Section 521 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k) indicates that State or local requirements applicable to medical devices would be preempted only when a corresponding FDA requirement becomes applicable to a particular device by operation of the Act (see 42 FR 30383; June 14, 1977). Therefore, at the present time, the regulations of non-agreement States would not be preempted because FDA has not imposed any corresponding requirements under the Federal Food, Drug, and Cosmetic Act.

In summary, we would like to stress the NARM program being developed in cooperation with the CRCPD and the Federal Agencies--NRC, FDA, and EPA. The States through the CRCPD have indicated their support of the NARM Guide program. The NARM Guides were not developed in 1974 when the Agreement States recommended Federal legislation governing naturally occurring and accelerator-produced radioactive material. However, developmental work has now been completed on this project, and time is needed to evaluate the effectiveness of this collaborative approach. We would be interested in participating in such an evaluation which should provide a firm basis for determining whether Federal legislation may be needed in the future. This should be accomplished with the support of all interested Federal Agencies as well as the CRCPD.

Sincerely yours,

Joseph P. Hile

Joseph P. Hile
Associate Commissioner for Compliance

APPENDIX F, Attachment 2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

18 AUG 1977

Honorable Samuel J. Chilk
Secretary of the Commission
Nuclear Regulatory Commission
1717 H Street, NW
Washington, D.C. 20555

Dear Mr. Chilk:

The Environmental Protection Agency has reviewed the Task Force Report on the Regulation of Naturally-Occurring and Accelerator-Produced Radioactive Materials which was provided to us for comment by Mr. D.A. Nussbaumer. We have also noted the publication (42 F.R. 37854) of a request for comments on the recommendations of the Task Force; this letter is in response to both of these requests. The Task Force has made a commendable effort to summarize many of the issues related to the control of naturally-occurring and accelerator-produced radioactive materials. However, we do not believe the recommendation that the NRC seek additional new legislative authority to regulate naturally-occurring and accelerator-produced radioactive materials (NARM) is warranted, based upon the information presented in the report.

Creation of such additional radiation control authority in the Nuclear Regulatory Commission would imply that the NRC's mission is the general protection of public health from radiation exposure per se, rather than its more limited role as regulator of atomic energy related facilities, materials, and by-products. On pages 37 through 42 of the report, it is noted that in 1946, 1954, 1959, and again in 1975, when Congress significantly modified legislation affecting NRC (or its predecessor AEC), it consistently limited the Agency's authority to atomic fission related facilities, materials, and by-products. Clearly, Congress could have permitted the NRC to become the Federal agency with total jurisdiction over the control of all radioactive materials and radiation exposure if it so desired. Rather, Congress has chosen to assign the various responsibilities for the control of radiation, and radioactive materials other than source, by-product, and special nuclear materials, to agencies such as the Consumer Product Safety and Health Administration, the Department of Health, Education, and Welfare, the Occupational Safety and Health Administration, the Mining Enforcement and Safety Administration, and the Environmental Protection Agency. Such legislation has generally dealt with radiation as one of several pollutants or hazards to be controlled under the general functional responsibilities of these respective agencies.

8-25-77

[illegible] to include [illegible] by the Atomic Energy Act. We believe that such a definition [illegible] would be inappropriate to [illegible] and other [illegible] products of the fission process.

The reason expressed by the Task Force for their recommendation is "that these materials (naturally-occurring and accelerator-produced radioactive materials) present significant radiation exposure potential, and present controls are fragmentary and non-uniform at both the State and Federal level." We believe that the recommendations in the report would not bring about appropriate control over major sources of exposure to these materials, and would act to increase fragmentation of Federal agency responsibilities related to these sources of exposure. For example, the report states that "the recommendations do not cover activities where NARM is encountered in-situ, is incidentally present in mineral industry activities outside of the fuel cycle, or is an incidental contaminant in consumer products." However, work by this Agency, some of which was discussed in the Task Force Report, suggests that these exposure situations are considerably more significant to public health than the NARM sources which would be encompassed by the proposed legislative changes.

Existing law, including the Resource Recovery and Conservation Act, the Toxic Substances Control Act, the Federal Water Pollution Control Act, the Clean Air Act with 1977 amendments, and the Marine Protection and Sanctuaries Act, provides EPA with a variety of authorities to control NARM in environmental media, wastes, effluents, emissions, and as a toxic material in products. As recognized in the report, additional authorities exist in the authorizing legislation for the Consumer Product Commission, the Food and Drug Administration, and the Occupational Safety and Health Administration for regulating NARM in consumer products, in medical devices, and as a hazard to workers. If there are any deficiencies in regulation of these items, this should be corrected through properly coordinated increased use of these authorities, not through additions to the already voluminous authority to deal with radiation hazards. With the recently passed legislation cited above and the existing Federal Water Pollution Control Act, we believe there is available within EPA the necessary authorities to provide radiation protection from naturally-occurring radionuclides. Currently we are developing an overall plan and rationale to draw those authorities administered by EPA into a consistent program of uniform regulations which precludes the need for further legislation. We would welcome the participation of NRC in this effort.

With respect to uranium mill tailings, EPA has held initial meetings with staff members of NRC to insure that EPA's newly enacted responsibility to regulate radioactive NARM wastes is exercised effectively, so that together we can provide adequate public health protection from this

[illegible] purpose set forth by the Atomic [illegible] Act of 1974. In [illegible], the proposed Task Force recommendations, as they apply to [illegible] mill tailings, would duplicate responsibilities now assigned to the Environmental Protection Agency under the Resource Conservation and Recovery Act, and the Clean Air Act Amendments.

In summary, we believe that extension of NRC's authority to NARM is outside the purpose set forth for the Commission by the Atomic Energy Act and the Energy Reorganization Act of 1974, and would represent an inefficient use of resources and duplication of existing Federal responsibilities. Therefore, we recommend that the Commission not seek the additional authority recommended by the Task Force. We would welcome the opportunity to meet with your staff to discuss these mutual concerns, and to explore further the alternatives and needs for improved control of NARM materials.

Thank you for providing us the opportunity to comment on these proposals.

Sincerely yours,

W. D. Rowe, Ph.D.
Deputy Assistant Administrator
for Radiation Programs (AW-458)

STATUTE SUMMARIES

I. Toxic Substances Control Act

Public Law 94-469, October 11, 1976, 90 Stat. 2003, 15 U.S.C. § 2601 et seq.

The purpose of the Toxic Substances Control Act is to prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances and mixtures. The Act is designed to fill a number of regulatory gaps which currently exist, such as pre-market scrutiny of chemical substances prior to first manufacture, direct regulation of chemical substances, and consideration of all risks associated with chemical substances.

The Act gives EPA broad authority to (1) require the development by manufacturers and processors of adequate data with respect to the effect on health and environment of chemical substances which they manufacture or process, (2) regulate hazardous chemical substances and mixtures, namely those with respect to which the Administrator has found that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal thereof presents or will present an unreasonable risk of injury to health or the environment, and (3) to carefully control, through court-ordered seizure or other relief when necessary, chemical substances or mixtures or any article containing such substances or mixtures which present imminent hazards.

The term "chemical substance" is defined in the Act as "any organic or inorganic substance of a particular molecular identity, including-- (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and (ii) any element or uncombined radical." The term "chemical substance" does not include mixtures which are separately defined, in part, as "any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; ..." Although source, byproduct and special nuclear material are expressly excluded from the definition of "chemical substance", NARM clearly falls within the scope of the definition. Thus, EPA has authority to regulate NARM in accordance with the provisions of the Toxic Substances Control Act.

II. Resource Conservation and Recovery Act of 1976
Public Law 94-580, October 21, 1976, 90 Stat. 2795, 42 U.S.C. 6901 et seq.

The objectives of this Act, which is administered by EPA and amended the Solid Waste Disposal Act are to (1) assist counties, cities and States in the solution of the discarded materials problem; (2) provide nationwide protection against the dangers of improper hazardous waste disposal; and (3) spark a cooperative effort among Federal, State and local governments and private enterprise to recover valuable materials and energy from solid waste. The Act defines "solid waste" as

> "...any garbage, refuse, sludge from a waste treatment plant, water supply treatment plant, or air pollution control facility and other discarded material, including solid, liquid, semi-solid, or contained gaseous material resulting from industrial, commercial, mining, and agriculture operations, and from community activities, but does not include solid or dissolved material in domestic sewage, or solid or dissolved materials in irrigation return flows or industrial discharges which are point sources subject to permits under section 402 of the Federal Water Pollution Control Act, as amended (86 Stat. 880), or source, special nuclear, or byproduct material as defined by the Atomic Energy Act of 1954, as amended (68 Stat. 923)."

Hazardous waste is defined as:

> "...a solid waste, or combination of solid wastes, which because of its quantity, concentration, or physical, chemical, or infectious characteristics may--
>
> "(A) cause, or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or
>
> "(B) pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed."

Subject to certain exceptions, any NARM contained in discarded material resulting from industrial, commercial, mining, and agriculture operations and from community activities would be considered solid waste within the meaning of the Act. However, the statutory definition of solid waste would not include NARM found in solid or dissolved form in domestic sewage or in irrigation return flows or NARM found

in industrial discharges which are point sources subject to permits under section 402 of the Federal Water Pollution Control Act, as amended. Any NARM found to be solid waste within the meaning of the Act, would in most instances, in our opinion, also meet the statutory definition of hazardous waste.

Under the provisions of the Resource Conservation and Recovery Act, EPA has jurisdiction over uranium mill tailings because solid waste is defined to include discarded material from mining activity and uranium mill tailings do not qualify as source, byproduct or special nuclear material.

EPA's regulatory responsibilities with respect to hazardous wastes are set out in Subtitle C. of the Resource Conservation and Recovery Act. Any NARM determined to be hazardous waste would be subject to regulation by EPA pursuant to this authority.

The relationship between the Resource Conservation and Recovery Act and other federal laws is specifically provided for in section 1006 of the Act which states in part:

> "Nothing in this Act shall be construed to apply to ... any activity or substance which is subject to the Federal Water Pollution Control Act, ... the Safe Drinking Water Act, ... the Marine Protection, Research and Sanctuaries Act of 1972, ... or the Atomic Energy Act of 1954 ... except to the extent that such application (or regulation) is not inconsistent with the requirements of such Acts...."
>
> "The Administrator shall integrate all provisions of this Act for purposes of administration and enforcement and shall avoid duplication, to the maximum extent practicable, with the appropriate provisions of the Clean Air Act, ... the Federal Water Pollution Control Act, ... the Federal Insecticide, Fungicide, and Rodenticide Act, ... the Safe Drinking Water Act, ... the Marine Protection, Research and Sanctuaries Act of 1972 ... and such other Acts of Congress as grant regulatory authority to the Administrator. Such integration shall be effected only to the extent that it can be done in a manner consistent with the goals and policies expressed in this Act and in the other acts referred to in this subsection."

Section 6003 of the Act directs all Federal agencies having functions relating to solid waste or hazardous waste to cooperate with the EPA Administrator in carrying out his functions under the Act to the maximum extent permitted by law.

III. Federal Water Pollution Control Act, as amended
33 U.S.C. 1151 et seq.

The objective of the Federal Water Pollution Control Act (FWPCA) is to restore and maintain the chemical, physical and biological integrity of the Nation's waters. To this end, the Act establishes national policies which include prohibition of discharges of toxic pollutants in toxic amounts, and sets national goals which include elimination by 1985 of discharges of pollutants into navigable waters. The Administrator of EPA has broad authority under the Act to achieve these goals and objectives, including, among other things, authority to establish effluent limitations for point sources, establish pre-treatment effluent standards, prohibit or establish effluent standards for discharges of toxic pollutants, prescribe water quality criteria, review and approve or disapprove state water quality standards and implementation plans, issue permits for the discharge of pollutants, and seek judicial relief upon receipt of evidence that a pollution source or combination of sources presents an imminent and substantial endangerment to the health or welfare of persons.

Section 511(c) of the Act specifically provides that nothing in the National Environmental Policy Act of 1969 shall be deemed to authorize any Federal agency to review any effluent limitation or other requirement established pursuant to the FWPCA or the adequacy of any certification under section 401 of the Act, or to impose, as a condition of any license or permit, any effluent limitation other than one established pursuant to the FWPCA.

The term "pollutant" is defined in the Act to mean, among other things, "solid waste, ... chemical wastes, ... radioactive materials, heat, ... rock, sand, cellar dirt and industrial, municipal, and agricultural waste discharged into water...." The term "toxic pollutant" means

> "those pollutants, or combinations of pollutants, including disease-causing agents, which after discharge and upon exposure, ingestion, inhalation or assimilation into any organism, either directly from the environment or indirectly by ingestion through food chains, will, on the basis of information available to the Administrator, cause death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions (including malfunctions in reproduction) or physical deformations, in such organisms or their offspring."

On June 1, 1976, in Train v. Colorado Public Interest Research Group, Inc., 426 U.S. 1, the U.S. Supreme Court held that source, byproduct and special nuclear materials regulated by NRC are not pollutants within the meaning of the FWPCA. NARM, on the other hand, is clearly a pollutant within the meaning of the Act, and could, in many instances, depending on the facts, be found to be a toxic pollutant within the meaning of the Act.

IV. Clean Air Act with 1977 Amendments

SECY-77-448A, October 31, 1977 contains a general account of the regulatory framework of the Clean Air Act and a detailed analysis of the Clean Air Act Amendments of 1977. Although this paper is primarily concerned with the impact of the 1977 amendments on facilities and materials regulated by NRC, the presentation makes it quite clear that NARM which is emitted into or otherwise enters the ambient air is an air pollutant within the meaning of the Act and as such fully subject to the regulatory provisions of the Act, including the provisions for the control of hazardous air pollutants.

(See detailed Analysis of 1977 Clean Air Act Amendments attached to SECY-77-448A, especially pp. 1-3, 4-5, 13-14, 26-37.)

V. Marine Protection, Research and Sanctuaries Act of 1972
Public Law 92-532, as amended, October 23, 1972, 86 Stat. 1052, 33 U.S.C.A. § 1401 et seq.

The purpose of Title I of the Act, which is administered by EPA, is to regulate the dumping of all types of materials into ocean waters and to prevent or strictly limit dumping into those waters of any material that would adversely affect human health or welfare, or the marine environment, ecological systems or economic potentialities. Dumping of radiological warfare agents or high-level radioactive waste 1/ is prohibited. Permits are required for dumping other materials.

1/ "High-level radioactive waste" is defined in the Act as

> "the aqueous waste, resulting from the operation of the first cycle solvent extraction system, or equivalent, and the concentrated waste from subsequent extraction cycles, or equivalent, in a facility for reprocessing irradiated reactor fuels, or irradiated fuel from nuclear power reactors."

The term "material" is broadly defined in the Act to mean "matter of any kind or description, including, but not limited to,.... [among other things] solid waste, ... radiological ... warfare agents, radioactive materials, ... and industrial, municipal, agricultural, and other waste;" ...

The term "dumping" is also broadly defined as "a disposition of material." This statutory definition, however, does not mean

> "a disposition of any effluent from any outfall structure to the extent that such disposition is regulated under the provisions of the Federal Water Pollution Control Act, as amended, ... under the provisions of section 13 of the Rivers and Harbors Act of 1899, as amended, ... or under the provisions of the Atomic Energy Act of 1954, as amended ... nor does it mean ... the construction of any fixed structure or artificial island nor the intentional placement of any device in ocean waters or on or in the submerged land beneath such waters, for a purpose other than disposal, when such construction or such placement is otherwise regulated by Federal or State law or occurs pursuant to an authorized Federal or State program ..."

NARM falls squarely within the statutory definition of "material" and would therefore be subject to EPA's regulatory authority under the provisions of this Act.

VI. Occupational Safety and Health Act of 1970
Public Law 91-596, December 29, 1970, 84 Stat. 1590, 29 U.S.C.A. § 651, et seq.

The objective of the Occupational Safety and Health Act of 1970 is to assure so far as possible safe and healthful working conditions for every working man and woman in the Nation. Towards this end, the Act requires each employer to furnish to each of his employees "employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees." The Act also requires each employer to "comply with occupational safety and health standards promulgated under this Act." The Act places a similar obligation on employees, requiring each employee to "comply with occupational safety and health standards and all rules, regulations, and orders issued pursuant to this Act which are applicable to his own actions and conduct."

The Act prescribes standards and procedures for the development and promulgation of occupational safety and health standards and authorizes the Secretary of Labor, who is responsible for its

administration, "to set mandatory occupational safety and health standards applicable to businesses affecting interstate commerce, ..." Section 6(b)(5) 2/ contains guidelines which the Secretary is required to follow in promulgating standards dealing with toxic materials or harmful physical agents. In addition, the Secretary has authority to establish emergency temporary standards if he determines "... (A) that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards, and (B) that such emergency standard is necessary to protect employees from such danger." The Act provides that emergency temporary standards shall take immediate effect upon publication in the Federal Register and shall remain in effect until replaced by a standard promulgated in accordance with the procedures specified in section 6(b) of the Act.

When conditions or practices in a place of employment are so dangerous that they could reasonably be expected to cause death or serious physical harm immediately or before the imminence of such danger can be eliminated through the enforcement procedures otherwise provided by the Act, the Secretary may petition the courts for immediate judicial relief.

Section 4(b)(1) of the Act states:

> "Nothing in this Act shall apply to working conditions of employees with respect to which other Federal agencies and State agencies acting under section 274 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2021), exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health."

2/ Section 6(b)(5) reads as follows:

> "The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired."

Although this provision limits the reach of OSHA so far as source, byproduct and special nuclear materials are concerned, it does not affect the applicability of the Act to NARM.

VII. Consumer Product Safety Act
15 U.S.C.A. §§ 2051-2081.

The purposes of the Consumer Product Safety Act, which is administered by the Consumer Product Safety Commission, are to protect the public against unreasonable risks of injury associated with consumer products, assist consumers in evaluating the comparative safety of consumer products, develop uniform safety standards for consumer products and minimize conflicting State and local regulations, and promote research and investigation into the causes and prevention of product-related deaths, illnesses and injuries. The Act defines "consumer product" as "any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise; ..." Articles which are "not customarily produced or distributed for sale to, or use or consumption by, or enjoyment of, a consumer, ..." are not "consumer products" within the meaning of the Act. In addition, certain specific items, such as tobacco and tobacco products, motor vehicles or motor vehicle equipment, food, drugs, devices and cosmetics, are expressly excluded from the definition of consumer product.

The Act authorizes the Consumer Product Safety Commission to promulgate consumer product safety standards, and to promulgate rules declaring certain consumer products banned hazardous products. Requirements included in a consumer product safety standard must be reasonably necessary to prevent or reduce an unreasonable risk of injury 3/ associated with the product. These requirements may relate to such matters as product performance, composition, contents, design, construction, finish, packaging, and any warnings or instructions which may be needed. A consumer product which is or will be distributed in commerce may be declared to be a banned hazardous product if the product presents an unreasonable risk of injury and no feasible consumer product safety standard would adequately protect the public from the unreasonable risk of injury associated with the product.

The Commission is authorized to issue orders prohibiting manufacturers, distributors or retailers of consumer products which present a "substantial

3/ "Risk of injury" is defined in the Act as "... a risk of death, personal injury, or serious or frequent illness."

product hazard" from importing such products, from manufacturing or offering such products for sale, or from distributing such products in commerce. The Commission is also authorized to order manufacturers, distributors or retailers to bring the product into conformity with an applicable consumer product safety standard or repair the defect in the product, to replace the product or to refund the purchase price. A "substantial product hazard" exists where the failure of the consumer product to comply with an applicable consumer product safety rule creates a substantial risk of injury to the public, or where the consumer product contains a "defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public."

In the case of an imminently hazardous consumer product, namely a product which presents imminent and unreasonable risk of death, serious illness, or severe personal injury, the Commission is authorized to seek judicial relief by seizure of the product and/or action against the manufacturer, distributor or retailer.

Section 31 of the Consumer Product Safety Act (15 U.S.C.A. § 2080) provides that:

> "The Commission shall have no authority ... to regulate any risk of injury associated with a consumer product if such risk could be eliminated or reduced to a sufficient extent by actions taken under the Occupational Safety and Health Act of 1970; the Atomic Energy Act of 1954; or the Clean Air Act. The Commission shall have no authority ... to regulate any risk of injury associated with electronic product radiation emitted from an electronic product (as such terms are defined by section 263c(1) and (2) of Title 42) if such risk of injury may be subjected to regulation under subpart 3 of part F of title III of the Public Health Service Act."

Except to the extent that regulation is precluded by this provision, consumer products containing NARM would be subject to the jurisdiction of the Consumer Product Safety Commission.

VIII. Nuclear Medicine

The Federal Food, Drug and Cosmetic Act of 1938 (21 U.S.C.A. §§ 301 et seq.) authorized the Food and Drug Administration to regulate the safety of drugs, including radioactive drugs, offered for interstate commerce through control of product labeling. Legislative amendments

in 1962 gave the FDA tighter controls over drug safety and introduced controls over the efficacy of drugs to foreclose the marketing of safe, adequately labeled drugs that do not work. The Federal Food, Drug and Cosmetic Act of 1938, as amended, also authorized the FDA to control the manufacture of drugs, including radioactive drugs. In 1976, Congress enacted the Medical Device Amendments of 1976, (Public Law 94-295, May 28, 1976, 90 Stat. 539-583) which gave the Food and Drug Administration authority to regulate medical devices similar to its authority to regulate the safety and efficacy of drugs. Drugs and medical devices containing NARM would be covered by this authority.

REPORT TO THE CONGRESS

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

The Environmental Protection Agency Needs Congressional Guidance And Support To Guard The Public In A Period Of Radiation Proliferation

A clearer understanding of the Environmental Protection Agency's responsibilites for providing guidance in radiation matters could lead to more efficient protection of the American people and their environment from the hazards of radiation.

This report discusses a need to better define radiation authorities assigned by law to the Agency so that jurisdictional confrontations may be eliminated and staffing and funding limitations may be corrected.

CED-78-27

JANUARY 20, 1978

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-166506

To the President of the Senate and the
Speaker of the House of Representatives

This report discusses a need to define the radiation authorities of the Environmental Protection Agency to eliminate jurisdictional confrontations and correct existing staffing and funding limitations. A clearer understanding of the Environmental Protection Agency's role could lead to a more efficient program to protect the American people and their environment from the hazards of radiation.

We made our review pursuant to the Budget and Accounting Act, 1921 (31 U.S.C. 53), and the Accounting and Auditing Act of 1950 (31 U.S.C. 67).

Copies of this report are being sent to the Acting Director, Office of Management and Budget; the Administrator, Environmental Protection Agency; the Chairman, Nuclear Regulatory Commission; the Secretaries of the Departments of Energy; Health, Education, and Welfare; and Labor; and to interested congressional committees, various Members of Congress, and other interested parties.

Comptroller General
of the United States

COMPTROLLER GENERAL'S
REPORT TO THE CONGRESS

THE ENVIRONMENTAL PROTECTION AGENCY NEEDS CONGRESSIONAL GUIDANCE AND SUPPORT TO GUARD THE PUBLIC IN A PERIOD OF RADIATION PROLIFERATION

D I G E S T

Everyone in American society is exposed to some form of radiation daily. Sources include natural environment, dental and medical X-rays, nuclear powerplants, homes built on radioactive landfill, clocks and watches with luminous dials (to a much smaller degree), and some food products. (See pp. 1 to 5.)

The Environmental Protection Agency in 1970 was given unclear authority to protect the American people and their environment from radiation hazards. Its officials agree with GAO that the Agency currently is unable to provide complete protection under its ambiguous authorities and that clarification by the Congress is needed. (See pp. 7 and 36.)

The Agency's radiation programs have been plagued by

--jurisdictional challenges to the Agency's authority,

--staffing and funding reductions,

--an inability to retain competent professionals,

--limited cooperation with other agencies and research groups, and

--low priority placed on radiation protection.

Of all Environmental Protection Agency programs, radiation protection is the least funded. Continual reductions in radiation protection staff and budget, transfers of professionals to other Agency programs, and discussions with Agency officials currently working at the Office of Radiation Programs lead GAO to the conclusion that

the Environmental Protection Agency has not been given enough support in its radiation protection efforts. (See pp. 15 to 19 and 21 to 26.)

This means that (1) the Agency's program for monitoring radiation levels to which the American people currently are exposed is limited and (2) without extensive changes, the Environmental Protection Agency will continue to be limited in its ability to protect public health and the environment from radiation dangers.

The Agency does not know the scope of dangers caused by all current radiation sources and is unable to anticipate future problems adequately. Some data is incomplete and inadequate. It does not have sufficient staff or money to perform necessary research and so it has not fully secured available data or developed new data. It has been unable to issue timely standards and guidance and has been consistently unable to meet its own deadlines for issuing significant reports, standards, and guidelines. (See pp. 29 to 33.)

The Agency received two authorities for providing radiation protection when it was created in 1970. It can

--issue standards for radioactivity in the environment, including general environmental guidelines for particular industries and for radiation doses to the public, and

--provide guidance to Federal agencies affecting all forms of radiation protection in Federal activities. (See pp. 7 to 9.)

To date from these authorities the Agency has issued one standard--currently not enforced--and has issued no new formal guidance to other Federal agencies. (See pp. 11 to 15.)

Much of man's exposure to radiation is from unavoidable natural background sources as compared to manmade sources. It is recognized that improvements in radiation techniques and control could reduce exposure.

As the sources of radiation increase, the health of the general population may be adversely affected. Because genetic effects are involved, radiation exposure affects the lives of future generations.

Many of the materials that emit radiation have the potential to contaminate the environment for years, some for hundreds of thousands of years. After they've been used in the production of weapons, in the manufacture of electricity, etc., these materials become waste which must be disposed of safely without contaminating drinking water, future home sites, food supplies, or the natural environment.

There have been problems in disposing of nuclear waste materials safely. In some instances accidents have occurred, and in others the dangers were not understood until after contamination had already taken place. (See p. 1.)

RADIATION PROTECTION PHILOSOPHY AND STANDARD

Federal policy is based on the axiom that nuclear energy and the medical, agricultural, scientific, and industrial uses of radiation are essential for human advancement. The proliferation of existing applications and the development of new technology mean that the total sources of radiation are increasing and will continue to increase. The Environmental Protection Agency currently sees its radiation responsibility as balancing potential damage to health and the environment against the benefits of radiation use.

When the Agency issued its first standard on January 13, 1977, after 6 years of development and delays, it established a new criteria for exposure to individual members of the public and limited the quantities of long-lived radioactive materials entering the general environment. (See pp. 10 to 11.)

A HISTORY OF PROGRAM REDUCTIONS

Over the years the Environmental Protection Agency has reduced its emphasis on radiation control. In

1972 funding and overall staffing levels were at a high of $8.8 million and 335 positions. The Agency's request for fiscal year 1978 is $4.8 million and 184 positions for radiation abatement and control. As a result, morale in the Agency's radiation program is low and most people interviewed said that there is not adequate staff, data, laboratory support, or research to do an effective job.

In the beginning of the program, all of the Agency's radiation efforts were centralized in its Office of Radiation Programs. This office had the task of developing guidance and standards and monitoring the environment. Agency officials said that funding and staffing for the office has been cut drastically over the years to the point that further reduction will directly affect its mission capabilities. They explained that because the Congress has not mandated specifically that the Agency provide radiation protection, this protection has not received the same priority as other authorized Agency programs. (See pp. 21 to 22.)

AN INADEQUATE MONITORING NETWORK

The Environmental Protection Agency operates the only nationwide network for monitoring levels of radiation in the environment. Officials responsible for development of criteria, guidance, and standards repeatedly emphasized to GAO that the network and individual field measurement studies are limited and do not support the Agency's full informational needs in all areas. Network monitoring officials said that because of program curtailments, periodic population exposure readings result in an estimated 40 percent of American people not being monitored. (See pp. 22 to 23.)

INABILITY TO SET PRIORITIES

In October 1976 the Agency outlined a draft of the Agency's radiation protection strategy. This called for placing priority on radiation problems that pose the greatest threat to public health and the environment. However, officials told

GAO that staff shortages have prevented the Agency from projecting all needed standards and guidance for the future.

In May 1976 the Environmental Protection Agency acknowledged in a published report that " * * * there are radiation sources for which data are either incomplete or not available * * *" and that much of the existing information is of questionable value. For example, medical X-rays contribute to a large, significant dose of radiation, but the Agency does not know how large and significant the dose actually is. Nor does the Agency sufficiently understand the relationships between exposure to some forms of radiation and their consequences in order to issue reliable predictions. More must be learned about the effects of amount and duration of exposure. The Agency admits that it does not know all the radiation sources that may provide a danger to health and the environment nor do measurements exist for many of the sources that have been identified as a potential threat. (See pp. 29 to 30.)

RECOMMENDATIONS TO THE CONGRESS

To overcome the apparent controversies regarding the role of the Environmental Protection Agency in developing standards and Federal guidance for environmental exposure to radiation, the Congress should:

--Define more clearly the Agency's role as the Federal overseer of environmental radiation.

--Outline the scope of radiation dangers to be determined by the Agency.

--Require timely development of necessary standards and guidance and periodic advisement of the Agency's progress in meeting its radiation protection goals.

RECOMMENDATIONS TO THE ADMINISTRATOR

The Administrator of the Environmental Protection Agency should provide his radiation protection program with sufficient support to do its job. Specifically the Administrator should:

--Assign additional staff and resources as available to the Office of Radiation Programs and to the radiation research program.

--Reexamine the environmental monitoring network and develop the capability to provide accurate and complete information on radiation dangers.

--Coordinate Agency research with that performed by others so that appropriate data can be compiled and developed in a timely manner.

--Require that reports on radiation levels in the environment be continued and issued at least annually.

--Develop a comprehensive assessment of the need for standards and guidance such as those required for radioactive air pollutants.

--Develop standards and guidance based on an explicit time and priority determination of the greatest or potential risks.

--Issue Federal guidance and standards based on that timetable. (See p. 35.)

AGENCY COMMENTS

In a December 1977 letter (see app. II) commenting on GAO's proposed report, the Environmental Protection Agency advised that it has planned or started actions on all GAO recommendations. The Agency recognized the problems in operating a national radiation protection program under its authorities and agreed that congressional clarification of its authorities would be valuable. (See p. 36.)

Comments on the proposed report from other Federal agencies are contained in appendixes III to VI. These agencies cite their own radiation protection activities as active, aggressive, and comprehensive efforts even in the absence of Environmental Protection Agency actions. They generally agreed, however, that a need exists for the Congress to mandate a clearer understanding of responsibilities for environmental and public health protection. (See pp. 37.)

APPENDIX G

Information Considered by the Staff Subsequent to NUREG-0301

APPENDIX G

Information Considered by the Staff Subsequent to NUREG-0301

NUREG-0299, Draft Task Force Report on the Agreement States Program. This task force, in the course of its study of the Agreement State Program, reviewed other NRC studies for possible impacts upon Agreement States. It concluded that only the Study of Federal/ State Regulation of Low Level Waste Burial Grounds would have significant impact. Following publication of the draft report, two of the States which provided comments, Kentucky and Colorado, sharply disagreed with this conclusion and identified the NARM task force report as another report which would have significant impact. The Agreement State task force agreed, and further, in its final report (NUREG-0388, SECY-77-621) endorsed the recommendation of the NARM task force that NRC seek regulatory authority over NARM.

SECY-77-303A. The staff is now drafting proposed legislation which would give NRC authority to directly regulate, as licensed material, naturally occurring radioactive materials in Uranium mill tailings in non-Agreement States.* Such legislation would be, in principle, consistent with the task force recommendation and could be folded into proposed legislation giving NRC authority to regulate NARM in other areas.

NARM Guides. Under sponsorship of the Conference of Radiation Control Program Directors, a task force composed of State, FDA, EPA and NRC representatives, has prepared "Guides for Naturally Occurring and Accelerator-Produced Radioactive Materials (NARM)," FDA Publication FDA-77-8025. These guides provide regulatory assistance to the States and also provide assistance to manufacturers, assemblers and distributors with respect to radiation safety aspects for NARM sources and devices. NRC participated in the development of these guides and they are considered to be comparable with existing NRC regulatory practices for source, by-product and special nuclear materials. As such, they can easily be integrated into the NRC regulatory program if NRC were to assert jurisdiction over NARM.

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* In Agreement States, all radioactive materials, including NARM associated with milling operations and tailings, are regulated by the States.

Iodine-123. NUREG-0301 noted that the availability and use of accelerator-produced radioisotopes has increased rapidly in recent years, especially in nuclear medicine. In August, 1977, FDA published a report, "The Developing Role of Short-Lived Radionuclides in Nuclear Medicine" (FDA Publication FDA-77-8035) which further highlights this observation. Most of the short-lived radioisotopes considered are accelerator-produced and are considered because they provide improved diagnostic information with lower radiation dose. Iodine-123 was used as the model for this report. On October 18, 1977, FDA published a Federal Register notice (p. 55649) concerning FDA's consideration of issuance of voluntary recommendations for the evaluation of diseases of the thyroid gland. The recommendations were developed from the FDA report. It is expected, if implemented, that these recommendations will probably result in significant increases in the use of Iodine-123. The report also discusses other short-lived, accelerator-produced radioisotopes and advocates support of further studies and research concerning their use.

NCRP Report 56. On November 1, 1977, the National Council on Radiation Protection and Measurements (NCRP) published Report No. 56, "Radiation Exposure from Consumer Products and Miscellaneous Sources. The report identifies sources of exposure, numbers of persons in the United States exposed to the source and average annual dose equivalents to the exposed persons and to the population. NCRP classified the sources into two groups. The first involves exposure of many people and relatively large dose equivalents and the second either involves exposure to large numbers of people and relatively small dose equivalents or vice-versa.

In the first category, radioluminous products, tobacco products, building materials and glasses and ceramics were identified. NCRP commented that elimination of some sources including tobacco products and building materials may "require alterations in basic human behavioral patterns and may be difficult to accomplish." NCRP also commented that ..."certain sources or applications serve little or no useful purpose and should be eliminated" and cited the use of radium-226 in luminous compounds as an example.

Mineral Industry Tailings. New information obtained by the State Agreements Program, SP, indicates that some mineral industry tailings may contain naturally occurring radioactive materials at levels comparable to those found in uranium mill tailings. For example, a zirconium extraction process in Oregon has produced tailings containing radium-226 in concentrations of 300 to 1000 picocuries per gram in a soluble, leachable form. Colorado has licensed a waste pile from a fluorospar

operation which contains radium-226 in concentrations of 300 to 400 picocuries per gram. These radium-226 concentrations are of the same magnitude as those encountered in the tailings from uranium mills, i.e., 100 to 1000 picocuries per gram.

The regulation of such industries for the purpose of radiation health and safety does not fit the established NRC role inasmuch as these minerals are not utilized as source material in the nuclear fuel cycle. As noted in the task force report, EPA should provide regulation of radiation hazards from such industry tailings by application of the Resource Conservation and Recovery Act.

APPENDIX H

Evaluation of Options

APPENDIX H

Evaluation of Options

NUREG-0301 Recommendation

The task force recommendation in NUREG-0301 was:

"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: (footnote omitted)

"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."

"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."

"* 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."

Options

The staff evaluated this recommendation in light of the public comments and information subsequent to issuance of NUREG-0301 and identified six options for Commission action:

Option 1: No Action by NRC;

Option 2: NRC support action giving other Federal agencies the authorities and resources necessary to correct the NARM problems;

Option 3: NRC seek partial authority only (e.g., mill tailings);

Option 4: NRC seek partial authority for itself and support action giving other Federal agencies any other necessary authorities and resources;

Option 5: NRC seek the recommended authority; and

Option 6: NRC seek authority over all radioactive materials.

The pros and cons of these options are as follows:

Option 1. NRC takes no action.

Pros

-- Requires no new or additional commitments of NRC fiscal or staff resources.

-- Preserves the present regulatory framework for NRC.

-- Is consistent with past Congressional actions to limit NRC authority to source, byproduct and special nuclear materials.

-- Does not require changes in the Atomic Energy Act, as amended.

-- Is responsive to the views of some that the hazards to the public health and safety from NARM are not sufficient to merit additional Federal action and that current Federal authorities are adequate.

-- Is consistent with the recommendations contained in the GAO report to Congress concerning EPA's responsibilities for radiation protection.

Option 1. NRC takes no action. (continued)

Cons

-- Is unresponsive to the specific requests from the States that NRC seek regulatory authority over NARM.

-- Is unresponsive to the great majority (84%) of the commentors on NUREG-0301 who supported the recommendation. These include NBS, DOE, GSA and all of the States who commented on the report.

-- Ignores the need for clarification of Federal regulation of these materials, especially where NRC has strong interests, i.e., naturally occurring radioactive materials in mill tailings in non-Agreement States.

-- Serves to continue the present fragmented, non-uniform controls over NARM.

-- Is unresponsive to the implicit recommendation of IAEA and WHO that a single regulatory agency in member countries be responsible for all radioactive materials.

-- Ignores the indications of unnecessary and possibly excessive radiation exposure of workers and the public from these sources.

-- Ignores the strong likelihood of continued rapid growth of use of some of these materials, including the substitution of these materials for byproduct, source and special nuclear materials.

Option 2. NRC supports action giving other Federal Agencies the authorities and resources necessary to correct the NARM problems.

Pros

-- Is responsive to the conclusion of NUREG-0301 that present regulatory controls over NARM are fragmented and non-uniform.

-- Requires no new routine staff or fiscal commitments by NRC.

-- Does not require changes in the Atomic Energy Act, as amended.

Option 2. (continued)

Pros (continued)

- Is consistent with past Congressional actions to limit NRC authority to source, byproduct and special nuclear materials.
- Preserves the present regulatory framework for NRC.
- Is consistent with the recommendations contained in the GAO report to Congress concerning EPA's responsibilities for radiation protection.

Cons

- Is not responsive to State requests that specifically identified NRC as the Federal Agency to seek this authority.
- Is not responsive to commentors on NUREG-0301 that endorsed NRC as the Federal Agency to seek this authority.
- Serves to continue, and may worsen, the present fragmentation of regulatory control over NARM.
- Ignores NRC's regulatory interests in certain areas, particularly the regulation of mill tailings in non-Agreement States.
- Except for EPA, no other Federal Agency has indicated specific interest in seeking additional regulatory authority over NARM.
- Ignores the advantages of using and building upon existing NRC pools of expertise and regulatory programs.
- Would complicate State relations with the Federal Government. Recognition of adequate State programs would be uncertain and State agreements with additional Federal Agencies may become necessary.
- Is unresponsive to the implicit recommendation of IAEA and WHO that a single regulatory agency in member countries be responsible for all radioactive materials.

Option 3. NRC seeks partial authority.

Note: Examples of alternatives for this option include:
(a) seeking authority to regulate naturally occurring radioactive materials in mill tailings in non-Agreement States (SECY-77-303A); and
(b) seeking authority to regulate accelerator-produced radioactive material (as recommended by NCRP).

Pros

-- Would serve to accommodate identified needs of NRC for improved regulatory authority in specified areas.

-- Limits the impact of requirements for additional NRC staff and other resources.

-- Would be consistent with staff actions already approved by the Commission (SECY-77-303A).

-- Except for new, limited authorities requested by NRC, would serve to preserve the present regulatory framework for NARM.

Cons

-- Is not fully responsive to the requests of the States that NRC seek regulatory authority over NARM.

-- Is not fully responsive to most of the comments received on NUREG-0301.

-- Will not necessarily clarify Federal regulation of NARM.

-- Is not totally responsive to the implicit recommendation of IAEA and WHO that a single regulatory agency in member countries be responsible for all radioactive materials.

-- May ignore some sources of unnecessary and possibly excessive radiation exposure of workers and the public.

-- Requires Congressional action.

Option 4. NRC seeks partial authority and supports action giving other Federal Agencies any other necessary authorities and resources.

Pros

-- Is responsive, in principle, to the State requests for additional Federal regulation of NARM.

-- Is responsive, in principle, to the comments supporting the task force recommendation.

-- NRC's involvement in the regulation of NARM would be limited to those areas where NRC has an established interest, e.g., mill tailings in non-Agreement States.

-- Limits the impact of requirements for additional NRC staff and other resources.

-- Would be consistent with staff actions already being undertaken (SECY-77-303A).

-- Is consistent, in principle, with the recommendations contained in the GAO report to Congress concerning EPA's responsibilities for radiation protection.

Cons

-- Is not fully responsive to State requests for Federal regulation of NARM by NRC.

-- Is not fully responsive to most of the comments on NUREG-0301.

-- Serves to continue the present fragmented Federal regulation of NARM.

-- Is not responsive to the implicit recommendation of IAEA and WHO that a single regulatory agency in member countries be responsible for all radioactive materials.

-- There is no guarantee that other Federal Agencies would seek, desire, or exercise additional authorities over NARM.

-- If other Federal Agencies are not given other necessary authorities, or do not exercise them, some sources of unnecessary and possible excessive radiation exposure of workers and the public may continue.

-- Requires Congressional action.

Option 5. NRC seeks the authority as recommended in NUREG-0301.

Pros

-- Would be responsive to States' requests that NRC seek such authority.

-- Would be responsive to the great majority (84%) of the comments on NUREG-0301.

-- Would serve to clarify Federal regulation of NARM and to make the regulation of these materials more uniform.

-- Would serve to fill regulatory gaps for NARM.

-- Would be responsive to the implicit recommendation of IAEA and WHO that a single regulatory agency in member countries be responsible for all radioactive materials.

-- Would assure adequate regulation of all radioactive materials regardless of changes in patterns of use or replacement of one radioactive isotope by another for a particular use.

-- Takes advantage of, and builds upon, existing NRC expertise and programs.

-- Provides for recognition of existing, adequate State programs for regulating NARM by folding in the existing Agreement State program.

-- Current voluntary, cooperative FDA-State regulatory programs can easily be integrated into existing NRC and Agreement State programs.

-- Would be responsive to the recommendation of the NRC task force on Agreement State Programs (NUREG-0388, SECY-77-621).

-- Is consistent with NRC staff actions already underway (SECY-77-303A).

Option 5. (continued)

Cons

-- Requires increase in NRC staff and other resources.

-- Is not consistent with Congressional action taken, to date, which has excluded NARM from NRC control.

-- Is not consistent with the views of EPA, with respect to naturally occurring radioactive materials.

-- Is not fully consistent with the views of FDA.

-- Ignores in-situ naturally occurring radioactive materials and naturally occurring radioactive materials occurring as an incidental contamination in mineral industry or consumer products.

-- Requires Congressional action.

Option 6. NRC seek authority over all radioactive materials, including in situ and as incidental contamination present in mineral industry or consumer products.

Pros

-- Would recognize and establish NRC control over any radioactive material regardless of source or origin.

-- Would be more fully responsive to the implicit recommendation of IAEA and WHO that a single regulatory agency in member nations be responsible for all radioactive materials.

-- Would help assure adequate regulation of all radioactive materials regardless of patterns of use or changes in radioisotopes being used.

Cons

-- Such comprehensive authority for NRC was not requested by the States.

-- Only a very small minority of commentors on NUREG-0301 (two) advocated such authority.

Option 6. (continued)

Cons (continued)

-- Would require significant additions to NRC staff and of other resources.

-- Would conflict with EPA's view that there is sufficient, existing authority to regulate naturally occurring radioactive materials.

-- Requires Congressional action.

Decision Criteria

In evaluating the options, the staff considered the pros and cons in light of the following decision criteria:

-- Would the option provide adequate protection of the public health and safety from the hazards of NARM?

-- Would the option assure Congress and the public that a comprehensive, fully coordinated program exists for controlling the hazards from NARM?

-- Does the option provide adequate definition of Federal and State roles?

-- Does the option simplify the regulation of NARM?

-- Is the option responsive to requests made by the States, and other expressions of interest and concern, including comments on NUREG-0301?

-- Is the option consistent with present NRC policies, actions and concerns?

-- Is the option one which keeps to a minimum new expenditures of Federal funds by NRC and does not detract from other, presently authorized NRC activities?

-- Is the option consistent with Presidential, Congressional and Commission policies to be responsive to State interests and to involve the States in activities affecting the interests of their citizens?

Staff Evaluation

It is the staff's view that Option 5, NRC seek the authorities recommended in NUREG-0301, best fits the decision criteria.

APPENDIX I

Estimation of NRC Resources Needed

APPENDIX I

ESTIMATION OF NRC RESOURCES NEEDED

Data available from SP, based upon Agreement State experience, indicates 25% of existing NRC licensees also use NARM. NARM only users constitute about 5% of Agreement State licensees.

Currently, NRC administers about 8,800 licenses. Twenty-five percent (25%) of these, or 2,200 probably also use NARM.

NARM only users in non-Agreement States are estimated to be 5% of 8,800 or 440. In addition, NRC may need to issue licenses authorizing distribution of NARM to persons exempt from licensing and licenses authorizing distribution of medical sources and generally licensed devices. By comparing existing NRC licensing patterns for these categories with present NARM use, another 50 to 60 licenses issued by NRC may be needed. The total of new licenses to be handled by NRC is estimated to be about 500 assuming existing Agreement State programs for NARM will be recognized by NRC.

Based upon Agreement State experience, about one-half of these licenses will be for medical uses, about one-third will be for industrial purposes and the remainder for other purposes. Assuming inspection intervals corresponding to current IE practice:

Type of License	No.	Inspection Interval	Inspections/Year
Medical	250	3 years	83
Industrial	183	3 years	61
Other	67	10 years	7
Totals	500		151

This will require about 2 person-years of professional IE effort.

NMSS experience suggests that their effort to handle 500 new NARM licenses will also require 2 person-years of professional effort.

SD professional effort should not exceed 1 person-year.

The NRC professional effort needed to handle 500 new NARM licenses is expected to be primarily in IE, NMSS and SD and will be about 5 person-years.

The incremental increase in professional effort due to 25% of existing NRC licenses also authorizing NARM is estimated to be another 2 person-years. For many NRC licenses, the use of NARM is limited to check and calibration sources or is substantially the same as the use of byproduct material, e.g., Iodine-123 vs. Iodine-131 in diagnostic nuclear medicine. The impact upon NRC licensing and inspection and enforcement efforts for these users should be quite small. On the other hand, more impact is expected from the regulation of medical licensees who also use radium and radon brachtherapy sources.

The routine total professional effort needed for NRC regulation of NARM as recommended in NUREG-0301 is therefore estimated to be about 7 person-years. The cost, including salaries, fringe benefits, administrative support, travel and overhead, is estimated to be about $500,000. This appears to be a modest figure which is believed to reflect the efficiencies of folding this Federal authority into an existing, similar Federal program that also provides for relinquishing authority to qualified States.

These efforts do not include additional effort that will be needed in the initial phases of NRC regulation of NARM, e.g., to locate and educate NARM users.

If existing non-Agreement State licensing programs are recognized and NRC authority over NARM is relinquished in those States as well as in Agreement States, the impact upon NRC will be significantly less. These five States (Illinois, Michigan,* New Jersey, Pennsylvania, and Virginia) currently regulate nearly half of the NARM users in non-Agreement States. The reduction in NRC resources will not be in direct proportion (SD effort would not be significantly altered, for example) but the NRC professional effort required would probably drop to 4 to 5 person-years.

* SP is actively negotiating a Section 274 Agreement with Michigan.

APPENDIX J

Letters to State and Territorial Health Officers, Radiation Control Program Directors, Federal Agencies and NARM Manufacturers and Distributors

APPENDIX J

Letter to be sent to
State Health Officers, State Radiation
Control Program Directors, Federal Agencies
Manufacturers and Distributors

Dear _____:

In July 1977, a Nuclear Regulatory Commission (NRC) Task Force completed a study on the regulation for health and safety of naturally occurring and accelerator-produced radioactive materials. These materials are not now regulated by NRC, but NRC has been requested by the States to seek authority to regulate these materials.

The Task Force recommended NRC seek such authority. The Commission recognized the need for input from potentially affected persons, including State and Federal regulatory agencies, and manufacturers and distributors of these materials. A Federal Register notice was published July 21, 1977 which announced the availability of the report for public review and comment. On July 20, 1977, I wrote you informing you of these actions.

Twenty-five public comments were received and have been placed in the NRC Public Document Room. The overwhelming majority (84%) expressed some measure of support for the Task Force recommendation.

I wish to now inform you that the Commission, after evaluation of the Task Force report and analysis of the public comments has approved the drafting by NRC staff of proposed legislation which would give the NRC authority over these materials.

Should you have any questions, please feel free to contact me.

Sincerely,

D. A. Nussbaumer, Assistant Director
for Material Safety and Licensing
Office of Nuclear Material
Safety and Safeguards

APPENDIX K

Letters to Congressional Committees

APPENDIX K

Letter to Congressional Committees

Dear _____:

In July 1977, a Nuclear Regulatory Commission (NRC) Task Force had completed a study on the regulation for health and safety of naturally occurring and accelerator-produced radioactive materials. These materials are not now regulated by NRC, but NRC had been requested by the States to seek authority to regulate these materials.

The Task Force recommended NRC seek such authority. The Commission recognized the need for input from potentially affected persons, including State and Federal regulatory agencies, and manufacturers and distributors of these materials. A Federal Register notice was published July 21, 1977 which announced the availability of the report for public review and comment. A copy of the report is enclosed.

Twenty-five public comments were received and have been placed in the NRC Public Document Room. The overwhelming majority (84%) expressed some measure of support for the Task Force recommendation.

Because of your interest in the control and regulation of hazards from radiation sources, I wish to inform you that the Commission, after evaluation of the report and analysis of public comments, has approved the drafting by NRC staff of proposed legislation giving NRC regulatory authority over these materials.

Should you have any questions, please contact us.

Sincerely,

Lee V. Gossick
Executive Director
for Operations

Enclosure:
As stated

APPENDIX L

OPE Comments and Response

APPENDIX L

Staff Response to OPE Comments

No changes were made to this paper as a result of OPE comments. (Attached). The paper already took note (on p. 5) of the Commission's approval of a staff proposal to draft proposed legislation to give NRC authority to regulate naturally occurring radioactive materials associated with mill tailings in non-Agreement States (SECY-77-303A). Chilk's November 11, 1977 memo to Gossick (attached to OPE's comments) also observed that the Commission has not made a final decision to submit this legislation. Hence, we do not believe the NARM recommendation necessarily complicates the issue. Rather, we believe the Commission should now be provided an opportunity to consider a more comprehensive proposal concerning NRC control over NARM as well as the more limited proposal embodied by SECY-77-303A. The proposed legislation for mill tailings would be consistent, in principle, with the recommendation of the NARM task force.

OPE expressed concurrence with ELD's comments concerning the possible impact of the extension of NRC jurisdiction on other agencies and suggested the Commission may wish to consider a broader study treating reorganization of existing radiation protection authorities. The recommendations of the NARM task force were developed in response to requests from the States for specific, limited action by NRC: To exert control over NARM. We were not requested to seek a broad reorganization of radiation protection authorities. A broader study as proposed may be warranted but would seem to more properly be in the province of Congress or the Executive Office.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

March 31, 1978

MEMORANDUM FOR: Tom Rehm

FROM: Ken Pedersen

SUBJECT: FINAL RECOMMENDATIONS OF THE TASK FORCE REGULATION OF NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS (NARM)

I do not concur with the final recommendation of the NARM Task Force to begin to develop a legislative proposal to exert NRC control over NARM, which would include uranium mill tailings. The question of NRC authority with respect to uranium mill tailings is vital and timely and is already the subject of active, concentrated attention by the staff, the Commission and the Congress. On November 11, 1977 the Commission asked the staff to draft legislation providing NRC with regulatory control over mill tailings. (See Attachment A.) We should deal with the mill tailings issue now rather than mixing it in with other kinds of NARM which can only lengthen substantially the time to prepare the legislative proposal, complicate further the issue in terms of Commission and Congressional consideration, and provide additional fronts on which other agencies, particularly EPA and FDA, may oppose us.

With respect to NARM other than mill tailings, I would much prefer them to be treated in an overall study of what the organizational structure for radiation protection at the Federal level should be. In this regard, I concur in part with the ELD note in the Coordination section of the subject paper which notes that because of the impact extension of NRC jurisdiction to include NARM would have on other agencies, the Commission might wish to consider a broader study treating reorganization of existing radiation protection authorities. Such a study should include options which foresee NRC acquiring as well as relinquishing authority where duplication or uncertainty now prevail.

Attachment:
As Stated

CONTACT:
Pat Comella (OPE)
634-1541
George Sege (OPE)
634-1643

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

November 11, 1977

OFFICE OF THE
SECRETARY

MEMORANDUM FOR: Lee V. Gossick, Executive Director for Operations

FROM: Samuel J. Chilk, Secretary

SUBJECT: REGULATORY CONTROL OVER URANIUM MILL TAILINGS (SECY-77-303A)

The Commission has approved the staff's recommendation in SECY-77-303A that the staff develop legislation which would give the Commission statutory authority to regulate mill tailings as a licensable material and which would provide a basis for long-term control of tailings disposal sites following final disposal by the mill operator.

The Commission has not made a final decision to submit this legislation. Furthermore, the General Counsel has raised the issue of, and the Commission has not made a final decision on whether the draft legislation should seek regulatory authority over tailings at inactive sites.* Consequently the staff should:

1. Draft the legislation without "inactive site authority," as proposed by staff. (SECY Suspense: December 23, 1977)

2. Draft a separate insertable statutory section which would provide for authority over inactive sites. (December 23, 1977)

The staff paper putting forward the draft legislation should reflect OGC and OPE views on the inactive sites issue and should also contain the staff's recommendation on whether the Commission should seek such authority. That staff paper should also discuss and take into account DOE's course of action for inactive sites.

*See attached memorandum from OGC to the Commission dated October 26, 1977.

cc:
Chairman Hendrie
Commissioner Gilinsky
Commissioner Kennedy
Commissioner Bradford
General Counsel
Director, Policy Evaluation
Director, Congressional Affairs
Director, NMSS

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

October 26, 1977

MEMORANDUM FOR: Chairman Hendrie
Commissioner Gilinsky
Commissioner Kennedy
Commissioner Bradford

FROM: Jerome Nelson, General Counsel

SUBJECT: COMMENTS ON SECY-77-303A, "REGULATORY CONTROL OVER URANIUM MILL TAILINGS"

Although I agree with the legal analysis presented in SECY-77-303A, I am not ready to concur in the staff's recommendation that legislation proposed to give the NRC direct statutory authority over uranium mill tailings should specifically exclude tailings at the inactive sites covered by ERDA's remedial action program. Putting such a limit on the proposed new authority would take away most of its potential usefulness. As the paper notes, under the Atomic Energy Act and NEPA, the NRC already has ample authority to regulate the handling of tailings at active sites and to condition issuance of new licenses on adequate provision for disposal of the tailings.[1] This authority is "unclear" only in the sense of being indirectly rather than explicitly derived from the statutes. Apart from clarification, the main benefit NRC would derive from the legislation which the staff proposes would be authority to maintain control over tailings disposal sites after the mill operator has completed all the disposal actions required by the licensing conditions. Such authority could be useful, as the staff paper observes, "to assure the disposal sites are not disturbed over the long term." But this problem of potential disturbance at disposal sites lies relatively far in the future, and does not afford much incentive to push for new authority right now.

---

1 SECY-77-303A points out that requiring surety arrangements at time of licensing compensates effectively for any practical limitations on the NRC's ability to enforce these conditions years after milling operations cease.

Contact:
E. Leo Slaggie
254-8017

In contrast, problems with tailings accumulations are current and pressing at presently inactive and abandoned sites, where it is reasonably clear that NRC has no regulatory authority, either direct or indirect. Here the need for direct authority over tailings is potentially the greatest. The staff argues that ERDA's recommendations for remedial action at these sites are imminent and that in some unspecified way "[f]or NRC to attempt to exercise regulatory control over these tailings ... would serve to complicate an already difficult situation and to possibly delay initiation of the remedial actions." I believe that the appropriate response to this argument is to wait and see what ERDA comes up with rather than go to Congress now with a legislative proposal which omits authority the NRC might later wish it had. It may turn out that the remedial action ERDA proposes will in fact call for NRC authority over tailings at abandoned sites. Alternatively, the Commission may find that the ERDA proposals fall short of what the Commission believes necessary to cope with health and safety problems associated with exposed tailings piles (for example, long-term population dose from radon emissions). The Commission might then choose to seek the additional authority necessary to set up an adequate remedial program. Either way, a premature commitment now to a limitation on proposed NRC authority over mill tailings would reduce the Commission's ability to respond later on to potential developments in the abandoned site tailings problem.

Since, apart from this question of tailings at abandoned sites, there appears to be no urgent need for new legislative authority over mill tailings, I suggest that the submission of the proposal to Congress be deferred until the ERDA recommendations are available and the draft GEIS on uranium milling is substantially complete, probably by fall of 1978. Having this deferred submission in mind, the staff can adjust its efforts appropriately for the development of a legislative proposal. In my view, the new legislation should include NRC authority over tailings at sites now inactive, but should embody sufficient flexibility that the NRC could choose not to exercise this authority, should such a policy turn out to be desirable as an accommodation to ERDA or perhaps EPA.

cc: OPE (2)
SECY (2)

December 18, 1978

UNITED STATES
NUCLEAR REGULATORY COMMISSION

SECY-78-667

POLICY SESSION ITEM

For: The Commissioners

From: L. V. Gossick
Executive Director for Operations

Subject: NRC ACTION ON NARM TASK FORCE RECOMMENDATION

Purpose: To provide the Commission with further analysis and a revised NMSS position on the NARM Task Force recommendations.

Discussion: In April 1978 the staff briefed the Commission on the final recommendations of the Task Force on Naturally Occurring and Accelerator-produced Radioactive Materials (NARM). The Commission did not take any action on the paper (SECY-78-211), but asked the staff to resubmit it for reconsideration after addressing questions about the magnitude of NARM overexposures, the compatibility of the proposed NRC regulatory authority with other agencies, and other issues.

The staff response to those questions is contained in a draft paper included as Enclosure #1. The staff continues to recommend that NRC seek legislative authority over NARM. The Director of NMSS did not concur in the staff paper. In a separate paper, included as Enclosure #2, the Director, NMSS, recommended that NRC:

1. Forward the Task Force findings to the Congress, Federal agencies and State Governors;

2. Offer to assist others in developing model control programs; and

3. Review NARM control programs after several years to determine further appropriate NRC action.

Contact:
R. Lawrence Vandenberg, MPA
49-27721

OTNI-1
NARM

Discussion: (Continued) I believe there are three major issues to be considered in determining what action should be taken.

1. Risk to Public Health and Safety

   The consensus is that there are risks to the public health and safety from NARM and that these risks could be reduced through nationwide uniform regulation. However, the available data appear insufficient either to determine the magnitude of the problem or estimate the value to the public of Federal regulation of NARM.

2. Scope and Cost of Regulatory Control

   The boundaries of an effective regulatory program for NARM may be broader than those suggested by the task force recommendation. For example, both the NARM task force and R. Cunningham in his memo to Dr. Smith (in Enclosure #2) question whether accelerator-produced material can be adequately regulated without also regulating the accelerators. Currently, NRC is not organized to deal with accelerator safety issues.

   Regarding cost, Dr. Smith believed that the NRC resource requirement to regulate NARM may be far in excess of the seven professional staff years estimated in SECY-78-211. The needed NRC resources cannot be accurately determined because the scope of the problem (including undefined start-up problems) is not well defined. Further, the issue of costs incurred by industry and the public to comply with new regulations has not been addressed.

3. Federal Regulatory Conflict and NRC's Role

   The task force identified twenty-two Federal agencies having some NARM regulatory authority. Nonetheless, several of the agencies have declined to issue regulations. The task force reported that the Consumer Products Safety Commission, for example, has not determined that any NARM article is sufficiently hazardous to warrant control. The reasons for taking this position need to be further explored. In addition, we have received comments on the task force report from only seven of the twenty-two agencies. Of the seven, two (EPA and FDA) expressed some objection to the recommendation. This argues for more extensive discussion among the involved agencies.

NRC's role also needs to be clarified. The issue has been raised that by taking on NARM regulation, NRC may add general radiation protection functions to our primary role of national regulation of the nuclear fuel cycle. Yet from the public health and safety standpoint, the hazards from NARM do not differ substantially from those of material already regulated by NRC (except fissile material). The issue of the appropriate NRC role probably cannot be decided apart from the other issues. Rather, the issue needs to be examined in conjunction with a better definition of the full scope of any needed regulatory program, the resources required and resolution of current Federal regulatory overlap.

As a result, I conclude that the NARM question is not yet well enough defined for a Commission decision on the task force recommendation. What is needed is a value-impact analysis to resolve the first two issues (Public Health and Safety Risk, Scope and Cost of Regulatory Control) and extensive coordination with other agencies, OMB, Congressional Committees and States to resolve the apparent regulatory overlap. In particular, the value-impact analysis should contain alternative regulatory boundaries (i.e., whether or not to include accelerator regulation) and alternative regulatory structures to meet the defined regulatory scope.

Since these tasks may require substantial resources and high level government coordination, Commission policy guidance is needed in the following areas:

1. Should NRC take the lead in preparing a complete value-impact analysis or should we request that OMB, Congressional staff or an interagency group head up this task?

2. In the interim, what position should NRC take in terms of assisting other Federal and State agencies in developing model control programs?

3. Should the task force report (recommending that NRC seek legislative authority over NARM) be sent for comment to higher level officials in Federal and State governments than was already done at the time of the Federal Register notice in July 1977?

If you feel a Commission meeting on this subject will be of value, I will have the staff present their views.

Lee V. Gossick
Executive Director for Operations

Enclosures:
1. Proposed staff paper entitled, "Staff Responses to Commissioner Comments on the Final Recommendations of the Task Force on Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials (NARM) (SECY-78-211) (SECY Memo dated June 30, 1978)"

2. Proposed staff paper entitled, "NMSS Position on Recommendations of Task Force on Regulation of Naturally Occurring and Accelerator-Produced Radioactive Material (NARM) (SECY-78-211)"

This paper is tentatively scheduled for consideration at an Open Meeting during the Week of January 15, 1979. Please refer to the appropriate Weekly Commission Schedule, when published, for a specific date and time.

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ENCLOSURE 1

For: The Commissioners

From: Lee V. Gossick
Executive Director for Operations

Subject: STAFF RESPONSES TO COMMISSIONER COMMENTS ON THE FINAL RECOMMENDATIONS OF THE TASK FORCE ON REGULATION OF NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS (NARM) (SECY-78-211) (SECY MEMO DATED JUNE 30, 1978)

Purpose: To provide the Commission with responses to the comments of Chairman Hendrie and Commissioner Gilinsky transmitted by memorandum from the Secretary to the Executive Director for Operations.

Category: This paper covers a major policy matter.

Issue: Whether NRC should regulate naturally occurring and accelerator produced radioactive materials.

Discussion: Background

NRC was requested by the Agreement States and by the Conference of Radiation Control Program Directors to regulate naturally occurring and accelerator-produced radioactive materials. On March 4, 1976, the Commission approved formation of an internal task force to review this matter (SECY-76-20).

Contacts:
Donald A. Nussbaumer, NMSS
427-4130

Joel Lubenau, SP
492-7767

Discussion: (continued)

The task force report was published in July, 1977 (NUREG-0301) and a Federal Register notice was published and a news release was issued announcing its availability and inviting public comment for a sixty-day period. The report was given wide distribution.

A report on the public comments was furnished to the Commission on April 14, 1978 (SECY-78-211). The staff recommended that NRC 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.

3. In any activity where NARM is introduced into products intended for distribution to persons exempt from licensing. (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.)

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.

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* e.g., sealed sources such as gauging devices, radiography sources, oil well logging sources and devices, etc.

** Radioactive materials used in normal form or loose form as, for example, in medical diagnosis.

Discussion: (continued)

On April 26, 1978, the staff briefed the Commission on SECY-78-211 at an open session.

Following the briefing the paper was returned without Commission action. Chairman Hendrie and Commissioner Gilinsky provided comments which the staff was requested to respond to when the paper was resubmitted (Enclosure A). The staff's responses are attached (Enclosure B).

The primary purpose of this paper is to provide the staff's responses to Commissioner comments on SECY-78-211. The pros and cons of such an action as well as other possible alternative actions were discussed in SECY-78-211, Appendix A.

A central issue in both Chairman Hendrie's and Commissioner Gilinsky's question concerned the significance of health and safety hazards from NARM.

Because there are gaps in regulatory control of NARM, data on the uses of NARM, incidents, and overexposures is fragmentary and incomplete. Thus, there are no adequate data available which can be used to create statistics on NARM uses and incidents that are, of and by themselves, convincing that the present regulatory scheme in the United States for NARM is either adequate or inadequate. The very deficiencies or gaps in present regulatory control of NARM preclude accumulation of data that could convincingly demonstrate that significant health and safety problems exist. The NARM Task Force was aware of this dilemma at the earliest stages of its deliberations.

The staff believes that the potential hazard from the use of NARM materials is at least as great as it is from NRC regulated materials which are used for comparable purposes. Further, there are no national or State-wide programs in operation except for the Agreement States which regulate the use of NARM materials to the same level as byproduct materials subject to NRC regulation. The data that are available, however, indicate that overexposures and unnecessary exposures are occurring from NARM. Although somewhat speculative, the staff concludes that this lack of regulatory control leads to a somewhat greater risk in the case of NARM materials. Radium constitutes a particularly troublesome problem because of its radiotoxicity (equivalent to plutonium), long half-life (1625 years), gaseous radon daughter and high energy gamma emission (similar to cobalt-60).

Discussion: (continued)

Regarding questions concerning the need for NRC to regulate NARM and of the roles of the other Federal agencies and states, the fact that the states have turned to the NRC for leadership indicates that problems remain. At the Agreement States meeting held October 3-5, 1978, the Agreement States repeated their request that the NRC actively seek the necessary legislation to regulate NARM. The staff continues to believe NRC is uniquely qualified to fill the Federal regulatory role for regulation of NARM because of its licensing system which is already in place and demonstrated to be effective.

Chairman Hendrie's final question about the ability of NRC to regulate NARM in view of recent problems experienced in our radioisotopes licensing program is an important issue. Progress has been made in recent months in improving the efficiency in radioisotopes licensing and we expect progress to continue. Given appropriate resources, the NARM program could be accommodated. However, if we were to be given responsibility for NARM without an increase in resources, there would be a very deleterious effect on the entire program.

Recommendation: The staff continues to agree with the task force recommendation that NRC seek legislative authority over NARM. Specific staff recommendations to accomplish this are set out for Commission approval in SECY-78-211, p. 7.

Coordination: The Offices of State Programs, Inspection and Enforcement, and Standards Development concur in this paper. OGC has no comments. The Office of the Executive Legal Director has no legal objections to the contents of this paper. The Director, Office of Nuclear Material Safety and Safeguards does not agree with the recommendation and his views are set forth in a separate paper.

Lee V. Gossick
Executive Director for Operations

Enclosures:
See next page

Enclosures:
A - Commissioner Comments on SECY-78-211
B - Staff Responses to Commissioner Comments
on SECY-78-211

Note: Commissioners' comments should be provided directly to the Office of the Secretary by c.o.b. _____.

Enclosure A

Commissioner Comments on
SECY-78-211

NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

OFFICE OF THE SECRETARY

June 30, 1978

Rehm
Nussbaumer
Lubenau
Shapar
Minogue
Volgenau
Haller
Hayden
Hanauer

MEMORANDUM FOR: Lee V. Gossick
Executive Director for Operations

FROM: Samuel J. Chilk, Secretary

SUBJECT: SECY-78-211 - "FINAL RECOMMENDATIONS OF THE TASK FORCE ON REGULATION OF NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS (NARM)"
(Commissioner Action Item)

Chairman Hendrie and Commissioner Kennedy have non-concurred in the recommendations of the staff. Commissioner Bradford has requested that the matter be reconsidered by the full Commission. Commissioner Gilinsky would like to see the staff gather information on incidents and risks associated with the use of radium and other NARM isotopes from those States now regulating such material, revise the paper accordingly and resubmit it.

The paper is being returned without Commission action at this time. When the staff resubmits the paper for consideration, the issues raised by Chairman Hendrie (attached) and Commissioner Gilinsky should be fully treated in order that these issues can be properly considered.

The tentative date for completion of these actions is September 1, 1978, or sooner, after reconstitution of the entire Commission.

Enclosure:
As stated

cc: Chairman Hendrie
Commissioner Gilinsky
Commissioner Kennedy
Commissioner Bradford
Acting General Counsel
Director, Policy Evaluation
Director, Congressional Affairs
D. Nussbaumer, NMSS
J. O. Lubenow, SP

CONTACT:
S. J. S. Parry (SECY)
634-1410

Chairman Hendrie's Comments on SECY-78-411 - Proposed Regulation of NARM

1. I am unconvinced that a case has been made that NRC licensing of NARM, as proposed, is necessary from a health and safety standpoint. In particular, what is the magnitude of overexposure now occurring from these sources that would be prevented by NRC licensing? Note that our licensing of byproduct materials does not prevent overexposures from careless handling: the same would be true for NRC-licensed NARM.

2. How would the proposed legislation be made compatible with the assorted existing laws across which it would cut? It appears to me that the proposal would complicate and further fragment an already complex set of authorities and agency responsibilities.

3. I do not see that the FDA/State voluntary NARM guidelines program has had time to become fully operative, so that a fair judgment can be made of its effectiveness.

4. Since it is unlikely that NRC would ever be assigned sole authority for all Federal regulatory activity for radioactive materials, why should we attempt to move into an area unrelated to our primary responsibility for nuclear fuel cycle-related matters? This seems especially unattractive to me since it requires that we seize authority from other Federal agencies who object to the attempt.

5. Finally, I am unconvinced that our byproduct material licensing effort is in such satisfactory shape that we should look for new materials of similar kind to add to the licensing list there.

Enclosure B

Staff Responses to Commissioner

Comments on SECY-78-211

Staff Responses to Commissioner Comments on SECY-78-211

Background

NRC was requested by the Agreement States and by the Conference of Radiation Control Program Directors to bring naturally occurring and accelerator-produced radioactive materials under its control. In response, the Commission created an internal task force to review the matter. The task force assessed 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 and reviewed existing rules and regulations, the sources and uses of materials (including wastes), and available information on incidents involving these materials.

The conclusions of the task force were (1) there are significant health and safety problems that arise from the present use of NARM, (2) there is a need for increased Federal involvement in regulating NARM, and (3) the NRC should seek legislative authority to regulate NARM.

1. Comment

I am unconvinced that a case has been made that NRC licensing of NARM, as proposed, is necessary from a health and safety standpoint. In particular, what is the magnitude of overexposure now occurring from these sources that would be prevented by NRC licensing? Note that our licensing of byproduct materials does not prevent overexposures from careless handling: the same would be true for NRC-licensed NARM. (Chairman Hendrie)

[I] would like to see the staff gather information on incidents and risks associated with the use of radium and other NARM isotopes from those States now regulating such material, revise the paper accordingly and resubmit it. (Commissioner Gilinsky)

Response

As noted in the staff paper, we do not have good documentation about overexposures from NARM, and for those cases which are documented, we can only speculate about what would have happened had NARM been subject to regulation. The staff agrees that no amount of regulation will preclude all careless use of materials. Regulation does, however, offer potential for reducing overexposure or unjustified exposure through a systematic evaluation system which controls the uses of materials, the design of equipment and facilities in which the materials are used, operating procedures, transfer to others and disposal as radioactive waste.

The available data indicate that both overexposures and unnecessary exposures are occurring from NARM. Some recent (1974-1978) incidents involving NARM have been:

o A patient receiving radiation therapy for cervical cancer had two radium applicators implanted. Subsequently, the attending physician removed only one although both were scheduled for removal. No surveys were made of the patient

to confirm all sources were removed. The second applicator (containing 60 mgm of radium) was then noticed to be missing from inventory one month later and traced to the patient. It was then removed. The dose to the cervix was estimated to be 220,000 rads. Of members of the patient's family and friends, a dozen persons received an average of 200 mrem whole body dose with a maximum of 5 rem (1976).

NRC requires a radiation survey of the patient and room to assure that all sources are accounted for.

- An investigation into the history of a 50 mgm source brought to a hospital disclosed that for three months previously, it was stored in a bedroom of a private residence. The whole body dose for one family member for the three months period was estimated to be 10 rads with lesser amounts to other family members (1977).

  NRC requires accountability of sources and evaluates safety of storage areas as part of the license process.

- As a result of improper storage of radium, a hospital secretary received an estimated whole body dose of 5 rem (1974).

  NRC evaluates safety of storage areas as part of the license review.

- The Denver, Colorado office of GSA put up for bids a moisture gage containing a 3 mCi Radium-Beryllium source as a Federal surplus item. A Colorado citizen, believing it to be a radiation counter and small calibration source successfully bid on it. It was transferred to him by GSA even though he did not possess

a State license to possess the radium. He has had no radiation safety training in handling this device. He recognized, however, the potential hazard to an untrained individual handling it and contacted the State for assistance in disposing of it. No excessive exposures to members of the public are known to have occurred; however, the incident served to illustrate the potential problems resulting from the present practices of the Federal Government in surplusing NARM (1978).

NRC requires that licensed material be transferred only to a person authorized to possess it. Transferor must make this determination prior to transfer.

- Personnel in a hospital handling 2-20 mgm radium sources failed to follow procedures. One individual received a skin dose of 73 rads (1976). NRC would require description of steps to be taken to prevent a recurrence, e.g., re-instruction.
- A 10 mgm radium plaque broke while being used for therapy in a large clinic. The entire clinic was shut down for two days and portions of the clinic were shut down for up to three weeks for decontamination. In some cases, portions of walls and floors as well as equipment were removed and disposed of as was some duct work. The cost was estimated to be $70,000, not including the costs incurred from the shut down of the clinic's facilities. More serious problems, such as spread

of the contamination outside the building were narrowly averted by the actions of an x-ray technician who was called from an adjacent hospital shortly after the source was broken. He quickly instituted appropriate steps to contain the contamination and the contaminated personnel. The source was made at least 35 years ago, was never registered with the State, and was never leak tested (1977).

NRC evaluates adequacy of sealed source design and requires that sealed sources be checked for leakage periodically.

The last case is reminiscent of the Americus, Georgia case in 1964 when a hospital was contaminated following a radium incident. The x-ray department was shut down for three weeks. Government agencies assisted the decontamination. If commercial services had been used, it was estimated it would have cost $100,000. Another contamination incident which occurred in 1968 involved a hospital in Pennsylvania. This hospital became contaminated with radium when a resident mishandled radium sources in a medical applicator and broke one source. A total of 17 55-gallon drums and one large crate of radium contaminated wastes were generated from the cleanup.

While these reports clearly show that when NARM is improperly handled there can be significant overexposures, similar incidents occur

for NRC-regulated materials. With better regulatory control, some NARM incidents might not have occurred. For example, there are very few cases of source failure in NRC's regulatory program because of stringent requirements for source design. Our principal source of information about NARM incidents is from the Agreement States which regulate these materials. The situation in states which do not regulate NARM is speculative. David Lacker, Administrator of Texas' Radiation Control Program provided the following comments to the NARM task force (NUREG-0301, pp. 20-21):

"These [NARM] incidents [in Texas] 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?... 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 exposures could go on for extended periods of time."

This view is supported by the reports by States of initial inspection findings when NARM regulatory programs were implemented. For example, Pennsylvania, a non-Agreement State which has a strong licensing and inspection program for NARM inaugurated an intensive regulatory effort for 54 private medical practitioners using a total of 1.8 grams of radium. None of the users had performed an annual leak test and of the 54 users, 25 possessed sources which were suspected of leaking or were contaminated. Leaking or contaminated radium sources have been found in medical facilities at rates ranging from 13 to 53% in surveys by Alabama, Georgia, Indiana, Kansas, Kentucky, Minnesota, and New York.

Other health and safety problems were also found. The Pennsylvania survey showed 46% of the users failed to provide adequate security and shielding for storage. In Wisconsin, a study of 39 medical facilities using radium disclosed radiation levels from the radium in uncontrolled areas up to 100 mrem per hour and in four facilities, estimated that workers in unrestricted areas may have received more than 500 mrem in a year, the radiation protection standard for individual members of the public.

2. Comment

How would the proposed legislation be made compatible with the assorted existing laws across which it would cut? It appears to me that the proposal would complicate and further fragment an already complex set of authorities and agency responsibilities. (Chairman Hendrie)

Response

By defining NARM as byproduct material it would be exempt from most other Federal statutes. Actually the proposed legislation, carefully constructed, would simplify the regulation of NARM. Under the proposed legislation, any person proposing to possess or use radioactive materials will be subject to licensing requirements of either NRC or an Agreement State, regardless of the isotope, its origin, or place of use.* This will be a significant simplification of the present regulatory picture by placing uniform requirements upon all users of radioactive materials.

Today, to determine if you need a license to use radioactive materials, one must first determine if the material is byproduct, source, or special nuclear material. If it is, it is subject to NRC or Agreement State licensing. If it is not, one must determine what State it is being used in. In 30 States, licensing requirements apply. In 13 States, the sources need to be registered. In 7 States, there are no requirements being applied.

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* Radioactivity occurring in-situ, in mineral industries where its presence is incidental, or is an incidental contaminant present in products, (e.g., building materials) would not be covered by the legislation contemplated.

Regarding regulation of the workplace, if the material is byproduct, source or special nuclear material, a user in compliance with NRC or Agreement State regulations is deemed to be in compliance with OSHA requirements (in effect, exempt from OSHA). Users of NARM are not exempt from OSHA regulation, but OSHA does not license NARM. Federal users of byproduct, source and special nuclear materials are subject to NRC license requirements (except for certain DOD and DOE activities). Federal users of NARM are not subject to any licensing requirements.

3. Comment

I do not see that the FDA/State voluntary NARM guidelines program has had time to become fully operative, so that a fair judgment can be made of its effectiveness. (Chairman Hendrie)

Response

The staff does not believe the FDA/State voluntary NARM guidelines program will ever be as effective as a regulatory program. A detailed analysis of this program was made in SECY-78-211, pp. F-4 and F-5. The essential ingredient of this program is also its flaw: It is voluntary. It is not now fully effective because one key State Agency - New York State Department of Labor, because of budgetary reasons - is not actively participating. This is significant because Radium Chemical Co., a major and possibly the largest supplier of radium in the U.S., is located in New York. The sealed sources it distributes nationally and internationally have

not been evaluated by the State Department of Labor with respect to adequacy of design, fabrication and quality controls for manufacture.

This is a potentially significant deficiency. The Agreement States' experiences with NARM suggest that there is a higher incidence of leaking NARM sources than for sources fabricated using agreement materials. In part, this reflects the presence of NARM sources, particularly older radium sources, which would not meet current standards for fabrication and whose manufacture would not meet current requirements for quality controls that are applicable to agreement material sources.*

The problem, however,is not limited to radium. James Blackburn, from Illinois, a non-Agreement State which licenses NARM, recounted his experience with a Co-57 source, (an accelerator-produced isotope):

> "A recent search for the manufacturer of [this] 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."

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* The problems created by lack of Federal manufacturing standards for sealed NARM sources are more fully discussed in NUREG-0301. See pp. 10-13.

The use of accelerator-produced radioisotopes is increasing very rapidly, especially in medicine and frequently as substitutes for NRC regulated isotopes. FDA has actively pressed for the substitution of I-123 for I-125 and I-131 to reduce patient dose in certain diagnostic procedures. The Wall Street Journal, on July 27, 1978, reported that New England Nuclear expects its sales of Tl-201 to increase to "'well over $5 million' this fiscal year, up from about $2 million in fiscal 1978. About 400 hospitals are using it, up from 200 last December." The company has 2 cyclotrons, is installing a 3rd, and is planning to build a linear accelerator.

In Pennsylvania, of 302 licenses for medical users of NARM, 260 include authorizations for accelerator-produced isotopes. In New Jersey, there has been recently a 40% increase in NARM licenses, mostly to authorize accelerator-produced isotopes.

The FDA/State voluntary NARM guidelines program has been an interim asset to states that have chosen to establish regulatory, and in particular, licensing programs for NARM. However, there are no incentives that would cause development of minimal state programs nor is there any program to assure maintenance of adequate state programs. Further,

this program does not cover areas that need Federal - not State - action for effective control: Importing and exporting of NARM, supplying of NARM by Federal Agencies (including surplusing) and transfer of NARM in interstate commerce; e.g., as consumer products.

4. Comment

Since it is unlikely that NRC would ever be assigned sole authority for all Federal regulatory activity for radioactive materials, why should we attempt to move into an area unrelated to our primary responsibility for nuclear fuel cycle-related matters? This seems especially unattractive to me since it requires that we seize authority from other Federal agencies who object to the attempt. (Chairman Hendrie)

Response

The potential hazards arising from the use of NARM are similar to those arising from the use of byproduct material in medicine, research and industry. Regulation of NARM would be similar to the regulation of byproduct material. The main reason for NRC assuming control of NARM is that it has a regulatory system in place which has been demonstrated to work fairly well. This apparently is the reason the states have asked the NRC to step into the picture. Although incidents do occur with byproduct materials, the number of reported incidents is relatively small in relation to the size of the program (e.g., approximately 37,000 patients treated per day with byproduct materials).

With respect to other Federal agencies, 22 were identified by the task force as having potential regulatory interests in NARM.* Of these, only two expressed objections to the proposal that NRC seek legislative authority to license NARM.* EPA felt it had sufficient existing authority and FDA, while endorsing as a long term goal increased Federal regulatory control, recommended deference be given to their voluntary state program.

5. Comment

Finally, I am unconvinced that our byproduct material licensing effort is in such satisfactory shape that we should look for new materials of similar kind to add to the licensing list there. (Chairman Hendrie)

Response

This is a very important issue. There is no question that the efficiency of the radioisotopes licensing process must be improved. We have taken a number of long-term measures to improve efficency and have taken some additional steps to reduce the licensing backlog in the interim. Among the long-term measures are a reorganization of the radioisotope licensing function to give greater emphasis to license reviews, request for and partial granting of, additional

* See SECY-78-211, pp. D-1 and 2 for list. These agencies were sent copies of the Task Force report under cover of a letter from the Task Force Chairman asking for comment. Seven responded; five expressed support.

manpower for FY79, and a contracted paperflow study to identify ways of improving and streamlining the license support activities. The short-term steps to reduce backlog include establishment of a special licensing task force to augment the radioisotope licensing staff and use of overtime by the regular staff. As a result of the short-term measures, the number of applications for new licenses and amendments pending NRC review for more than 90 days is being reduced. In addition, the licensing task force completed review of over 300 license renewal applications, a significant portion of the renewal backlog.

The key here is that we must improve efficiency, regardless of whether or not we regulate NARM. We do not believe that the addition of NARM would make a substantial difference in the outcome of this effort provided that adequate resources are made available for the increased workload. If, however, we obtained legislative authority over NARM without an appropriate increase in resources to do the job, our ability to carry out our present radioisotope licensing responsibilities would be severely impacted.

ENCLOSURE 2

For: The Commissioners

From: Clifford V. Smith, Jr., Director
Office of Nuclear Material Safety and Safeguards

Thru: Executive Director for Operations

Subject: NMSS POSITION ON RECOMMENDATIONS OF TASK FORCE ON REGULATION OF NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIAL (NARM) (SECY-78-211)

Purpose: To provide the Commission with further analysis and a revised NMSS position on the NARM Task Force recommendations.

Category: This paper covers a major policy issue.

Discussion: SECY-78-211 recommended that the NRC seek legislative authority to license and regulate NARM. NMSS concurred with the recommendations. SECY-78-211 was returned without Commission action. Chairman Hendrie and Commissioner Gilinsky provided comments and raised questions about the paper (SECY Memo dated June 30, 1978).

In addition to having the NARM Task Force prepare responses to the Commissioners' comments, the Director, NMSS, requested Mr. Richard E. Cunningham, Acting Director, Division of Fuel Cycle and Material Safety, to independently evaluate the merit of the recommendations in SECY-78-211 in view of questions raised by the Commissioners. Cunningham's analysis is contained in the enclosure. The Task Force responses to the Commissioners' comments are being forwarded by the EDO.

Cunningham's memorandum raises two important issues:

a. Resources

The resource requirements to bring NARM under NRC regulatory control might be far in excess of that projected in SECY-78-211.

Contact:
R.E.Cunningham, FC
42-74485

b. Policy

An NRC program to regulate NARM would expand the NRC regulatory role from that of assuring safety in nuclear fuel cycle and power production activities to that of a "radiation protection agency." This raises questions about where to logically draw the line (e.g., NARM, x-rays, etc.) in view of limited NRC resources and responsibilities of other Federal and state agencies.

Recommendations: Because of the issues raised in Cunningham's memorandum, the Director, NMSS, recommends that the Commission consider the following as an alternative to adopting the recommendations in SECY-78-211:

a. Forwarding the findings of the NARM Task Force to Federal agencies, State governors and Congressional committees having responsibilities in this area.

b. Offer NRC assistance in developing model control programs based on our regulatory experience in the byproduct materials program.

c. Review NARM control programs in a few years to determine if progress is made and whether further NRC action might be appropriate.

Clifford V. Smith, Jr., Director
Office of Nuclear Material
Safety and Safeguards

Enclosure:
Memo fm R.E.Cunningham

NOTE: Commissioner comments should be provided directly to the Office of the Secretary by close of business

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

NOV 2 1 1978

MEMORANDUM FOR: Clifford V. Smith, Jr., Director
Office of Nuclear Material Safety and Safeguards

FROM: Richard E. Cunningham, Acting Director
Division of Fuel Cycle and Material Safety

SUBJECT: STAFF RESPONSES TO COMMISSIONER COMMENTS ON THE FINAL RECOMMENDATIONS OF THE TASK FORCE ON REGULATION OF NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS (NARM) (SECY-78-211) (SECY MEMO DATED JUNE 30, 1978)

The NARM Task Force has prepared responses to questions raised by the Commission regarding the NRC seeking legislative authority over NARM. Some members of the FC staff as well as other NRC staff and state officials hold strong views that the NRC should seek legislative authority over NARM as recommended in SECY-78-211. This memorandum responds to your verbal request to take an independent look at the situation.

The staff paper responding to questions raised by Commissioners has attempted to elaborate on the risks from NARM and the benefits that might accrue from NRC exercising regulatory control over NARM. Although the information provided is not as precise as either we or the Commission would like it to be, I believe the staff has gone about as far as it can to gather information without significantly increasing expenditure of resources on the study. Data gathering in the absence of some regulatory leverage to acquire further information is particularly difficult.

There is no doubt in my mind that NARM materials are at least as hazardous as byproduct materials which we currently regulate. Also, the protection of the public health and safety would be enhanced over that which is provided by current voluntary Federal programs and state programs if the NRC were to regulate NARM. Whether it would be worth the cost is difficult to say. I believe, however, the staff in its analysis has greatly underestimated both the problems it would encounter in mounting a regulatory program for NARM and its cost.

The resource requirements estimated by the staff, which are relatively small, did not include the additional effort that would be needed initially to bring the program under control. I believe the initial effort could be significant and offer the following observations:

1. Radium has been used in this country for approximately 75 years; often carelessly by today's standards. Once we embark on a program to regulate radium, I am sure that we will find old leaking sources, contaminated buildings, etc., which will embroil us in a substantial cleanup campaign with all the technical and administrative work this requires. This work would be complicated because many of the radium users will have disappeared from the scene leaving complex legal problems about financial responsibility for cleanup.

2. The radiotoxicity of radium is roughly equivalent to that of plutonium and it has a long half-life. Therefore, by current thinking, concentrated radium wastes should be placed in an HLW or TRU repository. Since we do not have a repository, it would be necessary to develop a program for interim safe storage.

3. The distinction between regulating accelerator produced radioisotopes and regulating the accelerators themselves is very marginal. In the past, we have evaluated shielding around accelerators which used licensed tritium targets although the licensed material itself (tritium) could not contribute measurably to worker dose. In the case of accelerator produced NARM, there is a close coupling of the accelerator and its radiation hazards, to that of the NARM itself in terms of the facilities and workers involved. In the course of licensing accelerator NARM, we would undoubtedly become involved in the safety evaluation of the accelerator. We are not currently organized to deal with accelerator safety problems.

These observations do not diminish the importance of NARM control. In my opinion, however, seeking regulatory control over NARM would embark the NRC on a major program requiring substantial resources. The legislation would not only need to deal with the authority question but contain provisions for financing cleanup of contaminated sites and storing wastes. If resources to do the job were not provided with the legislation, our ability to discharge existing responsibilities with today's tight budget would suffer badly. It is difficult to estimate the resources that would be required to regulate NARM as proposed in SECY-78-211 because we do not know the full dimensions of the problem. However, my guess is that it would be somewhere between 15-25 man-years/year (plus

funds for various studies) for about the first five years until the problem is brought under control; following which requirements would taper off to a level required for maintenance of the program.

There is also a major policy question associated with the proposal in SECY-78-211. Heretofore, the NRC's regulatory authority, and that of its AEC predecessor, has been confined to activities associated with the nuclear fuel cycle. This includes the radioisotope byproducts of the nuclear fuel cycle used in medicine, industry, etc., as well as the new legislative authority over radium in mill tailings which is a byproduct of a fuel cycle operation. A movement to regulate NARM would be a major departure from the NRC's existing regulatory role. It would involve the NRC in an area where the states traditionally have responsibility for protection of the public health and safety. This would run counter to our broad program direction of attempting to have the states assume greater responsibility for regulation of byproduct materials where state and local issues rather than national issues are involved. It would also raise an open-ended question of where to draw the line logically. The public is exposed to a number of radiation sources in addition to those which we currently regulate and NARM. Exposure to x-rays is an outstanding example. While some states have good programs to control these other sources, not all do. There are also national programs to control these other sources which are roughly equivalent to the national programs for NARM but they are not as rigorous as an NRC program would be.

In view of (a) the potential resource requirements to regulate NARM, (b) the tight budget, (c) our present commitments in materials licensing and waste management which will be difficult to meet, and (d) the broad policy implications of embarking on such a course, I believe it would be prudent to reconsider the recommendations contained in SECY-78-211. More specifically, I suggest that we do not pursue the legislative proposals recommended in SECY-78-211 at this time. Rather, the NRC should bring its findings to the attention of Federal agencies currently responsible for health and safety in this area, appropriate Congressional committees, high level state officials, the Conference of State Governors, etc. to encourage more rigorous action on their part. The NRC could offer assistance in developing model control programs based on our regulatory experience in the byproduct materials program. The

NRC might reexamine the situation in a few years to determine if improvements have been made and whether legislative initiatives might be appropriate at that time.

Richard E. Cunningham
Acting Director
Division of Fuel Cycle
and Material Safety

NUREG-0976

Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials

An Update

U.S. Nuclear Regulatory Commission

Office of State Programs

L. A. Bolling, J. O. Lubenau, D. A. Nussbaumer

This report was prepared by employees of the United States Nuclear Regulatory Commission. It expresses opinions that do not necessarily represent a staff position of the NRC. The report has been neither approved not disapproved.

NOTICE

Availability of Reference Materials Cited in NRC Publications

Most documents cited in NRC publications will be available from one of the following sources:

1. The NRC Public Document Room, 1717 H Street, N.W.
   Washington, DC 20555
2. The NRC/GPO Sales Program, U.S. Nuclear Regulatory Commission,
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NUREG-0976

Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials

An Update

Manuscript Completed: September 1984
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L. A. Bolling, J. O. Lubenau, D. A. Nussbaumer

Office of State Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

PREVIOUS DOCUMENTS
RELATING TO THIS REPORT

D.A. Nussbaumer, J.O. Lubenau, W.S. Cool, L. J. Cunningham, J.R. Mapes, S.A. Schwartz and D.A. Smith, "Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials, A Task Force Review," USNRC Report NUREG-0301, July, 1977. Available for purchase from National Technical Information Service, Springfield, Virginia 22161.

ABSTRACT

In 1977, NRC published a report (NUREG-0301) of a task force review of the need for, and feasibility of, the Federal government regulating naturally occurring and accelerator-produced radioactive materials (NARM). Since that time, the Federal regulatory role has not significantly changed but State calls for increased Federal involvement have continued. In 1983, a National Governors' Association report on the NRC Agreement State program recommended amendment of the Atomic Energy Act to authorize NRC regulation of these materials. Based on that recommendation, and with the cooperation of the Conference of Radiation Control Program Directors, Inc., NRC staff undertook a review of the current status of use and regulation of NARM. This report contains the results of that review.

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REGULATION OF NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

An Update

1. BACKGROUND

Following the October 1974 meeting of the Agreement States in Bethesda, Maryland, the Agreement States developed several requests and recommendations for NRC (then AEC) to bring accelerator-produced and naturally occurring radioactive material (NARM) under its regulatory jurisdiction. On May 8, 1975, the Executive Committee of the Conference of Radiation Control Program Directors (CRCPD) met with the Commission. One of the points discussed at the meeting and also summarized by the CRCPD in a letter to then Commissioner Kennedy was the need for Federal control of radioactive material not being regulated by the non-Agreement States or the NRC. The Agreement States were including NARM under the same regulatory control as materials coming under the Atomic Energy Act when these agreements were signed. It was recognized by the then 25 non-Agreement States that there was a definite gap existing in the proper control of these non-agreement materials.

In response to these requests, in January, 1976 NRC established a task force to review the matter of regulation of these materials. Representatives from the Offices of State Programs, Inspection and Enforcement, Nuclear Material Safety and Safeguards, Executive Legal Director and Standards Development were appointed. Resource persons representing Agreement and non-Agreement States and Federal agencies also participated. The scope of work and conclusions reached by the task force were detailed in NUREG-0301, "Regulation of Naturally Occurring and Accelerator Produced Radioactive Materials" (Ref.1).

The conclusions made by the task force in 1977 were:

"1. The regulation of naturally occurring and accelerator-produced radioactive material (NARM) was 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 material 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 was being used by 1/5 of all radioactive material users. There were about 85,000 medical treatments using ^{226}Ra each year.

"3. All of the 25 Agreement States and 5 non-Agreement States had licensing programs covering NARM users. The Agreement States'

programs for regulating NARM are comparable to their programs for regulating byproduct, source and special nuclear material under agreements with NRC. But there are 7 States who exercise no regulatory control over NARM users, and the remaining States had 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 was fragmentary. Thus, it was difficult to know, in an overall sense, whether proper protection was being provided to workers and the public. A number of the incidents involving NARM and other data, however, which had 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 the study, data and evidence gathered in support of the study showed that the regulatory control for radiation safety for accelerators (which can be used to produce NARM) may also be fragmented and incomplete."

In conclusion, the Task Force recommended 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.

In April, 1978 the staff briefed the Commission on the task force's final recommendations (Ref.2). The Commission did not take action on the paper but asked the staff to resubmit it for reconsideration after addressing specific questions relating to the staff's proposals. The staff responses to the questions were conveyed to the Commission on December 18, 1978 (Ref. 3). The staff continued to recommend that NRC seek legislative authority over NARM. The Commission, on May 10, 1979, returned the paper to the staff with instructions to (1) forward the report to Federal Agencies, State Governors, cognizant Congressional committees and the Interagency Task Force on Ionizing Radiation, (2) discuss the matter with staffs of Congressional committees and Federal and State agencies and (3) offer to assist Federal and State agencies to further develop model NARM control programs (Ref. 4). The key instruction was the first: (The transmittal letter) "should note that, while NRC could logically regulate NARM --given legislative authority -- NRC is not pursuing that authority because it believes such efforts

should be integrated into the larger effort to properly allocate Federal responsibilities for radiation protection." The staff prepared letters to forward the staff report. The Interagency Task Force recommended the establishment of a Federal Radiation Policy Council to, among other things, address the overall direction and effectiveness of Federal regulatory programs. The Federal Radiation Policy Council was informed of the issue by NRC staff. However, it did not fully address the issue before its demise.

In 1978, Congress enacted the Uranium Mill Tailings Radiation Control Act (UMTRCA) (Ref. 5). Among other things, UMTRCA amended the Atomic Energy Act definition of byproduct material to include certain mill tailings, in effect expanding NRC authority to regulate naturally occurring radioactive material but only to the extent that it occurs in mill tailings covered by Section 11.e.(2) of the Act.

In January 1983, the National Governors' Association issued a report on its study of the Agreement State program (Ref. 6). A number of recommendations were offered as a result of this study including a recommendation that the Atomic Energy Act be amended to authorize the regulation of radioactive materials not presently affected by the Act, that is, NARM.

Based on this recommendation, NRC staff undertook a review to update the NRC report, NUREG-0301 "Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials," published in June 1977.

2. SCOPE OF THE REVIEW

A questionnaire was developed for distribution to all Agreement and non-Agreement States. The Conference of Radiation Control Program Directors, Inc., assisted in assembling the data. The questionnaire is shown in Appendix A. It was designed to gauge the extent of NARM regulation by the State radiation control agencies as of June 1983. Additional information was obtained through meetings and discussions with individual State representatives.

3. RESULTS

3.1 State Regulation of NARM - Status

In the 27 Agreement States, NARM is regulated in the same manner as byproduct, source and special nuclear material (agreement material). All Agreement States inspect NARM users. In the 23 non-Agreement States, 5 States have NARM licensing programs, 2 States have voluntary or partial licensing programs and 16 States have at least an initial registration requirement. There are 14 non-Agreement States with NARM inspection programs, 4 additional States conduct partial inspections and 5 States do not conduct NARM inspections. (Individual State responses to the questionnaire are tabulated in Appendices B and C.)

3.2 NARM Usage

Analysis of the State data shows that since 1977, overall use of NARM has not changed significantly (See Appendix D).

Discussions with State staffs suggest that accelerator produced materials used in medical diagnosis have increased, but earlier predictions of a very rapid growth in this area apparently did not occur. Counter balancing this has been a gradual decline in the use of radium as medical and industrial sealed sources are replaced by other isotopes.

The overall figure of 5.6% for NARM only users as a fraction of all licenses is close to the figure of 5% citied in NUREG-0301 indicating little, if any, change has occurred since 1977. More striking, however, is the disparity between the figures for Agreement and non-Agreement States: 2.6% vs. 10.0%. This breakout was not available for the 1977 report. It supports the notion that when strong regulatory programs (typically including licensing) are implemented, a significant number of NARM only users who have no strong incentive to retain their sources elect to dispose of those sources.

3.3 NARM Incidents

Since the NARM task force report, NUREG-0301, was issued in 1977, there continue to be numerous NARM incidents. The numbers of incidents reported to State agencies involving NARM (both medical and industrial users) range from 30 to 50 per year.

As recently as 1981, a large number of radioactive contaminated gold items were discovered in the Northeast*. Four shipments of radioactive gold were identified as having originated from one gold reprocessor in 1982. An investigation by one State agency revealed that between 1977 and 1981 a former radon plant lost 2.3 kg. of gold from its inventory. The disposition of the gold is unknown but one cannot rule out the possibility that it has entered the gold market.

*Radon-222, a short-lived (3.8 day) noble gas daughter of Radium 226 can be collected into and sealed in gold seeds which can be permanently implanted in tissue. After decay of the radon and its immediate short lived daughters, collectively a strong gamma source, the residual activity is from Pb-210 (22 year half-life) and its daughters (Bi 210 and Po 210). This chain is often termed "Radium DEF." Two of these isotopes are beta emitters and one is an alpha emitter. These emissions are contained by the gold. Gamma and bremsstrahlung emissions are relatively insignificant. Therefore the seeds can be left permanently in place. If the seeds are subsequently removed or if unused seeds are collected and these recycled into the gold market, the resulting gold will be contaminated. The activity, no longer contained inside the seed, but intimately mixed with gold, is now an exposure source, particularly if placed adjacent to skin as in rings.

The States have reported other NARM incidents such as improper packaging for air transport and wide-spread contamination at an electronics plant where radium painted aircraft gauges were being refurbished.

3.4 New Applications of NARM

A new application of NARM in the United States has occurred since the last NRC review of NARM; lightning rods containing radium are being imported and distributed in the United States. The utilization of radioactive sources to enhance the performance of lightening rods was reported at a symposium on radioactivity in consumer products in Atlanta, Georgia in 1977 (Ref. 7). Although there appeared to be some controversy over the effectiveness of radioactive sources for this purpose, evidently their use is permitted in at least some European countries. The isotopes that are utilized are ^{241}Am and ^{226}Ra. NRC has never received an application for the use of ^{241}Am for this purpose and the 1977 study of NARM did not disclose domestic utilization of NARM for this purpose. Since 1977, however, a New York firm has been importing ^{226}Ra from Great Britain and distributing lightning rods containing ^{226}Ra. Four models are available containing between 7.5 to 80 microcuries of radium per unit. The State licensing agency imposed a license condition upon the distributor limiting transfers to lease arrangements only and prohibiting sales of the sources. The intent is to help assure that when the sources are no longer used they will be returned to the distributor for disposal.

Under the Atomic Energy Act, as amended, the NRC regulates the import of source, by-product and special nuclear materials (see Sections 53., 57.a., 62. and 81.) (Ref. 5). This authority is reserved to the NRC where section 274.b. agreements have been entered into with States (see Section 274.c.(2)) (Ref. 5). Implementing regulations are contained in 10 CFR Part 110 and essentially require prior approval of possession by the Commission or an Agreement State for nuclear equipment, source or byproduct material. No such requirement, of course, exists in NRC regulations for radium or other NARM.

The only presently known importer and distributor of radioactive lightning rods is located in an Agreement State. Thus, in this case, there is existing authority to require prior approval of possession through licensing of the distributor and by license condition impose controls on distribution. This case illustrates the point that since only the 27 Agreement States and a few non-Agreement States have implemented licensing programs for NARM*, effective regulatory controls over distribution of radium or other NARM for radiation protection purposes will not always be assured but rather will be an accident of location of the place of business of the distributor. With respect to control of importation of NARM, notwithstanding individual State efforts, it can be argued that this is more properly the responsibility of the Federal government.

*Non-Agreement States reporting implemented licensing programs are Delaware, Illinois, New Jersey, Pennsylvania and Virginia. See Appendix C.

3.5 NARM Wastes

Data from the Center for Devices and Radiological Health of the Food and Health Administration indicate that in 1968 there were 50,000 radium sources totaling 330 curies. Since 1965, about 10,000 sources totaling 95 curies have been shipped for disposal. Based on this data there remains about 40,000 sources with a total activity of about 235 curies in use or storage.

Assuming that 50% of this material will be disposed of by the year 2000, this results in an estimated annual rate of about 7 curies per year (about 1200 sources per year) of radium sources that will need disposal. Due to the closing and decommissioning of the EPA radium storage facility at Montgomery, Alabama, there have been extensive problems and uncertainties with the disposal of radium waste. At present, there are only two licensed disposal sites accepting radium waste (in Beatty, Nevada and Hanford, Washington). The NRC staff, at the request of the States, is developing limits for shallow land burial of radium using the methodology for establishing radioisotope limitations in 10 CFR 61.

Since NRC's last examination of NARM regulation, a significant new development has arisen involving possible dual regulation of low-level radioactive waste burial sites by NRC and EPA. Presently, at low-level radioactive waste burial sites, NRC and the Agreement States regulate materials covered by the Atomic Energy Act and the States regulate NARM disposal. In a letter dated August 17, 1983 from EPA to US Ecology EPA stated "We have concluded that the wastes and disposal facilities which you discuss are not completely exempt from regulation under RCRA" (Ref. 8). US Ecology was advised to submit permit applications to EPA. The US Ecology request which prompted this response pertained to disposal of NARM and to toxic wastes contaminated with radioactive material. The Resource Conservation and Recovery Act (RCRA), which EPA administers, exempts byproduct, source and special nuclear material but not NARM.

The principal difficulty created by the dual regulation is that the basic regulatory approaches are different. EPA regulations under RCRA permit no degradation of ground water from the buried materials whereas NRC regulations under the Atomic Energy Act specify limitations on concentrations of radioactivity and performance objectives in terms of radiation dose limits. Dual regulation under such different philosophical approaches would be counterproductive. A more detailed discussion of this problem is contained in Chairman Palladino's letter to Congressman Udall dated March 16, 1984 (Ref. 9). Adding NARM to NRC authority (e.g., by adding another category to the definition of byproduct material) would eliminate this problem and provide a uniform standard for low-level radioactive waste disposal, while leaving EPA its traditional role of developing generally applicable environmental standards for disposal of radioactive wastes.

The two problems that must be resolved to make the regulation and management of radium and other NARM wastes consistent with that of other low-level radioactive wastes are (1) inconsistency between States in the regulation of NARM and (2) NARM has not been adequately addressed at the Federal level. Fragmentary controls, or in some jurisdictions a total lack of control over NARM, pose a potential threat to public health and safety.

4. CONCLUSIONS

Fragmentary control of NARM, as is currently the case, leads to confusion on the part of the licensees and a real potential for excessive radiation exposure to workers and the public. The regulation of NARM should be uniform - the responsibility of a single Federal agency which would set national standards to be followed by the other Federal agencies, the Agreement States and the licensees. That agency would regulate the design and fabrication of sealed sources and the processing, use and disposal of NARM. The NRC and the Agreement States are already conducting similar programs for the regulation of reactor-produced radioactive material.

An important issue to be considered in any proposal to add NARM to NRC regulation is the matter of how to recognize existing State regulatory programs for NARM. For example, Agreement States and a few non-Agreement States currently regulate NARM in the same fashion as agreement materials. (In the Agreement States, NARM is incorporated into the Agreement State program.
Five non-Agreement States report they have implemented similar licensing programs for NARM.) Thus, if NRC were to receive authority over NARM, NRC staff believes Agreement States should be allowed to continue to regulate NARM without interruption subject to the same Commission Policy for review that is currently applied to their Agreement material programs (Ref. 10). Amendment of the 27 Agreements should not be made necessary. With respect to the other licensing States, it would be in the NRC's interest (to conserve resources) to take into account their programs, provided they met applicable criteria for demonstrating they are adequate to protect public health and safety and are compatible with NRC's program.

5. APPENDICES

5.1 Appendix A

NARM Questionnaire*

As of June 30, 1983, does your State or Territory have:

1. Enabling Legislation to regulate radiation sources, including NARM? Yes No

2. Comprehensive Regulations for Radiation Protection, including NARM Yes No

3. Requirements for Registration of NARM? Yes No

4. Requirements for Licensing of NARM? Yes No

5. An implemented program for licensing NARM? Yes No

6. A NARM Inspection Program licensing NARM? Yes No Partially

7. How many NARM only users are located in your jurisdiction?

8. What proportion of licensees in your State or Territory who are licensed to use source, byproduct or special nuclear material also use NARM?

9. Do you support the regulation of NARM by NRC (assuming provisions are made for recognizing existing State programs which meet the same guidelines, as appropriate, that Agreement State Programs must meet)?

Any additional comments you may have on NARM regulation would be appreciated.

*NARM, as used for this questionnaire, does not include naturally occurring radioactive materials (NORM) except for activities where the concentration (or introduction into product) of NORM is deliberate and has as a purpose utilization of its radioactive properties.

5.2 Appendix B

Results of NARM Survey

Agreement States

State	Questions from Survey								
	1	2	3	4	5	6	7	8	9
1. Alabama	Y	Y	Y	Y	Y	Y	4	10%	Y
2. Arizona	Y	Y	N	Y	Y	Y	12	U*	Y
3. Arkansas	Y	Y	N	Y	Y	Y	2	25%	Y
4. California	Y	Y	N	Y	Y	Y	10	10%	Y
5. Colorado	Y	Y	N	Y	Y	Y	31	22%	Y
6. Florida	Y	Y	N	Y	Y	Y	6	10%	Y
7. Georgia	Y	Y	N	Y	Y	Y	12	33%	Y
8. Idaho	Y	Y	N	Y	Y	Y	30	U	Y
9. Kansas	Y	Y	N	Y	Y	Y	2	5%	Y
10. Kentucky	Y	Y	N	Y	Y	Y	25	50%	Y
11. Louisiana	Y	Y	N	Y	Y	Y	10	10%	Y
12. Maryland	Y	Y	N	Y	Y	Y	17	22%	Y
13. Mississippi	Y	Y	Y	Y	Y	Y	0	50%	Y
14. Nebraska	Y	Y	N	Y	Y	Y	52	33%	Y
15. Nevada	Y	Y	N	Y	Y	Y	0	25%	Y
16. New Hampshire	Y	Y	N	Y	Y	Y	3	25%	Y
17. New Mexico	Y	Y	N	Y	Y	Y	20	U	Y
18. New York	Y	Y	Y	Y	Y	Y	U	75%**	Y
19. North Carolina	Y	Y	N	Y	Y	Y	10	U	Y
20. North Dakota	Y	Y	N	Y	Y	Y	3	31%	Y
21. Oregon	Y	Y	Y	Y	Y	Y	U	10%	Y
22. Rhode Island	Y	Y	N	Y	Y	Y	4	41%	Y
23. South Carolina	Y	Y	Y	Y	Y	Y	10	7%	Y
24. Tennessee	Y	N	N	Y	Y	Y	U	U	Y
25. Texas	Y	Y	N	Y	Y	Y	8	10%	Y
26. Utah	Y	Y	Y	Y	Y	Y	0	U	Y
27. Washington	Y	Y	N	Y	Y	Y	33	U	Y
#Total							342#	25%##	

*U - stands for unknown.
** Value is for New York State Health Dept. only.
# Total for 24 States reporting is 304. 304 divided by 24 x 27 = 342.
##Average for 20 States reporting.

5.3 Appendix C

Results of NARM Survey

Non-Agreement States

State	Questions from Survey 1	2	3	4	5	6	7	8	9
1. Alaska	Y	Y	Y	Y	N	Y	0	5%	Y
2. Connecticut	Y	Y	Y	N	N	Y	U**	5%	Y
3. Delaware	Y	Y	Y	Y	Y	Y	20	33%	N
4. District of Columbia	No Reply to Survey								
5. Hawaii	Y	N	Y	N	N	N	2	30%	Y
6. Illinois	Y	Y	Y	Y	Y	Y	175	20%	Y
7. Indiana	Y	Y	Y	N	N	P*	75	25%	Y
8. Iowa	Y	Y	Y	N	N	Y	15	20%	Y
9. Maine	Y	N	Y	N	N	N	3	30%	Y
10. Massachusetts	Y	Y	Y	N	N	Y	110	80%	Y
11. Michigan	Y	Y	Y	Y	N	Y	50	50%	N
12. Minnesota	Y	Y	Y	N	N	P	22	24%	N
13. Missouri	Y	Y	Y	N	N	Y	20	30%	Y
14. Montana	Y	Y	N	Y	N	N	U	U	Y
15. New Jersey	Y	Y	N	Y	Y	Y	20	32%	undecided
16. Ohio	Y	Y	Y	N	P	Y	25	55%	undecided
17. Oklahoma	Y	N	Y	N	N	Y	5	10%	N
18. Pennsylvania	Y	Y	N	Y	Y	Y	63	33%	Y
19. Puerto Rico	No Reply to Survey								
20. South Dakota	Y	N	N	Y	P	P	0	10%	Y
21. Vermont	Y	Y	Y	N	N	Y	0	10%	Y
22. Virginia	Y	Y	N	Y	Y	Y	65	25%	Y
23. West Virginia	Y	Y	Y	N	N	P	U	50%	Y
24. Wisconsin	Y	N	Y	N	N	N	U	U	no reply
25. Wyoming	Y	N	Y	N	N	N	0	1%	Y
#Total							882#	27%##	

* P - stands for partially.
**U - stands for unknown.
Total for 19 States reporting is 670. 670 divided by 19 x 25 = 882.
##Average for 21 States reporting.

5.2 Appendix D
Analysis of State Survey Data on NARM Use

	Agreement States	Non-Agreement States	Total
1. NARM only users (no. licenses)	342	882	1224
2. NARM only users % of all licenses*	2.6%	10.0%	5.6
3. % of all licenses where NARM is also used*	25%	27%	(26%)
4. Number of current licenses where NARM is also used**	3250	2380	5630

* Based on 13,000 licenses in Agreement States and 8,800 licenses in non-Agreement States. The latter includes about 1,000 NRC licenses in Agreement States.

**Obtained by multiplying line 3 by 13,000 in Agreement States and 8,800 in non-Agreement States.

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In 1977, NRC published a report (NUREG-0301) of a task force review of the need for, and feasibility of, the Federal government regulating naturally occurring and accelerator-produced radioactive materials (NARM). Since that time, the Federal regulatory role has not significantly changed but State calls for increased Federal involvement have continued. In 1983, a National Governors' Association report on the NRC Agreement State program recommended amendment of the Atomic Energy Act to authorize NRC regulation of these materials. Based on that recommendation, and with the cooperation of the Conference of Radiation Control Program Directors, Inc., NRC staff undertook a review of the current status of use and regulation of NARM. This report contains the results of that review.

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For: The Commissioners

From: Victor Stello, Jr.
Executive Director for Operations

Subject: NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

Purpose: To obtain Commission approval of the staff recommendations on the issue of whether NRC should seek legislative authority to regulate naturally occurring and accelerator-produced radioactive materials (NARM).

Category: This paper covers a major policy matter.

Introduction: NARM is in the environment, in homes, in consumer products, in industrial applications and in medical departments. Congress has never seen fit to expand Atomic Energy Commission/Nuclear Regulatory Commission (AEC/NRC) jurisdiction into the NARM arena, apparently because other agencies already have jurisdiction, and because the States have the primary responsibility for protecting the public health and safety. Thus, NRC's responsibilities and activities have remained linked to the neutron chain reaction.

In deciding whether NRC should seek legislative authority over NARM, it is important to understand what NARM encompasses; how it is used; how the NARM risks compare to other related risks; previous Congressional and Federal agency actions on radiation protection matters; and what the States are now doing to regulate NARM. Enclosure 1 to this paper is a report on a detailed examination of these matters.

Defining the universe of NARM is extremely important, since naturally occurring radioactive materials are ubiquitous. Radon-222 and radium-226 are significant sources of radiation to which the public is exposed. Radium can be unintentionally concentrated through routine operations such as phosphate mining

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and purifying drinking water. Radium use in medical departments, in industrial gauges, and in consumer products appears to be diminishing. Thousands of cyclotrons produce NARM and NARM wastes in hospitals, and in industrial and research applications. Eight radionuclides important to the medical community are produced exclusively by cyclotrons. They are: carbon-11; nitrogen-13; oxygen-15; cobalt-57; gallium-67; indium-111; iodine-123; and thallium-201. Two other important radionuclides produced through cyclotrons or nuclear reactors are fluorine-18 and strontium-87. Most of these isotopes have half-lives in the order of minutes to hours.

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

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

There has never been an explicit decision on the Federal role versus the State role, in protecting the public from exposures to ionizing radiation, except that set out in Section 274 of the Atomic Energy Act of 1954, as amended. Federal agencies exercise discretion regarding the degree to which they implement their authorities to control exposures to ionizing radiation. Furthermore, Congressional mandates to the above agencies vary so greatly that it is not clear whether the worst

and most controllable exposures are being addressed without undue attention to lesser ones. As a consequence of all of the above, Federal controls over ionizing radiation, in general, and over NARM, in particular, are fragmented and uneven.

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

Issues: Based on an analysis of the sources and uses of NARM, the incidents and problems with it, and the current jurisdictions and activities of other Federal agencies and the States, we believe that the answers to the following eight questions will clarify the issue of whether NRC should seek regulatory authority over NARM:

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

These eight questions were examined through an extensive literature search, and are addressed in Section VII of Enclosure 1.

Alternatives: Based on analyses of these questions, the following five options, regarding possible NRC involvement with NARM, are evaluated in Section VIII of Enclosure 1:

1. Status quo, but continue to encourage the CRCPD efforts on NARM regulations;
2. Seek legislative authority over NARM;

3. Seek authority to regulate radium disposal;
4. Seek authority to regulate cyclotron-produced radionuclides for medical use only; and
5. Refer the issue of NARM regulation to the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC).

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

Recommendations: Two recommendations evolve from this review:

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

2. Inform the Governors of the states not within the "CRCPD Recognized NARM Licensing States" program that NRC is not seeking legislative authority to regulate NARM because such regulation is a responsibility of the States, and because other Federal agencies already have jurisdiction over most facets of NARM hazards; urge those Governors to take the necessary actions and to assign appropriate resources to become such recognized States.

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

Coordination: With regard to recommendation 1, we contacted the Chairman of CIRRPC on February 11, 1988, and read that recommendation to him. The Chairman concurred with the recommendation.

The Office of Governmental and Public Affairs participated in the development of the enclosed report and concurs in this paper and the enclosed report.

Note: The Conference of Radiation Control Program Directors has expressed an interest in meeting with the Commissioners, in an open meeting, to discuss their most recent urging that NRC seek legislative authority over NARM. We recommend a Commission meeting on this subject with an invitation to the CRCPD to participate. We believe benefits would derive from the Conference having this paper, and Enclosure 1, in advance of any such meeting with the Commission. If the Commission agrees, we will forward this paper, and Enclosure 1, to the Conference in appropriate advance of the meeting.

Victor Stello, Jr.
Executive Director
for Operations

Enclosures:
1. "Naturally Occurring and Accelerator-Produced Radioactive Materials - The 1987 Review"
2. August 26, 1987 CRCPD Position Paper on NARM

CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS, INC.

August 26, 1987

Harold R. Denton, Director
Office of Governmental and Public Affairs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Denton:

The purpose of this letter is to formally share with you and the Nuclear Regulatory Commission the position of the Conference of Radiation Program Directors on naturally occurring and accellerator produced radioacive material (NARM).

The issue, simply stated, is that NARM radioactive material is not adequately or uniformly regulated in the United States, and as a result, has the potential for significant exposure to the public and for contamination of the environment.

The concern for nonuniform control of NARM has been voiced by state radiation control directors since the early 1960's and has been brought to the attention of the NRC on many occasions over the last several years. This same concern has been expressed by the Agreement States, as a group, and by the Conference of Radiation Control Program Directors, Inc. (CRCPD), which represents both Agreement and non-Agreement states. Let me also draw your attention to the June 26, 1987, letter to Samuel Chalk from Warren Sinclair, President of NCRP, in which Mr. Chalk specifically addresses the NARM issue. A copy is enclosed.

The most recent action on the NARM issue taken by the Conference is the adoption of a "Position Paper on NRC Regulatory Control of NARM," which was approved by the membership at our 1985 annual meeting. The 1985 position has been updated to reflect current concerns. A copy of our position paper is enclosed.

The Conference strongly urges the Nuclear Regulatory Commission to begin the appropriate actions necessary to regulate this hazardous radioactive material in the states which are not currently regulating NARM. It is our belief that because (1) there is no single federal agency where uniform guidance on NARM is provided and that (2) in some states there is no control of NARM, the resulting potential for public health exposure and environmental contamination presents an intolerable situation. We believe a uniform regulatory program operated by the NRC

is the best solution. The details of our rationale for NRC control of NARM is clearly described in our position paper.

The Conference is developing a compilation of recent incidents involving NARM which we will share with you as soon as possible. In the meantime, we believe the position paper adequately describes the need for NRC action.

The Conference is ready and willing to present its position to the Commission as the NARM issue is considered. Please do not hesitate to contact me at (206) 753-3468 or Chuck Hardin, our Executive Secretary, at (502) 227-4543.

Sincerely,

T. R. Strong
Chairman

TRS/db

Enclosure

Revised

August 24, 1987

CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS

POSITION PAPER ON

NRC REGULATORY CONTROL OF NARM

Introduction

The Atomic Energy Act of 1954, as amended, authorizes the U.S. Nuclear Regulatory Commission (NRC) to control the manufacture, transfer, import, export, use and disposal of radioactive materials classified as byproduct, source and special nuclear materials. The Act does not provide for the regulatory control by the NRC of naturally occurring and accelerator produced radioactive material (NARM). This 1954 decision to exclude NARM was based on the fact that controlling the radioactive materials associated with weapons development was the nation's only significant concern. Even when the use of NARM became more widespread, this omission was never corrected. Reference 1 (see page 15) has a more complete legislative history on why NARM was never included under the Atomic Energy Act.

NARM represents the same types of public health and safety risks, and in fact includes some of the identical radionuclides, which are regulated by the NRC under the Atomic Energy Act. Due to these similar characteristics, and in order to ensure the adequate protection of the public health and safety, the Conference of Radiation Control Program Directors believe NARM should be controlled in the same way other radioactive materials are regulated under the Atomic Energy Act.

Characteristics and Use of NARM

Most common substances contain small quantities of naturally occurring radioactive materials. For clarification, the radioactive materials proposed to be added the the authority granted by the Atomic Energy Act would (1) be those materials either concentrated in nature as a result of man's activities or deliberately concentrated for their radioactive properties; or (2) discrete sources. Diffuse sources such as phosphate residues, nonuranium ores, and slags are not intended to be included. The NRC would be required to determine which materials pose a potential threat to public health and safety and which should therefore be covered under the Act.

The most common example of NARM is Radium-226. Radium is considered to be one of the most hazardous of all radionuclides for at least two reasons: it has a 1600 year half-life and it decays to the radioactive gas Radon-222. Radium also has one of the lowest allowable concentrations of any radionuclide in water. It has been estimated that about 20 percent of all radioactive material

users possess Radium sources. Between 1912 and 1961, nearly 2,000 grams (2000 curies) of Radium were processed in, or imported into, the United States. A recent survey of all state radiation control programs identified about 130 curies of Radium currently registered. Since less than 200 curies have been disposed in licensed disposal facilities, this may indeed be a significant public health and safety problems, due largely to the inconsistent regulation of NARM. Because Radium is the most common NARM and presents the greatest of potential problems, it will receive most of the attention in the discussion that follows.

There are numerous other radionuclides considered to be NARM (see Reference 1 for specific examples). NARM is used in every state in the United States. In the areas of medicine, NARM is used for applications such as diagnostic nuclear medicine imaging where the radionuclide is injected into the patient, and in therapeutic applications where sealed sources are used to treat cancerous tumors. NARM is used in industry for things like integral parts of gauges, in devices for various measurements, and in the academic field for various research and teaching applications. There is currently estimated to be about 10,000 users and possessors of NARM in the United States. The use of Radium in most applications appears to be declining, thus creating a disposal problem to be discussed later. At the same time, it appears that the use of accelerator-produced radionuclides is growing.

Present Control of NARM

The regulation of NARM is fragmented, nonuniform, and incomplete at both the federal and state levels. Absent a federal mandate, most states have established some sort of program for the control of NARM. However, these programs vary greatly in their degree of regulatory responsibility and control.

The Atomic Energy Act provides for states after they qualify to assume regulatory control for radioactive materials specified in the Act. Twenty-eight states have agreements with the NRC for full regulatory control of certain radioactive materials as allowed under the act. These NRC Agreement States regulate and control NARM in the same way they do for Atomic Energy Act materials for which they have regulatory responsibility and authority.

Those states which have not entered into agreements with the NRC have widely differing regulatory authority and control over NARM,[2] and this is where the major problem lies. Of the twenty-two non-NRC Agreement States, only five have a NARM licensing program. Of the remainder, two states have voluntary or partial licensing programs, while 15 have very limited initial registration requirements. At the same time, the interstate transportation of NARM is covered by uniform U.S. DOT regulations.

In the area of NARM inspections, the regulatory picture is somewhat better[2]. In non-NRC Agreement States, fourteen have inspection programs while four states conduct partial inspections. Five states conduct no NARM inspections.

The Conference of Radiation Control Program Directors (CRCPD) has attempted to correct this nonuniform regulatory control situation at the state level by developing a "NARM Licensing State" qualification program. This program is intended to provide a thorough review of NARM regulatory control in both Agreement and Non-Agreement States using consistent review criteria. It is assumed that a state which has been certified as a "Licensing State" has a program compatible with the requirements of an NRC agreement. Because of this program, and to alleviate the concerns of some states which would not otherwise support the position, it is recommended that an amendment to the Atomic Energy Act provide for recognition of the NARM regulatory programs in those non-Agreement States which do not want to enter into a full agreement. It would be desirable to provide for a mechanism for these states to continue this adequate program without the additional administrative burden of applying for NRC Agreement State status.

The lack of uniform licensing and regulatory control at both the federal and state level has led to a variety of problems which present both potential and real public health and safety threats. Some of these problems are described as follows.

— There have been numerous incident reports dealing with NARM. Most have involved Radium sources. From 1966 to 1969 the Federal Bureau of Radiological Health conducted a voluntary program to document NARM incidents in the states. During this period, there was an average of

twenty-nine incidents per year involving Radium alone, most of which involved loss of the material[1]. Because of nonuniform regulations, this is believed to be an underestimate of the problem. In more recent years, the frequency appears to be decreasing. However, without uniform regulations and the uniform reporting system which this would require, the real threat and impact to public health and safety cannot be determined.

— As with Atomic Energy Act materials, there have also been misadministrations of NARM radiopharmaceuticals. However, these events are not being captured in any national incident reporting system, and lessons learned are not adequately shared.

— The nonuniform state-to-state regulation of NARM creates interstate commerce problems. If a manufacturer in a state with an adequate NARM regulatory program ships NARM sources to a state not regulating NARM, or vice versa, control over how this source will be used can be lost. This has lead some states to deny reciprocal regulatory agreements to states not designated as "Licensing States".

— Where NARM sealed sources and devices containing NARM are manufactured in or distributed from states without adequate NARM control programs, such sources and devices (which can include medical sources) probably have not undergone a regulatory review for adequacy of radiation safety design and manufacturing controls.

— NRC regulations allow for the distribution to the public of very small quantities of radioactive materials contained in consumer products, such as smoke detectors. These materials are called "generally licensed", (i.e., no "specific" license is required), and an evaluation must be performed to show that this general distribution will not result in risks to health and safety. Products that include NARM may not receive adequate evaluation and these consumer products may create health and safety problems.

— Due to the lack of adequate regulatory control, various instruments and devices containing radium have been manufactured in the past for the military without any distribution limitations or markings. Such devices have been found in numerous instances in the public's possession and may have caused significant radiation exposures.

— In non-Agreement States with NARM inspection programs, about 70 percent of the NARM users are also licensed by the NRC to possess and use material[2]. This requires both State and NRC inspectors to inspect the same facility, in many cases duplicating efforts and wasting already limited resources.

— Ensuring the proper disposal of NARM is probably the greatest and most visible problem that has been exacerbated by nonuniform regulation.

Disposal of NARM

Since most accelerator produced radionuclides have relatively short half-lives, they are typically stored on-site for decay and do not present a disposal problem. The exceptions to this may be accelerator targets and other components; however, nonuniform reporting requirements again make data gathering difficult. Therefore, the focus of this section will be on naturally occurring radionuclides, particularly Radium. It should be noted that the proposed Super Collider is estimated to separate from 10,000 to 40,000 cubic feet of LLRW annually, which will be classified as NARM.

One of the major problems with disposal is that although states have made a strong case for it, NARM was not included as a low-level radioactive waste covered by the Low-Level Radioactive Waste Policy Amendments Act of 1985. Like mixed wastes, this material was left as an orphan waste stream. As a result, it is very uncertain how it will be properly disposed. Note that none of the Compact regions has included NARM as a low-level waste for which it must be responsible.

Because Radium is considered by many to be as toxic as transuranic materials, it is currently very difficult to dispose in a licensed low-level radioactive waste disposal site. The Barnwell site will not accept any discrete Radium sources. The Hanford site has imposed limits for disposal of Radium more stringent than are those for transuranics. Although the Beatty site will

accept Radium, other problems beyond the scope of this paper have limited such disposals. Inclusion of NARM under the Atomic Energy Act would require that the NRC include Radium in its waste classification system. Such classification would lead to the setting of uniform standards for acceptance of Radium at the disposal sites. It would also serve to establish a Class C limit for Radium which would specify the assignment of responsibility, either state or federal government, for disposal.

It should be noted that the Conference of Radiation Control Program Directors is in the process of establishing a disposal mechanism for discrete Radium sources. It is hoped that through this program many Radium sources, now being stored because disposal is difficult, can be properly disposed.

It should also be noted that forced Radium storage creates other radiological hazards. Unwanted or unneeded Radium must be stored if disposal in a licensed low-level radioactive waste site is difficult, impractical, or too expensive. Storage requires adequate shielding and proper security. In addition, Radium sources frequently leak and become contaminated.

2. In addition to sealed sources, there are other discrete Radium contaminated waste which will probably be generated in increasing quantities and require safe disposal. These include clean-up resins from drinking water supplies contaminated with Radium, and scale on piping used for oil and gas collection and transmission which has been discovered to trap relatively large concentra-

tions of Radium? Uniform regulation of NARM will provide assurance that these sources and others will be properly controlled and safely disposed in the future.

NARM and RCRA

The Resource Conservation and Recovery Act (RCRA) exempts materials which are covered under the Atomic Energy Act. The Environmental Protection Agency (EPA) is authorized to regulate NARM under RCRA but has not proposed regulations to do so. It is strongly believed that discrete NARM sources should not be regulated under RCRA because (1) this would not provide for the up-front control of its use, and (2) it would not adequately solve the disposal problems. Diffuse NARM, such as phosphate residues, nonuranium ores and slags, is probably more appropriately regulated under RCRA.

It is strongly believed that NRC disposal regulations are much more appropriate for discrete NARM waste than are RCRA disposal regulations. If discrete NARM is not included under the Atomic Energy Act, then it would probably eventually come under the control of RCRA. Not only would this create a dual regulatory problem at those disposal sites which currently accept NARM, it would also create a dual regulatory problem in those Agreement States which regulate NARM under regulations which NRC represents to be compatible with radioactive materials covered by agreements with NRC. This would lead to a situation similar to the one which currently exists with mixed wastes.

NARM and CERCLA

The Congress has provided authorization to the U.S. Environmental Protection Agency to "clean-up" areas contaminated by hazardous substances. This authority is provided by the Hazardous Substances Response Trust Fund, established under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) of 1980. Some areas and facilities which have been contaminated with NARM have received funding for "clean-up" under this Act.

A question has been raised: If the Atomic Energy Act is amended to include NARM would such amendment affect or restrict the use of CERCLA funds for NARM contaminated areas or facilities? To clarify the issue, a new section is proposed in CERCLA which would allow the continuation of such funding for NARM contaminated areas and facilities.

Other Studies and Opinions

Over the past several years other organizations and groups have taken the position that NARM should be included under NRC regulatory control.

— The NRC Agreement States, following their October 1974 meeting, recommended that NRC bring NARM under its regulatory control.

— The Conference of Radiation Control Program Directors in a May 8, 1975, letter to the then NRC Commissioner Kennedy, stressed the need for NARM to be regulated at the federal level.

— A task force established in 1976 by NRC to study the NARM issue recommended that NRC seek legislative authority to regulate NARM.

— The National Governors' Association, in its publication, The Agreement State Program: A State Perspective, dated January 1983,[3] states, "The Atomic Energy Act should be amended to authorize the regulation of radioactive materials not presently affected by the Act, that is, naturally-occurring and accelerator-produced radioactive material (NARM)."

— A 1984 survey (NUREG-0976) of the states by NRC showed that all the (then) twenty-seven Agreement States and sixteen of the twenty-three nonagreement states supported the regulation of NARM by NRC. Of the remaining seven, only four were opposed to NRC regulating NARM with two undecided and one with no reply.

— At the October 1984 meeting of the NRC Agreement States, a resolution was again adopted which called upon the NRC to include NARM under the Atomic Energy Act.

— In May 1985, the Conference of Radiation Control Program Directors again adopted a position that NARM should be included under the Atomic Energy Act control.

— At the October 1986 meeting of the Agreement States, the attending states again advocated inclusion of responsibility to regulate NARM in the Atomic Energy Act.

Conference Position

The Conference of Radiation Control Program Directors has evaluated the NARM issue in the United States and has observed that the use of NARM is common and widespread throughout the country and that the control of NARM is varied and fragmented. The resulting nonuniform control of NARM creates confusion on the part of users and waste generators, and creates a potential for excessive radiation exposure to both radiation workers and the general public.

Based on the information contained in this paper and in a 1985 Conference resolution, the Conference recommends that the Atomic Energy Act of 1954 be amended to authorize the Nuclear Regulatory Commission to regulate discrete sources of naturally-occurring and accelerator-produced radioactive materials in the same way it is authorized to regulate other radioactive material identified in the act.

The Conference concludes that there are some non-NRC Agreement State radiation control programs adequately protecting the public through the regulation and control of NARM. Since the twenty-eight Agreement States control and regulate NARM in the same manner as material currently identified in the Atomic Energy Act, the NRC Agreement State members recommend that NRC establish procedures to maintain the continuation of NARM regulatory authority and control immediately following amendment of the Act.

Suggested language amending the Atomic Energy Act is attached to this Position Paper.

SUGGESTED AMENDMENT

for

The ATOMIC ENERGY ACT of 1954

to

AUTHORIZE THE U.S. NUCLEAR REGULATORY COMMISSION

to REGULATE

NATURALLY-OCCURRING & ACCELERATOR-PRODUCED RADIOACTIVE

MATERIAL (NARM)

The following suggested changes in the Atomic Energy Act would authorize the U.S. Nuclear Regulatory Commission to regulate and control Naturally-Occurring & Accelerator Produced Radioactive Material (NARM) in a similar manner as radioactive material currently authorized by the Act.

Note: Bracketed word or words indicate the word(s) are to be deleted. Underlined words or words, indicate new word(s) are to be added.

1. Ref: Chapter 2, Section 11 e.

Add a new (3) with the following wording:

e. The term "byproduct material" means (1) any radioactive material (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, [and] (2) the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content,

and, (3) discrete naturally-occurring or accelerator produced radioactive material (NARM) as determined by the Commission.

2. Ref: Chapter 2, Section 11

Add a new definition to read as follows, then re-alphabetize appropriately:

The term "naturally-occurring radioactive material" means a material or substance that is radioactive as it exists in nature.

3. Ref: Chapter 2, Section 11

Add a new definition to read as follows, then re-alphabetize appropriately:

The term "accelerator-produced radioactive material" means a material or substance made radioactive by exposure to the radiation of a particle accelerator.

4. Ref: Chapter 2, Section 11

Add a new definition to read as follows, then re-alphabetize appropriately:

The term "particle accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum, and of discharging the resultant particulate or other radiation into a medium at energies usually excess of 1 MeV.

5. Ref: Chapter 14

Add a new Section to read as follows, then re-number appropriately:

The Commission shall, on January 1, 1992, assume regulatory responsibility for the regulation and control of byproduct materials as defined in Section II e (3) and shall by this date have established rules, regulations, and standards to govern the possession and use of byproduct materials as defined in Section II e (3).

Prior to January 1, 1992, any reference made to byproduct materials, when a specified type of byproduct materials is not mentioned, shall mean byproduct materials as defined in Section II e (1) and (2). On January 1, 19982, and thereafter, any references made to byproduct materials when a specific type of byproduct materials is not mentioned, shall mean byproduct materials as defined in Section II e (1), (2), and (3).

6. Ref: Chapter 19, Section 274b.

Add a new sub-item (3) with the following wording, and re-numbering as appropriate.

b. Except as provided in subsection c., the Commission is authorized to enter into agreements with the Governor of any State providing for discontinuance of the regulatory authority of the Commission under chapters 6, 7, and 8, and section 161 of this Act, with respect to any one or more of the following materials within the State-

(1) byproduct materials as defined in section 11 e. (1);

(2) byproduct materials as defined in section 11 e. (2);

(3) byproduct materials as defined in Section 11 e (3);

[(3)] 4 source materials;

[(4)] 5 special nuclear materials in quantities not sufficient to form a critical mass.

7. Ref: Chapter 19, Section 274

Add a new subsection to read as follows, and re-alphabetize as appropriate.

The Commission shall on January 1, 1992, assume responsibility for the regulation and control of byproduct materials as identified in subsection b (3) of Section 274. No agreement pursuant to byproduct materials as identified in subsection b (3) of Section 274 shall become effective prior to January 1, 1992.

Agreements entered into prior to January 1, 1992, pursuant to byproduct materials as identified in subsection b (1) of Section 274 shall as of January 1, 1992, be deemed to also include byproduct materials as identified in subsection b (3) of Section 274 unless the Commission determines to the contrary based on public health and safety considerations, or unless the State which has entered into such an agreement prior to January 1, 1992, determines that it does not desire regulatory authority over byproduct materials as identified in subsection b (3) of section 274.

The Commission shall establish a procedure to maintain the continuation of regulatory authority for those materials identified in subsection b (3) of section 274 in a state which has not entered into an agreement prior to January 1, 1992.

8. Ref: Chapter 19, Section 274

Add a new subsection to read as follows, and re-alphabetize as appropriate.

Agreements entered into pursuant to subsection b shall not exclude states from being eligible for the assertion of claims against the Hazardous Substance Response Trust Fund established under the Comprehensive Environmental Response Compensation and Liability Act of 1980 when such claims relate to any of the materials included in the agreements.

REFERENCES

1. Office of Nuclear Material Safety and Safeguards, NRC, Regulation of Naturally Occurring and Accelerator Produced Radioactive Materials: A Task Force Review, NUREG-0301, July, 1977.

2. Office of State Programs, NRC, Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials: An Update, NUREG-0976, October, 1984.

3. H. Brown, The Agreement State Program: A State Perspective, National Governors' Association, Washington, D.C., January, 1983.

POLICY ISSUE

September 22, 1992 (NEGATIVE CONSENT) SECY-92-325

For: The Commissioners

From: James M. Taylor, Executive Director for Operations

Subject: CHARACTERIZATION OF DISCRETE NARM AND EVALUATION OF THE NEED TO SEEK LEGISLATION EXTENDING NRC AUTHORITY TO DISCRETE NARM

Purpose: To provide the Commission with a response to Item No. 6 of a Staff Requirements Memorandum (SRM) dated October 5, 1990, in which the Commission indicated that the staff should reevaluate and report to the Commission on the public health and safety significance of discrete sources of naturally-occurring and accelerator-produced radioactive materials (NARM), and evaluate whether legislation extending NRC's jurisdiction to include NARM is necessary or desirable.

Background: In Item No. 6 of a Staff Requirements Memorandum (SRM) dated October 5, 1990, (Enclosure 1) the Commission indicated that the staff should reevaluate and report to the Commission on the public health and safety significance of discrete sources of NARM and evaluate whether legislation extending NRC's jurisdiction is necessary or desirable. As a basis for its evaluations, the staff was directed to consider results and recommendations from a report being prepared at the request of former NRC Chairman Lando Zech by the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC). The requested report was to consist of a characterization of risks from discrete sources of NARM and an identification of the need for appropriate action by Federal agencies to regulate various aspects of discrete NARM.

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(301) 504-2629

NOTE: TO BE MADE PUBLICLY AVAILABLE WHEN THE FINAL SRM IS MADE AVAILABLE

Discussion: Response to the October 6, 1990, SRM has been delayed because the requested CIRRPC report has not been completed. The staff's effort to respond to the SRM has included continued monitoring of the CIRRPC efforts, placement of a small contract to assess the sources and risks associated with discrete NARM in order to supplement information expected from CIRRPC, and review of work conducted by the Environmental Protection Agency (EPA) and the National Council on Radiation Protection and Measurement (NCRP) on discrete NARM.

Although a final CIRRPC report is not yet available, the staff has evaluated the issues related to NARM based on other information available at this time, including a draft CIRRPC report which was received in January 1992. This evaluation, which includes a definition of discrete and diffuse NARM, is presented in Enclosure 2. The following is a synopsis of Enclosure 2:

(1) Background information - a discussion of earlier Commission actions taken on NARM and previous NRC staff reports prepared on NARM including NUREGs-0310, 0976, and 1310. Specifically, it is noted that in NUREG-1310 the staff concluded that, based on its review of the hazards associated with NARM and of the oversight exercised by other agencies, NRC should not seek legislative authority over NARM. However, NUREG-1310 did recommend that the issue of NARM regulation be referred to CIRRPC for the purpose of developing an integrated policy and Agency assignments on NARM. Subsequently, NRC Chairman Zech referred the NARM issue to CIRRPC;

(2) Current actions related to discrete NARM - a discussion of current actions being conducted by CIRRPC, EPA, NRC staff, and the States. Specifically discussed are: i) the revised draft CIRRPC report received in January 1992 in which CIRRPC reviews NARM characterization in a relatively qualitative manner, and also indicates that broad authorities exist under the jurisdiction of the EPA through the use of the Toxic Substances Control Act (TSCA) to implement Federal controls if an unreasonable risk has been identified, and that this authority could be applied to the regulation of NARM; ii) EPA projects that have developed information on sources and risks from NARM as well as regulatory products, and were conducted based on the authority of TSCA; iii) a small NRC contract placed to review sources and risks associated with discrete NARM as a means of supplementing information expected from CIRRPC; and iv) efforts by the States, largely under the auspices of the

Conference of Radiation Control Program Directors (CRCPD), to improve the existing State programs for NARM licensing.

3) Characterization of NARM - characterizations of source and dose estimates made in reports on NARM prepared by CIRRPC, EPA, and NRC. These reports are draft and preliminary; however, they do provide an estimate of the range of possible exposures. The following summary can be made based on those reports:

a) For some NARM it is uncertain as to what sources exist, their use, and the attendant risks (e.g., the risks from discrete NARM remaining in use and/or storage) because the information on existence and use is currently unknown, unavailable, or not contained in the data sources listed;

b) Based on the data that is available, the principal concern appears to be unregulated disposal that could result in substantial public exposures of certain discrete NARM sources and of certain higher activity diffuse NARM sources, such as pipe scale. This concern has been addressed by EPA in previous documents developing data on NARM discussed in Enclosure 2. Also, risks from NARM used in medicine appear to be similar to those from regulated byproduct material.

4) Authority over NARM -

a) As noted above, the draft CIRRPC report identified TSCA as authorizing the EPA to impose regulatory requirements on NARM, and thus concluded that: (1) Federal authorities and responsibilities (principally EPA) appear sufficient to address any new health problem should it arise in a manner requiring immediate or long-term attention and (2) inasmuch as TSCA could be invoked to control identified unreasonable risks (as defined in the Act) due to discrete NARM, that no gaps in regulatory jurisdiction were identified.

b) EPA has invoked the authority it has under TSCA in proceeding with development of an information base and regulatory requirements on the disposal of both discrete and diffuse NORM, which it sees as the most pressing problem.

c) The states, under their constitutional authority and responsibility to protect the health and safety of

their citizens, have acted to institute requirements in the area of discrete NARM. Most of this work is carried out under the auspices of the CRCPD. Currently, the CRCPD has developed a program to certify the adequacy of State NARM regulatory programs. CRCPD's recommended regulatory control requirements for discrete NARM and ARM are similar to those which are required by NRC for byproduct material in the Agreement State program. Currently about one-third of the states are recognized as NARM licensing states by the CRCPD, while most of the rest have at least some NARM registration program. CRCPD has prepared a strategy document for uniform regulation and control of discrete NARM which includes development of data, improvements in State licensing efforts, and seeking national controls under TSCA, if necessary.

The conclusions reached by the staff in Enclosure 2, are:

a) It appears to the staff that EPA has the legislative authority to adequately regulate NARM, and to assist CRCPD, if necessary, with national standards in certifying States. Although recent discussions by the staff with CIRRPC staff have raised concerns over the authority of EPA to issue broad-scale regulations under TSCA, EPA legislative authority over identified problems caused by NARM appears clear. Therefore, as in the draft CIRRPC report and NUREG-1310, the staff has concluded that there is no need for NRC to seek legislative authority to regulate discrete NARM.

b) Based on considerations regarding authority over NARM, the staff concluded that further NRC efforts to perform detailed analysis of discrete NARM sources and risks, or analysis of the economic impact of regulation of NARM by NRC are not warranted.

Conclusion: Based on the above conclusions reached in Enclosure 2, the staff concluded that:

1. The Commission should not seek legislative authority to extend its jurisdiction over the regulation of discrete NARM.

2. Further NRC efforts related to discrete NARM should focus on assisting EPA in its efforts to apply TSCA to NARM and be conducted pursuant to the NRC/EPA Memorandum of Understanding dated March 16, 1992.

3. The NRC should inform the CRCPD by letter that the Commission will not seek legislative authority to regulate NARM, and indicate the Commission support of the ongoing CRCPD program (a draft letter to the CRCPD is included as Enclosure 3).

Recommendation: Unless otherwise directed by the Commission, within 10 working days after the date of this paper the staff will:

1. Assume its recommendations concerning not seeking legislation over NARM is acceptable to the Commission;

2. Continue its efforts to work with EPA and other Federal and State agencies with regard to NARM regulation;

3. Proceed to finalize and send the letter to the CRCPD presented in Enclosure 3.

Coordination: The Office of the General Counsel has no legal objection to this paper.

James M. Taylor
Executive Director
for Operations

Enclosures:
1. SRM, October 5, 1990
2. Evaluation of Issues Related to NARM
3. Draft Letter to CRCPD

SECY NOTE: In the absence of instructions to the contrary, SECY will notify the staff on Wednesday, October 7, 1992, that the Commission, by negative consent, assents to the action proposed in this paper.

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Enclosure 1

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

OFFICE OF THE
SECRETARY

October 5, 1990

IN RESPONSE, PLEASE
REFER TO M900816A

Action: Bernero, NMSS
Beckjord, RES
Murley, NRR

Cys: Taylor
Sniezek
Thompson
Blaha
Norry, IRM
Jordan, AEOD
Bird, OP
Springer, CONS
Scinto, OGC -
Scroggins,OC

MEMORANDUM FOR: James M. Taylor
Executive Director for Operations

William C. Parler
General Counsel

Harold R. Denton, Director
Office of Governmental and Public Affairs

FROM: Samuel J. Chilk, Secretary

SUBJECT: STAFF REQUIREMENTS - COLLEGIAL DISCUSSION OF ITEMS OF COMMISSIONER INTEREST, 8:30 A.M., THURSDAY, AUGUST 16, 1990, COMMISSIONERS' CONFERENCE ROOM, ONE WHITE FLINT NORTH, ROCKVILLE, MARYLAND (OPEN TO PUBLIC ATTENDANCE)

The Commission met to discuss topics of individual Commissioner interest. The topics discussed and associated staff requirements are described below.

1. The Commission discussed the potential for use of an electronic system to aid communication in the rulemaking process. No staff requirements were initiated from this discussion.

2. The Commission discussed plans for the review of the PIUS and CANDU designs. The staff requirements covering this area will be handled separately.

3. The Commission discussed the matter of Staff Requirements Memoranda developed from votes on proposed actions and the need to communicate the basis for Commission decisions in order to assist the staff in responding appropriately to Commission requests. The staff should make every effort to communicate with Commission staff for clarification if a question arises regarding Commission requests.

4. The concept of creating an elite NRC group of experts to conduct design reviews of the advanced reactors was briefly discussed.

5. The issue of Agreement State compatibility was discussed in the context of recent Commission review of State programs and the development of the **Below Regulatory Concern** policy. A clear and sound policy on compatibility is integral to ongoing reviews of Agreement State programs and rulemakings affecting State programs. Accordingly, an **interoffice** group **should be formed to evaluate the compatibility issue**, including past practice and current policy, and provide policy reccommendations and options for Commission consideration. In addition to general policy options, this evaluation should specifically provide answers to the following questions:

   a. What is the legal basis for compatibility determinations? What is the relationship between compatibility determinations and protection of the public health and safety?

   b. Are these determinations limited to State statutes and regulations only, or do they also include other aspects such as programs, staffing, and policies? What is NRC's basis for requiring States to adopt compatible regulations within a three-year timeframe?

   c. How often does NRC review State regulations after the Commission enters into an Agreement with a State to ensure continued compatibility of the programs?

   d. If NRC determines that a State program is not compatible with NRC's program for similar materials, what options does the Commission have to encourage and/or require compatibility?

   e. In light of the answers to the above questions, should the Internal Procedure B.7 be revised or modified? Should these procedures be published for review and comment by States and members of the public? Should the existing categorization of NRC requirements be reevaluated?

   f. Discuss the various arguments, pro and con, related to the question whether the Low-Level Radioactive Waste Policy Amendments Act of 1985 and its legislative history provide a basis for concluding that Agreement States are to be given a greater degree of latitude in fashioning their own standards for low-level waste (LLW) disposal, in view of the States' increased responsibility in this area?

(GPA/OGC/~~EDO~~ NMSS/RES) (SECY Suspense: 2/15/91)

6. The Commission discussed the potential need for legislation in the areas of naturally occurring and accelerator-produced radioactive material (NARM) and mixed waste.

The Commission requests that, as part of the joint survey with EPA on mixed waste, staff determine whether joint NRC/EPA permitting should be pursued, and whether the existing regulatory guidance on mixed waste is adequate for generators and States to make progress in treatment and disposal of mixed waste. Staff should evaluate as a matter separate from the upcoming legislative proposals whether legislation is necessary or desirable to address the mixed waste issue, so as to permit timely development of low-level waste disposal capacity.

(~~EDO~~/GPA) (SECY Suspense: 60 days after completion of survey) 9000218
NMSS

While the mixed waste survey and in-depth evaluation of the need for legislative action is progressing over the next two years, the staff should provide preliminary recommendations on the need or potential need for legislation if sufficient information is available. The technical staff in coordination with OGC should closely monitor the development of RCRA reauthorization legislation and provide timely recommendations based on currently available information for early Commission input into these deliberations (e.g., into a potential Administration RCRA reauthorization proposal).

(~~EDO~~) (NMSS/OGC) (SECY Suspense: 12/28/90 and continuing as necessary) 9000219

On the subject of NARM, staff should reevaluate and report to the Commission on the public health significance of discrete sources of NARM, focusing on the questions identified in the Commission's earlier referral to CIRRPC. Staff should also evaluate whether legislation extending NRC's jurisdiction to include NARM is necessary or desirable. This evaluation should include a discussion of the advantages and disadvantages of our seeking jurisdiction over NARM.

(~~EDO~~) (RES/NMSS) (SECY Suspense: 8/30/91) 9000220

Subsequent to the Commission's consideration of this information on mixed waste and NARM, the Commission will provide guidance on the need to address these issues in the future legislative submittals.

7. The Commission discussed the proposed Part 35 medical rule which is currently out for public comment. No requirements were identified for staff action.

8. The continuing need for a licensing review basis document was discussed by the Commission. Staff should submit its recommendations on this issue by October 26, 1990, so that the Commission can factor the decision that it reaches on this issue into the agency's schedule and resource estimates for ALWR reviews.

(~~EDO~~) (NRR) (SECY Suspense: 10/26/90) 9000142

9. Several other items were very briefly discussed without initiating requirements for the staff. These items were:

- o Plant operating data
- o Speaking opportunities
- o ACRS reports to Congress
- o BRC policy
- o Personnel recruiting
- o Memos to the staff
- o Second building status

cc: Chairman Carr
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
ACRS
PDR - Advance
DCS - P1-24

Enclosure 2

CHARACTERIZATION OF DISCRETE NARM AND EVALUATION OF NEED TO SEEK LEGISLATION EXTENDING NRC AUTHORITY TO DISCRETE NARM

I. INTRODUCTION

In Item No. 6 of a Staff Requirements Memorandum (SRM) dated October 5, 1990, the Commission indicated that the staff should reevaluate and report to the Commission on the public health and safety significance of discrete sources of naturally-occurring and accelerator-produced radioactive materials (NARM), and evaluate whether legislation extending NRC's jurisdiction is necessary or desirable. As a basis for its evaluations, the staff was directed to consider results and recommendations from a report being prepared by the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC) on characterization of risks from discrete sources of NARM and identification of the need for appropriate action by Federal agencies to regulate various aspects of discrete NARM.

In general, NARM includes both NORM and ARM as described below:

A. NORM (Naturally Occurring Radioactive Material) -

1. Diffuse - generally large volume, low activity sources of radioactivity, principally radium-226 (Ra-226), such as phosphate ore, mineral processing wastes, coal ash, phosphate fertilizers, geothermal wastes, water treatment plant sludges and resins, uranium mining overburden, and oil and gas pipeline scale.

2. Discrete - typically small volume, high specific activity sources. The generally recognized lower limit for discrete NORM is 2 nanocuries/gm equivalent Ra-226 concentration. Sources of discrete NORM can include:

   a. Products containing Ra-226 such as medical sources, industrial sources, and certain consumer products. Generally, such sources are no longer produced in large quantities, although sources remain in storage and in some cases in use, although the exact quantity in use is not certain;

   b. Certain wastes containing Ra-226, such as oil pipe scale and water treatment plant resins, which, although generally diffuse, might in certain instances become concentrated enough and confined enough to be considered discrete.

B. ARM (Accelerator-Produced Radioactive Material) - radionuclides produced by bombardment of non-radioactive materials with charged particles or neutrons. A number of radionuclides are produced by accelerators (e.g., Ga-67, I-123, Tl-201) and are used in:

1. Medical uses - used in diagnostic medicine and therapy in a manner similar to that of byproduct material; and

2. Industrial/research uses.

As directed by the Commission, the subject of the remaining sections of this enclosure is discrete NORM and ARM, although diffuse NORM is at times referred to in order to provide a context for the discussion on discrete NARM.

II. BACKGROUND

The subject of regulation of NARM by NRC has been considered several times over the past several years. Specifically:

A. In June 1977, in response to requests from the States, an NRC Task Force reviewed the use and regulation of NARM (NUREG-0301, Ref 1). The Task Force concluded that the regulation of NARM was fragmentary, non-uniform, and incomplete at both Federal and State levels. The Task Force found that NARM was widely used, particularly Ra-226, and that the use of accelerator produced nuclides was growing rapidly, and noted the potential for exposure incidents involving NARM. The Task Force recommended NRC seek legislative authority to regulate NARM and a Commission Paper (SECY-78-211) on the subject was prepared in April 1978. However, the Commission chose not to act on the recommendations in the paper because it did not believe that a case had been made that NRC regulation of NARM was necessary and because it believed that other Federal or State agencies more properly should exercise such authority. Nonetheless, the Commission asked that the staff resubmit the paper for reconsideration after addressing specific questions on NARM risks and authority of other agencies over NARM.

B. In May 1979, the Commission directed the staff to forward NUREG-0301 by letter to Federal agencies, State governors, and Congressional committees having reponsibilities in the regulation of NARM, and in particular to note that "while NRC could logically regulate NARM - given legislative authority - NRC is not pursuing that authority because it believes such efforts should be integrated into the larger effort to properly allocate Federal responsibilities for radiation protection." The Federal Radiation Policy Council, established to address the overall direction and effectiveness of Federal regulatory programs, was informed of the issue by the NRC staff. However, the Council did not address the issue before it was disbanded.

C. In October 1984 the NRC staff published NUREG-0976 (Ref. 2) which updated NUREG-0301. The staff had reviewed the use of and regulatory control over NARM and concluded that fragmentary control of NARM leads to confusion and the potential for exposure to workers and the public. The staff also concluded that the regulation of NARM should be uniform - the responsibility of a single Federal Agency which would set national standards to be followed by the other agencies, States, and licensees.

D. In August 1987, the Conference of Radiation Control Program Directors (CRCPD) indicated that they believed that, because there was no single Federal Agency where uniform guidance on NARM is provided and because in some States there was no control of NARM, the NRC should begin the appropriate actions necessary to regulate NARM in the States which are not currently regulating NARM.

E. In March 1988, the staff published NUREG-1310 (Ref. 3) which contained (1) an updated discussion of NORM and of ARM, including trends and problems, (2) an extensive discussion of Federal and State government involvement with NARM, (3) issues related to NARM, and (4) options related to regulation of NARM (including a discussion of the impact that NRC involvement with NARM regulation might have on NRC resources). These options included:

1. Maintaining the status quo, i.e., not seeking NRC legislative authority over NARM;

2. Seeking legislative authority over NARM;

3. Seeking regulatory control over radium disposal;

4. Seeking regulatory authority over cyclotron produced nuclides for medical use only;

5. Referring the issue of NARM regulation to CIRRPC.

The staff concluded that, based on the jurisdiction over NARM existing in other Federal agencies and on the increased State regulatory activities related to NARM, the level of risk from unregulated NARM was not sufficient for NRC to seek legislative authority over NARM. However, the staff also recommended referring the issue of NARM regulation to CIRRPC for the purposes of developing an integrated policy and Agency assignments on NARM, because as the staff pointed out:

> "CIRRPC was created to coordinate radiation matters between agencies and to advise the Office of Science and Technology on issues involving Federal radiation policy. NARM cuts across existing jurisdictions of other agencies. There is a need for an integrated control program over ionizing radiation, in general, and over NARM, in particular, to ensure that the dominant hazards are appropriately addressed

without undue attention to the lesser hazards. Thus, CIRRPC is the logical entity to resolve the NARM issue. In fact, in 1979, the Commission referred the NARM issue to the predecessor of CIRRPC, but action was never completed."

In NUREG-1310 the staff also recommended that NRC inform the Governors of those States, which were not CRCPD-recognized NARM licensing States, that NRC is not going to seek legislative authority to regulate NARM because such regulation is a responsibility of the States and because other Federal agencies already have jurisdiction over most facets of NARM hazards.

F. SECY-88-64, dated March 2, 1988, transmitted NUREG-1310 to the Commission and a Commission meeting was held to discuss the matter on May 5, 1988. Following the Commission meeting, on July 26, 1988, former NRC Chairman Lando Zech wrote to Dr. William Graham, Science Adviser to the President, indicating that the Commission had decided to refer the issue of Federal regulation of NARM to CIRRPC. Chairman Zech indicated in his letter that "CIRRPC, as the body created to coordinate Federal policy on radiation issues, will be able to make recommendations on the appropriate designation of responsibilities for regulation of NARM."

Four specific requests were included in the NRC's scope of referral to CIRRPC, as follows:

1. Develop a definition of discrete sources of NARM that might be regulated by the Federal government;

2. Where Federal jurisdiction exists over aspects of NARM, characterize the nature of public health and safety concerns that are going unaddressed by Federal controls and recommend how to remedy the situation;

3. Identify gaps in Federal jurisdiction over discrete NARM and characterize public health and safety concerns associated with those sources;

4. To the extent the concerns identified above merit Congressional action, recommend which Federal Agency or agencies might seek legislative authority to regulate various aspects of those discrete sources of NARM.

G. In response to Chairman Zech's letter, CIRRPC submitted a draft report (Ref. 4) to the NRC in June 1990 in which it concluded that the NRC should not seek legislative authority over regulation of NARM. This affirmed the NRC staff's conclusion in NUREG-1310. The bases for CIRRPC's conclusion as given in the draft report were that a significant public health and safety problem had not been identified and sufficient authorities to regulate NARM already exist in other agencies. However, the Commission was not satisfied with the level of detail provided in the report,

particularly the characterization of public health and safety concerns associated with discrete NARM. Therefore, in November 1990 the NRC sent a letter to CIRRPC requesting that the draft report be revised to address a number of specific questions related to risk levels associated with discrete NARM.

III. CURRENT ACTIONS RELATED TO DISCRETE NARM

At the time of the November 1990 request to CIRRPC, the Commission issued a Staff Requirements Memorandum (SRM) indicating that the staff should reevaluate and report to the Commission on the public health and safety significance of discrete sources of NARM and evaluate whether legislation extending NRC's jurisdiction to include NARM is necessary or desirable. As a basis for its evaluations, the staff was directed to consider results and recommendations from the report being prepared by CIRRPC on characterization of risk from discrete sources of NARM and identification of the need for appropriate action by Federal agencies.

Several actions are underway, which provide input to the response to the SRM:

A. In January 1992 a revised draft CIRRPC report was received by the staff for review in parallel with a review by the CIRRPC Science Subpanel. The revised draft report presents the following:

1. Discrete NARM is discussed in a relatively qualitative manner indicating that, in the absence of detailed data on risks due to NARM, the CIRRPC Working Group members have relied on information available from their agencies and from studies such as those done by the National Council on Radiation Protection and Measurements (NCRP) presented in NCRP Report Nos. 95 and 96 (Refs 5, 6). It is also indicated that a comprehensive study of risks was not contemplated or conducted by the CIRRPC Working Group because such would be inappropriate, if not impossible, particularly in the absence of requested information from the States.

2. Broad authorities do exist under the jurisdiction of the Environmental Protection Agency (EPA) through the use of the Toxic Substances Control Act (TSCA) to implement Federal controls if an unreasonable risk has been identified. Section 6(a) of TSCA authorizes EPA to impose regulatory requirements on a chemical substance or mixture if EPA finds that there is a "reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment." The term "chemical substance" is very broad and would include all NARM.

Under Section 6(c)(1) of TSCA, EPA must consider the following factors when determining whether a chemical substance or mixture presents an unreasonable risk:

a. Effects of such substance or mixture on health and the environment, and the magnitude of the exposure of human beings or the environment to such a substance or mixture;

b. Benefits of such substance or mixture for various uses;

c. Economic consequences of the rule, after consideration of the effect on the national economy, small business, technology, the environment, and public health.

3. Based on the above, in the revised draft report CIRRPC concluded that:

a. No public health and safety problem has been identified, though studies are underway by EPA and NRC which may result in recommendations for Federal control;

b. Federal authorities and responsibilities (principally in EPA under TSCA) appear sufficient to address any new health problem due to discrete NARM should it arise in a manner requiring immediate or long-term attention;

c. Inasmuch as TSCA could be invoked to control identified unreasonable risks (as defined in the Act) due to discrete NARM, no gaps in Federal jurisdiction over discrete NARM have been identified;

d. Detailed studies should be conducted by NRC on current medical and industrial uses of unlicensed NARM sources to determine if Federal action is needed;

e. The EPA study on diffuse NARM risks should be extended to include discrete NARM waste streams resulting from man's production and treatment systems;

f. CRCPD should continue to identify discrete sources of NARM that are candidates for regulation under TSCA.

B. Several projects have been conducted by EPA based on the fact that, as noted above in the draft revised CIRRPC report, the EPA could use its authority under TSCA to regulate NARM. Based on this authority, the EPA has developed information on sources and risks from both discrete and diffuse NARM, and has also developed regulatory products, as follows:

1. EPA, using its authority under TSCA, has prepared draft standards for discrete NARM waste disposal (draft 40 CFR Part 764) and a Draft Environmental Impact Statement (EIS) (Ref.7) regarding the characterization and risk from radium in discrete NARM such as used in medical applications, certain industrial applications, and in certain consumer products (smoke detectors, instrument dials, watches). The NRC plans to complete its review of EPA's draft NARM waste regulations under the framework provided in the new Memorandum of Understanding between NRC and EPA. EPA's draft NARM waste EIS provides an assessment of the characteristics and risk associated with disposal of discrete NARM wastes but not of the use of discrete NARM.

2. EPA has also released for comment a draft report on diffuse naturally occurring radioactive material (NORM) (Ref. 8). Although the subject of this draft EPA report is diffuse NORM, certain of these diffuse sources can become concentrated and confined (e.g., oil pipe scale, water treatment resins) and in certain instances might be considered as discrete. The draft report characterizes all of these sources and estimates associated exposures, which it emphasizes are preliminary and therefore uncertain, and also discusses the potential need for establishing EPA's regulatory controls over these NORM sources through TSCA. The draft report was reviewed by the NRC staff and comments sent to EPA. A final report is under preparation by EPA.

C. To supplement information developed by CIRRPC and to assist the NRC staff in its evaluation of the risk associated with NARM, the Office of Nuclear Regulatory Research (RES) placed a small contract to review sources and risks associated with discrete NARM. The staff is now reviewing a draft report from the contractor. The draft contractor report summarizes some of the information in the draft EPA reports on NORM and also discusses the use of accelerator-produced radioactive materials, principally in the area of medical applications. The draft report indicates that the use of ARM appears to have increased in recent years and the exposures and risks from medical uses of ARM are similar to those from byproduct materials currently regulated under the AEA.

D. The States, under their constitutional authority and responsibility to protect the health and safety of their citizens, have acted both individually and as a group to institute requirements in the area of discrete NARM. Most of this work is carried out under the auspices of the CRCPD. Currently, the CRCPD has developed a program to certify the adequacy of State NARM regulatory programs. CRCPD's recommended regulatory control requirements for discrete NORM and ARM are similar to those which are required by NRC for byproduct material in the Agreement State program. Currently about one-third of the states are recognized as NARM licensing states by the CRCPD, while most of the rest

have at least some NARM registration program. CRCPD has prepared a strategy document for uniform regulation and control of discrete NARM which includes development of data, improvements in State licensing efforts, and seeking national controls under TSCA, if necessary.

IV. SUMMARY AND CONCLUSIONS

The following is a summary of the preceding sections including the conclusions that can be drawn from the available data and information:

A. Characterization of NARM

1. The CIRRPC, EPA, and NRC contractor reports referenced above are in draft form and hence the characterizations of sources and dose estimates made in those reports are preliminary and subject to change. However the reports do provide an estimate of the range of possible exposures.

   Based on the draft reports, there are areas where it is uncertain what sources or risks exist, because the information is either currently unknown or not contained in the data sources listed. These include:

   a) the amounts of and risks from discrete NORM remaining in use vs. storage, and

   b) the amounts of and risks from ARM in certain uses, including certain medical uses and industrial and research uses.

   Of the draft data that is available, certain statements can be made, including:

   a) the impact of unregulated disposal of discrete NARM could, in some cases, be greater than the public dose limits in 10 CFR Part 20 and was found by EPA, in its draft GEIS and in draft regulations noted in Section III.B.1 above, to be sufficiently high to warrant regulation;

   b) the unregulated disposal of certain higher specific activity diffuse NORM sources such as pipe scale appears to result in substantial maximum exposed individual and worker doses (this source was addressed by EPA in its draft report on diffuse NORM noted in Section III.B.2 above);

   c) the risks from ARM use in medicine appears to be similar to those from byproduct materials.

2. Obtaining the missing information sufficient to make definitive statements regarding the health and safety impact of the NARM sources and the cost effectiveness of regulations would require an extensive effort making use of information-gathering surveys and detailed pathway and dose analysis of the data obtained. However, based on the apparent sufficiency of EPA authority over NARM, the staff has concluded that NRC efforts should not be expanded further except to assist other agencies as noted below.

B. Authority over NARM

1. As can be seen from Section II above, more than one previous Commission has expressed reluctance in assuming control of discrete NARM, and in fact Chairman Hendrie, in his comments on SECY-78-211, saw this area as unrelated to NRC's primary responsibility for nuclear fuel cycle matters. Also, earlier Commissions have sought to obtain guidance from interagency Federal policy councils, such as the Federal Radiation Policy Council (FRPC) in 1978 and CIRRPC in 1988, in their roles as organizations created to coordinate Federal policy on radiation issues, and to obtain recommendations on the appropriate designation of responsibilities for regulation of NARM. Previously, the FRPC did not provide guidance; however, the CIRRPC draft conclusions and recommendations regarding authority over NARM as discussed above are contained in the draft CIRRPC report of January 1992.

2. In their draft revised report, CIRRPC identified the Toxic Substances Control Act (TSCA) as authorizing the EPA to impose regulatory requirements on a chemical substance or mixture, such as NARM, if EPA finds that there is a reasonable basis to conclude that the manufacture, processing, distribution, use, or disposal of the chemical substance or mixture, or any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment. Based on that, the draft CIRRPC report concludes that: (1) Federal authorities and responsibilities (principally in EPA) appear sufficient to address any new health problem should it arise in a manner requiring immediate or long-term attention and (2) inasmuch as TSCA could be invoked to control identified unreasonable risks (as defined in the Act) due to discrete NARM, no gaps in regulatory jurisdiction are identified.

3. EPA has invoked the authority it has under TSCA in proceeding with development of an information base and regulatory requirements on the disposal of both discrete and diffuse NARM which it sees as the most pressing problem. Based on these actions, it appears to the staff that, if

problems in other areas related to NARM are identified, EPA has the authority to act in a like manner.

4. State efforts under CRCPD appear to be directed towards improved State certification in the regulation of NARM and towards setting uniform requirements with reference to TSCA, as necessary.

5. As was concluded in the draft CIRRPC report and in NUREG-1310, the staff concludes that there does not at this time appear to be a need for NRC to seek legislative authority to regulate NARM, although there should still be NRC involvement as noted in Section 5 below.

V. RECOMMENDATIONS

A. Based on the above, the staff recommends that the Commission not seek legislative authority to extend its jurisdiction over the regulation of discrete NARM. This recommendation is based on the draft reports and other information currently available that are discussed above. While it is not expected that the recommendation would change, the staff will continue to interact with EPA and other agencies on this matter.

B. Under Section 26(a) of TSCA, upon request by the EPA Administrator, other Federal agencies are authorized to make their services available to the Administrator to assist in the administration of the Act. The staff recommends that NRC assistance under Section 26(a) in support of EPA regulation of NARM should be pursuant to the NRC/EPA Memorandum of Understanding dated March 16, 1992.

C. The staff recommends that the NRC inform the CRCPD, by letter, that the NRC will not seek legislative authority to regulate NARM, because such regulation is a responsibility of the States and because other Federal agencies already have jurisdiction over most facets of NARM hazards, and that the NRC supports the ongoing CRCPD NARM program (a draft letter to the CRCPD is included in Enclosure 3).

VI. REFERENCES

1. Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials, NUREG-0301, U.S. Nuclear Regulatory Commission, June 1977.

2. Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials - An Update, NUREG-0976, U.S. Nuclear Regulatory Commission, October 1984.

3. Naturally Occurring and Accelerator-Produced Radioactive Materials - 1987 Review, NUREG-1310, U.S. Nuclear Regulatory Commission, March 1988.

4. CIRRPC Policy Report - Naturally Occurring and Accelerator-Produced Radioactive Materials (NARM), DRAFT, Committee on Interagency Radiation Research and Policy Coordination, June 1990.

5. Radiation Exposure of the U.S. Population from Consumer Products and Miscellaneous Sources, NCRP Report No. 95, National Council on Radiation Protection and Measurement, December 1987.

6. Comparative Carcinogenicity of Ionizing Radiation and Chemicals, NCRP Report No. 96, National Council on Radiation Protection and Measurement, December 1989.

7. Low-Level and NARM Radioactive Wastes - Draft Environmental Impact Statement for Proposed Rules, EPA 520/1-87-012-1, U.S. Environmental Protection Agency, June 1988.

8. Diffuse NORM - Waste Characterization and Preliminary Risk Assessment, DRAFT, U.S. Environmental Protection Agency, May 1991.

Enclosure 3

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

DRAFT

Mr. Charles Hardin, Executive Director
Conference of Radiation Control Program
Directors, Inc.
205 Capital Avenue
Frankfort, KY 40601

Dear Mr. Hardin:

The Nuclear Regulatory Commission (NRC) has been in the process of evaluating the possibility of NRC seeking legislative authority for the regulation of Naturally-Occurring and Accelerator-Produced Radioactive Material (NARM). This evaluation was initiated, in part, as a result of the August 26, 1987 letter from the Conference of Radiation Control Program Directors, Inc. (CRCPD) signed by Terry R. Strong, the Chairman at that time.

In March 1988, NRC published NUREG-1310, "Naturally-Occurring and Accelerator-Produced Radioactive Materials - 1987 Review." The Commission then referred the issue to the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC) and requested a report to consist of a characterization of the risks from discrete sources of NARM and an identification of the need for appropriate action by Federal agencies to regulate various aspects of discrete NARM. This report has not been completed. However, we have reviewed a draft of the report. Progress has been made on the Federal front through recent actions of the Environmental Protection Agency to develop NARM regulations through its authority under the Toxic Substances Control Act (TSCA).

After reviewing the currently available information, the NRC staff has recommended that the Commission not seek a change in its legislative authority for NARM material because a) EPA authority under TSCA, b) State authority, and c) the CRCPD program for States to be designated as a NARM licensing State. The Commission agreed with the staff recommendation.

The Commission continues to believe that the licensing State program developed by the CRCPD to enhance uniform minimum regulatory programs at the State level is an excellent effort to protect the public health and safety and will continue its support of the program.

I want to thank you for your support in this effort. Please contact me if you have any further questions.

Sincerely,

Carlton Kammerer, Director
Office of State Programs

STRATEGIC ASSESSMENT ISSUE PAPER

DSI 7: MATERIALS/MEDICAL OVERSIGHT

INTRODUCTION

In August 1995, the Nuclear Regulatory Commission (NRC) staff initiated a Strategic Assessment and Rebaselining Project. This project was intended to take a new look at the NRC by conducting a reassessment of NRC activities in order to redefine the basic nature of the work of the agency and the means by which that work is accomplished, and to apply to these redefined activities a rigorous screening process to produce (or rebaseline) a new set of assumptions, goals, and strategies for the NRC. The results of this project are intended to provide an agency-wide Strategic Plan which can be developed and implemented to allow the NRC to meet the current and future challenges.

A key aspect of this project was the identification and classification of issues that affect the basic nature of NRC activities and the means by which this work is accomplished. These issues fall into three categories. The first category includes broad issues defined as Direction-Setting Issues (DSIs). DSIs are issues that affect NRC management philosophy and principles. The second category includes subsumed issues. Subsumed issues are those that should be considered along with the DSIs. The third category includes related issues. These are issues that should be considered after the Commission makes a decision on the option(s) for a DSI. Also, as part of the project, other issues of an operational nature were identified. These are not strategic issues and are appropriately resolved by the staff, and are not discussed in the issue papers.

Following the reassessment of NRC activities, issue papers were prepared to provide a discussion of DSIs and subsumed issues, and to obtain a review of these broad, high-level issues. These papers are intended to provide a brief discussion of the options as well as summaries of the consequences of the options related to the DSIs. Final decisions related to the DSIs will influence the related issues which are listed, but not discussed, in each issue paper. As part of the Strategic Assessment and Rebaselining Project, the issue papers are being provided to interested parties and to the public. Following distribution of the issue papers, a series of meetings are planned to provide a forum to discuss and receive comment on the issue papers. After receiving public comment on the issue papers, the Commission will make final decisions concerning the DSIs and options. These decisions will then be used to develop a Strategic Plan for the NRC. In summary, the Strategic Assessment and Rebaselining Project will analyze where the NRC is today, including internal and external factors, and outline a path to provide direction to move forward in a changing environment.

I. SUMMARY

A. Direction-Setting Issue

The Nuclear Regulatory Commission (NRC) Byproduct Materials Program currently regulates approximately 6,400 specific and 35,000 general licenses for the possession and use of nuclear materials in medical, academic, and industrial applications. The Materials Program includes licensing and inspection activities, primarily administered by the NRC regional offices, and exempt distribution licenses and sealed source and device (SS&D) reviews, which are handled by NRC Headquarters. The various regulated products and uses range from large quantities of radioactive materials in complex devices or in the manufacture of radiopharmaceuticals to small quantities in radioactive tracer studies or in simple devices. The NRC is evaluating the level of control and regulation needed to oversee its diverse Nuclear Materials Program. Many of the applications pose similar risks and could be regulated by other Federal and State agencies. Specifically, the NRC has been considering whether to continue to regulate or to revise its oversight of the medical uses of nuclear byproduct materials. To obtain input on the medical regulation issue, the NRC contracted with the National Academy of Sciences (NAS), Institute of Medicine (IOM), to perform an external review and to assess the adequacy and appropriateness of the current regulatory framework. The IOM final report, "Radiation in Medicine: A Need for Regulatory Reform," provides recommendations to give regulatory authority over medical uses to the States, with a Federal agency other than the NRC providing leadership and guidance[1]. A decision on the Medical Use Program may effect a rethinking of the NRC's fundamental philosophy on the extent to which it should regulate other nuclear materials. This issue paper provides options associated with the Direction-Setting Issue (DSI) of what should be the future role and scope of the NRC's Nuclear Materials Program, and in particular, NRC's regulation of the medical use of nuclear material. The options include expanding, retaining and revising, retaining in part, or eliminating the Nuclear Byproduct Materials Program with particular emphasis on medical use.

B. Options

Option 1: Increase Regulatory Responsibility With Addition of X-Ray, Accelerators, and Naturally Occurring and Accelerator-Produced Radioactive Materials

This option would transfer the regulatory responsibility for non-Atomic Energy Act of 1954, as amended (AEA), sources of ionizing radiation, such as x-ray, linear accelerators, and naturally occurring and accelerator-produced

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[1] See Attachment, "Regulation of Radiation in Medicine - IOM Issues"

radioactive materials (NARM), from other Federal agencies and the States to the NRC. An Agreement States Program would continue. Legislation would be required to implement this option.

Option 2: Continue Ongoing Program (With Improvements)

This option would maintain the current regulatory responsibility of the NRC and the States, while making continual improvements to increase efficiency and revising regulations to be more risk-informed and performance-based rather than prescriptive. Some of these improvements are currently ongoing (business process reengineering [BPR]) or are on temporary hold (revision of Part 35 of Title 10 of the Code of Federal Regulations [10 CFR Part 35]). Legislation would not be required.

Option 3: Decrease Oversight of Low-Risk Activities With Continued Emphasis of High-Risk Activities

This option would decrease regulatory responsibility for all materials that pose a low risk to the workers and the public. Examples of these materials include diagnostic nuclear medicine, gas chromatographs, some portable gauges, and so on. The NRC would retain oversight of SS&D reviews, manufacturers and distributors, and high-risk applications, such as medical therapy, radiography, and large irradiators. Specific regulations and guidance in the high-risk area would be revised to make them more risk-informed and performance-based.

Option 4: Discontinue Regulation of All Medical Activities Except NRC Oversight of Devices and Manufacturers (National Academy of Sciences Recommendation)

In this option, the regulatory authority over all medical uses of byproduct material would be given to the States, with a Federal agency (not NRC) in a guidance leadership role. The NRC would retain authority for SS&D reviews, manufacturers and distributors, and all nonmedical applications. Findings under Section 81 of the AEA for exemption or legislation would be required to discontinue NRC responsibilities over medical uses. Legislation would be required to give authority to the States and to name a lead Federal agency.

Option 5: Discontinue Materials Program

In this option, the regulatory authority for byproduct material applications would be given to another Federal agency or the States, with the assumption that an acceptable level of safety would be maintained. The NRC would have no remaining authority for any byproduct materials oversight. Legislation would be required.

II. DESCRIPTION OF ISSUES

A. Background/Bases

The key considerations in reexamining the role and scope of NRC's Byproduct Materials Program, and specifically its regulation of the medical use of byproduct material, are NRC's responsibilities as defined by the AEA to protect public health and safety, the common defense, and the environment. Although the Byproduct Materials Program must be performed in response to the AEA, the AEA also provides NRC with broad authority regarding the standards and processes that it applies in implementing this responsibility. This issue paper addresses the extent or scope of a Byproduct Materials Oversight Program necessary to ensure adequate protection in the use of byproduct materials.

Section 81 of the AEA directs the NRC to regulate the manufacture, production, transfer, receipt in interstate commerce, acquisition, ownership, possession, import, and export of byproduct material. Among other things, Section 81 authorizes the NRC "to issue general or specific licenses to applicants seeking to use byproduct material." Byproduct material is defined in Section 11e(1) of the AEA as nuclear materials created or made radioactive by exposure to the radiation during the fissioning process in a reactor. As provided under the AEA, the NRC also regulates Federal licensees in all States. The NRC has only limited responsibility, however, for regulating uses of nuclear material by the Department of Energy or the Department of Defense.

The nuclear materials licensees can be categorized into several major groups covering various products and uses regulated by the NRC and the Agreement States, under either a specific license or a general license.[2]

1. Specific Licensed Nuclear Materials

These groups include (1) broad-scope materials licenses; (2) manufacturers and distributors; (3) hospitals, clinics, nuclear pharmacies, and private physicians; (4) limited research and development operations; (5) measuring systems; (6) irradiators; (7) industrial radiography; (8) well logging; and (9) other material licenses. All of these licensees are regulated under applicable provisions in 10 CFR Parts 19, 20, and 30 for byproduct materials. In addition, individual sections of Title 10 provide specific requirements for some activities, such as medical, radiography, and irradiators.

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[2] In addition, the Commission has exempted certain nuclear material uses, activities, and products from regulation. The most widely exempted products are residential smoke detectors that contain small quantities of americium-241.

Presented below are descriptions of the major groups of nuclear materials licensees regulated by NRC and the Agreement States that require a specific license.

a. Broad-Scope Materials Licenses

The broad-scope licensees include universities, medical schools, large medical centers, large manufacturers, and research and development facilities that cannot operate under a more limited specific license without seriously disrupting their programs. These licensees use nuclear materials for a wide variety of activities, including research and development, laboratory testing, and medical diagnosis and therapy. Broad-scope licenses authorize the use of any byproduct material by anyone in accordance with review and approval procedures and criteria established by the radiation safety committee. Under the broad-scope license, the NRC places significant reliance on the organization's radiation safety committee and radiation safety officer to ensure that NRC's regulations are met. At present, the NRC regulates about 300 broad-scope licensees.

b. Manufacturers and Distributors

Manufacturers and distributors of nuclear materials include those that fabricate SS&Ds (e.g., brachytherapy sources, portable gauges, radiography cameras), as well as those that make radiopharmaceuticals. The manufacturers usually use unsealed nuclear materials that must be controlled to a greater extent than sealed materials. Currently, NRC licenses 129 manufacturers and distributors under 10 CFR Part 32. Twenty of these manufacturers also have received broad-scope licenses from the NRC.

c. Hospitals, Medical Clinics, Nuclear Pharmacies, and Private Physicians

The Medical Use Program represents approximately one-third of NRC's nuclear materials licensees and includes uses of byproduct material in medical diagnosis, therapy, and research. Currently, there are approximately 2,000 NRC licenses authorizing the medical use of byproduct material under 10 CFR Part 35.

d. Limited Research and Development Operations

Research and development licenses are issued for possession and use of specifically designated radionuclides in academic institutions, industrial facilities, and medical institutions for nonmedical use. The NRC regulates approximately 500 limited research and development licensees under applicable sections of 10 CFR Parts 20 and 30.

e. Measuring Systems

Measuring system licenses are issued for the possession and use of measuring devices and are regulated under applicable sections of 10 CFR Parts 20, 30, and 70. Measuring systems include fixed gauges for measuring or controlling parameters, such as material density, flow, thickness, or weight; portable gauges, such as moisture-density gauges used at fixed locations; x-ray fluorescence analyzers; gas chromatographs; and others. The NRC regulates approximately 2,200 measuring system licensees.

f. Irradiators

Irradiator licensees use radiation for purposes such as sterilizing blood products, disposable medical supplies, and food and polymerizing compounds in wood finishes. Irradiators are also used for some research applications. Approximately 40 irradiator licensees are authorized, pursuant to 10 CFR Part 36, to possess radioactive material in excess of 10,000 curies each for use in irradiation activities. Several commercial NRC-licensed irradiator licensees use more than 6 million curies to process materials in their facilities. The NRC regulates 204 irradiator licensees.

g. Industrial Radiography

In industrial radiography, radiographers use sealed radiation sources to make x-ray-like pictures of metal objects such as pipes and valves. Radiography is a form of nondestructive testing that uses radiation from sealed sources (principally iridium-192 and cobalt-60) to examine the internal structure of objects. The portable radiography devices may contain radioactive sources with as much as 200 curies of iridium-192 or 100 curies of cobalt-60. The NRC has issued about 160 industrial radiography licenses pursuant to 10 CFR Part 34.

h. Well Logging

In well logging, sealed nuclear sources, unsealed radioactive trace material, and radioactive markers are used for subsurface surveying to obtain geological information. The testing procedures are primarily used in oil, gas, and mineral exploration to identify subsurface geologic formations. NRC licenses about 60 firms for well logging under the provisions of 10 CFR Part 39.

i. Other Material Licenses

The other types of materials uses that require a specific license include such diverse activities as nuclear laundries, which clean protective clothing contaminated with radioactive material; leak test and other service companies that provide services to other licensees to leak test sealed sources or

devices containing sealed sources, to analyze leak test samples, to calibrate radiation survey or monitoring equipment, or to repair devices containing sealed sources; waste disposal services; and others. The NRC has about 900 licensees performing these remaining diverse activities.

2. General Licensed Devices

Although specific licensees must submit a license application to the NRC and receive a written specific license, this is not the case for most general licensees. An NRC general license becomes effective on the basis of the general license provisions in NRC's regulations. In most cases, a general license is effective without the filing of an application with the Commission or the issuance of a licensing document to the license holder. An example would be the acceptance of a nuclear materials product at the point of sale, which would make the buyer a general licensee.

General license provisions authorize a variety of activities, such as holding title to licensed material, as well as use of licensed material contained in a device. The generally licensed devices must meet regulatory standards for design and manufacture so that they may be used by persons with minimal instruction in their proper use. (As previously discussed, manufacturers and distributors of devices intended for use under a general license must be specifically licensed for this purpose.)

Examples of these devices include static eliminators, nuclear gauges, and self-luminous signs. An NRC database indicates that there are approximately 35,000 general licensees that use about 600,000 regulated devices.

3. Exempt Distribution Licenses

In addition to specific and general license products and uses, the Commission has exempted certain nuclear material products, quantities, or concentrations from the requirements for a license and from the regulations. These exemptions have been made with prior findings that such exemptions will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public. Exemptions have been authorized for products such as gemstones, watches with tritium paint, and smoke detectors, once there has been an initial transfer or distribution of the product.

4. Sealed Source and Device Reviews

The NRC further exercises its statutory responsibilities by the certification or registration of SS&Ds. SS&D manufacturers submit specific information on manufacturing techniques, prototype test results, and other data related to engineering and radiation safety to the NRC or the appropriate Agreement State. These data are evaluated and an SS&D certificate is issued after a

determination is made that the product is safe for the proposed uses. The NRC maintains a registry of SS&Ds approved by the NRC and the Agreement States. Applicants for specific licenses can reference these approved products in their applications.

B. External Factors

Notwithstanding the aforementioned oversight process, the operational history and knowledge base inherent in the current nuclear materials industry allows opportunities for streamlining NRC's Regulatory Program. The nuclear materials industry, with an operational history exceeding 40 years, has a firm foundation in the knowledge and understanding of the properties of nuclear materials and the applicable handling and radiation safety procedures, as well as the metallurgical and engineering requirements for fabricating SS&Ds. However, even with such an operational history, some factors, such as technological advances and aging equipment, may affect streamlining considerations.

1. Technological Advances

The nuclear materials industry has been and will continue to be affected by technological advances in other fields. For example, advanced computer technology has been combined with the use of sealed sources for new products and devices. This has been the case especially in radiation medicine with the advent of the gamma knife (used for brain radiosurgery) and remote afterloading brachytherapy devices. Technological enhancements are not limited to radiation medicine. As the SS&Ds are affected by more sophisticated nonnuclear technology, the regulations, review process, and qualifications of NRC technical staff required to review these applications may change. In the case of the gamma knife, for example, there are no specific medical use requirements in 10 CFR Part 35, although the regulations do address procedures for conventional cobalt-60 teletherapy devices.

2. Aging Equipment

Additionally, with a mature industry, some licensed nuclear material devices are becoming old and/or obsolete. One result may be increased mechanical and metallurgical problems. Aging devices may warrant special consideration when and if the NRC undertakes to streamline its Regulatory Program, especially in the areas of routine inspections and guidance to licensees.

3. External Interest

Unlike the organized opposition to nuclear reactors or nuclear waste disposal, the public (in most cases) has been supportive (at times, by remaining silent) on the use of nuclear materials in medicine, industry, and commerce. There

have been times, however, when the public has expressed concern about new uses of nuclear radiation (e.g., opposition to irradiation of fresh foods). For the most part, the external interests in the Materials Program have involved a few concerned citizens, licensees and their associations and professional societies, and the news media. The print media have published in-depth articles on issues such as radiation medicine misadministrations that have resulted in deaths; radioactively contaminated sites whose licenses have been terminated; and reconcentrated radioactive sewage sludges found at sewer treatment facilities. Additionally, Congress has shown and continues to show interest in the Nuclear Materials Programs of both NRC and the Agreement States.

An example of this external interest is found in the medical use of byproduct materials. During the past several years, the medical community, regulated by NRC and Agreement States, has been very vocal on specific requirements of Part 35. In general, this medical community, including physicians, physicists, pharmacists, hospitals, professional associations, and others, regards the detailed prescriptive requirements of Part 35 as unnecessarily burdensome. A specific target has been the regulation on "Quality Management Program and Misadministrations" (the QM rule), which became effective on January 27, 1992. The medical community has asserted that the requirements are an intrusion into medical practice, are cost-ineffective, and have no utility. The QM rule was strongly opposed by several professional societies, which made their views known to the Office of Management and Budget (OMB). In June 1992, OMB disapproved the record collection requirements of the QM rule on the basis that the NRC had not demonstrated that the rule would yield significant benefits. The NRC Commissioners overrode the OMB determination, citing the necessity of the information collection requirements for public health and safety. In addition, the American College of Nuclear Physicians and the Society of Nuclear Medicine took the NRC to court to overturn the QM rule. The court ruled in favor of the NRC. Shortly after, in November 1992, a patient in Indiana, Pennsylvania, died as a result of a therapy misadministration. A month later, the Cleveland Plain Dealer ran a week-long series entitled "Lethal Doses: Radiation That Kills." These events resulted in congressional hearings on NRC's Medical Radiation Program and its Agreement States Program that raised questions about the adequacy of control of the medical use of byproduct material by the NRC and the Agreement States. As a result of the two opposing, strongly held views of the regulated medical community, and Congress and the media, the Commission directed the staff to reevaluate the Medical Use Program with the assistance and advice of the NAS. To that end, the staff contracted with the Institute of Medicine of the NAS to perform the external review mentioned earlier in this issue paper. The report of that review, "Radiation in Medicine: A Need for Regulatory Reform," is discussed in the Attachment to this paper, "Regulation of Radiation in Medicine - IOM Issues"

4. Full Cost Recovery

Another significant external factor is the Omnibus Budget Reconciliation Act of 1990, which requires that the NRC recover almost 100 percent of its budget authority. The number of NRC licensees has declined since about 1990 due primarily to the requirement for full fee recovery. This declining trend will continue, with the number of licensees decreasing by about one third if States that are currently negotiating agreements (Massachusetts, Pennsylvania, Ohio, and Oklahoma) become Agreement States and additional States continue to pursue this status, The reduced number of NRC licensees will further compound the full-fee-recovery cost issue, even though the BPR efforts will likely reduce licensing fees for some categories of NRC licensees. Also, State interest in becoming an Agreement State may be reduced by NRC changes in funding for Agreement State training and technical assistance.

C. Internal Factor

In addition to the described external factors, an ongoing internal initiative could affect any decision on the role and scope of the Nuclear Materials Program.

Business Process Reengineering

In 1994, the staff began a major reevaluation of the regulatory process in NRC's oversight of licensed materials. This reevaluation is being carried out as part of a BPR effort. Phase I was completed in the spring of 1995. This phase was directed toward proposing a fundamentally new approach to materials licensing designed to (1) perform at least an order of magnitude faster than the current system; (2) be supported by clear, consistent, and timely regulatory guidance; and (3) ensure that no adverse effect on public health and safety results from its implementation. The new process will use modern information technology to streamline operations. The new approach focuses on including performance requirements in NRC's regulations, discontinuing the current practice of incorporating licensee practices and procedures in license conditions, and considering changes to the duration of materials licenses. As part of these efforts, a rulemaking has been promulgated to extend qualified materials licenses for an additional 5 years.

It is envisioned that the BPR will have a significant impact on the entire Nuclear Materials Program during the next several years. The number of licensing actions should significantly decrease, as should the amount of required review time. Inspections for certain materials licensees will be streamlined or eliminated. Overall, as a result of the reengineering efforts, the NRC's Materials Program should be significantly more efficient and responsive to both the public and licensees. During the past several years, the NRC's Materials Program has remained at about the same level in the use of

staff and resources. However, in fiscal year 1997 the program will begin to decrease in both staff and technical assistance contractual support. This decrease is due, partially, to the increased efficiencies in licensing and inspection anticipated from BPR, and partially from additional Agreement States.

III. DISCUSSIONS

A. Discussion of Direction-Setting Issue

The key considerations in reexamining the role and scope of NRC's Byproduct Materials Program, and specifically its regulation of the medical use of byproduct material, are NRC's responsibilities as defined by the AEA to protect public health and safety, the common defense, and the environment. Although the Byproduct Materials Program must be performed in response to the AEA, the AEA also provides NRC with broad authority regarding the standards and processes that it applies in implementing this responsibility.

Also to be considered is the interpretation that the Commission has adopted and implemented that medical patients are included in the "public."

The options on the role and scope of the Nuclear Materials Program are the result of management and staff review and subsequent initiatives such as the Medical Management Plan, BPR, and planned revisions to 10 CFR Parts 34 and 35. Other factors influencing the development of options included resource limitations, growth in the number of Agreement States, a desire for increased efficiency and effectiveness, and the recommendations of the IOM.

Although the primary focus of the Byproduct Materials Program is on protecting public health and safety, it must also ensure that the extent of control is tempered by the risk to the public. The focus should be on the safety-significant issues and on providing timely and consistent guidance and licensing that will allow licensees to meet the regulations and standards in the most efficient and economic way. In turn, these considerations need to be viewed in terms of a broader, changing environment. For example, it is anticipated that the number of Agreement States will increase over the next 5 years, significantly reducing the number of NRC licensees. The NRC will need to consider what steps to take to account for the anticipated reduction in resources. Although the BPR process is a step in the right direction, additional steps need to be initiated. The NRC may also have to consider changes in how it regulates areas of low public risk. This issue paper addresses the extent or scope of a Byproduct Materials Oversight Program necessary to ensure adequate protection in the use of byproduct materials.

B. Discussion of Subsumed Issue

As a part of selecting an option on the future role and scope of the NRC's Byproduct Materials Program, the following strategic issues should be considered and resolved as a result of this issue paper.

Issue: What should be the role of NRC in regulating the medical use of nuclear material?

Under the AEA, NRC has responsibility for two categories of radiation medicine use. Regulation of these two broad categories represents approximately one-third of NRC's Nuclear Materials Program. One category of radiation medicine is nuclear medicine, which employs radioactive drugs (radiopharmaceuticals). These drugs usually contain only very small quantities of radioactive material, which is used primarily for the diagnosis and followup of disease. Nuclear medicine occasionally includes the use of larger quantities of unsealed radioactive material for therapy, especially for diseases of the thyroid gland. The other category of radiation medicine is radiation therapy (radiation oncology). In radiation therapy, larger quantities of radioactive material, usually in the form of sealed sources, are used primarily in cancer treatment. Sealed quantities of radioactive material are used both external to and within a patient. Sealed radiation sources regulated under the AEA are used in about 25 percent of radiotherapy treatments. Radiation produced by electronic devices not regulated under the AEA, such as x-ray equipment and linear accelerators, is used in the other 75 percent of treatments. Therapeutic radiation devices, such as a gamma knife, may contain more than 6,000 curies, while diagnostic nuclear medicine procedures may be limited to microcurie or millicurie quantities.

By authority of the AEA and Commission policy, the NRC regulates the medical use of nuclear materials as necessary to provide for the radiation safety of workers and the general public. NRC also regulates the radiation safety of patients when justified by the risk to patients, but minimizes the agency's intrusion into medical judgments affecting patients and into other areas traditionally considered to be the practice of medicine. The NRC recognizes that physicians have primary responsibility for the protection of their patients. NRC regulations assume that authorized physician users, with appropriate training and experience, will make decisions in the best interest of their patients.

Over the years, the Commission has made a concerted effort to improve and strengthen the Medical Use Program. Following a 1976 report of hundreds of patient overexposures at Riverside Methodist Hospital in Columbus, Ohio, NRC took action to upgrade its regulation of radiation sources in medical use. Also, in February 1979, NRC issued a policy statement to guide its Regulatory Program in the medical area. A fundamental tenet in the policy statement is

the commitment to protect patient safety without intrusion into the practice of medicine. However, there has been frequent tension with the regulated medical community on a number of medical use regulatory initiatives that have been opposed by members of the regulated community as an intrusion into the practice of medicine. This tension and opposition to NRC's regulation of the medical uses of byproduct material have been a continuing problem.

Additional problems arise from the jurisdictional responsibilities for the different sources of radiation. Jurisdiction over various aspects of the regulation and use of ionizing radiation in medicine is exercised by both the Federal Government, primarily through the Department of Health and Human Services, the Food and Drug Administration (FDA) and the NRC, and the States. Within this regulatory framework, the NRC has jurisdiction over the medical use of byproduct and special nuclear material and regulates radiation safety associated with the actual use of these products. The FDA regulates the manufacture and distribution of radiopharmaceuticals, biologics, and medical devices for safety and efficacy. For the most part, FDA does not regulate at the user level. The States have broad regulatory authority over the general public health and safety of their residents. This includes authority over the use of all sources of ionizing radiation, except AEA material, which is regulated by the NRC. The States control most of radiation medicine, but the degree to which they exercise control varies from State to State.

In 1992, the staff began to develop a Medical Management Plan to guide the conduct of the Medical Use Regulatory Program. Although delayed as a result of staff actions in response to a radiation therapy misadministration and the associated patient fatality, media interest, and congressional hearings, the plan was subsequently completed and initiated. In parallel, the staff was directed by the Commission to initiate an external review of the Medical Use Regulatory Program.

As a result, NRC contracted with the NAS in 1994 for the IOM to conduct that external review, addressing not only the role of the NRC but also the roles of the FDA and the States in this area. The IOM has completed its review and recommended that regulatory authority over medical uses of byproduct material be given to the States. The IOM also recommended that only licensed users have access to byproduct material and identifies the Department of Health and Human Services (DHHS) as the agency that should exercise a leadership role in the radiation safety community. Further, the report suggests that DHHS assist in developing recommended State laws and regulations, act as an information clearinghouse, and distribute resources for training and research.

The NRC has reviewed the IOM recommendations at length and has held several public meetings on them. As of August, 1996, the NRC had received 41 comments on the subject. Although some commentors supported the recommendations, the CRCPD expressed concern about the elimination of the entire medical use

program and the absence of Federal authority in the medical use area. DHHS stated that it could not support the recommendation that it provide the leadership role suggested by IOM. A more extensive summary of the recommendations and comments appears in the Attachment to this paper, "Regulation of Radiation in Medicine - IOM Issues"

IV. OPTIONS

In this section, the five options described earlier are detailed, including, if applicable, required regulatory or legislative changes, impacts, resource implications, and the reaction of stakeholders.

Option 1: Increase Regulatory Responsibility With Addition of X-ray, Accelerators, and Naturally Occurring and Accelerator-Produced Radioactive Materials

Option

Under this option, the NRC would continue with its ongoing program and improvements and seek legislation for regulatory oversight of other sources of ionizing radiation, including x-ray, accelerators, and discrete NARM. Discrete sources of NARM include radium sources used in medicine and industry and the wastes resulting from cyclotrons and linear accelerators. They do not include wastes from the mining and processing of radium or other radionuclides. An Agreement States Program would continue. This option would significantly increase NRC's jurisdiction in the control of ionizing radiation; it would result in responsibility being taken away from other Federal agencies and the States. Variations of this option could include consideration of limiting oversight to specific applications, such as industrial and commercial uses, or to only those applications that pose a high risk (Option 3).

Regulatory Changes

Legislation would be needed to remove the responsibility for the regulation of these sources of radiation from other Federal agencies and the States and to transfer it to NRC. Coupled with this action would be new and revised policy statements, such as the 1979 Medical Policy Statement, memoranda of understanding with other Federal agencies, and agreements with the Agreement States. Rulemaking to expand and modify existing regulations and generation or revision of the companion guidance documents for the NRC staff and licensees would be necessary.

Impacts

This option would ensure increased uniformity and consistency in the regulation of all sources and uses of ionizing radiation. It would avoid substantive differences in regulations and oversight between AEA and non-AEA sources of radiation. Also, it could eliminate regulatory advantage of one radiation modality over another for a given application (e.g., x-ray radiography versus gamma radiography). This option would require an expansion of NRC's technological base to include specialists in x-ray and accelerator equipment, and the medical and commercial uses of this equipment. It would result in a significant increase in the number of NRC licensees (which would multiply 5 to 10 times), especially in the medical area. This increase would require additional personnel and physical resources, including the possibility of additional regional offices. Such wide-sweeping legislation may be difficult to support in the absence of a compelling safety problem.

The resources required to develop the necessary legislation would include resources from the other Federal agencies currently providing some radiation protection or source and device oversight (e.g., FDA, the Environmental Protection Agency [EPA]), as well as NRC. A comprehensive program that would implement such legislation, that is to regulate all discrete NARM, including promulgation of regulations, guidance development, and inspection at frequencies comparable to those of similar NRC licensees, could require several hundred full-time equivalent (FTE) positions.

The Advisory Committee on Medical Uses of Isotopes (ACMUI) would need to be expanded to include other areas of expertise such as diagnostic and interventional radiology.

Reaction of Stakeholders

As described in more detail in Option 4, the Agreement States that now have authority for non-AEA sources support the approach for a single Federal agency to be responsible for all radiation use.

Option 2: Continue Ongoing Program (With Improvements)

Option

Under this option, the current regulatory responsibility of NRC and the States would be maintained. However, there would be continual improvements to increase efficiency and revision of regulations to make them more risk-informed and performance-based rather than prescriptive. Some of these improvements are ongoing or are on temporary hold (e.g., BPR and Part 35 revisions).

The ongoing BPR of the licensing process will result in the use of modern information technology to streamline operations. The envisioned new licensing process is composed of three major concepts: (1) a Regulatory Product Design Center in which technical members of the materials licensing and inspection community can interact face to face or by way of the computer, to design and prepare the regulatory products necessary to support, maintain, and enhance the new licensing process; (2) improved processing of licenses through reviewer-performed and computer-assisted licensing, using a graded approach commensurate with the safety hazards the application poses; and (3) a new way of working in agency-wide teams. The agency-wide team concept, based on BPR philosophy, will include such attributes as collaborative team-based decisions and parallel concurrences.

In addition, NRC is identifying regulations that are obsolete, unnecessarily burdensome, too prescriptive, or that overlap or duplicate the regulations of other agencies. As part of this effort, NRC is reviewing Part 35 to evaluate whether it can be revised to reflect a more risk-informed, performance-based regulation. To this end, the staff has requested input from the ACMUI and the Agreement States on what revisions should be made to Part 35 if NRC were to retain its current statutory authority and also if NRC were to ramp down in the regulation of patient safety. Examples of staff-identified and staff-suggested requirements needing revision or possible rescission include the As Low As it Reasonably Achievable (ALARA) Program, the Quality Management Program, the misadministration definitions and reporting, dose calibrator checks, surveys, calibration of devices (using industry standards where possible), and training and experience requirements. Other sections of the regulations pertaining to materials are also being reviewed for appropriate revisions.

Regulatory Changes

No legislative changes are needed to implement this option. However, rulemaking would have to be initiated to revise the byproduct materials regulations, such as Part 35. In addition, internal guidance documents (e.g., inspection procedures, standard review plans, etc.) as well as several regulatory guides, including Regulatory Guide 10.8, would have to be revised to reflect the proposed changes.

Impacts

This option would result in the development of more risk-informed, performance-based regulations and increased agency efficiencies obtained by implementation of BPR initiatives.

Amending the regulations and modifying guidance documents and associated regulatory guides has already been budgeted as part of the Medical Management Plan. No additional resources would be necessary for the medical use area. Also, an overall reduction in needed materials resources is anticipated over the next 5 years. This reduction is predominantly due to the increased efficiencies anticipated with the implementation of planned BPR initiatives, as well as anticipation that there will be an increase in the number of Agreement States within the next 5 years. This possibility could result in a reduction of approximately 20 FTEs by the year 2000.

Reaction of Stakeholders

Based on IOM interviews and comments on the IOM report, many medical licensees would continue to support NRC's divesting itself of responsibilities in the medical area.

Option 3: Decrease Oversight of Low-Risk Activities With Continued Emphasis of High Risk-Activities

Option

This option places priority on the tenet that the regulation of byproduct materials should be consistent with the risk involved. Although the NRC has effectively regulated areas of high risk (e.g., manufacturers, large irradiators, etc.), it may be overregulating areas that involve low-risk activities or sources. Low-risk activities could include the use of devices such as gas chromatographs and certain gauges, and diagnostic nuclear medicine. The oversight of these low-risk activities may be an unnecessary expenditure of resources because of the limited additional protection it provides.

Under this option, the NRC would modify its existing regulatory responsibility of low-risk activities and maintain its current responsibility (with some program modifications) for high-risk activities. This could be accomplished through policy decisions on decreasing or discontinuing oversight in certain areas, rulemaking, or an agreed-upon definition of low risk established and coordinated with other Federal agencies, the States, and the conduct of a public comment process. This option would encompass the overall Materials Program and would affect medical as well as nonmedical programs. The low-risk applications could be placed in a category of licenses (such as general licenses) that warrants minimal regulatory oversight with no formalized inspection frequency and minimal licensing requirements. However, some audit activity might have to be established to periodically assess the general licensee's byproduct material possession and performance.

Once low risk has been defined, this option would necessitate reevaluation of those licensees currently licensed by the general license provisions, as well as those activities previously determined to be exempt from regulation. A reassessment of these licensing categories may result in moving activities and uses from one category to another.

In this option, the NRC would probably maintain its current level of regulatory oversight for the manufacturers of radiopharmaceuticals and sealed sources because these activities would most likely be considered higher risk activities.. The NRC would also maintain its current level of regulatory oversight for other high-risk applications, such as therapeutic uses of byproduct material, large irradiators, and industrial radiography. For the high-risk applications, the existing specific regulations would be revised to be more risk-informed and performance-based, or consideration may be given to limiting oversight to Part 20 compliance only.

Regulatory Changes

The transfer of some of the current specific licenses to general licenses or to some other category that warrants minimal regulatory oversight would not require legislative changes. The transfer of low-risk activities to general licenses would require modifications to current general license regulations in Part 31, as well as modifications to current licensing regulatory guides, internal standard review plans, and inspection procedures.

Impacts

This option would result in increased efficiency and effectiveness within the agency by focusing NRC's limited resources on higher risk activities and those licensees that warrant enhanced oversight because of poor performance. This option might result in the elimination of approximately 50 percent of the NRC's current specific licensee base. For the remaining high-risk licensees, the NRC would revise the applicable regulations and guidance documents using a risk-informed, performance-based approach.

It is anticipated that a few FTEs over about a year would be required to complete an analysis and recategorize licensees. If NRC completely discontinues its oversight of the low-risk activities, associated legislative efforts may also require several FTEs over several years.

With NRC either completely discontinuing its regulatory oversight of lower risk activities or reducing its oversight, the current specific licensee base could be decreased by about half. Allowing for some resources to track and audit general licensees, a reduction of approximately 50 FTEs from current licensing, inspection, and other materials activities might be realized. This reduction includes those FTEs eliminated by the BPR.

Option 4: Discontinue Regulation of all Medical Activities Except NRC Oversight of Devices and Manufacturers (National Academy of Sciences Institute of Medicine Recommendation)

Option

Under this option, the NRC would request that Congress (1) discontinue NRC's regulatory authority over all medical uses of byproduct material (including biomedical research), (2) give this regulatory authority to the States, and (3) name another Federal agency (not NRC) to a guidance leadership role. The IOM report has recommended that this Federal agency be the DHHS. The leadership role would be nonregulatory and would assist in developing recommended State laws and regulations, act as an information clearinghouse, and distribute resources for training and research. In this option, the NRC would retain responsibility for oversight of the manufacture and distribution of byproduct material (including SS&Ds) used in medicine. Further, NRC would condition these licenses to require that products could only be distributed to users who were licensed by a State. Also, the Conference of Radiation Control Program Directors (CRCPD) would continue to develop its model regulations for adoption by the States. The CRCPD would be expected to continually reevaluate its regulations to maintain congruence with any scientific advances in knowledge on radiation bioeffects, and benefits and risks of the medical uses of ionizing radiation. The NRC's ongoing program for nonmedical licensees would remain as in Option 2.

Regulatory Changes

Legislation would be needed to remove responsibility for the regulation of the medical uses of byproduct material from the AEA. In lieu of legislation, if NRC made the requisite findings under Section 81 of the AEA, the NRC could by "exemption" eliminate this aspect of the Materials Program. Rulemaking to rescind or modify regulations in Parts 30, 33, and 35, among others, would follow. This route would require public notice and comment rulemaking. Coupled with these actions would be a revision or rescission (in whole or in part) of the 1979 Medical Policy Statement, the enforcement policy, agreements with the 29 Agreement States, and the memorandum of understanding with the FDA, as well as NRC regulatory guides, manuals, and directives.

Impacts

This option would result in the elimination of approximately one-third of the NRC's current specific licensee base. The States would be responsible for all radiation medicine applications, which would result in the potential for increased uniformity of the regulation of all radiation medicine within a given State. However, the level of oversight may vary considerably from State to State because currently some States provide oversight (licensing and

inspection) through State radiologic health personnel, and others by a simple registration process. Additionally, inconsistencies could develop between regulation of basic radiation safety in medical and nonmedical applications. Finally, DHHS does not support the IOM's recommendation that DHHS be given a leadership role.

Some of the non-Agreement States may lack the resources, including qualified personnel, to set up their own safety programs and decide not to regulate in this area and both the Agreement States and the non-Agreement States may view the action as an unfunded mandate. Also, revision of the agreements with each of the 29 Agreement States would be necessary. Additionally, the event database would no longer include misadministrations or events involving overexposures to workers or members of the public (non-patients) as a result of the medical use of byproduct material. Federal facilities would be responsible for self-regulation of the medical uses of byproduct material. Proposed legislation would need to address State regulation of Federal authorities or facilities.

For those facilities conducting both biomedical and nonmedical research, there would continue to be a dual system of regulation.

Resources associated with efforts for legislation and rulemaking would entail a few FTEs for a period of about 5 years.

The Medical Use Program includes approximately 50 FTEs, which would be eliminated. The majority of these FTEs, approximately 70 percent, come from the regional materials licensing, inspection, and event evaluation activities. Also, the number of medical consultants under contract to NRC could be reduced from approximately 12 (current) to less than half that number. These consultants are used on an as-needed basis in response to medical misadministrations resulting in an overexposure, as well as nonmedical events that might require the services of a physician or a scientist consultant to assess radioactive dose estimates and possible consequences. Currently, the majority of provided services is in response to medical misadministrations.

Reaction of Stakeholders

As of the end of August 1996, the staff had received 50 written comments on the IOM report. The two major categories of responses are either in support of, or opposition to, the overall recommendations of the IOM committee. However, within each of these major categories, there are subsets with respect to the specific direction or focus of the comments. None of the comments received specifically indicated that there should be no Federal involvement.

The Secretary of the Department of Health and Human Services (DHHS), the Federal agency that would be most directly affected by the IOM recommendations, indicated that the report does not make a compelling public health agreement for DHHS to assure the recommended new role. Furthermore, DHHS raised a concern that Congress would not provide resources commensurate with the added responsibilities.

The majority of comments received (32 out of 47) did not endorse the full range of recommendations put forth by the IOM committee. Four of the 15 respondents that supported the recommendations indicated that the recommendations should encompass all uses of byproduct materials. The Department of Veterans Affairs, in its support of the IOM report, indicated that legislative initiatives should ensure that Federal facilities are not subject to State and local regulations.

The comments that did not support all the IOM recommendations varied dramatically in the focus of their viewpoints and opinions. The degree of regulatory reform perceived to be necessary ranged from simply recognizing the merits of the issues raised by the IOM committee to a need for a complete restructuring of the regulatory program. The non-Agreement States that responded were particularly concerned about the substantial financial impact of the recommendations and the issue of this being, in effect, an unfunded Federal mandate. For example, as indicated in the response from Hawaii, public health and safety could be jeopardized in those States with insufficient resources or capability to adequately implement the regulation of byproduct materials. The Department of Defense response, which summarized the responses from the three Service Medical Departments (Army, Navy, and Air Force), supported the need to re-evaluate the current regulatory structure, but emphasized the need for a uniform regulatory authority. There were several responses that recommended the need for Federal oversight for all uses of radiation.

The Organization of Agreement States response provided a summary of the consensus of the participants of the NRC and Agreement State technical workshop conducted March 5-6, 1996, which included that all radiation use (medical and non-medical uses) should be consolidated under one Federal agency. The CRCPD prepared a position paper, which supported the leadership role of a single federal agency for all forms of ionizing radiation, at their May 6 meeting. The comments of these organizations are summarized in Appendix 3 to the Attachment to this Issue Paper.

Option 5: Discontinue Materials Program

Option

Under this option, the NRC would request that Congress discontinue NRC's regulatory authority over all byproduct material uses, give this regulatory authority to the States, and name a Federal agency (not NRC) to a guidance role for all sources of radiation, as discussed in Option 4. This option presumes that an acceptable level of safety would be maintained by the States. The NRC would have no remaining authority for any byproduct materials oversight. This option is an extension of the previous option to all materials uses.

Also, there would be no change in the proper disposal of byproduct materials at low-level waste disposal sites.

Regulatory Changes

This might be viewed as subject to the procedures of the Unfunded Mandate legislation. Legislation would be needed to remove responsibility for the regulation of all uses of byproduct material from the AEA. Rulemaking would be needed to rescind the regulations in 10 CFR Parts 30 through 39, and certain policy statements and memoranda of understanding would have to be rescinded or drastically revised. Also, all agreements with the 29 Agreement States would have to be rescinded.

Impacts

In addition to the impacts described in Option 4, this option would result in elimination of NRC's oversight of all specific and general byproduct materials licenses, thereby dramatically decreasing the resources of the Office of Nuclear Material Safety and Safeguards (NMSS) and the Office of State Programs. The States would be responsible for all medical, academic, and commercial applications of byproduct materials.

The lead Federal agency could possibly serve as a safety backup if a State requested assistance. The lead Federal agency role could be filled by an existing Federal agency such as the EPA, DHHS, or the Occupational Safety and Health Administration, with legislation modifying its authorities and responsibilities. Alternatively, a new agency or office within an existing agency could be created, thereby consolidating activities currently vested among several agencies. Greater uniformity might be achieved by consolidating a guidance role in one federal agency. However, because each State would be responsible for implementing its regulatory program as it deems appropriate, there could potentially be quite diverse programs among the 50 States.

Resources associated with efforts for legislation and rulemaking would entail several FTEs over a period of 5 to 7 years.

The number of budgeted FTEs for the Byproduct Materials Program is approximately 140 FTEs in Headquarters and the regions. These FTEs include all managers and technical, administrative, and support staff. Nearly all of these FTEs could be eliminated or redirected, in part, to other activities, recognizing that a few FTEs would be needed to handle residual activities. In addition, staff from other NRC offices who support the NMSS Byproduct Materials Program could be reduced by the current number of FTEs that handle byproduct materials issues or provide support to this NMSS Program.

Reaction of Stakeholders

Reaction from the regulated community could depend on whether consensus develops among the States to follow the guidance established by the federal agency. Manufacturers of some sources and devices could be particularly concerned about the possibility of having to comply with a multiplicity of State requirements.

The Agreement States might support this option to the extent they find it consistent with their consensus view described in Option 4.

Federal agencies would self-regulate. Some indicated in their comments on the IOM report that they did not have the resources necessary to develop and implement an oversight program, as indicated in the Department of Defense's comments on that report.

V. RELATED ISSUES

After the Commission has made decisions concerning the Direction-Setting and Subsumed Issues discussed above, additional issue(s) such as those related to implementation details will be addressed as the Strategic Plan is implemented. The Related Issues are listed in this section to provide a more complete understanding of the higher level Direction-Setting and Subsumed Issues.

A. Is escalated enforcement effective in preventing future violations by materials licensees? Would it be more effective to augment the inspection process than to impose civil penalties?

This is a Commission issue because it involves the Commission's reconsideration of its policy on its Enforcement Program for materials licensees and may lead to rulemaking. It is related to the DSI because NRC's enforcement policy for materials must reflect the philosophy established by the DSI. It is a related issue rather than a subsumed issue because it will

reflect the extent to which the materials licensee community follows NRC's enforcement activities and will be addressed in more detail than is appropriate for the DSI.

B. What should be the NRC's policy relative to the need for and the frequency of renewals for materials licensees?

This is a Commission issue because a change to the current frequency of renewals will involve policy and perhaps rulemaking. This issue is related to the DSI because the DSI will establish how important materials license renewals will be in the future. It is a related issue rather than a subsumed issue because different classes of materials licensees may require different renewal policies. Such differentiation will lead to more detail than is appropriate for the DSI. The staff is actively engaged in addressing this issue.

C. What should be NRC's policy relative to frequency of renewals for fuel fabrication facility licenses?

This is a Commission issue because a change in the current frequency of renewing fuel fabrication facility licenses will involve policy and perhaps rulemaking. The issue is related to the DSI because the philosophy for renewing fuel fabrication facility licenses should be consistent with the philosophy for renewing materials licenses to be developed here. It is a related issue rather than a subsumed issue because it will reflect such aspects of fuel fabrication facility regulation as criticality concerns, which are beyond the scope of this DSI.

D. Does NRC have an acceptable program, given that history and operating experience have required revocation of very few licenses? Is there a set of licensees that NRC should be regulating differently?

Rather than revoke licenses or reject applications, NRC generally helps bring weak licensees and applicants up to acceptable standards. Such activities are often very staff-intensive and include multiple deficiency letters, pre-licensing meetings, and site visits; confirmatory action letters; increased inspection frequencies; enforcement conferences; and imposition and monitoring of "Get Well Programs." Although such activities generally bring weak licensees up to acceptable standards, this may not be the most cost-effective use of NRC's limited materials resources.

This issue, originally a subsumed issue, goes beyond the question of whether NRC should regulate a certain materials area and concentrates on the "how" or the methodology of regulation. As such, this issue will be directed by the decisions made on the Byproduct Materials Program and will require an in-depth

evaluation that is beyond the scope of the current issue paper. For these reasons, and depending on decisions by the Commission, this subsumed issue will be addressed as a related issue.

E. Should a single Federal agency regulate radiation safety?

This issue is directly linked to the Agreement States' comments on the IOM recommendations in which the Agreement States technical staffs said that "All radiation use (medical and nonmedical uses) should be consolidated under one Federal agency to include NARM, AEA material, and machine-produced radiation. Consensus was not reached as to which Federal agency should have the authority, or whether it should be an existing agency."[3]

It appears most appropriate to consider the issue of single agency jurisdiction from several perspectives. As stated above, a single agency could be responsible for radiation regardless of source, to include AEA material, NARM, and machine-produced radiation. Alternatively, a single agency could hold all authorities, to include such authorities as standard-setting (now vested in EPA), approval of medical devices and radiopharmaceuticals (now in DHHS),and applications (now in NRC).

This is a Commission issue because it involves policy concerns that are fundamental to NRC's mission, that in fact go beyond NRC's regulation of materials to include its regulation of nuclear reactors as well. It is clearly a related, rather than a subsumed, issue, because it is well beyond the scope of this DSI.

V. COMMISSION'S PRELIMINARY VIEWS

Staff actions regarding the various options should be held in abeyance pending the Commission's final decision on this issue paper.

The Commission preliminarily favors a combination of Option 2 (Continue the Ongoing Program with Improvements) and Option 3 (Decrease Oversight of Low-Risk Activities with Continued Emphasis of High-Risk Activities). In implementing Option 3, the NRC would utilize the risk-informed performance based approach, as discussed in DSI 12, to determine which activities in the materials area, and specifically in the medical area, are low-risk activities. The general approach described in Option 3 of this DSI appears to be a reasonable starting point for identifying the types of activities that can be affected by this process.

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[3] Report of Joint NRC/Agreement State technical workshop, March 5-6, 1966

In implementing these options with regard to the NRC's medical program, the NRC would consult with its Advisory Committee on the Medical Uses of Radioisotopes (ACMUI) for guidance on low-risk medical activities, revisions to 10 CFR 35, and possible implementation methods. The NRC would also evaluate the feasibility of using professional medical organizations and societies as a potential source for developing professional standards and guidance that would be adhered to by NRC medical licensees and could be adopted by the NRC as regulatory requirements.

In the public comments on this issue, the NRC particularly solicits the views of other affected organizations such as the Organization of Agreement States and the CRCPD on applying a risk-informed performance based approach to NRC's oversight of medical activities. The NRC also solicits the public's views on the feasibility and desirability of NRC's striving to have the remaining non-Agreement States acquire Agreement State authority for medical-use only. In addition, the Commission solicits the public's views on whether a single agency should regulate radiation safety. Finally, the NRC specifically seeks comments on the Attachment to this issue paper titled "Regulation of Radiation in Medicine - IOM Issues."

ACRONYMS

ACMUI	Advisory Committee on Medical Uses of Isotopes
AEA	Atomic Energy Act
ALARA	As Low as is Reasonably Achievable
BPR	Business Process Redesign
CFR	Code of Federal Regulations
CRCPD	Conference of Radiation Control Program Directors
DHHS	Department of Health and Human Services
DSI	Direction-Setting Issue
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FTE	Full-Time Equivalent
IOM	Institute of Medicine
NARM	Naturally Occurring and Accelerator-Produced Radioactive Materials
NAS	National Academy of Sciences
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	Nuclear Regulatory Commission
OMB	Office of Management and Budget
QM RULE	Quality Management Program and Misadministrations
SS&D	Sealed Source and Device

REGULATION OF RADIATION IN MEDICINE - IOM ISSUES[1]

I INTRODUCTION

Under the Atomic Energy Act (AEA), the Nuclear Regulatory Commission (NRC) regulates the medical use of reactor - generated radioactive materials to provide for the radiation safety of workers and the general public. It also regulates the radiation safety of patients when justified by the risk. NRC's responsibilities include the regulation of radiopharmaceuticals and sealed sources, but not machine-produced x-rays nor naturally occurring or accelerator produced radioisotopes.

Over the years, NRC has had a concerted effort to improve and strengthen its Medical Use Program. In these efforts, it has repeatedly addressed two difficult issues; how can it best protect patient safety without intruding into the practice of medicine; and how can it best deal with the numerous jurisdictional responsibilities for different sources of radiation? To obtain external advice on these and other issues, in 1994 the NRC contracted with the Institute of Medicine (IOM) of the National Academy of Sciences (NAS) to review NRC's Medical Use Program and to address the roles of the regulatory agencies in this area. In December, 1995, the IOM provided NRC with a prepublication copy of its report, "Radiation in Medicine - A Need for Regulatory Reform." The final report was issued in March 1996.

The report documents the committee's consideration of seven alternative regulatory systems, ranging from no regulation (laissez-faire) to Federal control of all aspects of medical care. Between these extremes, the committee considered a variety of Federal and State regulatory systems. The committee concluded that the Federal government should relinquish regulation of radiation in medicine to the States, with the Department of Health and Human Services (DHHS) providing support, coordination, and guidance to them. To bring about this change, the committee made eight recommendations; two to Congress, three to the NRC, and three to the Conference of Radiation Control Program Directors and the States.

This document provides an overview of the committee's report, including issues identified by the NRC staff about each of the recommendations, and a summary of the public comments received to date.

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[1] Some of the text in this paper closely parallels text in the Institute of Medicine report which is the subject of this paper.

The second section of this report, "Background," briefly discusses the use of radiation in medicine, the regulatory authorities of the Federal and State agencies, NRC's particular responsibilities, regulations, and activities, and a summary of the history of the NRC program which led the agency to seek a review of its Medical Use Program.

The third section of this report summarizes the IOM committee's view of the present situation, and describes the seven alternative regulatory systems considered by the committee. It describes each alternative and presents the committee's views of the positive and negative aspects of that alternative. It concludes with the committee's basis for selecting its preferred alternative, State Regulation with Federal Guidance.

The fourth section of this report addresses the committee's recommendations associated with the preferred alternative. It contains a brief description of each recommendation, a summary of the committee's rationale for the recommendation, the NRC staff's principal issues, and some pertinent public comments.

The fifth section documents NRC actions on the report to date and provides a general summary of the 47 comments received so far. Lists of specific commentors and brief summaries of their comments appear in appendices.

II BACKGROUND

This section contains a brief description of the ways ionizing radiation is used in medicine, followed by a discussion of the Federal and State regulatory authorities over that radiation. It then summarizes NRC's medical use program including its applicable regulations, its licensee community, and its activities. It then sketches the history of NRC's efforts to improve the program, including the events and issues that led NRC to seek a review by the NAS. Finally, the section documents NRC's goals for the study and the recommendations NRC requested from NAS.

Ionizing radiation is used for both diagnosis and treatment. Diagnostic uses are classified under two basic headings; radiology and nuclear medicine. In radiology, (such as the use of x-rays) the radiation administered is external to the patient; in nuclear medicine, it is internal. Nuclear medicine employs radioactive drugs (radiopharmaceuticals). When used for diagnosis or followup, these drugs usually contain only very small quantities of radioactive material.

Ionizing radiation used for treatment is also typically classified into categories depending on whether the source of radiation is external or internal to the patient. These areas are called teletherapy (external

sources), brachytherapy (internal) and therapeutic nuclear medicine (internal). Brachytherapy and teletherapy use sealed sources; therapeutic nuclear medicine uses radiopharmaceuticals. In radiation therapy, larger quantities of radioactive material, usually in the form of sealed sources, are used primarily in cancer treatment. Sealed radiation sources regulated under the AEA are used in about 25 percent of radiotherapy treatments. Radiation produced by devices not regulated under the AEA, such as linear accelerators, is used in the other 75 percent of therapy.

Regulatory authority over ionizing radiation in medicine is widely dispersed among several government agencies at the Federal, State, and local levels. At the Federal level, by authority of the Atomic Energy Act (AEA) and Commission policy, the NRC regulates the medical use of byproduct material[2] to provide for the radiation safety of workers and the general public. NRC also regulates the radiation safety of patients when justified by the risk to patients. NRC's regulatory authority is limited to byproduct material (such as cobalt^{60} or iodine^{131}), so it does not regulate naturally occurring or accelerator produced materials (NARM), or accelerator produced radiation. For example, NRC does not regulate the use of radium or x-ray equipment in medicine.

The Food and Drug Administration (FDA) in the Department of Health and Human Services (DHHS) oversees the approval of radiation-producing devices (including x-ray equipment) and radiopharmaceuticals (including NARM). In addition to these approvals, FDA's regulatory program includes review of problem reports, enforcement actions including product removal and recall, and civil prosecution of manufacturers. The Department of Transportation (DOT) regulates the transportation of radionuclides. The Environmental Protection Agency (EPA) sets generally applicable environmental standards to protect the public from radiation, and the Occupational Health and Safety Administration (OSHA) is responsible for worker safety.

States have broad regulatory authority over the general public health and safety of their residents, including authority over all sources of ionizing radiation except the authority preempted by the Federal Government as discussed above[3]. The AEA does permit States to obtain authority to regulate byproduct material by becoming one of NRC's Agreement States. In that case,

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[2] Byproduct material is defined as nuclear material created or made radioactive by exposure to radiation during the fissioning process in a reactor.

[3] Although Federal pre-emption applies to source and special nuclear material as well as byproduct material, regulation of those materials is beyond the scope of this document

the NRC formally relinquishes its regulatory authority to a State based on the NRC's determination that the State's program is adequate and compatible with NRC's. (As provided under the AEA, the NRC retains regulatory authority over Federal licensees in all States.) Presently there are 29 Agreement States.

The degree to which States exercise control over all medical uses of radiation varies from State to State. The Agreement States normally apply the standards which they have developed for NRC materials to other sources of radiation within their State, although there is no requirement that they do so. Likewise, there is no requirement for non-Agreement States to regulate the sources of radiation for which they are responsible. This situation has led to inconsistencies in the regulation of other sources of radiation in those States.

NRC's (and its Agreement States') regulation of radiation in medicine is based principally on two parts of the Code of Federal Regulations(CFR); 10 CFR Part 20, Standards for Protection Against Radiation, and 10 CFR Part 35, Medical Use of Byproduct Material. These regulations limit the amount of radiation that a worker or member of the public may receive, establish the controls that a licensee must exercise over radioactive materials, establish training and experience requirements for users of the materials, set quality management and reporting requirements, and provide a number of technical and administrative requirements for the possession and use of the materials.

NRC's medical program constitutes about one-third of its Nuclear Materials Program. Currently there are about 2,000 NRC licensees authorized for the medical use of byproduct material under 10 CFR Part 35. In addition, the 29 Agreement States have issued about 4,500 licenses authorizing the medical use of nuclear material. These medical-use licensees include hospitals, clinics, and physicians in private practice.

NRC's regulatory program consists of developing regulations and guidance issuing new licenses, and ensuring compliance. NRC promulgates new regulations and modifies existing ones through staff-initiatives or in response to petitions. NRC provides guidance to its staff and licensees by issuing regulatory guides for licensing and procedures for inspection. NRC's medical licensing activities include issuing about 85 new licenses a year, and approving about 1,400 amendments. NRC ensures compliance with its regulations by communicating safety issues to licensees, inspecting them to observe their performance, and exercising its enforcement authority over licensees who are in violation.

Over the years, and especially since the mid 1980s, the Commission has made a concerted effort to improve and strengthen the medical use program. In 1967 the Atomic Energy Commission codified its medical regulations into 10 CFR Part

35. Following a 1976 report of hundreds of patient overexposures at Riverside Methodist Hospital in Columbus, Ohio, NRC took action to upgrade its regulation of radiation sources in medical use. In February 1979, NRC issued a policy statement to guide its regulatory program in the medical area. A key issue in the policy statement is NRC's commitment to protect patient safety without intrusion into the practice of medicine. NRC regulates the radiation safety of patients when justified by the risk to patients, but minimizes the agency's intrusion into medical judgments affecting patients and into other areas traditionally considered to be the practice of medicine. The NRC recognizes that physicians have primary responsibility for the protection of their patients. NRC regulations assume that authorized physician users, with appropriate training and experience, will make decisions in the best interest of their patients. Since then, the tension inherent in NRC's commitment has arisen in a number of key medical-use regulatory initiatives that have been opposed by members of the regulated community as an intrusion into the practice of medicine. The doctor/patient relationship and NRC's regulation of medical use of nuclear material has been a continuing problem, up to the present.

A second set of problems arises from the jurisdictional responsibilities for the different sources of radiation. As discussed above, jurisdiction over various aspects of the use of ionizing radiation in medicine is exercised by a number of agencies in the Federal Government and by the States. Because of the diversity of, and occasionally overlapping, responsibilities, dual regulation or gaps in regulation may occur.

In 1992, the staff began to develop a medical management plan to guide the conduct of the medical use regulatory program. The plan was delayed as a result of staff actions in response to a radiation therapy misadministration and the associated patient fatality, media interest, and congressional hearings on administrations in both the Senate and the House. The staff subsequently completed the medical management plan, and, in parallel, was directed by the Commission to initiate an external review of the NRC's and the Agreement States' medical use regulatory program.

As a result, in January 1994, NRC contracted with the IOM to conduct that external review, including a review of NRC's regulations, policies, practices, and procedures. NRC set three goals for the study; 1) examination of the overall risk associated with the use of ionizing radiation in medicine; 2) examination of the broad policy issues that underlie the regulation of the medical uses of radioisotopes; and 3) a critical assessment of the current framework for the regulation of the medical use of byproduct material. The NRC sought specific recommendations on two major issues. First, it requested recommendations on a uniform national approach to the regulation of ionizing radiation in all medical applications, including consideration of how the regulatory authority and responsibility for medical devices sold in interstate

commerce for application to human beings should be allocated among Federal Government agencies and between the Federal and State governments. Second, the NRC requested recommendations on appropriate criteria, to measure the effectiveness of regulatory programs needed to protect public health and safety.

III IOM REPORT - ALTERNATIVES

This section presents IOM alternatives and recommendations. It begins with the IOM broad view of the regulation of radiation in medicine to provide insight into the basis for IOM decisions on the regulatory alternatives it considered and the recommendations it made.

1) IOM committee's View of the Current Situation

The IOM committee noted that NRC regulates only 10% of all ionizing radiation found in medicine, and that public health and safety would be better served by uniform regulation of all such use. It therefore concluded that NRC's current system of regulation and enforcement should be revised and that regulation of all radiation uses in medicine should be conducted by the States.

The committee examined the existing regulatory system and identified several problems that it concluded needed to be addressed. In particular, it judged the NRC's present set of regulations and its approach to regulation to be burdensome, costly, and unduly prescriptive. In addition, it found that actions taken by the NRC against user institutions, in its public announcements and its unrealistic paperwork demands, tended to be disproportionate to the violations.

The committee determined that the benefits resulting from the NRC's efforts to reduce adverse events may not be commensurate with the constraints imposed. It stated that the NRC's regulatory policy, although seemingly effective, might have gone beyond the point where "an additional dollar spent on regulation achieves an equivalent dollar benefit to patients or the public."

The committee judged that, given the strength and leadership of the Conference of Radiation Control Program Directors (CRCPD) and the *Suggested State Regulations for the Control of Radiation (SSRCR)* which the CRCPD promulgates, that State programs would remain intact and expand to cover byproduct use if Federal regulation were to be relaxed. The committee believed that all sources of ionizing radiation would be treated more uniformly, in that they would *all* be subject to State regulation.

The committee's recommendation would eliminate NRC's medical use program, but retain the basic structure of federal regulation and responsibility. In particular, the committee would have Federal agencies retain responsibility for the generation, transport, non-medical use, and disposal of radionuclides and for the approval of radiopharmaceuticals and of equipment that generates ionizing radiation. A Federal agency would assume a guidance role for the States.

2) Alternative Regulatory Systems

The committee considered NRC's request for recommendations on a uniform national approach to regulation broadly. It examined a wide spectrum of alternative structures through which all ionizing radiation in medicine might be regulated. The committee report discusses seven alternatives, which are

A Continue the Existing Situation
B Laissez-Faire (No Regulation)
C State Regulation Only
D State Regulation with Federal Guidance
E State Regulation with Reserve Federal Authority
F Centralized Federal Regulation
G Health Finance Agency

After considering the alternatives, the committee found Alternative D, State Regulation with Federal Guidance, to be its preferred choice. Brief descriptions of the seven alternatives, and the basis for the committee's choice follow.

A Continue the Existing Situation

The committee considered two ways to continue the existing situation, which it describes as A1, Status Quo, and A2, Status Quo Modified. Alternative A1, Status Quo, would be for the NRC to continue to operate exactly as it does today. Alternative A2, Status Quo Modified, would have the NRC eliminate, or announce that it will not enforce, its requirements for quality management programs (10 CFR Part 35.32) and for notifications and records of misadministrations (10 CFR Part 35.33). The committee's considered this modification because NRC has received considerable criticism from the medical community for promulgating these requirements.

The committee found no positive aspects to the Status Quo. It found a positive aspect of the Modified Status Quo in that this Alternative would not require legislative change and thus would be the easiest way to change the existing system to address the medical community's concern. Further, in the committee's view, the NRC could make useful changes to its work culture. The committee found the negative aspects of the Status Quo to be that this

alternative did not address two of the committee's concerns; first, that ionizing radiation in medicine is not treated consistently - sources used regularly in the practice of medicine are treated unevenly. The committee raised the issue of whether NRC regulation is necessary, given that NARM and machine-produced regulation has been left to the States and the FDA. Second, this alternative does not address the committee's concern that safety can be maintained at lower cost.

B Laissez-Faire (No Regulation)

In this Alternative, all forms of regulation, Federal and State, would be eliminated and responsibilities for radiation safety would be left to medical practice, medical societies, and the marketplace.

The committee found that a positive aspect of Laissez-Faire would be the cost savings resulting from an absence of regulation. The committee found negative aspects of this Alternative to be that not everybody is conscientious about radiation protection, and the committee had little expectation that the marketplace, the malpractice system, and the professional societies could, by themselves, weed out incompetent practitioners and ineffective procedures. Further the committee noted that most States now regulate ionizing radiation to some degree and it seemed unlikely that they could all be convinced to follow this alternative. This approach would be unwieldy, as the existing federal regulatory structure for radiation control of non-medical applications would continue unchanged.

C State Regulation Only

This Alternative would eliminate NRC control of medical uses of byproduct material and would give regulatory authority to the States. Under this alternative, byproduct materials would be regulated the same way x-ray machines, linear accelerators, pharmaceuticals and other medical devices and materials are currently regulated. Under this alternative, Federal agencies would still have a number of responsibilities; FDA would continue to regulate safety and efficacy of radiopharmaceuticals and radiation devices, DOT would continue to regulate the transportation of byproduct material, and NRC would license the manufacture of byproduct material. The committee noted that this alternative would permit States to choose the laissez-faire approach. However, the committee expected that under this Alternative, the CRCPD would encourage States to adopt its Suggested State Regulations for Control of Radiation (SSRCR).

The committee found the positive aspect of this Alternative to be the assumption that all States with existing programs would continue and expand them based on the SSRCR and thus reinforce the movement toward greater uniformity. The committee found negative aspects to be that it had no

assurance that States want this responsibility, that not all States currently have strong regulatory programs in place for NARM and machine-produced radiation, and that some State legislatures might be responsive to strong antiregulatory interest groups. The committee also felt that the lack of Federal leadership under this Alternative would make it difficult to encourage States to adopt CRCPD guidelines and that States might abandon the radiation safety programs now in place without the incentive from a Federal agency to continue operating them.

D State Regulation with Federal Guidance

This Alternative modifies Alternative C by identifying a Federal Agency, other than the NRC, to exercise a leadership role in the radiation safety community, with DHHS as a suggested agency. This is the committee's preferred Alternative.

As the committee has developed this Alternative, the Federal agency would assist in developing recommended State laws and regulations for all ionizing radiation in medicine. It could work with CRCPD to enhance the existing SSRCR and promote their adoption. The committee felt that development of guidelines through a collaborative process with the Federal agency, the States, the CRCPD, and professional organizations would result in successful implementation by all participants. Additional functions of the Federal Agency could include assisting States, investigating crises, educating the public, collecting risk data, conducting research, and monitoring the effects of shifting responsibility for regulating radiation in medicine to the States.

Under this Alternative, States would have to establish a regulatory program that includes byproduct material. Since, under this Alternative, the NRC and Agreement States would continue to regulate the manufacture of byproduct material, manufacturers would not be able to distribute byproduct material to their users unless the users were licensed by their States. Consequently this requirement would provide an inducement to States to expand or revise their existing radiation control programs to include byproduct material. Federal facilities would be encouraged to either expand their existing procedures for NARM to include byproducts or adopt the SSRCR for byproduct material.

The committee found several positive aspects of this Alternative. It includes the advantages of Alternative C, State Regulation Only, with the additional advantage of a Federal agency to provide non-regulatory oversight and leadership. The committee would expect the Federal agency to assume a leadership role for the Federal government as a whole. In addition, this Alternative would ensure that a State would be required to have a regulatory program for byproduct material for that material to be used in the State. The

committee found negative aspects of this Alternative to be the costs of the Federal agency, and that the agency could not guarantee either the quality of any State program or the safety of ionizing radiation in,medicine.

E State Regulation with Reserve Federal Authority

This Alternative would go beyond Alternative D, State Regulation with Federal Guidance, and empower the Federal agency identified in that Alternative to exercise regulatory authority over any State unwilling or unable to enact a regulatory, structure that encompasses ionizing radiation in medicine.

This Alternative would be identical to Alternative D, with the exception that if a State did not have a radiation control program it would become subject to the regulations for byproduct material devised for Federal medical centers. The Federal agency would enforce its authority only if the State did not assume any responsibility to adequately protect public health and safety. This authority would be analogous to the NRC's present authority to resume regulatory control over an Agreement State.

The committee found this alternative to have all of the positive aspects of Alternatives C and D, with the advantage that placing DHHS in the leadership role would, in the committee's view, yield more reasonable regulations if they are needed. The committee found negative aspects to be the need to set minimum standards for State programs and the need to assess those programs. This would have the effect that all States would become similar to NRC's present Agreement States. The committee was also concerned about funding, and Federal authority over what it expected to be a minority of States.

F Centralized Federal Regulation

This Alternative would make a Federal agency responsible for regulating medical uses, not only of byproduct material, but of NARM and machine-produced radiation as well. The Alternative would federalize regulation of all ionizing radiation in medicine, including standard-setting, licensing, and inspection. If this Alternative were to be adopted, the committee would recommend centralization within DHHS rather than NRC because the committee considered it best suited to administer public health programs and because it already has various levels of authority over ionizing radiation in medicine. If NRC were to be the lead federal agency, its legislative authority would need to be expanded beyond byproduct materials.

The committee found positive aspects of this alternative to include promotion of uniformity in regulation of radiation in medicine, provision for States who do not want responsibility for radiation control programs, and the development of national standards. The committee noted that the positive aspects of the Federal role described in Alternative D, State Regulation with Federal

Guidance, also apply to this Alternative. The committee found negative aspects to include the increased Federal costs of such a role, and the difficulty in achieving uniformity due to the regulatory involvement of a number of Federal agencies (DOT, EPA, OSHA) in addition to the committee's proposed DHHS. Finally, the committee noted that since NRC would continue to be responsible for the non-medical uses of byproduct material, it would be necessary for NRC and DHHS to work very closely together to avoid inconsistencies.

G Health Finance Agency

This Alternative would place regulatory authority for all health care into a single, centralized agency to counter inconsistency and inefficiency. The new agency would acquire the regulatory power now held by the medical components of the NRC and by parts of DHHS. The agency would have the power to regulate health care, broadly eliminating practices that were shown not to be effective or beneficial. The committee considered this Alternative an extreme approach for addressing a very specific issue and recognized that it had not been developed to its full logical extent. The committee considered an advantage to this approach is that it could improve minimal standards and define the goals of safety and high quality care. However, such a centralized system would mean a large increase in bureaucracy and reduce provider incentives and responsibility.

3) Assessment of Alternatives

The committee documented its consideration of the above alternatives by examining the extremes and moving toward its preferred alternative. It rejected Alternative A, Continue the Existing Situation, because it did not address the committee's concern that all ionizing radiation in medicine be administered and regulated more consistently. It rejected Alternative B, Laissez-Faire, because many committee members were not convinced that the marketplace, the malpractice system, and the professional societies could, by themselves, weed out incompetent practitioners and ineffective procedures. The committee rejected Alternative G, Health Finance Agency, because it was an all-encompassing and overwhelming solution to a very specific problem. The committee rejected Alternative F, Centralized Federal Regulation, because from a cost-benefit perspective the committee as a whole saw little reason to pursue this alternative. Thus the committee focussed on Alternatives C, State Regulation Only, D, State Regulation with Federal Guidance, and E, State Regulation with Reserve Federal Authority.

While the committee found Alternative C, State Regulation Only, attractive, it was concerned that State regulation evolve with technical advances, that Non-Agreement States be assisted in any transition from NRC regulation, and that information sharing be enhanced, so it rejected this alternative. The

committee found that Alternative E, State Regulation with Reserve Federal Authority, could result in a program very much like NRC's present Agreement State program which would not resolve the committee's concerns about that program's funding characteristics and practical drawbacks. The committee therefore arrived at its preferred choice, Alternative D, State Regulation with Federal Guidance.

As discussed above, Alternative D would give regulatory authority over medical uses of byproduct material to the States. The States would expand their existing radiation control programs that apply to NARM to include byproduct material as well. The committee recommends that a Federal agency, DHHS, exercise a leadership role in the radiation safety community. The leadership role would be non-regulatory and would assist in developing recommended state laws and regulations, acting as an information clearinghouse, and distributing resources for training and research. The Federal agency would work in conjunction with the CRCPD and other professional organizations to develop recommended state laws and regulations for all ionizing radiation in medicine. The NRC would retain responsibility for the manufacture and distribution of byproduct material (including sealed sources and devices) used in medicine. Further, NRC would condition these licenses to require that products could only be distributed to users who were licensed by a State.

IV IOM REPORT - RECOMMENDATIONS

To implement its preferred alternative, the committee made a total of eight specific recommendations; two to Congress, three to the NRC, and three to the CRCPD and States. First, the committee recommended that Congress: 1) eliminate all aspects of the NRC's medical use program to include 10 CFR Part 35 and applicable activities conducted under 10 CFR Part 20; and 2) direct the Secretary of Health and Human Services to support, coordinate, and encourage activities involving regulation of all ionizing radiation in medicine including support the operation of the CRCPD, assist States in implementation of regulations, oversight of State programs, enhance training and standards for health care personnel, and investigate future significant radiation medicine incidents.

The recommendations to the NRC were to: 1) immediately relax enforcement of 10 CFR 35.32 and 35.33; 2) if Congress fails to act within 2 years to the committee's recommendations above, initiate formal steps under the Administrative Procedures Act to revoke 10 CFR Part 35 in its entirety; and 3) separate the costs of formulating regulations from costs of administering those regulations.

The recommendations to the CRCPD and the States were to: 1) incorporate into the SSRCR any relevant concepts from 10 CFR Part 35; 2) enact legislation to incorporate the regulation of reactor-generated byproducts into existing state

regulatory programs; and 3) continually reevaluate regulations and procedures to ensure congruence with evolving scientific understanding of radiation bioeffects and associated risks and benefits.

The committee did not reach total unanimity on the final recommendations. A committee member stated that federal regulatory authority should be reformed, not repealed. This dissenting opinion is included as a separate Appendix to the report.

The following sections discuss the recommendations individually. Each section contains a brief description of the recommendation, a summary of the committee's rationale for the recommendation, the NRC staff's principal concerns, and some pertinent public comments.[4]

A RECOMMENDATIONS TO CONGRESS

A1. *The committee recommends that Congress eliminate all aspects of the NRC's Medical Use Program, 10 CFR Part 35, and those regulatory activities conducted under 10 CFR Part 20 that are applicable to medical uses.*

DESCRIPTION

By this action, Congress would relinquish responsibility for regulation of byproduct material used in medicine to each state. NRC would retain regulatory authority over manufacturers of byproduct material used in medicine. Other federal agencies, such as the FDA, the DOT, and the EPA, would retain their regulatory authority over radiation.

IOM RATIONALE

The intensity with which the byproduct area of radiation medicine is being regulated at the federal level far exceeds the rest of ionizing radiation used in medicine and most of the rest of medical practice and has little if any justification. In fact, the concentration of resources spent to reduce adverse events involving byproduct material, although seemingly effective, appears to have gone beyond the point at which the additional dollar spent on regulation achieves an equivalent dollar benefit.

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[4] A list of commentors organized by commentor affiliation, a list of commentors by general view, and a summary of specific comments appear in Appendices 1, 2 and 3, respectively.

All ionizing radiation, with the exception of byproduct material, is currently regulated or subject to regulation at the State level. States have the ability to regulate radiation effectively. Although the committee cannot guarantee that states will effectively regulate byproduct material, it believes they will. Further, States with insufficient resources could join a consortium of states for the purposes of implementation and oversight.

Rescission of authority at the federal level for regulation of the medical use of byproduct material has three benefits: 1) it eliminates prescriptive and costly regulations that yield marginal risk reduction; 2) it shifts responsibility, by giving state governments authority over the health and safety of their citizens; and 3) it promotes uniform treatment, in that radionuclides and machine-produced radiation are regulated by a single level of government at equal intensity, regardless of their source.

NRC STAFF ISSUES

1. The committee recognizes that not all states currently have strong regulatory programs in place for NARM and machine-produced radiation. In fact, not all States currently regulate ionizing radiation used in medicine. What assurance does the committee, or Congress or the NRC, have that all States will assume the responsibility for medical use of byproduct material?

2. This recommendation assumes that federal facilities will expand the scope of their existing regulations to cover all ionizing radiation in medicine - what existing regulations currently apply to federal facilities (other than those of the NRC)?

3. How would the goal of "uniform treatment" and regulation by a single level of government at "equal intensity" be achieved through legislation and rulemaking giving responsibility to the States.

PUBLIC COMMENTS

NRC has received 47 comments on the committee's report. About one third of the commentors support this recommendation and the rest of the committee's recommendations as well. These commentors included the Department of Veteran's Affairs, several State agencies, four professional societies associated with the use of radiation in medicine and six individuals. Several of these commentors not only supported this recommendation, but believed that NRC should discontinue all of its regulation of byproduct materials, and give that responsibility to the States.

A second third of the commentors supported the concept of regulatory reform, but with retention of Federal authority. These commentors included three Federal agencies, three professional societies involved in radiation in medicine, 10 States and NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI). Nine of these commentors favored continued regulation by the NRC, eight were not specific on which Federal agency should have authority, and two, the State of California and the ACMUI would vest authority with DHHS.

Four commentors, including the State of New Jersey favored regulatory reform, but only after additional analysis.

Nine commentors supported the concept of uniform regulation for all radioactive materials, including NARM, with Federal oversight.

Several specific comments are of interest. The EPA felt that the report reflected the concerns of the regulated community more than those of the public at large. The Department of Defense indicated that the Federal regulatory authority over medical use of byproduct material should be reevaluated and perhaps relaxed and restructured, but not abolished. The States of Utah and Virginia were concerned that State legislatures might view this as an unfunded mandate and would need additional Federal support. The CRCPD does not support the recommendation. "CRCPD is concerned that elimination of the entire program, as recommended, could have immediate and undesirable consequences on citizens in non-Agreement States which cannot or will not have developed a state program consistent with the national model prior to Congressional action. In addition, the absence of federal authority in the medical use area may also have long term consequences for Agreement States as they try to maintain a nationally consistent program in the face of budget cutbacks and a changing regulatory philosophy."[5] Several non-Agreement States indicated that they had neither the resources nor the capability to develop a program to adequately protect public health and safety.

A2. *Congress direct the Secretary of Health and Human Services to support, coordinate, and encourage the following activities involving regulation of all ionizing radiation in medicine:*

a. supporting the operation of the CRCPD;
b. providing a venue for the review and evaluation of Suggested State Regulations for Control of Radiation;

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[5] CRCPD position on the NAS report, reached at their meeting in Albuquerque, New Mexico, on May 8, 1996

c. assisting states in implementation of their regulations;
d. aiding in assessment of the effectiveness of state programs through the collection and analysis of data;
e. helping develop survey methods by which the rate of adverse events for a wide range of procedures and devices might be measured;
f. monitoring the effects of deregulation;
g. enhancing training and standards for health care personnel; and
h. investigating future significant radiation medicine incidents.

DESCRIPTION

In addition to the above, DHHS would educate the public for the primary purpose of "... putting radiation risk in a more accurate and balanced perspective." Adverse events for investigational drugs and blood products must be reported to FDA as are adverse events involving radiation devices resulting in serious injury or death.

As noted in the previous recommendation, NRC and Agreement States would continue to regulate the manufacture of byproduct material for use in radiation devices and radiopharmaceuticals; thus manufacturers would not be able to distribute radioactive byproduct material to users unless they were licensed by their states.

IOM RATIONALE

A Federal agency, such as DHHS, would assist states to establish regulatory programs; train state radiation control personnel; build liaisons between smaller states that wish to share regulatory systems; develop survey methodology; and monitor the success of regulatory programs.

DHHS has an extensive history in regulating radiation in medicine. Within DHHS, FDA exercises direct authority to determine the safety and effectiveness, and to approve the marketing, labelling, and manufactur of all radiation products used in medicine. FDA has promulgated regulations establishing quality control standards and a certification program for medical facilities that provide mammography services. FDA has issued guidelines and recommendations regarding public exposure to ionizing and non-ionizing radiation.

The NRC should not regulate the education and training of health care personnel - it should be done by professional organizations and by the states.

NRC STAFF ISSUES

1. Would DHHS have any regulatory responsibility for Federal facilities other than the Public Health Service? If not, who would have authority over Federal facilities?

2. Current reporting requirements for FDA are not identical to those of NRC - they only require reporting adverse events resulting in serious bodily injury (to manufacturer) or death (to FDA). There are no reporting requirements for radiopharmaceuticals other than investigational drugs except on a voluntary basis. To what extent should administration errors be reported?

3. In view of the overall reduction in federal spending, whether DHHS would be provided any appropriations to carry out these additional responsibilities cannot be predicted. With the reduction in federal spending and with the knowledge that the NRC is supported by user fees rather than taxpayer dollars, would Congress appropriate sufficient funds for even the minimal expenses of this agency?

4. How would the effects of deregulation be monitored? The report states that the committee did not possess the requisite expertise to address the issue of appropriate criteria for measuring the effectiveness of regulatory programs.

PUBLIC COMMENTS

As mentioned above, about a third of the commentors support this recommendation along with all the committee's recommendations. A number of commentors support the role of a Federal agency described in this recommendation, but do not necessarily endorse DHHS. Many of these latter commentors believe that the Federal agency should have at least some authority and that it should be responsible for at least NARM as well as byproduct material. The CRCPD view is illustrative. CRCPD supports the concept of a single federal agency with a strong leadership role, and believes that consolidation of authority presently found in several agencies including NRC, DHHS, OSHA, and EPA is very desirable. However, CRCPD, in addition to several states, do not support the automatic selection of DHHS as the lead agency, but consider that radiation protection should be a major responsibility of the lead agency. The OAS[6] recommended a revision to recommendation A2 to include that a single federal agency should be directed (by Congress) to support, coordinate, and oversee specified activities involving regulation of all ionizing radiation in medicine. The OAS did not reach consensus on which agency should have the responsibility.

The agency most affected by this recommendation is DHHS, who does not support it. DHHS does not find the committee's arguments compelling and does not consider the legislation recommended by the committee likely. Further, in the

[6] The OAS comment provided the recommendations of and consensus reached at a NRC and Agreement State technical workshop conducted on March 6, 1996.

event of such legislation, DHHS considers the probability low that it would receive funding from Congress commensurate with its additional responsibilities.

B RECOMMENDATIONS TO THE NRC

B1. *The NRC should immediately relax enforcement of 10 CFR 35.32 and 35.33 through its present mechanisms.*

DESCRIPTION

NRC's 10 CFR Part 35.32, Quality Management Program, requires, among other things, that medical licensees have written procedures to ensure that direction for a therapeutic administration is made in writing, that the patient's identity is verified by more than one method, that unintended deviation from the written directive is evaluated, and that the licensees review this program at least once every 12 months.

NRC's 10 CFR Part 35.33, Notifications, Reports, and Records of Misadministrations, requires, in part, that medical licensees notify the NRC within one calendar day of the discovery of a misadministration, and that they submit a written report within 15 days, and that they retain a record of each misadministration for five years.

The information required by 10 CFR 35.33 would not be entirely abandoned. NRC could continue to cooperate with the FDA as provided in their MOU to obtain data on devices, drugs, and biological products that relate to device malfunction, serious injury, or death.

IOM RATIONALE

NRC's Quality Management (QM) rule lacks the basic elements of a QM program: comprehensive process and outcomes data, feedback mechanisms for health care providers, education of clinicians to achieve continuous improvement, and follow-up measurement to monitor change/improvement.

The regulation of byproduct material greatly exceeds the regulation of chemotherapy, surgery, anesthesia, and the use of general pharmaceuticals except for controlled substances, all of which are unregulated at the federal level.

A lower rate of adverse incidents in radiation medicine is not a result of stricter regulatory oversight. The more detailed reporting and enforcement systems required for byproduct materials do not seem to result in even a marginal decrease in risk to providers, patients, or members of the public.

The level at which the NRC currently enforces 10 CFR 35.32 and 35.33, through detailed and voluminous documentation, reporting, and penalties, is inconsistent with the NRC's Medical Policy Statement, which favors minimum regulatory intrusion into the practice of medicine.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has a performance standard which requires intensive assessment when performance varies from recognized standards, but does not specifically require reporting of medication errors except in accordance with written procedures of the hospital.

Elimination of the QM rule would not lessen the radiation protection of the public, occupational worker, or the patient.

The regulated community has expressed reservations about seeking advice from the NRC, fearing that they might become the target of punitive reprisals.

When the NRC levies a fine, the agency also issues a press release describing the violation and the fine. Licensees assert that adverse economic impact of such press releases is considerable.

NRC STAFF ISSUES

1. The lack of data for comparing byproduct material, NARM and machine-produce radiation limited the scientific basis of the committee's findings. How can we achieve improved data collection on actual incidence and rates of adverse incidents and misadministrations? Is there a need for improved databases?

2. What is the rationale or basis for the necessity for immediate action?

3. Assuming that NRC were to immediately relax enforcement, NRC would be in the position of having a regulation for which there would have been no monitoring or enforcement. If NRC were to follow this recommendation, what followup actions should NRC conduct in the event of a misadministration resulting in serious injury or death?

4. If NRC lacked statutory or regulatory authority governing the medical and biomedical research use of byproduct material, why should NRC continue to gather data on user errors, drugs, and biological products to share with FDA under the MOU (unless reimbursed by another Federal agency)?

PUBLIC COMMENTS

A number of commentors supported the concept that many of, NRC's requirements are overly prescriptive and burdensome. CRCPD supports relaxation of these requirements because it finds them overly prescriptive and unnecessarily burdensome. The Organization of Agreement States believes that NRC should immediately relax enforcement of these requirements, and further considers that the Quality Management Rule should not be an item of Agreement State compatibility.

B2. *The committee recommends that the NRC initiate formal steps under the Administrative Procedure Act to revoke Part 35 in its entirety, if Congress fails to act within two years in response to the two recommendations to Congress stated above.*

DESCRIPTION

NRC's 10 CFR Part 35, Medical Use of Byproduct Material, contains technical and administrative requirements that apply specifically to medical applications. It sets quality management and reporting requirements, and establishes training and experience criteria for users of byproduct material. It sets requirements including dose calibration, leak testing, source inventory, patient release, instructions to nurses, and survey requirements as well as use of syringe shields and storage of waste for decay.

IOM RATIONALE

In addition to NRC's overly stringent enforcement, the regulations themselves are excessive and duplicative. 10 CFR Part 35 covers areas that either are already regulated at the institutional level or are best left to the states, to professional societies, and to patients in consultation with their doctors.

States regulate the medical uses of other forms of ionizing radiation and, could easily fold byproduct material into their regulatory programs.

The CRCPD could add byproduct material to its suggested state regulations. These additions could incorporate relevant concepts currently in Part 35.

Doctors have ethical obligations, codified in professional standards, for informing patients of medical errors. The relatively low misadministration rate could be maintained by less stringent programs that are administered at the state level by professional societies, and by existing liability law.

The FDA collects data on adverse effects of radiopharmaceuticals and incidents of failure of radiation-emitting medical devices, and it could assume the monitoring responsibilities of the NRC.

Public safety in the medical use of ionizing radiation would yet exist in the fact that the NRC would still retain responsibility for the licensing of manufacturers and, consequently could ensure that byproduct material was withheld from any state that failed to license users and regulate the use and safety of byproduct material.

The committee strongly endorses the formal route of notice and comment rulemaking, subject to the Administrative Procedure Act, to accomplish the rescission of all of Part 35.

NRC STAFF ISSUES

1. This recommendation presupposes Congress will not act, and therefore will not vest DHHS with a leadership role. This could result in the laissez faire or state control regulatory structures, both of which were rejected by the committee. How would this recommendation achieve the goal of the preferred alternative?

2. With the lack of data cited in the report, on what scientific basis might NRC make a finding that there is no unreasonable risk to public health and safety, and thereby exempt medical use of byproduct material from the requirements of a license, as set forth in Section 81 of the Atomic Energy Act?

PUBLIC COMMENTS

Many commentors, to include professional organizations, State agencies, and individuals, were in favor of the need to revise Part 35. While CRCPD considers that a major revision to 10 CFR Part 35 is needed, it does not support this recommendation. OAS believes that 10 CFR Part 35 should be revised significantly, but that it should not be revoked in the absence of legislation. OAS believes that a minimum level of radiation protection must be available.

B3. *The committee recommends that the NRC separate the costs of formulating regulations from the cost of administering those regulations.*

DESCRIPTION

The Omnibus Budget Reconciliation Act of 1990 requires NRC to recover 100% of its budget by charging fees to NRC applicants and licensees. As a result, NRC licensees bear all of the agency's costs both of developing its regulations and of administering them. Separating these costs would enable NRC to recover development costs from its licensees differently than it recovers its administrative costs.

IOM RATIONALE

Only NRC-licensed institutions should bear the NRC's costs of licensing and inspection, whereas the costs of developing standards should be borne by all institutions, whether or not they are located in NRC-regulated states.

Licensing fees charged to health care facilities to meet the cost of the existing NRC program are becoming more expensive as more states become Agreement States.

Several individuals interviewed during site visits voiced concern that excessive costs force laboratories to stop using radionuclides, which in turn delays or prohibits the development and implementation of new uses of radionuclides in medicine.

NRC STAFF ISSUE

If NRC were to separate the costs of formulating regulations from the cost of administering these regulations, how would the Agreement State licensees bear the cost of developing standards?

PUBLIC COMMENTS

CRCPD supports this recommendation and recommends that Congress provide general funds to support development of essential regulatory standards. OAS identified the issue of how Agreement States would bear the costs of developing standards if NRC were to accept this recommendation.

C RECOMMENDATIONS TO THE CRCPD AND THE STATES

C1. *The committee recommends that the Conference of Radiation Control Program Directors incorporate into its Suggested State Regulations for Control of Radiation any relevant concepts from 10 CFR Part 35 that are not already integrated in those suggested regulations.*

IOM RATIONALE

All states will be able to provide regulatory oversight for AEA material in a manner similar to that provided for non-AEA material through the adoptions of CRCPD's Suggested State Regulations for the Control of Radiation. "[T]he committee expects that byproduct materials can be accommodated in the state systems."

Although State laws, regulations, and administrative practices vary, States can and do achieve a level of uniformity in many areas through cooperative, voluntary, and informal arrangements.

Although States cannot be compelled to accept the voluntary guidelines or the SSRCR, a variety of forces can greatly influence them to do so such as a collaborative effort, professional peer pressure, consumer groups and the media, and State medical societies.

CRCPD will continue to provide SSRCRs of the current level of quality without the assistance of the NRC, but with another federal agency providing "voluntary guidelines and model regulations for states"

NRC would continue to fund the CRCPD's efforts with respect to all nonmedical uses of byproduct material.

NRC STAFF ISSUES

1 Will the states voluntarily adopt the CRCPD's SSRCR in the absence of any real compelling mandate placed on either CRCPD or the states? For example, in the case of the recently passed mammography law, Congress provided a compelling reason for hospitals and clinics to meet the quality standards: i.e., in order to be reimbursed for mammography services, the hospital or clinic must be certified as meeting the standards.

2 The level to which the states currently adopt the SSRCR varies from state to state. Would there be greater uniformity under the proposed recommendation?

PUBLIC COMMENTS

CRCPD considers that it already has accomplished this.

C2. *The committee recommends that all state legislatures enact enabling legislation to incorporate the regulation of reactor-generated byproducts into existing state regulatory programs.*

IOM RATIONALE

States have effectively regulated naturally-occurring and NARM in the past and continue to do so. Therefore all States can regulate the medical use of byproduct material effectively.

Congress will modify the AEA to revoke the NRC's authority to regulate the medical use of byproduct material, give another Federal agency the responsibility for providing guidance, and allow all States, at their option, to exercise regulatory authority over the medical use of byproduct materials.

All States will devote the additional necessary resources to provide adequate protection of the public health and safety related to the medical use of byproduct materials with "little", if any, additional federal funding.

The possibility of precluding users from obtaining byproduct material from manufacturers in those "states that did not include byproduct material into their existing regulatory programs" would be acceptable to Congress and the public.

NRC STAFF ISSUE

Will all States in fact have the will, the resources, and the competence to regulate the medical use of all sources and uses of ionizing radiation safely?

PUBLIC COMMENTS

OAS endorses this recommendation, but as applied to all ionizing radiation. CRCPD endorses the recommendation, although it recognizes that not all States will choose to establish comprehensive programs that include byproduct materials. However, the CRCPD continues to support consistent application of radiation protection standards nationwide and believes that this can be best accomplished by having all radiation programs in a single state agency which can deal comprehensively with all forms of ionizing radiation within the state.

C3. *The committee recommends that the Conference of Radiation Control Program Directors and the states continually reevaluate their regulations and procedures pertaining to radiation medicine to ensure congruence with evolving scientific understanding of radiation bioeffects and to be in accord with advances in knowledge regarding benefits and risks related to medical and biomedical research uses of ionizing radiation in medicine.*

IOM RATIONALE

Continual reevaluation and maintaining congruence is a necessary step for providing adequate protection of the public health and safety.

The CRCPD and all states will devote the necessary resources to maintain congruence with evolving scientific understanding of radiation bioeffects and be in accord with advances in knowledge regarding the benefits and risks of the medical use of ionizing radiation.

NRC STAFF ISSUE

Many states have adopted regulations for non-AEA materials that are similar to those that NRC implements for AEA materials and requires Agreement States to adopt as items of compatibility (e.g., NRC's QM rule for cobalt teletherapy versus State regulations for accelerator teletherapy). Will the CRCPD be able to effectively "ensure congruence" of the States' regulations and procedures to "be in accord with advances in knowledge regarding benefits and risks ..." by using voluntary mechanisms in the absence of the regulatory presence and resource support of NRC?

PUBLIC COMMENTS

Both OAS and CRCPD endorse this recommendation.

V NRC ACTIONS AND COMMENT SUMMARY

A NRC Actions to Date

The IOM provided NRC with a prepublication copy of the committee's report in December 1995. The NRC provided copies of the report to all Agreement States and non-Agreement States and Territories, appropriate Federal agencies, CRCPD, OAS, Congressional Oversight Committees and NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI). In addition, the NRC published a Federal Register notice (61 FR 1648) on January 22, 1996, and issued a press release acknowledging receipt of the report and requesting comments on the possible impacts of the report, to include any views on policy, legislative, rulemaking, and guidance issues. The Commission directed the staff to consider the report and comments received within its Strategic Assessment and Rebaselining efforts. While the report is being considered, the NRC is continuing to implement the ongoing medical use program.

Several public meetings have been held to discuss the report. The ACMUI met on February 21-22, 1996 and subsequently briefed the Commission on May 3, 1996 to discuss their recommendations. Briefly, the ACMUI did not recommend any of specified alternatives. They reached consensus that the medical use regulatory program should be rebuilt, reassessing the objectives of the regulations and encompassing all uses of ionizing radiation in medicine, and that States should be federally mandated to administer the program, with appropriate incentives to encourage States to comply. State programs should be monitored by a Federal agency with an overall medical use perspective (e.g., DHHS).

The OAS and the members of the IOM committee briefed the Commission on February 26 and 27, 1996, respectively. In addition, the report was discussed at a joint NRC and Agreement State technical workshop on March 5-6, 1996. The workshop included representatives of 18 Agreement States and two non-Agreement States. More recently, the report was discussed with the Conference of Radiation Control Program Directors on May 6, 1996.

B COMMENTS ON IOM REPORT

As of the end of August 1996, the staff had received 47 written comments on the report. The two major categories of responses are either in support of, or opposition to, the overall recommendations of the IOM committee. However, within each of these major categories, there are subsets with respect to the specific direction or focus of the comments. None of the comments received specifically indicated that there should be no Federal involvement.

The Secretary of the Department of Health and Human Services (DHHS), the Federal agency that would be most directly affected by the IOM recommendations, indicated that the report does not make a compelling public health agreement for DHHS to assure the recommended new role. Furthermore, DHHS raised a concern that Congress would not provide resources commensurate with the added responsibilities.

The majority of comments received (32 out of 47) did not endorse the full range of recommendations put forth by the IOM committee. Four of the 15 respondents that supported the recommendations indicated that the recommendations should encompass all uses of byproduct materials. The Department of Veterans Affairs, in its support of the IOM report, indicated that legislative initiatives should ensure that Federal facilities are not subject to State and local regulations.

The comments that did not support all the IOM recommendations varied dramatically in the focus of their viewpoints and opinions. The degree of regulatory reform perceived to be necessary ranged from simply recognizing the

merits of the issues raised by the IOM committee to a need for a complete restructuring of the regulatory program. The non-Agreement States that responded were particularly concerned about the substantial financial impact of the recommendations and the issue of this being, in effect, an unfunded Federal mandate. For example, as indicated in the response from Hawaii, public health and safety could be jeopardized in those States with insufficient resources or capability to adequately implement the regulation of byproduct materials. The Department of Defense response, which summarized the responses from the three Service Medical Departments (Army, Navy, and Air Force), supported the need to re-evaluate the current regulatory structure, but emphasized the need for a uniform regulatory authority. There were several responses that recommended the need for Federal oversight for all uses of radiation.

The Organization of Agreement States response provided a summary of the consensus of the participants of the NRC and Agreement State technical workshop conducted March 5-6, 1996, which included that all radiation use (medical and non-medical uses) should be consolidated under one Federal agency. The CRCPD prepared a position paper, which supported the leadership role of a single federal agency for all forms of ionizing radiation, at their May 6 meeting. The comments of these organizations are summarized above under the specific recommendations to which they apply.

The NRC will continue to evaluate comments as part of the strategic assessment and rebaselining efforts. A summary of the comments is provided in Attachments 1-3.

Categories of Responses Received on IOM Report

Federal Agencies:

Department of Defense (DOD) - consolidates views for three services
Department of Health and Human Services (DHHS)
Department of Labor, Occupational Safety and Health Administration (OSHA)
Department of Veterans Affairs (DVA)
Environmental Protection Agency (EPA)

Agreement States:

Arkansas
California
Florida (Office Radiation Control) - R
Florida (State Health Office) - H
Illinois
Kentucky
Maryland
New Mexico
New York (Dept. Environmental Conservation) - E
New York (Dept. Health) - H
New York (Dept. Labor) - L
Tennessee
Texas
Utah
Vermont
Washington

Non-Agreement States/Territories:

Alaska
American Samoa
Delaware
Hawaii
Massachusetts
New Jersey
Virginia
Wyoming

Organizations/Committees:

American Association of Physicists in Medicine (AAPM)
American College of Cardiology (ACC)
American College of Medical Physics (ACMP)
American College of Nuclear Physicians/Society of Nuclear Medicine (ACNP/SNM)
American College of Nuclear Physicians - California chapter (ACNP-CA)
American College of Radiology (ACR)
American Pharmaceutical Association (APhA)
American Society of Nuclear Cardiology (ASNC)
Conference of Radiation Control Program Directors (CRCPD)
NRC's Advisory Committee on Medical Uses of Isotopes (ACMUI)
Organization of Agreement States (OAS)[7]

Other Respondents:

CBeasley, St. John's Regional Health Center, Springfield, MO
MHafermann, Virginia Mason Cancer Center, Seattle, WA
DJones, Northwest Medical Physics Center, Lynnwood, WA
CMarcus, University of California, Los Angeles, CA
CPerez, Washington University, St. Louis, MO
GPoteat, OH
JRieke, Virginia Mason Cancer Center, Seattle, WA
DSchumacher, Northwest Medical Physics Center, Lynnwood, WA
MSelikson, RSO, University of Pennsylvania, Philadelphia, PA
St. John's Hospital, Jackson, WY

[7] The OAS comment provided the recommendations of and consensus views reached at the NRC and Agreement State Technical workshop. The session on the NAS report included representatives from 18 Agreement States (CA, NY, SC, NV, IL, WA, TX, MS, TN, GA, NE, CO, KY, KS, NYC, FL, AR, AZ) and two non-Agreement States (OH, PA).

General Comments on IOM Report

Respondents in favor of IOM recommendations:

Support IOM report/recommendations as written:

AAPM
ACNP/SNM
ASNC
DVA
NM
MHafermann (Virginia Mason Cancer Ctr)
DJones (Northwest Medical Physics Ctr)
CMarcus (UCLA)
CPerez (Washington Univ)
JRieke (Virginia Mason Cancer Ctr)
DSchumacher (Northwest Medical Physics Ctr)

Support IOM report/recommendations, but as applied to all materials:

FL (R)
NY (H)
NY (L)
ACNP-CA

Respondents not in agreement with IOM recommendations:

Support concept of regulatory reform[8] but retain Federal authority[9]:

DHHS oversight: ACMUI, CA

NRC oversight: EPA, ACMP, ACR, HI, KY, NY(E), UT, WA, GPoteat(OH)

Unspecified oversight: DHHS[10], DOD, ACC, AK, DE, TN, VA, WY

Support concept of regulatory reform, but after additional analysis:

CBeasley (St John's Regional Health Center)
MSelikson (RSO, Univ. of Pennsylvania)
NJ
St. John's Hospital

Support concept of uniformity for all radioactive materials regulation with Federal oversight:

CRCPD
OAS
APhA
AR (NRC as lead agency)
FL (H)
IL
MA
MD
TX

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[8] It should be pointed out that the degree of regulatory reform perceived to be necessary by different respondents varied from recognizing the concerns raised by the IOM to a drastic change in the approach to regulation of medical uses.

[9] Some States (e.g., VA, WY, DE) were primarily concerned with the substantial financial impact of the NAS recommendations and the issue of unfunded Federal mandates, rather than more specific concerns on the overall approach for regulation.

[10] DHHS did not address the issue of regulatory reform, Federal authority, or concerns raised by the IOM, but focussed on the implications of the recommendation to DHHS.

Respondents indicating report under review

DOL
AS
VT

Specific Comments on IOM Report

Category of Response	Respondent	Specific Comments
RESPONDENTS IN AGREEMENT WITH IOM RECOMMENDATIONS		
Support IOM report/ recommendation as written	DVA	The Veterans Health Administration generally concurs with and endorses the findings and recommendations of IOM. Principal concern is lack of specifics regarding regulation of Federal entitities and also the regulation of medical research programs.
	New Mexico	Agrees with IOM recommendation that Congress remove regulation of possession and use of material subject to AEA from NRC's purview. Supports leadership role of DHHS so long as all states maintain regulatory programs that measure comprehensive standards of performance and effectiveness.
	AAPM	AAPM fundamentally supports position, conclusions, and recommendations of the IOM report. NRC should be removed from its current regulatory role for medical use. Establish programs for implementing States' regulations monitored by appropriate Federal health agency with assistance of user community and professional organizations.
	ACNP/SNM	The ACNP and SNM believe the report proposes a sound and thoughtful approach to the regulation of nuclear medicine and urges NRC to implement the IOM recommendations, allowing for comment on specific means to achieve implementation.
	ASNC	Concur with the IOM's conclusions and support their recommendations for a uniform policy to be set at Federal level which can be enforced by the States. DHHS should include medical radiation safety as part of its health care management plan.
	MHafermann	Endorses recommendations of IOM. Does not agree with sentiments of Robert Adler in Appendix L.

Category of Response	Respondent	Specific Comments
RESPONDENTS IN AGREEMENT WITH IOM RECOMMENDATIONS		
Support IOM report/ recommendation as written	DJones	Endorses recommendations of IOM. Does not agree with sentiments of Robert Adler in Appendix L.
	CMarcus	Supports the IOM report and expresses disagreement with statements made by Robert Adler in his supplemental statement (Appendix L)
	CPerez	Expresses strong support for many of recommendations.
	JRieke	Endorses recommendations of IOM. Does not agree with sentiments of Robert Adler in Appendix L.
	DSchumacher	Supports recommendations proposed by IOM committee.
Support IOM report/ recommendations, but as applied to all materials	Florida (Rad. Control)	Support idea of delegating regulation of medical byproduct material to states in addition to all agreement materials.
	New York (Dept. Health)	Support the IOM's conclusion that the regulation of medical use of byproduct materials should be carried out at the state level. Encourages the NRC to not limit its response to the IOM report to the narrow medical focus of the report.
	New York (Dept. Labor)	Supports the IOM's recommendation that NRC discontinue regulation of medical use of byproduct materials, but considers it illogical to limit the recommendation to this one area (should include nuclear pharmacies, manufacturers, distributors, and industrial users)
	ACNP-CA	NRC's entire materials program should be given to the States and Federal entities

Category of Response	Respondent	Specific Comments
RESPONDENTS NOT IN AGREEMENT WITH IOM RECOMMENDATIONS		
Support concept of regulatory reform but retain Federal authority	ACMUI	ACMUI indicated a preference for a variant of the IOM preferred alternative in which there would be substantial Federal oversight of State programs with a mechanism to ensure compliance of States and users. State programs should be monitored by a Federal agency with overall medical use perspective (DHHS).
	DHHS	Report does not make a compelling public health argument for DHHS taking on a substantial new role. The probability is low that Congress would provide adequate resources. DHHS does not support the recommendation.
	DOD	Federal regulatory authority over medical use of byproduct material should be reevaluated and perhaps relaxed and restructured, but not abolished in favor of a voluntary or State-operated system.
	EPA	Report reflects the concerns of the regulated community more than the public at large. There may be aspects of NRC's program that can be improved, but NRC should continue to assure public is protected.
	ACC	Transfer of oversight of the medical use of isotopes to the States seems reasonable. However, strongly encourage Federal oversight of this state initiative. An obvious drawback would be if all States had separate regulations for licensure and compliance.
	ACMP	Supports the need for a drastic change in regulation of radiation in medical use including use of Advisory Panels (comprised of users, manufacturers, and public) to determine the regulatory framework to be applied uniformly in medical profession. Current regulations should be modified.
	ACR	In lieu of Congressional action to eliminate NRC's medical use program, the ACR believes that NRC's medical use program must be rebuilt and its objectives thoroughly reassessed.

Category of Response	Respondent	Specific Comments
RESPONDENTS NOT IN AGREEMENT WITH IOM RECOMMENDATIONS (continued)		
Support concept of regulatory reform but retain Federal authority (continued)	Alaska	This would not be a cost effective nor efficient reform for Alaska. It is in the best interest of the State to support the existing method of regulating nuclear medicine licensees by a Federal agency.
	California	In view of split regulatory authority at federal level and apparent reluctance of NRC to expand jurisdiction, agree that Congress remove NRC's authority. DHHS should be given authority to ensure that every state maintains a radiation program that meets minimum, comprehensive, consensus standards of performance and effectiveness.
	Delaware	The impact of the IOM recommendations would be substantial in terms of our increased need for funding, staffing, training and infrastructure requirements.
	Hawaii	Does not have resources or capability to adequately implement regulation of byproduct materials. Without assistance (training and development) to States, the removal of NRC's authority may significantly jeopardize public health and safety.
	Kentucky	A better approach would be to have NRC revise its medical program to go along with the recommendations the Institute has given in preferred alternative D.
	New York (Dept. Environ. Conservation)	Many unforeseen consequences may occur if AEA is modified. Commission should proceed cautiously in pursuing IOM recommendations that may alter the present AEA.
	Tennessee	While the findings of the Committee have some merit, there is no conclusive support provided to document them. Sweeping changes are not well thought out and may result in chaos.
	Utah	State legislatures may view this as another unfunded Federal mandate and may provide no additional support to the State program. Medical community should work with NRC, States, and other parties to resolve the regulation issue.

Category of Response	Respondent	Specific Comments
RESPONDENTS NOT IN AGREEMENT WITH IOM RECOMMENDATIONS (continued)		
Support concept of regulatory reform but retain Federal authority (continued)	Virginia	The Commonwealth is in no position to assume any additional unfunded Federal mandates. Could only assume regulatory responsibility if NRC provides funds to defray cost of implementing the program.
	Washington	NRC should focus on radiation safety of worker and non-patient public (oversight of production, distribution, and handling of byproduct materials) while protection of patient is best handled through State boards of medicine and pharmacy.
	Wyoming	The conclusions of the report neglect the considerable hardship to be incurred by smaller, less populous, and less affluent States. Only through continued Federal regulatory participation can the goals of uniformity and public access to safe medical procedures be achieved.
	GPoteat	Potential decrease in safety may result from a transfer to State regulators of NRC's authority. Minor changes are necessary but overall NRC's regulations balance the need to protect workers, patient and the public with the requirements of medical practice.

Category of Response	Respondent	Specific Comments
RESPONDENTS NOT IN AGREEMENT WITH IOM RECOMMENDATIONS (continued)		
Support concept of regulatory reform, but after additional analysis	New Jersey	If NJ chose not to become an Agreement State, public may not be assured of adequate protection. If adopting the recommendations, NRC and Congress should not act precipitously, but allow the States to prepare for assuming regulatory programs in orderly fashion.
	University of Pennsylvania	Before moving in the direction of a State-based decentralized system, a better evaluation of potential both for increased risk to the public and increased cost to the medical industry is necessary.
	St. John's Hospital	Urges NRC to give every consideration to IOM report, particularly the review of risk assessment.
	CBeasley	The report missed part of its stated intended goal to review the current system of regulation (the issues of uniformity among states was not fully explored). Proposes review in more detail the regulation of non-nuclear medicine radiology and question of uniformity between states.
Support concept of uniformity for all radioactive materials regulation with Federal oversight	OAS	At NRC/Agreement State Technical Workshop, consensus was reached that all radiation use (regulated currently under NRC, FDA, EPA, and OSHA) should be consolidated under a single Federal agency.
	CRCPD	Absence of federal authority in medical use area may have immediate and undesirable consequences on citizens in non- Agreement States and long term consequences for Agreement States trying to maintain a nationally consistent program. CRCPD does not support automatic selection of DHHS as the agency to provide leadership role.
	APhA	All ionizing radiation should be grouped together under a uniform regulation. Transfer responsibility for medical uses of any ionizing radiation to the States. Some Federal authority should remain over the medical uses of ionizing radiation (NRC or a similar federal agency).

Category of Response	Respondent	Specific Comments
RESPONDENTS NOT IN AGREEMENT WITH IOM RECOMMENDATIONS (continued)		
Support concept of uniformity for all radioactive materials regulation with Federal oversight (continued)	Arkansas	The NRC should consider alternative A2 (status quo modified). If major changes are to be made, centralization of regulation within one Federal agency (NRC) would be the best approach for all uses of radiation. Congress would be required to expand the role of NRC and a change in the agency would be necessary. Expand current Agreement State program.
	Florida (Health Office)	Support idea that regulatory authority of all agreement materials be turned over to the states with consolidation of federal radiation oversight, guidance, and regulatory functions into one agency, not necessarily DHHS.
	Illinois	Prefer CRCPD proposed new organizational concept that recommends some consolidation of all radiation regulatory functions at federal level. Revise QM and pharmacy rules. Prepare white paper to use as a policy basis to clearly delineate the respective authority and responsibilities of various Federal and State agencies.
	Maryland	Rather than revoke NRC's authority and repeal the Federal regulations, such authority should be expanded to incorporate NARM, and the Federal regulations should be thoroughly reviewed and amended to clarify regulatory responsibility. DHHS does not have necessary expertise.
	Massachusetts	Do not support elimination of all aspects of NRC's medical program, but support relaxation of overly prescriptive and unnecessarily costly requirements. Support intent of single Federal agency providing a single leadership role but do not support automatic selection of DHHS.
	Texas	The basis for the report's recommendations do not seem to be substantiated. The merging of all federal radiation control oversight into a single regulatory program should be considered. The NRC should enhance the partnership with the States to jointly determine compatibility requirements.