
Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials

An Update

**U.S. Nuclear Regulatory
Commission**

Office of State Programs

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Office of State Programs
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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. Counterbalancing 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% cited 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 lightning 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 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

	<u>Agreement States</u>	<u>Non-Agreement States</u>	<u>Total</u>
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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12. SUPPLEMENTARY NOTES					
13. ABSTRACT (200 words or less)					
<p>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.</p>					
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