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].

<u>TENORM</u>. 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"

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