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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