



Evaluation of EPA's Guidelines for Technologically Enhanced Naturally Occurring Radioactive Materials (TENORM)

Report to Congress

Executive Summary

In reports accompanying the appropriations bills for the Departments of Veterans Affairs, Housing and Urban Development, and Independent Agencies for Fiscal Years 1996 and 1997, Congress requested the EPA arrange for the National Academy of Sciences (NAS) to conduct a study examining the basis for EPA's guidance on technologically enhanced naturally occurring radioactive material (TENORM). EPA was to submit the completed NAS study to Congress, along with Agency's own report on what it would do to implement the NAS's recommendations, including EPA's plans to revise its TENORM guidance documents. This report has been prepared to satisfy that requirement regarding TENORM.

In January 1999, the NAS published its report entitled, "Evaluation of Guidelines for Exposures to Technologically Enhanced Naturally Occurring Radioactive Materials." In this report, the NAS Committee found that there are differences in TENORM guidelines among federal agencies and others. The Committee found that these differences in guidelines represent differences in policies for risk management rather than differences in the technical evaluation of TENORM.

Although the NAS Committee found that most of the relevant and appropriate scientific information has already been incorporated into current TENORM guidelines, many of the Committee's recommendations point to areas where new information would be useful. For example, the Committee recommended further investigation of the varying chemical and physical forms of TENORM, and the development of better techniques to distinguish discrete TENORM levels from background radiation levels. EPA is already working in many of the areas the Committee cited for additional technical information.

EPA recognizes that there are differences in TENORM regulations and guidance documents among organizations. EPA intends to take into consideration the significance of TENORM risks to the public and the environment to determine which TENORM wastes should be addressed first and what actions, if any, should be taken in response to potential risks. EPA is working in virtually all areas of the NAS Committee's recommendations. In areas where EPA is not currently engaged, the Agency acknowledges the recommendations of the NAS. EPA will consult, as appropriate, with federal, state and other organizations involved with radiation protection issues as we progress toward TENORM solutions.

Evaluation of EPA's Guidelines on Technologically Enhanced Naturally Occurring Radioactive Materials (TENORM) Report to Congress

Introduction

Over the past 20 years, EPA and other federal as well as state government agencies, industries, and other organizations have identified an array of naturally occurring materials that, because of human activity, may present a radiation hazard to people and the environment. These materials are known generally as technologically enhanced naturally occurring radioactive materials, or TENORM.¹ In general terms, TENORM is material containing radionuclides that are present naturally in rocks, soils, water, and minerals and that have become concentrated and/or exposed to the accessible environment as a result of human activities such as manufacturing, water treatment, or mining operations. In its report,² the Committee on Evaluation of EPA Guidelines for Exposure to Naturally Occurring Radioactive Materials, of the National Academy of Sciences and National Academy of Engineering (the "NAS Committee" or "the Committee") defines TENORM as "*any naturally occurring material not subject to regulation under the Atomic Energy Act whose radionuclide concentrations or potential for human exposure have been increased above levels encountered in the natural state by human activities*" (p. 19). Much TENORM contains only trace amounts of radiation and is part of our everyday landscape. Some TENORM, however, contains very high concentrations of radionuclides that can produce harmful exposure levels. EPA is concerned about TENORM because of this potential for harmful exposure to humans and the environment.

In reports accompanying the appropriations bills for the Departments of Veterans Affairs, Housing and Urban Development, and Independent Agencies for Fiscal Years 1996³ and 1997,⁴ Congress requested that EPA arrange for the NAS to conduct a study examining the basis for EPA's TENORM and radon guidance. EPA was to submit the completed NAS study to Congress, along

¹Before 1998, the term used for these materials was "Naturally Occurring Radioactive Materials" ("NORM"). Based on more current industry and regulatory practice, the term "TENORM" now is considered more appropriate. We use "TENORM" throughout this report.

²Committee on Evaluation of EPA Guidelines for Exposure to Naturally Occurring Radioactive Materials, National Research Council of the National Academy of Sciences and National Academy of Engineering, "Evaluation of Guidelines for Exposures to Technologically Enhanced Naturally Occurring Radioactive Materials," 1999. Citations to this NAS Committee's report appear in parenthesis containing page citations.

³H.R. Rep. No. 104-384, p. 77 (1995).

⁴S. Rep. No. 104-318, p. 69 (1996).

with the Agency's own report on what it would do to implement the NAS's recommendations, including EPA's plans to revise its TENORM guidance documents. This report has been prepared to satisfy that requirement regarding TENORM. In February 1998, the NAS released the BEIR VI report entitled "Health Effects of Exposure to Radon." This new report is the most definitive accumulation of scientific data on indoor radon. The Agency is in the process of reviewing whether the BEIR VI findings warrant any changes in EPA's radon policy and will be issuing a separate Report to Congress on this issue.

Background

TENORM is found in a wide variety of waste materials, some raw mineral ores, and in trace amounts in some consumer products where molecules of radionuclides may be bound to specific minerals used in the manufacturing process (zircon, for example, contains minute quantities of uranium and thorium and used widely as a glaze for ceramics and metal molds). The radionuclide Radium-226, a decay product of uranium and thorium with a radiation decay half-life of 1600 years, commonly is found in TENORM materials and wastes and is the principal source of radiation doses to humans for natural surroundings. While normally occurring in soils of the United States⁵ at concentrations ranging from less than 1 to slightly more than 4 picocuries per gram (pCi/g, where picocuries are a measure of radiation content in a material), Radium-226 in TENORM materials can occur in concentrations ranging from undetectable amounts to as much as several hundred thousand pCi/g. In comparison, EPA has issued guidance⁶ that recommends that radioactively contaminated soils should be cleaned up so remnant radium concentrations are 5 pCi/g or less. Uranium, thorium and potassium radionuclides and their daughter products are also commonly found in TENORM wastes.

Total amounts of TENORM wastes produced in the United States annually may be in excess of 1 billion tons.⁷ Nuclear Regulatory Commission (NRC) staff calculations show that the disposal the

⁵Myrick, T., Berven, B., and Haywood, "Determination of Concentrations of Selected Radionuclides in Surface Soil in the U.S.," in *Health Physics Journal*, Vol. 45, no.3, pp. 631-642, 1983.

⁶U.S. EPA, 1998, Memorandum on Use of Soil Cleanup Criteria in 40CFR Part 192 as Remediation Goals for CERCLA Sites, Signed by Stephen T. Luftig, Director, Office of Emergency and Remedial Response, and Larry Weinstock, Acting Director, Office of Radiation and Indoor Air. Directive No. 92000.4-25, February 12, 1998.

⁷S. Cohen and Associates, Inc., 1993, Preliminary Risk Assessment of Diffuse NORM Wastes, Prepared for U.S. EPA under contract No. 68D20155, May 1993. (EPA will not be finalizing this report. Instead, the Agency will be issuing a series of technical reports on a waste-specific basis. These reports will include the most current information on the waste.)

annual production of TENORM in industrial landfills could easily exceed \$100 billion.⁸ In many cases, relatively low levels of radiation occur in large volumes of material that contain the TENORM. This situation causes a dilemma because of the high cost of disposing of radioactive waste in comparison with (in many cases) the relatively low value per ton of the product from which the TENORM is separated. In addition, relatively few landfills or other licensed disposal locations can accept radioactive waste. However, TENORM materials exempt from NRC regulation are routinely disposed of without being labeled “radioactive material.” Also, large quantities of TENORM are currently undisposed and may be found in many of the thousands of abandoned mine sites around the nation.⁹

Table 1, in Appendix A, provides a range of reported concentrations, and average concentration measurement in some cases, of TENORM in various wastes and materials. This table is not a comprehensive list, as TENORM radiation is known to occur in many other materials; however, it should provide a relative sense of the hazards posed by these particular radioactive substances.

NAS Committee’s Report

In the conference report accompanying H.R. 2099, the FY 1996 appropriations bill for the Department of Veterans Affairs and Housing and Urban Development, and Independent Agencies, the conferees included the following language:

The conferees direct EPA to enter into an arrangement with the National Academy of Sciences to investigate and report on the scientific basis for EPA’s recommendations relative to indoor radon and other naturally occurring radioactive materials (NORM). The Academy is to examine EPA’s guidelines in light of the recommendations of the National Council of Radiation Protection and Measurements and other peer-reviewed research by the National Cancer Institute, the Centers for Disease Control, and others. The Academy shall summarize the principal areas of agreement and disagreement among these bodies and shall evaluate the scientific and technical basis for any differences that exist. EPA is to submit this report to the appropriate committees of the Congress with 18 months of the date of the enactment of this act, and state its views on the need to revise the guidelines for radon and NORM in light of the Academy’s evaluation. The agency also shall explain the technical and policy basis for such views.¹⁰

EPA entered into an agreement with the NAS on March 31, 1997, to respond to the

⁸ New Jersey Department of Environment Protection, Commission on Radiation Protection, Soil Remediation for Radioactive Materials Proposed New Rules: N.J.A.C. 7:28-12, DEP Docket Number 11-99-06-697.

⁹ S. Cohen and Associates, Inc. 1989, Radiological Monitoring at Inactive Surface Mines, report prepared for the U.S. Environmental Protection Agency, February, 1989.

¹⁰ H.R. Rep. No. 104-384, at 77 (1995).

congressional requirement and reported the signing of the agreement to the Appropriations Committee as requested in 1997. The NAS Committee published its study in January 1999. EPA's transmittal to Congress of the NAS Committee study, along with this report by EPA, fulfills the legislative requirements discussed above.¹¹

The purpose of the NAS Committee's study was to investigate the scientific and technical bases for EPA's TENORM guidelines. Congress instructed that, as part of its investigation and report, the NAS Committee "summarize the principal areas of agreement and disagreement among [EPA and other organizations] and ...evaluate the scientific and technical basis for any differences that exist."¹²

The NAS Committee's charge included examining the following issues:

- 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 bases, what are the relative merits of the different scientific and technical assumptions?***
- 3) ***Whether there is relevant and appropriate scientific information that has not been used in the development of contemporary risk analysis for NORM.***

The NAS examined and compared the existing guidelines for TENORM developed by EPA and other organizations concerned with radiation protection. These other organizations include the Department of Energy, the Nuclear Regulatory Commission, the National Council on Radiation Protection and Measurements, the International Commission on Radiological Protection, the International Atomic Energy Agency, the Commission of European Communities, and the Health Physics Society. The NAS also reviewed guidelines published by the individual states.

NAS Committee's Conclusions

The NAS Committee made the following conclusions in response to the charge elements:

¹¹ The NAS report also presents an evaluation of the guidelines for indoor radon. The Committee found that this evaluation was relatively straightforward because the guidelines for the indoor radon exposure situation are well defined and the primary task for the Committee was to evaluate whether the differences among the various guidelines have a scientific and technical basis. This report does not address indoor radon guidelines because we are in the process of reviewing the NAS BEIR VI report and plan to send a report to Congress indicating whether the BEIR VI findings warrant any changes in EPA's policy on radon.

¹² H.R. Rep. No. 104-384, p. 77 (1995).

(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.

The NAS Committee conducted a comprehensive review of guidance and regulations, developed by regulatory and advisory organizations, for indoor radon and other TENORM substances. The Committee found that “*differences in the guidelines for TENORM developed by EPA and other organizations are based essentially on differences in policy judgements for risk management*” (pp. 4-5, 215-217).

The NAS Committee also found that the information used to evaluate risk from ionizing radiation arising from TENORM and other (generally man-made) sources of ionizing radiation was, and should be, the same. The risk assessment methods for TENORM are not different from methods used for assessing risk from other sources of ionizing radiation because absorbed dose (or risk) depends on radiation type (e.g., alpha, beta, gamma) and its energy, not the source. The NAS found that all of the organizations use epidemiological data developed from radon exposures of underground miners as the basis for risk assumptions involving indoor radon (p. 219). All the organizations also used the epidemiologic data gained from studies of Japanese atomic-bomb survivors, as extrapolated to the low doses of concern in environmental exposures, as the basis for TENORM guidelines, other than indoor radon (p. 219). Finally, all organizations that developed guidelines for TENORM accepted a linear, no-threshold dose-response relationship at low levels of exposure (p. 244).

(2) If the guidelines developed by EPA and other organizations differ in their scientific and technical bases, what are the relative merits of the different scientific and technical assumptions?

The Committee found this question to be moot, because the differences between current EPA risk assessment methods and those used by other organizations were not substantially different, and did not have a significant influence on the development of TENORM guidelines (p.6).

(3) Whether there is relevant and appropriate scientific information that has not been used in the development of contemporary risk analysis for NORM.

The NAS Committee identified research needs that could improve EPA’s understanding of TENORM. It did not, however, find “*a substantial body of relevant and appropriate scientific information that has been used in the development and implementation of contemporary risk analysis for TENORM for purposes of developing and implementing guidelines*” (p.243).

Risk Management Issues

The NAS Committee was not tasked with, nor initially concerned with, evaluating nonscientific risk management issues such as cost and policy judgements. However, because the NAS found that

the bases for the differences in the various agencies, TENORM guidelines rested primarily on these factors, rather than on scientific or technical factors, it identified important policy judgements that influenced the development of TENORM guidelines. The NAS did not, however, evaluate the merits of these policy judgements. These judgements vary from organization to organization because of policy decisions that may be based, in part, on congressional requirements or judicial decisions (pp. 145-146).

In its evaluation of the guidelines developed for TENORM by EPA and other organizations, the NAS Committee determined that, though all the guidelines and standards it evaluated were developed to protect individuals and populations from harmful effects of ionizing radiation, because of different statutory mandates, risk management approaches, and exposure situations, and expectation of consistency among these standards would be inappropriate. Each organization bases its radiation protection standards on the organization's judgements regarding several critical policy issues. These judgements include decisions about acceptability of the risk, achievability of the risk reduction, transference of existing guidelines to other exposure situations, and other risk management considerations. The following is a summary of the NAS discussion of these risk management issues.

Acceptability of Risk

The NAS concluded that different judgements on the maximum acceptable risk to the public have led to different risk management approaches. These approaches reflect in part the fundamental differences in each organization's statutory and judicial mandates, particularly a requirement to set a regulatory limit such as a standard that must be met, versus a regulatory goal that can be relaxed based on considerations embodied in other guidelines. Another critical difference dictated by statute is the applicability of the guidelines to either a specific environmental media (e.g., air) or pathway (e.g., drinking water), or a more extensive all-media, all-pathways limit. The NAS noted that a single source and exposure pathway standard would not be expected to be consistent with an all-source-and-exposure pathway standard. Further, the NAS noted that the doses and risks for the highest exposed individuals generally will be higher than those for average individuals in the population (pp. 8-10).

Achievability of Risk Reduction

The NAS noted in its report that EPA's judgement on the achievability of reducing the risk to public health considers the available technologies to control or reduce releases of radionuclides into the environment (p. 92). Organizations incorporate such judgements into regulations and guidance documents, depending on each organization's risk management approach. The organization's definition (or judgement) of achievable risk reduction depends largely on the application of the principle that exposures of individuals and populations should be as low as reasonably achievable (ALARA). An organization may incorporate the results of an ALARA application indirectly into a regulation in the standard setting process itself - as is the case for many EPA standards in setting a regulatory goal. Alternatively, the appropriate regulatory authority may require ALARA, in practice, to be carried out directly, in addition to the regulatory limit. For example, the Committee noted that "*compliance with the [ICRP's and NCRP's] primary dose limit of 1 mSv (100 mrem) per year for all controlled*

sources combined does not, by itself, provide acceptable radiation protection of the public, because doses should be reduced as far below the primary dose limit as practicable” (p. 93).

In spite of the differences in risk management approaches, and the consequent substantial differences in implied risk associated with the different guidelines (implied health risks vary over several orders of magnitude), the Committee concluded that “[t]he principle that exposures should be maintained ALARA, economic and social factors being taken into account, appears to be the most important factor in determining risks actually experienced for any controllable exposure situation” (p. 247). Therefore, to the extent that the ALARA objective is applied consistently to all exposure situations, all guidelines would be consistent with regard to the risks actually achieved, even though the risks that are ALARA can depend significantly on the particular exposure situation. The Committee also noted that, using the ALARA process, “[t]here is not a priori reason to expect risks judged reasonably achievable for one exposure situation (such as releases from operating nuclear facilities) to be consistent with risks judged reasonably achievable for a different situation (such as radioactive waste disposal).” (p.148) Finally, the Committee concluded that the current differences in approach for radiation risk management, though confusing, do not result in important differences in public health protection. However, “continued attention to the factors that affect radiation dose and risk for specific TENORM situations is crucial for consistently protective, cost-effective radiation control.” (p.247)

Although there are significant differences in radiation protection standards developed by the Federal agencies, the NAS Committee concluded that these differences do not result in important differences in public health protection; it is also important to note that in some cases the differences are for legitimate reasons. For example, NRC regulates its licensees under the ADA, for the most part on a site-by-site basis under the “umbrella” of an upper-bound dose limit, which is based on international and national recommendations from the ICRP and NCRP. The limit is coupled with the required application for procedures and engineering controls to reduce the potential public doses to levels that are ALARA. EPA, in its primary role as a standards-settings agency, regulates under the authority of both the AEA and environmental statutes. EPA regulates by class of facility or source, pollutant, or environmental medium. In setting its standards, EPA generally establishes a goal, often mandated by legislation, and considers technological feasibility, costs, and other factors in determining levels to be achieved in practice. Although not required, EPA aims for consistent regulatory policy concerning standards for radionuclides and chemicals.

Transfer of Existing Guidelines

The Committee found that another important factor in the development of standards or guidelines for TENORM is an organization’s judgement about transferability of existing standards/guidelines to other exposure situations. As the NAS stated. “[t]he committee strongly cautions against generalizing numerical guidance derived for a specific situation to another situation without sufficient thought as to the applicability to the new circumstance.” “[Because] many sources of TENORM have mineralogical characteristics and processing histories,...and

therefore, have different radon-emanation coefficients, leachability, and bioavailability.” (p. 246) The NAS recommended that organizations limit the transfer of standards or guidelines by the degree to which the physical and chemical properties and projected exposure pathways of the TENORM are substantially similar to those considered for existing guidelines. Exemption levels should consider the physical characteristics of a site, the extent of the TENORM source, and the projected land use.

Regulations and Guidelines

The NAS Committee noted that EPA has developed standards under several different environmental laws for the regulation of TENORM, including the Clean Air Act (CAA), the Clean Water Act (CWA), the Safe Drinking Water Act (SDWA), and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). The Committee found, however, that *“neither EPA, which has primary responsibility for setting federal radiation standards, nor any other federal agency with responsibility for regulating radiation exposures has developed standards applicable to all exposure situations that involve TENORM. Instead, federal regulation of TENORM is fragmentary, and many potentially important sources of public exposure to TENORM are not regulated by any federal agency”* (p. 246).

Recommendations on Additional Research Needs

The NAS identified a number of areas in which it recommends that EPA conduct additional research and study regarding TENORM. A discussion of these recommendations, and EPA’s responses, follows.

Recommendation: EPA’S ASSESSMENTS OF RISKS FROM TENORM SHOULD INCLUDE ASSESSMENTS OF EXISTING BACKGROUND RADIATION LEVELS

EPA’s Response:

The NAS Committee emphasized the importance of considering exposure to TENORM in the context of natural background radiation levels (p. 248). The Committee concluded that background radiation levels are highly relevant to TENORM regulation because the radionuclides in TENORM are identical to the radionuclides in nature. The NAS Committee urged EPA to include in our assessment of TENORM-related risks an assessment of existing background radiation and the risks that this radiation contributes to overall risks from radiation exposure. It noted that *“[a]rguments concerning small differences in the target regulatory level at small fractions of the natural background tend to pale into insignificance in comparison with natural background levels and their local and regional variations”* (p. 248). The Committee also stated that, *“[a]s a practical matter, the implications of [the] existing levels and [the] variability of natural radionuclide concentrations and doses received by humans should receive careful consideration in the*

regulation of TENORM” (p.248).

EPA agrees that the levels of background radiation need to be considered in the assessment of TENORM. EPA’s radiation regulations limit the amount of radiation above background because the radiation is controllable or was placed there by man and should be controllable, unlike radioactive materials not generated by man. There are numerous studies of background exposure dose and risk (e.g., NCRP Report 94, “Exposure of Populations in the US and Canada from Natural Background Radiation” and the National Research Council’s, “Risk Assessment of Radon in Drinking Water”).

Guidance has also been developed to help in the process of demonstrating compliance when background radioactivity is present and is variable. An example of this guidance is the Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM) which is used to characterize contaminated sites. EPA will continue to take into account these important background and radioactivity studies in developing TENORM guidance and regulations.

Recommendations: EPA SHOULD DEVELOP BETTER TOOLS FOR DISTINGUISHING DISCRETE TENORM FROM BACKGROUND

EPA Response:

Because of the importance that the NAS Committee placed on the role of background radiation in the regulation of TENORM, it recommended that EPA develop better tools for distinguishing discrete TENORM from background radiation levels. Because TENORM radionuclides are ubiquitous in the environment, the NAS Committee expressed concern that the inability to distinguish TENORM from background radiation levels could result in unnecessary or over-broad regulation. The Committee argued, and EPA agrees, that it makes little or no sense to require cleanup of TENORM to levels below those that would exist naturally at a particular location (p.95). This issue is especially important in regards to mining sites because these sites often have background radiation levels that are higher than non-mining sites (p.95).

Data from the National Uranium Resource Evaluation (NURE), state geological surveys, and nuclear power plants databases provide reliable estimates of background radiation for the United States. EPA is incorporating information on background levels of radiation into all aspects of its evaluation of TENORM risks and potential disposal solutions. EPA will include discussions of background radiation in the comprehensive source-specific reports that it will develop for TENORM wastes and products.

A number of private entities, are working to develop detection equipment that can provide more accurate instantaneous field radiation level measurements, on the order of what the NAS Committee recommended, than can the equipment currently available. Regardless of the tools developed for measuring these low levels of radiation, however, EPA’s principal concern is still the control of man-made and TENORM sources of radiation.

Recommendation: EPA SHOULD EXAMINE FURTHER THE CHEMICAL FORMS AND PHYSICAL STRUCTURES OF TENORM AND SHOULD DEVELOP A MORE COMPREHENSIVE SYSTEM TO DOCUMENT THE VARIOUS USES AND DISPERSAL OF TENORM

EPA Response:

The NAS Committee noted that, “*TENORM present[s] unique problems because of their large volumes and widespread occurrence in industrial products, byproducts, and wastes. The physical, chemical, and radiological properties of TENORM vary widely.*” (p.74)

EPA agrees with the Committee’s conclusions about the complexity of TENORM, and for this reason EPA already is working to establish a comprehensive means of documenting significant aspects of TENORM associated with various waste streams or products. EPA will conduct this documentation in cooperation with interested stakeholders, including representatives of state and local governments, industries and non-governmental and other entities. As previously mentioned, these reports will compile the most relevant information on the amount and location of waste, the associated risks, the varying physical structures and chemical forms, current disposal techniques, and applicable guidelines and regulations. The reports will build on efforts conducted across the Agency on specific industries, wastes and products.

For example, through EPA’s ongoing field projects, the Agency is gathering new information about TENORM wastes in uranium overburden and in-situ leach operations. EPA also is fostering relationships with the organizations at the forefront of these issues. Through this network of organizations, EPA will be able to continue to build on its comprehensive documentation of TENORM data issues. Once EPA releases a technical report on a particular type of TENORM, the Agency intends to invite a variety of stakeholders to review the report and provide input. At meetings with these stakeholders, EPA expects to gather information on the most appropriate approaches to dealings with the waste hazards, risks, and disposal issues.

Recommendation: EPA’S EXPOSURE ASSESSMENTS SHOULD CONSIDER TENORM’S BIOAVAILABILITY, LEACHABILITY, AND RADON EMANATION RATES

EPA Response:

The NAS Committee suggested that EPA consider TENORM’s bioavailability, leachability, and radon emanation rates in our assessments of the effects of exposure to TENORM (p.245). The NAS noted the potential importance of these factors in developing TENORM guidelines, and urged us to study them further in order to understand them better (p.245). The Agency is considering these factors, and many others, in our field studies and risk assessment modeling discussed above. EPA will also take them into account its future efforts in to determine how best to address that risks associated with TENORM.

Recommendation: EPA’S RISK ASSESSMENTS SHOULD INCLUDE CONSIDERATION OF EXPOSURE TO NON-RADIOACTIVE CHEMICAL AGENTS

EPA Response:

The NAS Committee urged EPA to include in our analysis of risks from exposure to TENORM the effects of the hazardous chemical agents commonly found in combination with TENORM. The development of an understanding of the relationship of the risks posed by mixed hazardous and radioactive wastes is one of the most complex and difficult issues facing the Agency as it tries to address the combined risks to human health and the environment from both radioactive and hazardous materials and wastes. Despite the difficulties associated with always achieving risk harmonization, it is a particularly desirable objective in the TENORM arena because many TENORM-containing wastes are, or have the potential to be, mixed wastes.¹³

Complete harmonization of the risks from hazardous and radioactive substances is particularly difficult to achieve under some statutes. For example, the Atomic Energy Act (AEA)¹⁴ authorizes EPA to establish generally applicable standards to protect human health and environment that are based on dose limits or calculations of risk. In contrast, the statute that regulates hazardous wastes, the Resource Conservation and Recovery Act (RCRA)¹⁵, uses either a technology-based, a risk-based or a dose-based, approach to hazardous waste management depending on the situation. Because of these differences in the statutory approaches to protection of human health and the environment, it is extremely difficult to make direct comparisons of the relative protection these statutes and their associated regulations provide. However, under other EPA statutes, risks have been harmonized between TENORM and chemicals. The CERCLA and SDWA address TENORM within the same risk management scheme as chemicals, thus accomplishing risk harmonization. The Agency will continue to work on identifying and resolving differences in chemical and radiation risk assessment and management.

Recommendation: BECAUSE FEDERAL REGULATION OF TENORM IS FRAGMENTARY, GUIDANCE FOR TENORM SHOULD FOCUS ON SPECIFIC PROCESSES; INDUSTRIES; WASTE

¹³ Mixed wastes are wastes that contain both hazardous and radioactive constituents.

¹⁴ 42 U.S.C. §§ 2011-2296 (1994). The radioactive materials subject to regulation under the AEA include source material, and byproduct material. The definition of “TENORM” used by the Committee in the Evaluation specifically excludes AEA-regulated materials. (p.19)

¹⁵ 42 U.S.C. §§ 6901-6992k (1994).

CHARACTERISTICS; AND SCIENCE, POLICY, AND SITES

EPA Response:

The NAS Committee expressed concern that there are no standards that cover all exposure situations that involve TENORM, instead there is a patchwork of inconsistent state and federal regulations. The Committee also expressed concern that the current fragmented federal regulatory framework does not completely cover some important sources of exposure to radiation from TENORM (p.246).

Despite its concerns regarding the fragmented nature of current federal regulation of TENORM, the NAS Committee recognized that development and implementation of a single, uniform national standard would be difficult and should not be expected (p.10). As discussed above, the NAS Committee noted that, although a uniform national standard for TENORM exposure is desirable in order to achieve complete protection from TENORM- related hazards, development of such a standard probably is not possible for a variety of reasons, including differences in statutory and judicial mandates, the primary bases for guidelines, guideline applicability (because of the tremendous variations in the potential sources and forms of TENORM), the population groups of primary concern, and the consideration of the varying levels of natural background radiation (p.246). EPA agrees with the NAS Committee that, while a single uniform national standard for TENORM is desirable, it probably is impossible to craft such a standard because of the tremendous variations in the sources and physical forms of TENORM. Therefore the Agency has focused its efforts on identifying the most potentially problematic sources of the exposures from TENORM and responding accordingly to them.

Further, the NAS Committee advised against applying guidance created to address one specific situation to another situation: “*considerable caution is warranted in transferring standards expressed in terms of activity concentrations of radionuclides from one exposure situation to another.*” (p.231). The Committee also stated that it “*generally supports the idea that standards for different exposure situations should be consistent to the extent reasonable, particularly standards expressed in terms of risk or dose.*” (p. 231). The Committee “*strongly caution[ed] against generalizing numerical guidance derived for a specific situation to another situation with sufficient thought as to the applicability [of the numerical guidance] to the new circumstance*” (p.246). For this reason EPA believes that federal guidance or regulation on a source-specific basis is useful to ensure that consistent protection is provided across all states.¹⁶

¹⁶ The Conference of Radiation Control Program Directors (CRCPD) has issued model regulation which attempts to cover all TENORM. This approach departs from NAS recommendation. EPA believes it could lead to inconsistent regulation if states choose to modify the model regulation before adoption. EPA will continue to work with CRCPD and states to ensure consistent protection of human health.

EPA is addressing environmental problems relating to TENORM on a specific, rather than on a general basis. The Agency does not anticipate using single board approach for addressing all potential sources of exposure to TENORM. Rather, EPA anticipates taking a more focused approach to addressing environmental and public health concerns from discrete TENORM problems. As the NAS Committee suggested, there are several approaches EPA could take to address the potential public health problems associated with exposure to TENORM. Because of the tremendous diversity in the sources of potential exposure to TENORM, it may be appropriate for the Agency to address this potential exposure from several perspectives. Initially, EPA is developing technical scoping reports on TENORM that are industry or source specific. EPA may use these reports in the future to inform our TENORM policy.

EPA coordinates its radiation protection activities within 15 other federal agencies such as the NRC, the Department of Energy, and the Department of Health and Human Services on the Interagency Steering Committee on Radiation Standards (ISCORS). EPA will continue to coordinate its TENORM activities with other government agencies through the ISCORS TENORM Subcommittee, which EPA chairs.

Recommendation: EXPOSURE AND DOSE OR RISK ASSESSMENTS USED TO DEVELOP STANDARDS SHOULD BE REASONABLY REALISTIC

EPA Response:

The NAS Committee recommended that, in developing standards for exposure to the various types of TENORM, EPA should use exposure and dose risk assessments that are “reasonably realistic” (p.245). The Committee defined “reasonably realistic” as “*not..*

.intended to greatly overestimate or underestimate actual effects for the exposure situation of concern” (p.245).

EPA agrees with the Committee’s recommendations that TENORM risk assessments be “reasonably realistic.” For EPA, “reasonably realistic” assessments will include a range of potential exposure scenarios for the maximally exposed individual. EPA will document the choices that make for the exposures scenarios. EPA will consult with ISCORS on the development of “reasonably realistic” scenarios for exposure to radiation from TENORM.

Recommendation: THE USE OF STYLIZED METHODS OF EXPOSURE IS APPROPRIATE

EPA Response:

The NAS Committee stated that it is appropriate for us “*to develop stylized methods of exposure and dose risk assessments for assumed reference conditions, provided that the*

assumed conditions are reasonably representative of the exposure situations of concern” (p.245). Stylized methods of exposure are particularly useful in situations involving radionuclides because of the uncertainties involved with making projections of the probabilities of events’ occurrences over extremely long time periods. Typically, stylized methods of exposure utilize extreme scenarios. Despite this fact, however, the NAS determined that the use of such methods is appropriate in analyses of potential TENORM exposures. For example, TENORM contains some of the same long-lived level radioactive waste. These radionuclides will persist for the same amount of time in any amount of waste, regardless of their concentration levels. Therefore, as the NAS Committee stated, it is appropriate to utilize stylized methods of exposure as a means of predicting the effects of possible future human exposure to TENORM-containing materials.

EPA will follow the NAS Committee’s recommendation to use stylized methods of exposure for appropriate scenarios when EPA evaluates both the radiation hazards and potential disposal options for TENORM. EPA has experience using this approach in other projects involving the management of radioactive wastes; however, the Agency also is committed to examining TENORM issues on an individualized basis by waste or product.

Recommendation: IT IS REASON TO TRUNCATE RISK ASSESSMENT IN TIME

EPA Response:

The NAS Committee concluded that, though there are arguments both for and against EPA’s current practice of setting an outer limit on time frames for risk assessments, it is reasonable for EPA to set such limits *“for the purposes of establishing standards and demonstrating compliance”* (pp. 230-31). The Committee also concluded that the selection of an appropriate time at which to truncate risk assessments is *“largely a matter of judgement”* involving *“a considerable degree of arbitrariness,”* the existence of which the regulatory agencies should acknowledge (p.231).

The Committee recommended that *“calculations of future risks should be carried out at least to the time of maximum projected effects, regardless of when they occur, even if the results are not used in establishing standards or in demonstrating compliance”* (p.231). The Committee concluded that *“presentation of the full range of information about future risks should add value to risk assessment, even if not all the information is used in decision-making”* (p.231).

EPA agrees that both technical and policy considerations can be the basis for time frames used to set standards or judge compliance. The Agency also agrees that information may be gained by extending risk assessments. This information sometimes is useful in exploring options, even if the information is not used directly in setting standards.

EPA Approach To TENORM

TENORM is particularly challenging problem because many industries generate it in varying amounts. Moreover, generation of TENORM occurs in a wide variety of materials and locations. Although EPA and others already have learned much about TENORM, we still do not understand fully all the potential radiation risks it presents to humans and the environment. EPA will continue to better understand the potential problems associated with TENORM and to develop effective ways to protect humans and environment from harmful exposure to the radiation in these materials.

EPA's TENORM strategy focuses on developing a program to address the diversity of TENORM's physical and chemical forms, and the issues associated with regulating these materials. We envision that this comprehensive strategy will enable EPA to effectively identify and address the most important issues concerning TENORM exposure. Of course, execution of this strategy is subject to the availability of resources.

EPA is pursuing a for-pronged approach to the problem.

1. Study and report on TENORM sources to determine what's in the wastes and how much risk the waste pose.

EPA is studying TENORM sources in the United States to learn which aspects of the problem, including health and environment risks, are unique to a given source and which are common across all sources. The results of these studies will appear as a series of reports on individual sources. Each report will contain information on the:

- generation of TENORM by source;
- volumes of the TENORM generated annually, and unreclaimed volumes;
- physical and chemical characteristics of the TENORM;
- ways that people could be exposed to specific TENORM sources;
- potential effects of exposure to TENORM
- how the sources are handled or disposed of;
- current guidelines or regulations; and
- ways the sites are reclaimed for safety and radiation protection.

This effort will result in a source-by-source synthesis of all the currently available information on TENORM. As the NAS Committee recommended, these source-specific reports will document TENORM's physical and chemical forms and disposal options. The reports also will discuss the influence of background radiation on the analysis of TENORM.

2. Identify and study existing TENORM sites to assemble a nation-wide view of the potential problems associated with TENORM: where the wastes are, what's in them, and the risks they present.

This effort consists of a variety of field projects that will give EPA more information on the sources, characteristics and risks of TENORM. These field projects will expand knowledge of

TENORM uses and disposal and the physical and chemical characteristics of the TENORM. In addition, the field projects will establish contacts between EPA and individuals who produce or manage TENORM industries, wastes, and products.

3. **Develop and provide education and guidance for safely and economically cleaning up and disposing of TENORM wastes.**

EPA will provide guidance to those who deal with TENORM cleanup and disposal problems.

Studies of existing TENORM sites will give us information we need to select appropriate methods for estimating risks from these sites, the best ways to clean up the sites, and the most economical ways to dispose of the TENORM.

On the basis of technical scoping reports on TENORM wastes and products, as well as stakeholder meetings, public hearings, and other mechanisms, EPA will identify the principal

problems and issues for each source of TENORM. Using this information, we will make decisions on the most appropriate response to TENORM-related exposures. These responses could range from developing industry and public oriented educational materials on radiation protection from TENORM hazards; to developing guidance; to promulgating regulations, if necessary, for providing for safe and economically viable means to treat and dispose of the wastes.

4. **Work with other organizations that are confronting the problem of TENORM, including states, tribes, other federal agencies, industry and environmental groups, and international organizations.**

Because of the variety of TENORM sources and exposure scenarios, working with a variety of organizations is integral to EPA's TENORM strategy. EPA is focusing on coordinating TENORM activities with states, tribes, federal agencies, industry, environmental, and international organizations to enhance data and information sharing, to combine TENORM resources, and to avoid duplicative efforts.

EPA already is building the foundation for working with these groups through a variety of ongoing projects. As a result of these projects, EPA recognizes the need for community education on radiation exposure. For example, a need for education on radiation exposure has also been identified by Navajo community leaders and educators. Both EPA and the Navajo community agree that children and adults need to be aware of the hazards from living and working near contaminated uranium mining sites. These communities all want to know how to minimize their exposure.

EPA also is working with other federal agencies through the NORM Subcommittee of the Interagency Steering Committee on Radiation Standards, to develop guidance and disposal options for TENORM. Agencies also work directly together, outside the ISCORS framework, on specific issues. For example, on March 19, 2000, the NRC required its staff to initiate discussions with EPA and the

States to assess their willingness to assume responsibilities for regulating materials containing less than 0.05% uranium and/or throrium (SECY-99-259). EPA will continue to engage directly with appropriate Federal agencies when addressing a specific source of TENORM.

Working with these organizations from the beginning will help EPA develop the appropriate public education, guidance, regulations and disposal options for TENORM. Input from these groups from problem identification to education and solutions will be essential to the success of any TENORM strategy.

Conclusions

In summary, the NAS Committee found that there are differences in TENORM guidelines among federal agencies and others. The Committee found that those differences in guidelines represent differences in policies for risk management rather than differences in the technical evaluation of TENORM (p. 243). EPA intends to incorporate most of the recommendations of the NAS Committee.

Although the NAS Committee found that most of the relevant and appropriate scientific information has already been incorporated into current TENORM guidelines, many of the Committee's recommendations point to areas where new information would be useful. For example, the Committee recommended further investigation of the varying chemical and physical forms of TENORM, and the development of better techniques to distinguish discrete TENORM levels from background radiation levels. As noted previously, EPA is already working in many of the areas the Committee cited for additional technical information.

EPA recognizes that there are differences in TENORM regulations and guidance documents among organizations. EPA intends to take into consideration the significance of TENORM risks to the public and the environment to determine which TENORM wastes should be addressed first and what actions, if any, should be taken in response to the potential risks. EPA is working in virtually all areas of the NAS Committee's recommendations. In areas where EPA is not currently engaged, the Agency acknowledges the recommendations of the NAS. EPA will consult, as appropriate, with federal, state and other organizations involved with radiation protection issues as we progress toward TENORM solutions.

Appendix A - Table 1, TENORM Materials and References

As a comparison to background levels, radium 226 concentrations in soils of the U.S. are shown at the top of the table.

TENORM Material	Range of Radioactivity Concentrations, Radium 226		
	Low	Average	High
<u>Soils of the United States</u> ¹	0.2	1.1	4.2
Uranium Mining Overburden ²	3	3.0	low hundreds
Uranium In-Situ Leach Evaporation Pond Solids ³	300	-	3,000
Phosphate Ore (Florida) ⁴	7	17.3-39.5	6.2-53.5
Phosphogypsum ⁵		11.7-24.5	36.7
Phosphate Fertilizer ⁶		5.7	21
Coal Ash ⁷ -Bottom Ash	1.6	3.5-4.6	7.7
Fly Ash	2	5.8	9.7
Petroleum (oil and gas)	0.1 pCi/l	-	9000 pCi/l
Produced Water ⁸	<0.25 pCi/g	<200 pCi/g	>100,000
Pipe/Tank Scale ⁹			pCi/g
Water Treatment Sludge ¹⁰	1.3 pCi/l	11 pCi/l	11,686 pCi/l
Treatment Plant Filters ¹¹	-	40,000 pCi/g	-
Rare Earths ¹²	5.7	-	3,244
Monazite			
Xenotime			
Bastnasite			
Titanium Ores ¹³	3.9	8.0	24.5
Rutile	-	19.7	-
Ilmenite	-	5.7	-
Wastes	-	12	-
Zircon ¹⁴	-	68	-
Wastes	87	-	1300
Aluminum ¹⁵ (Bauxite) Ores	4.4	-	7.4
Product	-	0.23	-
Wastes	-	3.9-5.6	-
Copper Wastes ¹⁶	0.7	12	82.6
Geothermal Energy Waste Scales ¹⁷	10	132	254

- Indicates data are not available

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