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March 11, 1994

Mr. Samuel J. Chilk
Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Re: Staff Draft Radiological Criteria for Decommissioning

Dear Mr. Chilk:

The American Mining Congress hereby submits to the docket its comments on the staff's January 26, 1994 draft notice on radiological criteria for the decommissioning of NRC-licensed facilities.

Yours very truly,

James E. Gilchrist

James E. Gilchrist
Vice President

Enclosure

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AMERICAN MINING CONGRESS

COMMENTS ON

THE NUCLEAR REGULATORY COMMISSION'S STAFF DRAFT RADIOLOGICAL CRITERIA FOR DECOMMISSIONING

March 11, 1994

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I. INTRODUCTION

The American Mining Congress (AMC) respectfully submits these comments on the Nuclear Regulatory Commission's (NRC's) January 26, 1994 "staff draft" (DRAFT) regarding radiological criteria for the decommissioning of NRC-licensed facilities. This DRAFT is part of NRC's enhanced participatory rulemaking process on decommissioning. AMC has submitted comments on NRC's Rulemaking Issues Paper on the potential criteria for residual radioactivity, on the Commission's notice of intent to prepare a Generic Environmental Impact Statement (GEIS) in conjunction with the development of the radiological criteria for decommissioning, and on NRC's related proposed rule on timeliness in decommissioning.[1/] In addition, AMC has participated in a number of the workshops related to the development of the draft criteria. AMC appreciates this opportunity to comment on the DRAFT.

While AMC supports NRC's efforts to develop radiological criteria for decommissioning, AMC is deeply troubled and concerned by several aspects of the draft criteria and urges the staff to modify the DRAFT substantially prior to preparing and

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1/ These comments specifically incorporate by reference AMC's comments filed with the Commission on the Rulemaking Issues Paper (June 28, 1993), the comments on the timeliness in decommissioning of materials facilities (April 19, 1993), and the comments on the GEIS (September 20, 1993). These comments also specifically incorporate by reference AMC's enclosed comments (Attachment A) in response to the Environmental Protection Agency's (EPA's) Advance Notice of Proposed Rulemaking for Radiation Site Cleanup Regulations (December 21, 1993).

publishing it as a formal proposed rule. AMC's main points of concern are:

- The draft proposal represents a political compromise whose potential benefits and costs cannot be justified in practical ("real world") terms.

- The decommissioning criteria should not contain a risk goal but rather provide a scientifically sound risk limit that in conjunction with ALARA (as low as reasonably achievable) adequately protects public health and the environment from significant potential adverse risks.

- The draft proposal has failed to consider ubiquitous naturally occurring radionuclides differently than man-made radionuclides.

- The draft proposed risk goal of 3 millirem per year (mrem/yr) and the risk limit of 15 mrem/yr are arbitrary and not based on sound scientific or regulatory policy. A risk goal (the "de facto" limit) that reduces concentrations of radionuclides which contribute to residual radioactivity at a site to a level that is indistinguishable from natural background levels is unnecessary for adequate protection of public health and unworkable. The decommissioning criteria should address only potentially significant incremental exposures above background.

- The draft proposal does not provide assurances that finality in the decommissioning process will be reached in a timely or reasonable fashion, if at all.

- There are inadequate explanations given and bold assertions made throughout the DRAFT. The DRAFT fails to adequately explain, support or justify the proposed criteria.

As a preliminary matter, AMC has found it extremely difficult to comment on the DRAFT without having an opportunity to review the analytical approach and findings in the Generic Environmental Impact Statement (GEIS) or the regulatory guidance NRC

intends to issue on the decommissioning criteria. The Commission is seeking comments on a document that appears to rely on a GEIS for many of its conclusions and that claims compliance with the proposed criteria will be achievable through regulatory guidance, none of which are available to the affected parties. Additionally, the summary of workshop comments (NUREG/CR-6156) was basically unavailable from the time the DRAFT was received by AMC until one week before the March 11 date that comments are due. Moreover, given the complexities and importance of the issues associated with the proposed decommissioning criteria, AMC requests that the staff extend this informal comment period on the DRAFT to give interested parties sufficient time to comment in a more meaningful fashion.

AMC is a national trade association representing: (1) producers of most of the United States' metals, uranium, coal and industrial and agricultural minerals; (2) manufacturers of mining and mineral processing machinery equipment and supplies; and (3) engineering and consulting firms and financial institutions that serve the mining industry. Many of AMC's member companies will be significantly and directly affected by the radiological criteria for decommissioning developed by NRC. As presently drafted, the criteria would be specifically applicable to uranium mills and related surface facilities (other than tailings piles) and in situ leach (ISL) facilities.

These comments first discuss AMC's general concerns with the staff's draft criteria followed by specific comments on the DRAFT. In the foreword to the DRAFT, Dr. Cool states that "this document is still under active consideration, and has not been reviewed or approved by the Commission." In light of this statement, AMC strongly urges the staff to reconsider several key elements of the DRAFT before preparing and publishing it as a formal proposed rule.

II. GENERAL COMMENTS

As an initial matter, the DRAFT appears to be a prime example of a classic political compromise.[2/] Earlier in the enhanced participatory rulemaking process, NRC proposed four approaches to developing decommissioning criteria: (1) risk limit in conjunction with ALARA (as low as is reasonably achievable)), (2) risk goals, (3) best effort (best available control technology), and (4) return to background. In an apparent attempt to please everyone the draft proposal adopts three of these four approaches (leaving out only best effort). In practical terms, however, the proposal may have negative implications for site decommissioning.

2/ In the DRAFT NRC notes several commenters suggested that NRC's radiological criteria be consistent with the advice of expert scientific organizations and that one commenter suggested "NRC should determine whether the standards are to be technologically-based or politically-based; if the latter don't waste time on technological input." (pp. 15-16). AMC is concerned that NRC has allowed the politics to shunt aside sound scientific and technological policies and methods.

Given that the staff admits throughout the DRAFT that the risk goal and risk limit it has selected may be very difficult to achieve, this draft proposal could result in assuring that complex sites are never finally and fully decommissioned.

This fundamental problem with the proposal can be seen in the DRAFT's struggle to clearly explain its choices and to address substantive comments by participants in the process. As a result, in many key areas of the DRAFT, the reader is left to ponder what exactly NRC means by a statement or requirement or what the basis for the statement or requirement might be.

The following discusses several of the central elements to the DRAFT that AMC strongly believes need to be clearly addressed and modified in the next draft of the proposed criteria.

A. Exemption For Uranium Mills And Other Uranium Recovery Facilities

The DRAFT states that the disposal of uranium mill tailings will not be covered by the decommissioning criteria. AMC requests that in addition NRC exempt uranium mills and ISL facilities from the decommissioning criteria. Conventional mills and ISL facilities are already subject to comprehensive regulation during active operations, standby periods, and closure. See 10 C.F.R. Pt. 40 and Appendix A. The licensing standards of 10 C.F.R. Pt. 40 and Appendix A provide an ample margin of safety in protecting public health and the environment. These existing

decommissioning regulations establish specific standards for cleanup of land and buildings contaminated with residual radioactive materials from inactive uranium processing sites and establish specific allowable residual gamma radiation levels. For example, criterion 5A-5D and criterion 13 of Appendix A provide standards for control of groundwater contamination from uranium production operations; criterion 6 addresses longevity and control of radium in soil concentrations above background levels; criterion 9 requires financial surety; criterion 11 focuses on site and by-product material ownership; and criteria 10 and 12 address long-term site surveillance and monitoring. The operating and closure decisions for uranium mill and ISL facilities are highly licensee-specific and site-specific.

Additional decommissioning criteria would be unnecessary and may even be counterproductive. For example, the DRAFT would require removal of all "readily removable residual radioactivity from the site before it is decommissioned." (p. 55) This could conceivably include equipment, structures and portions thereof that the licensee intends to bury in the mill tailings pile during the decommissioning process. Moreover, if the licensee had already buried such materials in the tailings pile the DRAFT could be interpreted to require removal of such previously buried radioactive wastes prior to decommissioning the site. (p. 56) At uranium mill facilities the radioactive mill material is put into tailing piles. This proposed removal requirement and its

obviously inappropriate application to uranium mills demonstrate yet another reason why uranium production facilities should be exempt from NRC's generally applicable decommissioning criteria.

B. Risk Goal Approach

AMC has long suggested the use of a risk limit approach in conjunction with the As Low As Reasonably Achievable (ALARA) policy. AMC, however, strongly opposes a risk goal approach in developing the decommissioning criteria. Such an approach adds an extra and unnecessary complication to the decommissioning decisionmaking process. Indeed, the "goal" is virtually certain to become the "de facto" limit. As AMC has noted in previous comments, where the goal is unreasonable (such as a low background level like 3 mrem), it tends to drive compliance to unreasonable and inordinately costly levels, effectively negating the application of ALARA. The more direct and better approach would be for NRC to set an appropriate limit and apply ALARA to that limit.

1. Natural Background Levels of Radiation

The DRAFT provides that "[t]he *Goal* for decommissioning a site is to reduce the concentration of each radionuclide which could contribute to residual radioactivity at the site to a level which is indistinguishable from background." (p. 39) Acknowledging that it may not be possible to achieve or measure such a level in all circumstances, the draft criteria would allow a

residual radioactivity level above natural background levels if it does not exceed 3 mrem/yr. This goal is in fact a return to background approach. As set forth below, such a goal (or approach) is unreasonable and unnecessary. As noted, it in turn drives the risk limit to unreasonably low levels, thereby resulting in an unrealistic "Polyanna wish list" approach to site closure limits.

In developing its criteria, AMC urges NRC to use an approach that is grounded in sound scientific policy rather than one that merely responds to wishful public perceptions, and one that takes appropriate account of the "real world" context in which such rules must operate. This means that in assessing appropriate levels of exposure, the regulatory focus can only be on significant incremental exposures above background or the variations therein since minor increments present minimal risks. In AMC's view, this point cannot be emphasized too strongly and should be consistently reflected in NRC's regulatory approach in developing decommissioning criteria.

The NRC DRAFT on decommissioning criteria notes that the Commission received comments recommending that NRC establish a limit within the variability of natural background radiation. The staff's sole response was that it "believes that the goal for decommissioning should be the return of the facility to levels approximating background." (p. 17) The staff do not address

AMC's prior comments that setting a standard within the variations of natural background is, as explained below, unnecessary, impractical and contrary to scientific principles. AMC's concern is scientifically sound and needs to be evaluated and addressed by NRC prior to formally noticing the proposed rule.

Indeed, at the outset, the 3 mrem/yr proposed goal needs to be put into context. A comparison of this radiation level to that an individual receives from sleeping in the same bed with another person demonstrates the almost frivolous nature of potential risk associated with the proposed goal 3 mrem/yr:

> Estimates of the annual dose received from a bed partner range from 3 mrem/y to 0.1 mrem/y. The 30-fold difference between the two estimates depends on a variety of assumptions, but a large factor is how closely the two people are assumed to sleep. It turns out that the difference is nearly the same as that from two people sleeping in an ordinary double bed as opposed to their sleeping in a king-size bed. The dose from sleeping in twin beds in the same room falls below those for a king-size bed and is highly dependent on how the beds are arranged; the dose from sleeping in separated twin beds might be as low as 0.05 mrem/y.[3/]

NRC's proposed "double bed" exposure level is trivial and does not represent significant risk to public health. Accordingly, the 3 mrem/yr goal cannot be sustained.

3/ John M. Matuszek, Low-Level Radioactive Waste Regulations: Science, Politics and Fear, Michael E. Burns, Ed., Lewis Publishers, Inc. 1988, Chelsea, Michigan, pp. 270-71 ("Low-Level Radioactive Waste Regulation").

Traditional analyses of radiation exposures in terms of radiation risks have always been assessed in comparison to natural background. Failure to consider natural background levels will result in serious overestimation of the effect of the particular radionuclide at issue. This concept is unfamiliar in a chemical risk paradigm, particularly for man-made chemicals, where natural background levels do not exist and the focus is on trace amounts of chemicals.

The concept of using natural background radiation levels to address appropriate radiation exposure limits is not new. In 1960, an ad hoc committee of the National Council on Radiation Protection and Measurements (NCRP), in examining the issue of controlling man-made (or enhanced) exposures of the public to radioactive materials, noted that "maximum permissible doses for the general population should be related to the average natural background level of radiations."[4/] The reasoning behind this approach begins with the premise that "the most pertinent information we have is the fact that, throughout all of human history, the environment has been providing a continuous, low dose-rate exposure."[5/] Because the human race has developed acceptably in

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4/ NCRP, Somatic Radiation Dose for the General Population (February 1960) ("Somatic Radiation Dose").

5/ Adler & Weinberg, Health Physics 7209 (1978). In BEIR V, the authors note that studies of populations chronically exposed to low-level radiation, such as those residing in

Footnote continued on next page.

such an environment, the risks of natural background are essentially accepted as a "normal factor of life."[6/] Indeed, "[t]here are regions of the world, in India and in Brazil, where natural background radiation is up to tenfold higher than usual (~ 1 rem/yr) and deleterious health effects have been looked for and not found. It should be appreciated that over 25 years, these exposures equal the acute exposures of the Hiroshima-Nagasaki survivors."[7/]

Since, in the course of human existence no statistically discernible adverse health effects have been associated with background radiation or its variations (which may be comparable in magnitude with the average background), "the effects of increments in dose and dose rate are small compared to background fluctuations and will be small compared to an already undetectable level of effects."[8/] A recognized international organization on atomic energy has noted that "[a] level of dose which is

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regions of elevated natural background radiation, have not shown consistent or conclusive evidence of an associated increase in the risk of cancer." Committee on Biological Effects of Ionizing Radiations, "Health Effects of Exposure to Low Levels of Ionizing Radiation," (1990), p. 5 (emphasis added.)

6/ Somatic Radiation Dose For the General Population, p. 484.

7/ "Low-Level Radioactive Waste Regulation," p. 242.

8/ American Physical Society, Reviews of Modern Physics, Vol. 50, p. S72 (1978).

small in comparison to natural background can be regarded as trivial."[9/] The greater the increment to background levels, accordingly, the less the confidence that any effects will be similarly indiscernible and therefore tolerable.

Recently, EPA's Science Advisory Board (SAB) issued a report noting that it is unfortunate and unsound that radiation risks and risks from chemical contaminants are often treated identically.[10/] Average background exposure to radiation is approximately 100 mrem per year exclusive of radon and, if this exposure rate were "calculated with EPA's current risk coefficient for radiation carcinogenesis . . . [it would predict] cancer risks of almost 3 in a thousand." Id. at 4. Consequently, as pointed out by the SAB, traditional radiation risk assessment paradigms implicitly or explicitly account for natural background and seek to regulate the potential incremental excess cancer risk above that from background and the variations therein. Id.

Use of a chemical risk paradigm to regulate radiation exposure is not appropriate for radiation control programs because this paradigm evolved at least in part from the assumption that exposure to man-made chemicals could be eliminated

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9/ International Atomic Energy Agency, Vienna (IAEA), Technical Reports Series No. 334, p. 3 (1992) ("IAEA Report").

10/ SAB, Harmonizing Chemical and Radiation Risk-Reduction Strategies - A Science Advisory Board Commentary (May 18, 1992).

entirely. According to the SAB, "[t]he application of standard chemical risk reduction criteria to radionuclides in these situations leads to limitations on excess radiation doses that are small in comparison to natural background radiation . . . [i]t should come as no surprise that some radiation scientists see such limitations on radiation exposures as unworkable or even misguided."[11/]

It is important that the potential health risks from radiation be addressed in a different fashion than potential chemical carcinogens given the levels of naturally occurring radiation to which the public is routinely exposed.[12/]

2. Linear Non-Threshold Concept vs. Radiation Risk Paradigm

The DRAFT states that "[i]n the absence of convincing evidence that there is a dose threshold or that low levels of radiation are beneficial, the Commission believes that the assumptions regarding a linear nonthreshold dose-effect model for cancers and genetic effects and the existence of thresholds only for certain nonstochastic effects are prudent for formulating radiation protection standards and planning radiation protection

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11/ Harmonizing Chemical and Radiation Risk Strategies, p. 1.

12/ Somatic Radiation Dose For the General Population, p. 484. The NRC DRAFT states that "the Commission agrees . . . that, as a guiding principle, radiation protection standards do not warrant different treatment than those for other health issues." (p.30) As seen from the foregoing discussion, this statement is misguided and susceptible to misinterpretation.

programs." (p. 17) This statement is made without any explanation and may mislead the general public about what the linear-nonthreshold assumption means and does not mean. This is a classic example of the frequent failure of the presumed "expert" agency to explain its meaning in a fashion that will lead to general public understanding.

The linear non-threshold theory evolved after World War II when regulatory bodies went from basing radiation protection on a "tolerance dose" -- "a dose below which there were believed to be no harmful effects of radiation," to the "no-threshold" concept.[13/] It has been explained that

> [t]he basis for the changeover was philosophical rather than scientific, in that it was not based on epidemiologic or experimental data that reliably demonstrated that there was increased carcinogenesis at low doses delivered at low dose rates. Rather, it was a consequence of the development of highly sensitive radiation detection equipment and the establishment of health physics programs in the Manhattan Project during World War II which made practical the establishment of guidelines that would not have been possible when exposures were only roughly evaluated, as had been done previously, on the basis of skin erythema doses. Id.

By proposing risk goals within the lower range of natural background levels the staff is essentially relying on the policy assumption that there is no threshold below which exposure to residual radiation does not pose some health risk. The linear

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13/ Rosalyn Yalow, "Low-Level Radioactive Waste Regulation," pp. 239-40.

nonthreshold theory is widely accepted in the scientific community as an appropriate analytical method for estimating the upper bound of radiation risk. However, the scientific community has repeatedly warned against using the linear nonthreshold theory as a substitute for judgment. As NCRP has stated:

> The NCRP wishes to caution governmental policymaking agencies of the unreasonableness of interpreting or assuming "upper limit" estimates of carcinogenic risks at low radiation levels, derived by linear extrapolation from data obtained at high dose and dose rates, as actual risks, and of basing unduly restrictive policies on such an interpretation or assumption. The NCRP has always endeavored to insure public awareness of the hazards of ionizing radiation, but it has been equally determined to insure that such hazards are not greatly overestimated. Undue concern, as well as carelessness with regard to radiation hazards, is considered detrimental to the public interest.[14/] (Emphasis Added)

The D.C. Circuit has stated:

> "This method [linear extrapolation] . . . will show some risk at every level because of the rules of arithmetic rather than because of any knowledge. In fact the risk at a certain point on the extrapolated line may have no relationship to reality; there is no particular reason to think that the actual line of the incidence of harm is represented by a straight line." Natural Resources Defense Council Inc. v. EPA, 824 F.2d 1146 (D.C. Cir. 1987).

NRC needs to acknowledge and explain to the public at large that the lower bound for estimating radiation risk under the linear

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14/ NCRP, "Review of the Current State of Radiation Protection Philosophy," Report No. 43 (1975), p. 4.

non-threshold assumption may be zero.[15/] As noted previously, there has been no direct evidence of adverse public health impacts from background radiation, even in areas where levels are significantly elevated above those experienced by the average member of the American public.

Essentially, the linear non-threshold model drives the regulatory goal down towards zero and fails to acknowledge the negligible risks associated with such low (3 mrem/yr) doses of radiation. The NCRP has established an annual effective dose above background of 0.01 MSV as a Negligible Individual Dose (NID) per source or practice.[16/] The NID is based on the Negligible Individual Risk Level (NIRL) which is defined "as the level of average annual excess risk of fatal health effects attributable to radiation below which efforts to reduce radiation exposure to the individual is unwarranted." Id. The NID/NIRL of 0.01 is equivalent to 1 mrem/yr. NCRP explained:

> In deriving the recommended value of the NIRL, several criteria relevant to the low level of risk or triviality of risk were considered which, taken together, offer degrees of reasonableness and perspective that tend to minimize subjective aspects of judgment. Smallness of risk was considered in relation to:

15/ BEIR V notes that "the possibility that there may be no risks from exposures comparable to external natural background radiation cannot be ruled out. At such low doses and dose rates, it must be acknowledged that the lower limit of the range of uncertainty in the risk estimates extends to zero." BEIR V, p.181.

16/ NCRP, Limitation of Exposure to Ionizing Radiation, NCRP Report No. 116, March 1993, pp.51-52.

(1) magnitude of dose,

(2) difficulty in detection and measurement of dose and health effects,

(3) natural risk for the same health effects,

(4) estimated risk for the mean and variance of natural background radiation exposure levels,

(5) risks to which people are accustomed and

(6) perception of, and behavioral response to, risk levels. Id.

NRC's draft risk goal is only 2 mrem/yr above the NID which is considered to be a trivial level to which one does not even apply ALARA.

Any NRC regulatory limits (or goals) should address only potentially significant incremental exposures. As Dr. Warren Sinclair, former President of NCRP, has testified, "[y]ou don't try to set standards within variations of natural background."[17/] To do so ignores the radiation risk paradigm (i.e., address only significant increments to background) because there is no demonstrable risk from background and, therefore, none from essentially equivalent levels. As NRC moves forward, it must focus on potential risks that are based on significant increments to natural background and variations

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17/ Transcript of April 28-29, 1983, Hearings before the Procurement and Military Nuclear Systems Subcommittee of the House Committee on Army Services, 97th Cong. 2d. Sess., p. 255.

therein. To do otherwise ignores basic and well accepted scientific principles.

Indeed, the staff concedes that, as a practical matter, it does not make sense to set a risk goal within the variations of natural background levels of radiation. The DRAFT states:

> "[I]nformation obtained by the NRC staff from its GEIS studies indicate that the general trend for typical NRC licensed facilities is for remediation costs to rise rapidly when attempting to reduce doses from residual radioactivity in the vicinity of 3 mrem/yr. However, when all risks to the public including those from transportation and waste disposal are considered there is not a commensurate reduction in risk." (p.45)

Elsewhere, in discussing radon, the DRAFT states:

> "[T]he Commission believes that it is not possible using current technology to measure or distinguish concentrations of radon which will produce radiation doses of a few mrem TEDE/y above background. This believe [sic] is based on (1) recognition of the ubiquitous nature of radon in the general environment, (2) large uncertainties in the models used to project radon concentrations in indoor air based on soil concentrations, and (3) limitations of existing measurement techniques in distinguishing between elevated radon concentrations and radon attributed to natural sources." (p.36)18/

The conclusion from these statements is that NRC should not set a limit (de facto or otherwise) in the lower range of natural

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18/ Radon is a dominant contributor to natural background exposure. The NCRP (Report No. 94) estimates an annual average radon dose to the U.S. population of about 2 mSv/year (200 mrem/year). This is primarily due to background soil containing about 1 pCi/g of radium-226. Therefore, to meet a goal of 15 mrem/year, the soil would have to contain 15/20 = 0.075 pCi/g radium-226, a ridiculously low level.

background and variations therein. This is particularly true where naturally occurring radionuclides are involved. For example, NRC states that it is not possible to measure or distinguish radon concentrations producing doses of a few mrem/yr above background in part because of "large uncertainties in the models used to project radon concentrations in indoor air based on soil concentrations." Yet in the next breath, NRC states that it will require licenses to reduce soil concentrations of radon's precursors. It is entirely nonsensical to acknowledge the standard will not work and then set it at a few mrem/yr anyway particularly with no demonstrable and significant public health threat to justify such a decision.

3. Questionable Basis for Draft Criteria

NRC has failed to explain in the DRAFT what its "legal" basis is for setting such an unrealistically low risk goal (and subsequent risk limit). As a general guiding principle, regulatory bodies do not concern themselves with trivial matters. The D.C. Circuit has recognized that in our society decisions about the acceptability of risk are in most cases the result of a balancing judgment, not the application of a "bright line." Thus, this threshold judgment must determine what risks are acceptable "in the world in which we live." Natural Resources Defense Counsel v. EPA, 824 F.2d 1146 (D.C. Cir. 1987) ("Vinyl Chloride" decision). NRC's risk goal approach is not based on such sound analysis. The proposed criteria move away from the idea, as the Supreme Court said in the "Benzene" decision, that

agencies should be regulating "significant" risks. Industrial Union Dept. AFL-CIO v. American Petroleum Institute, 448 U.S. 607 (1980). In rejecting OSHA's arguments, the Court noted that "in light of the fact that there are literally thousands of substances used in the workplace that have been identified as carcinogens or suspect carcinogens, the government's theory would give OSHA power to impose enormous costs that might produce little, if any, discernible benefit." Id. at 645. NRC has failed to explain why it is addressing trivial rather than potentially significant incremental levels above naturally occurring radiation levels. Merely relying on the linear nonthreshold assumption that there is "some" risk down to zero exposure is not legally sufficient basis for NEC's defaults risk limit of 3 mrem/y.

Moreover, it is entirely unclear how NRC determined that the risk goal should be 3 mrem/yr. The DRAFT merely states "[t]hree millirem per year was selected because it is a small fraction of the 15 mrem/yr limit, is comparable to local variations in dose from background radiation, and is substantially smaller than national variations in dose from background radiation." (p.45) This statement does not provide an adequate explanation. Where did this number come from? It appears to be an entirely arbitrary level pulled out of nowhere.

4. Naturally Occurring Radionuclides vs. Man-made Radionuclides

It is imperative that NRC distinguish as a general matter between man-made radionuclides and naturally occurring radionuclides, particularly if the Commission ultimately determines to follow the

ill-advised proposal to set a cleanup goal in the lower ranges of natural background. Radioactive wastes are, and have been, regularly classified in different ways and there is no reason not to classify such wastes as man-made versus naturally occurring to inject a critical real world distinction into site cleanup evaluations.

NRC failed to distinguish between man-made and naturally occurring radionuclides in establishing the 10 C.F.R. Part 20 limits. As a result, it set a limit for radon that is totally unrealistic to comply with and impossible to measure. NRC had to make some hurried and not altogether intelligible adjustments, including a "generic adjustment factor," for licensees to demonstrate compliance with the 0.1 pCi/l concentration limit for radon at the restricted area boundary line. NRC was forced to recognize that the necessity for, and frequency of, changes, if any, in any site's generic adjustment factor would be a highly site-specific matter. Thus, in some senses the Part 20 limits for naturally occurring radionuclides have of necessity led to regulation by exemption. As a practical matter, NRC must not make the same mistake in establishing the decommissioning criteria, but instead must account for different treatment of naturally occurring radionuclides in its final criteria, particularly if the return to background goal remains a focus of NEC's decommissioning criteria.

Naturally occurring radionuclides are ubiquitous in the environment. Radiation exposure is, has been, and always will be unavoidable. Radiation exposure comes from cosmic sources, the

earth's surface and human activities such as medical practices, tilling of soils, combustion of carbon-based fuels, use of groundwater and construction. The concept that any radiation is harmful ignores the reality that radiation is pervasive in the environment including our own bodies. NRC's decommissioning criteria need to acknowledge this and focus on significant incremental doses to natural background levels or variations therein, particularly where naturally occurring radionuclides are concerned. As AMC has explained at length in prior comments, a dose exposure limit cannot be set based on an application to insignificant background levels of naturally occurring radionuclides. Indeed, the Health Physics Society (HPS) ir finding a return to background approach scientifically unjustified notes that:

> [t]he important consideration should be the quantities and distributions of all radionuclides in the contaminated materials and the potential exposures to humans. Conditions that produce a distribution of radiation doses and risks to people within the normal range of natural background should be regarded as natural.19/

In a subsequent Position Paper ("Return to Background", HPS Newsletter February 1994, pp. 10-12), the HPS suggests that variations in background are typically 10 to 30 mrem/y (exclusive of radon).

19/ Health Physics Society, Position Statement on Radiation Standards for Cleanup and Restoration, p.6, May 28, 1993 (HPS Position Paper).

C. Risk Limit Approach

The DRAFT states that "[t]he Commission believes the dose limits and ALARA requirements of the proposed radiological criteria for decommissioning provide a reasonable basis for protection of public health and safety and the environment." (p.17) AMC agrees with this statement to the extent that such a risk (dose) limit approach alone (without a risk goal) can result in public health protective and cost effective solutions. A risk limit strategy reflects past and current NRC practice and essentially mirrors EPA's Clean Air Act radionuclide strategy.

AMC, however, strongly opposes the DRAFT's limit of 15 mrem/yr Total Effective Does Equivalent (TEDE) for residual radioactivity distinguishable from background. AMC continues to believe that the appropriate limit for the radiological criteria for decommissioning should be 100 mrem/yr with a 25 mrem/yr TEDE screening level for the critical group.

Nowhere in the DRAFT is an adequate explanation given for why a limit of 15 mem/yr was chosen. Again, NRC appears to be selecting a number at random. NRC merely states that a 15 mrem/yr standard is consistent with the risks of 10 C.F.R.

§ 61.41 and NRC practices but does not explain how this is the case.[20]

In most instances, the primary radiation exposure of concern will be from gamma radiation or alpha radiation, particularly with naturally occurring radionuclides. Gamma radiation requires close proximity to the source to create significant exposure. Alpha radiation requires ingestion or inhalation to create significant exposure At the typical environmental or occupational exposure levels being addressed by future site cleanup regulations, both gamma and alpha radiation require long-term exposure in order to create significant health effects.

Gamma radiation poses little significant potential for off-site effects. EPA has indicated that gamma exposures decrease by at least a factor of three from the center to the edge of a waste pile.[21] Furthermore, EPA also notes that the primary risk from such wastes is inhalation of radon, which poses risks approximately three orders of magnitude higher than risks from gamma exposures. Id. at D-3-1. Hence, as long as wastes do not migrate off-site and humans are prevented from remaining in

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20/ It should be noted that the ICRP recommends against the use of dose limits for setting clean-up criteria. "The use of these dose limits, or of any other pre-determined dose limits, as the basis for deciding on intervention [clean-up] might involve measures that would be out of all proportion to the benefit obtained." ICRP Publication 60 (1991), p.32.

21/ See EPA: Diffuse NORM - Waste Characterization and Preliminary Assessment (May 1993), p. D-B-14.

extremely close proximity to waste piles, there is little potential for off-site human health effects from gamma radiation.

With regard to alpha radiation, which requires ingestion or inhalation to create significant health effects, the primary path of exposure is through inhalation of the decay products of radon gas (radon daughters). The primary threat to health associated with radon comes not from breathing air containing radon itself, but from inhalation of radon daughters.[22/] Radon gas is inhaled and exhaled too quickly during human breathing to allow for decay to radon daughters.[23/]

The potential health hazard comes from the attachment of radon daughters to the lining of the bronchial epithelium, which subsequently results in that tissue being irradiated by the decaying radon daughters. The risk associated with this

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22/ NCRP, "Ionizing Radiation Exposure of the Population of the United States," Report No. 93, September 1, 1987, p. 12 (NCRP No. 93). As used hereafter, in referring to the risk from radon, AMC is actually referring to the risk from radon daughters, unless otherwise stated.

23/ Because of their short half-lives, the radon daughters rapidly approach radioactive equilibrium with their radon parent in close spaces. The daughters are said to have "grown" into radioactive equilibrium with the radon. This is an important observation because almost all of the radiation dose (and hence risk) to lung tissue arising from exposure to radon gas actually is from the radiation emitted by the short-lived daughters of radon rather than by the radon gas itself. Even at a very low radon daughter equilibrium factor of 0.1, the dose to the lung from radon daughters is more than 15 times the dose from radon. Nuclear Energy Agency, "Dosimetry Aspects of Exposure to Radon and Thorium Daughter Products," (Sept. 1983).

irradiation is based on long-term cumulative exposure.[24/] As NRC has noted, even the radiation exposure to the public from uranium mill tailings piles presents no acute health hazard because "long and sustained exposure to radioactivity in the tailings pile would be required to produce any significant chance of adverse effect."[25/]

Therefore, the greatest risk comes from long-term exposure to air in confined areas where radon has disintegrated to its daughter products. Id. As EPA has stated: "people need to be occupying a structure and not just standing outdoors" for radon health risks to be applicable. 48 Fed. Reg. 15,076, 15,083, (Apr. 6, 1983). Outdoor radon concentrations, such as those from a tailings pile, are limited by the fact that the radon that diffuses out of the ground is generally dispersed by air currents to low concentrations prior to undergoing its radioactive disintegration to radon daughters. As a result, external sources of radon, such as tailings piles, make relatively small contributions to public exposure, compared to sources that emit radon directly into buildings.[26/]

24/ NCRP No. 93 at 12.

25/ NRC, NUREG-0706, (Sept. 1980) NRC, Generic Environmental Impact Statement (GEIS) Vol. I, pp. 12-31 (emphasis added).

26/ Hurwitz, The Indoor Radiological Problem in Perspective, (Feb. 1981), pp. 5-6.

In fact, "the risk from radon emissions diminishes rapidly with distance from the tailings pile (declining by a factor of 3 for each doubling of the distance beyond a few hundred meters)"[27/] and "at distances of kilometer or more from tailings piles . . . the equilibrium of radon with its daughters is roughly the same as for radon in background air."[28/] For reasons such as this, "the health risks posed by exposures to radon from uranium mill tailings piles are trivial for the average U.S. citizen by virtually any measure." Id.

Thus, for naturally occurring radionuclides, the primary risks will be from radon daughter inhalation in dwellings or buildings built on top of contaminated areas, or in some limited cases, from external gamma exposure. Accordingly, where NRC can restrict or control access to prevent the construction of dwellings on such sites, there is little or no risk from either gamma or alpha exposure. Hence, NRC should recognize that the primary risk it needs to address in setting appropriate levels of protection is an on-site, rather than an off-site risk and that control of site access and use can play an extremely important role in meeting appropriate levels of protection.

27/ EPA, Final Environmental Impact statement for standards for the control of by-product materials from Warian Ore Processing, Sept. 1983, p. 10-12.

28/ National Academy of Sciences/National Research Council (NAS/NRC) Scientific Basis for Risk Assessment and Management of Uranium (1986), pp. 74, 165, 181.

In setting an appropriate level of protection for radiation (other than alpha radiation received from radon daughters), AMC believes that NRC should use its current limit of 100 mrem/yr TEDE[29/] to any member of the public, regardless of the pathway of exposure for above background levels from all man-made sources except radon. NRC has codified this limit at 10 C.F.R. 20.1301 and this approach has been endorsed by the American Nuclear Society which has stated that "this approach permits the site-specific situation to be evaluated with public protection assured."[30/]

In addition, AMC agrees with the recommendation of the HPS that "a compliance screening level of 25 mrem/yr [can] be applied to mean annual TEDE to the critical population group, defined as the most highly exposed homogeneous group affected by the restored site."[31/] Under this screening system, "[i]f the mean

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29/ AMC agrees with the Health Physics Society's explanation of TEDE: "For purposes of these recommendations, we use the term 'total effective does equivalent' (TEDE) adopted by the NRC (1991), which is the same quantity as the 'effective dose, defined by NCRP (1993); it is the sum over all tissues of the committed dose equivalent from penetrating external radiation and from intakes of radioactive materials. For site cleanup and restoration standards, we recommend that the dose limit be applied to all site-specific, nonoccupational sources, except "indoor radon, including natural radionuclides." (HPS Position Paper) p. 2.

30/ Comments of the American Nuclear Society on NRC's Proposed Radiological Criteria for Site Decommissioning (May 25, 1993).

31/ HPS Position Paper, p. 2.

annual TEDE to the critical group is likely to exceed 25 mrem, an evaluation should be made to ensure that no individual is likely to receive an annual TEDE exceeding 100 mrem (1 msv) from all site-specific, nonoccupational sources, excluding indoor radon." Id.

NRC presently considers a public radiation dose level of 100 mrem/yr to be an acceptable lifetime risk. See 10 C.F.R. § 20.1301 ("the total effective dose equivalent to individual members of the public from the licensed operation [shall] not exceed 0.1 mrem (1 msv) in a year.")[32/] This limit accounts for doses from all pathways and is consistent with the NCRP's recommendation and the recommendation of the International Commission on Radiological Protection (ICRP) that the annual effective radiation dose to the public should not exceed 100 mrem.[33/] Neither of these organizations suggest that general public dose limits should be set below 100 mrem/yr. Indeed, the risks from a 100 mrem/yr dose limit are consistent with the risks from naturally

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32/ Robert Bernero, Director of the Office Nuclear Material Safety and Safeguards, recently stated that when "push comes to shove 100 millirem a year to a member of the public is safe." Transcript of NRC public meeting on Briefing on Status of Efforts for Risk Harmonization, (May 26, 1993), p. 59.

33/ NCRP Report 116; ICRP, 1990 Recommendations of the International Commission on Radiological Protection, ICRP Pub. 60, ¶ 191, Nov. 1990.

occurring carcinogens.[34/] NCRP allows even higher levels in certain instances. For example, NCRP recommends an annual limit of 500 mrem for remediating NORM.[35/]

A 100 mrem/yr dose limit, however, is reasonable when compared to the limits set for a very specific activity - such as disposal of low level radioactive wastes - where it is likely that potentially highly active radioactive materials will be involved. See 10 C.F.R. Part 61 (Section 61.41 provides that "[c]oncentrations of radioactive material which may be released to the general environment in groundwater, surface water, air, soil, plants, or animals must not result in an annual dose exceeding an equivalent of 25 millirems to the whole body, 75 millirems to the thyroid, and 25 millirems to any other organ of any member of the public.") Thus 25 mrem/yr exposure limit to the public for a commercial low level radioactive waste disposal facility (which assumes restricted public access) is higher than the proposed limit of 15 mrem/yr (and the de facto limit of 3 mrem/yr) for the sites NRC will be regulating under its general decommissioning criteria. Most sites that will fall under NRC's general decommissioning criteria will not be commercial disposal

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34/ Kocher, D.C. and Hoffman, F.O., Regulating Environmental Carcinogens: Where Do We Draw the Line?, Environ. Sci. Technology, 25, No. 12, pp. 1986-91.

35/ NCRP Report 116.

facilities and likely will involve much lower levels of radioactivity.

AMC is aware that current EPA regulatory guidelines suggest a risk limit for excess cancer of one in ten thousand (10^{-4}) to one in one million (10^{-6}) and under some calculations, a 100 mrem/yr TEDE appears to reduce risks of excess cancer to approximately one in a thousand (10^{-3}).[36/] AMC believes that the application of ALARA, used in conjunction with a 100 mrem/yr TEDE and after consideration of natural background, results in substantially equivalent protection to a risk limit of 10^{-4} to 10^{-6}.[37/]

Indeed, in another context NRC appears to share this view by noting that with regard to these apparently differing standards "current information suggests that the level of protection achieved under both agencies' programs is comparable."[38/] In fact, establishing radiation site cleanup levels at the CERCLA risk levels of 10^{-4} to 10^{-6} would be inappropriate for many radiologically contaminated sites since this risk range would correspond to an external exposure rate of about 0.003 µR/hr to 0.3 µR/hr. This is about 0.06 to 6 percent of the natural

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36/ See e.g., supra, p. 11 (SAB comments regarding risk range of a 100 mrem/yr TEDE).

37/ NRC consistently fails to address this specific point in the DRAFT.

38/ NRC SEC'Y 93-134 (May 14, 1993), p. 7.

background levels from the external pathway alone. Thus, AMC believes that NRC should use the 100 mrem/yr TEDE level.

The draft criteria only allow a 100 mrem/yr limit as the "safety net" when the conditions for either unrestricted or restricted use cannot be met. NRC fails to explain why the 100 mrem/yr limit cannot be the primary standard. In practical terms, the draft NRC standard may result in a 100 mrem/yr limit for many complex sites or sites involving large amounts of contaminated material but only after huge expenditures of money without any significant discernible incremental benefit.

D. Finality

The DRAFT purports to seek finality in the decommissioning process, but as presently drafted no facility will have any assurance that NRC considers the decommissioning process completed. The DRAFT rightly acknowledges that "[u]ncertainty with future criteria and the potential need for additional remediation introduces havoc in the planning and conduct of effective decommissioning." (p.23) The DRAFT, however, leaves open the possibility that the decommissioning of a site may be reopened in the future if "there is reason to believe that residual radioactivity remaining at the site could result in significant public or environmental harm." (p. 22) (emphasis added). The DRAFT also provides that additional remedial action may be necessary in the future "if significant additional contamination is discovered at

a site." (p.23) The DRAFT further states that more remediation may be necessary "if the technical basis on which the criteria are founded changes significantly." (p.23) The DRAFT provides no explanation of what these criteria mean or examples of how they might be applied in the real world. What is NRC's definition of significant public harm? An extra millirem or two above the 15 mrem/y limit? Merely identifying significant additional contamination or a new technical basis for radiological criteria are not enough. NRC should not be able to reopen a decommissioned site unless it can be affirmatively demonstrated that the risk to public health is significant and there will a positive net benefit to do so.

Moreover, in the past, as NRC acknowledges with respect the Site Decommissioning Management Plan (SDMP) and other decommissioning programs, the Commission has reopened decisions. Facilities subject to the decommissioning criteria have no reason to believe that such action will not happen again in decommissioning activities, particularly in light of the "soft" finality criteria. Similarly, to the extent the draft criteria would cause decommissioned sites to undertake additional remedial activities, it directly contradicts to the DRAFT's assertion that the criteria "would not apply to sites already covered by a decommissioning plan approved by the Commission prior to the effective date of this rule." (p. 1) This inconsistency provides no assurances to regulated facilities.

E. Practicality Issues

The DRAFT fails to consider in a meaningful fashion the real world implications the criteria could have that would make implementation and enforcement enormously difficult. For example, NRC should bear in mind the potential role that treatment and control solutions may have in creating increased exposures for remediation workers and in generating additional amounts of waste. As NRC acknowledges in the DRAFT, requiring offsite disposal poses the possibility of worker and public exposure during loading and unloading and during transportation to a disposal site. Calculating the additional exposure potential from further treatment and storage of such materials should also be part of the analysis in considering levels and types of control. Given that the proposed 3 mrem/yr de facto limit is so low it is bound to create significant additional exposures requiring a more thorough net risk analysis by NRC than is in the DRAFT.

AMC believes that in considering practicality issues, NRC should adopt, in essence, the approach embodied in ALARA and to some lesser extent outlined in the D.C. Circuit's opinion in the Vinyl Chloride case. There, recognizing the necessity for cost effective solutions, the D.C. Circuit urged EPA first to define acceptable risks in the absence of cost considerations and to then look at economic factors in imposing specific control conditions. 824 F. 2d 1146 (D.C. Cir. 1987). A similar approach,

unconstrained by the statutory limitations of the Clean Air Act imposed in Vinyl Chloride, makes considerable sense in the radionuclide context as a means of first assessing health risk independent of cost considerations and then later balancing that risk against the costs of control and relevant socioeconomic factors to reach an overall risk/benefit determination. AMC urges NRC to discard the proposed specific risk goal and to use this traditional framework in the context at hand.

The DRAFT notes that NRC intends to issue specific guidance "for use by licensees who elect not to apply models to demonstrate compliance." (p. 32) It is not clear what the Commission is trying to do here. This statement seems to imply that, contrary to normal scientific principles, the use of models over actual measurements is the preferred means of demonstrating compliance. The problem, as NRC concedes, may be due to the fact that models will have to be relied on in most instances to demonstrate compliance under the criteria as presently drafted because it is enormously difficult to measure radionuclides levels within the low level variations of background involved -- particularly naturally occurring radionuclides. Moreover, it is not clear what are "sufficient" confirmatory measurements. This tremendous difficulty in measuring, which the staff acknowledges (see p. 18), demonstrates part of the practical problems with setting a risk goal within the lower range of variations in natural background radiation.

Moreover, the entire structure set up by the draft decommissioning criteria, in realistic terms, would not allow finality to the process to be reached in a timely or sensible fashion. If a facility plans to release the property for unrestricted use, it is faced with the virtually impossible and inordinately costly task of bringing radiation levels down into the lower range of variations in natural background. If a facility chooses instead to decommission the property for restricted use, it will be impossible to meet the 18-month timetable NRC has proposed in its timeliness in decommissioning rulemaking given the apparent scope of the tasks assigned to the Site Specific Advisory Board (SSAB) to oversee decommissioning of sites and enforcement of requirements. (pp. 22-23). By grafting an officially sanctioned group of "about" 10 additional individuals plus an ex officio NRC representative onto existing processes for public participation, NRC is building in inevitable time delays and significant additional costs. Although it is "anticipated" that the SSAB will be dissolved after termination of the license, as a practical matter, it is by no means certain that a SSAB will not take on a life of its own.

Finally, costs to reclaim a site must bear a reasonable relationship to the risks associated with a site. The criteria as presently drafted, however, would require huge expenditures of money that, in the end, may not achieve the 15 mrem/yr or 3 mrem/yr limits. As NRC is well aware, spending millions of

dollars to clean up a site to meet an arbitrary limit has worked quite poorly in EPA contexts, such as the CERCLA program. NRC should take heed of this experience in crafting its radiation site cleanup requirements.

F. Consistency With EPA

The DRAFT notes that EPA has been an important participant in this enhanced participatory rulemaking process. Indeed, EPA is presently in the process of developing radiation site cleanup regulations. (AMC's comments in response to EPA's Advance Notice of Proposed Rulemaking for Radiation Site Cleanup regulations are enclosed as Attachment A.) While AMC supports NRC's efforts to involve EPA in the decommissioning criteria process and is pleased that EPA has actively participated, NRC should not lower its risk limit simply to accommodate EPA. The DRAFT states that "[t]he objective is that EPA will be able to make a finding that NRC decommissioning criteria provide adequate protection for the public and the environment and will exclude NRC licensees from the EPA cleanup standards." (p.21) AMC agrees that consistency between the agency's regulations is a desirable and necessary goal. However, AMC is concerned that NRC is abdicating its rulemaking responsibilities simply to accommodate EPA. Such a reaction will not result in an informed or sound rulemaking.

Also troublesome is the suggestion that if EPA accepts the NRC criteria, no further EPA remediation requirements would be

imposed. While this may ultimately be true, in the meantime EPA will make its determination on the final NRC criteria through a formal rulemaking involving notice and public comment which, in effect, will cause the entire NRC decommissioning criteria rulemaking to be reopened. Such a process, in many ways, defeats the purpose and benefits of NRC's enhanced participatory rulemaking process. The EPA rulemaking could result in the entire NRC criteria being revisited and possibly redone.

The DRAFT's discussion on the cooperation between NRC and EPA in developing decommissioning criteria is in response to comments urging all regulatory agencies to use the same radiological criteria for decommissioning. The DRAFT notes that "some commenters said that the NRC's adoption of a risk/dose limit of 100 millirem per year, with a proper allocation of ALARA, would result in a 10^{-6} annual risk and a 10^{-4} lifetime risk, which would be consistent with EPA's Superfund remediation goals." (p.21) As in other places in the DRAFT where the 100 mrem/yr limit is discarded without adequate explanation, NRC does not respond to this comment. NRC merely states that its proposal is consistent with past EPA and NRC decisions but does not reference them, leaving the reader once again to guess at what the draft means and what the explanation is.

III. SPECIFIC COMMENTS

The following sets forth several comments directed at specific sections of the DRAFT.

A. Community Involvement

While AMC agrees the public should be provided with information on decommissioning activities and plans and agrees that public input is valuable, it is concerned that the DRAFT has not sufficiently thought through all the implications or answered all the questions raised by the SSAB proposal. For example, the DRAFT states that it is important for the public "to be able to effectively participate in site decommissioning decisions." (p.24) It is unclear what "effectively participate" means. Does it mean that to participate an individual must have some basic technical understanding of the issues involved? If so, who is responsible for the education and training of the public? The DRAFT further notes that "it is anticipated that the SSAB would be dissolved once the license has been terminated." (p.54) (Emphasis added.) In fact, the Board may not be dissolved as the SSAB is also expected to give advice on technical and enforcement issues. Is the NRC not abdicating its role by expanding the scope of the Board to encompass such issues? In terms of licensee fees, has NRC factored in the additional costs of either educating the public or including them in decommissioning

decisions? Since NRC must recoup its costs through licensee fees, this issue must be addressed in the GEIS.

Moreover, by requiring that whenever the Commission receives a decommissioning plan notice be given to the public and local and state governments seeking public comment for restricted release of a site or "wherever the Commission deems such notice to be in the public interest," NRC is inviting political interference in NRC oversight of the decommissioning process by legislators and other interest groups. The SSAB, furthermore, is expected to be composed of "individuals who could be directly affected by residual radioactivity at the decommissioned site." It is entirely unclear what universe of individuals this is meant to encompass. In effect, the criteria presently provides NRC with unfettered discretion to abrogate and circumvent its own rules. The proposed requirements also could significantly lengthen the decommissioning process and in some cases prevent the process from coming to final closure. The "affected" public is entitled to be involved in and informed about decommissioning decisions but the outlines of such participation must be more clearly drawn.

B. Site-Specific Implementation of Generic Criteria

The DRAFT states that the proposed rule would allow for site-specific implementation of the generic criteria. The DRAFT notes that the Commission "recognizes the need for flexibility in

applying these criteria because of constraints posed by site specific conditions (e.g. geology, hydrology, meteorology, and radiation background levels) and to provide opportunity for meaningful participation by local communities in individual decommissioning actions." (p.27) The DRAFT further states that "[l]icensees need to be able to take advantage of whatever safe methodologies may be available for achieving remediation which approaches or meets the goal for decommissioning." (p.31). AMC agrees that flexibility is necessary because the nature of decommissioning and the extent of closure required to protect public health and the environment at different sites will vary significantly.

NRC's proposed regulations should explicitly provide in the criteria for licensees to be able to propose site specific alternatives to any of the goals (i.e. unrestricted use) or risk goal/limit if site specific circumstances warrant, including allowing releases above the limit. The Atomic Energy Act (AEA), as amended by the Uranium Mill Tailings Radiation Control Act (UMTRCA), provides that a licensee may seek alternatives to specific requirements given "local or regional conditions including geology, topography, hydrology and meteorology." 42 U.S.C. § 2014. NRC's decommissioning criteria should include this specific language along with language that allows alternatives that consider the prior and potential future uses of the affected property and demographics.

C. Critical Group

AMC supports the Commission's use of the critical group concept rather than basing the criteria on the maximally exposed individual concept. AMC believes that assessing population distribution of estimated individual risks is essential for state-of-the-art risk analyses. Such an approach includes evaluation of the risk of the most exposed population subset. NRC should continue to use the critical group concept in its radiation protection calculations.

D. Facilities Licensed Indefinitely

The DRAFT suggests that "the Commission anticipates that [in some complex situations] the sites would have to remain under a license indefinitely until new, more efficient technologies are developed or the financial resources become available to pay for more complete remediation." (p. 31) The DRAFT, however, fails to explain who will pay for keeping a facility under a license indefinitely or why other alternatives that would protect the public health and safety could not be considered and utilized.

E. Waste Disposal

In response to comments on how waste from the decommissioned sites would be disposed, the DRAFT merely states that these sites may generate some low-level radioactive wastes but does not address the issue in realistic or concrete terms. As a result,

the waste disposal issue is not discussed in a manner that the public can understand. Once again, the DRAFT's explanation is inadequate.

F. Restricted Use

The DRAFT's discussion on when restricted use is permissible and what kinds of restrictions are acceptable is hazy. It is not clear what criteria NRC will use to evaluate restricted uses. The DRAFT does not explain what are "adequate" institutional controls or "sufficient" financial resources. In discussing land use or institutional controls to allow termination of a license and release of a site under restricted conditions, the DRAFT notes that land use controls such as zoning controls, deed restrictions, restrictive covenants and negative easements, to name a few, must "have a reasonable expectation of enforcement." What does "reasonable expectation of enforcement" mean? The DRAFT should address markers, deed restrictions (i.e., no structures) and techniques such as soil mixing and soil layering for on-site disposal in the context of restricted use. Additionally, the proposed criteria for restricted use do not explicitly require consideration of future land use as they must.

Finally, as noted above, if the bottom line ("safety net") of the criteria is that there is to be no dose to the public greater than 100 mrem, why not just let the licensee choose

between restricted and unrestricted use if the criteria can be met?

G. Minimizing Generation of Waste

The DRAFT provides that "[t]he proposed rule would require applicants for licenses after the effective date of the rule to describe in the application how facility design and procedures for operation will minimize contamination of the facility and the environment, facilitate eventual decommissioning, and minimize the generation of radioactive waste." (p. 36) Is this not what NRC should be doing with its standard? The DRAFT de facto risk limit will inevitably generate large volumes of radioactive waste for disposal.

H. Background Radiation -- Definition

In explaining its definition of "background radiation," the DRAFT states "[t]he Commission does not believe it is reasonable for licensees to be required to remediate material over which they have no control, and which is present at comparable levels in the environment both on and off site." (p. 41) AMC agrees with this statement. In light of this definition, why is NRC proposing a standard within the variations of natural background radiation?

I. Readily Removable Residual Radioactivity

The DRAFT defines "readily removable" as residual radioactivity "which is removable using non-destructive, common, housekeeping techniques (e.g., washing with detergent and water) that do not generate large volumes of radioactive waste requiring subsequent disposal." (pp.42-43). What does the staff mean by "detergent"?

Later the DRAFT notes that "the Commission proposes to require that all readily removable residual radioactivity be removed from a site before it is decommissioned." (p.55) It is not clear why such removal would be required, particularly if on-site burial is a necessary option. Indeed, such removal is inconsistent with ALARA principles and, in practical terms, may be impossible to do.

J. Previously Disposed of Materials on Site

The DRAFT provides that if certain, existing "buried radioactive material is considered to be part of the licensee's total site inventory for decommissioning purposes, some licensees will likely be required to remove all or part of this material prior to decommissioning the site." (p.56) What does "likely have to move" mean? NRC's proposed requirement, moreover, is inconsistent with ALARA principles and renders NRC's "promise" to bring finality to decommissioning activities somewhat meaningless.

In the final analysis, a risk limit approach with ALARA must be flexible. ALARA assumes that, as an inherent part of socially beneficial activities, there will be some radiation exposure beyond that received naturally, and provides an approach for balancing the risk of such additional exposure with the benefits of the activity to society. Therefore, any requirement to bring concentrations to as low as is feasible, which routinely requires removal to a disposal site regardless of site specific conditions, or which equates ALARA with a single dubious local or regional background number (level), would ignore the balancing of the elements per the ALARA definition which is necessary to permit the continuation of activities that benefit society.[39/]

K. Radiological Criteria

The DRAFT states that the 15 mrem/yr standard is consistent with EPA's "generally applicable environmental standards" and CERCLA criteria. (p.44) On which EPA standards is NRC relying? NRC does not offer an adequate explanation to support this purported "basis" for the proposed 15 mrem/yr criteria. Indeed, NRC appears to ignore the 25 mem/yr limit for commercial low-level radioactive waste disposal facilities.

39/ See York Committee for a Safe Environment v. USNRC, 527 F.2d 812,815 (D.C. Cir. 1975) (the court observed that NRC has recognized that an ALARA type of analysis "requires individualized consideration of the costs and benefits of reducing radioactive emissions").

In rejecting NRC's 100 mrem/yr dose limit for individual members of the public (10 C.F.R. § 20.1301), the DRAFT notes that an additional margin of safety is "necessary" because "the limit in 20.1301 is intended to apply to all sources under the licensee's control. However, in the case of decommissioning, the site is no longer under the control of the license." (p.44) What does this mean? Why does this matter? The DRAFT suggests that the purpose is "to avoid a summation of exposures approaching the dose limit." (p.45) Again, what is the reasoning behind this statement? If the purpose is to take the limit so low that 100 mrem/yr cannot be reached, why then does this same logic not apply during active site operations?

The DRAFT further notes that the computer models for estimating the annual TEDE to the critical group "will be screening models which employ generically derived conservative assumptions and factors." (p.46) In effect, therefore, the 15 mrem/yr limit may not really be 15 mrem but a much lower level.

L. Time Frame

In establishing a time frame of 1,000 years for TEDE estimates, NRC notes that "long term modeling of near background doses may be virtually meaningless." (p.58) Long term modeling of near background levels is meaningless and the Commission should so state clearly rather than using such ambiguous language.

IV. CONCLUSION

For the foregoing reasons, AMC respectfully requests that NRC significantly modify the DRAFT prior to formally proposing decommissioning criteria.

3136:003XTS.94

AMERICAN MINING CONGRESS

COMMENTS ON

THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY'S ADVANCE NOTICE OF PROPOSED RULEMAKING FOR RADIATION SITE CLEANUP REGULATIONS

57 Fed. Reg. 54474
(October 21, 1993)
AIR DOCKET NO. A-93-27

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CONTENTS

II. GENERAL COMMENTS

A. Scope of the Rulemaking

The scope of EPA's rulemaking effort, as outlined in the ANPR, is enormous. EPA indicates that in the course of this rulemaking, it will consider all radioactively "contaminated" sites in the United States, and consider using an extremely wide range of statutory and regulatory authorities, including the Atomic Energy Act (AEA), 42 U.S.C. § 2014, 2021 et seq., (including EPA's AEA authority under Reorganization Plan No. 3, 5 U.S.C., Appendix 1), the Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. § 9601 et seq., (CERCLA), the Resource Conservation and Recovery Act, 42 U.S.C. § 6901 et seq., (RCRA) and perhaps the Toxic Substances Control Act, 15 U.S.C. § 2607 et seq. (TSCA) as well. ANPR at 54474, EPA Issues Paper On Radiation Site Cleanup Regulations (Sept. 1993) (EPA Issues Paper) at 56. EPA indicates that it will address AEA regulated substances, as well as mixed waste and possibly Naturally Occurring and Accelerator Produced Radioactive Materials (NORM and NARM). ANPR at 54475.

EPA has estimated that there are a minimum of 45,300 radioactively contaminated sites potentially deserving attention and that figure does not include upwards of 1.5 million sites that EPA has estimated may be contaminated with NORM. EPA: Preliminary Draft--Sites Contaminated and Potentially Contaminated With Radioactivity. Contract

I. INTRODUCTION

The American Mining Congress (AMC) submits these comments in response to the Environmental Protection Agency's (EPA) advance notice of proposed rulemaking on radiation site cleanup regulations. 57 Fed. Reg. 54474 (Oct. 21, 1993) (ANPR). These comments address a number of general issues raised by EPA's ANPR that are of concern to the AMC membership, as well as a number of specific radiation site cleanup issues identified by EPA in the ANPR.

AMC is a national trade association representing: (1) producers of most of the United States' metals, uranium and coal and industrial and agricultural minerals; (2) manufacturers of mining and mineral processing equipment and supplies; and (3) engineering and consulting firms and financial institutions serving the mining industry. A wide variety of AMC's membership--particularly those in the uranium production sector, but many other mineral processing and production activities as well--potentially could be affected by EPA's wide-ranging radiation site cleanup regulations. Accordingly, AMC is vitally concerned that EPA's radiation site cleanup regulations are cost effective, scientifically justified and demonstrably in the best long-term interests of all involved parties. AMC is committed to working with EPA to achieve this important result.

No. 68090107 (Feb. 1991) at 1-6. These sites include United States Nuclear Regulatory Commission (NRC) licensed sites, federal facilities and former federal facilities (including Department of Energy (DOE) and Department of Defense (DOD) facilities) as well as thousands of privately owned and operated radioactively contaminated sites. Id. As noted in the ANPR, "the total number of sites eventually requiring cleanup may number in the thousands and may cost hundreds of billions of dollars to remediate." ANPR at 54474.

As is apparent, the potential reach of EPA's future radiation site cleanup regulations is immense and comparable in magnitude to other congressionally mandated and EPA supervised programs such as CERCLA. Given this fact, and as discussed more fully below, EPA will need to take extreme care as it makes decisions regarding the coverage of its rule.

In 1991, then EPA Administrator William K. Reilly observed:

> [A]s major new environmental problems arise, I propose we approach them as scientifically as possible, asking: How much do we know? What are the critical questions to which we need answers? Are we organizing to get key information? What did the data tell us about the seriousness of the problem and the magnitude of the appropriate response?[1]

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[1] The Washington Post, Aug. 20, 1991, at A15, Col. 1. Although Reilly was not specifically discussing radiation issues, his comments are extremely appropriate in this context.

According to Reilly, "we also need to recall that to equate every incident, every problem with a major risk undermines our ability to focus on the most significant issues. Nothing is 100% safe. Neither are all risks equal." Id. It is this analysis of defining and understanding the realistic parameters of the potential problems and the best methods to address them that must inform EPA's future radiation site cleanup rules.

AMC believes that many of the areas EPA is considering for regulation involve as yet undemonstrated risks to public health and the environment. This is particularly so for materials such as NORM in which no clear pattern of problems or excess exposure has emerged and which involve widely varying levels of radioactivity and methods of use and exposure. It is also true for the vast majority of sites that are regulated by NRC and the DOE under the Atomic Energy Act. Furthermore, it is equally uncertain whether all of these risks (such as they may be), are amenable to control, or that such control involves the most efficient expenditure of resources in relation to the risk reduction benefit to be received. Prior to promulgating regulations, EPA will need to answer conclusively these questions if the challenges cited by Administrator Reilly are to be met fully and effectively.

Thus, before EPA decides to regulate particular kinds of facilities or materials, the Agency will not only need to

consider carefully the extent of its congressionally provided radiation related authorities, but perhaps more importantly, EPA will also need to determine, as definitively as possible, the need for, effect of, and potential benefits gained from, regulation of each type of radioactive material and each instance of coverage at particular kinds of sites.

For instance, regardless of the particular statutory authority involved, how will EPA determine that a site is radioactively "contaminated" at a level appropriately requiring control given the fact that some level of natural background radiation exists virtually everywhere in the United States? Radiation, and hence risk from radiation, is as old (or older) than man and exists everywhere on earth. Unlike recent environmental programs developed specifically to respond only to emerging and uniquely man-made risks, efforts to control exposure to radiation must always be evaluated in light of the fact that for all humans, some exposure to some radiation is unavoidable. Hence greater care must be taken in identifying perceived radiation contamination than in other nonradiological risk circumstances that EPA has traditionally been involved in regulating. This is particularly so in the NORM context where EPA will need to focus solely on risks that involve significant increments above natural background and natural background variability and that also involve some form

of human enhancement. Otherwise EPA may find itself engaged in the task of cleaning up sites that are, for radiological purposes, untouched by human hands.

In addition, EPA also needs to consider the total exposure effect of particular site cleanup requirements, since some cleanup solutions, such as exhumation of waste, may involve additional or increased exposure to radiation, thereby negating or reducing the potential benefit from such a requirement. The agency must consider the net risk benefit and focus on solutions that significantly reduce the overall risk rather than simply moving risk from one exposure path to another. For this reason, the agency will need to adopt some form of an as low as reasonably achievable (ALARA) type philosophy, which is a traditional radiation risk management tool not unlike the risk management approach adopted by EPA for regulation of radionuclides under the Clean Air Act, in wake of the decision of the United States Court of Appeals for the D.C. Circuit in Natural Resources Defense Council v. EPA, 824 F. 2d 1146 (D.C. Cir. 1987) (Vinyl Chloride).

AMC believes that EPA's initial approach, as outlined in the ANPR, is appropriately open-minded and without significant preconceptions. AMC supports EPA's decision to seek comment from interested and knowledgeable parties prior to releasing draft rules. AMC urges EPA to develop further information, particularly on issues such as NORM (which the agency has only

recently begun to study seriously), in a thorough and logical fashion,[2] and to address such information in such a way as to avoid unduly alarming the public about radiation risks that may be relatively small, particularly when compared to other radiation risks and to natural background.

Indeed, despite the concern expressed in the ANPR over the pace and quality of radioactively contaminated site cleanups, it remains true that there is no clear public concern over many sites potentially covered by EPA's rule and it remains unclear if there is a real need for EPA control over many of the materials identified in the ANPR. This is especially true given the fact that EPA's rulemaking effort does not appear to be aimed at the radioactive wastes of greatest hazard (i.e., high level waste and transuranic wastes), but focuses primarily on low level, NORM, NARM and mixed wastes with much smaller hazard potentials and correspondingly smaller levels of public concern.

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[2] In fact, as EPA is well aware, prior to promulgating its rule, it will need to develop sufficient information that clearly demonstrates the need for its regulations. As the D.C. Circuit has noted on a number of occasions, no matter how reasonable a rule is, it is nevertheless "highly capricious" if a need for the rule has not been established by the agency. See e.g., Home Box Office v. FCC, 567 F. 2d 9, 36 (D.C. Cir.), cert. denied, 434 U.S. 829 (1977), City of Chicago v. FPC, 458 F. 2d 731, 742 (D.C. Cir.), cert. denied, 405 U.S. 1074 (1974).

B. Scientific Basis and Real World Context

In crafting its rule, AMC urges EPA to use an approach that is grounded in sound science, rather than public perception and one that takes appropriate account of the "real world" context in which such rules must operate. In the radioactivity context, this means at least two things. First, it means that in assessing appropriate levels of exposure, the regulatory focus can only be on significant incremental exposures above background or the variations therein since, as discussed below, minor increments present minimal risks. In AMC's view, this point cannot be emphasized too strongly and should be consistently reflected in EPA's regulatory approach, particularly as applied to low activity radioactive materials such as diffuse NORM. Second, as discussed in the following section, EPA must take great care to preserve site specific flexibility so that cleanup solutions can be tailored to fit their "real world" context. AMC believes the ultimate success of EPA's efforts hinges upon its ability to adopt and implement these basic principles.

With regard to radiation risks, traditional analyses of radiation exposures have always been assessed in comparison to natural background. Failure to consider natural background levels will result in serious overestimation of the effect of the particular radionuclide at issue. This concept is unfamiliar in a chemical risk paradigm, particularly for man-

made chemicals, where natural background levels do not exist and the real issue concerns trace amounts of chemicals.

The concept of using natural background radiation levels to address appropriate radiation exposure limits is not new. In 1960, an ad hoc committee of the National Council on Radiation Protection and Measurements (NCRP), in examining the issue of controlling man-made (or enhanced) exposures of the public to radioactive materials, noted that "maximum permissible doses for the general population should be related to the average natural background level of radiation."[3] The reasoning behind this approach begins with the premise that "the most pertinent information we have is the fact that, throughout all of human history, the environment has been providing a continuous, low dose-rate exposure."[4] Because the human race has developed acceptably in such an environment, the risks of natural background are essentially accepted as a "normal factor of life." NCRP Somatic Radiation Dose For the General Population (February 1960) at 484.

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[3] NCRP, Somatic Radiation Dose for the General Population (February 1960) ("Somatic Radiation Dose").

[4] Adler & Weinberg, Health Physics 7209 (1978). In BEIR V, the authors note that "studies of populations chronically exposed to low-level radiation, such as those residing in regions of elevated natural background radiation, have not shown consistent or conclusive evidence of an associated increase in the risk of cancer." Committee on Biological Effects of Ionizing Radiations, "Health Effects of Exposure to Low Levels of Ionizing Radiation," (1990) at 5. (emphasis added.)

It follows from this that, because in the course of human existence no statistically discernible adverse health effects have been associated with background radiation or its variations (which may be comparable in magnitude with the average background), "the effects of increments in dose and dose rate are small compared to background fluctuations and will be small compared to an already undetectable level of effects."[5] A recognized international organization on atomic energy has noted that "[a] level of dose which is small in comparison to natural background can be regarded as trivial."[6] The reasoning continues that, the greater the increment to background levels, the less the confidence that any effects will be similarly indiscernible and therefore tolerable. Somatic Radiation Dose at 484.

Recently, EPA's Science Advisory Board (SAB) issued a report noting that it is unfortunate and unsound that radiation risks and risks from chemical contaminants are often treated identically. Harmonizing Chemical and Radiation Risk-Reduction Strategies - A Science Advisory Board Commentary (May 18, 1992). Average background exposure to radiation is approximately 100 mrem per year exclusive of radon and, if this exposure rate were "calculated with EPA's current risk

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[5] American Physical Society, Reviews of Modern Physics, Vol. 50, at S72 (1978).

[6] International Atomic Energy Agency, Vienna (IAEA), Technical Reports Series No. 334, at 3 (1992) ("IAEA Report").

coefficient for radiation carcinogenesis . . . [it would predict] cancer risks of almost 3 in a thousand." Id. at 4. Consequently, as pointed out by the SAB, traditional radiation risk assessment paradigms implicitly or explicitly account for natural background and seek to regulate the potential incremental excess cancer risk above that from background and the variations therein. Id.

Use of a chemical risk paradigm to regulate radiation exposure, however, is not appropriate for radiation control programs because this paradigm evolved at least in part from the assumption that exposure to man-made chemicals could be eliminated entirely. According to the SAB, "[t]he application of standard chemical risk reduction criteria to radionuclides in these situations leads to limitations on excess radiation doses that are small in comparison to natural background radiation . . . [i]t should come as no surprise that some radiation scientists see such limitations on radiation exposures as unworkable or even misguided." Id. at 1.

Thus, any future EPA regulatory limits should address only potentially significant incremental exposures. As Dr. Warren Sinclair, former President of NCRP, has testified, "[y]ou don't try to set standards within variations of natural

background."[7] To do so ignores the radiation risk paradigm (i.e., address only significant increments to background) because there is no demonstrable risk from background and, therefore, none from essentially equivalent levels. Hence, as EPA moves forward, both in developing necessary risk information and in designing its regulatory problems, it must only recognize those risks that involve significant increments to natural background and variations therein. To do otherwise ignores basic and well accepted scientific principles.

Furthermore, once EPA has identified a problem based on a comparison with natural background levels, AMC believes it should adopt some form of risk limit (or range of risk limits) and impose additional controls as are cost effective. In the ANPR, EPA states that "the agency is developing cleanup levels for soil and groundwater contaminated with radionuclides. These will correspond to an acceptable risk limit . . . ." ANPR at 54474. AMC supports the use of a risk limit approach and believes that when used in conjunction with an ALARA type principle (or "graded decision guidelines"), such a strategy can result in environmentally protective and cost effective solutions. This approach reflects past and current NRC practice and essentially mirrors EPA's Clean Air Act radionuclide strategy, which looks first at an acceptable risk

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[7] Transcript of April 28-29, 1983, Hearings before the Procurement and Military Nuclear Systems Subcommittee of the House Committee on Army Services, 97th Cong. 2d. Sess. at 255.

level and then at the cost, feasibility and effect of additional controls to determine whether the risk limit provides an "ample margin of safety."

This latter approach was developed to be consistent with the decision of the United States Court of Appeals for the District of Columbia Circuit in Natural Resources Defense Council v. EPA, 824 F. 2d 1146 (D.C. Cir. 1987) (Vinyl Chloride). In assessing risk, the D.C. Circuit called upon EPA to engage in a two part analysis. First, Vinyl Chloride called for EPA to use the best scientific tools available to evaluate the potential health hazards from the source of a hazardous air pollutant to determine a level of "acceptable risk." The "acceptable risk" level (or limit) must be determined purely on a health based analysis without regard to cost or technological feasibility.

As a second step, the Vinyl Chloride decision directed EPA to engage in an ALARA-type analysis. The D.C. Circuit recognized that in our society, decisions about the acceptability of risk are in most cases the result of balancing various factors, not the application of a "bright line." Thus, this threshold judgment must determine what risks are acceptable "in the world in which we live." Accordingly, the opinion authorized EPA to bring to bear a second level of evaluation to reduce risks further where necessary to achieve an ample margin of safety after

considering costs, technological feasibility, and other relevant factors. In essence, the second tier analysis is an ALARA type analysis.

The use of a risk limit plus ALARA has been the general approach taken to radiation health protection since the inception of federal government policies in this field, and while the approach may need refining in light of new information, there is no need to abandon it as a basic regulatory approach. AMC urges EPA to build upon this basic radiation control methodology.

C. **Site Specific Flexibility**

For those materials and facilities that EPA ultimately regulates under its radioactive site cleanup standards, preserving site specific flexibility for site owners and operators to fashion appropriate control solutions will be critical to achieving timely and cost effective cleanups. Although EPA will need to review generic data and make broad assumptions in developing its radiation site cleanup rules, it must also allow for considerable variability between sites, even those sites contaminated with similar types of materials.

In drafting its standards, EPA's overall goal should be to provide itself, licensees and other regulatory bodies with the flexibility to address site-specific circumstances in a

reasonable and meaningful fashion. The International Commission on Radiological Protection (ICRP) notes that:

> necessary remedial actions vary greatly in complexity and scale and may themselves give rise to problems of occupational exposure and waste disposal. These should be dealt with in accordance with [the United States Nuclear Regulatory Commission's] recommendations for [such] practices [i.e., ALARA]. The need for and extent of remedial action has to be judged by comparing the benefit of the reductions in dose with the detriment of the remedial work, including that due to the doses incurred in the remedial work.[8]

This type of flexibility is consistent with an ALARA-type analysis requiring a case-by-case examination of site specific circumstances. As the D.C. Circuit observed, NRC has recognized that an ALARA type analysis "requires individualized consideration of the costs and benefits of reducing radioactive emissions." York Committee for a Safe Environment v. USNRC, 527 F.2d 810 at 815 (D.C. Cir. 1975).

Flexibility in the EPA's cleanup criteria should apply to decommissioning technologies (such as soil mixing), time frames, measurements, consideration of background and residual levels, and waste disposal. The cleanup criteria should require a local site assessment to determine where to place the emphasis on closure activities and remediation. The assessment should consider what more or less needs to be done at a particular site. Such an assessment may eventually find

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[8] ICRP 60, Section 6.2.2.

that certain requirements would not be appropriate because of a unique situation at a specific site. Each operation should be required to show some basis for its plan of action and site operators should be given the opportunity to propose alternatives that provide an equivalent level of safety to the public.[9] AMC agrees with the Nuclear Management and Resources Council's (NUMARC) observation to NRC that "a standard that lacks appropriate flexibility could result in some cases in extreme measures being required to achieve cleanup at costs and impacts that are far out of proportion to benefits achieved by cleanup to those levels. This potential underlies the need for permitting flexibility in evaluating appropriate actions."[10]

The nature of cleanup requirements necessary at a site varies dramatically between sites, and what needs to be done to protect public health and the environment at different sites will also necessarily vary. The radiological activity and, therefore, exposure to the public, at any site depends on

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[9] For example, in developing regulations for uranium milling operations, NRC stated that:

> The staff considers that the revised regulations being implemented provide appropriate flexibility. The staff has developed regulations mindful of the fact that the problem of mill tailings management is highly site-specific. The precise details of a program can be worked out only when unique conditions of a site are known.

[10] Comments of NUMARC on NRC's Radiological Criteria For Decommissioning of NRC Licensed Facilities. (June 28, 1993) at 7.

a large number of factors such as the length of the active life of the radionuclide at issue and its level of activity, the nature of the radionuclide (natural or man-made), the hydrological conditions, the mobility of the relevant radionuclide(s), the geology and climate of the area, the area's demographics, and the past and future uses of the land. EPA's rulemaking effort must acknowledge these factors and recognize how the circumstances of any specific site may make certain criteria inapplicable or inappropriate for cleanup of a particular facility. In particular, cleanup standards should take account of both restricted and unrestricted site use scenarios, with more stringent cleanup standards applicable to sites to be released for unrestricted use and correspondingly less stringent standards for sites subject to varying degrees of institutional control.

In its 1986 ANPR on radiation site cleanup standards, EPA stated that "EPA has expressed its preference to not rely primarily on institutional controls for long-term protection from radiation hazards." 51 Fed. Reg. 22264, 22265 (June 18, 1986). This is a preference that NRC has also expressed in its workshops on the site decommissioning issues, in which NRC indicated its unwillingness to entertain disposal options 3-5 of NRC's Branch Technical Position On Onsite Disposal of Uranium Wastes From Past Operations. (42 Fed. Reg. 52061 (1981)). See NRC: Updated Report on Site Decommissioning Plan, NRC SEC'Y Document 92-200 (May 29, 1992) at 10-11.

However, EPA appears to have re-evaluated its previous preference and stated in the most recent ANPR, that "cleanup levels for soil and groundwater contaminated with radionuclides . . . may be based on different land use scenarios, such as residential or commercial/industrial use." ANPR at 54474. NRC also now appears to be considering such an option in its parallel path rulemaking. According to NRC, in its decommissioning rulemaking, NRC may "establish criteria that would allow for land use restrictions after decommissioning to ensure protection of humans and the environment by limiting exposure to residual radioactivity." 58 Fed. Reg. at 33573.

Furthermore, in the EPA Issues Paper, the Agency notes that "EPA recognizes the importance of tailoring cleanup levels to particular land uses and of involving the public--which will likely have a strong interest in establishing future uses--in the process of determining appropriate cleanup levels site by site." EPA Issues Paper at 10. The Issues Paper goes on to note that "EPA may want to develop radiation site cleanup regulations for a range of future uses, from residential and recreational to agricultural/commercial industrial." Id.

Thus, both EPA and NRC appear to recognize the importance of not always requiring cleanup of a site to levels suitable for residential use when it is plain that no such use is

likely in the foreseeable future and that access to the site and potential exposure to the public can be adequately controlled by other means. AMC supports this approach and believes it provides a good example of the type of regulatory strategy EPA will need to develop if sufficient site specific flexibility is to be provided in the radiation site cleanup regulations.

Site specific flexibility has long been an important part of the AEA/NRC approach to radiological control. Section 84 of the AEA, as amended by the Uranium Mill Tailings Radiation Control Act (UMTRCA) provides that a licensee may seek alternatives to specific requirements given "local or regional conditions including geology, topography, hydrology and meteorology." 42 U.S.C. § 2014. EPA should provide for the same type of flexibility in its regulations to give both owner/operators, licensees and regulatory authorities the ability to work out mutually acceptable actions that provide a level of environmental protection equivalent to existing standards.

AMC strongly supports retention of flexibility to consider specific cleanup goals at any given site. Indeed, alternatives such as deed restrictions, permanent markers, and soil mixing or on-site burial provide relatively straightforward means of protecting the public safety and health in appropriate situations. If the scope of EPA's rule

ultimately proves as broad as is suggested in the ANPR, EPA will need to utilize such alternatives if its regulations are to be either rational or functional.

D. Consistency With Other Existing and Ongoing Regulatory Programs.

As EPA itself has recognized, EPA's rulemaking will not take place in a "regulatory vacuum." EPA Issues Paper at 50. For instance, EPA is well aware that NRC is actively engaged in a parallel path effort to develop standards and radiological criteria for decommissioning of NRC licensed sites. ANPR at 54475, EPA Issues Paper at 50. See also 58 Fed. Reg. 4363 (Jan. 14, 1993) (NRC's rulemaking notice). In fact, as part of its strategy of using an "enhanced participatory rulemaking," NRC has held a series of roundtable discussions on its future standards in which EPA participated.

In addition, as noted in the ANPR, NRC and EPA have signed a Memorandum of Understanding (MOU) "to establish a basic framework within which EPA and NRC will endeavor to resolve issues of concern to both agencies that relate to regulation of radionuclides in the environment." EPA/NRC MOU (March 16, 1992) at 1. As EPA has noted, "the MOU governs the proposed NRC regulations and the proposed NRC decommissioning standards." ANPR at 54475. Furthermore, and based on the MOU, EPA and NRC are also engaged in a task force effort to explore jointly opportunities to harmonize their respective

risk assessment approaches for radiological risks. See NRC SEC'Y 93-134 (May 14, 1993).

Finally, in the ANPR, EPA has promised to exempt NRC regulated facilities from the scope of EPA's rule so long as NRC's decontamination and decommissioning standards provide a level of protection that meets the standards set by EPA. ANPR at 54474. EPA has also stated its intention to create a "unified federal approach that combines the best scientific and technical resources and real world experiences of [EPA, NRC, DOE and DOD]." Id.

AMC strongly supports this approach to EPA's radiation site cleanup regulations and EPA's commitment to a "unified federal approach." AMC believes, however, that EPA has not yet conclusively demonstrated the need for EPA regulation and control of many of the materials and facilities EPA is considering for regulation. Indeed, AMC believes that the vast majority of radioactive wastes and materials are adequately covered by existing statutory programs and while a "unified federal approach" to regulation of radionuclides is extremely desirable, simply adding yet another layer of regulatory controls on top of pre-existing NRC, DOE and EPA programs will only increase the difficulties faced by all parties involved in radioactive waste issues.

The radioactive waste arena provides an excellent example of the problems from jurisdictional conflicts between NRC,

DOE, EPA and the states. Authority formerly held exclusively by the Atomic Energy Commission (AEC) is now split between EPA, NRC and DOE. EPA regulates NRC licensed AEA § 11(e)(2) byproduct material under the Clean Air Act and AEA wastes contaminated with RCRA hazardous wastes (i.e., mixed wastes) are regulated by EPA, NRC and DOE under both RCRA and the AEA. NRC's standards at 10 C.F.R. 40, Appendix A, for control of AEA § 11(e)(2) byproduct material must conform to EPA standards set forth at 40 C.F.R. 192. EPA's 40 C.F.R. 192 standards, in turn, reflect and are based in part on EPA's RCRA groundwater protection standards at 40 C.F.R. 264.

Former AEA regulated sites, such as the Maxey Flats site in Kentucky, are regulated under CERCLA by EPA. Transportation standards for radioactive waste are set by NRC, DOE and the United States Department of Transportation (DOT). Finally, a number of states (including Louisiana, Texas, Colorado and New Jersey) have begun regulating NORM/NARM, and the state sponsored Conference of Radiation Control Program Directors (CRCPD) has released several versions of a model NORM rule. CRCPD: Model State Regulations for the Control of Radiation, Proposed Rule for Part N, Regulation and Licensing of Naturally Occurring Radioactive Material (Draft 6) (June 6, 1988).

The interplay and conflict between these statutes has led in the past (and could lead in the future) to a variety of

confusing, duplicative and sometimes inconsistent regulatory approaches that EPA, NRC, DOE and the states have been forced to expend significant resources to resolve. See e.g., Thompson and Goo, Mixed Waste, A Way to Solve the Quandary, Env'tl Law Rep'tr., News and Analysis, 23 ELR 10705 (December 1993).

It is into this morass of conflicting agency authority that EPA proposes to insert its radiation site cleanup regulations using AEA, CERCLA[11] and perhaps TSCA authorities. Furthermore, because EPA is considering regulating NORM/NARM as part of its rulemaking effort, additional regulatory participation of states already regulating NORM/NARM will also be involved.

In crafting its rule, EPA will need to keep in mind the difficulties it has already encountered in the radioactive waste area as a result of the jurisdictional conflict with other federal and state agencies. Perhaps the best example of such conflict is EPA's and NRC's experiences in co-regulating

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[11] AMC notes that EPA's legal authority under CERCLA for regulating NORM materials is unclear. EPA has noted in the past that emissions of gamma radiation do not constitute a CERCLA release. Thus, to the extent EPA intends to rely on CERCLA authorities it would need to demonstrate actual releases of radionuclides into the environment. Since many NORM radionuclides remain in matrices composed of other materials, many NORM situations may not involve releases or threats of releases of radionuclides into the environment. Absent such releases, the agency appears to lack clear CERCLA authority over NORM.

uranium mill tailings under the Atomic Energy Act and the Clean Air Act.

Under the Reorganization Plan No. 3 of 1970, EPA acquired the AEC's authority to promulgate "generally applicable environmental standards for the protection of the general environment from radioactive material," including "limits on radiation exposures . . . in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material." 5 U.S.C. Appendix 1 (emphasis added). Authority for regulation within site boundaries at such facilities remained with AEC and was later passed on to AEC's successor agencies, NRC and DOE.

It appeared that this same division of responsibility was adopted by Congress for uranium mill tailings under UMTRCA in 1978. EPA was given authority to promulgate "generally applicable standards" for "the protection of public health and safety from radiological and non-radiological hazards." 42 U.S.C. § 2022 (a) and (b).

Given the similarity of the language used in Reorganization Plan No. 3 and UMTRCA, it should have been clear that EPA's UMTRCA standards for protecting public health and the environment found at 40 C.F.R. 192 were to apply to offsite releases outside the facility boundary. The AEA provides that NRC must conform its regulatory requirements to EPA's "generally applicable standards" and shall use its

implementation and enforcement authority over site operations to see that contamination outside the facility boundary does not exceed EPA's limits. 42 U.S.C. § 2022(b).

Yet, despite this congressional division of jurisdiction between EPA and AEC/NRC, EPA's standards, published in 1983, did apply in some important respects within the facility boundary. For example, EPA required installation of a liner at new mill tailings sites -- despite the fact that such a requirement is undeniably an implementation decision for the on-site authority (i.e., NRC). See 40 C.F.R. 192.32(a)(1), citing, 40 C.F.R. 264.221 (requiring a liner unless a no migration standard can be met). EPA's justification for applying these standards within the facility boundary was that they were necessary to protect against offsite releases. 48 Fed. Reg. at 945, 947 (Oct. 7, 1983).

This duplication led to litigation challenging the EPA standards. In 1985, the United States Court of Appeals for the Tenth Circuit upheld EPA's view in American Mining Congress v. Thomas, 772 F.2d 640 (10th Cir. 1985). Therefore, EPA's standards currently apply within the facility boundary, and NRC has conformed its regulations to comply with EPA's standards as required by the AEA.

Another excellent example of conflict between EPA and NRC involves EPA's regulation of uranium mill tailings under Section 112 of the CAA. A number of these standards have been

the subject of litigation that demonstrates how easily inter-agency conflict can occur and how difficult it can be to undo.

Under 40 C.F.R. Part 61, Subpart T (Subpart T), non-operational mill tailings piles are subject to standards for control of radon emissions. After promulgation of the Part 61 standards in 1989, several lawsuits were filed challenging the rule, including suits by AMC and the Environmental Defense Fund (EDF).

As the lawsuits were pending, Congress turned its attention to the problem of dual regulation by NRC and EPA in the Clean Air Act Amendments of 1990. In the so-called "Simpson Amendment" to Section 112, Congress expressly authorized EPA to exempt radionuclide emissions from regulation under the CAA if EPA determined, after public comment, that NRC had in place a regulatory program for a given source category that "provides an ample margin of safety to protect public health." 42 U.S.C. § 7412(d)(9).

Relying upon the Simpson Amendment, AMC supplemented an earlier petition to EPA for rescission of Subpart T. In October, 1992, EPA and NRC entered into an MOU designed to avoid duplicative regulation at inactive uranium mill tailings sites (tailings MOU).

After extensive negotiations, and based on the tailings MOU, AMC, EDF and EPA agreed to a framework for a negotiated

settlement. The settlement agreement provides a procedural approach to rescinding Subpart T based on modifications and amendments to existing EPA 40 C.F.R. Part 192, Subpart D regulations and conformance of NRC 10 C.F.R. Part 40 Appendix A, mill tailings site closure requirements to the amended EPA regulations to establish: (1) time frames for closure, (2) measurement requirements to determine compliance with the 20 $pCi/m^2/sec$ standard, and (3) flexibility for licensees to adjust closure schedules based on site specific conditions and circumstances beyond the control of licensees.

Although several actions are necessary before final rescission of Subpart T, it is clear that the rescission will open the door to a more effective, cost-efficient, and less burdensome approach to regulation of inactive uranium mill tailings facilities. The regulated entities, the federal government, the public health, and the environment will all benefit.

At least two critical points emerge from the following discussion of EPA and NRC's regulation of uranium mills and mill tailings piles. First, it should be obvious that mill tailings are more than adequately controlled and further regulation of these materials cannot be justified and would threaten existing agreements only recently put in place after years of effort. Second, EPA will need to take great care in crafting its radiation site cleanup regulations to ensure

consistency between agencies if it is to avoid the types of regulatory and jurisdictional conflict experienced in the past in the uranium mill tailings area.

In its 1986 ANPR on radiation site cleanup regulations, EPA stated that it would not address mill tailings sites already covered by UMTRCA. 51 Fed. Reg. 22264 (June 18, 1986) (1986 ANPR). However, the most recent EPA ANPR fails to make a similar promise. Regardless of whether EPA ultimately decides to exempt all NRC regulated sites from the scope of its regulations, AMC strongly urges EPA to exclude uranium recovery facilities, including uranium milling sites and tailings piles, from its radiation site cleanup standards, since the risks from these facilities are well (if not exhaustively) documented and equally well controlled with regard to releases to both air and groundwater and with regard to cleanup standards for radionuclides in soil.

The Subpart T rescission process appears to be bringing to conclusion a decade-long cycle of needless, counterproductive and duplicative regulatory effort and conflict. The extensive negotiations among EDF, NRC, EPA and AMC and other affected licensees required to rescind an EPA CAA standard that was virtually identical to regulation already imposed by NRC and EPA demonstrates this fact.

The cooperative approach signaled by the two EPA/NRC MOU's (general and tailings) and EPA's statement in its ANPR

that it will exempt NRC licensees from its radwaste cleanup rules if NRC's D & D rules are satisfactory, give hope that EPA and NRC will avoid the mistakes of the past.

AMC supports EPA's suggestion that it will exempt NRC licensed facilities from its radiation site cleanup regulations[12] and indeed, AMC believes that it would be wise for the agency to await the outcome of the NRC rulemaking before deciding to press forward with any radiation site cleanup regulations on its own. Although both agencies may be beginning from different points, they ultimately need to reach essentially the same result. The best and most efficient way to do this is to avoid generating inconsistent information and duplicative regulations. Information developed by both NRC and EPA during the rulemaking effort may well demonstrate that not only are NRC facilities adequately controlled (or will be adequately controlled), but also that many other facilities under consideration by EPA also pose little or no hazard warranting further regulation.

In addition, EPA will need to consider carefully (and consult with NRC) regarding the meaning of its possible exemption for NRC licensed sites. For example, how will such an exemption be applied and what will it mean for sites that

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[12] AMC also notes that EPA should limit its regulations to avoid any interference with existing transportation standards since NRC, DOE and DOT regulations adequately control all risks from transportation of radioactive materials.

are not regulated exclusively by NRC or an agreement state? Will the presence of materials (such as source materials or NORM/NARM) at levels below NRC regulatory control (i.e., 0.05% uranium or thorium) cause a facility to become EPA regulated? How will a "facility" or "site" be defined? Will EPA continue to impose duplicative regulation of mixed waste under the AEA and RCRA? How will EPA account for changes in NRC regulations? In order for any such exemption to provide significant benefits, EPA will need to answer these questions prior to implementation.

In the ANPR, EPA states:

> all four agencies [EPA, NRC, DOE and DOD] understand the clear advantages of meeting these [radiation site cleanup] challenges with a unified Federal approach that combines the best scientific and technical resources and real-world experiences of each agency. It is EPA's intent to coordinate this Federal effort and to ensure that all facets of the technical implementation guidance are based on scientifically sound and technologically feasible principles and methods.

ANPR at 54476. This encouraging statement by EPA holds the promise that the mistakes of the past will not be repeated. EPA's radiation site cleanup rulemaking and NRC's enhanced participatory rulemaking provide an excellent opportunity for both EPA and NRC to put their experiences of the past into practice for the future. AMC urges them to make every effort to do so.

III. SPECIFIC COMMENTS

A. Levels of Protection

EPA has asked for comments on determining (an) appropriate level(s) of protection. In particular, EPA has asked

> What level or levels of risk should the proposed regulation achieve to ensure protection of human health and the environment after cleanup? Should the level apply to a maximally exposed individual, the average member of the most exposed group, or to some other entity? Should there be different levels of cleanup for different land use scenarios?

As noted previously, AMC believes that regardless of what particular level is set by EPA, such a level must recognize, account for, and be based on levels of radiation exposure above natural background and at levels that are greater than increments of natural background variability. In addition, AMC also believes that taking account of future land use scenarios is an integral component of any successful and cost effective radiation control approach and provides needed flexibility to tailor control requirements to site specific conditions. This is because it is basically impossible to determine accurately and cost effectively control human health risks from a radioactively contaminated site without thorough knowledge of site specific conditions.

In most cases potentially covered by EPA's radiation site cleanup regulations, the primary radiation exposure of concern

will be from gamma radiation or alpha radiation. Gamma radiation requires close proximity to the source to create significant exposure. Alpha radiation requires ingestion or inhalation to create significant exposure. At the typical environmental or occupational exposure levels being addressed by future site cleanup regulations, both gamma and alpha radiation require long-term exposure in order to create significant health effects.

Gamma radiation poses little significant potential for off-site effects. EPA has indicated that gamma exposures decrease by at least a factor of three from the center to the edge of a waste pile (see EPA: Diffuse NORM - Waste Characterization and Preliminary Assessment (May 1993) at D-B-14). Furthermore, EPA also notes that the primary risk from such wastes is inhalation of radon, which poses risks approximately three orders of magnitude higher than risks from gamma exposures. Id. at D-3-1. Hence, as long as wastes do not migrate off-site and humans are prevented from remaining in extremely close proximity to waste piles, there is little potential for off-site human health effects from gamma radiation.

With regard to alpha radiation, which requires ingestion or inhalation to create significant health effects, the primary path of exposure is through inhalation of the decay products of radon gas (radon daughters). The primary threat

to health associated with radon comes not from breathing air containing radon itself, but from inhalation of radon daughters.[13] Radon gas is inhaled and exhaled too quickly during human breathing to allow for decay to radon daughters.[14]

The potential health hazard comes from the attachment of radon daughters to the lining of the bronchial epithelium, which subsequently results in that tissue being irradiated by the decaying radon daughters. The risk associated with this irradiation is based on long-term cumulative exposure.[15] As NRC has noted, even the radiation exposure to the public from uranium mill tailings piles presents no acute health hazard because "long and sustained exposure to radioactivity in the tailings pile would be required to produce any significant chance of adverse effect."[16]

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[13] NCRP, "Ionizing Radiation Exposure of the Population of the United States," Report No. 93, September 1, 1987, at 12 (NCRP No. 93). As used hereafter, in referring to the risk from radon, AMC is actually referring to the risk from radon daughters, unless otherwise stated.

[14] Because of their short half-lives, the radon daughters rapidly approach radioactive equilibrium with their radon parent in close spaces. The daughters are said to have "grown" into radioactive equilibrium with the radon. This is an important observation because almost all of the radiation dose (and hence risk) to lung tissue arising from exposure to radon gas actually is from the radiation emitted by the short-lived daughters of radon rather than by the radon gas itself. Even at a very low radon daughter equilibrium factor of 0.1, the dose to the lung from radon daughters is more than 15 times the dose from radon. Nuclear Energy Agency, "Dosimetry Aspects of Exposure to Radon and Thorium Daughter Products", (Sept. 1983).

[15] NCRP No. 93 at 12.

[16] NRC, NUREG-0706, (Sept. 1980) NRC, Generic Environmental Impact Statement (GEIS) Vol. I at 12-31 (Emphasis added).

Therefore, the greatest risk comes from long-term exposure to air in confined areas where radon has disintegrated to its daughter products. Id. As EPA has previously stated: "people need to be occupying a structure and not just standing outdoors" for radon health risks to be applicable. 48 Fed. Reg. 15,076, 15,083, (Apr. 6, 1983). Outdoor radon concentrations, such as those from a tailings pile, are limited by the fact that the radon that diffuses out of the ground is generally dispersed by air currents to low concentrations prior to undergoing its radioactive disintegration to radon daughters. As a result, external sources of radon, such as tailings piles, make relatively small contributions to public exposure, compared to sources that emit radon directly into buildings. Hurwitz, The Indoor Radiological Problem in Perspective, (Feb. 1981) at 5-6.

In fact, levels of radon decrease by a factor of three from the center to the edge of a waste pile and "at distances of kilometer or more from tailings piles . . . the equilibrium of radon with its daughters is roughly the same as for radon in background air." National Academy of Sciences/National Research Council (NAS/NRC) Scientific Basis for Risk Assessment and Management of Uranium (1986) at 74, 165,181. For reasons such as this, "the health risks posed by exposures to radon from uranium mill tailings piles are trivial for the average U.S. citizen by virtually any measure." Id.

Thus, for most of the radionuclides that EPA will be focusing on, the primary risks will be from radon daughter inhalation in dwellings or buildings built on top of contaminated areas, or in some limited cases, from external gamma exposure. Accordingly, where EPA can restrict or control access to prevent the construction of dwellings on such sites, there is little or no risk from either gamma or alpha exposure. Hence, EPA should recognize that the primary risk it needs to address in setting appropriate levels of protection is an on-site, rather than an off-site risk and that control of site access and use can play an extremely important role in meeting appropriate levels of protection.

For this reason, AMC believes that use of a hypothetical "maximally exposed individual" (MEI) should be considered as a maximum upper bound, "worst case" risk parameter and should be generally avoided as a principal means of standard setting. Presumably the "maximally exposed individual" inhabits a dwelling either on top of or in very close proximity to relevant radioactive contamination and is exposed to gamma radiation by virtue of proximity and/or to alpha radiation from breathing radon daughters there over a lifetime. In some instances, current EPA exposure scenarios posit individuals living at the facility fenceline 24 hours a day, 365 days a year, for 70 years. Since this scenario is, at best, unlikely for most radioactive waste sites and at worst a virtual impossibility, use of an MEI should only be used to define the

conservative upper bound of possible risks and as such, should not be used as a primary basis for setting risk limits.[17]

Yet, regardless of whether the range of lifetime risk levels ultimately chosen falls between 10^{-4} to 10^{-6} or higher, the key issue is how risk estimates are derived. If EPA continues to use ultra-conservative risk estimating methodologies (such as the traditional MEI), it will make little difference what range of risk (or risk levels) EPA eventually chooses. EPA must use "best estimates" with quantified upper and lower bounds of uncertainty. The SAB has recommended this approach and it is the only approach that is fully consistent with EPA's commitment to rules based in "real world experiences." See e.g., SAB: Report of The Radiation Advisory Committee on EPA's Background Information Document For Radionuclide NESHAPS (May 2, 1989). Use of the most conservative assumptions and models, without revealing the ranges of uncertainty inherent in such analyses, ultimately leads to unrealistic conclusions about risk and hence to standards that lack "real world" context.

In setting an appropriate level of protection for radiation (other than alpha radiation received from radon daughters), AMC believes that EPA should at least begin with

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[17] In this respect, use of the MEI may be most useful as a preliminary screening criterion to eliminate situations that obviously merit no further regulatory attention.

NRC's current limit of 100 millirem per year (mrem/yr) Total Effective Dose Equivalent (TEDE)[18] to any member of the public, regardless of the pathway of exposure for above background levels from all manmade sources except radon. NRC has codified this limit at 10 C.F.R. 20.1301 and this approach has been endorsed by the American Nuclear Society which has stated that "this approach permits the site-specific situation to be evaluated with public protection assured." Comments of the American Nuclear Society on NRC's Proposed Radiological Criteria for Site Decommissioning (May 25, 1993).

In addition, AMC agrees with the recommendation of the Health Physics Society (HPS) that "a compliance screening level of 25 mrem/yr [can] be applied to mean annual TEDE to the critical population group, defined as the most highly exposed homogeneous group affected by the restored site." HPS Position Paper at 2. Under this screening system, "[i]f the mean annual TEDE to the critical group is likely to exceed 25 mrem, an evaluation should be made to ensure that no individual is likely to receive an annual TEDE exceeding 100

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[18] AMC agrees with the Health Physics Society's explanation of TEDE: "For purposes of these recommendations, we use the term 'total effective dose equivalent' (TEDE) adopted by the NRC (1991), which is the same quantity as the 'effective dose' defined by NCRP (1993); it is the sum over all tissues of the committed dose equivalent from penetrating external radiation and from intakes of radioactive materials. For site cleanup and restoration standards, we recommend that the dose limit be applied to all site-specific, nonoccupational sources, except "indoor radon, including natural radionuclides." Health Physics Society, Position Statement on Radiation Standards for Site Cleanup and Restoration, p. 2, May 28, 1993 (HPS Position Paper).

mrem (1mSv) from all site-specific, nonoccupational sources, excluding indoor radon." Id.

NRC presently considers a public radiation dose level of 100 mrem/yr to be an acceptable lifetime risk. See 10 C.F.R. § 20.1301 ("the total effective dose equivalent to individual members of the public from the licensed operation [shall] not exceed 0.1 rem (1 msv) in a year.")[19] This limit accounts for doses from all pathways and is consistent with the NCRP's and the ICRP's recommendations that the annual effective radiation dose to the public should not exceed 100 mrem.[20] Neither of these organizations suggest that general public dose limits should be set below 100 mrem/yr. Indeed, the risks from a 100 mrem/yr dose limit are consistent with the risks from naturally occurring carcinogens.[21] NCRP allows even higher levels in certain instances. For example, NCRP recommends an annual limit of 500 mrem for remediating NORM.[22]

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[19] Robert Bernero, Director of the Office Nuclear Material Safety and Safeguards, recently stated that when "push comes to shove 100 millirem a year to a member of the public is safe." Transcript of NRC public meeting on Briefing on Status of Efforts for Risk Harmonization, (May 26, 1993), p. 59.

[20] NCRP, Limitation of Exposure to Ionizing Radiation, NCRP Report 116, March 1993; ICRP, 1990 Recommendations of the International Commission on Radiological Protection, ICRP Pub. 60, ¶ 191, Nov. 1990.

[21] Kocher, D.C. and Hoffman, F.O., Regulating Environmental Carcinogens: Where Do We Draw the Line?, Environ. Sci. Technology, 25, No. 12, pp. 1986-91.

[22] NCRP Report 116.

A 100 mrem/yr dose limit, however, is reasonable when compared to the limits set for a very specific activity - such as disposal of low level radioactive wastes - where it is likely that potentially high levels of radioactive material will be involved. See 10 C.F.R. Part 61 (Section 61.41 provides that "[c]oncentrations of radioactive material which may be released to the general environment in ground water, surface water, air, soil, plants, or animals must not result in an annual dose exceeding an equivalent of 25 millirems to the whole body, 75 millirems to the thyroid, and 25 millirems to any other organ of any member of the public.") In contrast, most sites that will fall under EPA's rules will not be disposal facilities and likely will not involve potentially high levels of radiation exposure. Thus, a 100 mrem standard is appropriate. The 100 mrem/yr dose reflects considered judgment on the part of NRC.

Although AMC is aware that current EPA regulatory guidelines suggest a risk limit for excess cancer of one in ten thousand (10^{-4}) to one in one million (10^{-6}) and under some calculations, a 100 mrem/yr TEDE appears to reduce risks of excess cancer to approximately one in a thousand (10^{-3}),[23] AMC believes that the application of ALARA, used in conjunction with a 100 mrem/yr TEDE and after consideration of

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[23] See e.g., supra at 11 (SAB comments regarding risk range of a 100 mrem/yr TEDE).

natural background, results in substantially equivalent protection to a risk limit of 10^{-4} to 10^{-6}.

NRC appears to share this view and notes that with regard to these apparently differing standards "current information suggests that the level of protection achieved under both agencies' programs is comparable." NRC SEC'Y 93-134 at 7. In fact, establishing radiation site cleanup levels at the CERCLA risk levels of 10^{-4} to 10^{-6} would be inappropriate for many radiologically contaminated sites since this risk range would correspond to an external exposure rate of about 0.003 μR/hr to 0.3 μR/hr. This is about 0.06 to 6 percent of the natural background levels from the external pathway alone. Thus, AMC believes that EPA should use the 100 mrem/yr TEDE level as its initial standard in assessing an appropriate level of protection. Further, and at a minimum, AMC believes that the EPA should await the results of its harmonization of risk efforts with NRC before discarding NRC's 100 mrem/yr TEDE.

B. Consistency with Existing Regulations

As noted previously, AMC believes that achieving consistency and harmony with other statutory and regulatory programs will be essential for creating functional and manageable EPA radiation site cleanup regulations. In fact, there is virtually no area identified by EPA in the ANPR that remains wholly unregulated or that is not the target of future regulatory programs by other state or federal bodies. The

difficulty faced by EPA will be to fit its new regulations into this evolving matrix in such a way that clarifies, rather than confuses the issues. AMC believes that EPA will need to better focus both the scope and ultimate goals of its radiation site cleanup regulations if it is to avoid simply creating an additional regulatory burden for those with radioactive sites. As discussed above, this means, at a minimum, working with NRC on acceptable limits for NRC/DOE licensed facilities and, as discussed below, suggests that EPA should leave the vast majority of NORM/NARM materials to state regulation, especially diffuse NORM.

C. Specific Regulatory Approaches

In the EPA Issues Paper, EPA identifies four cleanup "approaches" that are available for "limit[ing] exposure and reduc[ing] radiation concentrations to acceptable levels." EPA Issues Paper at 4. The four cleanup approaches are as follows:

(1) Cleanup to detection limits;

(2) Cleanup to background levels;

(3) Cleanup to a radiation level that corresponds to a range of risks or a risk level considered protective of human health and the environment; and

(4) Cleanup to a level based on performance of the best demonstrated available technology.

In addition, EPA also identifies four "basic regulatory approaches" in its Issues Paper. These are described as

(1) Establishing a dose or risk limit;

(2) Requiring use of a look-up table of radionuclide and media specific concentrations applicable to all sites;

(3) Requiring use of a look-up table and a pathway model to calculate cleanup levels site by site; and

(4) Recommending specific technologies to be employed in radiation site cleanups.

As an initial matter, and as outlined in EPA's Issues Paper, the relationship between these two sets of "approaches" is not entirely clear. For instance, presumably, a regulatory approach of recommending specific technologies only makes sense if EPA adopts a technology based cleanup standard and similarly, establishing a dose or risk limit only appears consistent with a cleanup to risk based levels approach and not with a cleanup to either detection limits or background levels approach. In fact, as discussed below, AMC believes that neither the cleanup to detection limits approach nor the

cleanup to background levels approach merits significant consideration and that EPA recognizes this fact.

This leaves EPA with only two basic choices: a cleanup level based on an available technology approach or an approach based on acceptable risk levels. EPA's regulatory approach number 4 (recommending specific technologies) is EPA's suggestion for the form for a possible technology based cleanup standard and EPA regulatory approaches 1-3 (dose or risk limit; lookup table and lookup table plus pathway model) are presumably all potential forms of a risk based cleanup standard. The application of each of these types of approaches is discussed more fully below.

D. Cleanup Approaches

1. Cleanup to Detection Limits

AMC agrees with EPA that a standard requiring cleanup to detection limits poses significant difficulties. As EPA noted, "detection limits . . . can be difficult to define in a scientifically defensible manner and they do not relate directly to protection of human health and the environment." EPA Issues Paper at 5. In addition, EPA notes that "it is often technically impractical or infeasible to reduce radionuclide concentrations to below detection limits." Id. Finally, EPA notes that "implementing standards that are below detection limits cannot be justified scientifically." Id. AMC agrees wholeheartedly with these points and urges EPA to

eliminate a cleanup to detection limits approach from further consideration.

2. **Cleanup to Background**

A cleanup to background approach suffers from many of the same limitations as a cleanup to detection levels approach. Such an approach is neither scientifically defensible, nor is it always technically feasible.

First and foremost, as noted previously, (see supra, Section II B. at pp.8-12), setting cleanup levels within natural background levels and variations therein cannot be justified. Clean up levels should only address significant increments to background exposures if they are to address potentially significant risks to public health. AMC concurs with both EPA and NRC that such a standard makes little or no sense.

Furthermore, there are considerable difficulties associated with identifying natural background, particularly with respect to NORM where there is no accurate pre-operational data to establish baseline natural background levels. Background levels of radium, uranium, or thorium in soils, levels of ambient gamma radiation and levels of radon flux from soil vary widely across the United States. Background exposure levels vary with altitude because of increases in cosmic radiation levels at higher elevations and

with location because of differences in local rock types. Background radium, uranium, and thorium levels in soil vary with soil type and the rocks from which they derive, and according to the presence of evaporates and precipitates in the soil. Background levels of radionuclides in ground water vary geographically depending on the nature of the aquifer and other factors. Certain natural ground waters have high levels of natural radium.

Thus, background does not mean zero, but rather a level of radioactivity based on an average of the test results of a number of samples of soil, air or water or a number of readings of ambient radiation. Therefore, unless there are pre-operational baseline data, it generally will be enormously difficult to measure accurately concentrations of radionuclides for regulatory purposes and, depending on the radionuclides involved, whether there has been a significant incremental addition of radioactive exposure potential.

In addition, as EPA has recognized "background levels will often be much lower than risk based levels [and a return to background] alternative . . . might delay [ultimate cleanups] and might often require studies, even where levels were significantly below health and environmental based standards." EPA Issues Paper at 6. As is apparent, a cleanup to background levels approach, especially when used in the radiation context, bears little or no relation to protection

of human health and the environment. AMC therefore concurs with EPA that a cleanup to background levels approach is inappropriate and urges EPA to eliminate it from further consideration.

3. **Cleanup to Risk Based Levels**

AMC believes that a cleanup to risk based levels approach represents the most appropriate regulatory solution for radiation risk related issues and that EPA has already recognized this fact. AMC supports a cleanup to risk based levels (or range of risk levels) approach and believes that such an approach provides the best available means for achieving appropriate levels of environmental protection in a cost effective and site specific manner.

As noted previously, such an approach, if combined correctly with an ALARA type (or Vinyl Chloride type) analysis, would reflect current and previous NRC practice of looking first at an acceptable risk level and then applying an ALARA type approach to keep doses as low as possible, considering the costs of incremental regulation and their relation to public health and safety and considering the benefits to society from atomic energy or utilization of materials containing NORM. ALARA assumes that, as an inherent part of socially beneficial activities, there will be some radiation exposure beyond that received naturally, and provides an approach for balancing the risk of such additional

exposure with the benefits of the activity to society. A risk based limit plus ALARA remains an appropriate and scientifically sound approach to setting cleanup criteria and guidelines and is consistent with EPA's current approach to regulation of radionuclides under the Clean Air Act.

As noted above, assuming that EPA adopts, as AMC believes it should, risk based cleanup levels, there are three possible regulatory approaches that EPA has identified to date:

(1) establish a risk/dose limit and allow site owners to meet this limit in an appropriate fashion;

(2) create a "lookup" table of generic radionuclide concentrations applicable to particular environmental media such as soil or groundwater; or

(3) allow site operators to use the "lookup" table of generic radionuclide concentrations in combination with a pathway model to derive site specific radionuclide concentrations.

AMC believes that of these possible approaches, in most instances, EPA should rely upon a dose or risk based approach that allows site operators the maximum amount of flexibility in fashioning appropriate control solutions in the most scientifically defensible and cost effective fashion. AMC strongly urges EPA to consider using a range of dose or risk limits that varies with future site use conditions. Under

such a standard, sites to be cleaned up and released for unrestricted use might need to meet more stringent risk limits, and sites subject to a variety of active and passive use restrictions would need to meet correspondingly lower risk or dose limits.[24] A range of risk limits, such as a risk of cancer between one in ten thousand and one in one million, above background, would be consistent with current EPA practice and, as EPA noted in the Issues Paper, would provide considerable flexibility at individual sites subject to EPA's rule.

In the Issues Paper, EPA notes that "the agency might consider [using] the risk goal approach discussed in the NRC rulemaking issues paper." EPA Issues Paper at 7. (Emphasis added). EPA goes on to describe this risk goal approach as "a constraint on radiation doses below the 100 mrem/yr limit . . . and the application of requirements to reduce dose and risks "as low as reasonably achievable" (ALARA) below the dose constraint level." Id. As EPA has noted, "[b]ecause NRC and DOE already have adopted less than 100 mrem/yr plus ALARA for their current radiation protection regulations, this approach would be familiar to the regulated community . . ." Id. at 9.

[24] At such sites, because radionuclides cannot be destroyed or deactivated, appropriate solutions available to site operators should include a variety of techniques such as on-site mixing or burial, soil washing, conditions on waste form, etc.

As noted previously, AMC generally supports a 100 mrem/yr standard plus ALARA. However, AMC believes that in order to be consistent with NRC's terms used in the NRC Rulemaking Issues Paper, this approach should more properly be described as a risk limit rather than a risk goal approach. As described by NRC in its Rulemaking Issues Paper, a "risk goal" approach would essentially set a maximum contaminant level goal (MCLG) and then a maximum contaminant level (MCL), similar to the process that is embodied in the Safe Drinking Water Act (SDWA) for drinking water standards. This type of risk goal approach raises several serious concerns. In practical terms, there is a large difference between such a risk goal and a risk limit such as 100 mrem/yr plus ALARA. For example, if the risk goal is unreasonable (such as a zero risk for carcinogens), it can drive the risk limit to unreasonably low levels as demonstrated by certain SDWA standards. Thus, it creates the potential for an unrealistic "wish list" approach to setting limits.

In addition to opposing the use of a risk goal, AMC generally does not support the use of generic "default" radionuclide concentrations since, in AMC's experience, such standards often result in unrealistic levels of control due to inaccurate assumptions. AMC's experience with such approaches in the uranium mill tailings context is that the conservative assumptions necessary to generically "back calculate" from a dose or risk limit to an acceptable radionuclide concentration

almost always result in unrealistic standards and frequent over-control of radioactively contaminated sites.

For instance, in the past, in the uranium mill tailings area, NRC and EPA have assumed a 1 picocurie per square meter per second ($pCi/m^2/s$) radon flux (emission) relationship per 1 pCi/g of radium in uranium mill tailings piles. Thus, under this assumption, one pCi/g radium in a mill tailings pile equates to a radon emission into the air of one $pCi/m^2/s$. This generic assumption, however, has been labeled demonstrably incorrect by both SAB[25] and a study by NAS/NRC. This assumption, therefore in turn, has led to a potentially difficult to meet standard of 5 pCi/g radium in soil, which bears little true relationship to health or environmental protection. Use of such default exposure scenarios eliminates the ability to rely on actual site specific concentrations by using the most conservative assumption to account for the "lowest common denominator" in site specific variations.

AMC also believes that before pathway models can be relied upon in setting generic standards, they need to be calibrated and validated with actual measurements. EPA's Science Advisory Board has made this point recently and stated that: without convincing model validation data, EPA will be unsure of their degree of conservatism or accuracy and

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[25] Report of the Radiation Advisory Committee, Science Advisory Board; EPA-SAB-RAC-89-024 (May, 1989).

therefore will have continued difficulty in defending some of its regulatory positions." SAB: NESHAP Standards for Radionuclides, Review of Assessment Methodologies (Oct. 1988) at 8.

For this reason, AMC believes that while use of pathway models may be appropriate at specific sites in developing an acceptable radionuclide concentration, care needs to be taken with regard to their use in all cases and especially for setting generic standards. While AMC believes that a pathway approach combined with generic radionuclide concentrations represents some improvement over a straight "lookup table," AMC believes that uncalibrated and unvalidated pathway models can often introduce significant potential for error in calculating acceptable levels. Accordingly, AMC believes that EPA should adopt a dose or risk (or range of dose or risks) approach and that overall implementation costs from such a program may be rendered manageable by appropriately tailoring EPA's rule to apply only to those sites for which EPA has conclusive evidence of unmanaged risks.

Finally, AMC notes that in setting risk limits, the agency must always perform necessary uncertainty analyses and reveal these uncertainties to the public as part of the standard setting process. As noted by the SAB in the Radiation Advisory Committee Report on EPA's Background Information Document for NESHAPs (May 2, 1989).

> Uncertainty analysis must become a routine calculation that accompanies risk assessments. This entails a full disclosure of model details and is preceded by full literature review of parameter estimates relevant to the risk assessment question.

Id. at 17. According to the SAB,

> (1) EPA should quantify the uncertainty in the estimates for each source category in the assessment of dose, and define the "best estimate" in terms of relationship to uncertainty distribution.
>
> (2) EPA should carry out parameter and pathway sensitivity analyses, whenever and wherever possible.
>
> (3) EPA should use Monte Carlo calculations or use other state-of-the-art methods in its risk assessments.
>
> (4) EPA should discuss what potentially relevant parameters its models do not include.

The use and importance of uncertainty analyses and best estimates cannot be overlooked or minimized. It can, for example, provide supporting documentation to the risk assessment through a full disclosure of the current level of knowledge of parameter values. This would give a more scientifically defensible set of model results, and enhance the credibility of the modeling effort itself, which is often overlooked or forgotten. This in turn would create better and more defensible standards.

AMC agrees with the SAB and regardless of the particular risk limits chosen by EPA, AMC urges EPA to perform and disclose relevant uncertainty analyses, as an ongoing and integral part of this and any other rulemaking effort.

4. Cleanup to a Technology Based Performance Limit

There are a number of reasons why a technology based approach is not appropriate in setting general radiation site cleanup standards. First, a technology based standard such as Best Demonstrated Available Technology (BDAT) does not necessarily assure that the public will be protected at some appropriate risk level. Instead, the performance limit is driven by available technology and corresponds only to what is considered generically achievable for particular types of situations. Second, this approach creates the opportunity and even the probability for "moveable goal posts" as technology advances, so that decisions or even closures that were thought to be fi . could be revisited or reopened. Moreover, such an approach also may overprotect unnecessarily where the risk is small, thereby violating ALARA type principles.

In addition, a technology based approach that specifies the relevant control technology would discourage innovation and use of site specific control strategies. AMC believes that a better approach would be to set a risk limit and allow site owners to meet that limit as best as possible. While such a standard could be based in part on the performance of available technology, a risk/health based level is significantly more defensible. So long as EPA takes care in setting the scope of its rule properly, a risk based approach can manageably be applied to a finite set of facilities,

resulting in the most appropriate use of scarce agency resources. Although a specific technology requirement might appear to hold the promise of easy enforceability, in truth, since such a standard will likely result in significant over-control and under-control at a variety of sites, EPA will be forced to expend perhaps even greater resources tailoring its technology based standard to site specific conditions as a result of exemption requests and EPA perceived situations of under-control.

Furthermore, AMC believes it is worth noting that while specifying a particular technology may work well in contexts such as the Clean Air Act, RCRA and the Clean Water Act where media specific wastes can be passed through a particular treatment train, in the radiation context, where radionuclides cannot be destroyed or deactivated, the performance characteristics of a particular control "technology" (which in many cases is perhaps more accurately a "storage" technology) can only be assessed properly based on site specific conditions and measurements. Thus, if EPA adopted a technology specification requirement, it would have to either develop numerous generic models adaptable to a variety of sites or rely in the end on site specific modeling and monitoring. This would essentially defeat the primary purpose of adopting a technology based standard.

In the ANPR, EPA has asked "should the proposed regulation(s) be technology-based linked to an acceptable risk level." ANPR at 54475. This approach, although consistent with the current statutorily mandated strategy set forth under Section 112 of the Clean Air Act (Maximum Achievable Control Technology plus residual risk limits), has significant drawbacks when used in the radiation control arena. As noted previously, since radionuclides cannot be destroyed and since the performance of most "technologies" (which involve covering of waste and lining of waste impoundments) can only be monitored on a site specific basis once in place (unlike, for instance a test burn at a RCRA permitted incinerator) specification of a particular technology followed by application of a residual risk analysis may effectively be the same as initially using a site specific risk limit. Moreover, specification of a particular technology may also result in initial over-control, thereby obviating the need for further risk based controls, but nonetheless resulting in significant unnecessary expense to the site owner/operator.

E. Practicality Issues

As noted previously, the current scope of EPA's rulemaking is enormous and potentially covers thousands of sites and billions of tons of material, as well as substantial quantities of contaminated equipment. EPA must recognize that there are significant limits on the ability of site operators

to manage such huge amounts of material under stringent control conditions. Costs to reclaim a site must bear a reasonable relationship to the risks associated with a site. As EPA is well aware, spending billions of dollars to clean up a site to meet an arbitrary limit has worked quite poorly in other EPA contexts, such as the CERCLA program. EPA should take heed of this experience in crafting its radiation site cleanup requirements.

Furthermore, EPA should also always bear in mind the potential role that treatment and control solutions may have in creating increased exposures for remediation workers and in generating additional amounts of waste. For instance, some remediation technologies may create additional radioactive waste or, through use of solvents and chemicals, create additional mixed waste. Requiring offsite disposal poses the possibility of worker and public exposure during transportation. Calculating the additional exposure potential from further treatment and storage of such materials should also be part of the analysis in considering levels and types of control. Control strategies that simply "move" the risk around and do not account for the net risk benefit should be eliminated. In many cases, pollution prevention concerns and ALARA should dictate cleanup solutions that do not involve generation or concentration of additional waste or off-site waste transportation.

assessing health risk independent of cost considerations and then later balancing that risk against the costs of control and relevant socio-economic factors to reach an overall risk/benefit determination. AMC urges EPA to use a similar framework in the context at hand.

F. NARM/NORM Issues

As EPA is well aware, a number of states are now moving to regulate NORM materials. These states include Louisiana, Texas, New Jersey, Colorado and Mississippi and others. In 1991, EPA released a draft report entitled Diffuse NORM Wastes: Waste Characterization and Assessment ES-6 (Draft May 1991) (EPA Draft NORM Report). As demonstrated by that report, the mining, oil and gas and geothermal energy sectors alone generate more than 50 separate waste streams amounting to several billion tons of diffuse NORM wastes annually. Despite the fact that the costs of controlling these wastes could easily run into billions of dollars, and despite the fact that no conclusive evidence has yet emerged regarding risks from these wastes, EPA has requested comment in the ANPR on whether NORM should be included in any future EPA regulations.

Although EPA's draft NORM report represents EPA's best effort to date on the issue, SAB's review of that document indicates that "the NORM document may not meet its stated goal of providing a scoping analysis of the NORM problem sufficient

From a liability perspective, and regardless of the scope of EPA's ultimate rule, it is critical that EPA develop a standard that is capable of being met and that provides a safe harbor from subsequent liability concerns once it is met. When properly framed and supported, rules developed in a generic regulatory context (such the 100 mrem/yr TEDE standard that NRC staff has characterized as safe "when push comes to shove" see supra, footnote 19 at page 38) can provide significant liability protection in the more limited toxic tort context that involves assessing a specific source's contribution to a particular person's cancer. This is an appropriate role for federal standard setting and EPA should recognize and take advantage of this point in crafting its standards. Where a proper standard is set, future liability concerns should be minimal.

AMC believes that in considering practicality issues, EPA should adopt, in essence, the approach outlined in the D.C. Circuit's opinion in the Vinyl Chloride case. In that case, the D.C. Circuit, recognizing the necessity for cost effective solutions, urged EPA first to define acceptable risks in the absence of cost considerations and to then look at economic factors in imposing specific control conditions. See generally, 824 F. 2d 1146 (D.C. Cir. 1987). A similar approach, unconstrained by the statutory limitations of the Clean Air Act imposed in Vinyl Chloride, makes considerable sense in the radionuclide context as a means of first

to determine whether additional investigations or regulatory initiatives are warranted." EPA: SAB Report: Review of Diffuse NORM Draft Scoping Document, EPA-SAB-RAC-94-XXX (October 1993) at 1-2.

AMC has also reviewed the EPA Draft NORM Report and provided its comments. (See Attachment A.) As set forth therein, AMC believes that the EPA Draft NORM Report dramatically overstates the potential risks from NORM materials (in some cases by as much as a factor of six).

AMC believes that the primary threat from any NORM/NARM materials involves discrete NORM/NARM and that states generating significant amounts of such materials can adequately regulate such NORM on their own. In truth, for most diffuse NORM wastes containing radium or products of the uranium decay chain, the primary risk is from inhalation of radon daughters in dwellings built on waste sites. Given the site specific nature of this risk, it makes little sense for EPA to enter into regulation of this area.

Any regulators (such as EPA) interested in the NORM situation should weigh carefully the benefits of regulation before entering into regulation of the enormous NORM area. See, e.g., Thompson and Goo, Naturally Occurring Radioactive Material: Regulators Should Look Before They Leap, Env't1 Law Rep'tr, News and Analysis, 23 ELR 10052 (Jan. 1992). (See Attachment B.) As noted therein, not only is there no

currently demonstrated need for federal NORM regulation, but any attempt to do so will only confuse and complicate the issue further.

Any NORM regulations, whether federal or otherwise, should cover only those situations where there is a real world risk from NORM "technologically enhanced by human activity." Natural sources unperturbed by human activities and diffuse sources created as a result of human activity, but not "technologically enhanced" (e.g., mining overburden, soil tilling, etc.) should not be covered by the regulations. Only technologically enhanced material should be subject to the rules, unless some specific activity is known to create high level radiation sources without technological enhancement.

Moreover, in setting a limit for radiation exposures (besides radon related exposures), EPA should take heed of NCRP's recommended level of 500 mrem/yr. According to NCRP:

> natural radiation sources enhanced locally by man's operations for selected purposes, can give rise (sometimes quite inadvertently) to annual exposures above the level of 1 mSv. It then becomes necessary to consider at what exposure level remedial action, which may be possible only at substantial societal cost, should be undertaken. Remedial action levels involve a balance of risks and other socio-economic factors.
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> * * *
>
> The NCRP recognizes that an annual inhalation level for radon that corresponds to approximately 5 mSv effective dose would be about 1.75×10^{-3} Jh m^{-3} (see ICRP, 1981). However, this is only two and one-half times the present estimated average annual indoor radon background exposure of 7.0×10^{-4} Jh

m^{-3} and imposition of a remedial action level at this value could involve a very large number of homes and great societal cost.

Therefore, NCRP recommends that for gamma exposures:

> in the case of other exposure from natural radiation sources, considerations similar to those applied to radon would appear to be reasonable. Since the average exposure to individuals in the United States from natural radiation sources, excluding radon, is approximately 1 mSv annually, **it is recommended that remedial action be undertaken when continuous exposures from natural sources, excluding radon, are expected to exceed five times the average, or 5 mSv annually.** Id. at 50. [Emphasis in original.]

Thus, NCRP recommends a 500 mrem TEDE for non-radon related exposures from NORM. If EPA moves forward with NORM regulation, it should set the limit at this level or higher.

Use of standards such as a 5 pCi/g level for radium is inappropriate and ill considered. The 5 pCi/g standard was developed for elevated radium concentrations at uranium mill tailings facilities. These facilities are strictly regulated as they represent the presumed worst-case mining related process that actually concentrates NORM. To apply arbitrarily this standard to anything that involves concentrations of any radionuclide in excess of 5 pCi/g is unwarranted and unenforceable.

As noted above, in general, the main concern with radon is from the build-up of radon daughters within a structure -- i.e., what is popularly referred to as "indoor radon." The potential "indoor radon" exposure scenario, although often

relying on unrealistic factual assumptions (i.e., construction of a house on a waste pile and occupancy therein for 70 years), is the primary risk scenario utilized by EPA and NRC to evaluate potential public health risks from radon exposure. As a result, it is worth noting that the correlation between radium in soil concentrations and indoor radon concentrations is uncertain and should not serve as a basis for regulatory action. Radon flux rates for a given radium soil concentration are very sensitive to a variety of conditions including grain size distribution, moisture content, soil compaction, and barometric pressure. Indoor radon decay product levels are also dependent on the type of building materials and the configuration of structures. NRC recently has found that:

> The correlation between soil concentration of uranium, radium or thorium have shown to be not well correlated with the eventual levels of radon within a building . . . [T]he estimation of indoor radon concentrations attributable to licensed operations for present and future structures appears elusive.
>
> Based on information available to the NRC, there appears to be no practical way, using current technology, to distinguish between small amounts of radon from licensed operations and that radon resulting from natural background. This inability appears to be due to (1) the natural background levels of radium in rocks and soils and the resulting concentrations of radon, (2) the variability of doses at given site from naturally occurring radon, and (3) the difficulty in correlating indoor radon levels with the

concentrations of radon in the soil outside the structure.[26]

Given this fact, AMC believes that EPA's current preliminary information on the issue dramatically overstates potential risks for the vast majority of NORM wastes and site specific situations and that no need for federal NORM regulation (especially for diffuse NORM) has been or is likely to soon be, conclusively demonstrated.

G. Mixed Waste Issues

In the ANPR, EPA asks if mixed waste should be included in the radiation site cleanup regulations. In AMC's view, the present mixed waste system is ineffective. First, given the AEA's stringent regulation of low-level radioactive waste (LLRW), for wastes that are significantly radioactive, EPA's assertion of RCRA jurisdiction over the chemically hazardous component of mixed waste provides, at best, a marginal environmental benefit. At worst, it detracts from public health and the environment by unnecessarily diverting resources to deal with an artificial problem and by requiring long-term storage of some dangerously radioactive materials. Similarly, for wastes that are primarily hazardous, such as many scintillation fluids containing low levels of

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[26] "NRC: Decommissioning Rulemaking Issues Paper," pp. 31-32. (Emphasis added.)

radioactivity, assertion of AEA jurisdiction may also be unnecessary and ill-advised.

For the large portion of the mixed waste stream that cannot be readily incinerated and that contains significant levels of radioactivity, the primary long-term hazard is radioactive, not chemical toxicity. Potentially lethal doses of radioactivity cannot be perceived by human senses and, whereas the toxic components of chemical mixtures can be treated, neutralized or destroyed, only time and transmutation can eliminate radioactivity. Moreover, some radioactive materials remain hazardous for hundreds or even thousands of years.

Where mixed waste is composed primarily of chemically hazardous components, such as fluids that are readily incinerated and contain very low levels of radioactivity, NRC and EPA should be directed to exempt such materials from most applicable AEA requirements in a fashion similar to NRC's proposed (and withdrawn) below regulatory concern policy. Where the primary hazard from a mixed waste is radioactivity, the AEA, not RCRA, should assume the dominant role in the regulation of mixed waste. Under such a system, such mixed waste would be subject to only one set of regulations designed to eliminate and minimize, respectively, both the chemical hazards and the radioactive hazards of mixed waste. Disposal could take place at commercial LLRW disposal sites or at DOE

owned and operated sites licensed in perpetuity by NRC. EPA would retain both an advisory role through the Federal Radiation Advisory Counsel and an affirmative regulatory role through its authority under Reorganization Plan No. 3 to promulgate "generally applicable standards" for the protection of the public from off-site releases of radioactivity. A role for public participation and oversight at DOE LLRW disposal sites could also be incorporated into such a system.

Under such a system, mixed waste with very low levels of radioactivity (such as those identified by the NRC in its recently withdrawn below-regulatory-concern policy) would be exempt from the AEA's regulation and would fall under exclusive EPA jurisdiction. Nearly all other mixed wastes would be subject to exclusive AEA jurisdiction and perhaps some enhanced NRC standards[27]. For wastes that are easily treated, such as scintillation fluids, some provisions for incineration, prior to final disposal could be included. These wastes would remain AEA regulated wastes subject to exclusive NRC jurisdiction, however, unless levels of radioactivity were below the NRC's regulatory concern.

This program design is logical for several important reasons. First, most, if not all, mixed waste would become subject to a single set of regulations. This has long been

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[27] The NRC's LLRW regulations at 10 C.F.R. § 61.56(1)(8) already require "maximum treatment" to reduce nonradiological hazards.

sought by many in the mixed waste field, including the DOE, the NRC, some members of Congress, and virtually all generators and holders of mixed waste. Not only would it put a permanent end to inconsistency and duplication of mixed-waste regulation, it would also bring badly needed predictability to the mixed-waste field. This result would ultimately benefit the environment.

Although the RCRA regulations would need to be amended to make it clear that RCRA subtitle C requirements do not apply to mixed waste managed by the NRC/DOE, such a proposal has already been suggested by the DOE and entertained by EPA in EPA's recent deliberations regarding the definitions of solid and hazardous waste. In the context of that proposed rulemaking (which EPA later withdrew entirely), EPA stated that it:

> expects that the general approach in today's regulation would allow for exemption of mixed wastes that contain very low concentrations of chemically hazardous constituents . . . there is also a suggestion that for mixed wastes with higher concentrations of chemically hazardous constituents regulated because of RCRA listings, regulation under the AEA already requires measures intended to control exposure to, and release of, radioactive hazards that would also protect human health and the environment by limiting exposure to, and release of, chemically hazardous constituents from mixed waste. EPA solicits comments as to whether it . . . [should] develop . . . an approach for mixed waste where the conditional exemption criterion would be compliance with regulations that exist to control the radioactivity hazards.

57 Fed. Reg. 21450, 21463 (May 20, 1992).

Thus, it appears reasonable to assume that EPA would not reject this idea out of hand, because EPA, like others in the mixed-waste arena, recognizes the potential benefits to be derived from applying a single set of regulations to some, if not all, mixed waste.

The principal benefit of such a system would be that the applicable disposal requirements would acknowledge once and for all that the primary focus of control for mixed wastes that cannot easily be incinerated and that contain significant amounts of radioactivity should be on eliminating the long-term radioactive hazards. Thus, the NRC, which possesses the greatest amount of expertise in the field of radioactive material control, would once again assume the dominant role in the management of the AEA-regulated wastes. EPA's concerns regarding the need for enhanced groundwater protection could be met, and EPA would maintain a consultative role regarding these wastes consistent with its authority under the 1970 Reorganization Plan No. 3. The process of permanently disposing of mixed waste that is not amenable to treatment could begin in earnest. The result would be increased protection of the environment and an overall conservation of scarce government and industry environmental protection resources.

AMC believes that EPA should seriously consider a solution similar to that proposed above[28] and that EPA's radiation site cleanup regulations, combined with its parallel effort on waste management issues, provides an important opportunity and context for exploring such an option. However, to the extent that EPA is considering simply including mixed waste within the purview of its radiation site cleanup regulations and without significant changes to the current mixed waste regulatory regime, AMC believes that such an approach will only further complicate the mixed waste and radioactive materials control situation. Since AMC believes that the current system of dual regulation of mixed waste is unworkable, AMC believes that addition of a further set of regulations can only add increased difficulty for those faced with mixed waste. Therefore, AMC urges EPA to consider some form of radioactive site cleanup and waste management standards that avoids imposition of full RCRA controls (including the more problematic RCRA requirements such as the land disposal restrictions) and AMC opposes efforts simply to layer another set of mixed waste requirements onto the existing AEA/RCRA schemes.

Finally, AMC notes that if EPA includes NORM in its radiation site cleanup regulations and retains some form of

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[28] For a fuller treatment of these issues, see Thompson and Goo, Mixed Waste: A Way to Solve the Quandary Envt'l. Law Rept'r., News and Analysis 23 ELR 10705 (Dec. 1993). Attachment C.

the current mixed waste system, EPA will then need to contend with the creation of yet another set of jointly regulated substances, namely mixed NORM wastes. In 1989, EPA released a draft rule that proposed to regulate discrete NORM and NARM above 2000 pCi/g. EPA: Environmental Standards For The Management, Storage and Land Disposal of Low Level Radioactive Wastes and Naturally Occurring and Accelerator Produced Radioactive Waste Material. EPA: R-82-01, II-F-8 (May 8, 1989) at 119. Such wastes were to be disposed of in traditional low-level radioactive waste facilities. Id. Including such wastes within the purview of federal regulation and hence with the purview of a mixed waste system would only further complicate the already difficult situation at existing low-level and mixed waste sites. Including the much more voluminous quantities of diffuse NORM waste at activity levels below the 2000 pCi/g level would only exponentially complicate the situation. EPA must clearly avoid any further expansion of the current mixed waste regime that involves the inclusion of additional materials. Otherwise, NRC's, DOE's and EPA's current mixed waste problems could be dwarfed in comparison.

H. Waste Management Issues

EPA has indicated it will address waste management issues in a separate rulemaking from promulgation of its radiation site cleanup regulations. ANPR at 54474. These regulations will contain "standards for the handling and disposal of waste

generated during cleanup." Id. EPA has asked for comment on the relation between these standards and its cleanup regulations.

As EPA is well aware, development of new site capacity for low-level radioactive waste and NORM wastes has proceeded very slowly and only with great difficulty. Indeed, no new low-level radioactive waste sites have been built since enactment of the Low-Level Radioactive Waste Policy Amendments Act in 1986, and the current front-runner site located at Ward Valley, California, continues to struggle to gain final approval to begin operations. In addition, only one commercial NORM disposal site and only one commercial mixed waste site exist in the country.

This suggests three important points. First and most importantly, EPA should take care not to create new regulatory categories of waste for which no existing disposal capacity exists. EPA's and NRC's experiences in the mixed waste and low level waste arenas demonstrate the problems created by such an approach. Once an agency has broadly determined that a waste is suitable for regulation, regardless of its characteristics, it becomes extremely difficult to create disposal capacity anywhere. Thus, creation of new waste categories, cleanup standards and waste management standards should take place together and simultaneously, rather than separately or serially. AMC urges EPA to create a "total"

radiation site/radioactive waste package before finalizing any single part, such as cleanup standards or waste management requirements. This will allow EPA and affected parties to assess much better the entire impact of such regulations.

Second, to the extent EPA ultimately does attempt to impose site cleanup conditions for new waste types, it should allow use of on-site solutions such as soil mixing or washing to reduce radioactivity and thereby reducing the need for off-site transportation and disposal. For example, where there are relatively low concentration levels and naturally occurring material, it may be appropriate to mix the soil, on or off site, to meet existing concentration limits or to achieve levels even lower than such limits. Soil mixing makes good sense because it can provide a relatively straightforward method to achieve regulatory levels.

Soil mixing plans generally (1) require comparatively simple, although sometimes expensive technology; (2) avoid unnecessary additional occupational and general population exposures during transportation and disposal at another site; and (3) avoid unnecessary utilization of diminishing capacity at facilities designed for disposal of truly hazardous radioactive waste streams. Mixing on or offsite should be allowed anytime material can be mixed and used usefully at appropriate levels for non-residential uses, such as in roadbeds, beach restoration, golf courses, or airport runways.

Finally, to the extent that off-site disposal is unavoidable, EPA should create a framework in which existing dedicated sites, such as mill tailings piles, can accept these wastes, thereby preventing further proliferation of small sites in contravention of NRC's nonproliferation policy at 10 C.F.R. 40, Appendix A, Criterion 2. NRC already has policies in place to allow the use of mill tailings piles for disposal of certain materials under appropriate circumstances. See e.g., NRC: SEC'Y 91-243, Disposal of Material Other Than Atomic Energy Act of 1954, as amended, Section 11(e)(2) Byproduct Material into Uranium Mill Tailings Impoundments, (1991). EPA should follow NRC's example.

I. Recycle/Reuse/Issues

AMC believes that EPA should adopt approaches that maximize the ability to recycle and reuse radioactively contaminated materials. Technologies noted above, such as soil washing and soil mixing can help facilitate such uses. For instance, soil mixing can help bring radium bearing sands to acceptable concentration limits so that the sands can be used in construction of roads, bridges, golf courses, beaches or other non-residential structures. Such uses are environmentally beneficial and preserve valuable, engineered radioactive disposal capacity for radioactive wastes that, for whatever reasons, cannot otherwise be reused.

With regard to specific contamination levels for structures and equipment, acceptable levels for contamination of such materials are already established for NRC licensees in Regulatory Guide 1.86 Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use and Termination of License for Product, Source and Special Nuclear Material. These levels are well accepted and there is no reason to use or develop other guidelines.

IV. CONCLUSION

EPA's potential radiation site cleanup regulations are extremely broad in scope. Regulating all radioactively "contaminated" sites in the United States, especially if all NORM sites are included, is a task of enormous proportions. Given the wide range of pre-existing federal and state regulatory programs already in place to address exposures to excess radiation, EPA's basis for imposing another set of control conditions is unclear. Although AMC strongly supports EPA's commitment to a "unified federal approach," AMC believes that an additional EPA radiation control regime can only achieve this goal if it is narrowly tailored and fully consistent with NRC, DOE and state regulatory programs. AMC believes that EPA has not yet demonstrated a need for federal NORM regulation and that EPA should either eliminate mixed waste from the purview of its radiation site cleanup

regulations or substantially overhaul the entire mixed waste system.

AMC supports EPA's willingness potentially to exempt NRC licensed facilities from its radiation site cleanup regulations and believes, at a minimum that EPA must exempt uranium milling and mill tailings facilities from additional regulatory control. Further, regardless of the scope of EPA's rulemaking, EPA's approach to setting cleanup levels must be grounded in sound science and take account of the real world context in which such rules will operate. Cleanup levels must not be set within the increments of natural background and the variability therein and must provide the necessary flexibility to meet site specific conditions.

AMC supports use of a range of risk limits tailored to future site use conditions. AMC generally believes that NRC and DOE's 100 mrem/yr TEDE dose limit is an appropriate starting point for a risk limit when appropriately combined with an ALARA type principle. AMC opposes use of a risk goal such as the SDWA MCLGs for radon in drinking water.

AMC believes that unless EPA is careful in tailoring the scope of its regulation to address only situations clearly warranting attention, EPA will be forced to contend with a wide range of cost, practicability and administrative issues that could threaten the overall success of EPA's program. AMC urges EPA to consider the total effect of its regulations in

terms of both their cost and their overall impact on the environment. In considering such issues, EPA should consider pollution prevention and recycling opportunities and avoid creating additional difficult-to-manage mixed wastes and increased potential for worker and public exposure from storage and remediation activities and from off-site transportation and disposal. EPA should also, to the maximum extent practical allow use of on-site solutions, such as soil washing and mixing. Finally, where off-site disposal is unavoidable, EPA should rely on use of existing disposal capacity such as operational uranium mill tailings piles.

AMC appreciates being provided with this opportunity to comment. AMC is committed to working with EPA on these issues and will comment further on subsequent EPA activities and relevant proposals regarding these issues. For any questions regarding these comments, please contact Mr. James E. Gilchrist at the American Mining Congress (202/861-2800) or AMC's counsel on this matter, Mr. Anthony J. Thompson of Perkins Coie (202/434-1618).