UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
THE ADMINISTRATOR

Honorable William K. Reilly
Administrator
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

Subject: Commentary on Harmonizing Chemical and Radiation Risk-Reduction Strategies

Dear Mr. Reilly:

The Science Advisory Board's Radiation Advisory Committee would like to bring to your attention the need for the Agency to develop a more coherent policy for making risk-reduction decisions with respect to radiation and chemical exposures. As detailed in the attached commentary, *Harmonizing Chemical and Radiation Risk-Reduction Strategies*, the regulation of radiation risks has developed under a different paradigm than for regulation of chemical risks, and a significant potential exists for EPA decisions on radiation risk reduction to be seen as unjustified by the health physics community, the chemical risk management community, or both. Our concern has been stimulated by three recent reviews that we have conducted: the Idaho Radionuclides Study (EPA-SAB-RAC-LTR-92-004), the Radionuclides in Drinking Water proposal (EPA-SAB-RAC-COM-92-003), and the Citizens' Guide to Radon (EPA-SAB-RAC-LTR-92-005). In the first two reviews, we observed that application of the chemical paradigm to radiation issues was questioned by many in the radiation protection community. The Agency's treatment of radon in indoor air has been more in line with traditional radiation risk management, but it is inconsistent with the Agency's proposals for control of radon in drinking water.

Although the reasons for the differences between the two paradigms are historical as well as scientific, an important feature of radiation risk assessment and reduction is the existence of a natural background of radiation in the range of about 70 to 250 millirem (mrem) per year exclusive of indoor radon. With current EPA risk assessment assumptions, the average background – say, 100 mrems per year – is estimated to produce a cancer risk of about 3 per thousand people over a lifetime

of exposure. To many radiation scientists, reducing *excess* exposures much below 100 mrem/yr seems unnecessary and in any case exceedingly difficult to monitor for compliance because it is within the natural variability of background. By contrast, most EPA programs aimed at reducing risks from *chemical* exposures strive for risks of one in ten thousand or lower. When this paradigm is applied to radiation exposures, such as from radon in drinking water or radionuclides at Superfund sites, the reduction in radiation exposure is in the vicinity of 3 to 5-percent of the total exposure, a figure far below the variability of natural background exposures. In the case of guidelines for radon mitigation in homes, however, the Office of Radiation Programs appears to use the radiation paradigm. The current benchmark criterion for remediation of radon in homes is an annual average concentration of 4 picocuries per liter at the lowest lived-in area, which translates (again, with standard risk assessment assumptions) to a lifetime cancer risk near one in one hundred.

The Science Advisory Board Report, *Reducing Risk: Setting Priorities and Strategies for Environmental Protection* (EPA-SAB-EC-90-021, subsequently referred to as *Reducing Risk*), clearly enunciates the principle that EPA's priorities should be directed towards reducing the greatest risks first, especially when that can be accomplished economically. The corollary to that principle is that similar risks should be treated similarly, which calls for the harmonization, in so far as is possible, of risk-reduction strategies between chemicals and radiation. Harmonization does not necessarily imply identical treatment, but it does imply that any differences in treatment are clearly explained and justified.

A resolution to the seeming discrepancy between the radiation paradigm and the chemical paradigm could be achieved in any of several ways: bringing risk-reduction strategies for excess radiation exposures consistently in line with the chemical paradigm, as appears to be happening in some parts of the Agency; bringing chemical risk-reduction strategies more in line with the radiation paradigm; or achieving harmony between the two systems by modifying both in appropriate ways, explaining residual differences, and placing more emphasis on what can reasonably be achieved. In the last case, the importance of background risk could be incorporated and the balancing of the benefits and costs of risk-reduction measures could be strengthened while maintaining much of the Agency's current approach to chemicals. If none of these approaches seems appropriate, the Agency should at least explain why the risks from radiation and chemicals are treated differently under specified conditions and in specified exposure settings. The Committee appreciates the Agency's difficulty in establishing a coherent risk-reduction strategy under the variety of statutes governing EPA.

The ideas in this Commentary have been discussed with the chairs of two other SAB committees, Environmental Health and Drinking Water. While not

necessarily in agreement about the virtues of various approaches to the problem, both of these agree that the issue is important and should be addressed by the Agency. As always, we look forward to receiving your response to this Commentary.

Sincerely,

Raymond C. Loehr

Dr. Raymond C. Loehr, Chair
Executive Committee
Science Advisory Board

Oddvar Nygaard

Dr. Oddvar F. Nygaard, Chair
Radiation Advisory Committee

Attachment 1--Committee Roster
Attachment 2-Commentary

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HARMONIZING[1] CHEMICAL AND RADIATION RISK-REDUCTION STRATEGIES--A SCIENCE ADVISORY BOARD COMMENTARY

Introduction

Risk assessment and risk-reduction strategies for radiation have developed within a markedly different paradigm than has been the case for chemicals. Radiation risk assessment has been based largely on observations in humans exposed to relatively well-known doses of radiation, while chemical risk assessments are much more often based on projections from experiments with laboratory animals or on human epidemiology with relatively uncertain determinations of exposure. Perhaps more importantly, radiation risk-reduction strategies have developed almost from the start under the assumption that it would be necessary to balance these risks against the benefits of radiation or radiation-producing technologies, all within an environment that included unavoidable natural sources of background radiation. By contrast, chemical risk-reduction strategies evolveded from an initial assumption, developed early in this century for food additives, that public health could be completely protected. Only in the 1960s did a balancing approach become well established for chemicals, and (in retrospect) even then it was aimed at reducing risk to levels that would be considered low by almost any criterion, thereby favoring protection of health more than did the radiation paradigm. Furthermore, for many chemicals, significant natural sources were either absent or given relatively little consideration.

The discordance or lack of harmony between these different paradigms was not particularly evident until the Environmental Protection Agency (EPA) started to deal with radiation issues in the context of decisions that also needed to be made about chemicals, for example with respect to radionuclides as hazardous air pollutants under the Clean Air Act, or at hazardous waste sites, or in drinking water supplies where chemicals are also present. The application of standard chemical risk-reduction criteria to radionuclides in these situations leads to limitations on excess radiation dose that are small in comparison to natural background radiation. Knowing the history of the radiation paradigm, it should come as no surprise that some radiation scientists see such limitations on radiation exposures as unworkable or even misguided. Some chemical risk assessors who observe radiation protection

[1] As applied to environmental management, "harmonizing" is a word used extensively in Europe but not as much in the United States. Harmonization does not require that all environmental policies be identical or even wholly consistent; policies are in harmony when they are seen as in tune with an overall strategy and not discordant.

guidelines corresponding to risks greater than one in a thousand are similarly puzzled: how can such high absolute risks be tolerated?

Given this situation, some resolution of the discordance between the two paradigms is needed. The resolution could simply be to assert that radiation and chemicals are fundamentally different and should be assessed and managed differently, or some synthesis could be reached that takes into account both background issues and absolute risk levels. As an example of the latter approach, Kocher and Hoffman (1991) have recently proposed a specific risk management strategy that may be applied to both radiation and chemicals. The following sections describe the radiation and chemical paradigms in more detail and suggest some possible approaches to resolve the discordance between them.

The Radiation Paradigm

Current risk assessment approaches for radiation, whether from radionuclides or from other sources, developed out of the atomic energy program. It both served as a framework for radiation protection for atomic workers (and later for the general public) and, under the rubric of "damage assessment," was used to predict fatalities and residual health impacts from the radioactive fallout from nuclear weapons. In assessing risk, health physicists, radiobiologists, and radiation epidemi-ologists have been able to make risk estimates of relatively high precision from human data. While cancer risk estimates for radiation entail substantial uncertainties, especially at low doses and dose rates, they are seen as being sufficient to justify making a best estimate of risk within a *statistical* uncertainty factor of about 2 for all cancers combined for whole-body external radiation if the dose is known accurately (NCRP, 1989).[2] These best estimates of risk are used directly without further safety factors of any kind. Because best estimates are used and the degree of uncertainty is only moderate, risk assessment results for radiation can be compared with risk criteria for control decisions with some confidence.

Radiation risk assessment was heavily influenced by the thinking of physicists; in fact, "health physicists" are more likely to be involved in the practice of radiation protection than are the "radiobiologists" who study the fundamental biological aspects of radiation. Typically, the description of radiation risks emulated the mathematical treatments of physical systems, often using phenomenologic

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[2] Radiation scientists generally acknowledge that no firm conclusions about risk can be made for total doses below about 10 rem. If the linear dose-response hypothesis is accepted for low-dose extrapolation, however, the risk estimates are relatively precise. In this report the units of rad and rem have been used rather than the corresponding SI units of Gy and Se. For conversion to the latter units all numerical values are divided by one hundred.

models with consideration of biological theory only as a secondary factor. The fit of curves to cancer data from radiobiological experiments were interpreted as reflecting linear, simple quadratic, or linear-quadratic dose-response relationships, and the underlying mechanisms were described by "target theory" as "one-hit" or "two-hit" and so on. Later, it was postulated that radiation created breaks in DNA which, if not repaired, could result in somatic mutations and eventually in cancer. While it is now believed that additional mechanisms – e.g., radiation effects on oncogenes – may play a role, the mutation hypothesis for radiation carcinogenesis still heavily influences radiation risk assessment and management (NCRP, 1989).

The analysis of epidemiologic information followed similar models, whether the data were from acute doses of whole-body gamma irradiation (Hiroshima and Nagasaki), fractionated X irradiation (tuberculosis patients, for example), or protracted irradiation from internally deposited radionuclides (the radium dial painters and the uranium miners). Issues arose about the existence of thresholds for radiation carcinogenesis (e.g., in the dial painters) or at least "practical thresholds" (e.g., the idea that cancer latency was inversely related to dose such that manifestation of risks at low doses could be delayed so long that no cancers would occur during a normal lifetime).

Underlying all this development was the knowledge that background exposures to radiation in the range of about 70 to 250 millirem per year (mrem/yr) and averaging perhaps 100 mrem/year dose equivalent (NCRP, 1987) were inescapable. At least initially, these background exposures were generally assumed not to confer *significant* risks. Thus, as recommended radiation standards became more stringent with the discovery of adverse effects at ever lower levels of protracted exposure, the radiation scientists kept in mind the difficulty of separating *excess* exposures from natural exposures when the former did not substantially exceed the latter. Consequently, cancer risk-reduction strategies for excess radiation exposures have very probably included comparison to background radiation in addition to the comparison of risks and benefits resulting from radiation-producing technologies, even though the background exposure issue has usually not been explicitly presented in such decisions.

When in the early days the critical endpoints for radiation protection were effects seen only at what are now considered to be high (e.g., erythema) doses, the allowable excess doses were easily separable from normal variability in background radiation. The standards have been tightened as the assumption of no threshold for radiation carcinogenesis and the possibility of a linear dose-response relationship have taken hold among most radiation risk assessors. These assumptions have been

employed in the development of radiation protection policy. Scientists have also learned, however, that many people are experiencing exposures to the lungs from radon and its progeny that confer risks several times that from the 100 mrem/year that arises from cosmic radiation, terrestrial gamma radiation, and internal potassium-40 radiation, averaging perhaps 200 mrem/yr (NCRP, 1987). And, at least for a time, medical diagnostic and therapeutic radiation increased the average radiation dose about 100 mrem/year on the average.

The International Commission on Radiological Protection (ICRP) currently recommends limiting excess environmental radiation exposures to a total of 100 mrem/yr for the general population (ICRP, 1991). In addition, the ICRP requires that there be a net positive benefit and that the ALARA principle be adhered to that is, that exposures should be kept As Low As Reasonably Achievable when economic and social factors have been taken into account. The ALARA concept appears to be the radiation protection community's equivalent of feasible technology-based standards for chemicals.

The potential cancer burden from 100 mrem/yr exposure is not always made explicit in radiation protection guidance. If continued over a lifetime, however, 100 mrem/yr is calculated with EPA's current risk coefficient for radiation carcinogenesis to cause cancer risks of almost 3 in a thousand (3×10^{-3}) (NAS/NRC, 1990). Some analyses would predict risks up to three times higher, i.e., close to one in one hundred.

The Chemical Paradigm

For chemicals, the paradigm is different. Most cancer risk assessments are based on the results of bioassays in animals dosed with chemicals at levels thousands of times those expected in the environment, not from human data of high reliability. To deal with the uncertainty, EPA in particular has adopted the use of the upper confidence limit on the slope of the linearized multistage model to project risks at low doses and has used a conservative procedure -- the surface area scaling rule -- to project from animal bioassays to assumed human responses. Both of these procedures are widely believed to produce risk estimates that are more likely to overestimate than underestimate human risk (EPA 1986; 1989). Thus risk estimates for chemicals are biased high (even though such may not be the case with every chemical). This conservative method of dealing with uncertainty ensures that in the vast majority of cases, the actual risk level achieved will be lower than the risk criterion used in a control decision.

Furthermore, the prototype chemical carcinogens were synthetic substances with no or limited natural sources. In calculating excess risk from human sources of a chemical, background levels, if any, are therefore frequently seen as irrelevant, even though in actuality background levels from either natural sources or anthropogenic sources other than the one being considered often exist.

Risk assessment for chemicals developed from the ideas of medical epidemiologists, biostatisticians, experimental biologists, and -- perhaps most importantly -- public health regulators. Again the idea was to protect people from the adverse effects of chemicals on health, most particularly potential carcinogenicity. Here the tradition was chemical safety, deriving from the early food and drug protection ideas to keep chemical exposures low enough to protect health with a substantial margin of safety. This was typically accomplished by finding some "no-effect level" and then dividing by "safety factors" with the goal of achieving nearly absolute safety. This approach is still used for non-carcinogenic chemicals.

The idea that some chemicals might be a little dangerous at *any* level of exposure (the no-threshold idea, applied especially to what were then called "radiomimetic chemicals") came as quite a shock to the regulators. Congress responded in 1958 by attaching the "Delaney Clause" to the amendments for the Food, Drug, and Cosmetics Act, which prohibited the addition to the human food supply of any chemical that can cause cancer in humans or animals. The idea remained to provide absolute protection against cancer risk.

From the start, however, FDA scientists and others realized that assuring complete absence of carcinogens in the food supply was impossible, particularly in view of the rapidly advancing ability of the analytic chemists to detect ever lower levels of chemicals in food, and the abundance of naturally occurring carcinogens. Almost from the outset of the Delaney era, therefore, the FDA was looking for the practical equivalent to absolute safety in a world where thresholds for carcinogenesis could not be assured. FDA and NIH scientists soon proposed that if risks calculated under the no-threshold assumption were below some small value, the carcinogen was effectively not present in the food and the Delaney Clause would be satisfied. The first proposal for a "virtually safe dose" was to limit cancer risk to one in 100 million (10^{-8}) over a lifetime of exposure (Rodricks et al., 1987). The idea was clearly tied to the assumption that all the people in the United States could be exposed at or near the virtually safe dose; at the then-current population of about 150 million, only one or two people currently alive could be affected even if all the conservative assumptions about exposure and potency proved to be true.

Shortly thereafter, it was realized that the 10^{-8} criterion itself put an almost impossible burden on the regulator for assuring the safety of food additives with considerable benefits. Almost as a reflex, the idea arose that one in a million (10^{-6}) was a lifetime risk that most people would find negligible. At that level, everyone in the nation could be exposed and only about 3 excess cancer cases *per year* would be incurred, again even if the risk estimates were accurate and not conservative. Given that everyone would not be so exposed if one calculated the risk for a reasonably highly exposed person, the resulting cancer toll would clearly be invisible and, for most people, the risk insignificant.

Although quasi-scientific arguments have been offered to justify the one-in-a-million criterion for acceptable risk, we must not forget that it originated as a number of convenience. Nevertheless, it became institutionalized over the next several years and, when cancer risks from environmental exposures became recognized in the late '60s and early '70s, the concept of negligible risk at 10^{-6} was applied there.[3] Early on, the types of risks of most concern were widespread ones such as exposures to PCBs or pesticide residues in the environment. Later, the same risk criteria began to be applied to much less widespread risks such as around industrial facilities or hazardous waste disposal areas.

Eventually, it became evident that 10^{-6} was a very stringent criterion when relatively few people were exposed. Studies of EPA decision-making show that EPA often has chosen not to require reductions in exposure when the calculated risks were as high as 10^{-4} or even 10^{-3} when the population exposed was small (Travis et al., 1987; Rodricks et al., 1987).

Moreover, some of the statutes that govern chemical regulation by EPA and other agencies allow or even require a balancing of the risks against the benefits of the technologies involved and the cost of control strategies in determining what risk is acceptable in a specific situation. Others simply demand action whenever risks are determined to be "substantial" or "significant," and many judicial battles have been fought over the meaning of these directives. For example, in the *Vinyl Chloride* case litigated under the Clean Air Act, the court ruled that chemical safety did not imply a complete and unambiguous freedom from risk, but also that the

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[3] This level of risk limitation was not, and still is not, required in the occupational health arena where, both by virtue of arguably voluntary risk and by precedent from non-cancer risks, a lifetime risk criterion of about one in a thousand is considered reasonable for occupational exposure to carcinogens (See Rodricks et al., 1987, pp. 314). Even in the occupational arena, however, radiation exposure limits are less restrictive in risk terms than are chemical exposure limits. Currently allowable radiation doses, if actually incurred, would lead to a lifetime risk of well over one in a hundred, perhaps reaching one in ten (See NAS/NRC, 1990, pp. 172).

primary safety decision had to be made without considering benefits and control costs (Whipple, 1989). Later, risk/benefit balancing could be applied in determining an adequate margin of safety. Such risk-benefit balancing is conducted in the same spirit as the optimization principle in the radiation community, but at a different balance point, with radiation protection requiring lower expenditures per cancer avoided.

Recently, Don R. Clay, EPA's Assistant Administrator for Solid Waste and Emergency Response (which includes the Superfund program) has indicated that remediation at hazardous waste sites need not be undertaken when cancer risks for lifetime exposures are calculated to be below 10^{-4} (Clay, 1991). Cancer risk levels at or above 10^{-4} are also accepted in setting Maximum Contaminant Levels (MCLs) for carcinogens in drinking water (e.g., for chloroform from water disinfection) when limiting them further is not technically or economically feasible. Even so, many EPA programs still apply a risk criterion in the 10^{-6} to 10^{-4} range to a (sometimes only hypothetical) "maximally exposed individual" or "reasonable maximum exposure." This "individual risk" focus does not place as much weight on the overall protection of public health (individual risk times number of people exposed at that risk level) as does a "population risk" focus. Whether the Agency's judgment is focused on individual risk or on population risk for a specific situation depends on the provisions of the enabling legislation and the traditions of the EPA office implementing it. Risk-based legislation is more likely to result in an individual risk focus, whereas technology-based standards to some extent skirt the individual risk issue and implicitly favor a population risk approach.

Some chemical regulators and environmentalists are convinced that risk levels above one in a million are not acceptable for *any* person, invoking arguments regarding equity: why should any person bear a cancer risk for the benefit of other people? Why should all people not be afforded equal protection? Why should carcinogens be allowed in the environment at all? And everyone would agree that all opportunities to reduce risk should be seized as long as the costs -- economic, social, or other -- are not too high.

Progress toward such goals is much easier to measure when there is no natural background exposure. Synthetic organic chemicals often would not be observed in the environment at all if not for human activities; even when natural

sources can be identified, the risk levels for the natural levels of exposure are often not high when calculated with the linearized multistage model or an equivalent.[4]

Notwithstanding these similarities to the radiation paradigm, the chemical carcinogen paradigm tends to view any risk levels above 10^{-4}, even to a very few individuals, as potentially excessive and therefore requiring action to reduce exposure and risk.

Discordance between the Paradigms

Although similarities and differences in risk *assessment* techniques for chemicals and radiation have been discussed, (NCRP, 1989) and although the difference in the risk-reduction strategies between these two paradigms has been recognized by some scientists and regulators for several years, the provinces of the health physicists and the chemical risk managers stayed relatively distinct until recently. As the EPA gradually took on greater and greater responsibility for regulating radiation sources as well as chemical ones, the discordance became more visible.

The difficulty became evident in several EPA program areas. When EPA had to promulgate National Emissions Standards for Hazardous Air Pollutants (NESHAPs) for radionuclides, it needed to harmonize the residual risk levels with those allowable for other carcinogenic air pollutants such as benzene. In the course of analyzing sources of airborne radionuclides, more stringent controls were proposed for them than would have been thought necessary to keep radiation doses to 100 mrem/yr or somewhat less. Furthermore, EPA had to wrestle with the fact that prior emissions from (or other practices of) these facilities may have left residual radioactivity in communities across the country producing radiation doses with calculated risks greater than one in ten thousand. The Radiation Advisory Committee (SAB, 1992a) recently commented on the Idaho Radionuclides Study, in which some people may have received *excess* gamma radiation of the same magnitude as typical background radiation levels, i.e., about 100 mrem/yr, from uranium-series radionuclides in elemental phosphorus slags distributed in their community. Elsewhere, EPA is dealing with radon emanations from phosphogypsum stacks or with radionuclides from processing of rare earths for radium, thorium, or non-radioactive materials.

[4] In a few situations -- arsenic in drinking water comes to mind -- the calculated risk levels of natural exposure are high. In such cases, the idea of comparison to background of chemical carcinogens is more likely to be invoked, often by stipulating that there is no excess exposure if measured concentrations are not beyond the confidence limits on the distribution of background concentrations.

A second area of discordance grew out of the recognition of waste problems involving radioactive materials that were under the purview of EPA or state environmental agencies rather than the Nuclear Regulatory Commission or the nuclear/radiation safety agencies in agreement states. The most striking of these are the radioactive or mixed waste problems at sites that have been placed on the National Priority List for attention by the Superfund Program. Here the wastes of most concern are often the radionuclides of the uranium or thorium series that are also found in nature, and which have for the most part been "technologically enhanced" by human activities, rather than created by them.

The facilities of the Department of Energy that are part of the nuclear weapons complex form another group of problem sites where radionuclides are a significant or even dominating part of the cancer risk equation. Whether these facilities are treated as Superfund (CERCLA) problems or current waste disposal sites under the Resource Conservation and Recovery Act (RCRA), the treatment of radioactive materials is seen as necessarily being subject to the same types of risk analyses and remedial responses that EPA has used for chemicals. The document "Risk Assessment Guidelines for Superfund" (RAGS), for example, contains a section on how to assess the cancer risks from exposure to radionuclides, but does not suggest any different risk-reduction strategies than for carcinogenic chemicals. The implication is that remediation is expected if the lifetime risks from radionuclides are calculated to exceed about 10^{-4} (or lower in some proposals for radiation sites).

The differences in the radiation and chemical paradigms have also become apparent in EPA's actions with respect to radon in homes. The current EPA guidance ("action level") for home remediation is 4 pCi/L of radon in air in the lowest lived-in area, which by current EPA risk assessment methods translates to a lifetime risk of over 1 in 100 or 10,000 in a million (1×10^{-2}) for an average person (smokers and nonsmokers combined) (EPA, 1991a). The Agency is clearly not implying that such a level of risk is acceptable in an absolute sense, but appears to be applying a rule of practicality based on the difficulty of reducing exposure levels much below 4 pCi/L within a reasonable budget. EPA also must work on the radon issue without a clear legislative mandate encouraging the Agency to regulate homeowners' choices.

EPA has reacted differently to the legislative requirement to control levels of radon in drinking water. Using an approximation of the chemical paradigm, the Office of Drinking Water has proposed that public water utilities must treat water that contains radon above 300 pCi/L (EPA , 1991b), a level yielding a risk in the vicinity of one in ten thousand (1×10^{-4}), even though this level of risk is two orders

of magnitude lower than what is recommended for radon in air and the cost per calculated life saved is substantially greater than for remediation of radon in household air (SAB, 1992a).

It can be argued that the discordance between radiation and chemical risk-reduction strategies is simply another manifestation of necessary differences in regulatory choices in different situations. Indeed, good reasons exist to make all risk-reduction decisions within a framework intended to reduce overall risk levels without excessive attention to keeping the risks from any one situation within inflexible guidelines. Clearly, the requirements of the various statutes enabling EPA's regulatory activities force the Agency to formulate and apply some *discordant and* seemingly inconsistent policies. Nevertheless, the Committee believes that the differences between the chemical and radiation paradigms are more troublesome than the variation within each area of regulation.

In each new case of radiation risk management, EPA can follow the chemical tradition of regulating risks to the vicinity of 10^{-4} or lower or the radiation tradition of tolerating (where inexpensive remedies are not readily available) an approximate doubling of the risks from natural background radiation, which are in the vicinity of $3 * 10^{-3}$ for background exclusive of radon and nearly one in a hundred (10^{-2}) when radon is included. This disparity can and has led to considerable lack of understanding and conflicts between health physicists and chemical risk managers. Even the existence of an analogy in the chemical world to the radionuclide problem – the background levels of carcinogenic inorganic substances such as arsenic and the existence of substantial quantities of natural organic carcinogens in foods (Ames and Gold., 1990)– has not brought about any resolution of this discordance.

Need for Harmonization

Clearly, EPA needs to adopt policies that will allow its staff, the regulated community, scientific consultants to both parties, and the general public all to know what to expect in EPA's regulation of residual radioactivity and other radiation issues. The Radiation Advisory Committee does not claim any special insight in how the resolution should be accomplished, but does emphasize the importance of achieving such harmonization. Interest in the comparative risks of radiation and chemicals has a substantial history (NCRP, 1989) and is now becoming more widespread (Kocher and Hoffman, 1991).

One approach could be to assert that radiation and chemical regulations are fundamentally different, perhaps because of the unavoidability of background

radiation. The guidance of the ICRP on dose limitation (currently, 100 mrem/yr whenever the ALARA principle does not result in lower levels) could become the explicit policy of the Office of Radiation Programs (ORP), and other branches of EPA could explicitly defer to ORP on radiation and radioactivity issues.

A second set of alternative approaches would strive for clear consistency between the radiation and chemical risk-reduction strategies. The two extreme cases are:

a. Use the optimization principle along with background risks from radiation as guidance for how much excess risk can be tolerated from any source, be it chemical or radiation. Excess risks in the range of 10^{-3} or a bit higher would be used as a criterion for remedial actions or regulations where remediation is expensive and not easily achieved. Use the ALARA principle whenever it applies, that is, when risks can be reduced without excessive penalties in terms of social or economic costs. Make provisions for dealing with hazards in those cases where exposures even at the calculated 10^{-3} risk level are not detectable or distinguishable from background (i.e., ALARA should apply whenever risk reduction can be reasonably anticipated even though it cannot be measured).

b. Regulate radiation risks exactly as chemical risks are now regulated. Use 10^{-4} as a standard criterion for remediation or regulation, regardless of how the corresponding standards compare with background levels of exposure. Use the absolute value of risk in excess of background risk as a criterion, not the fractional increment relative to background risk. Make practical exceptions for the inability to detect some of the regulated exposures at the selected level of risk, just as is done for chemical substances when the detection limit exceeds the target for regulation, as is the case for dioxin in water. Take costs and benefits into account where the applicable legislation provides for that possibility.

The Radiation Advisory Committee recognizes that neither of these latter options may be practicable given the history of how the two paradigms developed. Probably more likely to be accepted would be a third option that seeks a compromise risk-reduction strategy with an intermediate risk acceptance criterion or criteria.

As a third option, the Agency could determine that, because the physical characteristics of the two types of agents are so different and because the approaches to monitoring and regulating them have developed so differently, bringing the two areas into rigid conformity in the near term is very likely not possible, however societally or ethically desirable as a long-term goal. The Radiation Advisory Committee strongly suggests in this case that the two approaches be *harmonized*--that is, fitted into a common policy framework aimed at aggregate risk reduction but not necessarily achieving such reductions in identical ways or with identical risk criteria in every case (see Deisler, 1984, for an example of harmonization in the chemical safety field). The harmonization between chemical and radiation risks of different types could occur by clearly and explicitly taking into account the differences in risk-reduction criteria or strategies between hazards that have natural sources (rather than, or in addition to, anthropogenic sources) and those that have only anthropogenic sources. For example, risk criteria for substances with no natural sources (including radionuclides such as plutonium or americium) could be different from those used for substances that have natural sources (including carcinogenic inorganic substances and organic materials with significant natural sources).

Whatever the nature of harmonization between the radiation and chemical paradigms, it will need to incorporate as well the differences among ambient environmental and indoor and occupational exposures, and the distributions of risks and benefits among exposed individuals and the sources of the exposure.

Clearly, the choice among these options – and others that may exist – is a policy choice that transcends scientific analysis. The leadership of the Environmental Protection Agency has the authority and the responsibility to make the choice. We urge the choice to be articulated clearly so that the scientists who assess the risks of radiation and chemicals can understand the basis for subsequent decisions about risk reduction.

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