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HARMONIZING CHEMICAL AND RADIATION RISK MANAGEMENT

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Risk assessment and risk management for radiation and chemicals have developed within markedly different frameworks. Radiation risk assessment has been based largely on observations in humans, whereas chemical risk assessment is based more often on projections from experiments done on laboratory animals (*1*).

Radiation risk management has developed under the assumption that risks should be balanced against the benefits of radiation or radiation-producing technologies, taking into account the unavoidable natural sources of background radiation. By contrast, chemical risk management evolved from an assumption that public health could be completely protected, favoring the protection of health more than radiation risk management. Furthermore, many regulated chemicals have no significant natural sources.

The discordance between these different ways of managing risk was not particularly evident until EPA started treating radiation risks in the same context as chemical risks. Applying standard chemical risk management criteria to radionuclides leads to limitations on excess radiation doses that are small in comparison to natural background radiation.

Given this disparity, some resolution of the discordance between radiation and chemical risk management is needed. The following sections describe the radiation and chemical frameworks in more detail and suggest some possible approaches to resolve the discordance between them.

Radiation framework

The current risk assessment approach for radiation developed out of the atomic energy program. For external radiation that affects the whole body, the risk estimates for all cancers combined have been derived from human data. The statistical uncertainty in the risk estimates is only about a factor of 2 if the dose is known accurately (*2*).

The best estimates of radiation risk are used directly without applying any safety factors. Because the 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 without significant bias.

Furthermore, background exposures to cosmic radiation, terrestrial gamma radiation, and internal potassium-40 radiation are inescapable. Total radiation from these background sources ranges from about 70 to 250 millirems (mrem) per year and averages perhaps 100 mrem/year (100 mrem = 1 mSv in SI units) (*3*).

For managing radiation risk, it was generally assumed at first that background exposures did not pose significant risks. But as adverse effects were found at ever lower levels of protracted exposure, the difficulty of separating excess exposures from natural exposures influenced the setting of more stringent standards. Consequently, cancer risk management for excess radiation exposures has included explicit or implicit comparison to background radiation, as well as comparison of risks and benefits resulting from radiation-producing technologies.

The International Commission on Radiological Protection (ICRP) currently recommends limiting excess environmental radiation (net exposures above background sources) to a total of 100 mrem/year for the general population (*4*). In addition, the ICRP requires that exposures be kept as low as reasonably achievable (ALARA) and that technologies that cause radiation exposures have a net positive benefit, taking into account economic and social factors.

If continued over a lifetime, 100 mrem/year produces a dose of about 7 rems. Using EPA's current risk coefficient, we project that 7 rems is about three cancer deaths per 1000 people exposed (3×10^{-3}). Some analyses would predict risks up to three times higher (*2*), and EPA is considering raising its risk coefficient. Furthermore, many people are exposed to indoor radon progeny and receive lung doses equivalent to perhaps 200 mrem/year (*3*), which increases the average risk of natural radiation to about one in 100.

Chemical framework

Current allowable occupational exposure to radiation, if actually incurred, would lead to a lifetime risk of well over one in 100 (*2*). By contrast, typical limitations on exposure to chemical carcinogens correspond to a risk of about one in 1000 (*8*).

For chemicals, the approach is different. Most cancer risk assessments are based on results of bioassays on animals. When human data are also available, they often are not suitable for quantitative risk assessment. Because of the uncertainty in predicting risks at low doses based on risks observed at high doses, most regulatory agencies use the upper confidence limit of the risk coefficient. Furthermore, some agencies (EPA in particular) use a conservative procedure—the surface area scaling rule—to predict human responses based on animal bioassays. Both of these practices are widely believed to produce risk estimates that are more likely to overestimate than underestimate human risk (*5, 6*).

Thus, risk estimates for chemicals are, on average, biased high. Using this conservative method of handling uncertainty means that the ac-

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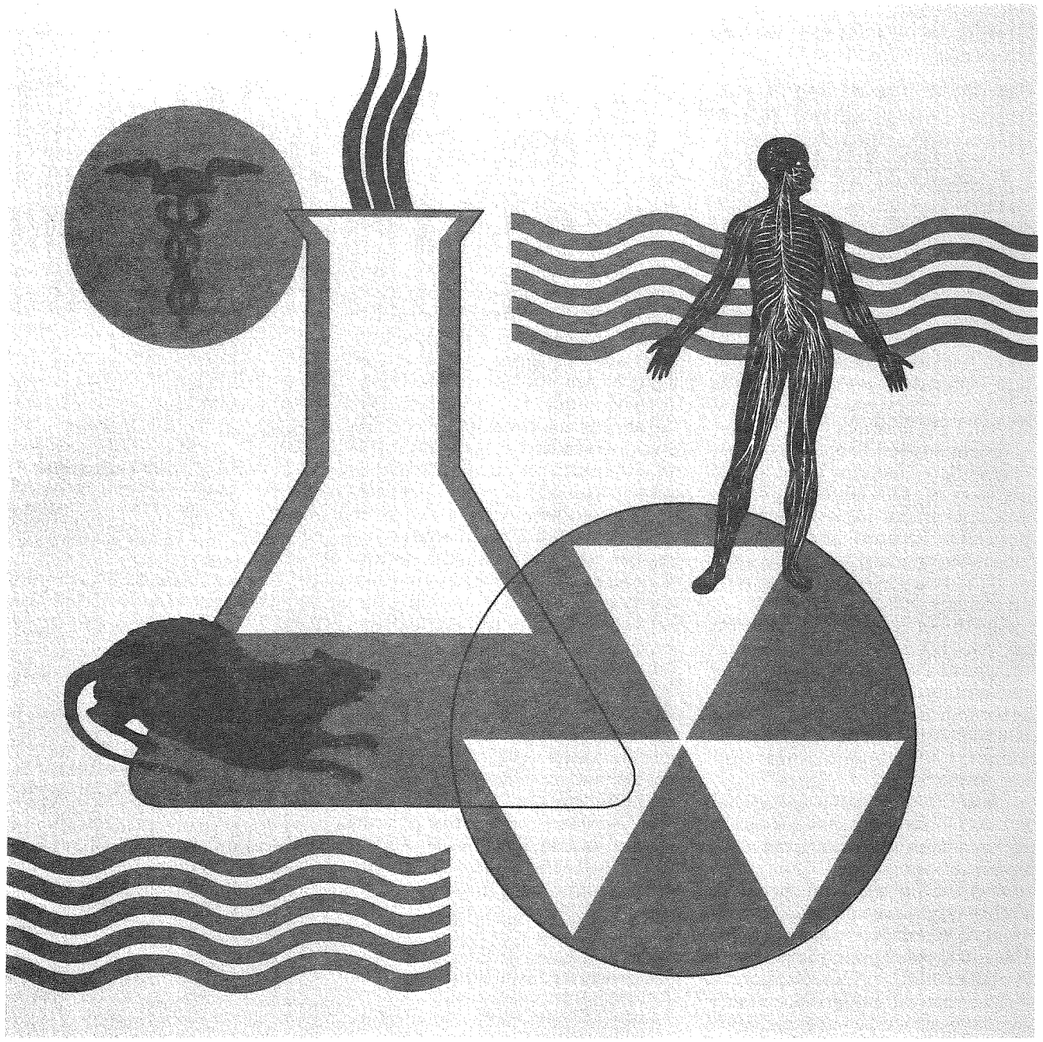

tual risk level achieved will usually be lower than the risk criterion used in a control decision. Note that the risks of cancer from chemicals are usually expressed in terms of cancer incidence, not mortality.

Furthermore, the first chemical risk assessments were performed for carcinogens that were synthetic substances having no or limited natural sources. In calculating excess risk from a chemical, background levels, if any, are now frequently seen as irrelevant.

The initial goal of chemical risk assessment was to protect people fully from any adverse effects of chemicals, particularly potential carcinogenicity. The finding that some chemicals might be a little dangerous at any level of exposure (the no-threshold concept) spawned the "Delaney Clause" [recently upheld with respect to pesticide residues in the Ninth Circuit Court (*7*)], which prohibited the addition of any human or animal carcinogen to the human food supply.

To comply with the Delaney restrictions without banning useful food additives and pesticides that technically were carcinogens, FDA looked for a practical equivalent to absolute safety. It argued that if risks calculated under the no-threshold assumption were below some small value, the carcinogen was effectively not present. 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 (*8*). Later, one in a million (10^{-6}) was proposed as a lifetime risk that most people would find negligible.

When cancer risks from environmental exposures became a concern, the statutes required "no significant risk" or the like. EPA began using the FDA precedent of 10^{-6}; however, when relatively few people are exposed, EPA often chooses not to require reductions in exposure when the calculated risks are as high as 10^{-4} or even 10^{-3} (*8, 9*). Also, regulations that balance risks and benefits allow tradeoffs in the same spirit as the optimization principle in the radiation field. Chemical standards, however, have generally required higher expenditures for each cancer avoided than have radiation standards.

Discordance between frameworks

The differences between the radiation and chemical risk management approaches have only recently led to difficulties, especially in several EPA program areas (*10–13*) (see Table 1). It can be argued that the discordance is simply another manifestation of necessary differences in regulatory choices for different situations. Nevertheless, the differences between the approaches are more troublesome than the variation within each area of regulation.

Need for harmonization

Harmonization is a concept used extensively in Europe but not as much in the United States. It does not require that all environmental policies be identical or even wholly consistent; policies are in harmony when they are in tune with an overall strategy.

Clearly, EPA and other regulatory agencies need to adopt policies that inform agency staff, the regulated community, risk scientists, and the general public about regulation of residual radioactivity and other radiation issues. Several approaches are possible:

- Assert that radiation and chemical regulations are fundamentally different because background radiation is unavoidable.
- Use the optimization principle and background radiation risks to set risk criteria in the range of 10^{-3}. Use the ALARA principle whenever it applies.
- Regulate radiation risks exactly as chemical risks are now regulated. Set risk criteria in the range 10^{-6}–10^{-4}, regardless of background risk. Take costs and benefits into account when legally possible.
- Use a compromise risk management strategy with intermediate risk criteria. Kocher and Hoffman (*14*) recently proposed a risk management strategy that could be applied to both radiation and chemicals.

Because the physical characteristics of radiation and chemicals are different and the approaches to monitoring and regulating them developed differently, to bring the two into rigid conformity quickly may not be possible. Even so, they should be harmonized, that is, fit into a common policy framework to optimize aggregate risk reduction. This does not mean that reductions must be achieved in identical ways or with identical risk criteria. For example, the harmonization between chemical and radiation risks of different types could occur by clearly and explicitly taking into account the differences in risk management criteria or strategies between hazards that have natural sources and those that have only anthropogenic sources.

Clearly, the choice among these options—and others that may exist—is a policy choice that transcends scientific analysis and is the responsibility of agency risk managers. Whichever approach is chosen should be articulated clearly so that scientists who assess the risks of radiation and chemicals—and the regulated community and the general public as well—can understand the basis for subsequent decisions about risk reduction.

The views in this article are condensed from "Harmonizing Chemical and Radiation Risk-Reduction Strategies," prepared for Administrator Reilly by the Radiation Advisory Committee of EPA's Science Advisory Board. Specific interpretations and any errors or omissions introduced in the condensation are the sole responsibility of the author. The views expressed are not necessarily those of the EPA.

TABLE 1
Risk management choices[a]

Program area	Framework: Chemicals	Framework: Radiation	Risk range
NESHAPs[b] for radionuclides	x		10^{-6}–10^{-4}
Residual radiation	?		NE
Radon in indoor air		x	10^{-2}
Radon in drinking water	x		10^{-4}
DOE site cleanup	?	x	NE
Superfund cleanup	x		10^{-6}–10^{-4}

[a] x indicates framework definitely used, ? indicates framework may be used, NE indicates not established.
[b] National Emissions Standards for Hazardous Air Pollutants.

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References

(1) National Council on Radiation Protection and Measurements. "Comparative Carcinogenicity of Ionizing Radiation and Chemicals"; NCRP Report No. 96; NCRPM: Bethesda, MD, 1989.
(2) National Research Council. "Health Effects of Exposure to Low Levels of Ionizing Radiation"; report of the Committee on the Biological Effects of Ionizing Radiations (BEIR V); National Academy Press: Washington, DC, 1990.
(3) National Council on Radiation Protection and Measurements. "Exposure of the Population in the United States and Canada from Natural Background Radiation"; NCRP Report No. 94; NCRPM: Bethesda, MD, 1987.
(4) International Commission on Radiological Protection. "Radiation Protection: 1990 Recommendations of the International Commission on Radiological Protection"; ICRP Publication 60; Pergamon: New York, 1990.
(5) *Fed. Regist.* **1986**, *51*, 33996.
(6) *Risk Assessment Guidance for Superfund*; U.S. Environmental Protection Agency. Washington, DC, 1989; Vol. 1; EPA/540/1-89/002.
(7) Holden, C. *Science* **1992**, *257*, 322.
(8) Rodricks, J. V.; Brett, S. M.; Wrenn, G. C. *Regul. Toxicol. Pharmacol.* **1987**, *7*, 307–20.
(9) Travis, C. C. et al. *Environ. Sci. Technol.* **1987**, *21*, 415–20.
(10) *Radionuclide Exposure Study: Pocatello and Soda Springs, Idaho*; U.S. Environmental Protection Agency: Las Vegas, NV, 1990; EPA/520/6-90/008.
(11) "Proposed Revisions in EPA Estimates of Radon Risks and Associated Uncertainties"; U.S. Environmental Protection Agency. Office of Radiation Programs. draft report submitted for SAB review, 1991.
(12) *Fed. Regist.* **1991**, *56*, 33051.
(13) "Reducing Risks from Radon"; Radiation Advisory Committee. U.S. Environmental Protection Agency Science Advisory Board. Letter to William K. Reilly, January 29, 1992; Drinking Water Criteria Documents, EPA-SAB-RAC-COM-92-003.
(14) Kocher, D. C.; Hoffman, F. O. *Environ. Sci. Technol.* **1991**, *25*, 1986–89.