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# The Precautionary Principle and Radiation Protection

Kenneth L. Mossman & Gary E. Marchant\*

## Introduction

Over the past decade, the precautionary principle has been incorporated into an ever-increasing number of international agreements and domestic statutes. Essentially, the precautionary principle states that when an activity or technology may harm human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. The precautionary principle remains vague and ill-defined notwithstanding its widespread use. While there have been some attempts to better define and “operationalize” the precautionary principle, most notably by the European Commission, substantial ambiguity remains about the applicability and requirements of the precautionary principle. One approach to better clarify and evaluate the precautionary principle is to examine its application to specific health and environmental problems, and perhaps just as importantly to consider cases where the principle does not apply. Control of ionizing radiation provides a useful case study for studying the application and meaning of the precautionary principle.<sup>1</sup>

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<sup>1</sup> Discussion is limited to the radiation protection of humans. Ionizing radiation refers to particulate and high energy electromagnetic radiation including alpha and beta particles, neutrons, x-rays, and gamma rays. Ultraviolet light, microwaves, and electromagnetic radiation associated with electric power generation are not considered ionizing radiation because they have insufficient energy per photon to cause ionization when absorbed.

*The Precautionary Principle*

The precautionary principle is often summarized by the phrase “better safe than sorry.”<sup>2</sup> It requires foregoing, postponing, or otherwise limiting a product or activity until uncertainty about its potential risks have been resolved in favor of safety. Over the past decade, the precautionary principle has been incorporated into a series of international environmental agreements. Perhaps most prominently known is the 1992 United Nations Rio Declaration on Environment and Development, which states: “Where there are threats of serious and irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”<sup>3</sup> Various formulations of the precautionary principle have also been adopted into other international agreements including: the United Nations Framework Convention on Climate Change, the Montreal Protocol on Substances that Deplete the Ozone Layer, the Cartagena Protocol on Biosafety, and the recent agreement on Persistent Organic Pollutants (POPs).

Europe has been at the forefront of adopting the precautionary principle. The European Community formally committed to implementing environmental policy in conformity with the precautionary principle with the 1992 Maastricht Amendments to the European Community Treaty. Individual European nations, most notably Germany and the Scandinavian nations, have selectively begun to implement the precautionary principle in their national regulatory programs, as have various non-European nations including Australia and Canada.

As presently formulated, the precautionary principle is ill-defined and vague. There is no standard definition of the precautionary principle, and the many versions that do exist are inconsistent on important aspects.<sup>4</sup> For example, compare the language of the Rio

<sup>2</sup> The Hippocratic Oath offers another interpretation of the precautionary principle. The oath instructs physicians to “prescribe regimen for the good of my patients according to my ability and my judgment and never do harm to anyone.”

<sup>3</sup> United Nations Conference on Environment and Development, *Rio Declaration on Environment and Development* (United Nations 1992).

<sup>4</sup> Per Sandin, *Dimensions of the Precautionary Principle*, 5 *Human and Ecological Risk*

Declaration cited above with the version put forward as a consensus statement by many proponents of the precautionary principle known as the Wingspread Statement which states that “[w]hen an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.”<sup>5</sup> The precautionary principle adopted by the Rio Declaration applies only to “serious and irreversible” risks, whereas the version provided by the Wingspread Statement is not limited to any subset of risks. The Rio Declaration requires any action taken under the precautionary principle to be cost-effective, while the Wingspread Statement makes no mention of economic considerations. The Rio Declaration is stated in the negative, in that uncertainty should not preclude preventive action, whereas the Wingspread Statement imposes an affirmative obligation to act notwithstanding uncertainty.

These and many other inconsistencies between the many different versions of the precautionary principle are compounded by the ambiguity in any specific formulation of the precautionary principle. No version of the precautionary principle is clear on when the precautionary principle applies, and, just as importantly, when the principle does not apply.

There remains many unanswered questions, among them includes whether the principle is triggered by the magnitude of a risk, the uncertainty associated with that risk, or some combination of both magnitude and uncertainty? How much of each is necessary to trigger the principle? If the principle applies only to “serious” or “irreversible” risks, how are such risks defined? If the principle is not so limited to serious or irreversible risks, how can the principle be applied in a principled and feasible manner given that every product presents some risks in some scenarios? What quantum of evidence is necessary to establish the necessary magnitude of risk and/or uncertainty? Can the unsubstantiated fears of one or more persons trigger the principle? Or

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Assessment 889 (1999).

<sup>5</sup> Carolyn Raffensperger et al., *Protecting Public Health and the Environment: Implementing the Precautionary Principle* (Island Press 1999) (alteration in original).

does the suspicion of a potential risk have to be supported by credible scientific evidence? What if there is some scientific evidence of a potential risk, but the total body of available evidence weighs against the existence of a significant risk? Who makes the decision regarding whether the evidence is sufficient to meet the standard for triggering the principle? What types of “precautionary measures” should be taken when a sufficient threat exists? Should the precautionary measures be proportional to the magnitude of the “threat?” If the precautionary principle requires blocking development of a product until sufficient safety data pertaining to that product is available, what is required before the product is permitted to move forward? If the available evidence indicates the potential existence of some risk, what level of risk, if any, is acceptable to allow the product to proceed? What factors can be considered in determining whether the product should or should not go forward? For example, can the economic benefits of the product be considered? Are the health and safety benefits of products considered?

These unanswered questions create substantial uncertainty about the applicability and requirements of the precautionary principle to any given risk. The European Union (EU) has made the most concerted attempt to try and reduce some of these uncertainties and provide some concrete guidance regarding the application and meaning of the precautionary principle. In particular, the twenty-nine page Communication on the precautionary principle issued by the European Commission (EC) in February 2000 provides the most detailed guidelines on the precautionary principle to date.<sup>6</sup>

The EC Communication provides some guidance on when recourse to the precautionary principle is triggered. The Communication defines the precautionary principle as a risk management tool which is to be applied only after a scientific evaluation of the available risk data (i.e., risk assessment). The Communication describes two outputs from this risk assessment that are necessary to justify recourse to the

<sup>6</sup> European Commission, *Communication for the Commission on the Precautionary Principle* (2000).

precautionary principle. The risk assessment must identify potentially negative effects resulting from the product or activity, and the available scientific data must be so insufficient, inconclusive, or imprecise to make it impossible to “determine with sufficient certainty the risk in question.” A “political decision” is then required to determine whether any precautionary action is appropriate, which is largely a function “of the risk level that is ‘acceptable’ to the society in which the risk is imposed.”<sup>7</sup>

If the precautionary principle does apply to a risk, the Communication describes a series of five general principles that should govern application of the principle. First, the principle of proportionality should apply, which requires the chosen risk reduction measure to be proportional to the seriousness of the potential risk, and should include less restrictive alternatives that achieve the desired level of protection. Second, the principle of non-discrimination which requires that risk reduction measures not be discriminatory in their application, and thus comparable situations should not be treated differently. Third, the principle of consistency requires risk reduction measures to be consistent with the measures already adopted in similar circumstances. Fourth, the costs and benefits of action and lack of action should be examined, including an economic cost/benefit analysis when this is “appropriate and feasible.” Finally, precautionary measures should be provisional, they should be reevaluated and, if necessary, modified with the development of scientific knowledge.

These principles are themselves largely general and vague in nature, and do not provide rigorous and precise definitions for when the precautionary principle should apply and what the principle should require when it does apply. Nevertheless, the EC Communication provides the most detailed and authoritative guidance to date on the application of the precautionary principle. Further clarity on the precautionary principle may require evaluation of its potential relevance to specific environmental or health threats. Control of ionizing radiation exposure provides such a case study for examining the applicability and limits of the precautionary principle.

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<sup>7</sup> *Id.*

## Applicability of the Precautionary Principle to Radiation Protection

The precautionary principle is implicit in existing radiation safety practice but is not explicitly required. The International Commission on Radiological Protection supports a precautionary approach to radiological protection by arguing that even small radiation doses may produce some deleterious health effects<sup>8</sup> although there is little direct evidence to support this view as discussed below. In practice, an “as low as reasonably achievable” (ALARA) philosophy is used to minimize radiation dose in occupational and environmental settings with appropriate considerations for social and economic costs. When used appropriately, the ALARA philosophy balances the public health goal of maintaining doses as low as possible against economic and other costs of achieving specific dose targets.

Is a more stringent approach to radiation protection premised on the precautionary principle necessary and appropriate? Ionizing radiation does not meet the criteria identified by the EC Communication for recourse to the precautionary principle. In the first place, the existing scientific database for radiation lack the requirements identified by the EC for triggering application of the precautionary principle. To the contrary, ionizing radiation is one of the most thoroughly studied human carcinogens. Health effects of radiation at occupational and environmental doses are well-known. Over fifty years of human epidemiology experience strongly supports the notion that doses below about 100 mSv and are not associated with significant radiogenic risks in adult populations. Health effects data at doses below about 100 mSv are available from a number of published studies.<sup>9</sup> Selected epidemiological studies are listed in Table 1. These studies examined mortality from leukemias and all other forms of cancer. Elevated radiogenic risks were not detected at statistically significant levels.

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<sup>8</sup> International Commission on Radiological Protection (ICRP), *1990 Recommendations of the International Commission on Radiological Protection*, ICRP Publication 60 (Elsevier Science 1991).

<sup>9</sup> United Nations Scientific Committee on the Effects of Atomic Radiation, *Sources and Effects of Ionizing Radiation UNSCEAR 2000 Report to the General Assembly (with Scientific Annex)* (United Nations 2000).

In adult populations, the lowest dose associated with significant radiogenic risk is 200 mSv. In children, the lowest dose associated with radiogenic cancer is approximately 100 mSv for thyroid cancer based on a pooled analysis of seven studies. These doses do not represent thresholds but reflect statistical limitations of radioepidemiological studies.<sup>10</sup> A recent analysis of atomic bomb survivor data from 1950 to 1990 suggested that the dose-response curve for cancer mortality is linear down to 50 mSv, which is the lowest dose linked to a statistically significant radiogenic risk.<sup>11</sup> However, in other independent analyses of the life span study data, a curvilinear dose-response also provided a satisfactory fit to the Japanese data<sup>12</sup> and, using different analytical methods, no evidence for increased tumor rates below 200 mSv was found.<sup>13</sup>

Risks from low doses of radiation are very difficult to detect in epidemiological studies because of the large background rate of cancer and the fact that radiogenic cancers are clinically indistinguishable from cancers that arise from most other causes. Figure 1 illustrates the magnitude of the problem. For a radiogenic risk of  $5 \times 10^{-4}$  (corresponding to a dose of 10 mSv and a lifetime radiogenic risk of 5%/Sv), power is 6% for a population of 0.1 million, 17% for a population of 1 million, and 90% for a population of 10 million. For a radiogenic lifetime risk of  $5 \times 10^{-3}$  (corresponding to a dose of 100 mSv), power is 90% for a population of 0.1 million, and 100% for a population of 1 million or larger.

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<sup>10</sup> Kenneth L. Mossman, *The Linear No-Threshold Debate: Where Do We Go From Here?*, 25 *Medical Physics* 279 (1998).

<sup>11</sup> Donald Pierce et al., *Studies of the Mortality of Atomic Bomb Survivors: Report 12, Part I. Cancer: 1950-1990*, 146 *Radiation Research* 1 (1996).

<sup>12</sup> Mark P. Little & Colin Muirhead, *Evidence for Curvilinearity in the Cancer Incidence Dose-Response in the Japanese Atomic Bomb Survivors*, 70 *Int. Journal of Radiation Biology* 83 (1996).

<sup>13</sup> W.F. Heidenreich et al., *No Evidence for Increased Tumor Rates Below 200 mSv in the Atomic Bomb Survivors Data*, 36 *Radiation Env. Biophys* 206, 207 (1997).

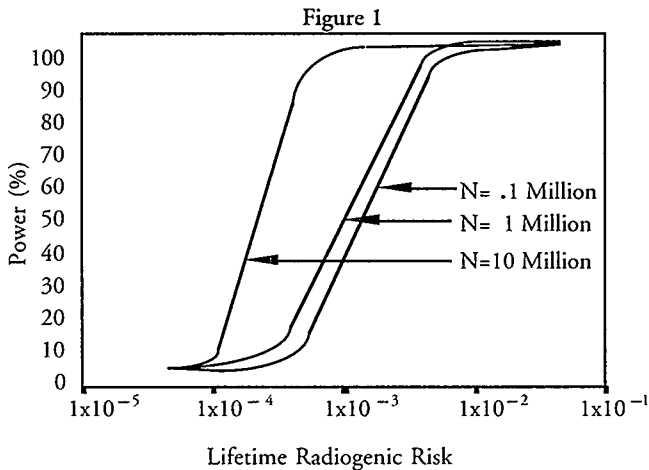


Table 1<sup>14</sup>  
 Selected Large Epidemiological Studies Involving  
 Radiation Delivered at Low Dose or Low Dose-Rate

<i>Study<sup>a</sup></i>	<i>Population</i>	<i>Mean Dose</i>	<i>Type of Exposure</i>	<i>Person-years<sup>b</sup></i>
Nuclear workers in Japan (mortality)	114,900 (all male)	14 mSv	Nuclear power plants, fuel reprocessing, research facilities	533,168
Nuclear workers in Canada, UK, US (mortality)	95,673 (85% male)	40 mSv	Nuclear power plants, fuel reprocessing, research facilities	2,124,526
Hanford Workers (mortality)	32,643 (76% male)	26 mSv	Nuclear fuel cycle, research	633,511
Yangjiang, China (mortality)	89,694 (50% male) (all ages)	6.4 mSv/y	Continuous background radiation	1,698,350

<sup>a</sup>Leukemias and all other cancers were studied in these investigations. No statistically significant radiogenic risks were found.

<sup>b</sup>Person-years is a product of the number of people in the population study and the average time of observations. The result is a measure of population size and years of observation.



*Figure 1: Power Curves*

Statistical power to detect an increased risk of cancer in epidemiological studies for population sizes of 0.1, 1, and 10 million

are shown. Power is the probability (in percent) that the given lifetime radiogenic risk will be detected. One hundred percent power means that the risk, if present, is detected all of the time. Power curves were generated using NCSS Statistical Software (Kaysville, UT 84037) assuming a baseline lifetime cancer mortality rate of 20% and  $\alpha$  error of 5%.

Although low dose and low dose-rate epidemiological studies with large populations may have sufficient statistical power to detect radiogenic risks, the use of low doses makes a clear demonstration of radiation effects difficult. Other factors including the "healthy worker effect,"<sup>15</sup> contributions of possible confounding influences of chemicals and other toxic agents in the workplace, accuracy of dose assessment, mortality follow-up, and various lifestyle factors (e.g., smoking histories) may also cloud the interpretation of data on radiogenic risk.<sup>16</sup> Notwithstanding these uncertainties, the scientific database is sufficiently rich and robust to guide policy decisions without recourse to the precautionary principle.

Perhaps even more critical to the issue of whether the precautionary principle should apply to ionizing radiation is the question of acceptable risk. As discussed above, the EC Communication states that the precautionary principle should only be triggered by risks with the potential to impose unacceptable risks. This inquiry necessitates establishing a level of risk that is acceptable (or perhaps trivial), below which neither regulatory intervention nor the precautionary principle is warranted.

The ALARA philosophy for ionizing radiation evolved from the linear no-threshold (LNT) theory that has, for many years, served as a basis for radiation protection practice and regulatory decision-making. The theory predicts that any dose of radiation, no matter how small, might cause cancer. Unfortunately, this has been interpreted to mean

<sup>15</sup> The "healthy worker effect" (HWE) is a form of selection bias in epidemiological studies where two or more groups of individuals are compared for disease. HWE allows relatively healthy people to become or remain workers whereas non-workers (including those who are retired, disabled, or who remain unemployed) are less healthy as a group. Workers probably have a minimum level of health to remain employed whereas the general population includes everyone sick or healthy.

<sup>16</sup> See United Nations Scientific Committee, *supra* n. 9.

that there is no safe dose of radiation. However, any residual risks remaining after a prudent application of the existing ALARA policy would likely be in the acceptable risk range.

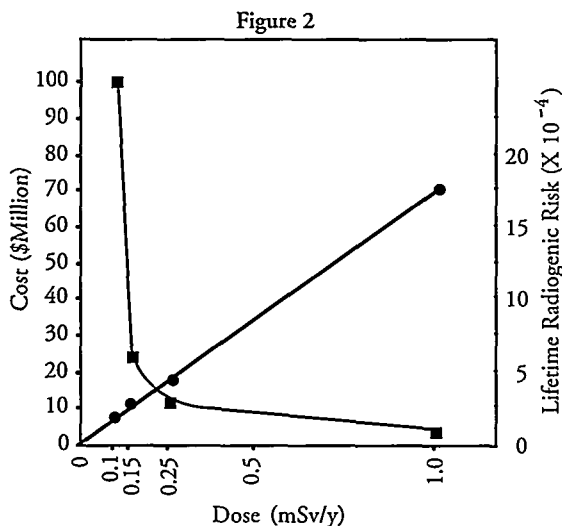
These arguments suggest that an application of the precautionary principle is neither necessary nor appropriate for radiation protection given existing protections and policies in place. Even if the precautionary principle were applicable to ionizing radiation, many of the actions based explicitly or implicitly on the precautionary principle are inconsistent with the policies in the EC Communication governing application of the principle. For example, the principles of proportionality and cost-benefit evaluation argue against regulatory action for very low radiation exposures. This guidance appears inconsistent with some extreme and inappropriate applications of ALARA (premised on the precautionary principle) in which doses are reduced to the lowest levels possible (if not zero) with little, if any, benefit-cost considerations.

This overly precautionary approach to radiation protection leads to substantial economic expenditures for a minimal public health benefit (Figure 2), and promotes public fear of radiation by fostering the idea that any dose of radiation is potentially harmful.<sup>17</sup> For example, the U.S. Environmental Protection Agency (EPA) set an individual-protection standard of 0.15 mSv/y in its final ruling on radiation standards for Yucca Mountain.<sup>18</sup> There is little evidence that doses in the range of natural background (approximately 1 mSv/y excluding contributions from radon gas and its progeny) are harmful to the public health or the environment. The EPA standard for Yucca Mountain is so low that it is within the variation of natural background radiation levels in the U.S.

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<sup>17</sup> Kenneth L. Mossman, *Deconstructing Radiation Hormesis*, 80 *Health Physics* 263 (2001).

<sup>18</sup> United States Environmental Protection Agency, *Public Health and Environmental Radiation Protection Standards for Yucca Mountain, NV; Final Rule*, 66 Fed. Reg. 32073, 32073-32135 (June 13, 2001).



*Figure 2: Excessive Costs of Environmental Cleanup*

Environmental cleanup to levels below natural background ( $\sim 1$  mSv/y excluding radon) is extremely expensive. Economic costs for soil cleanup at the Nevada Test Site are shown on the left ordinate.<sup>19</sup> Below 0.25 mSv/y, clean-up costs rise precipitously in spite of very small theoretical reductions in lifetime radiogenic risk. Calculations of theoretical lifetime radiogenic risks (right ordinate) are based on the following assumptions: a linear no-threshold dose-response, a lifetime cancer mortality risk of 5%/Sv, a seventy-year lifetime at a given annual dose, and a dose rate effectiveness factor of two to account for dose protraction.

### Conclusion

In radiation safety, implementation of the precautionary principle is unnecessary. Occupational and environmental radiation doses are well known, as well as information about the public health risks. At doses approximating natural background radiation levels (a few mSv/y), there may be no health risks from radiation exposure.<sup>20</sup> One of the greatest

<sup>19</sup> General Accounting Office, *Scientific Basis Inconclusive, and EPA and NRC Disagreement Continues* (United States General Accounting Office 2000).

ambiguities about the precautionary principle is the failure of its advocates to specify what level of risk is acceptable. Given that every product and human activity has the potential to create some risks, criteria (e.g., acceptable risk thresholds) are necessary to limit its applications to certain categories of risk. The alternatives are for the precautionary principle to apply to every risk, which is both impractical and imprudent, or for the principle to be applied in an arbitrary manner to some risks.

The demarcation of an acceptable risk range to which the precautionary principle does not apply would almost certainly exempt many low-level radiation exposures from further concern. Uncoupling radiation safety standards and practices from the precautionary principle, and defining "acceptable risk," which is critical for evaluating the need for recourse to the precautionary principle, would effectively address two major interrelated problems plaguing nuclear technologies: (1) economic costs associated with reduction of trivial risks; and (2) the idea that any radiation dose is harmful.

We therefore suggest the following. First, professional scientific and medical organizations such as the Health Physics Society, Radiation Research Society, and the American College of Radiology should issue official positions, preferably joint, defining an acceptable level of radiation risk. Second, the U.S. government should revisit its abandoned Below Regulatory Concern (BRC) policy. The federal government attempted to define what an acceptable level of risk is through a 1985 Congressional mandate to the U.S. Nuclear Regulatory Commission (NRC) to establish a BRC policy.<sup>21</sup> The policy was to establish a framework whereby the U.S. NRC would formulate rules or make licensing decisions exempting from regulatory control those practices that have such low estimated health risks that further reduction of those risks would be unwarranted. In July 1990, NRC established a BRC policy.<sup>22</sup> Special interest groups opposed the policy on the grounds that it would lead to uncontrolled release of large

20 According to the National Research Council's BEIR V Committee, at such low doses and dose rates, the lower limit of the range of uncertainty in radiogenic risk estimates extends to zero. National Research Council, *Health Effects of Exposure to Low Levels of Ionizing Radiation BEIR V* (National Academy Press 1990).

21 *Low Level Radioactive Waste Policy Amendments Act of 1985*, Pub. L. No. 99-240, 99 Stat. 1842 (1985).

22 U.S. Nuclear Regulatory Commission, *Below Regulatory Concern*, Policy statement, 55 Fed. Reg. 27522, 27522-27537 (1990).

quantities of radioactive material. This view coupled with the lack of consensus within the government regarding BRC risk levels ultimately led to Congressional revocation of the BRC policy in 1992.<sup>23</sup> Although there was some disagreement about BRC risk levels, federal agencies and the technical community generally agreed that a BRC-type policy was a worthwhile concept for effectively allocating and managing regulatory resources.



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<sup>23</sup> *Energy Policy Act of 1992*, 42 U.S.C. § 2901 (1992).

