HEALTH PHYSICS SOCIETY

"Specialists in Radiation Safety"

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November 19, 2007

The Honorable James M. Inhofe, Ranking Member
Environment and Public Works Committee
United States Senate
Washington, DC 20510

Dear Senator Inhofe:

Thank you for requesting the Health Physics Society's (HPS) position on comments submitted to the Senate Environment and Public Works Committee by Dr. Arjun Makhijani that includes the calculation of the risk of future radiation doses from the Yucca Mountain project. Dr. Makhijani's calculations of risk associated with the proposed Environmental Protection Agency's (EPA) radiation protection standards for Yucca Mountain are contained in the document "Comments of Dr. Arjun Makhijani on Yucca Mountain and the draft EPA standard submitted for the record of the Senate and Environment and Public Works Committee hearing on the 'Examination of the Licensing Process for the Yucca Mountain Repository'" dated October 31, 2007.

The HPS position is that calculation of risk associated with radiation doses for periods greater than 10,000 years into the future, like the calculations performed by Dr. Makhijani, are scientifically invalid. This position is contained in the HPS position statement "Managing Spent Nuclear Fuel", which I have attached and which can be found on at http://hps.org/documents/managing_spent_fuel_ps022-1.pdf. Specifically, the HPS position states

> "the HPS believes the scientific validity and reasonableness of assumptions regarding the estimation of cancer and genetic risk from radiation exposure only allows the risk estimates to be extrapolated out for a period on the order of several generations (that is, on the order of a hundred years) but no more than a few hundred years. The basis for this is that today's limited knowledge of radiation risk mechanisms results in the necessity of knowing the lifestyles and

underlying cancer and genetic experience of the population for which the risk is being estimated, and it is unreasonable to think these can be known beyond a few generations."

This position is based on the previous testimony of Dr. Dade W. Moeller to the Committee. In his letter to you and Senator Jeffords dated April 7, 2006, Dr. Moeller answered questions in follow-up to his testimony at the Committee's March 1, 2006, hearing on Yucca Mountain. The scientific basis for the HPS position is contained in Dr. Moeller's answers to your first two questions regarding the possibility of quantifying risk from the EPA proposed standard and in his enclosure "Implications of Risk Quantification on the Ruling of the Court of Appeals." I have attached Dr. Moeller's cover letter and the responses that are pertinent to the question of the validity of calculating risk in the context of the EPA proposed standard, such as those calculations performed by Dr. Makhijani.

I hope this is helpful in the Committee's deliberation of the Yucca Mountain project and in the understanding that calculations such as those submitted by Dr. Makhijani for periods far into the future do not have scientific validity. Please do not hesitate to contact me if you have any further questions on this, or any other radiation safety issue.

Sincerely,

Kevin L. Nelson, PhD, CHP

Enclosures

cc: Senator Barbara Boxer

HEALTH PHYSICS SOCIETY

MANAGING SPENT NUCLEAR FUEL

POSITION STATEMENT OF THE HEALTH PHYSICS SOCIETY*

Adopted: July 2006
Revised: June 2007

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The Nuclear Waste Policy Act of 1982 legislates a system of managing spent nuclear fuel that results in its permanent disposal in appropriate geological repositories. Although a repository site has been identified, studied, and mostly developed as provided for by this law, the actual completion and use of the repository is still decades off with the potential for public and legal actions preventing it from ever being operational. In the meantime, nuclear reactor technology, energy use and demand, energy production effects on the environment, public-policy mechanisms, and medical knowledge have all evolved and can be seen to continue to evolve such that the assumptions and basis for the Nuclear Waste Policy Act may no longer be appropriate for the current inventory of spent nuclear fuel. In addition, the proposal to change the nature of spent fuel management through the development of reprocessing techniques places new demands on managing possible spent fuel waste streams in the future.

In light of the current situation and prospect of future developments relevant to managing spent nuclear fuel, the Health Physics Society (HPS) takes the following **positions**:

1. The HPS believes the management of spent fuel from nuclear reactors should be conducted in a manner that (a) uses only scientifically valid and reasonable assumptions for setting protection standards, (b) adequately protects the public and environment from radiation exposure resulting from natural, accidental, or malevolent release of radioactive materials from the spent fuel, (c) accommodates evolving technologies, and (d) does not permanently dispose of potentially valuable material that is contained in a spent-fuel assembly.

2. The HPS believes that the development of new reactor technology that is intended for commercial production of electrical power must (a) integrate the characteristics of waste streams created by this new technology into the design of the new technology and process from the very beginning of its development, (b) design the framework to manage the new waste stream with equal importance to designing the technology itself, and (c) incorporate input and involvement from the regulatory authority that will regulate the technology and resulting waste stream once it is producing commercial power.

3. Regarding position 1.(a) above, the HPS believes the radiation protection standards recommended in its position statement "Ionizing Radiation-Safety Standards for the General Public" (HPS 2003) are appropriate for application to potential public exposure associated with management of spent nuclear fuel.

4. Regarding position 1.(b) above, the HPS believes the scientific validity and reasonableness of assumptions regarding the estimation of cancer and genetic risk from radiation exposure only allows the risk estimates to be extrapolated out for a period on the order of several generations (that is, on the order of a hundred years) but no more than a few hundred years. The basis for this is that today's limited knowledge of radiation risk mechanisms results in the necessity of knowing the lifestyles and underlying cancer and genetic experience of the population for which the risk is being estimated, and it is unreasonable to think these can be known beyond a few generations. Of course, this limitation may be changed as our knowledge of the radiation risk mechanisms improves, which is an example of needing to have a spent nuclear fuel management system that accommodates evolving technologies (i.e., position 1.(c) above).

Regarding positions 1.(c) and 1.(d) above, the HPS makes the following **recommendations**:

1. Spent nuclear fuel should be designated for monitored interim retrievable storage for a period intended to be at least 100 years but with a possibility of being as long as 300 years.

2. An independent expert study should be performed to inform a risk-based decision on whether the location of the interim retrievable storage for up to 300 years should be on-site where the spent nuclear fuel is generated, should be centralized in the Yucca Mountain repository, or should be in some other configuration or location. This study should evaluate if any of these options present an unacceptable risk to the public and the environment from radiation exposure due to the presence of the spent nuclear fuel and due to the natural, accidental, or malevolent release of radioactive materials from the spent fuel.

3. Radiation protection standards should be developed for the interim storage facility or facilities based on a 300-year storage period. Radiation protection standards should not be developed for final permanent disposal/disposition of the spent nuclear fuel or wastes produced by processing the spent fuel until technologies and knowledge advance to the point of allowing a scientifically valid decision on final disposition.

4. The storage facility or facilities should be designed to have appropriate monitoring to ensure the integrity of the storage containers and facility or facilities remain intact throughout the storage period.

Reference:

Health Physics Society. Position statement "Ionizing Radiation-Safety Standards for the General Public," last revised June 2003.

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* The Health Physics Society is a nonprofit scientific professional organization whose mission is excellence in the science and practice of radiation safety. Since its formation in 1956, the Society has grown to approximately 6,000 scientists, physicians, engineers, lawyers, and other professionals representing academia, industry, government, national laboratories, the Department of Defense, and other organizations. Society activities include encouraging research in radiation science, developing standards, and disseminating radiation safety information. Society members are involved in understanding, evaluating, and controlling the potential risks from radiation relative to the benefits. Official position statements are prepared and adopted in accordance with standard policies and procedures of the Society. The Society may be contacted at 1313 Dolley Madison Blvd., Suite 402, McLean, VA 22101; phone: 703-790-1745; fax: 703-790-2672; email: HPS@BurkInc.com.

Extract from Dr. Moeller's letter of April 7, 2006

April 7, 2006

Dade W. Moeller, Ph.D., CHP
President Emeritus
Health Physics Society
257 River Island Road
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The Honorable James M. Inhofe, Chairman
The Honorable James M. Jeffords, Ranking Member
Committee on Environment and Public Works
United States Senate
Washington, D.C. 20510

Dear Senators Inhofe and Jeffords:

Thank you for expressing your appreciation for my testimony before the Committee on Environment and Public Works on March 1, 2006, as your committee examines the status of the Yucca Mountain project. I am very pleased you believe my testimony was helpful and will be beneficial to the committee staff.

I am very appreciative also of the follow up questions you forwarded to me. They are very important to the future of the Yucca Mountain project and I am pleased to be able to provide further input on these issues.

I have enclosed my responses to your questions. In addition, during the hearing Senator Boxer posed a question regarding a statement attributed to Dr. Thomas Cochran of the Natural Resources Defense Council in which I gave a preliminary response but which required more study for a complete answer. I have enclosed my detailed response to Senator Boxer's question with this letter. Finally, I consider that some of the scientific principles provided in response to questions from Senator Inhofe have a profound implication on the ruling of the Court of Appeals on the EPA proposed standards and I have taken the liberty to share my view on this issue in a separate enclosure to this response. I hope this material will be helpful to you and your staffs.

Extract from Dr. Moeller's letter of April 7, 2006

On behalf of the Health Physics Society, I am honored to have been asked to assist you in this important and challenging task facing the Committee. Please do not hesitate to contact the Health Physics Society, or me, at any time you believe we can be a resource on any radiation safety issue.

Sincerely,

Dade W. Moeller, Ph.D., CHP

Enclosures

cc: Senator Barbara Boxer

RESPONSES TO QUESTIONS FROM SENATOR INHOFE

1. Is it possible to quantify radiation risk at 350 millirem per year, which is the EPA proposal?

Summary Response

It is not possible to quantify the radiation risk at any level of radiation exposure for a population 10,000 to 1 million years from now, which is the time period for which the EPA proposal is applicable. This is due to the fact that there is no technical basis for forecasting the causes of death among, and the life spans that will be experienced by, the affected groups. Without this, and related information, the risk estimates cannot be quantified and any proposed dose rate limit is meaningless. This point is so important to the evaluation of the EPA proposal for Yucca Mountain that I have covered this is a separate enclosure to this submittal titled “Implications of Risk Quantification on the Ruling of the Court of Appeals.”

Risk coefficients exist for quantifying the health effects (i.e., fatal cancers) that may occur in a large existing population exposed to 350 millirem (mrem) per year. The resulting estimates, however, incorporate so many assumptions that they are highly uncertainty and, as noted above, they are applicable only to populations with today’s (i.e., known) cancer rate experience and human life spans. As for the range of the uncertainties, the Health Physics Society (HPS, 2004) cautions that the “Estimation of health risk associated with radiation doses that are of similar magnitude as those received from natural sources should be strictly qualitative and encompass a range of hypothetical health outcomes, including the possibility of no adverse health effects.”

Introduction

There are multiple factors that must be considered in estimating the risks of radiation exposures. The more important of these are discussed below.

<u>Quantifying Risk</u>

Lifetime risk estimates are developed through the science of epidemiology. Fundamental to this process is the comparison of the health outcomes of a group of people, exposed to higher doses, to the health outcomes of a similar group (i.e., similar age, gender, nationality, cancer rates, etc), exposed to lower doses. After accounting for all potentially confounding factors, increases in the number of cases of illness and death that occur in the exposed group, as compared to the non-

exposed, or less exposed (control) group, are attributed to the radiation exposure. It is important to recognize, however, that this is the observed increase in the risk for the exposed group at the time the comparison was made. To obtain the lifetime risk estimate, the observed difference must be projected to a time when everyone in both the exposed and control groups has died. This is particularly significant in terms of the survivors of the atomic bombings in Japan. In that case, only slightly more than half of the original atomic bomb survivors had died by 2005, 55 years after they were exposed (NRC, 2006, page viii). In order to project the health effects to the end of their lives, assumptions must be made about the relationship between radiation induced, and "naturally occurring" cancers, and the projected life spans of the people remaining in the study. Since the risk estimates currently available are applicable only to populations with known cancer rates and life spans, it is not appropriate to apply these estimates to populations who will be living 10,000 to 1 million years from now, the reason being that it is not scientifically possible to project the baseline cancer rates, or the extent of the life spans that populations will be experiencing, three or four decades from now, much less 10,000 to 1,000,000 years from now.

The problem of transferring risk coefficients derived from the Japanese atomic bomb survivor data to a population far into the future is more completely examined in the enclosure to this submittal, titled "Implications of Risk Quantification on the Ruling of the Court of Appeals."

Perspective on 350 millirem per year

Although the current risk estimates cannot be responsibly used to predict risks to populations at the time the EPA proposed dose rate limit of 350 mrem (0.350 rem) per year would apply, they can be used to provide perspective on the health impacts on current populations that might be affected by radionuclide releases from the proposed repository. Assuming that the Amargosa Valley population was exposed at this rate throughout an average lifetime of 70 years, their total dose would be:

(0.350 rem/year) (70 years) = 24.5 rem = 0.245 Sv.

In this regard, it is important to note that this is higher than 0.1 Sv (10 rem), the minimum dose for which the BEIR VII committee states that fatal cancer risks can be estimated without unacceptable statistical limitations (NRC, 2006, page 7). Assuming a population consisting of 50% men and 50% women, the applicable fatal cancer risk coefficient would be 570×10^{-4} per Sv. (NRC, 2006, Table ES-1, page 15). On this basis, the estimated percentage of the Amargosa Valley population that might incur excess fatal cancers would be:

$$(570 \times 10^{-4} \text{ per Sv})\ (0.245 \text{ Sv}) = 0.014 = 1.4\%.$$

For a population the size of that residing in the Amargosa Valley (about 1200 people; Rautenstrauch et al., 2003), this would mean that the estimated number of excess deaths due to radiation-induced cancer could be:

$$(1200)\ (0.014) = \sim 17.$$

Because the exposed population is so small, this estimate should probably be expressed as representing something in the range of perhaps 10 to 20 deaths. Since these would be expected to occur, if at all, over the 70 year lifetime of this population group, the average number of excess deaths would range from perhaps one every 7, to one every 3.5, years. The implications of this are discussed in the response to question #2 below. Concurrently, this same population group would be expected to suffer a total of 245 fatal cancers, or about 3 to 4 deaths per year, in the absence of the postulated doses due to radionuclide releases from the proposed repository (NRC, 2006, Table ES-1, page 15).

2. Is it fair to extrapolate the effects of instantaneous high levels of radiation doses to low level exposure over an individual's lifetime?

Summary Response

No, it is not, the key words being "over an individual's lifetime." Although risk models for fatal cancer have been developed for extrapolating the health effects of radiation exposures involving high doses received at high dose rates to those involving low doses received at low dose rates, the estimated health effects (for example, the number of fatal cancers that might result) can be expressed only for the affected population as a whole. They cannot be expressed in terms of the impacts on individual members of that group. At the same time, it must be recognized that estimates based on these processes are reasonably accurate only if the population group, being evaluated, is large, i.e., numbering in the tens of thousands. Compounding the situation is that assessments of health effects that involve either small population groups, or small doses will, in general, not be meaningful due to the lack of statistical rigor.

Even when the potentially affected population group is relatively large, the interpretation of the risks is not easy. This is well demonstrated by the information provided in the BEIR VII report (NRC, 2006). Within a group of 100,000 members of the U.S. population, for example, even in the absence of additional exposure from

the proposed repository, there will be, on average, about 20,420 cancer deaths due to natural causes. If each member of this population group is exposed to an average dose of 1 rem over his/her lifetime, one can statistically estimate that an additional 57 of them may die from cancer. No method is available, however, to differentiate which members of this population will be among the 20,420 who will die from cancer due to “natural causes,” or will be among the 57 additional members who may die due to the added average dose of 1 rem. Also of note is that, in this example, the increase in the estimated cancer deaths, due to the radiation exposure, is less than 0.3% of what otherwise would have occurred.

Implications of Risk Quantification on the Ruling of the Court of Appeals

Introduction

On July 9, 2004, the United States Court of Appeals ruled that the “10,000-year compliance period selected by EPA violates section 801 of the Energy Policy Act (EnPA) (U.S. Congress, 1992) because it is not, as EnPA requires, ‘based upon and consistent with’ the findings and recommendations of the National Academy of Sciences.” (U.S. Court of Appeals, 2004) This being the case, the Court ruled that it was incumbent upon EPA to establish a dose rate limit extending from 10,000 to one million years. In contrast, close examination reveals that the recommendation of the National Research Council Committee on Technical Bases for Yucca Mountain Standards (NRC, 1995, pages 6-7) stipulated that the “assessment be conducted for the time when the greatest risk occurs …” Compliance with the ruling of the Court would, therefore, require that the EPA proposed *dose rate limit* be converted into an equivalent limit in terms of *risk*. This can be accomplished only if data on the health effects (cancer risks) per unit of radiation exposure to a *future* U.S. population, anticipated to exist 10,000 or more years from now, can be estimated. The ramifications of such a task are discussed in the sections that follow with the conclusion that the risk cannot be estimated. The implications of how the scientific issues discussed below impact the implementation of the ruling of the Court of Appeals is strictly that of Dade W. Moeller.

Sources of Information on Radiation Risks

Radiation health-effects experts world-wide agree that the primary sources of data on the cancer related risks of ionizing radiation are those generated through the epidemiological studies of the survivors of the World War II atomic bombings in Japan.

Transfer of Risk Estimates to the U.S. Population

Although the Japanese data are comprehensive, they are directly applicable only to the population group that was exposed at the time of the bombings. They cannot be applied, without modification, to the U.S., or any other population, particularly for interpreting the health effects from potential radionuclide releases from the proposed Yucca Mountain high-level radioactive waste repository. Even more importantly, they cannot be applied under any conditions for assessing the risks of exposures that occur 10,000 to 1 million years into the future. This is due to a host of reasons, the most prominent of which can be described as follows:

- The exposures in Japan involved relatively high doses received at high dose rates. In contrast, potential radionuclide releases from the proposed repository will involve low doses received at low dose rates. This is important because the health effects, per unit dose, received at low rates are less than those received at high dose rates. This difference is taken into account through the application of what is called a Dose and Dose Rate Effectiveness Factor (DDREF).

- The *baseline* risks for specific cancers within a population play a dominant role in terms of the magnitude of the excess cancer risks due to radiation exposures. Since the baseline risks for specific cancers within the U.S. population are not the same as those for the Japanese population, there are country-to-country, or *spatial*, differences in the risks of cancer in different body organs.

- The characteristics of the U.S. population in the *future* will be different than they are today. This means that there will be *temporal* differences in the risks of cancer in different body organs, per unit of dose – now as contrasted to the future.

Challenge #1: Converting Health Effects of High Dose and Dose Rates to Low Dose and Dose Rates

Based on extensive reviews and evaluations, the International Commission on Radiological Protection (ICRP, 1991, paragraph B62, pages111 - 112), and the National Council on Radiation Protection and Measurements (NCRP, 1993, Section 7, page 29), have recommended that, for the evaluation of the health effects (per unit dose) of low dose and dose rate exposures, the estimated risks (increased cancers) observed among the Japanese a-bomb survivors be divided by a factor of 2.0. As noted above, this is known as the dose and dose rate effectiveness factor (DDREF). Although the BEIR VII committee recommended a value of 1.5 for DDREF (NRC, 2006, page 274), the value being almost universally applied today is 2.0.

Challenge #2: Transfer of Risk Estimates to the U.S. Population

Once the health risks have been modified, taking into account the dose and dose rates, the next step is to interpret (or translate) the risks from the radiation exposures that were observed among the Japanese population, to those that would be anticipated for people *currently* living in the United States. To accomplish this task, it is necessary to account for critical differences in the characteristics of the populations in the two countries.

Epidemiologists use the term, “risk,” for describing the excess health effects (e.g., cancer incidence and mortality) observed in populations who have been exposed to radiation. One methodology that has been developed for this purpose is the Excess *Relative Risk* (ERR) model. The basis for this model is that the excess risk of developing a specific cancer, due to radiation exposure, is assumed to be proportional to the baseline risk, and that the proportionality (percentage increase) due to a unit dose of radiation will be the same for the U.S. population as for the Japanese population.

Data show that the baseline risks for cancers of the colon, lung, female breast, and male prostate are higher in the U.S. population than in Japan. In contrast, the baseline rates for cancers of the stomach and liver are higher in Japan (NRC, 2006, pages 269 and 275). In applying the concept of proportionality, it is assumed that if a given radiation exposure increases the baseline risk of a specific cancer in the Japanese population by 10%, it will do likewise in the United States population. In a sense, this implies that the higher rates of colon, lung, female breast, and male prostate cancers in the United States mean that the U.S. population is more susceptible to these cancers. That being the case, they will similarly be assumed to be more susceptible to these same cancers, if exposed to radiation. Extending this concept, if vaccines (similar to that for cervical cancer) are developed for preventing additional types of cancers, and their baseline rates are reduced, then the probability of those cancers being caused as a result of being exposed to radiation will be similarly reduced. That is, if a vaccine reduces the baseline rate for a specific cancer, it will be assumed to reduce the probability that radiation will cause that same cancer.

Further complicating the transfer of data from one population to another is that the lifestyles and baseline cancer rates in populations do not remain constant with time. This was exemplified by the changes that occurred in the rates for cancers of the stomach, colon, lung, and female breast, among the Japanese population during the period from 1950 to 1988. This was attributed to the fact they were becoming more “westernized.” (NRC, 2006, page 268).

Challenge #3: Transfer of Risk Estimates to Future U.S. Populations

In contrast to the discussion above, the ruling by the Court of Appeals stipulated that a dose rate limit be established for the time-period from 10,000 to one million years after closure of the proposed repository. Again, it is important to note that, while the National Research Council Yucca Mountain Committee (NRC, 1995) recommended that compliance be assessed on the basis of the time of "greatest risk," the Court stipulated that EPA promulgate a dose rate limit for purposes of determining compliance. The only way that a dose rate limit, regardless of its magnitude, has any relevance is if the risk of cancer, associated with that dose rate limit, can be quantified. As noted above, this depends on a host of characteristics of the presumed future population. Only after those characteristics have been defined, can such a transformation be made. That this will be a daunting task is exemplified by the example, discussed immediately above, of the impacts of "westernization" on the Japanese population. This occurred during a period of less than 4 decades. Currently, there is no scientific basis for projecting the changes that will occur during time-periods ranging from 10,000 to one million years.

Since there are multiple characteristics that determine the risks of cancer among exposed members of a population, and many of these are organ specific, this means that a host of characteristics, lifestyles, medical practices, and other factors, within the postulated *future* population must be specified. The examples that follow illustrate the magnitude and challenges of this task. :

- Cancer screening approaches, such as colonoscopies, during which pre-cancerous lesions can not only be detected, but also removed, thus reducing the incidence of colon cancer. *Note*: Such a statement presumes that colonoscopies will still be the common among populations living 10,000 to a million years from now! The same general concept applies to the other examples that follow.

- Procedures for vaccinating children for chronic hepatitis B, since such a practice reduced the incidence of liver cancer. In contrast, the increasing rate for Hepatitis C, for which a vaccine does not exist today, may lead to an increase in liver cancer.

- The age at which women have their first child – the younger the age the less risk they have of developing breast cancer in the future.

- The racial composition of the population. African-American men, for example, have higher rates of prostate cancer. In a similar manner, genetic susceptibility to cancer is different for various races.

Since, as noted, the National Research Council Committee (NRC, 1995, pages 6-7) recommended that "compliance assessment be conducted for the time when the greatest risk occurs …," it will be necessary to convert the EPA 3.5 mSv (350 mrem) per year dose rate limit (EPA, 2005) into an equivalent risk rate limit. If this is to be accomplished in any reasonably accurate manner, it will be necessary to know the baseline rates for all types of cancer at that time. This, in turn, will require having accurate information not only on the information listed above, but also on:

- How long members of the exposed population are anticipated to live – the risk of cancer increases with longevity, as well as the distribution of the population by age, since the susceptibility to cancer varies with age.

- Projections of future developments of cancer preventive therapies – most especially vaccines for cancers in specific body organs.

- The anticipated exposure of the population group to other carcinogens, such as tobacco.

In short, data will be needed on their age distribution, life spans, baseline cancer rates, exposures to other carcinogens, and dietary habits. In addition, it would require an accurate projection of the status of medical care, medical technology (including the availability of artificial lungs, stomachs, livers, etc.), and multiple other items of information relative to the postulated *future* population.

Conclusions and Commentary

The recommendation of a dose rate limit, without the ability to estimate the risk that it would represent, would provide essentially no benefit in terms of protecting future population groups. Unless the items of information enumerated above can be made available, it will not be possible to provide a useful dose rate limit. Since the data are not available (and cannot be projected), one can only conclude that it is not scientifically possible for EPA to respond to the ruling of the Court in any meaningful manner.

What the Circuit Court failed to recognize is that the time of "greatest risk" will not necessarily coincide with the time of "peak dose." The relationship between dose and risk is not linear with time, especially when dealing with tens of thousands to a

million years. The time of peak dose could, in reality, occur at a time of minimum risk.

References

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