The EPA Public Health and Environment Standards for Yucca Mountain, NV

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Spent nuclear fuel and other forms of high-level radioactive waste are produced mainly as a result of commercial nuclear power generation and defense activities. High level wastes (HLW) contain some amount of long-lived radionuclides. HLW derived from the use of uranium fuel in a nuclear reactor contains the fission products and transuranic elements generated in the reactor core. Because HLW contains relatively high concentrations of both highly radioactive and extremely long-lived radionuclides, special disposal practices are needed.

To ensure that no significant environmental releases occur over tens of thousands of years, HLW is isolated from the environment using a multiple barrier approach. Barriers include glass and other insoluble matrices to immobilize waste, non-corrosive containers such as stainless steel to store the waste, and repositories in deep underground geologically stable rock structures to provide long-term environmental isolation.

Yucca Mountain NV is proposed as a national repository for spent nuclear fuel (generated from nuclear power production) and other forms of HLW.[2] Disposal of HLW is the responsibility of the federal government. The Nuclear Waste Policy Act of 1982 *(12)* formalizes the current federal program for HLW disposal. The Department of Energy (DOE) is responsible for siting, building and operating a suitable underground geologic repository. The Environmental Protection Agency (EPA) is required to set generally applicable environmental radiation protection standards. The Nuclear Regulatory Commission (USNRC) is charged with implementing EPA standards by incorporating standards into licensing requirements. DOE must demonstrate compliance with these standards.

The Energy Policy Act of 1992 *(1)* specifically directs the EPA to set standards for the Yucca Mountain site. Under the Act, EPA is required to contract with the U.S. National Academy of Sciences to provide recommendations to the EPA on reasonable standards for protection of the public health and safety *(10)*. The USNRC will incorporate the EPA final standards into its licensing regulations. The USNRC licensing regulations will be used to determine whether DOE has demonstrated compliance with EPA standards prior

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[2] The Yucca Mountain repository is currently not licensed and is not operational at this time. The Waste Isolation Pilot Plant (WIPP) is the only fully operational geologic repository in the U.S. Located near Carlsbad NM. WIPP is used for long-term disposal of defense related transuranic waste. This waste comes from the U.S. Department of Energy's defense-related operations at 27 DOE sites across the country.

to receiving the necessary licenses to store or dispose of radioactive material in Yucca Mountain.

EPA issued final environmental and public health protection standards for Yucca Mountain in 2001 based on recommendations from the National Academy of Sciences *(2)*. The standards establish annual dose limits to the public up to 10,000 years post closure. The standard was challenged by various groups including the State of Nevada and the Natural Resources Defense Council claiming that the 10,000 year time interval was too short. The U.S. Court of Appeals found in favor of plaintiffs and vacated portions of the standards that addressed the period of time for which compliance must be demonstrated. In response, EPA issued a revised two-tiered standard in 2005 *(3)*. The revised standard retains the health protection standard finalized in the 2001 rule that is applicable for the first 10,000 years post closure and added a second standard applicable for the period extending from 10,000 years to 1 million years post closure.

The first part of the standard, applicable out to 10,000 years post closure, requires that individuals not be exposed to doses greater than 0.15 mSv per year.[3] The second part of the standard extends from 10,000 years to 1 million years and limits exposure to individuals near the repository to doses not to exceed 3.5 mSv per annum *(3)*.

The near-term standard limits an individual's annual radiation exposure from all pathways (ingestion, inhalation, physical contact, etc.). An individual exposed to the annual limit for a lifetime (0.15 mSv per year for 70 years) would have a lifetime risk of developing a fatal cancer of about 5 in 10,000. This risk estimate assumes a lifetime fatal cancer risk factor of 0.005% per mSv *(8)*. This is a tiny fraction of the natural lifetime cancer mortality risk of about 2,000 in 10,000. The radiogenic risk is well within statistical variations in cancer mortality in the U.S. Accordingly the public health detriment would be almost impossible to measure reliably. The standard is consistent with a lifetime risk of the order of 1 in 10,000 that is the basis for setting standards for other carcinogens that EPA regulates.

Beyond 10,000 years, the standard is relaxed substantially to 3.5 mSv per year for up to 1 million years. During that time period, people living near Yucca Mountain for a lifetime during the 1 million-year time frame will not receive total radiation any higher than natural background radiation levels that the public is currently exposed to in other areas of the country. The long-term standard is roughly twenty times higher than the short-term standard and it is unclear what the rationale is for such a large discrepancy.

Both standards are associated with risks that are too small to measure reliably. A substantial margin of safety is incorporated in these limits for the protection of the public health. Cancer risks are detectable at doses exceeding about 100 mSv based on over 50 years of studying human populations exposed to a wide range of doses *(7, 11)*. This

[3] In this document ionizing radiation is expressed in units of millisievert (mSv). One mSv is equal to 1/1000 of a sievert (Sv). The Sv is a measure of radiation dose and accounts for differences in tissue radiation sensitivity and differences in radiation types. For the purposes of radiological protection radiation dose is directly related to health risk.

suggests a margin of safety by a factor of about 30 for the long-term standard (3.5 mSv per year) and by a factor of about 600 for the near-term standard (0.15 mSv per year).

The near-term and long-term individual protection standards are risk-based but are expressed as dose limits *(3)*. The National Academy of Sciences *(10)* recommended that EPA adopt a risk-based standard because a risk-based standard would be insensitive to changes in the shape of the dose-response relationship, and the concept of risk is more readily understood by the public and can be used to make comparisons with other sources of radiation exposure (e.g. medical exposures).

The EPA claims to use a dose-based standard because the limits are expressed in dose units. A dose standard was used in order to be consistent with the Energy Policy Act of 1992 *(1)* that states that the standard prescribes the maximum annual dose equivalent to individual members of the public. But, in reality, the proposed standard is risk-based since dose limits are determined directly from calculations of risk. The linear no-threshold theory (LNT) is assumed to translate risk into dose and vice-versa.

In recommending a risk-based standard the National Academy of Sciences *(10)* considered "risk" as a coin of the realm. Using risk, exposures from various carcinogens (including ionizing radiation and chemicals) could be easily compared and a total health detriment determined. However it is unclear that cancer risks from different agents are comparable. For example exposure to radioactive iodine and radon gas produce different cancers. Radioiodine is associated with thyroid cancer (about 10% mortality rate); radon exposure is associated with lung cancer (about 90% mortality rate). It is unclear how these risks can be combined or compared in a meaningful way.[4] The National Academy of Sciences also views risk as readily understandable by the public. However, for very small risks it is unclear that this is the case.

There is some merit in using a dose-based standard. A risk standard will not allow a convenient comparison with the numerous existing dose guidelines and standards promulgated by other Agencies such as USNRC. National and international radiation protection guidelines developed by bodies of nongovernmental radiation experts, such as the International Commission on Radiological Protection (ICRP) and the National Council on Radiation Protection and Measurements (NCRP), generally have recommended that radiation standards be established in terms of dose. Combining doses is neither necessary nor useful. If carcinogens are associated with different health outcomes the respective doses producing the effects are not comparable. As discussed in the example above, cancer mortality from thyroid cancer and lung cancer cannot be easily compared because the diseases are clinically different.

The EPA near-term dose limit of 0.15 mSv per year assumes an annual cancer mortality risk of 8.5 fatal cancers per million members of the population based on an average population lifetime cancer mortality risk coefficient of 5×10^{-5} per mSv. The level of risk

[4] In radiation protection, the quantity "effective dose" (measured in sievert or millisievert) combines different radiation risks to arrive at a single risk-based dose. However, there is considerable controversy regarding the conceptual validity of this approach.

has been determined to be acceptable to the EPA. A linear no-threshold relationship (LNT) between dose and health risk is assumed. Under LNT, any dose, no matter how small, is associated with non-zero risk. Further risk is determined by the total dose and not the rate at which the dose is delivered. The long-term dose limit of 3.5 mSv per year is not based on risk but is coupled to the annual natural background radiation level that individuals in the US receive annually.

LNT is the preferred theory used by federal agencies such as the EPA and the Nuclear Regulatory Commission to calculate cancer risks. The assumption is that risk extends to zero dose and that health effects are proportional to dose. There is no dose below which the risk is zero. This theory has emerged as the dominant predictive theory in risk assessment and risk management because it serves as a reasonable middle ground in risk assessment. Although no single theory satisfactorily fits all of the data, LNT provides the most consistent fit to the broadest range of experimental animal and human epidemiological data.

Over the range of doses where direct observations of health effects can be made, there is compelling evidence that the probability of health effects is linear with dose and that the risk per unit dose is independent of the size of the dose. Most malignancies are believed to be clonal in origin implying that it only takes damage to a single cell to create cancer. It is generally accepted that the initial damage involves genetic mutation. Most carcinogens are also mutagens (agents that cause genetic mutations) and it has been known for decades that mutagens produce DNA damage in a linear fashion. For many cancers (particularly certain forms of leukemia and lymphoma) there are specific mutations that characterize the disease.

LNT theory also predicts the absence of a dose threshold. Proving no threshold is difficult because the chances of observing health effects is very small and absence of effects at a given dose level does not mean that effects are absent. Without clear evidence for a threshold, LNT proponents argue that it is prudent to assume no threshold. Based on what is known about cancer induction and the difficulties in measuring health effects at small doses, the LNT theory would appear to provide a reasonable approach to risk assessment and risk management,. However, certain key assumptions underlying the LNT theory are now in question. For example, LNT assumes that the same cellular response mechanisms occurring at high dose also occur at low dose. This is in accordance with the prediction that the probability of effect is proportional to dose. However, at high dose, effects such as cell killing occur with higher frequency than at lower doses, and cell killing is an important competitive process when assessing carcinogenic potential. A dead cell cannot be a cancerous cell. Conclusions and recommendations in two reports published in 2005 by the US National Academies and the French Academy of Sciences illustrate the nature of the LNT controversy and the uncertainties associated with selecting an appropriate dose-response function to predict low-dose risks *(4, 11)*. The National Academies' BEIR VII Report *(11)* argues for LNT; the French Academy report *(4)* argues against it. Both reports reviewed and analyzed the same data. Risk assessment is critically dependent on the shape of the underlying dose-response function. If the dose-

response function is non-linear (i.e., curvilinear) in the low dose range (below 100 mSv) the risks predicted would be expected to be lower than risks predicted under LNT.

EPA recognizes that risks at low doses of ionizing radiation are uncertain *(2)*. At 0.15 mSv per year, the near-term standard represents a tiny fraction of the natural background radiation level. The National Research Council's BEIR V Committee noted that risks at doses at or below natural background radiation levels (3.5 mSv per year) are so uncertain that the lower bound of the risk confidence interval includes zero and the most likely outcome is zero health effects *(9)*. An uncertainty analysis published by NCRP estimates that the actual risk of cancer from whole-body exposure could be between 1.5 times higher and 4.8 times lower (at the 90-percent confidence level) than the EPA basic estimate of 5.75×10^{-4} per mSv *(8)*. But the NCRP uncertainty analysis excludes the contribution of dose extrapolation because it is based on cancer epidemiology data collected at doses in excess of about 200 mSv.[5]

Dose extrapolation is a serious source of uncertainty particularly when extrapolations are large. Radiogenic risks are known with a high degree of certainty at doses about 100 mSv risks *(7, 11)*. At doses below this level risks cannot be observed directly and are determined theoretically. Risk estimates associated with a dose of 0.15 mSv per year (the EPA near-term standard) requires a 600-fold reduction in dose (from 100 mSv down to 0.15 mSv). For most carcinogenic agents (including ionizing radiation) very large doses are needed in order to observe a statistically significant increase in cancer. This is because small doses typically encountered in environmental and occupational settings are associated with very low risks of cancer and, in the absence of any exposure, cancer occurs at a very high rate naturally (about 1 in 3 Americans will get cancer). Predicting radiogenic health effects at environmental and occupational exposure levels requires that directly observable dose response data be extrapolated 2-3 orders of magnitude (i.e., 100-1000 times). This degree of dose extrapolation strains the credibility of risk assessment at low dose.

Health risks associated with waste repository performance and other sources of very small public exposures need to be interpreted with great care. These risks are theoretically determined and are not based on direct observations of health detriment. There are no scientific data to support the position that doses at or below natural background radiation levels are harmful. Even if such risks are considered real (i.e. non-zero) because zero risk has not been proven, they are so small that they cannot be measured.

In developing the Yucca Mountain standard, EPA considered recommendations from national and international nongovernmental bodies (e.g., NCRP and ICRP), and federal Agencies such as USNRC that promulgate similar standards. EPA developed its standards based on risk using the constraint that standards should not result in individual

[5] NCRP report 126 considers the dose and dose-rate effectiveness factor (DDREF) as the major source of uncertainty in lifetime radiogenic cancer risk. Uncertainties in DDREF focus on correction in risk due to changes in temporal delivery of dose (i.e., dose-rate correction). DDREF does not address extrapolation of dose.

cancer mortality risks from environmental exposures in excess of 10^{-6} per year or 10^{-4} per lifetime. Other Agencies such as the USNRC use a dose apportionment method based on the constraint that radiation doses to individual members of the public not exceed 1 mSv per year from all radiation sources excluding the natural background and medical procedures. Apportionment of the total dose limit among different sources of radiation is used to ensure that the total of all included exposures is less than 1 mSv per year. USNRC apportioned 25% of the total dose limit to exposures from radioactive waste sources.

The EPA and USNRC have duplicative oversight of nuclear energy facilities (including Yucca Mountain) but the EPA has Presidential federal guidance authority. Federal guidance is a set of guidelines developed by the EPA for use by other federal and state agencies responsible for protecting the public from the harmful effects of radiation. The EPA develops guidelines for the President's review and approval.

The EPA individual protection standard is 0.15 mSv per year; the USNRC developed a similar standard of 0.25 mSv per year (for decommissioning and decontamination of licensed sites). The difference in the EPA and USNRC protection standards is small but nonetheless significant. The EPA standard provides no measurable improvement over the USNRC standard in public health protection. It is not possible to measure public health effects at either dose limit. Any effects on the US cancer mortality burden at either dose limit can only be theoretically determined.

International bodies have also used an apportionment method to arrive at a dose-based standard for individual protection. The ICRP recommends apportionment of the total allowable radiation dose among specific practices (including radiation exposure from buries radioactive waste) *(6)*. Thus, ICRP recommends that national authorities apportion or allocate a fraction of the 1 mSv per year limit to establish an exposure limit for disposal of HLW. Most countries have endorsed the apportionment principle and have set limits between 25-30 mSv per year for exposures from waste disposal facilities. EPA near-term limit is 15% of the ICRP-recommended total dose limit for exposure to all sources of radiation excluding natural background and medical sources.

The International Atomic Energy Agency (IAEA) has made recommendations similar to ICRP recommendations using the apportionment method. The objectives of the IAEA safety standards is that "radiation doses to workers and members of the public exposed as a result of operations at the disposal facility shall be as low as reasonably achievable, social and economic factors being taken into account, and the exposures of individuals shall be kept within applicable dose limits"*(5)*. IAEA recommends that the average dose or average risk to members of the public who may be exposed in the future as a result of activities involving the disposal facility does not exceed a dose constraint of 0.3 mSv per year. Radiation doses to individuals in the future can only be estimated and uncertainties will increase for times farther into the future. Great care needs to be exercises in interpreting doses and risks to individuals or groups risks far into the future particularly as it pertains to decision making.

References

1. The Energy Policy Act of 1992 (EnPA) *Energy Policy Act of 1992*, Public Law 102-486, 106 Stat. 2921.

2. Environmental Protection Agency. June 13, 2001. Public Health and Environmental Protection Standards for Yucca Mountain, NV; Final Rule. *Federal Register* **66:** 32074-32135.

3. Environmental Protection Agency. August 22, 2005. Public Health and Environmental Protection Standards for Yucca Mountain, NV; Proposed Rule, *Federal Register* **70:** 49014- 49065.

4. French Academy of Sciences. 2005. *Dose Effect Relationships and Estimation of the Carcinogenic Effects of Low Doses of Ionizing Radiation*. The report may be accessed at: http://www.academie-sciences.fr/publications/rapports/pdf/dose_effet_07_04_05_gb.pdf

5.International Atomic Energy Agency. 2005. *Geological Disposal of Radioactive Waste, Draft Safety Requirements*, IAEA Safety Standards Series WS-R-4, Vienna: IAEA.

6. International Commission on Radiological Protection. 1985. *Radiation Protection Principles for the Disposal of Solid Radioactive Waste*. ICRP Publication No. 46. *Annals of the ICRP* **15** (4).

7. Mossman, K.L. 2003. Restructuring nuclear regulations. *Environmental Health Perspectives* **111:**13-17.

8. National Council on Radiation Protection and Measurements (NCRP). 1997. *Uncertainties in Fatal Cancer Risk Estimates Used in Radiation Protection*. NCRP Report No.126. Bethesda, MD: NCRP.

9. National Research Council. 1990. *Health Effects of Exposure to Low Levels of Ionizing Radiation,* BEIR V Report. Washington, DC: National Academy Press.

10. National Research Council. 1995. *Technical Bases for Yucca Mountain Standards*. Washington, DC: National Academy Press.

11. National Research Council. 2005. *Health Risks from Exposure to Low Levels of Ionizing Radiation,* BEIR VII Report. Washington, DC: The National Academies Press.

12. The Nuclear Waste Policy Act of 1982 (NWPA), *Nuclear Waste Policy Act of 1982*, Public Law 97– 425, 96 Stat. 2201.