[RSH LETTERHEAD]

VIA HAND DELIVERY June 20, 2000

W-00-12 Radionuclides Rule Comments Clerk
U.S. Environmental Protection Agency
Drinking Water Docket
401 M Street, S.W.
East Tower Basement (Room EB 57)
Washington, D.C. 20460

RE: National Primary Drinking Water Regulations; Radionuclides, Proposed Rule;
65 Fed. Reg. 21,575 (April 21, 2000); Water Docket W-00-12.

Dear Comments Clerk:

We are pleased to submit the enclosed comments on the proposed rule of the U.S. Environmental Protection Agency entitled "National Primary Drinking Water Regulations; Radionuclides; Notice of Data Availability," 65 Fed. Reg. 21,575 (April 21, 2000). RSH is an international nonprofit organization of independent experts on radiation and public policy, committed to apply current scientific data and theories to radiation protection policy.

Please call if you have any questions.

Regards,

Theodore Rockwell, Vice President

Enclosures

COMMENTS OF RADIATION, SCIENCE & HEALTH, INC. ON EPA's PROPOSED RULE ENTITLED "NATIONAL PRIMARY DRINKING WATER REGULATIONS; RADIONUCLIDES; NOTICE OF DATA AVAILABILITY," 65 FED. REG. 21,575 (April 21, 2000)

Executive Summary

We oppose the proposed rule because it is based upon application of the linear non-threshold model ("LNT") regarding the health risk associated with low-dose ionizing radiation. Our grounds for opposing LNT follow:

- The scientific basis for using the LNT is flimsy. The National Council on Radiation Protection and Measurements (NCRP) itself, in its report NCRP-121 (1995) defends the LNT as follows:

> Few experimental studies, and essentially *no human data,* can be said to prove or *even to provide direct support* for the concept … It is *conceptually possible,* but with a *vanishingly small* probability, that any of these effects *could* result from the passage of a single charged particle, causing damage to DNA that *could* be expressed as a mutation or small deletion. It is a result of this type of reasoning that a linear non-threshold dose-response relationship *cannot be excluded.* (emphasis added)

- A large body of scientific evidence directly refutes the arbitrary LNT presumption that small doses of ionizing radiation, in the range of high natural background levels, are deleterious to human health. Some of this key evidence is discussed below and included in the attached Data Document, which also includes other supporting references, and in the other documents accompanying these comments.

- The proposed rule would set radiation limits so low that it would define nature, through its background radioactivity, as a public hazard.

The proposal is just the latest step in a series of LNT-based policies by EPA that do a disservice to available scientific data. EPA acknowledged as much when it responded to the Scientific Advisory Board ("SAB") regarding the establishment the radium limits (56 Fed. Reg.

33,050-127).“The SAB/RAC urged EPA to base its risk assessment for radium on human epidemiology data on radium watch dial painters, rather than on modeled estimates,…and that if EPA continued to use the modeling approach, uncertainties in the modeling be addressed.”

EPA elected to use LNT in the face of scientific data that refute application of a linear dose-response model at low exposures, stating that::

use of the dial painter data requires either deriving a linear risk coefficient from significantly non-linear exposure-response data, or abandoning EPA policy.

Background

EPA sets primary drinking water standards through a three-step process. First, EPA identifies contaminants that may adversely affect public health and occur in drinking water with a frequency and at levels that pose a threat to public health. 42 U.S.C. § 300g-1(b)(1) (1999). EPA identifies these contaminants for further study, and determines contaminants to potentially regulate. The contaminants at issue here are various radionuclides found in drinking water. 65 Fed. Reg. at 21, 576.

Second, EPA determines a maximum contaminant level goal (“MCLG”) for the contaminants it decides to regulate. 42 U.S.C. § 300g-1(b)(1)(A). This goal is the level of a contaminant in drinking water below which there is no known or anticipates risk to human health, allowing for an adequate margin of safety. Id. § 300g-1(b)(4)(A). Here, EPA set a MCLG level of zero for all the radionuclides:

> The radionuclides emit ionizing radiation and, absent data indicating that there is a threshold level at which exposure does not present a risk, EPA uses a linear, non-threshold model to a zero MCLG for radionuclides. This means that exposure can potentially cause harm and that risk associated with the exposure increases proportionally to the concentration of the radionuclide.

65 Fed. Reg. at 21,579 (section II.D); see also id. at 21,578 (table I-1), 21,600 (appendix II.A).

Third, EPA specifies a maximum contaminant level ("MCL"), the maximum permissible level of a contaminant in drinking water that is delivered to any user of a public water system. Id. § 300g-1(b)(4)(B). These levels are enforceable standards, and are set as close to the MCLGs as "feasible." Id. "Feasible" means that level which may be achieved with the use of the best technology, treatment techniques, and other means which EPA finds (after examination for efficiency under field conditions) are available, taking cost into consideration. Id. § 300g-1(b)(4)(D). In its proposal, EPA set a variety of MCLs for the radionuclides at issue, with each MCL generally based upon zero as the goal. 65 Fed. Reg. at 21,578 (table I-1).

When setting MCLGs and MCLs, EPA "shall use": (i) the **best available, peer-reviewed science and supporting studies conducted i**n **accordance with sound and objective scientific practices**"; and (ii) "data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data)." 42 U.S.C. §§ 300g-1(b)(3)(A)(i), (ii) (emphasis added). EPA's *Proposed Guidelines for Cancer Risk Assessment*, meanwhile, provide that EPA should utilize a threshold standard when data show that a linear model is inaccurate and there is sufficient evidence to support a threshold standard. 63 Fed. Reg. 17, 960 (1996).

In *Chlorine Chemistry Council v. EPA*, the U.S. Court of Appeals for the District of Columbia Circuit found that EPA violated its statutory mandate to use the "best available" science when it issued a zero MCLG standard for chloroform in the face of evidence demonstrating a safe threshold level. *Chlorine Chemistry Council v. EPA*, 206 F.3d 1286 (D.C. Cir. 2000). The court also concluded that EPA violated its carcinogen risk assessment guidelines when it applied a non-threshold model to chloroform. Id.

Comments

We oppose the proposed rule because it is based upon application of the LNT model regarding the health risk associated with low-dose ionizing radiation:

> In estimating the health effects from radionuclides in drinking water, EPA subscribes to the linear, non-threshold model which assumes that any exposure to ionizing radiation has a potential to product deleterious effects on human health, and that the magnitude of the effects are directly proportional to the exposure level. The Agency further believes that the extent of such harm can be estimated by extrapolating effects on human health that have been observed at higher doses and dose rates to those likely too be encountered from environmental sources of radiation. The risks associated with radiation exposure are extrapolated from a large base of human data. **EPA recognizes the inherent uncertainties that exist in estimating health impact at the low levels of exposure and exposure rates expected to be present in the environment.** EPA also recognizes that, at these levels, the actual health impact from ingested radionuclides will be difficult, if not impossible, to distinguish from natural disease incidences, even using very large epidemiological studies employing sophisticated statistical analyses. **However, in the absence of other data, the Agency continues to support the use of the linear, non-threshold model in assessing risks associated with all carcinogens.** 65 Fed. Reg. at 21,600 (appendix II.A) (emphasis added).

EPA's use of linear non-threshold modeling underpins the zero MCLGs and other aspects of the rule. Every calculated health risk in this proposed rule, and all limits and rules based on that risk, are based on this faulty LNT premise. That premise fails to consider the "best available" scientific data regarding the health effects of low-dose radiation. Under this rubric, there is no limit to actions that can be required, to reduce radiation without regard for public health.

The fact that ionizing radiation, delivered rapidly and in high doses, can be injurious to health is not at issue here. The proposal deals with low-dose exposures. In lieu of considering data regarding low-dose exposures -- including the natural occurrence of radiation at levels EPA is regulating here -- EPA relies upon the LNT. Id.; *Technical Support Document*, at III-1. We believe that EPA has done so erroneously here. Our views are shared by others. Philip Abelson, Editor Emeritus of *Science*, in an editorial on "Risk Assessments of Low-Level Exposures, wrote:

> The current mode of extrapolating high-dose to low-dose effects is erroneous for … radiation. Safe levels of exposure exist. The public has been needlessly frightened and deceived, and hundreds of billions of dollars wasted. A hardheaded, rapid examination of phenomena occurring at low exposures should have a high priority. *Science* 265 (Sept. 9, 1996).

See also Austin M. Brues , "Critique of the Linear Theory of Carcinogenesis," *Science* Vol. 128, No. 3326 pp.693-699 (Sep 26, 1958); Daniel Billen, "Spontaneous DNA Damage and its Significance for the 'Negligible Dose' Controversy in Radiation Protection," *Radiation Research* 124, pp. 242-245 (1990); E.J. Calabrese *et al.*, "Hormesis: A Highly Generalizable and Reproducible Phenomenon with Important Implications for Risk Assessment," *Risk Analysis*, 19-2 pp. 261-281 (April 1999), abstract; Klaus Becker, "Threshold or No Threshold, that is the Question," editorial in *Radiation Protection Dosimetry* 71-1 pp.3-5 (1997); and Health Physics Society, "Radiation Risk in Perspective: Position Paper" January 1996; all accompanying these comments.

Regulations based on these extreme premises produce baseless public fear, provide no possible public health or safety benefit, prevent the application of low-dose radiation applications for biological and health benefits, and unnecessarily constrain the cost-effective application of radiation technologies. Some of these costs are described in Klaus Becker, "Low-Dose Cost/Benefit Assessment – A View from Europe" American Nuclear Society Meeting, President's Special Session, June 2, 1997, accompanying these comments.

The data relied upon by EPA to support a zero MCGL are inconclusive. For example, Federal Report No. 13 (EPA 1998), which is cited throughout the Technical Support Document, acknowledges that LNT might be inapplicable at low-doses. *Federal Report No. 13*, at iv, v. *Estimating Radiogenic Cancer Risks* (EPA 1994), which also is referenced in the TSD, acknowledges throughout the existence of data demonstrating the beneficial effects of low-dose radiation. EPA cites favorably to *Lyman et al*. (1985), that indicates a potential adverse effect of radionuclides in groundwater and leukemia, but subsequently concludes that "there was no evidence of a dose-response relationship" in that study. TSD, at III-6.

The following scientific literature partially represents the extensive data that refute application of the arbitrary presumption that small doses of ionizing radiation are potentially hazardous, *i.e.*, for acute doses in the range of high natural levels of background radioactivity, and chronic doses at multiples of the natural variation in background radioactivity.[1]

I. Human Epidemiology

1. Occupationally-exposed populations

a. Nuclear facility workers

Early nuclear weapons facility radiation workers have negligible indications of excess cancers or other adverse effects, and have substantial indications of lower cancer rates and all cause effects than the general population. These reduced health effects results are generally rationalized by ascribing the effect to undefined and unanalyzed "healthy worker effects" that reflect the fact that the workers do not include general population members that are not able to work. (However this ignores the fact that, for the delayed effects of cancer and other work-related illnesses, workers in carcinogenic and hazardous work environments show an excess of cancers vs. the general population, not fewer cancers.)

In the most highly exposed workers, there are no excess cancers in UK high-dose workers (Berry, R.J. et al. (1994) Biological markers, morbidity, and mortality in a long-serving radiation worker population, ANS Trans., Vol. 71 (Nov), p. 40, see Data Document § 1.2.2.1 p.

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[1] Sources are provided in the attached RSH report: "Low Level Radiation Health Effects: Compiling the Data," referred to as the "Data Document, and other documents accompanying

1); or the U.S. AEC/DOE and nuclear Navy high-dose workers requested by Congress (Fry, S. (1995), Follow-up study of workers exposed to >50 mSv/y radiation, ANS Transactions Vol. 72, p. 8, see Data Document § 1.2.2.1 p. 1).

Much higher doses were experienced by USSR nuclear weapons facility workers. This includes the ingestion and internal exposure from plutonium, a long-lived alpha-emitting radioactive element, which is specifically relevant to EPA proposal. Excess cancers were found in workers only at very high doses, with substantial indication of lower than expected cancers in low to moderate doses. Hohryakov, V. & Romanov, S. (1994), Lung cancer in radiochemical industry workers, The Science of the Total Environment, 142, pp. 25-28, Elsevier Science B.V. Hohryakov states:

> The frequency of lung cancer was investigated among 2346 workers in the radiochemical plant 'Mayak' who were exposed to radiation, both externally and internally from incorporation of plutonium.
>
> Table 3 shows that the subgroups with the lower cumulative doses have fewer observed cases of lung cancer deaths than expected, while the cohort with dose equivalent in excess of 4 Sv exhibits an observed number of lung cancer deaths that is 2.7 times larger than the expected number." See Data Document § 1.2.2.1. p. 3.

Other USSR data shows a reduction in lung cancer for workers with low to moderate body-burdens of Pu, while lung cancer is increased at high doses. Tokarskaya, Z.B., et al (1997), Multifactorial analysis of lung cancer dose-response relationships for workers at the Mayak Nuclear Enterprise, Health Phys., 73, 6, see Data Document § 1.2.2.1, p. 5.

The U.S. also has substantial data on health effects from internal Pu exposure, which also show no adverse effects. Tietjen, G.L. (1987) Plutonium and lung cancer, Health

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these comments The Data Document provides a wealth of supporting materials beyond that discussed above, including animal and plant data.

Phys., 52,5, see Data Document § 1.2.2.1, p. 6. U.S. data on ingestion of another long-lived radioisotope, ^{210}Po, also shows no adverse health effects. Wiggs, L.D., Cox-DeVore, C.A. and Voelz, G.L. (1991), Mortality among a cohort of workers monitored for 2l0Po exposure: 1944-1972, Health Phys, 61,1., see Data Document § 1.2.2.1 p. 7.

The scientific literature demonstrates that exposure to carcinogens in the industrial workplace is a significant contributor to human cancer. Therefore, if radiation were a carcinogen at the worker doses, these workers would have higher cancer rates than the general population. But that is not the case. The nuclear workers have lower adverse health effects than the general population. This condition for the nuclear workers is rationalized to be a result of the "health worker effect" without substantial analysis as required to confirm these conclusions.

However, to avoid the unjustified rationalization that lower cancer and other adverse health effects are ascribed to the "healthy worker effect," the health effects of radiation workers can be compared between equivalent worker groups. The most significant and well-defined group of workers is the shipyard workers on U.S. Navy nuclear ships. They have moderately significant radiation doses in a large population (108,000 nuclear workers in a 700,000 worker population), with high quality dosimetry, and with limited confounding effects from chemical exposures and other work conditions. The 10-year, $10 million study of the shipyard workers was undertaken in 1978, and completed in 1987.[2] The nuclear workers were compared to a well-matched case-control shipyard non-nuclear worker group. The study report

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2 DOE funded this study by Dr. Genevieve Matanoski, then Chairman of the Dept of Epidemiology at Johns Hopkins University. The study was not published in the scientific literature; it was released by DOE with a 2-page press release, in 1991. (Matanoski 1991). These results have still not been formally reported in the literature, although substantial funding and data analysis continues. However, the study was reported in the UNSCEAR 1994 Report. Although Dr. Arthur Upton was Chairman of the Technical Advisory Panel for the study, and he

in 1991 documented that radiation workers show significantly reduced total mortality. They show an expected increase in mesothelioma from working with asbestos.

Professor Emeritus Dr. John Cameron, a member of the Technical Advisory Panel and the Dosimetry Panel for the study reported on this study. Cameron, J. (1992), The good news about low level radiation exposure: Health effects of low level radiation in shipyard workers, Health Phys. Soc. Newsletter 20:9; Cameron, J. (1994), What does the nuclear shipyard worker tell us, ANS Trans, Vol. 71, p 36, see Data Document § 1.2.2.2, p. 1. Dr. Cameron states:

> The most significant and surprising finding of the [Nuclear Shipyard Worker Study, or NSWS] research was that the nuclear workers with the greatest radiation exposure, a cumulative lifetime occupational dose-equivalent of 5 mSv or more, had a standardized mortality rate (SMR) of deaths from all causes of only 0.76 that for their age and sex in the general population, while the non-nuclear workers had an SMR of 1.0.

A similar conclusion was reached by Professor Emeritus Myron Pollycove, M.D. Pollycove, M. (1994), Positive health effects of low level radiation in human populations, In: Biological Effects of Low-Level Exposures: Dose-Response Relationships (BELLE), Calabrese, Ed., Lewis Publishers, Boca Raton, FL. Dr. Pollycove states, based on the DOE summary report:

> The nuclear worker groups had a lower death rate from all causes, leukemia, and LHC than the non-nuclear workers.
>
> However, the summary of the study issued by the author and the U.S. DOE suppressed the most significant data in the study by failing to report that the detailed data for "All-Cancer" mortality show that the nuclear workers have statistically significant lower cancer than the non-nuclear workers. The failure to report this data constitutes misrepresentation of the data and results of the study in order to maintain the false LNT.

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chaired the BEIR V Committee, the study was not included in BEIR V (though other then-recent, unpublished work was included in the data and report).

Prof. Emeritus Dr. T.D. Luckey has summarized the results of worker studies that show that substantial studies show a consistent reduction in cancer, and that internal worker comparison studies that eliminate the unjustified rationalization of the "healthy worker effect" further confirm this effect. Luckey, T.D. (1994a) A Rosetta stone for ionizing radiation, Radiat. Protect. Manag. 11:pp 73-79, see Data Document § 1.2.2, p. 1; Luckey, T.D. (1997b), Estimation of a Minimum Yearly Radiation Allowance (MYRA) J. Clean Technol., Environ. Toxicol., & Occup. Med., Vol. 6, No. 3, pp 239-252, see Data Document § 1.2.2 p. 2; Luckey, T.D. (1994b), Radiation hormesis in cancer mortality, Intl. J. Occup. Med. Toxicol. 3:pp 175-191.

An additional assessment of the relevant studies has been made by Dr. Shu-Zheng Liu of the Radiobiology Research Unit of Norman Bethune Univ., Changchung, China. Liu, S.Z. (1996), Radiations risks: Threshold or no threshold?, Chinese Medical Journal 109(2); 99-133, see Data Document § 1.2.2.1, p. 7; These results have also been shown for the UK workers. Carpenter, L.M., Higgins C.D., Douglas A.J., Maconochie N.E.S., Omar R.Z., Fraser., P., Beral, V. and Smith, P.G. (1998), Cancer mortality in relation to monitoring for radionuclide exposure in three UK nuclear industry workforces, British Journal of Cancer, 78,(9), pp 1224-1232, see Data Document § 1.2.2, p. 6.

Nuclear worker studies, although generally from marginal data, consistently show lower age-adjusted cancer rates to nuclear workers than non-nuclear workers in the same plants, and to the general population. This is also the case of the International Agency for Research on Cancer (IARC) review of the nuclear workers of the U.S., UK, and Canada -- funded by DOE, and reported in the literature as Cardis, E. et al. (1995), Effects of low doses and low dose rates of external ionizing radiation: Cancer mortality among nuclear industry workers in three countries, Radiat. Res., 145, 647, see Data Document § 1.2.2.1, p. 2.

The IARC study is another significant DOE-funded study that is used to claim the existence of adverse health effects in nuclear workers. The study found no association between low-dose radiation and adverse health effects. The IARC study included approximately 95,000 nuclear workers, but excluded the most significant and most scientifically definitive study of government nuclear workers, the US Nuclear Shipyard Worker Study, of 108,000 nuclear workers.

The IARC analysis reported instead only on a "test for linear trend." From a single data point for only one cancer, leukemia, with 6 deaths versus 2.3 expected (in 238 deaths in workers exposed to more than 40 cGy with no excess in any other cancer), there was no increase with dose in the 113 leukemia deaths in the workers exposed to doses less than 40 cGy. The IARC study misrepresents this data to claim that the LNT is supported. This result was widely announced in a media campaign in scientific, trade, and public press long before the study data were made available for peer review, reporting that a "linear dose response" from low-level radiation was found in nuclear workers.

However, the IARC study misrepresents its own data to report that it is consistent with the LNT. See, e.g., Patterson, H.W. (1996), former editor of the journal *Health Physics*, fellow of the Health Physics Society, and retired radiation safety specialist from Lawrence Livermore National Laboratory, personal communication, see Data Document § 1.2.2.1, p. 2. Patterson states:

> …from the [Cardis study] text (referring to leukemia): 'When the analyses were restricted to cumulative doses below 400 mSv and below 200 mSv, to assess the influence of death in the higher dose categories on the dose-response relationship, the association was no longer statistically significant.…'
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> This data and analysis in this study does not indicate support for the LNT, contrary to the representations made by the authors and others. See also Analyses

by Pollycove (1995) in Data Document § 1.2.2.1, p. 2, and Schillaci (1995) in Data Document § 1.2.2.1, p. 3.

Similar results were found by in a study of Canadian nuclear vs. non-nuclear workers, as summarized by Dr. Zbigniew Jaworowski, former Chairman and member of UNSCEAR. Jaworowski, Z. (1995b) Stimulating effects of ionizing radiation: New issues for regulatory policy, Regulatory Toxicology and Pharmacology, 22:2, see Data Document § 1.2.2.2 p. 2. Dr. Jaworowski states:

> From several studies of people occupationally exposed to low radiation doses discussed in UNSCEAR (1994), data on mortality of 13,491 employees of the Atomic Energy of Canada Limited, (Gribbin et al., 1992), 5,504 were not exposed to radiation. The mean radiation dose of exposed persons was 49 mSv for men and 5.5 mSv for women. As shown in Table 6 the mortality due to all leukemias in the exposed group was only 32% of that in the general Canadian population. The observed mortality among employees of AECL from all cancers and from all noncancer diseases was also less than expected.

Further indication of the basis for the lack of adverse health effects in nuclear workers has been shown in cytogenic studies in exposed workers that show “adaptive response.” See Akhmatullina, N.B., Leonard, A., Gerber, G.B., Iskandarova, K.A. and Tcherednitchenko, O.G. (1999), Studies on the Adaptive Response: modifications in people professionally exposed to low doses and search for a transmissible conditioning factor, In: Proceedings on "The Effects of Low and Very Low Doses of Ionizing Radiation on Human Health," World Council of Nuclear Workers, June 16-18, St. Quentin en Yvelines, Versailles, France. Elsevier (in press) (Data Document § 1.2.2.2, p. 4; Barquinero, J.F., Barrios, L., Caball, M.R., Miró, R., Ribas, M., Subias, A. and Egozcue, J. (1996) Decreased sensitivity to the cytogenetic effects of bleomycin in individuals occupationally exposed to ionizing radiation, Mutation Research 354, pp 81-86 (Data Document § 1.2.2.2, p. 5); Hadjidekova V., Bulanova, M., Benova, D., Georgieva, I., Hristova, R. and Nikolova, T. (1999) Cytogenetic effects study of in vitro irradiation in peripheral blood lymphocytes of persons working with ionizing radiation, , In: Proceedings on "The Effects of Low and Very Low Doses of Ionizing Radiation on Human Health," World Council of Nuclear Workers, June 16-18, St. Quentin en Yvelines, Versailles, France. Elsevier (in press) (Data Document § 1.2.2.2 p. 8).

b. Radium dial painters

The radium dial painters are another group of workers with high ingestion of long-lived alpha-emitting radionuclides that are specifically relevant to assessing the risk of radionuclides in water. EPA claims in the Technical Support Document that the radium dial painters data supports application of the LNT. Yet EPA failed to consider all of the relevant data and took the position that it must be modeled on a linear model, contrary to SAB recommendations. Thomas, R.G. (1995) Radiation is not always harmful to human health, ANS Transactions, see Data Document § 1.2.4.1 p.9.

In decades of study of the radium dial painters and others with internal radium, there is no case of bone cancer or nasal sarcoma in the population with less than about 1000 cGy doses. Recent analyses confirm these conclusions reached at MIT by Dr. Robley Evans in the 1960s, Evans, R.D. (1974) Radium in Man, Health Physics, 27, pp497-510, see Data Document § 1.2.4.1 p.1. This was followed by more comprehensive reviews that confirmed these results in studies reported in an international conference in 1981, published in 1983. Rowland, R.E., Stehney, A.F., and Lucas, H.F. (1983) Dose response relationships for radium-induced bone sarcomas, Health Physics, Suppl. 1, Vol. 44, pp 15-31, see Data Document § 1.2.4.1 p. 4.

In decades of study of the radium dial painters and others with internal radium, there is no case of bone cancer or nasal sarcoma in the population with less than about 1000 cGy

doses. Recent analyses confirm these conclusions reached at MIT by Dr. Robley Evans in the 1960s (Evans 1974), followed in more comprehensive reviews in studies reported in an international conference in 1981, published in 1983. (In the US, these studies were then terminated by DOE starting in 1983, although more than 1000 subjects remained alive.) Evans, R.D. (1974) Radium in Man, Health Physics, 27, pp497-510, see Data Document § 1.2.4.1 p.1. More recent follow-up data and analyses by Dr. Constantine Maletskos working with Evans, reports an estimated threshold of 1100 cGy. Maletskos, C.J. (1994) Radium in man - 20 years later, ANS Transactions, vol. 71, p33, see Data Document § 1.2.4.1 p.2.

Further research by Dr. Otto Raabe addressing the more definitive beagle dog studies and the relationship to the human studies reports a threshold of about 1000 cGy. Raabe, O.G. (1996) Oh Wunder! The inverse dose-rate effect is quelled by the effective threshold, IRPA9 - Proceedings of the Ninth IRPA International Congress on Radiation Protection, Austrial, Association for Radiation Protection, Seibersdorf, Austria, see Data Document § 1.2.4.1, p.3.

Dr. Robert Thomas reports that a log-normal projection of just the homogeneous group of female dial painter cases, ignoring the fact of thousands of cases with no cancers, projects to a minimum threshold of about 400 cGy. Thomas, R.G. (1994) The US radium luminisers: A case for a policy of "below regulatory concern," J. Radiol. Prot., 14, 2, pp 141-153, see Data Document § 1.2.4.1, p.8.

Dr. Robert Rowland was the Director of the Center for Human Radiobiology at Argonne National Laboratory, the program established in 1970 on the retirement of Dr. Evans, to collect all of the U.S. data together to study the radium dial painters for their lifetimes. Rowland, R.E. (1994) Radium in Humans, A review of U.S. Studies, Argonne National Laboratory, September 1994, pp 106-112.

Dr. Rowland produced an updated analysis with corrections for the body-burden-dependent elimination rate of radium that provides more accurate dose data, and confirms the explicit threshold "in the neighborhood of 10 Gy." Rowland, R.E. (1997) Bone sarcoma in humans induced by radium: a threshold response? In: Proceedings of the 27th Annual Meeting of the European Society for Radiation Biology, Radioprotection colloquies, 32, C1/331-338.

Prof. Emeritus Dr. Sohei Kondo reports on the cancer and all-cause mortality, including the beneficial effects demonstrated in all-cause mortality in the early decades following exposure, and in non-cancer effects, in both the US and UK populations of radium dial workers. Leukemia and other potential radiogenic cancers and adverse health effects are not found in this population, highly exposed to both external and internal radiation, which contradicts the LNT. Kondo, S. (1993) Health Effects of Low-Level Radiation, Kinki University Press, Osaka, and Medical Physics Publishing Co., Madison, WI, see Data Document § 1.2.4.2 p.2; Kondo, S. (1993) Health Effects of Low-Level Radiation, Kinki University Press, Osaka, and Medical Physics Publishing Co., Madison, WI, see Data Document § 1.2.4.3 p.1.

A later review and conclusions on the radium dial painter data is more recently provided by Dr. Shirley Fry. Fry, S.A. (1998) Studies of U.S. radium dial workers: an epidemiological classic, Radiat. Research 150 (Suppl.), pp S21-S29, see Data Document § 1.2.4 p.3. Dr. Fry states:

> Epidemiological follow-up of the U.S. female dial workers for over 70 years has failed to unequivocally identify causal associations between delayed health outcomes and their prior occupational exposure to radium, other than the bone sarcomas and 'head' carcinomas, and these only among workers whose residual body burdens of radium exceeded the 'tolerance dose' proposed by Evans more than 50 years ago (Evans 1943). The simple intervention in the mid 1920s of

> banning the practice of tipping brushes contaminated with radium-enhanced paint by drawing them through the lips apparently prevented ingestion of hazardous amounts of radium by subsequent generations of dial workers, thereby supporting the hypothesis of a 'practical' threshold dose below which there are no clinically detectable effects.

c. Radiology workers

Radiation exposure of radiology workers (radiologists, radiological technicians, and others) has occurred for more than 100 years. Practitioners in radiology have received significant doses compared to natural background or nuclear workers. Radiologists in practice before 1925 had very high doses, including many with World War I experience with wounded military personnel in which case loads, x-ray equipment, and "hands-on" x-ray practices led to very high doses. Marie Curie practiced at the front lines in France with her "radiologic cars", and trained hundreds of radiologists, receiving very high doses in the process.

Early radiologists, many with WWI experience similar to Dr. Curie, were claimed to have excess cancers and leukemia in 1950s studies. Even these reports at these high doses are substantially questioned. Dr. Hugh Henry, then of Oak Ridge National Laboratory, summarized the data on the radiologists in the Journal of the American Medical Association in 1961. Henry, H. F. (1961) Is all nuclear radiation harmful?, J. Am. Med. Assoc., 176, 671, <u>see</u> Data Document § 1.2.3.1 p. 2. In addition, Nobel Laureate Dr. Rosalyn Yalow summarized significant results about radiological exposures. Yalow, R.S. (1994) Concerns with low level ionizing radiation, Mayo Clinic Proc., Vol. 69, pp436-440, <u>see</u> Data Document § 1.2.3.1 p. 1. Dr. Yalow states:

> British radiologists before 1921 [that included extreme WWI exposures] had 75% excess cancer-related deaths compared to other physicians. However, those starting after 1921 (with general improved radiation protection practices) had no excess cancer deaths, with typical excess exposures estimated at 100 to 500 rem (Smith and Doll 1981) …

> In WWII, 6500 radiologic technicians had an estimated 50 rem in training, with 24 months median service. A 29-year follow-up found no increased malignancies compared to army medical, laboratory, and pharmacy technicians. (Jablon 1978)

Numerous studies of specific cancers have also been conducted. For example, in a study by the National Cancer Institute of the more than 100,000 U.S. female radiologic technicians certified since 1926, more than 500 eligible breast cancer cases were case-compared to 5 controls each that showed that with a mean of follow-up of 29 years since certification. No association was found for breast cancer to experience in radiotherapy, radioisotopes, or fluoroscopy, nor to personal fluoroscopy or multifilm procedures. Boice, J.D., Mandel, J.S. and Doody, M.M. (1995) Breast cancer among radiologic technologists, JAMA Vol. 274 No. 5, pp394-401, see Data Document § 1.2.3.1 p.1.

BEIR V reports that prostate cancer in radiologists with estimated lifetime exposures of 2 to 20 Gy (200-2000 rad) for 1920-1939, and 1940-1969, showed no excess. BEIR V (1990) Health effects of exposure to low levels of ionizing radiation, Report of the Advisory Committee on the Biological Effects of Ionizing Radiations (BEIR Committee) NAS-NRC, Washington, D.C.; Cancer at Specific Sites, Prostate, United States Radiologists, p317, see Data Document § 1.2.3.1 p.1.

2. Medical Patient Health Effects

Medical patients receive significant radiation doses from both external sources, e.g., x-rays, and the ingestion and injection of radionuclides in nuclear medicine as internal sources of radiation exposure. Both types of exposure are used for both diagnostic and therapeutic applications, at low-moderate, and high-very high doses, generally at low to moderate dose rates. These exposures are generally well-controlled, with potentially good to excellent dosimetry.

Early radiation patients have had adverse long-term health effects from high doses from both chronic and acute dose rates. However, there are millions of procedures with low to moderate exposures every year subject to prospective studies. Some historical records enable credible retrospective studies. The results of these studies consistently refute the LNT. Radiation protection interests fail to either adequately consider these studies or, as with the radium dial painters studies, to support adequate credible research on these most significant populations.

Moderate medical treatment doses are not found to cause adverse health effects in dozens of studies that carefully consider significant potential confounding factors from health conditions. Dr. Yalow reports on representative studies. Yalow, R.S. (1994) Concerns with low level ionizing radiation, Mayo Clinic Proc., Vol. 69, pp436-440, see Data Document § 1.2.3.2, p.1. She states:

> Hyperthyroid patients treated with I-131 have about 10 rem whole-body (bone marrow) irradiation. In a study of 36,000 patients, 22,000 received I-131, with 14,000 mostly receiving surgical treatment. At 7- and 10-yr follow-ups, sufficient for leukemia effects, no difference exists in the two groups. (Saenger 1968; 1971)

This contradicts the LNT predictions according to BEIR V (1990) that leukemia would more than double.

Dr. Yalow reports that before 1968 (before the lower dose by radioimmunoassay), 1 to 3 million U.S. patients received internal doses for I-131 thyroid diagnosis. She reports that a Swedish study finds no excess thyroid cancer from diagnostic I-131 use (mean thyroid doses estimated to be 50 cGy) for patients that were not suspected of having thyroid cancer, and that these patients have a 62%, statistically significant, reduction in thyroid cancer. Yalow, R.S. (1994) Concerns with low level ionizing radiation, Mayo Clinic Proc., Vol. 69, pp436-440, see Data Document § 1.2.3.2 p. 5.

BEIR V reports the same result for patients given I-131 for diagnostic purposes stating that these results "do not support the conclusion that diagnostic doses of I-131 significantly increases the risk of thyroid cancer." BEIR V (1990) Health effects of exposure to low levels of ionizing radiation, Report of the Advisory Committee on the Biological Effects of Ionizing Radiations (BEIR Committee) National Academy of Sciences-National Research Council, Washington, D.C.; Cancer at Specific Sites, Thyroid Cancer, p288, see Data Document § 1.2.3.2 p. 5.

Studies of significant x-ray exposures and leukemia incidence are also negative. Boice, J.D. Jr., Morin, M.M., Glass, A.G., Friedman, G.D., Stovall, M., Hoover, R.N. and Fraumeni, J.F. Jr. (1991) Diagnostic x-ray procedures and risk of leukemia, lymphoma, and multiple myeloma, Epidemiology and Biostatistics Program, National Cancer Institute, Bethesda, MD 20852. JAMA 265:pp1290-1294, see Data Document § 1.2.3.2 p.6.

Dr. Yalow also reports on one such study of leukemia from radiation exposures up to 300 cSv from normal x-ray practices over many years,. Yalow, R.S. (1994a) Concerns with low level ionizing radiation, Mayo Clinic Proc., Vol. 69, pp 436-440. Dr. Yalow states:

> A case control study by Linos et al (1980) of 138 cases of leukemia, which represent all known cases in Olmstead County, Minnesota between 1955 and 1974 and matched controls, revealed that there was no statistically significant increase in the risk of developing leukemia after radiation doses up to 300 rads to the bone marrow when these doses were administered in small doses over long periods of time, as in the case of routine medical care.
>
> Virtually all medical care is provided by the Mayo Clinic and one other private medical group practice and the record keeping and estimations of bone marrow dose is very reliable.

In an assessment of breast cancer from low to high doses from multiple fluoroscopies to Canadian female tuberculosis patients, Miller et al. (1989) find that the data at doses below 30 cSv demonstrate highly significant reductions in breast cancer. However, the paper nevertheless projects a linear dose-response from high dose data, effectively dividing all excess cancers by the total dose, claiming that there is an excess of breast cancer. As a result, the study erroneously reports a dose-response of 60 excess cancers at 1 cGy in one million women. This equates to 900 excess breast cancers at 15 cGy. However, the actual study data finds that, at 15 cGy, there are 10,000 fewer breast cancer cases than controls. These results are presented in UNSCEAR 1994. Pollycove, M. (1994) Positive health effects of low level radiation in human populations, In: Biological Effects of Low-Level Exposures: Dose-Response Relationships (BELLE), Calabrese, Ed., Lewis Publishers, Boca Raton, FL, see Data Document § 1.2.3.2 p.2; Pollycove, M. (1996) Positive health effects of low-level radiation ... and why, University of California, San Francisco, see Data Document § 1.2.3.2 pp. 2, 4.

3. Natural background radioactivity

a. External radiation

Natural background radioactivity is by far the largest source of exposure to ionizing radiation around the world. Background radiation varies by a factor of about 100. Significant populations are exposed to differences of factors up to about 10 locally.

The EPA references a small ecological epidemiological study in a few counties in the phosphate industry region of Florida (Lyman 1985) to provide a potential association between increased radium concentrations and adverse effects. The correlation in this study is poor and weak.

More substantial and definitive studies of larger populations with significant radiation dose differences consistently find either statistically significant lower cancer rates in the more highly exposed groups, or no effects in populations that are poorly differentiated, in direct conflict with the LNT. One of the most extensive studies is ongoing in Guangdong

Province in China shows no adverse effect in the stable populations of high background area group compared to the well-matched control group of more than 70,000 persons each. Wei, L. (1997) High background radiation area-an important source of exploring the health effects of low dose ionizing radiation, In: High Levels of Natural Radiation 1996: Radiation Dose and Health Effects, Editors: Wei, L.; Sugahara, T. and Tao, Z., Beijing; Elsevier, Amsterdam, pp1-14; 58-59, pp63-66, see Data Document § 1.2.6.2 p.7. UNSCEAR Member and former Chairman, and Head of the Radiological Protection Laboratory of Poland, Prof. Dr. Zbigniew Jaworowski has reported on these studies. Jaworowski, Z. (1995a) Beneficial Radiation, Nukleonika, 40, pp3-11, see Data Document § 1.2.6.2 p.3; Jaworowski, Z. (1995b) Stimulating effects of ionizing radiation: New issues for regulatory policy, Regulatory Toxicology and Pharmacology, 22:2, see Data Document § 1.2.6.2 p.3; and Zbigniew Jaworowski, "Radiation Risk and Ethics," *Physics Today*, pp.24-29 (Sept 1999), accompanying these comments.

Prof. Jaworowski states:

> The best radioepidemiological study at low doses to date has been carried out in China. Between 1970 and 1986, 74,000 people in Yangjiang county, which has a high level of natural background radiation (5.5 mSv per year), were compared to 77,000 people in two adjacent low-background counties (Enping and Taishan, 2.1 mSv per year). In the high-background county, the inhabitants receive a 70-year lifetime dose of 385 mSv, which is higher than the intervention level for evacuation adopted for Chernobyl, and 5.5 times higher than the dose limit proposed in the EPA.
>
> Should the Chinese government evacuate Yangjiang county? The epidemiological data show that ...i n an age group of 10-79 years the general (non-leukemia) cancer mortality was 14.6% lower in the high-background county than in the low-background counties. The leukemia mortality among men was 15% lower and among women 60% lower in Yangjiang (Wei et al. 1990) …
>
> The question arises: why governments of various countries do not relocate populations living in areas where lifetime dose of natural radiation is higher than 350 mSv. For example, why are people not evacuated from Norway where all country average lifetime dose is 365 mSv (Henriksen 1988), or from high background regions in India with a lifetime dose of > 2000 mSv (Sunta 1990) and

> in Iran with lifetime dose of > 3000 mSv (Sohrabi 1990)? Perhaps in Iran, for example, the government considered not to follow the ICRP guidelines when it considered the fact that in a house in the city of Ramsar several generations were receiving average individual lifetime doses of natural radiation of 17,000 mSv (240 times more than the current ICRP limit for exposure of members of the public to natural sources of radiation). Yet these individuals show no increased incidence of any disease, and some of them lived to 110 years of age (Sohrabi 1990).

In the United States, in a preliminary analysis funded by the U.S. AEC, Dr. Norman Frigerio at Argonne National Laboratory studied external radiation dose and national cancer data by U.S. state, with rigorous statistical analysis testing various linear models. Dr. Frigerio found that the "high background states," with a factor of 3 higher doses than the low background states, and twice the national average, have consistently and significantly lower cancer rates, with analysis of all readily identifiable potential confounding factors. Frigerio, N.A., Eckerman, K.F. and Stowe, R.S. (1973) Carcinogenic Hazard from Low-Level, Low-Rate Radiation, Part I, Rep. ANL/ES-26, Argonne Nat. Lab, see Data Document § 1.2.6.2 p.4)

Subsequent summary analyses with later U.S. radiation dose and cancer data has confirmed these results, for example, Luckey reported (1991):

> …this negative correlation is clear for leukemia, $p<0.001$ (Figure 6.5), it fits most types of cancer and has been amply confirmed in surveys of counties, states, and regions. (Cohen 1980; Eckhoff 1974; Hickey 1981a,b; Jacobson 1976; Mason 1974; Sanders 1978; Sauer 1982; Wachsmann 1987, 1989; Webster 1981; Yalow 1981)
>
> The western states, Colorado, Indiana, Montana, North Dakota, South Dakota, Utah, and Wyoming, had a considerably lower cancer mortality rate when compared with the average of the other U.S. (Kaplan 1949; Wachsmann 1989) Both coastal areas were found to have higher cancer mortality rates than the average.
>
> Webster compared common cancer mortality rates in the western states with that of the general U.S. population (Table 6.1); hormesis was evident. (Webster 1983) The total cancer mortality of the western states was 84.5% of that for the average

of the U.S. Lung cancer mortality of the western states was only 71% of the average for all states.

Higher dose areas exist in several countries, especially Brazil, India, and Iran. Recent more extensive studies of the populations in these countries continues to confirm early results that even with such high doses these populations demonstrate no adverse health effects. An extensive study of the population in Kerala India has been conducted for the last decade. Kesavan, P.C. (1997a) Indian research on high levels of natural radiation: pertinent observations for further studies, In: Elsevier Science B.V, High Levels of Natural Radiation, Radiation Dose and Health Effects, pp111-117, see Data Document § 1.2.6.2 p.9; Nair, M.K., Nambi, K. S. V., Sreedevi Amma, N., Gangadharan, P., Jayalekshmi, P., Jayadevan, S., Cheriano, V. and Reghuramo, K.N. (1999) Population study in the high natural background radiation area in Kerala, India, Radiation Research 152, ppS145-S148, see Data Document § 1.2.6.2 p.11.

Another study of newborns in the Kerala area, with dose rates from 1 mSv/yr to 35 mSv/yr, shows no adverse reproductive effects from high radiation levels. Jaikrishan G., Andrews V.J., Thampi M.V., Koya P.K., Rajan V.K. and Chauhan P.S. (1999) Genetic monitoring of the human population from high-level natural radiation areas of Kerala on the southwest coast of India. I. Prevalence of congenital malformations in newborns, Radiat Res. Dec;152(6 Suppl): S149-153, see Data Document § 1.2.6.2 p.12.

b. High Radon and Internal Radioactivity Areas

Dr. R. Piispanen of the Institute of Geosciences and Astronomy at Univ. of Oulu in Finland reviewed regional studies of cancer in areas with high radioactivity. Piispanen, R (1995) Radiation hormesis - fact or fiction?, Environ. Geochem. and Health, 17, pp95-102, see Data Document § 1.2.6.3.1 p.22. He concluded:

Dr. Piispanen states:

> Regional studies carried out in the USA, China, India, Japan and Finland also suggest a negative correlation between cancer and radioactivity. According to recent reports by Cohen (1991 and 1993), lung cancer in the USA is rare in regions with high radon levels … In China, cancer mortality rates are slightly lower in Guangdong province than elsewhere, although (or because) the natural background radiation level there is three times the [control area] average (Loken and Feinendegen, 1993, p. 447). The same is true in India (Nambi and Soman 1987) and Japan, where Mifune (1992) demonstrated low mortality rates for cancerous diseases (with 46-54% reductions) in Misasa, where hot baths in waters having radon activity levels as high as 400 Bq L-1 are fashionable.

Dr. Piispanen conducted his own study in 1991, concluding:

> In Finland, I observed statistically significant negative correlations between various types of cancer and the concentration of uranium in the groundwater (Table 1), and areas with high radon levels similarly do not coincide with areas with high incidences of lung cancer or leukemia, a relationship known since 1984 (Castren 1994). Regional longevity studies carried out in various countries have also produced results which show higher life spans among peoples living in areas of high natural background radiation (Henry 1961; Neafsey 1990; Parsons 1990).

In Devon and Cornwall in the U.K., a study of 14 major cancers in the high radon areas found no increase in any cancer except non-melanoma skin cancer. Etherington, D.J., Pheby, D.F. and Bray, F.I. (1996) An ecological study of cancer incidence and radon levels in South West England, Department of Social Medicine, University of Bristol, U.K. Eur. J. Cancer 32A:pp1189-1197.

Numerous studies of lung cancer as a function of high radon exposures find a consistently lower cancer rate in high radon areas, or ambiguous or null effects in studies of poorly differentiated populations. None of these studies supports the use of LNT to estimate low-dose effects. Brooks, A. and Frazier, M. (1993) Understanding the relationships: Dose-response: A Review of the Latest Evidence for Radon Risk Overestimation and Underestimation, Radon Research Notes Oak Ridge Nat. Lab., Nov., 1993, Issue 12, see Data Document § 1.2.6.3 p.5; Suzuki, Y., Honjo, H., Kawamura, H., Koishi, T., Suzuki, T. and Hirohata, T. (1994) Cancer Mortality in Low Radon Spa Area, Jpn J Cancer Research, November, 85, 1063-1066, see Data Document § 1.2.6.3.1 p.26; Ye, W., Sobue, T., Lee, V., Tanooka, H., Mifune, M., Suyama, A., Koga, T., Morishima, H. and Kondo, S. (1998) Mortality and cancer incidence in Misasa, Japan, a spa area with elevated radon levels, Jpn. J. Cancer Res. 89, pp789-796, see Data Document § 1.2.6.3.1 p.26.

Another study of cancers in a high radon area in Hungary by Dr. Ester Toth and colleagues showed lower cancer risk in the higher radon area. Toth, E., Lazar, I. Selmeczi, D. and Marx, G (1998) Lower cancer risk in medium high radon, Pathology Oncology Research 4, 2, pp125-129, see Data Document § 1.2.6.3.1 p.21.

Analyses of radon effects versus the LNT premise appear in ecological studies conducted by Professor Emeritus Bernard Cohen at the University of Pittsburgh. This program incorporates multiple independent analyses that consistently demonstrate higher lung cancer in areas with the lowest radon levels. Dr. Cohen found low lung cancer in the high radon area of Cumberland County Pennsylvania, confirmed by a small study of radon tests in the homes of 450 physics professors in 101 universities in 42 states that showed lower lung cancer in the respective counties, and reports on similar results in reviews other published results. Cohen, B.L. (1987) Tests of the linear, no-threshold dose-response relationship for high-LET radiation, Health Phys., 52, 5, see Data Document § 1.2.6.3.1 p.7.

Dr. Cohen noted that the result in Cumberland County could be confounded and expanded his study to other large U.S. counties. Since radon data by county were not available, Dr. Cohen obtained radon data by providing residential radon measurements in the 10 large counties each with the highest and the lowest lung cancer rates in the U.S. He again found a strong negative correlation that was highly unlikely to have confounding effects. Cohen, B.L.

(1989) Expected indoor 222-Rn levels in counties with very high and very low lung cancer rates, Health Phys., 57, 6, see Data Document § 1.2.6.3.1 p.9.

Dr. Cohen continued his documentation of radon levels by county, ultimately obtaining approximately 272,000 measurements. He also obtained all independent state and EPA sponsored residential radon measurements. From more than 300,000 home radon data measurements and cancer data from 1792 counties, covering almost 90% of the U.S. population, he demonstrates conclusively that LNT cannot be valid. Cohen, B.L. (1995) Test of the linear-no threshold theory of radiation carcinogenesis for inhaled radon decay products. Health Phys., 68, pp157-174, see Data Document § 1.2.6.3.1 p.1; see also Pollycove, M. (1994) Positive health effects of low level radiation in human populations, In: Biological Effects of Low-Level Exposures: Dose-Response Relationships (BELLE), Calabrese, Ed., Lewis Publishers, Boca Raton, FL, see Data Document § 1.2.6.3.1.

Dr. Cohen's results have been rejected under the rubric that he is conducting an "ecological" epidemiology study that may have "confounding" factors. However no possible confounding factor has been identified despite almost a decade of trying. In addition, in an interim study with the data from about 900 counties, one of the world's premier epidemiologists, Dr. Graham Colditz of Harvard University, co-authored a paper with Dr. Cohen that determined that the epidemiological results of analyzing the data were sound. Cohen, B.L. and Colditz, GA, (1994) Tests of the linear-no threshold theory for lung cancer induced by exposure to radon. Environ Res; 64(1):65-89.

In the former USSR uranium mining areas of Saxony in the former East Germany (GDR), Prof. Dr. Werner Schuttmann of the Faculty of Industrial Hygiene and Department of Health and Prof. Dr. Klaus Becker of the German Standards Institute report on the studies that show that women residents (mostly at home and with low smoking) have lower lung cancer in the high radon areas. Schuttmann, W. and Becker, K. (1998) Residential radon in Saxony: Another test for the LNT hypothesis? Unpublished, see Data Document § 1.2.6.3 p.1; Becker, K. (1999) How dangerous is residential radon? In: Proceedings on "The Effects of Low and Very Low Doses of Ionizing Radiation on Human Health," World Council of Nuclear Workers, June 16-18, St. Quentin en Yvelines, Versailles, France. Elsevier (in press), see Data Document § 1.2.6.3 p.3)

4. Medical Applications for Health Benefits

Low-dose radiation, or LDR, stimulates the immune system, enzymatic repair, and physiological functions, contrary to the LNT premise. Such capabilities are successfully applied to treat cancer, and other diseases and debilities. Dr. Kiyohiko Sakamoto, Prof. Emeritus of Tohoku University Medical School documented successful applications of the stimulation of immune response and successful treatment of cancer, conducted confirmatory studies of immunological responses to LDR in mice that succeeded in preventing, and reducing, cancers in mice. Sakamoto, K and Myojin, M. (1996). Fundamental and clinical studies on tumor control by total body irradiation, Am. Nucl. Soc. Trans. 75, 404, see Data Document § 1.2.3.3 p.1; Sakamoto, K., Myojin, M., Hosoi, Y, Ogawa, Y., Nemoto, K., Takai, Y., Kakuto, Y., Yamada, S., Watabe, N., (1997) Fundamental and Clinical Studies on Cancer Control with Total or Upper Half Body Irradiation, J. Jpn. Soc. Ther. Radiol. Oncol. 9:161-175; accord Takai, Y., Ogawa, Y. Nemoto, K., Yamada, S. and Sakamoto, K. (1991) Direct anti-tumor effect of low dose total (or half) body irradiation and changes of the functional subset of peripheral blood lymphocytes in non-Hodgkins lymphoma patients after TBI (HBI), J. Jpn. Soc. Ther. Radiol. Oncol. 3: pp9-18, see Data Document § 1.2.3.3 p.2.

More recent studies that confirm successful treatment of cancer by LDR. Richaud, P.M., Soubeyran, P., Eghbali, H., Chacon, B., Marit, G., Broustet, A., Hoerni, B., (1998) Place of low-dose total body irradiation in the treatment of localized follicular non-Hodgkin's lymphoma: results of a pilot study., Int. J. Radiat. Oncol. Biol. Phys., 40(2):387-90; and Safwat, A., (2000) The immunobiology of low-dose total-body irradiation: more questions than answers. Radiat Res. 153(5 Pt 1):599-604.

5. Japanese Atomic Bomb Survivors

The study of this population is claimed to provide the preeminent foundation for the assessment of radiation health effects at low doses. However, this population has negligible scientific application to low-dose, low-dose-rate, dose-response and associated radiation protection policies. This population was exposed to the near-instantaneous radiation of atomic bomb detonation with both neutron and gamma-ray components. The population has many confounding factors of various individual war-time conditions, with the stress and nutritional effects and contaminations of other war-time life, the ancillary effects of the bomb conditions, and follow-up medical and health conditions. The exposure of individuals is largely unknown and the result of radiation dose estimates that today are substantially unknown, especially due to the uncertainty in the asymmetric neutron component in the Hiroshima bombing, with doses that are known and accepted to be significantly in error.

The control population is persons who were in the area following the atomic bombing with a dose estimated to be less than 0.5 cGy. The pathology of disease and cause of death determinations is also uncertain. These circumstances make the health effects of the Japanese survivor population of minimal value to the knowledge of radiation dose-response for radiation protection purposes.

Further, unlike most government-funded population studies, raw data produced by the Radiation Effects Research Foundation (RERF) is not available to reviewers, including even reviewers and analysts for the government-funded BEIR V report. Further, U.S. DOE attempts to reassign RERF from the National Academy of Sciences to a DOE-recruited principal investigator at Columbia University, and, failing that, to further control the program through a review committee of radiation protection LNT supporters, provides additional uncertainty in the potentially biased results that are being produced by RERF.

Notwithstanding its limitations, Japanese survivor data contradict the LNT. Kondo, S. (1993) Health Effects of Low-Level Radiation, Kinki University Press, Osaka, and Medical Physics Publishing Co., Madison, WI. § 3.2, see Data Document § 1.2.1.1 p.2); Kondo, S. (1994) Atomic bomb survivors and the sigmoidal response model, ANS Trans, Vol. 71, p34, see Data Document § 1.2.1.1 p.2; Hattori, S. (1994a) State of research and perspectives on radiation hormesis in Japan, Intern. J. Occup. Med. Toxicol.,3:pp203-217, see Data Document § 1.2.1.1 p.2; Luckey, T.D. (1991) Radiation Hormesis, CRC Press, Boca Raton, FL, see Data Document § 1.2.1.1 p.4; Pollycove, M. (1994) Positive health effects of low level radiation in human populations, In: Biological Effects of Low-Level Exposures: Dose-Response Relationships (BELLE), Calabrese, Ed., Lewis Publishers, Boca Raton, FL, see Data Document § 1.2.1.1 p.6; Alvarez, J.L. and Seiler, F.A. (1996) New Approaches to Low-Dose Risk Modeling, Technology: J. Franklin Inst. 333A, pp33-51, see Data Document § 1.2.1.1 p.8.

Confirming these results, the BEIR V report states that the Life Span Study indicates no significant increases for leukemia below 0.4 Gy, yet in typical fashion applies a linear result to presume effects down to zero dose. BEIR V (1990) Health effects of exposure to low levels of ionizing radiation, Report of the Advisory Committee on the Biological Effects of

Ionizing Radiations (BEIR Committee) National Academy of Sciences-National Research Council, Washington, D.C. p. 242, see Data Document § 1.2.1.1 p.1.

The RERF data also find no increases, and statistically significant decreases in non-cancer health effects below the estimated 200 cGy doses. Kondo, S. (1993) Health Effects of Low-Level Radiation, Kinki University Press, Osaka, and Medical Physics Publishing Co., Madison, WI, see Data Document § 1.2.1.2 p.1. There are no genetic effects in approximately 90,000 children and grandchildren of the highly exposed survivors who have parental exposures in the range of 30-60 cGy. Kondo, S. (1993) Health Effects of Low-Level Radiation, Kinki University Press, Osaka, and Medical Physics Publishing Co., Madison, WI, see Data Document § 1.2.1.4 p.1.

II. Biological Models and Hormesis

The LNT premise is a physics-based, rather than a biology-based, model, and is wholly refuted by the biological studies of the effects of radiation on living organisms. Some of this literature is discussed in the RSH attachment to these comments.

Myron Pollycove, MD, in "Dose Response of the Organism to Ionizing Radiation," Society of Nuclear Medicine, REIR Continuing Education: Radiobiology II, June 2000, describes a biological model that he and Ludwig Feinendegen, MD, are developing to explain the mechanisms and processes that occur when a living organism is irradiated. At low levels, the radiation is seen to be beneficial as it stimulates the body's defenses -- *i.e.*, hormesis. At high levels, the radiation overwhelms the body's defenses, and the result is detrimental.

They demonstrate that known fundamental cellular and molecular biology refutes the LNT premise with several crucial facts:

- Ionizing radiation, even at many multiples of background radiation levels, makes only a trivial contribution to the normal DNA damage, both for single-strand breaks and double-strand breaks, continually occurring as a result of the organism's routine metabolism.
- Carcinogenesis is a complex multi-step process involving tissue-level failures (as a failure of cell society, not of an individual cell), following DNA damage, through billions of cell divisions before initiation, promotion, and progression to a cancer or tumor. This process also requires a series of at least five DNA failures. As such, the response cannot be linear.

The biological response to low-dose ionizing radiation is explicitly opposite to the response to high-dose radiation. Low-dose, low-dose-rate, radiation does not overwhelm the organism's biological defense mechanisms. To the contrary, it activates chemical, molecular, and physiological factors that are inherently beneficial to the biological function and maintenance of the organism. In response to a trivial addition to the background of DNA damage from normal oxidative metabolism, a substantial contribution is made to the control, repair and removal of the enormous background of DNA damage, inflammations and infections, and cancerous and pre-cancerous cells. These actions include protective actions (e.g., anti-oxidants), repair actions (e.g., enzymes and proteins), and removal actions (e.g., apoptosis, 'cell-suicide'). See "The Nutrient-Toxin Dosage Continuum in Human Evolution and Modern Health," by L. Gerber, *et al.* in *The Quarterly Review of Biology*, Vol 74 No. 3 pp. 273-289 (Sept 1999); "Hormesis: A Highly Generalizable and Reproducible Phenomenon with Important Implications for Risk Assessment," by E.J. Calabrese *et al.* in *Risk Analysis,* Vol. 19 No. 2 pp. 261-281 (April 1999); "Radiation Hormesis Overview," by T.D. Luckey in *Radiation Protection*

Management, Vol. 16 No. 4 pp. 22-34 (Jul/Aug 1999); *Hormesis with Ionizing Radiation* (1980); *Radiation Homesis* (1991).