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June 9, 1994

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCHUCLA SCHOOL OF MEDICINE
HARBOR - UCLA MEDICAL CENTER
DEPARTMENT OF RADIOLOGY
1000 CARSON STREET
TORRANCE, CALIFORNIA 90509Samuel Chilk, Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555DOCKET NUMBER
PETITION RULE PRM 20-23
(59FR17746)Attention: Docketing and Service Branch, No. PRM-20-23; FR 59
(72), 14 Apr 94, p. 17746.

Dear Mr. Chilk:

I wish to comment on a petition submitted by Mr. Steve Gannis that urges NRC to lower the yearly maximum radiation dose to the general public from 100 mrem to 1 mrem or as close as possible to it. I urge you to disapprove Mr. Gannis' petition.

First, I would like to clarify certain of Mr. Gannis' statements so that we are accurate. Second, I would like to introduce some risk comparisons to put mrem radiation absorbed doses in perspective. Third, and by far most important, I would like to discuss the pitfalls of assuming the validity of the linear hypothesis in assuming carcinogenesis and mutation (stochastic effects). (The linear hypothesis of radiation damage assumes that the risk of adverse effects at high radiation absorbed dose may be more or less accurately extrapolated down to lower doses all the way to zero. This is opposed to a threshold theory which assumes that absorbed doses below some limit are effectively harmless.)

It is obvious that the adoption of a 1 mrem limit would wipe out all activities involving byproduct material and other sources of radiation not regulated by NRC, because 10 CFR Part 20 attempts to set a radiation limit for all activities involving ionizing radiation. Nuclear power, the use of fossil fuels, nuclear medicine, radiation oncology, diagnostic radiology, laboratory pathology, virtually all pharmaceutical development, a huge portion of life sciences (and other sciences) research, well logging, thickness gauging, luminous dials for ships and airplanes, smoke detectors, airplane travel, skiing in the Rocky Mountains, television---all of these activities, and many, many more, would cease. The U.S. would become a third world country, our mortality rate would soar, and the NRC would cease to exist. For this last reason alone, if not for at least some of the others, the NRC should want to disapprove this petition.

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June 9, 1994
Samuel Chilk, Secretary
Page -2-

It will be difficult for NRC to do so without challenging the linear hypothesis. However, it is a relative conflict of interest for NRC to support a threshold theory for stochastic effects, because that would mean that most of what NRC does now is scientifically of no importance. NRC is indeed faced with a Hobson's choice. It can clutch the linear hypothesis and end when it has lost all its licensees and therefore all its needed User Fees. Or, it can embrace an effective threshold theory, and fundamentally change its regulatory behavior. NRC could also do something less intellectually pure and dodge the issue entirely. NRC could say that the deaths that would be caused by depriving this nation of the vital activities that result in mrem radiation absorbed doses are far greater than the theoretical deaths from this radiation, and that therefore there is less relative hazard with radiation than without it. Indeed, levels far higher than 100 mrem may be justified by this argument, and we could easily return to the previous 500 mrem limit.

One thing appears certain, however. NRC's current regulatory construct is irrational, and it strongly merits revision.

I. CLARIFICATION OF STATEMENTS

The petitioner quotes NRC's defunct "Below Regulatory Concern" policy statement when he states that an extra 100 mrem/yr over a lifetime would result in 1 fatal cancer in every 285 people. His calculation is quite correct from the probabilities listed in the policy statement for low L.E.T. radiation. For high L.E.T. radiation the death risk would be even higher (by a factor of up to about 10 or 20). However, the BRC statement references UNSCEAR 1988 and BEIR V, which assume the linear hypothesis. I believe that this is where the problem lies. After 99 years of research, we have been unable to associate any hazard at all with 100 mrem (or 1000 mrem for that matter). So the premise upon which Mr. Gannis judges risk is by no means validated. Not for him, not for NRC, not for UNSCEAR, NAS, NCRP, ICRP, EPA, or Greenpeace.

Mr. Gannis also states that U.S. Government policy limits fatal carcinogenic risk from pollutants and contaminants to about one in a million. This is true, but in addition there is often a one in ten thousand risk limit for the group most heavily exposed. However, there is no "linear hypothesis" for any pollutant or contaminant. All have thresholds below which risk is taken to be zero. This is because no hazard has been observed at these low levels. Ionizing radiation is the only agent denied a

June 9, 1994
Samuel Chilk, Secretary
Page -2-

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June 9, 1994
Samuel Chilk, Secretary
Page -3-

"threshold". When we define one, these hazard figures might make some sense. At present, they only scare members of the public, while many nuclear professionals scoff at them.

Mr. Gannis also states that the average person receives about 90 mrem/yr from background radiation. This number has been reevaluated because of radon-222. The average radiation dose from background is now considered to be about 300 mrem/yr. This number increases with altitude and with soil and rock high in radium and other naturally-occurring radionuclides. Living in Denver adds about 200 mrem more/yr, and skiing in the Colorado Rockies adds about another 100 mrem. The highest measured yearly radiation dose in the U.S. that I know of is in a small town in Colorado, at nearly 900 mrem/yr. The cancer death rate in Colorado is tied for the third lowest in the nation. (Washington, D.C., with a relatively low background radiation rate, has the highest cancer death rate.)

II. RELATIVE RISK

Sleeping in bed with another person for 10 years results in 1 mrem. Traveling 1000 miles in an airplane results in 1 mrem. Breathing ordinary air for 3 1/2 hours results in 1 mrem to the bronchial epithelium (1). Watching color TV for 2 hours sitting 2 inches from the screen can give 1 mrem. Does anyone think that Americans are going to give up sex, air travel, TV, or breathing? Unlikely. We do not seem preoccupied with the presumed radiation danger from these activities. Attached is a document describing other sources of radiation in our everyday environment for comparative purposes.

III. LINEAR HYPOTHESIS VS. THRESHOLD THEORY

(a) Background

It is interesting to understand the background of the ultraconservative assumption of measurable stochastic risk at any level of radiation absorbed dose. It begins with the association of chromosomal abnormalities with cancer noted by David von Hansemann in 1890 (2).

June 9, 1994
Samuel Chilk, Secretary
Page -4-

In 1914, Theodor Boveri (3) first suggested that cancer might result from a disturbance in chromosome balance.

In 1927, Herman Muller (4) showed that ionizing radiation could cause genetic mutations.

In 1930, Öivind Winge established the stemline concept, with which malignant cell populations could be imagined to proliferate subject to Darwinian principles (discussed in 5).

In 1950's, further studies clearly documented the connection between malignancy and chromosomal abnormality. In 1960, the description of the Philadelphia chromosome in patients with chronic myelogenous leukemia by Nowell and Hungerford (6) left no lingering doubts. The association of malignancy with mutation led naturally to the assumption that mutation caused cancer, and that anything that caused mutation was carcinogenic.

The delicate biochemistry of a cell is characterized by reactions that take place at energy quanta well above thermal energy levels and well below ionization levels; this is necessary for biological stability. Ionizing radiation, which by definition imparts quanta higher than ionization levels, thus causes biochemical chaos. Even one quantum from one atomic disintegration could cause a genetic mutation; the simplistic reasoning goes that therefore even only one disintegration could cause a fatal cancer.

The rabid antinuclear terrorists of the pseudoenvironmentalist movement have kept this flimsy concept alive. However, they are not alone. Other, more "scientific" groups have done so as well. Groups whose members have something to gain from antinuclear hysteria, such as regulators (e.g. NRC, EPA), scientists whose comfortable professional life depends on it (e.g. NCRP, ICRP), and lawyers, are happy to not "rock the boat".

There are some knotty problems with this paradigm. First, we have the embarrassing problem of the "lag time". If radiation hits a cell, causes a mutation, and that mutation causes cancer, why does it often take 20, 30, or 40 years to develop? There is no clear answer to this, so scientists have conveniently invented a "two-step" theory. In essence they hypothesize that radiation initiates the genetic change and a second promotional event, at some, future time, enables the expression (carcinogenesis) of the initiation event. Convenient, but weak.

A second problem involves linear energy transfer (LET). Whereas low LET radiation damage may be significantly repaired by a

number of mechanisms, high LET damage (e.g. alpha particle damage) is poorly repaired. High LET damage often results in cell death. As dead cells do not become cancer cells, one would imagine that high LET radiation would have much less carcinogenicity per rad than low LET radiation. However, this is not the case. High LET radiation, on a per rad basis, is much more carcinogenic than low LET radiation. In fact, if we compare the relative biological effectiveness (RBE) of high and low LET radiation for cell death and for carcinogenicity we see that whatever the RBE for cell death, the RBE for carcinogenicity is rather similar.

The RBE for high LET particles for both mammalian cell killing and mammalian carcinogenesis are dependent on the dose at which the comparison to low LET is made; this is because of the differences in shape of the dose-response curves for the two types of radiation. RBE_{death} for 4-5 Mev α -particles is about one at high dose and approaches 6-10 at low doses (25-50 rads), depending on the radiosensitivity of the system studied (7,8). It is not possible to calculate RBE's at lower doses because the shape of the 250 kev x-ray dose response curve is uncertain. The RBE_{carcinogenesis} for α -particles goes from one at high doses and high dose rates toward a maximum of about 10 at doses in the range of 25-100 rads (9,10). The RBE_{death} of fast neutrons approaches a low of one at high doses and rises to a high of about 3-7 at low doses, again dependent upon the system under study and its dose-response curves (11,12,13). The RBE_{carcinogenesis} for fast neutrons is about one at high doses and dose rates corresponding to an x-ray dose of 150-400 rads (14,15). At x-ray doses corresponding to 25-150 rads, the RBE increases to between 7 and 10 (10,13,14), being especially high at low dose rates.

This suggests the possibility that the primary importance of ionizing radiation is that it simply kills cells. In examining the standard paradigm for radiation carcinogenesis, one realizes that no one has ever really seen radiation cause mutation in a cell and that cell go on to become a cancer. One could logically hypothesize that the cell that gives rise to a cancer is another cell, one that was undamaged by radiation. By what possible mechanism could this occur? By a stem cell depletion mechanism.

(b) Stem Cell Depletion

When parenchymal cells die for any reason, such as old age, trauma, toxic compounds, infectious agents, metallic poisons, or ionizing radiation, the response is basically the same. Stem

June 9, 1994
Samuel Chilk, Secretary
Page -6-

cells are induced to divide and produce more parenchymal cells for replacement purposes. Research during the 1970's on the biology of aging by Leonard Hayflick (16) demonstrated that stem cells have a genetically limited division allowance. Once they reach this limit, they can no longer divide and no longer replace missing cells. An organ in which extensive cell death has occurred will therefore experience non-specific fibrosis when its stem cell division potential has been depleted.

Let us imagine a stem cell being maximally signalled to divide beyond its allowable ration. Any process that could inactivate an essential suppressor gene and permit normal or near-normal cell division in this situation may be the first step in neoplastic transformation. After that, a Darwinian evolution of cells with unlimited division potential occurs, going all the way from benign neoplasia to carcinoma in situ to frank malignancy with metastatic spread. The triggering event for cancer production may thereby be a process that is independent of the noxious agent that killed parenchymal cells. It may take many years before the effects of one (or more) noxious agents drive stem cells to the end of their division potential. This delay may be related to the "lag time" phenomenon.

(c) Effective Carcinogenic Threshold

Let us imagine a tissue with extensive parenchymal cell replacement potential such as the liver. Let us imagine that with normal aging, there is enough stem cell division potential to take care of replacement needs for 140 years. Let us imagine that moderately large alcohol intake has gotten that down to 100 years, that chronic active hepatitis has gotten it down to 60 years, and that exposure to various toxins has gotten it down to 50 years. This individual is at risk for liver cancer beginning at the age of 50. He may only acquire liver cirrhosis (fibrosis). But he may develop hepatocellular carcinoma as well.

Let us imagine an individual who acquires a relatively small absorbed dose of ionizing radiation. His stem cell replacement lifetime goes from 140 years to 130 years, because of "spending" extra divisions to replace parenchymal cells killed by the radiation. However, he is probably going to die by the age of 90 from something else, such as coronary artery disease. He would only be at risk for radiation-induced cancer if he lived to 130. Therefore, one may imagine an effective carcinogenic threshold for radiation damage.

The realization that the stem cell depletion concept of

carcinogenesis requires an effective threshold theory rather than a linear hypothesis theory appears to be an intellectual contribution of Joob ("Jacob") Thiessen, most recently of the Radiation Effects Research Foundation and before that, the Department of Energy.

(d) Advantages of the Stem Cell Depletion Theory

The attraction of the stem cell depletion theory for carcinogenesis is that we (1) have a more appealing concept of the "lag time", (2) can easily understand the carcinogenicity of high LET radiation, (3) can replace our low dose radiation hysteria, and all the evils it brings, with an effective threshold concept, bringing ionizing radiation into the same framework as other harmful agents, and (4), can even begin to understand a scientific basis for that terribly "dirty" scientific word, "hormesis". After all, so long as radiation has not been delivered in a dose exceeding an effective threshold, it is effectively harmless. However, because of the free radicals induced and oxidation that occurs in injured cells, there is maximum production of repair enzymes. These enzymes are not specific to radiation-induced damage, but cross-react to repair damage induced by a wide variety of other toxic agents, agents which might themselves have killed or injured the individual. This maximally protected individual now lives longer. Ergo, "hormesis". Nothing magic or farcical in this concept. Just basic biology.

(c) Paradigm Shifting

The NRC has scientists in its employ who understand the extreme difficulty of paradigm shifting in the area of radiation carcinogenesis. This is, after all, not only a scientific paradigm, but a political paradigm. It will not be an easy task, to make this change, but I believe it can be done.

In my opinion, it must be done. When I first began working for the NRC, I had hoped to help straighten out a terrible "medical" program and then convince the Agency to embark on meaningful activities. As I end my second term, I see a reactor industry that is effectively dead and a materials program reaching the heights of insanity and malignant destruction. The NRC is now a greater danger to public health and safety than the materials it purports to regulate. If there is not a "sea change" soon, NRC will either be destroyed by its own licensees or destroy itself by

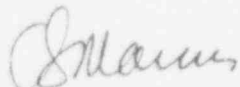
June 9, 1994
Samuel Chilk, Secretary
Page -8-

There is much real work to be done, and the largest "growth" area at NRC is scientific truth, not bureaucratic murder. One would hope that there are enough individuals left at NRC with the brains, courage, and power to steer NRC back "on course".

IV. CONCLUSION

In conclusion, I recommend that NRC turn down this petition with minimal User Fee wastage, and then turn to the real questions raised by Mr. Gannis. Hopefully, the concepts in this letter will help.

Sincerely,



Carol S. Marcus, Ph.D., M.D.
Director, Nuclear Med. Outpt. Clinic
and
Assoc. Prof. of Radiological Sciences
UCLA

cc: Interested parties

Encl: BRC: Facts and Information

CSM:sfd

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June 9, 1994
Samuel Chilk, Secretary
Page -10-

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application. An importer must submit a copy of the importer's report or a cancelled check. Evidence submitted with a refund application shall not be returned to the applicant.

(d) *Payment of refund.* Immediately after receiving the property executed application for refund, the Board shall make remittance to the applicant.

39. Section 1210.521 is revised to read as follows:

§ 1210.521 Reports of disposition of exempted watermelons.

The Board may require reports by handlers or importers on the handling/importing and disposition of exempted watermelons and/or on the handling of watermelons for persons engaged in growing less than 10 acres of watermelons or in the case of importers, the importing of less than 150,000 pounds per year. Authorized employees of the Board or the Secretary may inspect such books and records as are appropriate and necessary to verify the reports on such disposition.

§ 1210.530 [Amended]

40. Section 1210.530 is amended by removing the word "handler" from the introductory text and adding in its place "handler and importer".

§ 1210.531 [Amended]

41. Section 1210.531 is amended by removing the word "handler" and adding in its place "handler and importer".

42. Section 1210.532 is revised to read as follows:

§ 1210.532 Confidential books, records, and reports.

All information obtained from the books, records, and reports of handlers and importers and all information with respect to refunds of assessments made to importers shall be kept confidential in the manner and to the extent provided for in § 1210.352.

Dated: April 6, 1994.

Lon Hatamiya,
Administrator.

[FR Doc. 94-8857 Filed 4-13-94; 8:45 am]

BILLING CODE 3410-02-P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 20

[Docket No. PRM-20-23]

Steve Gannis; Receipt of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; receipt.

SUMMARY: The Nuclear Regulatory Commission (NRC) is publishing for public comment a notice of receipt of a petition for rulemaking, dated January 8, 1994, which was filed with the Commission by Steve Gannis. The petition was docketed by the NRC on February 8, 1994, and has been assigned Docket No. PRM-20-23. The petitioner requests that the NRC amend its regulations to limit the annual dose of ionizing radiation that is received by the general public from 100 millirems annually to under 1 millirem annually. The petitioner also requests that if the NRC does not establish a limit of 1 millirem annually, it establish a substantially lower limit than the current 100 millirems annually.

DATES: Submit comments by June 28, 1994. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Submit written comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m. Federal workdays.

For a copy of the petition, write the Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

The petition and copies of comments received may be inspected and copied for a fee at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Michael T. Lesar, Chief, Rules Review Section, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 301-492-7758 or Toll Free: 800-368-5642.

SUPPLEMENTARY INFORMATION:

Background

The NRC has established standards for protection against ionizing radiation resulting from activities conducted under licensees and has issued these standards in the regulations codified in 10 CFR part 20. These regulations are intended to control the receipt, possession, use, transfer, and disposal of licensed material by its licensees. Licensed material is any source,

byproduct, or special nuclear material received, possessed, used, transferred, or disposed of under a general or specific license issued by the NRC.

The Petition

The petitioner believes that it is vital to the public interest and public health that a low radiation dose limit be established because the higher dose limit is a possible source of an unacceptable number of additional cancers. The petitioner indicates that the NRC stated in its "Below Regulatory Concern" policy statement (issued July 3, 1990; 55 FR 27522, and withdrawn August 24, 1993; 58 FR 44610) that if the public is exposed to 100 millirems of radiation annually over a lifetime, 1 person out of every 285 people would get fatal cancer. The petitioner states that this number does not include the nonfatal cancers that would be caused. Furthermore, the petitioner states that the 100 millirems is in addition to the approximately 90 millirems of radiation the average person receives annually from natural background radiation sources.

The petitioner states that the Federal Government standards on how much cancer can be caused among the public by cancer-causing pollutants and contaminants generally permit, at most, approximately 1 cancer per million people. The petitioner therefore requests that a lower radiation dose limit be established.

Specifically, the petitioner requests that the NRC issue a regulation that would limit to under 1 millirem the annual dose of ionizing radiation received by any member of the public. The petitioner's requested limit would include the exposure received from the combined sources of radiation exposure resulting from activities regulated by the NRC. The petitioner also requests that in the event the NRC does not establish an exposure limit of under 1 millirem, the NRC establish a substantially lower limit than the current 100-millirem limit.

Dated at Rockville, Maryland, this 8th day of April, 1994.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Assistant Secretary of the Commission.

[FR Doc. 94-8915 Filed 4-13-94; 8:45 am]

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The Society
of Nuclear
Medicine

BRC: FACTS AND INFORMATION

as approved by the Society of Nuclear Medicine
Radiobiological Effects of Ionizing Radiation Committee

&

The Environmental Radiation Committee of the
American College of Nuclear Physicians

This document was published on March 29, 1993, as a result of a joint effort between the American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM). Participants on the editorial committee were as follows:

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BRC: FACTS AND INFORMATION

- o What does it stand for?
- o What does it mean?
- o Is it new?
- o Why were some people so upset?
- o Are there any risks at all?
- o Where does it come from?
- o What should we do about it?
- o Where do we go for more information?

WHAT DOES IT STAND FOR?

BRC stands for "Below Regulatory Concern". Keeping in mind that everything in nature is radioactive to some extent, BRC refers to levels of radioactivity so low that they present no measurable health or environmental hazards and need no special controls other than careful initial identification and review by radiation regulators. For example, waste containing trivial contamination from patient body fluids, as a result of a nuclear medicine procedure, is then disposed of in household or hospital trash, requiring no extra care. Likewise, patient excreta also enters the sewer system without the need for special segregation. Mildly radioactive consumer goods also fall under this category.

WHAT DOES IT MEAN?

It means that there are materials containing extremely small amounts of radioactivity that are not dangerous, and that society need not waste resources needed elsewhere by treating this material as though it were hazardous.

IS IT NEW?

Definitely not. For decades, the law has recognized very small quantities of radioactivity, associated with hundreds of different activities as "de minimus", a term which has been replaced by "BRC". "De minimus" is part of a legal phrase, "De minimus non curat lex.", which translates as, "the law does not concern itself with trifles". Congress asked the Nuclear Regulatory Commission (NRC) to outline a logical policy for determining whether new waste streams and activities should or should not be regulated; NRC did so in 1990. The resulting BRC policy document, in an attempt to extend historically proven safe standards of practice for future waste streams, caused a national uproar because it was not properly explained.

WHY WERE SOME PEOPLE SO UPSET?

First, the BRC document was oversimplistic and led numerous people to think that there would be many cancers and cancer deaths occurring at the levels of radiation considered BRC. This is because NRC took estimates of cancer deaths determined from moderate and high levels of radiation and extrapolated them down to negligibly small levels of radiation, even though there is no scientific evidence of increased mortality from low levels.

Second, one of the NRC Commissioners disagreed with the other four, and his dissenting opinion was published, along with a rebuttal by the Chairman of the Commission. To those who are unfamiliar with radiation biology, the existence of dissention suggested that the hypothetical dangers were real.

Third, fear of nuclear weapons and concern about nuclear pollution from defense and major accidents has carried over to fear of radioactivity in any quantity. Special targets of concern are nuclear power plants. One of the most important BRC activities that NRC is undertaking is to determine the level below which pipes and concrete from old nuclear power plants have little enough radioactivity that they present no hazard and are therefore BRC.

Fourth, there is the question of trust in NRC's judgment and enforcement activities, and the perception that the NRC is too lenient with the nuclear power industry. The NRC has in recent times become very conservative in its judgment and regulatory activities. In addition, the Environmental Protection Agency (EPA) now shares in this responsibility. NRC and EPA have established BRC activities in a manner that protects public health and safety.

ARE THERE ANY RISKS AT ALL?

No, the radiation levels are so low that they represent no measurable health or environmental risk. From the invention of the x-ray tube in 1895 and the discovery of naturally-occurring radioactivity in 1896 until the present, hundreds of millions of dollars have been spent to study effects of low level radiation. No statistically significant deleterious effects of low levels of radiation in normal populations of humans or animals have been shown in well-controlled studies. In fact, some studies suggest benefits from chronic, low level radiation exposure, possibly because by stimulating enzyme production this can protect the organism from damage by stronger radiation and toxic chemicals.

A well-known study compared cancer in nuclear shipyard workers with workers in the shipyards who were not exposed to radiation.¹ Overall, the nuclear workers had slightly lower rates of cancer than the non-nuclear controls. There was, however, one cancer that was higher in the nuclear shipyard workers than the non-nuclear workers, and that was mesothelioma. This is a rare type of lung cancer that is not associated with radiation, but rather with asbestos exposure which occurred at the shipyards.

Another example involved a study of cancer in radiologists as compared with other physicians.² Prior to the sensible radiation protection practices of today, early 20th century radiologists received moderate to large doses of radiation. In those days, radiologists had a higher cancer rate than their non-radiologist physician colleagues. However, for radiologists practicing after 1940, by which time practices were much safer, the only cancer that consistently shows a statistically significant increased mortality for radiologists vs. other physicians is oral cancer.³ This is more likely to be due to smoking habits than to occupational radiation exposure.

¹ Matanoski GM: Health Effects of Low-Level Radiation in Shipyard Workers. DOE Contract no. DE-ACO2-79EV10095, 1991.

² Matanoski GM, Sartwell P, Elliott E, Tonascia J, Sternberg A: Cancer Risks in Radiologists and Radiation Workers. In Boice JD, Jr., Fraumeni JR, Jr. (eds), Radiation Carcinogenesis: Epidemiology and Biological Significance. New York: Raven Press; p. 83-96, 1984.

³ Siegel BA (ed): Radiation Bioeffects and Management Test and Syllabus. Amer College of Radiology, Reston, VA; 1991.

An excellent study comparing hyperthyroid patients treated with radioactive iodine with those treated surgically, found there was no increased incidence of leukemia in the group treated with radioiodine over those treated surgically.⁴

The radiation doses to the workers and patients in the studies described above were at the level of several hundred to several thousand radiation units (millirem). Radiation doses from BRC are much, much lower than this. In the NRC policy statement, no single activity, such as the decommissioning of a nuclear power plant can impose more than 10 mrem/year to the most exposed member of the general public. This means that nearly the entire American population will receive far less radiation, certainly under 1 mrem/yr. Let us keep BRC in perspective. The levels of radiation found in this waste can be compared to the difference between living in a brick vs. a wood frame house, living in Denver, Co. for 6 weeks, or taking two round trip flights to California from Washington, D.C.

Background radiation at sea level in average radon areas is about 300 mrem/y (ed)⁵. The highest levels in the United States are in Colorado, because of high altitude, double the average radon levels, and variable radioactive soil content. Background in Colorado ranges from 350 - 890 mrem/year, with Denver about 530 mrem and ski areas about 600

⁴ Tompkins E: Late Effects of Radioiodine Therapy. AEC Symposium Series 20, Medical Radionuclides: Radiation Dose and Effects, CONF - 691212, Springfield, VA. 1970.

⁵ The (ed) is a weighted sum of radiation dose received by different organs.

mrem.⁶ (Colorado is tied for the third lowest cancer death rate in the nation). Most Americans therefore get at least 1-2 mrem per day from background, which is why a BRC rate of generally under 1 mrem per year is insignificant. A round-trip coast-to-coast airplane ride results in 5 mrem; many Americans get 50-100 mrem/y from air travel.⁷

In the accompanying tables, a number of ordinary and medical sources of radiation are listed for comparison and a relative risk table is included as well.

WHERE DOES IT COME FROM?

Everywhere. To begin with, we really have to talk about two kinds of BRC. "Below Regulatory Concern" implies that a regulatory agency has the power to do something about it, and chooses not to. "Beyond Regulatory Control" means that it exists outside the influence of human control. We judge that which is "Below Regulatory Concern" in part by comparing it to that which is "Beyond Regulatory Control" and see how significant it is.

⁶ NCRP report #93, 1987; BEIR IV, 1988; Colorado Radiation Control Division.

⁷ Kathren R., Masse F., Mossman K., Roessler G., and Schaiger K: Scientific and Public Issues Committee Position Statement, Health Physics Society's NewsLetter, Vol 20 (11), November 1992, p. 8-9.

We cannot control the production of carbon-14 and hydrogen-3 (tritium) in the atmosphere by the interaction of cosmic radiation with atmospheric gases. We cannot control the amount of potassium-40 or long-lived alpha emitters and their daughters (uranium, polonium, radium, thorium, radon, etc.) in the earth or in the seas. We have started to control atmospheric testing of nuclear weapons, but we cannot control other nations nor what has already entered our biosphere. The quantity of radioactive material spewed up by volcanoes is huge, and obviously beyond our control. We cannot control plants as they take up carbon dioxide and produce compounds containing carbon-14, or concentrate potassium-40 and cesium-137 through root and leafy uptake. People eat plants, or animals that have eaten plants, and drink water, and therefore take in radioactive material from these sources. We can encourage people to stop smoking, but we cannot control the quantity of inhaled polonium-210 that was concentrated by the tobacco leaf. We can encourage everyone to take remedial action if the radon content of his home is too high, but we cannot control the radon content of the soil below.

The wooden furniture in our homes and offices is radioactive, and so are our cotton, woolen, linen, and silk clothes, sheets, and blankets. They all come from plant or animal origin. All our common sources of heat and electrical power contain radioactive material; oil, coal, and natural gas come ultimately from vegetable origin complete with alpha emitters and radon. On a per kilowatt-hour basis, the radiation absorbed dose from low grade coal exceeds that of nuclear power plants to persons in the nearby areas. The pipes from oil fields have so much radium in their scale that they need to be buried

as low level radioactive waste (LLRW) or recycled. A "nice wood fire" is the worst of all, because the wood is millions of years younger than coal and contains radioactive material not yet decayed plus fallout products from our times that are not in oil or coal, either.⁸ If woodash were produced by a nuclear power plant, it would not be "BRC" but would have to go to a low level radioactive waste site because it exceeds 10 CFR 20 limits.

Yesterday's hamburger and tomorrow's chicken are of muscle origin and contain potassium-40. When airplanes equipped with radiation detectors fly over cities, the "hottest" areas are the cemeteries, because human muscle contains it also. When you share a bed with another person you irradiate each other. Bananas, touted as healthy because they are high in potassium, are high in potassium-40 as well.

One must realize living things have evolved in a sea of low level radiation, and most damage is repaired or the molecule is renewed or the cell is replaced. There are many substances that are hazardous at high doses but harmless at low doses. For example, oxygen is essential for life yet at high doses, it can cause blindness in the ^{premature} newborn.

⁸ Farber S: Preliminary Study of Cs-137 by trees and its implications for BRC, Waste Disposal, and Dosimetry. The Health Physics Society's Newsletter, Vol. 18(4): April, 1990: p. 1-5.

The NRC has exempted a number of familiar uses of radioactive material because the activity is beneficial and the radiation dose is ultra low level. Smoke detectors contain americium-241. The mantles of Coleman lanterns contain radioactive thorium. The radium dials of the earlier half of this century are no longer made, but we now use hydrogen-3 (tritium) for glow-in-the-dark watches, airplane and ship dials, hotel exit markers, and freeway signs.

Research activities in medicine, biology, chemistry, geology, anthropology, archeology, ecology, physics, engineering, art, consumer products, etc., use "tracer" quantities of various radioisotopes which yield either LLRW or BRC, depending on the type and amount that remain in the trash. NRC has published BRC limits for 764 radioisotopes in different chemical and physical states (10 CFR Part 20).

Certain medically-related uses are exempted as BRC as well. Patient excreta and effluent from renal dialysis machines contaminated with radioactive drugs that were given to the patient may go directly into sewage. We perform about 10 million of these nuclear medicine procedures on patients each year in this country. Laboratory tests on body fluids called "radioimmunoassay" generate very low levels of radioactive material and often go into the sewer as BRC; we perform about 100 million of these tests per year in the United States. Ordinary hospital trash contaminated with body fluids from patients who have had diagnostic nuclear medicine procedures is not associated with any radiation hazard and is rarely measurable above background levels. This trash may

contain paper cups, plates, and plastic utensils contaminated with radioactive saliva, diapers from babies who received radiopharmaceuticals, and mildly radioactive dressings, bandaids, kleenex, toothbrushes, disposable gowns with mildly radioactive sweat, catheter tubes and bags with trace urine contamination, etc. The patient generates some of these wastes at home as well, and it goes into household trash and to a landfill. These radioisotopes have short half-lives and decay away completely in a few days to a few weeks. Waste from the Nuclear Medicine Department is usually stored until total decay and then discarded as BRC. However, implantable radiation sources from the Radiation Oncology Department are not BRC, but are buried as LLRW. Cesium-137 blood irradiators and cobalt-60 radiotherapy units are highly radioactive and are buried specially in radioactive waste sites.

Nuclear power plants have limits for airborne emissions, effluent concentrations, and trash bound for landfills. They have more restrictive limits than for research institutions and medical and commercial facilities. The EPA has recently reviewed NRC's control of all licensees for airborne emissions and found it to be adequate.

Given the fact that everything is radioactive to some extent, all trash is a continuum, and there must logically be some point at which one decides the material is radioactive enough to require special handling. This is where BRC ends and LLRW begins.

If everything that contained radioactivity at any level had to be called LLRW, all our landfills would have to be turned into LLRW sites. For example, if one were to try and isolate all radioactivity generated by patients who have had diagnostic nuclear medicine procedures, all hospital trash would have to be sequestered because neither these patients nor their trash are restricted within the hospital. If we buried all hospital trash as LLRW, we would use up all our available LLRW site room within 1-2 months.

Radiopharmaceutical manufacturers and nuclear pharmacies would increase fees for their products and services because BRC waste would now become LLRW. Because LLRW is very expensive to bury, about \$300 per cubic foot beginning January, 1993, each hospital inpatient would have about \$2000 added to his bill.⁹ In addition, a huge quantity of research would have to stop, many commercial entities would be crippled, and electrical bills would increase substantially. The key here, however, is not cost, as there would be absolutely no benefit to such strict controls.

The EPA has performed a cost-effectiveness analysis of a BRC policy. Based on the most recent scientific data, by allowing American exposure to increase from 300 to 300.1 mrem/year, waste volumes would be reduced by 25% and save 380 million dollars over a 20 year period. An additional exposure of 15 mrem/year would reduce volumes by 43% and save 690 million dollars over 20 years. An exposure of 1 mrem/yr would reduce volume by 30% and save 470 million dollars while the cost would be 0.003 adverse health

⁹ Marcus, Carol S., Harbor - UCLA Medical Center, Nuclear Medicine Clinic, Torrance, CA.

effects per year. (This estimate uses a highly conservative extrapolation of health effects from moderate and high doses to ultralow doses). The International Atomic Energy Agency, International Labour Organization, World Health Organization, and Nuclear Energy Agency of the Organizations for Economic Cooperation and Development have all considered BRC; they call it "Exempt from Regulatory Control".¹⁰ There is no question about it. There has to be a "BRC" standard.

WHAT SHOULD WE DO ABOUT IT?

Nothing. We have lived with it all our lives, and will continue to do so. The exposure levels NRC has set on BRC are extremely conservative and constitute no hazard. A highly vocal minority has generated wild claims which have no basis whatever in scientific fact. If you have doubts, get the facts, and get them from professionals.

WHERE DO WE GO FOR MORE INFORMATION?

The American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM) maintain a Government Relations Office in Washington. The phone number is (202) 429-5120. Ask for Kristen Morris or David Nichols, or call the ACNP Public Information Program at 1-800-447-2267. They will put you in touch with a nuclear physician, nuclear pharmacist, or health physicist who can answer your questions.

¹⁰ Cohen, Bernard L., "Catalog of Risks" Health Physics Society Newsletter, Vol 61, No.3 p. 720.

COMPARISON OF RADIATION SOURCES

<u>SOURCE OF RADIATION</u>	<u>RADIATION DOSE (ED-mrem)</u>
Background radiation, sea level	300/year
Background radiation, Colorado ski areas	600/year
Color TV, 2 inches from screen, 1 hr/day	up to 180/year
Coast-to-coast round trip flight	5/trip
One week Colorado ski trip	11/week
Sleeping in bed with another person	0.1/year
Chest x-ray (mainly to chest)	10-25/film
Diagnostic nuclear medicine procedure	440/procedure
Abdominal x-ray procedure (i.e. upper G.I., mainly to abdomen)	2000-4000/procedure
Radiation oncology treatments	5,000,000/tumor area
Radium dial watch	20/day
NRC policy; 1 BRC practice involving a large population	1/year
NRC policy; All BRC practice involving a large population	10/year

COMPARISON OF RELATIVE RISKS

DECREASE IN LIFE EXPECTANCY FROM VARIOUS ASSOCIATIONS

<u>CAUSE</u>	<u>DAYS</u>
Unmarried-male	3500
Cigarette smoking-male (20 cigarettes/day)	2250
Heart disease	2100
Unmarried-female	1600
Overweight 30%	1300
Coal miner	1100
Overweight 20%	900
Less than an eighth grade education	850
Cigarette smoking-female (20 cigarettes/day)	800
Low socioeconomic status	700
Stroke	520
Pipe smoking	220
Increasing food intake 100 cal/day	210
JOB WITH RADIATION EXPOSURE (1 rem/yr for 40 yr)	40
Natural radiation (BEIR)	8
Medical x-ray films	6

COMPARISON OF RELATIVE RISKS (CONT'D.)

DECREASE IN LIFE EXPECTANCY FROM VARIOUS ASSOCIATIONS

<u>CAUSE</u>	<u>DAYS</u>
Coffee	6
Oral contraceptives	5
5 rem over a long period of time	5
Diet drinks	2
Reactor accidents-UCS*	2
Reactor accidents-Rasmussen report	0.02†
Radiation from nuclear industry	0.02†
Papanicolaou test (pap smear)	-4
Smoke alarm in home	-10
Air bags in car	-50
Mobile coronary care units	-125

*UCS, Union of Concerned Scientists, the most prominent group of nuclear critics.

†These Items assume that all U.S. power is nuclear.

This table of information is generated from Bernard L. Cohen's "A Catalog of Risks, Extended and Updated", published in Health Physics Vol.61, No. 3, pp. 317-335, 1991.