BAKER HUGHES INTEQ

DOCKET NUMBER PETITION RULE PRM 20-23

(59FR17746)

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USNRC

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DOCKETING & SERVICE
BRANCH

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555

6 June 1994

(5)

Attn: Docketing and Service Branch
RE: Steve Gannis (PRM-20-23)

Gentleman:

Baker Hughes INTEQ, Inc. opposes the reduction of the 100 millirem annual dose limit as proposed by Steve Gannis. We believe that the current level of 100 millirem, as recommended by the National Council on Radiation Protection and Measurements (NCRP), is sufficiently conservative for the protection of the general public.

We agree with the Health Physics Society's Position (September 1992) on Radiation Dose Limits for the General Public. A copy of their position statement is enclosed for reference.

Baker Hughes INTEQ requests that the NRC follow the recommendations of the NCRP and keep the annual dose limit for members of the general public at 100 millirem.

Very truly yours,

Joseph H. Dudek, Jr.

Joseph H. Dudek Jr.
Manager Radiation Protection
Baker Hughes INTEQ

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POSITION STATEMENT

HEALTH PHYSICS SOCIETY

Contact: Keith J. Schiager, President
Health Physics Society
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RADIATION DOSE LIMITS

FOR THE GENERAL PUBLIC

September 1992

The Health Physics Society is deeply concerned over the trend of individual agencies to set radiation dose limits that are very different from those adopted by national authorities without due consideration of the effectiveness or of the full impact on public health. If certain "zero dose" or "no added radioactivity" concepts are adopted, medical care and health research, as well as some economic benefits, may be seriously compromised by diverting resources that could provide much greater health and environmental benefits if used for other purposes. Such proposals are contrary to the recommendations of scientific advisory organizations and to the basic ethics of public health practice.

The National Council on Radiation Protection and Measurements (NCRP) recommends a dose limit of 100 millirem (mrem) per year from manmade sources for individual members of the public. The U. S. Nuclear Regulatory Commission (NRC) has adopted this recommendation as its basic dose limit applicable to any licensed facility. The NCRP also recommends that any facility that might contribute an annual dose of 25 mrem to any individual take special precautions to assure that the dose to that individual from all manmade sources does not exceed 100 mrem. The U. S. Environmental Protection Agency (EPA) imposes a limit of 25 mrem per year to any member of the public from nuclear fuel cycle facilities.

An annual dose of 25 mrem is approximately 10 percent of the average dose from natural background radiation, and is less than half of the increase that one encounters when moving from a southeastern state to the Rocky Mountain region. An incremental annual dose of 25 mrem is just large enough to be measured, thereby allowing legitimate verification of compliance. However, an annual dose of 100 mrem is much too small to produce any detectable biological effects in any exposed individual.

The Health Physics Society endorses the dose limits recommended by the NCRP and adopted by the NRC and EPA noting that (1) they are sufficiently conservative for public health protection, (2) compliance can be verified by actual measurement, (3) they can be achieved in most cases without sacrificing significant public benefits, and (4) they can be applied without discrimination to essentially all manmade sources.

The Minnesota Department of Health proposal for a dose limit of 0.054 mrem per year to individual members of the general public is of particular concern. This incremental dose rate is not only impossible to measure, but it is equal to the calculated increase in dose rate incurred by an increase of 14 feet in altitude due to natural cosmic radiation exposure. This is equivalent to saying that the maximum acceptable risk from a specific radiation source is the same as the added radiation risk that would accrue from living on the third floor instead of the first floor of a building.

We recognize the unwarranted fears of radiation expressed by many people and the good intentions of governmental agencies to accommodate such public concerns. However, we believe it is in the best interests of the public to follow nationally recommended limits based on scientific recommendations developed through an impartial consensus process.

FOOTNOTE

The Health Physics Society, formed in 1956, is a scientific organization concerned with the protection of people and the environment from radiation. Today its membership numbers more than 6,400 and includes professionals representative of all scientific and technical areas related to radiation protection drawn from academia, government, medical institutions, research laboratories and industry from the 50 states, the District of Columbia, and Puerto Rico. The Society has more than 350 members in nearly 50 foreign countries. The Society is chartered in the United States as a non-profit scientific organization, and as such it is not affiliated with any governmental or industrial organization.

POSITION STATEMENT

HEALTH PHYSICS SOCIETY

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HEALTH PHYSICS SOCIETY

Position Statement

on

RADIATION DOSE LIMITS FOR THE GENERAL PUBLIC PART II

Executive Summary

The Health Physics Society* recommends that regulations for radiation protection be based on the scientific consensus contained in the recommendations of the ICRP and NCRP. In particular, **we recommend that constraints[1] be applied to all regulated, nonmedical, nonoccupational sources of radiation exposure to the general public,** excluding indoor radon (hereinafter referred to as "constrained sources"), **such that no individual member of the public will receive in any one year a committed effective dose equivalent (CEDE)[2]** exceeding 100 mrem (1 mSv)[3] from all such sources combined.

We strongly recommend that dose limits be applied <u>only</u> to individual members of the public, <u>not</u> to the collective dose to population groups. However, evaluation of constrained sources should be based on the mean annual dose to the critical population group, defined as the most highly exposed homogeneous group affected by a specific constrained radiation source. If the mean annual dose to the critical group is likely to exceed 25 mrem CEDE, an evaluation should be made to ensure that no individual is likely to receive an annual dose exceeding 100 mrem from all constrained sources combined. As a practical measure, to preclude wasting public funds on nonproductive efforts, we recommend that if the mean annual dose to the critical group is less than 5 mrem CEDE, no further efforts toward dose evaluation or reduction should be required or expected.

We recommend that all radiation doses, including those below the annual dose limit, be kept **as low as reasonably achievable (ALARA), economic and social factors being taken into account.** Implementation of the ALARA principle implies some means for quantification of benefits, typically by placing a monetary value on dose avoided to balance against the cost of avoiding the dose. We emphasize, however, that **application of the ALARA principle, or optimization, is not a mechanism for assigning a value to human life, but is a process for optimizing the use of limited resources for improving life expectancy and health benefits, when all risks are considered.** We strongly advocate the ALARA principle when it is used as a professional tool for optimizing radiation protection efforts. **We equally strongly oppose any incorporation of the ALARA principle, directly or by implication, into a regulation or regulatory guidance that would imply that it is a legal requirement.**

For quantitative optimization of radiation protection efforts, the collective effective dose equivalent is an appropriate measure of societal dose and, therefore, of societal risk **if, and only if,** the collective dose can be determined with reasonable certainty. For situations involving undefined populations, collective dose should not be used as an indicator of societal risk, and risk should not be expressed in terms of numbers of cases or deaths. For such cases, the average individual dose is an adequate measure of risk, even preferable to collective dose, since the societal relative risk is exactly equal to the average individual relative risk.

For avoiding small radiation doses (i.e. less than 1 rem per year) distributed randomly throughout society, the appropriate expenditure is a few tens of dollars per person-rem avoided. For doses near the individual dose limits recommended by the ICRP and the NCRP in clearly identified populations, the appropriate expenditure may be as much as a few hundred dollars per person-rem avoided. Where larger sums are spent to avoid radiation doses to any population group, such expenditures should not be attributed to health protection and should be clearly identified and justified separately.

Scientific Consensus on Regulatory Dose Limits

The regulation of any substance for which there is no known absolutely "safe" level of exposure, i.e. no threshold dose below which there is no biological risk, presents a dilemma for the agency or official charged with protecting the public. Radiation protection professionals have faced this problem for several decades and have reached a consensus on an appropriate strategy for dealing with it. The documents describing this consensus are the publications of the International Commission on Radiological Protection (ICRP) and the reports of the National Council on Radiation Protection and Measurements (NCRP). Some of the following material is taken from very recent draft reports prepared by two NCRP Scientific Committees. Although these reports have not been adopted by the NCRP, the Health Physics Society (HPS) endorses the concepts contained in these draft reports and urges that they be used as the basis for radiation protection regulations.

Actual or Planned Doses from Constrained Sources

Both the ICRP (1991) and the NCRP (1987) have recommended an annual limit of 100 mrem CEDE to any members of the public from all nonmedical, man-made sources combined. **The Health Physics Society recommends that constraints be applied to all regulated, nonmedical, non-occupational sources of radiation exposure to the general public, excluding indoor radon (hereinafter referred to as "constrained sources"), such that no individual member of the public will receive a CEDE in any one year exceeding 100 mrem from all such sources combined.** The 100 mrem annual limit is intended to be applied to the average dose over several years; it should not be applied as a strict limit for a single year if there is a justified need for a small group to receive a somewhat higher dose temporarily (ICRP, 1991, page 5).

Intervention Level for Elevated Doses from Natural Radiation Sources

The annual limit of 100 mrem CEDE to an individual applies to actual or planned doses to real people, but not to intervention in situations where real people are already receiving elevated doses from natural sources of radiation. For such situations, the ICRP recommends that ALARA should be the controlling philosophy, with no absolute dose limit (ICRP, 1991, pages 49-50). The NCRP recommends that intervention be initiated whenever the annual dose exceeds 500 mrem (NCRP, 1987, page 40).

Potential Doses

The annual dose limit of 100 mrem should not be applied to potential dose, i.e. hypothetical individuals who might someday, someway be exposed to the source under evaluation. This restriction is addressed by the ICRP (Publ. 60, 1991). "Dose limits do not apply directly to potential exposures." (page 31) "If the doses, should they occur, will not be in excess of dose limits, it is adequate to use the product of the expected dose and its probability of occurrence as if this were a dose that is certain to occur." (page 48)

The ALARA Principle

Radiation protection efforts are usually directed to the control of doses for which the assumed effects in humans are stochastic and assumed not to require a threshold dose. The mechanisms of biological damage observed at high doses have led to the assumption that any radiation dose, no matter how small, may be capable of causing some detriment. On the other hand, there is also some evidence for the possibility of biological benefit at low doses, i.e. the radiation hormesis effect (Luckey, 1991).

For effective doses of less than approximately 1 rem per year, i.e. within the normal range of doses from natural background radiation, the effects in human populations, whether beneficial or detrimental, are too small to be detected or quantified. Since neither a detrimental nor beneficial effect from low effective doses may ever be "proven", it is considered prudent to assume that the effect may be detrimental. Based on the conservative assumption that there is no radiation dose that is absolutely safe, the NCRP has adopted and promoted the philosophy that all radiation doses shall be **kept as low as reasonably achievable (ALARA), economic and social factors being taken into account (NCRP, Report No. 91, 1987).** Based on this philosophy, which the HPS strongly endorses, we also recognize that it would be inappropriate to devote the same magnitude of effort or resources to reducing undetectable risks as are appropriate for risks that produce observable health effects.

Collective Dose as a Surrogate for Societal Risk

For assessment of risk to known populations exposed to known radiation doses, the CEDE is the appropriate measure of radiation dose. It is the sum of the individual effective dose equivalents to all members of the affected population, and will be referred to hereafter simply as collective dose. **A collective dose is valid only for a population that can be accurately identified and characterized.** Since the uncertainties in demography may far exceed those in dosimetry, both categories of uncertainty must be identified and carried forward in the calculations to express the overall uncertainty. **Collective dose should not be used as an estimate of societal risk when the uncertainty is substantially greater than the calculated most likely risk.**

For potential exposures to limited populations living now or in the next one or two generations, e.g. those living near a nuclear power plant or medical facility, the collective dose might be calculated accurately enough to be a reasonable representation of societal risk. Although individual doses will not be known, average population and pathway characteristics may be used provided that uncertainties are calculated and specified along with the calculated average and collective doses. The uncertainties in calculated collective doses may be primarily due to environmental and demographic variables, rather than to dosimetric factors.

For potential exposures to populations so far removed in time and space that there can be no meaningful prediction of population sizes or characteristics, it is not possible to establish ALARA criteria on the basis of collective dose avoided. **For situations involving undefined populations, collective dose should not be used as an indicator of societal risk, and risk should not be expressed in terms of numbers of cases or deaths. Instead, ranges and averages of potential individual doses and risks should be provided and compared with those from natural background radiation as a basis for decision making.**

Almost all radiation risk coefficients originate as relative risks, i.e. the ratio of observed to expected cases in a population. For most of the biological effects of radiation exposure, the relative risk model provides a somewhat better fit to the data than does the absolute risk model. For situations involving undefined populations, **the average individual dose is an adequate measure of risk, even preferable to collective dose, since the societal relative risk is exactly equal to the average individual relative risk.**

Quantification of ALARA

Because ALARA is a necessary concept in radiation protection as long as any non-threshold dose-response model is used, it is essential to address the question "What is reasonably achievable?" or, stated another way, "How safe is safe enough?" Although each individual may have a different subjective answer to that question, there are also rational bases for providing an objective, societal answer. For purposes of establishing public dose limits, **the "economic and social factors" that are to be taken into consideration in achieving radiation doses that are ALARA are essentially the same as those that relate to providing any other type of health protection.** The appropriate considerations are the reasons for allowing or choosing the practice that introduces the risk, the number of people potentially affected, the distributions and probabilities of health impacts, the severity of the consequences if they occur, the availability and cost of prevention or treatment methods, and the sources and availability of the funds to provide the protection. If all such factors could be considered, quantitative optimization of radiation protection would be possible. However, such complete quantification is rarely, if ever, possible; instead it is necessary in most situations to apply professional judgement within a framework of broad guidelines.

Monetary Value of Avoided Dose

Implementation of the ALARA principle implies some means for quantification of benefits, typically by placing a monetary value on dose avoided to balance against the cost of avoiding the dose. This need to quantify what is optimum, or as low as reasonably achievable, has probably been the greatest hindrance to the meaningful application of ALARA, notably by those who don't want to "place a dollar value on human life." The HPS emphasizes, however, that **application of the ALARA principle, or optimization, is not a mechanism for assigning a value to human life, but is a process for optimizing the use of limited resources for improving life expectancy and health benefits, when all risks are considered.**

The objective health detriment of a radiation dose that is less than any threshold for deterministic effects may be taken to be the expected amount of life impaired or lost, plus costs of medical care, as a result of that dose. For somatic effects, the loss of life expectancy from fatal cancer constitutes the major portion of the detriment. To this must be added the amount of life impaired by illness from non-fatal cancers, and preceding fatal cancers. It is the sum over all detrimental effects of the product of the probability of occurrence of the effect (risk coefficient) and the most probable amount of life lost or impaired in the event of occurrence. The detriment due to genetic effects is generally smaller than that due to somatic effects, but should be evaluated in the same way, i.e. amount of life lost or impaired.

The benefit of dose avoided is numerically equal and opposite to the detriment of the same dose received. As an example, if the effect avoided is the induction of a fatal cancer, with an average loss of life of 15 years (5,000 days), and a probability of occurrence of 5×10^{-4} per rem, the added life expectancy per rem avoided is 2.5 days. The total objective health detriment, including illness and genetic effects, is calculated by the

ICRP (1991) to be approximately 1.5 times this value, or equivalent to approximately 4 days of life lost or impaired.

Quantitative optimization is based on stochastic benefits (increased life expectancy), which should be balanced against stochastic costs, i.e. average loss of wealth within the analyzed population. In its simplest form, which is quite appropriate for statistical reduction of small risks, the current value of human productivity is taken to be the per capita gross domestic product (GDP), approximately $50 per day in the U.S. (Johnson, 1990). A reasonable monetary value of the collective dose avoided may be derived from the amount society voluntarily spends for prevention of disease, health maintenance and added life expectancy. Based on current expenditures for all forms of health benefits, including preventive health programs, the amount the public is willing and able to spend is 10% to 20% of current productivity (Johnson, 1990), or $5-$10 per statistical day of life. Therefore, **the societally defined, statistical value of dose avoided is approximately $10 per person-day x 4 day per rem = $40 per person-rem avoided.** If the U.S. was willing and able to spend its entire productivity on health protection and increased longevity, the maximum available would be ($50 per person-day) x (4 day/rem) = $200 per person-rem. The range of values suggested by the ICRP (1983) is $100-$200 per rem, indicating that for some population groups and for some health risks that are of special concern to the public, e.g. radiation, the societally accepted value is near the statistical maximum.

As noted above, completely quantitative optimization is generally not possible. Where many sources and large populations are involved, neither detriments nor benefits can be precisely determined. Consequently, there is no urgent need to invoke detailed formulas for discounting present costs or future benefits. **Comparisons with expenditures "per life saved" by other governmentally mandated programs are irrelevant for two reasons: (1) all "lives saved" are not equal in terms of added life expectancy, and (2) programs that are mandated on the basis of an arbitrary individual risk level, without regard to cost, should not be used for comparison when optimization is the goal.**

The HPS recommends that for avoiding small individual radiation doses (i.e. less than 1 rem per year) distributed randomly throughout society, the appropriate expenditure is a few tens of dollars per person-rem avoided. For doses near the individual dose limits recommended by the ICRP and NCRP in clearly identified populations, the appropriate expenditure may be as much as a few hundred dollars per person-rem avoided. Where larger sums are spent to avoid radiation doses, such expenditures should not be attributed to health protection and should be clearly identified and justified separately.

ALARA as a Regulatory Requirement

The HPS strongly advocates the ALARA principle when it is used as a professional tool for optimizing radiation protection efforts. The HPS equally strongly opposes any incorporation of the ALARA principle, directly or by implication, into a regulation or regulatory guidance that would imply that it is a legal requirement.

Critical Group and Compliance Screening Level

Although we strongly recommend that dose limits be applied only to individual members of the public, and not to the collective dose to population groups, evaluation should be based on the mean annual dose to the critical population group, defined as the most highly exposed homogeneous group affected by a specific constrained radiation source. If the mean annual dose to the critical group from that source is likely to exceed 25 mrem CEDE, an evaluation should be made to ensure that no individual is likely to receive an annual dose exceeding 100 mrem CEDE from all constrained sources (NCRP, 1984; NCRP, 1987).

The ALARA principle implies that not only the management of risk, but also the assessment of risk, should be optimized. The effort expended in assessing a risk should not be disproportionate to the risk itself. Screening techniques, as recommended by the NCRP (1989), should be adopted for demonstrating compliance with dose limits for exposures to the public resulting from releases of radionuclides to the environment. The extremely conservative nature of the assumptions that are incorporated into screening levels I and II provide assurance that sources that pass the screening calculations will not produce doses to any members of the public in excess of the screening assessment level.

Negligible Individual Dose or Risk Level; *de Minimis*

The concept of an individual dose that is negligible because it entails a negligible individual risk is appropriate for some applications, but should be used with caution. For example, it should not be used as a lower limit for integration in calculating a collective dose because the exclusion of any individual doses, regardless of how small, is contrary to the very nature of the non-threshold dose-response model. It is also important to avoid the implication that any dose in excess of a defined negligible individual dose level (NIDL) is not negligible.

De minimis is a shortened form of the latin phrase, *de minimis non curat lex,* meaning that the law is not concerned with trifles. It must be recognized that some practices produce radiation doses and concomitant risks that are so small that specific regulatory oversight is not needed and would be wasteful of societal resources. However, a legitimate threshold for optimization should not be confused with a negligible individual dose nor with a lower integration limit for calculating collective dose. Although potential individual and collective doses would be important in the evaluation of such a practice, **the regulatory position should not be expressed as a dose threshold, but as a procedural exemption for a practice.**

Assessment Threshold Screening Level

An obvious threshold for optimization occurs when the total collective dose is so small that even complete elimination would not justify the cost of evaluation. A threshold screening level should be established to prevent wasting of public resources on detailed assessment of risks that are unlikely to be reduced in a cost effective manner, but without implying that they are considered negligible or trivial by all members of society.

The selection of a threshold screening level is more a matter of practicality than of explicit risk assessment. While it may be tempting to be very cautious and recommend a value as low as 1 mrem per year, we believe it should be a value that is comparable to the variability of local background radiation. For each constrained source, **we recommend a threshold screening level of 5 mrem annual mean CEDE to the critical group from that source.** If the mean annual dose to the critical group from that source is unlikely to exceed 5 mrem, no additional assessment or management should be required. The threshold screening level would apply to doses delivered by any route, not only those from environmental releases that may be evaluated by use of the NCRP screening techniques (NCRP, 1989). We consider 5 mrem per year to be an appropriate screening level because it is highly unlikely that efforts to reduce doses below that level will do more good than harm.

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Footnotes

1 "Constraints" refer to restrictions placed on sources or practices in order to achieve the dose limits that apply to individuals (ICRP 1991).

2 The committed effective dose equivalent (CEDE) is the sum of the absorbed doses that will be delivered to the separate organs or tissues during the lifetime of an individual from one year's intake of radionuclides plus irradiation by external sources, with each organ or tissue dose weighted for the type of radiation producing the dose and the relative tissue susceptibility, using the weighting factors recommended by the ICRP.

3 The sievert (Sv) is the international (SI) unit of effective dose equivalent; 100 mrem = 1 millisievert (mSv). The HPS endorses the use of SI units; however, because U.S. regulatory agencies continue to use common units in regulations, this position statement uses the common unit for effective dose equivalent, i.e. mrem, throughout the remainder of the document.

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