UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

OFFICE OF THE
COMMISSIONER

October 13, 1989

Dr. Allen Brodsky
16312 Kipling Road
Derwood, MD 20855

Dear Dr. Brodsky:

Thank you very much for your letter and your paper on Below Regulatory Concern. I have read your paper, and also shared it with my staff. You have clearly given considerable thought to this important matter, and I appreciate your sharing your views with me.

As you know, the Commission is in the process of completing consideration on this matter. Since our action is not yet complete, I cannot discuss it in detail. However, I can say that, in the course of considering this issue, both the staff and the Commission have reviewed a wide range of proposals, including some along the lines you have described. Thus, I believe that in effect your arguments have been considered. Nevertheless, I am happy to forward your paper to the other Commissioner's offices and to appropriate members of the NRC staff to ensure the fullest possible distribution of your recent thinking on this subject.

I enjoyed meeting you at the ACNP/SNM seminar, and in having the opportunity to talk to you and your colleagues about some of our common concerns. I also appreciated the opportunity to read such a clear and self-explanatory analysis. I wish you great success in your future work in this important area.

Sincerely,

Kenneth C. Rogers

Kenneth C. Rogers
Commissioner

D-R-A-F-T

ESSENTIAL CONSIDERATIONS IN EXEMPTING CONSUMER PRODUCTS (AND OTHER ITEMS) CONTAINING RADIOACTIVITY.*

A. Brodsky
Allen B Consultants, Inc.
16412 Kipling Road
Rockville, MD 20855-1927

ABSTRACT

International and national organizations have been attempting for many years to develop principles for exempting from control small amounts of radioactive material for release to the environment or for use in beneficial consumer products. Regulatory agencies have been attempting to develop a consistent and acceptable policy for exempting items that are "below regulatory concern" (BRC). BRC means that after evaluation and with adequate conditions imposed for safety, small amounts of radioactive material may be distributed without further regulatory control during distribution, and/or use by the public. A re-evaluation of previous papers by the author indicated that they already presented a scheme that embodied all of the important international recommendations on this subject, and provided an organized scheme for ensuring that the total risk to the public from all future BRC applications would be limited to a very small fraction of current everyday risks, and that human benefits would exceed the risks.

---

* Presented at the 1989 annual meeting of the American Public Health Association, Chicago, Illinois, October 23, 1989.

The author's original paper (American Journal of Public Health, Vol. 55, pp. 1971-1992, 1965) discussed the philosophy and need to develop a scheme for limiting exposure from an infinite number of items classified according to an infinite number of "quantized" benefit levels, such that the total dose at equilibrium would not average more than 0.0001 Sv (10 mrem) per year to the U. S. population. Benefit/risk ratios were optimized within each application in such a way that each application was bounded by its own maximum risk level. This paper updates this work and provides simple examples to show how this scheme can provide workable solutions to the "BRC" problem that are consistent with more recent international recommendations.

Key Words

Radiation	Below regulatory concern	Regulatory
Radiation protection	De minimis	Exemptions
Health physics	Managing environmental risk	Limiting population exposures

INTRODUCTION

This paper presents a scheme for considering the exemption from regulation of an unlimited number of commercial items or applications of radioactive material (each of which is judged to be "below regulatory concern" (BRC)). The exemption is proposed to be applicable only after the radioactive product, or radioactivity, is released to the public or to the biosphere. The manufacturing of the product, or industrial usage of radioactive material, must be licensed or controlled; otherwise there would be no assurance that the conditions warranting the exemption would actually continue to prevail.

Much of the rationale and literature review leading to this scheme was published earlier (1) using consumer items as a limited example of how the exemption scheme could be applied. An updated paper in 1977 (2) simplified the presentation of the scheme somewhat. It was summarized further at a recent NRC public meeting (3). Yet, it is clear from current national and international discussions that some of the important principles introduced with this scheme have not been addressed, and that a consensus on the proper approach to establishing BRC or exemption policies has not been reached -- even within the responsible scientific communities (4,5). The purpose of the present paper is to update the earlier paper (1) and simplify the presentation further, so that important principles and philosophy are called to the attention of radiation protection practitioners and current decision makers.

Questions posed in the NRC meeting notice (3) and the papers and discussions of reference 4, provide good summaries of the issues of concern in developing BRC criteria. The questions posed (3) were essentially the same ones that were of concern in 1959-61, when the author performed radiation safety evaluations for the exemption by the U.S. Atomic Energy Commission of quantities and concentrations of radioactive materials in some early consumer products. Examination of these questions, and a search of the public health literature indicated that public confidence in any program that would allow uncontrolled release of radioactivity to the environment would depend upon the establishment of a firm plan of risk analysis and risk management. This plan must also be explainable to, and accepted by the public. This plan would also need to be capable of regulating the exemption of an unlimited number of items of public benefit, while at the same time ensuring control of the total risk from all exempt items. (A single application for exemption of radioactive material in any product, process, or commercial application -- in which some irradiation of the general public might occur -- is termed here an "item" for purposes of this paper. The term is similar to the term "practice" that has been used by others (4).) The public might well assume that the exemption of each item is a precedent, or "foot in the door", for exemption of an unlimited number of items.

Since it is the 25th anniversary of my completion of the earlier paper for the American Journal of Public Health, it is a special honor for me to be invited today to update my discussion for this annual meeting of the American Public Health Association.

CAPSULE PRESENTATION OF PRINCIPLES

Exhibit 1 shows one way of beginning a societal and regulatory development of BRC policy. The ways in which a democratic society can be involved in defining categories of benefit, and the limit of total risk, could be the subject of an entire monograph. Society may delegate to Congress, the administration, or both, the tasks of selecting categories of benefit and overall risk limits. Some guidance has been provided in Reference 1, and our society already has some mechanisms in place for making such decisions (including procedures and precedents for adapting recommendations of organizations such as the International Commission on Radiological Protection (ICRP), National Council on Radiation Protection and Measurements (NCRP), and National Academy of Sciences (NAS).

Once categories of benefit and the risk limit (which is still under debate (3-5)) are established, regulatory agencies can manage the assignment of risk limits for each item to be considered for exemption. They can evaluate the exposures as well as benefits for each item under an "auditing" system such as the following: First, a

risk limit for each category of items is selected so that the total for all categories will converge to a limit (Exhibit 2). Then, a risk limit for each item in a category is established, using a series of decreasing terms, so that the total risk for all BRC items in that category will never exceed the category limit (Exhibit 3).

These principles are illustrated by the example scheme developed in summary form in Exhibits 4 through 9. First, set categories of benefit, as in Exhibit 4. (A literature review and list of items considered to be of human benefit were presented in Reference 1). Exhibit 5 shows some items that might be considered in the top category of human benefit. This essentially "quantizes" levels of benefit (1).

Then, an overall risk limit is chosen (Exhibit 6). (As an example, a limit has been chosen corresponding to an effective dose equivalent of 10 millirem (0.1 millisievert) averaged over the United States population, with the restriction that no individual or subpopulation would receive more than 100 millirem (1 millisievert). The associated dose and risk limits are similar to those suggested in Reference 1. It is a value that the author would accept personally, and to his family, a priori, for the potential benefits of all radiation applications, if an ensured benefit/risk management system such as the one discussed here were in place.

This annual dose (and risk) limit for all exempt items is the same as that suggested more recently by Webb (which he estimates corresponds to an annual risk of death of 10^{-6} for the average person in a population (6). This risk level is on the order of that from variations in natural background level. Sinclair (7), adjusting risk estimates to take into account more recent international reviews of epidemiologic data, estimates that 10 mrem/year would correspond to a cancer risk of 5×10^{-6} per year, or a risk of death of 3×10^{-6} per year.

Next, Exhibit 7 shows how the limits of risk (related to the doses shown (1)) for categories can be constructed.

Exhibit 8 allocates dose (and thus risk) for each item within a category, showing an example for category I. Exhibit 9 evaluates the dose limit for a single (n^{th}) item in benefit category I.

This completes the development of a scheme for allowing an infinite number of items of benefit, while ensuring both: (1) that an a priori dose (and risk) limit to the public will not be exceeded; and (2) that the introduction of new items of human benefit will never be precluded, since some portion of the a priori dose (risk) limit has always been saved. However, in Exhibit 10 an example of the (doubly) infinite matrix of terms resulting from such a scheme is shown, with the added provision suggested that, in each benefit category, the n=0 term be saved

for future contingencies (discovery of new extremely beneficial applications, uncertainties in risk analysis, etc.)

The tabulation of terms in Exhibit 10 provides an overview of the scheme, which can be considered a dose-risk accounting system for all BRC items. In addition to placing the n=0 terms in reserve, the original scheme also suggests that the benefit/risk ratio be maximized for each item before conditions exempting the item as BRC are established (1). In this way, additional dose can be banked for contingencies. The original paper (1) suggests that both risk and benefit be converted to units of person-years of healthy life prior to a benefit/risk analysis, and that it is possible to consider in this manner the including of a term limiting morbidity as well as mortality. Furthermore, in this context, it is realized that any true "optimization" of benefit/risk, as proposed by ICRP, can only be valid if conducted within the framework of an upper limit of risk for each item; risks from exposure to an individual from multiple sources are not independent.

DISCUSSION

The values generated by the proposed scheme as shown in Exhibit 10, provide a reasonable compromise between those who prefer BRC levels of 1 mrem/year or less, and those who would accept 10 or more (8-14). The value suggested for nuclear power is not restrictive, considering that we are now dealing with effective dose equivalent, averaged over the United States population. (Alexander (15) recently quoted an estimate of only 0.007 millirem average effective dose equivalent to the U.S. population from nuclear power operations. This is well within the range projected from external radiation by inert gas radionuclides alone (16)). The value for medical diagnosis and therapy might seem restrictive until we again allow for the small fraction of the body exposed and apply appropriate risk weighting factors as suggested by ICRP (17) and NCRP (18). Many proposals would not include medical uses in such a scheme, since the benefit/risk considerations differ for the patient (4). Also, more could possibly be allowed for this category from the contingency bank, if necessary. Tritium in timepieces, one of the early exemptions (1), delivers less dose than that indicated in Exhibit 10, and much less than previously delivered by radium-dial timepieces (1,9).

This scheme as set up in Exhibit 10 is seen to allow an unlimited number of exempt items, in an unlimited number of benefit categories (although the number of categories could be limited for practical reasons). Thus, beneficial uses of

radioactive material can thus be encouraged. The decreasing series of terms in Exhibit 8 has been selected from the most slowly converging series, i.e., the successive terms decrease more slowly than those in other converging series. Although decreasing terms provide lower and lower limits for consecutive items in a category, it is the author's experience that ingenuity in selecting radionuclides of lower radiotoxicity and non-penetrating emissions could allow many uses of radioactivity in unlicensed items that could be of increasing benefit to human health and welfare. This experience seems confirmed by the values in Table 5.2 of Reference 9; the average population exposures from consumer products containing man-made radioactivity are in the 0.005 mrem/year (0.05 microsieverts/year) or lower range. Contributions from natural radioactivity in products produce much higher levels, and one of the highest contributors is the radium (and associated radon) in domestic water supplies, 1 to 6 mrem/year (10-60μSv/year).

Additional advantages of the above scheme have already been indicated in some detail in the earlier papers (1,2), and can be inferred in part from the above presentation. Also, the scheme can be seen to be generally consistent with the current safety philosophy of ICRP (17) (Exhibit 11), in that the benefit/risk ratio is optimized for each item, the item is justified (when evaluated and placed in the appropriate benefit category), and compliance with the ICRP system of public dose

limitation is guaranteed for even an infinite number of beneficial uses of radioactive material in consumer products or other commercial activities.

Exhibit 12 emphasizes the definition (concept) of BRC as used here. Exhibit 12 also questions whether the term "BRC" is in fact really advantageous and necessary, as discussed by Sinclair (12). This definition seems somewhat in contrast with those of Taylor (19,20), or Alexander (21), who believe that "justification on a case-by-case basis should not be required at or below the BRC level." However, the contrast is more apparent than real, since the scheme proposed in this article provides that any item of commercial value can be placed in an appropriate benefit category (at least "thrown into" whatever is the bottom category) since economic value is essentially related to human health and welfare. Experience indicates that a bit of ingenuity, and realistic dose assessments, would provide sufficient latitude for the development and approval of many major beneficial items as BRC when released to the public.

Exhibit 13 suggests that it would be appropriate to monitor the overall environmental and public exposure resulting from long-term operation of a BRC program. This could be carried out most economically if added to existing Environmental Protection Agency (EPA) and NRC programs for monitoring environmental exposures. Such programs would be consistent with the ICRP recommendation (ICRP-26, Reference 17, page 25) that, "National and regional

authorities should therefore keep under surveillance the separate contributions from all practices to the average exposure of the whole population so as to ensure that no single source or practice contributes an unjustified amount to the total exposure and that no individual receives undue exposure as a result of membership of a number of critical groups."

This latter statement in ICRP-26 is made in the context of a discussion about the possibility that a large number of sources exposing the same person, or same "critical groups", could (for a "large increase in the number of sources of exposure") conceivably cause individual doses above the 5 mSv (500 mrem) effective dose-equivalent limit, or the 0.05 Sv (5 rem) non-stochastic limit for an organ dose in the general population.

On the other hand, because the ICRP (correctly under present conditions) assumes that it is extremely unlikely that such limits will be exceeded, they maintain that it is acceptable to exceed such limits in some cases, even when the risk of mortality to a member of the public might exceed the intended limit of 10^{-6} per year, if the indicated benefits warrant according to the optimization analysis. They also point out that, in the case of exposure for medical diagnosis or therapy, there is no recommended individual limit; the benefits are to the same individual, so he and his physician must decide upon the acceptability of the exposure. ICRP-26 also has removed the population limit equivalent to the genetic dose of 5

rem/30 years, lest such a limit might suggest the "acceptability of a higher population exposure than is either necessary or probable, and a higher risk than is justified by any present or easily envisioned future development."

An examination of the NRCP position as stated by Sinclair (12), or the statements of Guimond and colleagues (14), as well as discussions with many other health physicists, make it clear that even experts in radiation health effects -- no less the American public - are not likely in the United States to accept 10 to 20 millirem per year as a "blanket" exemption (BRC) for any number of individually-considered radiation sources. This is true even though an overall limit of 10-20 millirem/year and its very low risks to the public from commercial applications is generally accepted as the "consensus" of most health physicists (15). Sinclair (12) states, "...the National Council on Radiation Protection and Measurements does not believe that a blanket exemption of sources contributing 0.1 millisievert (10 millirem) in a year to individuals is sound radiation protection policy. This level....is not negligible and, therefore, requires justification and ALARA considerations. In addition, exposure to a few such sources could bring an individual close to the annual limit of 1 millisievert (100 mrem) in a year." However, in the next paragraph Sinclair states, "...a source producing 0.1 millisievert (10 millirem) in a year could be exempted provided justification and ALARA are applied. Based on the fact that even for multiple sources, the proposed policy plans to ensure that no individual is likely to exceed 1 millisievert (100

millirem) in a year, exemption of a source producing 0.1 millisievert (10 millirem) in a year to individuals would not be unreasonable."

This recommendation seems reasonable as long as exposure to multiple sources is rare. But, what would happen if such an exemption policy were put into effect? Can we be sure that over the years ahead no single person, or critical group, would be exposed to more than a few, and certainly less than 10, sources? Do we really want to allow the possibility -- by a new BRC policy -- that rapid approval of ten (or even 50) individual sources (or items) can occur based on individual optimization analyses, which then use up the 100 mrem per year limit? This would then preclude any further BRC items from development and approval for exemption from regulatory control, even though they might be more beneficial than previously exempted items, and properly designed and packaged for public distribution.

Questions and concerns such as these led the author to develop the principles and methods as presented in the original paper in terms of consumer products (1), and to update and extend them to all potentially controllable releases of radioactive material or radiation sources in the present article. In fact, when the author was evaluating some of the early proposals to the Atomic Energy Commission for exemption, he had to delay the proposal to use Pm-147 in timepieces (since there was no definitive policy for limiting total population exposure from all consumer

products) while evaluating the benefits and risks of exempting tritium in timepieces distributed to the public. The evaluation of tritium was summarized in an appendix to Reference 1. Since tritium was to replace (unregulated) radium, there was no external irradiation, and leakage of tritium to the environment was calculated to produce negligible mutations even when incorporated into DNA (1), it was then easy to decide in favor of exempting tritium; doses to the public would be lowered by replacing radium. However, sufficient optimization, justification and limitation methods were then not available for quantitatively evaluating additional items that could expose members of the public.

The ICRP has since provided suggested methods for optimization when a single source or application exposes a single person or group in a controlled manner (22,23). ICRP-27 (22) confirms that it is feasible to consider all health effects (including morbidity) by linking them to the predominant years of life lost from mortality - under any assumed dose-response relationship, as in Reference 1. However, there has apparently been no guidance, outside of References 1 and 2, that addresses <u>how</u> to validly perform optimization when there can be an unlimited number of sources.

CONCLUSIONS

Important Principles Highlighted by This Study

A careful consideration of this matter under present ICRP philosophy leads to several principles and constraints in evaluating multiple items for approval as BRC:

1. Optimization for multiple exposures can not be done for one source at a time, without constraints on sub-limits for each source. Exposures, and risks, from multiple sources exposing the same individual, or population group, are not independent, but are interactive (including possible synergism with other environmental agents). Optimization can be applied for each successive application only when there is a sub-limit of risk allowed for each item in such a way that the total of an infinite number of sub-limits converges to a limit that would not violate the ICRP limitations on public exposure (as in Exhibit 8).

2. Justification can be carried out most feasibly only by using some set of discrete categories of benefit, such as in Exhibit 4. These categories should be decided in advance by societal consensus. Then, levels can be "quantized" as shown in Exhibit 7 to ensure that -- however large the number of categories judged to be needed for easy and fair placement of

items into categories by a priori justification -- the total population exposure for all items in all categories will comply with ICRP conditions of limitation.

3. The older concept of "balancing benefit vs. risk" should be replaced by the concept of maximizing the benefit/risk ratio, in order to be consistent with the recommendation to keep exposures ALARA (19). However, in some cases where benefit rises faster than risk by improved designs, it might not be possible to obtain the maximum benefit/risk ratio if the risk also rises to its sub-limit. The risk of each item must always be kept below its sub-limit to stay within the schemes for limiting total exposure. Future evaluators of successive items must always be assured of this.

4. To be properly compared, benefit and risk must be expressed in the same units. The unit, "person-years of healthy life lost per year," was used in the examples of Reference 1. An equivalent unit, which was stated to be "dimensionless," was suggested more recently (and apparently independently) in ICRP-27 (22). Such a unit is likely to be more acceptable to the public than units such as "dollars per life saved."

Persons acquainted with quantum physics might better understand how the above principles (or constraints) are introduced by the invocation of a limit on multiple

sources of exposure by contemplating the following crude analogy: the requirement that the integral over the "squared" wave function be bounded results in the constraints that the energy levels of the electron be quantized; the requirement that the dose from an infinite number of exempted items converge to the limit on public exposure requires that the levels of benefit be quantized.

Conservatism of the Linear-No Threshold Assumption

Implicit in the use of the ICRP methods of optimization, and in the practical application of the scheme of this article, is the (conservative) assumption of the "linear-no threshold" dose-response relationship between ionizing radiation dose and probability of cancer (13-23). Although this author concurs with the views of Bond (13) that the probabilities of cancer induction at the very low dose rates from BRC items are probably a factor of ten or more below those extrapolated linearly from the high-dose-rate observations, the actual shapes of dose-response relationships are currently too uncertain, and are likely to be too complex (24-26), for practical applications in carrying out the optimization recommendations of ICRP (22,23). More and more, research is indicating that it takes two specific, sequential, changes in DNA to produce a tumor cell, which must then survive, reproduce, and grow to a clinically-observable tumor, before cancer appears. Such a two-sequential-stage process requires a mathematical convolution over time between a probability of inducing the first change in DNA and a conditional

probability of inducing the second change given that the first change has already occurred; this must be integrated over each increment of the time (24-26). Such a convolution over time is necessary to produce a mathematical dose-(dose-rate)-response model that incorporates dose-rate as well as dose into the parameters of the model, as Bond (13) suggests is ultimately necessary in order to achieve realistic predictions of cancer incidence from (variable) low dose-rate scenarios. Still, it is important to recognize that the use of the linear dose-response model in the low-dose, low-dose rate, ranges provides additional safety factors in the optimization analyses.

Reference 1 provides a more detailed description of how equivalent units of benefit and risk may be selected, and how the public health literature can provide qualitative guidance for establishing categories of benefit.

RECOMMENDATIONS

The following recommendations can be drawn from the scheme presentation and discussion.

1. Industry should support the development of a Federal Policy and plan for exempting items from regulatory control, including a scheme for allowing an unlimited number of useful items to be exempted from regulatory control

once produced in a manner satisfying the scheme criteria. Industry has usually shown the ingenuity to meet regulatory safety requirements, once they are clearly and firmly promulgated. The debates over "BRC", and predecessor acronyms and "concepts", for more than 30 years without a definitive policy, have been more costly to industry and society in general than the (efficient) regulatory implementation of such a scheme would be.

Uncertainties in estimating health and economic detriments and benefits (22,23) do not usually permit justification of extremely complex optimization analyses. A good engineering approach can often be found that can bracket the rangesy of benefits and risks, to aid in judging within a few weeks whether an appropriate optimization has been obtained. Since, with a scheme such as the one presented here, the risks for each successive item would be suitably bounded, it would be reasonable to establish that the industry's own optimization analysis for each item should be accepted, if reasonably executed to minimize risk and maximize benefit/risk, and if production or commercial operations specifications are assured to guarantee the item's exposure to the public will remain within the allocated limit. Definitive guidance on the acceptable steps of such an optimization analysis could ensure that industrial innovation would not be discouraged by excessive paperwork and delay in the regulatory process.

2. The Federal government should begin development of a scheme that could be used for licensing industries that propose to produce an unlimited number of items exempted from regulatory control once they are released to the environment. This recommendation is made for reasons similar to those given in 1. above, and also because the type of schemes presented in Exhibit 10 could help bridge the controversy between those who prefer a 10 mrem/year limit and those who prefer a lower limit. The scheme would provide confidence for those who oppose the 10 mrem/year limit that adequate accounting for each item by this scheme would ensure the 10 mrem per year average population limit would not be exceeded. That scheme would also ensure that an individual dose limit of 100 mrem per year would certainly not be exceeded.

Those who are concerned that regulating items below 10 mrem/year would be too costly would be persuaded by the ease with which the lower limits could be applied, once industry and scientifically-competent NRC staff are given definitive criteria for easily judging benefit categories, definite risk (dose) limits for each item, and simple optimization methodologies. The greatest costs of regulating low risks have come from the long delay in providing industry with a definitive BRC policy that would encourage the invention of beneficial products, and the many years of expensive meetings deliberating these issues, without a solution to the problem.

As indicated by Dr. Taylor (19,20), health physicists are generally very professional, and would welcome simple schemes for exempting beneficial products or low levels of radioactivity in the environment. Any scheme such as that presented here, although it might seem complex at first due to the new principles presented, would upon brief study become very simple to implement -- once the basic overall dose limit is established, and simple generic decision aids provided for justification and optimization.

The scheme does not depend on the particular overall dose limit selected. The entire matrix of numbers in Exhibit 10 could be revised for a selected overall dose limit of 20 mrem/year, for example, by simply multiplying every number in the table by 2. Such an adjustment would not be of concern to the author, who believes that most persons acquainted with radiation risks would also accept limits up to 30 mrem/year, if limits on each item were established as recommended. The low levels of risk in the 10-30 mrem/year range have been summarized in the discussion. However, the author and many others would be concerned with a new BRC policy that had no provision for ensuring that the total exposure from many items was in fact really controlled and audited.

Weisbrod (27) clearly described how any society, no matter how wealthy, has only limited resources to expend on human health. It has two choices: spend wisely

or unwisely. Over-expenditure on insignificant risks means only that we are, in effect, wasting not only money, but life and health as well. At least some of the enormous resources currently planned for expenditure on negligible risks (e.g., much of the tens of billions of dollars currently projected to be spent to remove very low levels of environmental contamination, or to further reduce extremely low risks from nuclear waste disposal) would certainly find its way in our society to more beneficial applications, such as preventing or curing cancer -- which eventually attacks every third person in our society, mostly from causes other than radiation.

The author hopes this article will in some way help us expend our resources for human health more wisely.

EXHIBIT 1

PRINCIPLES FOR DETERMINING BRC CRITERIA:

- SOCIETY DEFINES CATEGORIES OF BENEFIT*

- SOCIETY DEFINES TOTAL RISK LIMIT*

- ASSIGN LIMITS OF RISK FOR ALL ITEMS IN EACH CATEGORY IN SUCH A WAY THAT TOTAL RISK TO PUBLIC FROM ALL MAN-MADE RADIATION IS LIMITED

---

* SOCIETY MAY ACCEPT RECOMMENDATIONS OF APPROPRIATELY CONSTITUTED BODY (E.G., NCRP)

EXHIBIT 2

SELECT RISK LIMITS FOR EACH BENEFIT CATEGORY IN SUCH A WAY THAT:

THE TOTAL RISKS FROM ALL CATEGORIES ARE BELOW THE

INDIVIDUAL (AND POPULATION) RISK LIMITS

ACCEPTED BY SOCIETY

EXHIBIT 3

ALLOCATE RISK LIMIT OF EACH SUCCESSIVE ITEM

IN A BENEFIT CATEGORY

SO THAT

TOTAL RISK OF ALL ITEMS IN A CATEGORY

CONVERGES TO THE CATEGORY RISK LIMIT

EXHIBIT 4

EXAMPLE SYSTEM

1. SET CATEGORIES OF BENEFIT; FOR EXAMPLE

I. ITEMS OBVIOUSLY BENEFICIAL

II. ITEMS WITH PLAUSIBLE BENEFIT

III. ITEMS OF SMALL VALUE TO HEALTH AND WELL BEING

IV. ITEMS OF ENTERTAINMENT VALUE

.

.

.

X. ITEMS OF NO BENEFIT OTHER THAN ECONOMIC THROUGH EXPANSION OF COMMERCE AND EMPLOYMENT

EXHIBIT 5

EXAMPLES

ITEMS OF OBVIOUS BENEFIT TO HEALTH AND WELL BEING (SEE REFERENCE 1 FOR DISCUSSION)

- NUCLEAR POWER
- MEDICAL DIAGNOSIS
- RADIATION THERAPY
- LUMINOUS SAFETY SIGNS
- RADIOGRAPHY SOURCES FOR INSPECTING SAFETY OF BUILDINGS OR AIRPLANES

EXHIBIT 6

SET RISK LEVEL FOR ALL USES EQUIVALENT TO:

E.G., 10 MILLIREM/YEAR EFFECTIVE DOSE EQUIVALENT

(FOR ANY SEGMENT OF THE PUBLIC, OR AVERAGED OVER THE ENTIRE U.S. POPULATION AS LONG AS INDIVIDUAL DOSES ARE ALWAYS BELOW 100 MILLIREM PER YEAR. I'LL ACCEPT EITHER. I RECEIVED 20,000 MILLIREM IN THE AGE RANGE 21-25, AND I'M STILL HERE. BUT THE POPULATION STANDARD SHOULD NOT BE JUST ONE INDIVIDUAL'S CHOICE. WITH PUBLIC INPUT AND NCRP/ICRP RECOMMENDATIONS, CONGRESS OR GOVERNMENT REGULATORY AGENCIES COULD DEVELOP THE PUBLIC CHOICE.)

EXHIBIT 7

LIMITS OF RISK FOR EACH CATEGORY

BENEFIT CATEGORY	RISK LIMIT
I.	0.9000 X 10 MILLIREM
II.	0.0900 X 10 MILLIREM
III.	0.0090 X 10 MILLIREM
.	.
.	.
.	.
TOTAL	(0.9999....) X 10 MILLIREM = 10 MILLIREM

EXHIBIT 8

ALLOCATE DOSE (AND THUS RISK*) LIMIT FOR EACH ITEM WITHIN EACH CATEGORY

E.G., FOR CATEGORY I, nth ITEM:

$$10 \text{ MILLIREM} \times 0.90 \times \frac{6}{\pi^2 \{ N+1 \}^2}$$

$$= 5.5 \, (1/N+1))^2$$

(NOTE: THIS WILL CAUSE THE SUM OF ALL TERMS, N=0,1,2,....∞ TO CONVERGE TO 10X0.9=9 MILLIREM FOR CATEGORY 1, SINCE $\Sigma \, 6/[\pi^2(N+1)^2] = 1$. SIMILARLY, THE SUM WILL CONVERGE TO 0.9 FOR CATEGORY II, 0.09 FOR CATEGORY III...., AND 9.9999....FOR THE SUMS OF AN INFINITE NUMBER OF ITEMS IN ALL CATEGORIES.) THE MOST SLOWLY CONVERGING SERIES HAS BEEN USED TO ALLOW HIGHER SUBLIMITS FOR THE EARLIER APPLICATIONS.

EXHIBIT 9

EXAMPLE FOR A SINGLE ITEM:

FOR n=1, CATEGORY 1,

UPPER LIMIT = $10 \times 0.90 \times 6/(\pi(n+1))^2$

= $10 \times 0.90 \times 6\ (0.5)^2/9.869$

= $10 \times 0.90 \times 0.15199$

= 1.37 MILLIREM/YEAR

EXHIBIT 10

ACCOUNTING FRAMEWORK FOR ALLOCATING RISK ACCORDING TO BENEFIT:

BENEFIT CATEGORY	BENEFIT FRACTION	UPPER LIMITS OF DOSE (RISK) (MILLIREM/YEAR) N = 0	N=1	N=2.....TOTALS
I.	0.900	RESERVE* 5.5 mrem/yr	1.37 (nuc.pwr)	0.61.....9 mrem/yr (med.diag.)
II.	0.090	0.55 mrem/yr	0.137 (lum. watches)	0.061.....0.9 (envir. tracer studies)
.				
.				
.				
TOTALS	0.999...	6.08*(TOTAL RESERVE)	1.52	0.68.....10 mrem/yr

* HELD IN RESERVE FOR FUTURE CONTINGENCIES.

EXHIBIT 11

MEETS ICRP-26 RECOMMENDATIONS:

JUSTIFICATION -- SELECTING BENEFIT CATEGORY

OPTIMIZATION -- MAXIMIZING BENEFIT/RISK RATIOS

LIMITATION -- LIMITS TOTAL DOSES (AND RISKS), FROM ALL ITEMS AS WELL AS EACH ITEM

EXHIBIT 12

BELOW REGULATORY CONCERN:

AFTER RADIOACTIVE MATERIAL LEAVES PRODUCTION PLANT OR FACILITY (LIMIT OF RELEASE IS APPLIED AT EFFLUENT POINT, BASED ON STANDARDIZED ENVIRONMENTAL ANALYSIS)

BUT

IS THE TERM BRC REALLY NECESSARY OR ADVANTAGEOUS?

BEFORE EXEMPTING ITEMS IN THE PAST, WE ALWAYS (IN NRC OR AEC) CARRIED OUT ANALYSES TO DETERMINE THAT PUBLIC EXPOSURES AND RISKS WOULD BE FAR BELOW THE RISKS MOST MEMBERS OF THE PUBLIC ACCEPT EVERY DAY FOR COMPARABLE SOCIO-ECONOMIC BENEFITS.

THUS, DOES NOT THE ANALYSIS TO SHOW WE ARE BELOW REGULATORY CONCERN SHOW THAT WE REALLY ARE CONCERNED?

EXHIBIT 13

EPA AND/OR STATES SHOULD MONITOR ALL ENVIRONMENTAL AND POPULATION EXPOSURES OF A PRODUCT OR APPLICATION -- TO VERIFY THAT LICENSEE'S PRODUCT DOES INDEED SATISFY DOSE LIMIT REQUIREMENT. NRC SHOULD MONITOR EFFLUENT AND/OR CONDITIONS OF MANUFACTURE, PRODUCTION AND DISTRIBUTION OF EXEMPT ITEMS FOR SAME REASONS.

-- TO ALLOW PRODUCT TO BE CONSIDERED BRC AFTER DISTRIBUTION TO PUBLIC (OR HAVE ITS RADIOACTIVE MATERIAL RELEASED TO THE ENVIRONMENT)

REFERENCES

1. Brodsky, A. Balancing Benefit Versus Risk in the Control of Consumer Items Containing Radioactive Material. American Journal of Public Health, Volume 55, 1965, pp. 1971-1992.

2. Brodsky, A and A. A. Moghissi. Constraints on Benefit-Risk Analysis of Consumer Items Containing Radioactive Materials. Presented at the Symposium on Public Health Aspects of Radioactivity in Consumer Products, Georgia Institute of Technology, Atlanta, GA, Feb. 2-4, 1977. Unpublished.

3. U.S. Nuclear Regulatory Commission. Policy Statement on Exemptions From Regulatory Control. Advance Notice of Proposed Statement of Meeting. Federal Register, Vol. 53, No. 238, Monday, December 12, 1988.

4. U.S. Nuclear Regulatory Commission (NRC) and Nuclear Energy Agency (NEA), OECD, "Workshop on Rules for Exemption from Regulatory Control" NUREG/CP-0101, U.S. Government Printing Office, Washington, DC 20013-7082, 1989.

5. Lindell, B. "Comments on Various Views on the Concepts of 'de Minimis'," Letter to the Editor, Health Physics, Vol. 57, No. 1, July 1989.

6. G.A.M. Webb, "The Concept of Negligible Risk," in NRC-NEA, NUREG/CP-0101, op.cit., pp. 35-42.

7. W.K. Sinclair, "Current Status of Risk Estimates for Assessing Health Consequences of Low Doses," in NRC-NEA, NUREG/CP-0101, op.cit., pp. 237-239.

8. Brodsky, A. Summary of Statement of Dr. Allen Brodsky at the Public Meeting of the Nuclear Regulatory Commission on: Policy Statement on Exemptions from Regulatory Control. Bethesda, MD., Jan. 12, 1989.

9. Moeller, Dade W., Chairman. Scientific Committee 28, NCRP, "Radiation Exposure of the U.S. Population from Consumer Products and Miscellaneous Sources," NCRP Report No. 95, National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Suite 1016, Bethesda, MD 20814, 1987.

10. International Atomic Energy Agency (IAEA), Safety Series No. 80, "Principles for the Exemption of Radiation Sources and Practices from Regulatory Control," IAEA, Vienna, Austria, January, 1988.

11. Huffert, A. M. "Current Issues Concerning NRC's Proposed Broad Exemption Policy (BRC)," unpublished literature review submitted as term paper for Radiation Science II, Georgetown University, April 25, 1989.

12. Sinclair, W. K. "NCRP's Position on BRC," The Health Physics Society's Newsletter, Vol. XVII, Number 4, April, 1989, p.1.

13. Bond, V. "Victor Bond's Position on BRC," The Health Physics Society's Newsletter, Vol. XVII, Number 4, April 1989, pp. 3-7.

14. Guimond, R. "Statement of Richard Guimond," presented at U.S. Nuclear Regulatory Commission Public Meeting on the Policy Statement on Exemption from Regulatory Control. Bethesda, MD: January 12, 1988; see also, R. Guimond, J.W. Gunter and F. Galpin, "EPA's Views on Regulatory Cutoffs for Radiation Exposure," in NRC-NEA, NUREG/CP-0101, op.cit., pp. 45-50.

15. Alexander, R. E. Introductory remarks, Plenary Session, Thirty-Fourth Annual Meeting of the Health Physics Society, Albuquerque, NM: June 26, 1989.

16. Klement Jr., A. W. Estimation of Dose From External Radiation, in A. W. Klement, Jr. Editor, Handbook of Environmental Radiation. Boca Raton, FL: CRC Press, Inc., 1982, p. 57.

17. International Commission on Radiological Protection, ICRP Publication 26 Recommendations of the International Commission on Radiological Protection. Elmsford, NY: Pergamon Press Inc., 1977.

18. National Council on Radiation Protection and Measurements (NCRP), "Recommendations on Limits for Exposure to Ionizing Radiation," NCRP Publications, 7910 Woodmont Avenue, Suite 1016, Bethesda, MD 20814, 1987.

19. Taylor, L. S., Chairman. Report of Working Group of the Health Physics Society State and Federal Legislation Committee, Health Physics Society Introductory Remarks," The Health Physics Society's Newsletter, Vol. XVI, Number 11, pp. 1-5, November 1988. (available from R. J. Burk, Jr. Health Physics Society, 8000 Westpark Drive, Suite 400, McLean, VA 22102).

20. Taylor, L. S. "HPS Comments on NRC Policy Statement," The Health Physics Society's Newsletter, Vol. XVII, November 3, pp. 1-4, March 1989.

21. Alexander, R. E. "Concern for Very Low Doses - Health Physics Society Introductory Remarks, "The Health Physics Society's Newsletter, Vol. XVI, Number 11, pp. 1-2, November 1988.

22. International Commission on Radiological Protection. ICRP Publication 27, Problems Involved in Developing an Index of Harm. Elmsford, NY: Pergamon Press Inc., 1977.

23. International Commission on Radiological Protection. ICRP Publication 37, Cost-Benefit Analysis in the Optimization of Radiation Protection. Elmsford, NY: Pergamon Press, Inc., 1983.

24. Brodsky, A. A stochastic Model of Carcinogenesis Incorporating Certain Observations from Chemical and Radiation Dose-Response Data. Health Physics, Volume 35, 1978, pp. 421-428.

25. Brodsky, A. Time and Dose Factors in Carcinogenesis (Letter to the Editor). Health Physics, Volume 36, 1979, pp. 468-471.

26. Brodsky, A. Experimental Support at the Gene Level for the Two-Sequential-Stage Model of Carcinogenesis (Letter to the Editor). Health Physics, Volume 46, 1984, pp. 1316-1317.

27. Weisbrod, B. A. Economics of Public Health. Philadelphia, PA: University of Pennsylvania Press, 1961.

A VIEW FROM THE COMMISSION

PRESENTED TO

AMERICAN NUCLEAR SOCIETY

DELAWARE VALLEY SECTION

AT

THE ENGINEERS' CLUB

PHILADELPHIA, PENNSYLVANIA

BY

DR. FORREST J. REMICK, COMMISSIONER

U.S. NUCLEAR REGULATORY COMMISSION

FEBRUARY 15, 1990

- However, there are some indications that the SALP process and results are being misused both within the NRC and by others outside the NRC.

- Therefore, the Commission needs to review the SALP process.

- I believe that this is a time for consolidation, for honing and refining our regulations and the associated processes in order that they are more coherent, understandable, rational and effective.

- There are a number of ongoing regulatory activities that I'd like to see brought to closure.

- Examples include:

  - Closure on the license renewal rulemaking and the provision of adequate staffing for the reviews.

    - Almost 20 percent of the electricity used in this country, that's one in five parts, is generated by nuclear power plants.

    - The first nuclear power plant licenses expire in the year 2000

    - Replacement energy costs, if these plants were retired from service, would exceed $15 billion per year

    - If plants are not relicensed, years of planning and construction are required to build replacement power plants.

    - In fiscal year 1991, NRC will begin to review the first of two lead applications to renew nuclear power plant operating licenses.

    - Therefore, we must issue a final Rule for license renewal as well as regulatory guidance at an early date.

    - The Commission has approved a plan to issue a draft rule this June, with a final rule by May 1991.

- This will require considerable effort and will require discipline and close management attention.

oo Other examples include closure on a rational Below Regulatory Control, or BRC, policy in order that public resources are devoted to the more important safety issues.

oo This would establish limits on the amount of radioactivity below which the Commission would not exercise regulatory control.

oo Incidentally, I am surprised to learn that the power reactor community may not be enthusiastic about the Commission's willingness to address this issue.

- I'd appreciate any views that you might have on the concept of defining limits on radioactivity which are BRC.

oo Another example is closure on the update of Part 20 of our regulations (Standards for Protection Against Radiation).

- It will be painful and costly, but I believe the update is needed and is overdue.

oo I believe we are close to providing some relief to licensees on our enforcement criteria associated with "hot particles or fuel fleas."

oo These are the tiny radioactive particles that sometimes are found on radiation workers clothing or skin and which in the past were not readily detected.

o I'm anxious for the Individual Plant Examination, or IPE, process to be done in a thorough, careful, and rational manner.

o In order that closure can be brought to the severe accident issues for current plants.

o And we have a better idea of how well the current plants can handle potential severe accidents.