

DOCKET NUMBER  
PROPOSED RULE

PR Chapel  
(53 FR 49886)

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US-NC

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# EDISON ELECTRIC INSTITUTE

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'89 APR 20 P3:53

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April 19, 1989

Mr. Samuel J. Chilk  
Secretary  
U.S. Nuclear Regulatory Commission  
Washington, D. C. 20555  
Attn: Docketing and Service Branch

Re: Advance Notice of Proposed Policy Statement on Exemptions from Regulatory Control, 53 Fed. Reg. 49886 (December 12, 1988)

Dear Mr. Chilk:

On January 30, 1989, the Nuclear Management and Resources Council, Inc. (NUMARC) submitted comments in response to the above referenced notice. The Edison Electric Institute (EEI) hereby endorses those comments.

Although the formal comment period on the referenced notice has expired, EEI would appreciate NRC's consideration of the enclosed supplemental comments to the extent practicable. These supplemental comments are provided in two general areas. First are comments on the specific issue of collective dose, and second are broader comments on the general topic of waste disposal. These comments were prepared by the EEI Health Physics Committee, and the Utility Nuclear Waste and Transportation Program. These supplemental comments were occasioned by our particular interest in the waste-related aspects of the proposed policy, by numerous statements placed on the current docket with which we disagree, and by our belief that additional comments would be more beneficial now than if presented after formal action was taken on the proposed policy. Accordingly, the purpose of these comments is to respond to the principal statements on the docket with which we disagree, and to provide NRC with additional information to utilize in its deliberations.

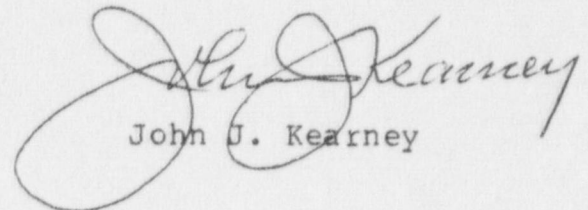
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Mr. Samuel J. Chilk, NRC  
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We appreciate the opportunity to provide these comments.  
If you should have any questions on them, please contact us.

Sincerely yours,



John J. Kearney

JJK:bfj

Enclosure

SUPPLEMENTAL COMMENTS  
OF THE EDISON ELECTRIC INSTITUTE  
ON THE NRC ADVANCE NOTICE OF  
PROPOSED POLICY STATEMENT  
ON EXEMPTIONS FROM REGULATORY CONTROL  
(53 Fed. Reg. 49886)

A. COLLECTIVE DOSE CONSIDERATIONS

1. Relationship to Prior Submittals

This document is submitted to supplement EEI's prior comments to NRC on this subject dated February 2, 1989. In that submittal, we stated that we are strongly opposed to a BRC criterion expressed in terms of collective dose. In this document we present, in more detail, the basis for our opposition to such a criterion.

2. The Concept of Collective Dose

As noted in a recent paper by Dr. Arthur C. Upton (Ref U-1), existing scientific data do not suffice to define directly the carcinogenic and genetic risks of low-level irradiation. "Estimation of such risks must, therefore, rely on interpolation or extrapolation from epidemiological and experimental observations at higher doses and dose rates, based on assumptions about the relevant dose-effect relationships and mechanisms of carcinogenesis. The risk models currently being used for the purpose generally assume no threshold, although the existence of a threshold cannot be rigorously excluded. They also generally assume that the dose-effect relationship is linear in the low dose domain...." These assumptions apply to correlations of individual dose and risk, and are a source of unavoidable uncertainties in calculated risk estimates.

On the basis of the same assumptions, "population risks" are inferred to be proportional to the collective dose equivalent; i.e., the average dose equivalent per capita times the number of persons exposed (Ref U-1). The use of the collective dose equivalent concept is an attempt to integrate doses of varying sizes and radiation qualities within a heterogeneously exposed population, and "its validity clearly depends on the linearity of the dose-response relationship over the dose range of interest" (Ref U-1). Dr. Upton states that the prevailing risk models currently in use for low-LET radiation



assume the dose-response to be essentially linear and invariant with dose rate over the dose range from zero to 0.5 Gy (50 rad). "The models also generally assume that the corresponding dose-effect relationship for high-LET radiation is linear and invariant with dose rate over the same dose range. It is noteworthy, therefore, that growing experimental evidence...is at variance with the latter assumption.... Hence, the appropriate method of integrating doses of different magnitudes, LET's, and temporal distributions for purposes of risk assessment involves questions that remain to be resolved." (Ref U-1)

Thus, we believe the concept of collective dose as a measure of the actual radiation risk to a heterogeneously exposed population has little foundation in science. The results of risk estimates based on collective dose calculations are, at best, subject to substantial uncertainties. However, as Dr. Upton states, "the concept of collective dose equivalent may represent the only practical basis for integrating doses within a heterogeneously exposed population." (Ref U-1) We believe health physicists and regulators must carefully examine every potential application of the collective dose concept to determine if its practical value as a rough estimate of risk outweighs the dangers inherent in using a measure that is so subject to uncertainty and controversy.

In the case here, we strongly believe that any practical value is clearly outweighed by the significant scientific and social detriments of its use. Our reasons will be discussed in further detail below. In summary, the use of collective dose in evaluating a broad range of very low doses over an essentially unlimited population for the purposes of determining compliance with an arbitrarily set absolute criterion of risk, by use of dose-risk coefficients that are well outside their range of scientific validity, is clearly unacceptable. Not only are the uncertainties involved tremendous, but the very act of calculating point values misleads the public into thinking that precise quantitative results are possible when they are not.

Furthermore, we do not believe that a criterion of population risk separate from individual risk is necessary or even meaningful. We recognize that the basis for such a determination includes philosophy and value judgments as well as scientific considerations, and that whatever position NRC takes will be controversial. As Dr. Upton notes, referring to a context where the dose to any one individual may be minuscule relative to that from natural background radiation, but the collective dose over a very large population is substantial, "the contrast...points up some of the philosophical, as well as technical, ramifications of radiation dosimetry and risk assessment which are yet to be resolved." (Ref U-1)



### 3. Need for Societal Impact Criterion

NRC's December 12, 1988 Advance Notice implies that there are two possible bases for imposing a collective dose (or societal) criterion for BRC in addition to the individual dose level criterion. The first is the possible existence of "societal impact" distinct from the impact addressed by the maximum individual dose criterion applicable to all persons in the population. The second is a suggested relationship to "the multiple exposure issue." In addition, NRC has explicitly asked for comments on the need for a collective dose criterion and the basis for that need, implying that additional bases may exist.

#### a. Societal Impact

NRC states that it is considering a dual criterion system to ensure that no individual will be exposed to significant risk and that the population as a whole does not suffer a significant impact. (We interpret this to mean a significant detrimental impact.) This raises an important question: Can there be a significant societal impact if there is no significant impact on any individual? (i.e., is society more than the sum of its individuals?) This issue is the subject of considerable thought and debate in the risk assessment community. Some of the important aspects are discussed, e.g., in reference S-1. A host of complex technical and philosophical questions arise: If separate aggregate societal impacts do exist, do they merit the attention of today's decision-maker? Increased risk of death is clearly a detriment to an individual, but is it invariably detrimental to the overall welfare of society?

We believe that limitation of individual risk is all that is needed to adequately protect the welfare of our society. However, even if there might be some additional societal impacts, in this case their nature is so speculative and their magnitude (positive or negative) so small and uncertain, that including an additional criterion to address them would not improve the quality of NRC's decision-making. Indeed, it would detract from the major issue of concern to the people of the U.S., about which they look to the government for guidance, that is, the individual risk that each of them faces.

In summary, the purpose of a collective dose restriction would be to ensure that the cancer-fatality risk to members of the exposed population would be maintained at an acceptably low level. This purpose can be achieved through routine NRC compliance action to ensure that the BRC level to the maximally exposed person is not being exceeded.

b. Uncertainty Issues: Multiple Exposures;  
Widespread Exposures

It appears that proposals for societal impact criteria are often made on the basis that because the possibility of exposure, albeit at very low levels, is so widespread or is likely to occur from multiple sources, an additional criterion is needed. We believe this is really an attempt to reduce the effects of uncertainties in the dose projections by applying, in effect, an additional factor of conservatism, since a collective dose criterion would generally have the effect of reducing the individual dose criterion when a large number of people are involved. Rather than using this indirect method to arbitrarily reduce the individual dose criterion, we urge NRC to confront the issue of uncertainty directly. Because of the size or heterogeneity of the population affected, the pathways and scenarios involved, statistical variations in large populations, or the difficulties in modeling and verifying models of transport of essentially uncontrolled radionuclides in the environment, NRC may have little confidence in the predictive models used. The Commission is therefore justified in requiring conservative assumptions or uncertainty estimates to be used in the calculations. Rather than arbitrarily lowering the criterion because it has little confidence in the calculations, NRC should demand calculational results that are reliable enough or conservative enough to evaluate against the criterion. This will avoid the equity problem, discussed below, of a variable criterion -- which seems to imply that radiation levels that are "negligible" for a person who lives in one place (a low population area) are "significant" for someone who lives elsewhere (a high population area).

c. Equity Considerations

Use of collective dose as a criterion implies that the larger the population affected by a practice, the smaller the allowable average dose to members of that population should be, and, in general, by implication, the smaller the maximum dose to any individual. Thus, when both individual and collective dose criteria are specified, the individual maximum criterion will tend to be limiting when small populations are involved. However, for large populations, the lower, average dose limits will be controlling; and the actual maximum individual dose implicitly "allowable" as BRC may be significantly lower than that specified in the individual criterion. Under this system, the same individual dose that is considered to merit regulatory concern if a person exposed has many neighbors who are also exposed, is below regulatory concern if the person happens to be exposed in circumstances where his neighbors are not. Clearly, the basis for such "inequitable" treatment of individuals is the



idea (discussed above) that there is some societal detriment being mitigated by the limitation of average dose; but it may be impossible to explain any scientific basis for this perceived inequity to affected members of the public. We do not believe that the speculative nature of such societal detriments, if they exist at all, outweigh the rights of the individual to equal treatment under the law when the issue is exposure to very low levels of radiation exposure.

#### d. Relative and Absolute Measures of Risk

If a societal risk criterion were to be used, it should be one that puts the issues of concern in perspective. Usually this is best done by adopting a relative, rather than absolute standard. Thus, average dose per capita, regardless of population size, which is relatable to an individual risk, is a more meaningful criterion of societal effect than collective dose. (See, e.g., NRC's societal quantitative "safety goal.") The use of an absolute value of effect, e.g., projected number of "statistical health effects" (cancer deaths), is of little use in assessing the import of an action unless there is some reference to a meaningful standard of comparison; for example, the number of deaths actually occurring in the population of concern, the year-to-year variability of that statistic, the projected number associated with an alternative action, etc.

Setting an absolute criterion that is associated with a projected number of effects in the population affected of less than one may be comforting to the decision-maker, but in light of the large uncertainties involved, it is essentially meaningless. Such an approach does not necessarily, nor is it even likely to, lead to the overall benefit of society, especially with regard to the allocation of resources.

#### 4. Use of Collective Dose as the Societal Risk Criterion

Even if we posit, solely for the purpose of discussion, the existence of a societal detriment separate from individual risk considerations (which we feel is highly unlikely), and we hypothesize further that it may be possible to develop an index or criterion to address that detriment, we do not believe that collective dose is the appropriate criterion.

It is our position that a collective dose restriction would be scientifically unsound as well as unnecessary. The Commission's decision on this issue should take into account both the strengths and weaknesses in the radiation risk data base and the likelihood that the number of cancer fatalities calculated by correlating collective dose with risk would actually occur.



To help quantify the likelihood of actually observing cancer fatalities, assuming a person is exposed for a lifetime at the BRC level proposed by NRC (10 mrem/yr) (an extremely improbable situation), we can calculate the apparent factor of safety associated with that exposure. The results of the atomic bomb survivor study show radiation-induced leukemias associated only with doses greater than 10 rads to the bone marrow (reasonably approximated as a 10 rem dose equivalent), and solid tumors only with doses greater than 40 rads.

The dose to a person receiving 10 mrem/year for 70 years is 0.7 rem. That is a factor of about 14 below the level where leukemia incidence is inferred, assuming dose-risk linearity. Furthermore, the Japanese exposures were essentially instantaneous, while those involved in the BRC issue would be protracted. Thus, another factor of safety can be attributed to the fact that protracted radiation is generally less efficient in carcinogenesis. In the Commission's current reactor safety study analyses, the value of this factor is estimated at 3. Therefore, the overall safety factor is about 43. (This factor is applicable to large populations; approximately 54,000 people have been included in the atomic bomb survival study.)

The need for a collective dose restriction is predicated on the conservative linear non-threshold hypothesis formulated many years ago (before much of the radiobiological and epidemiological data we have today were available) for purposes of permitting the setting of standards despite uncertainties. Its use has extended far beyond the original purpose for which it was developed, and it is often accepted as an immutable principle of scientific fact by those who have limited knowledge of the field. Although the BEIR-III committee did not authorize the use of the dose-risk coefficients they developed for doses less than 10 rads (single exposure) or 1 rad/year (lifetime exposure), the coefficients are being used to infer fatalities among populations that receive much lower doses.

As a result, decisions of great importance are being made based upon a hypothetical relationship and a quantification that has little or no scientific foundation. The consequence is that resources are diverted from protection against manifest risks to comply with regulations for protection against risks that either do not exist at all or are so small that they cannot be detected using the most sensitive techniques available.

We believe that the numerical results of any calculation of fatalities using BEIR-III risk coefficients, with a collective dose composed of individual doses below 10 mrem/year or so, represent a maximum value. All that can be said with any confidence is that the actual outcome is between zero and that

value. It is also important to recognize that the likelihood of zero fatalities is very high, while the chance that the maximum projected number of fatalities will occur is close to zero.

The inescapable conclusions to be drawn, we believe, are: (1) the radiation risk data base for doses of the order of 10 mrem/year or below is too weak to support the imposition of a collective dose restriction in the BRC policy, and (2) the probability that any health effects will occur as a result of the Commission's BRC policy is vanishingly small.

## B. WASTE DISPOSAL CONSIDERATIONS

### 1. Principal Issues

NRC's advance notice, and the public comments on it, raise a number of issues regarding the scope and exercise of the Commission's authority to grant exemptions from the NRC's regulation of exposure to radiation. The complexities of these issues are significant. By addressing these concerns now, the Commission would provide a consistent, generic resolution of these issues rather than waiting to address them piecemeal in the course of a proceeding on a particular exemption. A comprehensive response to these matters would enhance the general understanding and appreciation of the Commission's policy, would conserve scarce resources, and would reduce the probability of delay in realizing specific exemptions. Therefore, the Commission should address the following issues.

#### a. NRC Authority

The principal purposes of the proposed policy statement are to identify radiation exposures levels which may be low enough in particular circumstances to warrant an exemption from NRC regulations, and to provide the information requirements necessary to support the grant of those exemptions. Some commentators have questioned whether this is within NRC's authority. A Commission determination of the conditions under which it will grant exemptions from its own regulations and the kinds of information it needs to make or to confirm regulatory decisions are clearly within the scope of the Commission's authority. The Commission's current regulations contain numerous provisions permitting or establishing exemptions from its regulatory requirements. See, for example, 10 CFR Sections 20.501, 50.12.

The only limits on the Commission's exemption authority are those imposed through applicable statutes. We are aware of no provision of the Atomic Energy Act or any other applicable statute that would preclude NRC from establishing reasonable



exemption policies or procedures for materials or practices below regulatory concern. Therefore, a policy statement that describes the general conditions under which the Commission will consider exemptions from its own rules is clearly within the Commission's authority to promulgate.

#### b. Exposure Limits

Some individuals have questioned whether the Commission should contemplate a policy that may increase or change exposures to radiation.

Some exposure to radiation has always been considered acceptable. The Atomic Energy Act of 1954 does not require zero exposure. Rather, it requires that measures be taken to provide reasonable assurance that public health and safety is adequately protected. Both the NRC and EPA have interpreted that standard to allow for public exposure as a result of various activities. The Courts and Congress have ratified those interpretations explicitly and implicitly. Thus, the real issue is not whether the NRC can regulate so as to permit some radiation exposures but, rather, whether the NRC can conclude, in the exercise of its expert judgement, that some levels of exposures are below regulatory concern and modify its regulations accordingly. The answer has long been well-established. Inherent in an agency's authority to make rules is its authority to change those rules. As long as those changes stay within the bounds established by statute, the agency is well-within its discretion.

Here, the statutory boundary is not even approached, let alone exceeded. In fact, most actions under this policy statement would involve only limited exposures at only a fraction of regulated limits. Thus, the Commission is acting well within its statutory discretion.

#### c. Involuntary Exposures

Some commentators have questioned whether it is appropriate to allow an individual to be exposed to a risk from a societally approved activity over which the exposed individual has no veto. This issue is not unique to either the BRC policy statement or the regulation of exposures to radiation. Indeed, the issue goes well beyond activities licensed by the NRC to include almost everything society does. Instead of having an individual veto over exposures to noise, congestion, or air pollution, individuals have the right to participate in the process for setting regulatory limits. Each of us gives up some of our autonomy in exchange for the benefits realized. Thus, the issue of involuntary exposure transcends this policy statement and therefore, does not require further consideration by the Commission.



#### d. Expert Uncertainty

Although radiation is one of the most studied environmental agents, not all the experts agree completely about the dose-response to radiation. This is especially true at very low doses. Uncertainty at low doses is caused by the lack of any directly observable effects and the need to rely on extrapolations from effects observed at far higher doses.

Despite these uncertainties, the NRC, EPA and DOE have enough confidence in the currently available dose-response information to set radiation exposure levels, including limits at fairly low-levels of exposure. (More recently, despite recognized uncertainties, the Federal Committee on Interagency Radiation Research and Policy Coordination (CIRRPC) has developed criteria for screening out clearly meritless claims of cancer-induction by exposure to radiation.) Similarly, the NRC can work within the range of uncertainty to establish reasonable BRC limits.

For these reasons UWASTE believes that the Commission should not delay promulgating a BRC policy until all uncertainties are resolved, but should rather move forward on the basis of what we believe to be a more than adequate foundation of existing knowledge.

#### e. DOE Waste

Concerns have been raised that somehow this policy statement will enable DOE to dispose of its wastes by alternative methods using commercially available disposal capacity. The Commission should allay these concerns. The Commission should explain that DOE's activities are for the most part subject to its own orders and that NRC generally lacks jurisdiction over DOE's transportation and disposal of BRC materials. NRC should clearly state that these factors render inappropriate the Commission's further consideration of this issue.

### 2. Procedural Considerations

Procedural matters can significantly affect the ability of a licensee to utilize or implement a regulatory initiative. For BRC exemptions, the procedures may be critical. Unless the procedures are clear and straightforward and lead to prompt decisions, the transaction costs and uncertainties could reduce significantly the savings to be realized from an exemption. Thus, the development of suitable procedures is an important issue.

a. BRC Waste

The advance notice touches on procedures only briefly. For example, it does not explain how the practice-specific exemptions contemplated by the Commission's previous statement on Radioactive Waste Below Regulatory Concern (51 Fed. Reg. 30839, August 28, 1986) would be coordinated with this policy statement. NUMARC has suggested that this policy statement should leave the prior BRC Policy statement intact. We strongly support that suggestion but add a request that the lessons of implementing that policy statement also be taken into account here.

The BRC Waste policy statement required a major, multi-million dollar research effort to provide the data necessary for responding to the Commission's decision criteria. As a result, to date only the utility industry has seriously attempted to take advantage of the BRC Waste policy statement by pooling their resources and conducting the research effort. Availability of the exemption policy should not be conditioned on the conduct of such extensive, industry-wide research efforts.

This experience should not be ignored. For BRC relief to be practical, the policy statement needs to make the process practical. Thus, the Commission should avoid recurrence of the experience with the BRC Waste policy statement.

b. Alternatives

It appears that the full intent of the policy statement would be realized by a process that minimizes the need for licensees to obtain formal NRC approval of regulatory alternatives before they are implemented. Instead of requiring licensees to submit requests for exemptions and obtain prior NRC approval before implementing a modified procedure, licensees should be permitted to adopt alternative procedures on the basis of a documented analysis that shows that the BRC criteria are satisfied. The NRC might then discharge its responsibilities by conducting a post-implementation review of the analysis and of the licensee's implementation of its modified program.

This approach would permit the Commission to maximize the regulatory relief it intends to provide by reducing the transaction cost of obtaining that relief, while fulfilling its obligations to ensure public health and safety. Post-implementation inspection would be sufficient because the impact of any regulatory alternative would, at a maximum, be only slightly greater than the impacts associated with current regulations. Indeed, in some cases, the alternative may actually result in a lesser impact. Thus, no significant impacts on public health and safety could occur before an NRC post-implementation review.



### c. Agreement States/Interstate Compacts

UWASTE supports the Commission's intent to make rulemakings and other decisions under the policy statement a matter of compatibility for the Agreement States. But to realize the uniformity that compatibility is intended to achieve, the Commission also needs to consider the role of the several interstate low-level waste compact commissions in the disposal of low-level radioactive wastes. Several compact commissions appear to have some authority over licensees' disposal of LLW. Therefore, to provide licensees with meaningful relief, the NRC's policy statement also needs to address how NRC exemptions will be realized consistent with any requirements imposed by the interstate compacts.

### 3. Technical Concerns

The proposed policy has raised questions regarding the consistency of the Commission's approach with the current regulation of radiation exposures and the generally accepted understanding of As Low As Reasonably Achievable (ALARA). Questions have also been raised about cost estimates for the disposal of LLW and the effect of a BRC exemption on landfills.

#### a. Consistency with Current Regulations

Much of the discussion over the consistency of this proposal with other radiation regulations appears to arise from misunderstanding over the scope of the NRC's proposal. For example, there is a misperception by some that the BRC policy will permit licensees to engage in the completely unregulated release of radioactive materials or the completely unregulated disposal of such material in areas designated for unrestricted use. In fact, the policy statement would permit a spectrum of alternatives to current regulation. It would also require controls at the point of transition from one regulatory regime to another.

Moreover, because the NRC will require licensees to maintain records of what, where and how radioactive materials were treated under alternative regulations, there will be sufficient information available to permit the determination of compliance with other regulatory requirements.



b. ALARA

The ALARA process includes the "economics of improvement in relation to benefits to the public health and safety" as well as any other relevant "societal and socio-economic considerations." After evaluating these considerations, the Commission proposes to conclude that the individual risk due to a 10 mrem/year exposure is already so low that there is no need to determine whether the exposure due to a practice should be still lower.

We agree with the Commission. If an exposure results in an inconsequential risk, then there is no need to further reduce that exposure to reduce that risk.

c. Disposal Costs

Concern has been expressed that any NRC action which authorizes the disposal of some low-level waste as below regulatory concern would necessarily increase the cost of disposing of the remaining low-level waste at licensed disposal facilities and, therefore, require the NRC to modify its cost-benefit analysis of any BRC waste proposal. These concerns are not relevant. They are also premature. The cost of disposing of low-level waste at licensed facilities will depend on many factors and not just the relative volumes presented for disposal. At this early stage in the facility development process, it is not possible to predict how those different factors will affect disposal costs.

What is clear now, however, is that substantial societal resources are being devoted to disposal requirements for wastes which could be disposed of by alternative means while actually decreasing their impacts on the public health and safety. It is also clear that this BRC policy statement could affect many regulated practices besides LLW disposal. Thus, a hypothetical concern relating only to waste disposal should not delay the Commission in issuing a BRC policy statement.

d. Effects on Landfills

Concern has been expressed that by exempting LLW as BRC, the NRC will inadvertently burden existing landfills and make it more difficult to site new landfills. These consequences are said to result from the diversion of LLW from licensed disposal facilities to landfills and the belief that local communities will oppose new landfills if they will accept radioactive materials. These concerns are unfounded. The volume of BRC waste is miniscule compared with the total volume of waste currently disposed of in landfills. Thus, a BRC exemption

cannot, in point of fact, significantly affect the availability of disposal capacity at current landfills. Similarly, the demand for new landfill capacity is based on many societal needs that far outweigh the possibility that some BRC material containing very low-level of radioactivity would be disposed of along with the much larger volumes of other wastes. Thus, these concerns should not affect the issuance of this policy statement.

#### C. RESPONSES TO COMMISSION QUESTIONS

##### 1. Justification/Social Acceptability

Justification refers to the practice itself and not to the modification of regulations applicable to that practice. There is no question that the disposal of low-level waste and the transportation of radioactive material from licensed facilities are justified. Indeed, the social acceptability of these practices rests on the clear expression of public will in the Congressional enactment of the Atomic Energy Act of 1954 and the subsequent adoptions of 10 CFR Parts 61 and 71 through the NRC's public rulemaking process.

##### 2. Individual Dose Criteria

The proposed 10 mrem/year limit is a radiation level below which the NRC would not require a petitioner to provide elaborate analyses to support a request for regulatory relief. The Commission appears to have chosen this level on the basis of an adequate protection analysis, i.e., it is a radiation level below which the impacts are of little concern to most members of society and, therefore, low enough to base an exemption decision on a simple analysis. We agree with this conclusion.

##### 3. Collective Dose Criterion

Collective dose criteria have never been established for the disposal of low-level waste or the transportation of radioactive materials. Nothing about the continued regulation of these activities under modified regulatory requirements appropriate to the very low dose levels involved requires a change in this long-standing practice. Indeed, for the NRC to change its regulatory approach in this case it would have to provide justification for such a change. No such justification has been provided.



No justification exists to establish collective dose limits on the disposal of low-level waste or the transportation of radioactive materials. Prior estimates of collective population doses due to these activities have been based on unrealistically conservative assumptions regarding the potential for exposure. While such calculations may serve as useful upper bound estimates for comparative purposes, or for tracking exposures over time, those calculations are too unrealistic to serve as the basis for a regulatory requirement. If, in spite of these factors, the Commission wishes to consider a collective dose criterion, we urge it to consider carefully the effects this may have on other regulatory activities.

#### 4. Multiple Exposures

The principal concern associated with multiple exposures is that an individual may inadvertently experience a total radiation dose near or above regulatory limits. Although such an exposure would not constitute a significant health hazard, an inadvertent exposure at this level would be inconsistent with the general philosophy behind the BRC policy. Thus to ensure consistency with this philosophy, the NRC should consider the potential for BRC exemptions to result in substantial inadvertent exposures due to cumulative doses from multiple sources. However, that consideration should be undertaken only if there is a substantial, demonstrable probability that such inadvertent exposures could occur.

In general, multiple exposures will be avoided by requiring a review of other proximate exemptions. For those exposures, probabilities and consequences should be evaluated and regulatory actions can be taken if necessary to minimize any substantial potential for overexposure. The need for and appropriate type of such regulatory actions should be determined in specific situations. The fact that such actions should be taken is enough for the purpose of promulgating a BRC policy statement.

#### REFERENCES

S-1. Spangler, M.B., "The Need for De Minimis Risk Standards in Regulatory Decision Making: An Individual or a Societal Risk Concept", presented at Symposium on Environmental Health Risks: Assessment and Management, University of Waterloo, Ontario, Canada (1985)

U-1. Upton, A.C., "Evolving Perspectives on the Concept of Dose in Radiobiology and Radiation Protection", 55 Health Physics, p. 605 (1988)