(143) 133

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

AUG 15 1988

MEMORANDUM FOR: Thomas E. Murley, Director
Office of Nuclear Reactor Regulation

Hugh L. Thompson, Jr., Director
Office of Nuclear Material Safety and Safeguards

Harold R. Denton, Director
Office of Governmental and Public Affairs

William C. Parler, General Counsel

FROM: Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

SUBJECT: OFFICE CONCURRENCE REQUEST: PROPOSED COMMISSION POLICY STATEMENT ON REGULATORY CONTROL EXEMPTIONS FOR PRACTICES WHOSE PUBLIC HEALTH AND SAFETY IMPACTS ARE BELOW REGULATORY CONCERN (BRC)

Your concurrence is requested on the enclosed Commission paper (Enclosure 1). The paper responds to the Staff Requirements Memorandum of March 30, 1988 (Enclosure 1 to the Commission paper) which requested options for a Commission policy which establishes a generic number for exposures that are below regulatory concern. This paper is a revision of the one sent to you on July 15, 1988 and includes staff consideration of comments from the Advisory Committee on Nuclear Waste and from staff within the Office of the General Counsel (Enclosures 2 and 3). As a result, extensive changes have been made in Section VII of the Proposed Policy Statement (Enclosure 2 of the Commission paper) regarding the calculation and use of collective dose assessments. Section IV, Principles of Exemption, has also been revised, although the substance has not been significantly altered. The current Commission schedule is that this paper be submitted by September 1, 1988. A subsequent Commission briefing is currently scheduled for September 16, 1988. RES plans to send the package to EDO on August 23, 1988.

The development of this paper has been undertaken with the assistance of an Interoffice Working Group which included the cognizant individuals listed below. RES believes the enclosed Commission paper reflects the consensus of this group as reflected in a June 9-10, 1988 meeting held in Baltimore, Maryland and follow-up meetings at headquarters on July 7 and July 29, 1988.

In view of the tight schedule, your assistance in expediting the review of the enclosed Commission paper would be appreciated. Copies of the paper have been provided to the cognizant individuals.

The following apply to this review and concurrence request:

1. Title: Proposed Commission Policy Statement on Exemptions from Regulatory Control for Practices Whose Public Health and Safety Impacts are Below Regulatory Concern

2. RES Task Leader: William R. Lahs, RDB, DRA, (492-3774)

3. Cognizant Individuals:

NMSS - R. Bernero
- R. Cunningham
- K. Dragonette
- D. Cool
- J. Austin

NRR - F. Congel
- L. J. Cunningham

OGC - R. Fonner

4. Requested Action: Review of, and concurrence in, Commission Paper.

5. Requested Completion Date: August 19, 1988

Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

Enclosures: As stated

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ENCLOSURE 1

(144)

For: The Commissioners

From: Victor Stello, Jr., Executive Director for Operations

Subject: PROPOSED COMMISSION POLICY STATEMENT ON EXEMPTIONS FROM REGULATORY CONTROL FOR PRACTICES WHOSE PUBLIC HEALTH AND SAFETY IMPACTS ARE BELOW REGULATORY CONCERN (BRC)

Purpose: To provide for Commission consideration, a proposed policy statement on exemptions from regulatory control for practices whose health and safety impacts are below regulatory concern.

Discussion: The Staff Requirements Memorandum of March 30, 1988 (Enclosure 1) directed the staff "... to submit for Commission consideration options for a Commission policy which establishes a generic number for exposures which are below regulatory concern." The staff was further directed to "...discuss the approach for implementing such a number for multiple sources of licensed activities which does not require justification by individual licensees."

Contact:
W. Lahs, RES
Ext. 2-3774

A proposed policy statement is provided as Enclosure 2. In the proposed policy, a practice is defined as a set or combination of a number of similar sets of coordinated and continuing activities aimed at a given purpose which could involve the potential for radiation exposure. To determine if an exemption for a practice is appropriate, the staff believes the Commission must determine if one of the following conditions is met: (1) the application or continuation of regulatory controls does not result in any significant reduction in the individual or collective dose received by the critical group and the exposed population or (2) the costs of the regulatory controls that could be imposed to reduce the individual and collective dose are not balanced by the benefits of dose reduction that can be realized.

The policy establishes basic principles for exemption and subscribes to continued Commission use of a linear model relating dose to health effects at the dose levels over which the policy applies. The principles require that acceptance of an exemption be based on a supporting cost-benefit or ALARA analysis whose degree of rigor would be a function of the individual and collective doses inherent to the exempted practice. It is possible that, in unusual circumstances, policy provisions would allow exemptions from regulatory control for practices for which individual doses to members of the general public approach, but remain below, 100 mrem per year total effective dose equivalent. The 100 mrem per year value is the limit in proposed revision to 10 CFR Part 20 which is applicable to an individual in an unrestricted area exposed to all sources of radiation under a licensee's control. For the most part, however, exemptions would be expected to involve practices in

which individual doses would be a smaller fraction (e.g., 1/10) of this dose limit.

Based on bounding estimates of risk for low doses, the proposed policy provides criteria for allowing exemptions for practices involving individual exposures in a range at or below 10 mrem per year. For a practice involving doses at the higher end of this range but which has no significant impact on the environment and complies with existing environmental regulations, only relatively straight forward cost-benefit analysis would be required. At lower doses, on the order of 1 mrem per year, which many characterize as a level of individual risk of no concern to individuals, an exemption could be granted on the basis of only a small benefit. The effort to evaluate the benefit and demonstrate justification and ALARA could be minimal provided the practice would not be expected to involve unacceptably or unnecessarily large collective doses. A collective dose on the order of 100 person-rem per year per practice is proposed as the test of significance for the potential exemptions involving individual doses equal to or less than about 1 mrem per year.

100,000 people

The staff believes that use of a threshold individual dose (with a test of significance for collective dose), below which NRC would allow "simple demonstration" of justification and ALARA for proposed exemptions, is consistent with the linear non-threshold hypothesis. The linear hypothesis is a mathematical model, which, in its simplest form, equates by direct proportion the risk of a statistical health effect (e.g., random risk of radiation induced cancer or genetic effect) from a radiation exposure to the level of that exposure, even down to the smallest exposure. The use of individual or collective

dose to define "simple demonstration" thresholds for exemption decisions is not based on an assertion that there is no biological damage or risk at these defined levels. Rather, the adoption of these levels is based on the argument that the risk entailed at exposure levels below these levels is sufficiently low in absolute magnitude and in comparison to everyday risk as to be beneath any reasonable threshold of concern.

Coupled with the establishment of a basis for simple demonstrations of justification and ALARA, the proposed policy also includes Commission guidance regarding frivolous practices for which regulatory exemptions normally will not be considered.

In measuring the impact (i.e., detriment) of a practice being considered for exemption, the staff believes, and contacts with the Environmental Protection Agency indicate, that an assessment or description of the components of total collective dose must be made to satisfy National Environmental Policy Act (NEPA) requirements. However, in performing cost-benefit analyses, several alternative approaches, which allow truncation or weighting factors to be applied to the components of collective dose, are identified as being appropriate to define the constraints on or extent of a practice under consideration for exemption from regulatory control.

The proposed policy statement includes the staff's recommendations of individual and collective dose values that provide the threshold and test of significance, respectively, for basing exemption decisions on simple demonstrations of justification and ALARA. Additional

perspective on these values is included in Enclosure 3. This enclosure also discusses the pros and cons of alternative numerical values. Enclosure 4 discusses three major policy considerations including: (1) the principle of "justification of practice", (2) whether certain practices should be excluded from the exemption policy, and (3) approaches for the calculation and use of collective dose assessments. Enclosure 5 contains responses to the Commission's request for an explicit identification of the assumptions and projected risk estimates used to establish certain BRC limits currently included in NRC regulations. This enclosure also discusses the uncertainties in the data base regarding the coefficients relating radiation dose to health risk.

A summary of the staff's recommendations on the major policy considerations, discussed in enclosure 4, is as follows:

Justification:
"Justification of practice" is a basic element of existing radiation protection policy currently applied both nationally and internationally. The staff recommends that "justification of practice" should be required before any regulatory exemption is allowed. The Advisory Committee on Nuclear Waste (ACNW) supports this recommendation.

Exclusions:
The policy identifies specific practices which should be excluded from the exemption policy. This exclusion provision reflects the staff's concerns regarding the social and ethical questions about the acceptance of small radiological risks associated

with frivolous or unjustified practices. The ACNW agreed with this staff position but emphasized that care must be exercised in defining frivolous practices.

Calculation and Use of Collective Dose Assessments: The collective dose associated with an exempted practice can serve as both a measure of the impact on the exposed population and a mechanism for assessing the benefits of regulatory constraints on the practice being exempted from regulatory control. The staff's view is that an assessment of the components of total collective dose must be made to satisfy NEPA requirements. However, in performing cost-benefit analysis, several alternative approaches can allow truncations in collective dose or weighting factors for the monetary value of averted dose to be applied.

Truncations in time and space have been used in the past and could continue to be used in situations where a choice between alternatives is not further clarified by unbounded collective dose assessments. An individual dose cutoff could also be considered on the basis that small individual doses (e.g., less than 0.1 mrem per year) represent an insignificant risk and that the collective dose from the summation of these individual exposures, will be very small both in the absolute and comparative risk sense. Finally, varying monetary values could be assigned to components of collective dose, e.g., $1000 per person-rem for collective dose composed of individual doses in excess of 1 mrem per year and $100 per person-rem for individual doses less than

this value. At this time, the staff believes that the use of any of the above approaches could be appropriate depending on the practice under consideration for exemption. The ACNW supports the graduated monetary weighting of individual dose contributions to collective dose.

In developing the proposed policy statement, the staff considered (1) the existing policy on consumer products (30 FR 3692), (2) the gemstone decision, and (3) the general statement of policy and procedures concerning petitions submitted pursuant to § 2.802 for disposal of radioactive waste streams below regulatory concern.

Regarding the existing consumer product policy, the proposed exemption policy is consistent with the 1966 policy statement on "Use of Byproduct Material and Source Material - Products Intended for Use by the General Public (Consumer Products)." On the gemstone issue, the Commission decision that the practice was justified could, under this policy, be based on a determination of marginal benefit and on a simple demonstration that individual and collective doses involved with gemstone distribution and use are small. Based on the anticipated ability of the defined practice (i.e., radioactive gemstone distribution to and use by the general public) to meet the 1 mrem per year total effective dose equivalent threshold and the test of significance on collective dose, the exemption would be allowed under this policy.

The Commission's statement on policy and procedures concerning petitions for disposal of radioactive waste below regulatory concern (specifically, its criteria for

individual doses of a few millirem per year and small collective dose) is encompassed in this proposed policy statement by the wide latitude of acceptable individual and collective doses which can be allowed for exempt practices.

Finally, the staff has attempted to provide a policy on exemptions which is consistent with emerging international guidance on the subject. It is important to have international consistency in this approach to exemptions particularly because of international trade in items such as recycled materials and consumer products. However, it should be noted that in assessing collective dose for cost-benefit analysis, one approach, the use of an individual dose cutoff, is not consistent with the international approach. This could be a controversial issue at the NRC-organized international meeting on exemptions scheduled for October 1988.

The staff has, as indicated previously, identified policy areas in which consensus with the ACNW has been reached. Enclosure 6 provides the staff's response to other ACNW comments.

Coordination: The Office of General Counsel has reviewed the proposed policy statement and has no legal objection.

Recommendations: That the Commission:

1. Approve discussion of the proposed policy statement and options at the NRC-organized, October 17-19, 1988 Workshop on Rules for Exemption from Regulatory Control.

2. Approve staff efforts to subsequently finalize the proposed policy statement for publication in the Federal Register.

Victor Stello, Jr.
Executive Director for
Operations

Enclosures:
1. Staff Requirements Memo
2. Draft Policy Statement
3. Options for Numerical Values
4. Major Policy Alternatives
5. Response to Specific Commission Questions
6. Response to ACNW Comments

Distribution:

ENCLOSURE 1 (Sec Record 4)

IN RESPONSE, PLEASE REFER TO: M880314

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

OFFICE OF THE SECRETARY

March 30, 1988

ACTION - Beckjord, RES

Cys: Stello
Taylor
Rehm
Thompson, NMSS
Murley, NRR
Murray, OGC
SNeuder, RES

MEMORANDUM FOR: Victor Stello, Jr.
Executive Director for Operations

FROM: Samuel J. Chilk, Secretary

SUBJECT: STAFF REQUIREMENTS - BRIEFING ON THE STATUS OF EFFORTS TO DEVELOP A DE MINIMIS POLICY, 2:00 P.M., MONDAY, MARCH 14, 1988, COMMISSIONERS' CONFERENCE ROOM, D.C. OFFICE (OPEN TO PUBLIC ATTENDANCE)

The Commission was briefed by the staff on the status of efforts to develop a Commission policy statement identifying a level of radiation risk or dose below which government regulation would be limited or unwarranted.

The Commission requested and the staff agreed to submit for Commission consideration options for a Commission policy which establishes a generic number for exposures that are below regulatory concern. The paper should discuss the uncertainties in our data base regarding radiation risk and should include the supporting scientific and legal rationale for all proposals. Consideration should be given to the assumptions made in establishing de facto BRC levels that appear in current NRC regulations. The staff should also discuss the approach for implementing such a number for multiple sources or licensed activities which does not require justification by individual licensees. This options paper is to be acted upon by the Commission prior to the staff meeting with international groups on this subject.

~~(EDO)~~ (RES) ~~(SECY Suspense: 9/9/88)~~ ~~(EDO Suspense: 8/31/88)~~ SECY 8/1/88

Commissioner Bernthal requested the staff to provide him the bases and analytical techniques used by other agencies (e.g., EPA and FDA) in developing a de minimis policy/regulation on toxic waste (e.g., did they use a linear hypothesis?).

~~(EDO)~~ (RES) (SECY Suspense: 4/29/88)

Rec'd OM, EDO
Date 3-30-88
Time 1045

Subsequent to the meeting, Commissioners Roberts and Bernthal requested that the staff's options paper should explicitly identify the undergirding assumptions and projected risk estimates, both societal and individual, used in the establishment of such BRC limits appearing in NRC regulations. Specific points staff should address include:

- In 1981, the Commission revised Part 20 to permit disposal of scintillation cocktail and animal carcasses containing trace concentrations of ^{14}C or ^{3}H without regard for their radioactivity. Also, specified curie amounts of both isotopes may be released annually into the sewerage system. Some regulatory control remains (e.g. record-keeping and limitation on use of contaminated carcasses) but in effect, once released to the environment NRC exerts no further control, thereby setting a floor to ALARA for these specific isotopes and applications. What calculations of societal and/or individual risk were employed in determination of these exempted levels? Were the models and assumptions the same as those used to arrive at tables of exempt quantities elsewhere in NRC regs?

- Staff raises the question on page 4 of SECY-88-69 as to whether a definition of "radioactive" can be usefully established. Not mentioned in Enclosure 2 is the fact that DOT regulations do precisely that (49 CFR 173.403). For purposes of transportation, a radioactive material is defined as a material having a specific activity of 2 nCi/g or greater. This definition is incorporated in NRC regulations (10 CFR 71.10) not as a definition per se, but as an exempt quantity under NRC transportation regulations. What is the origin of this 2 nCi/g limit? Given that a limit on total specific activity limit applies to any and all isotopes, what assumptions were made regarding chemical form, pathways to the environment, critical organs, etc.?

- For purposes of enforcing the many de facto BRC limits which exist in NRC regulation what explicit allowance is made for instrument and measurement uncertainties? (Recall, that the Commission only just recently promulgated requirements for some measure of QA for dosimetry processors.)

- Acceptable levels of residual surface contamination are designed in Reg. Guide 1.86. Facilities with surface contamination levels below those specified may be released for unrestricted use. How many and what types of licensee facilities have been decommissioned using these criteria?

- The Commission was recently made aware of some of the history behind the licensing of 3M static eliminator devices. The general license for these devices allowed up to 5 nCi of removal activity without any action being required on the part of the general licensees. Do similar provisions exist in other licenses? What is the origin of the 5 nCi allowable leakage rate? What assumptions of risk were made to justify this number?

cc: Chairman Zech
Commissioner Roberts
Commissioner Bernthal
Commissioner Carr
Commissioner Rogers
OGC (H Street)
GPA
PDR - Advance
DCS - 016 Phillips

DRAFT

Enclosure 2

Proposed Commission Policy on Exemptions from Regulatory Control for Practices Whose Public Health and Safety Impacts are Below Regulatory Concern

I. INTRODUCTION AND PURPOSE

Over the last several years, the Commission has become increasingly aware of the need to provide a general policy on the appropriate criteria for release of radioactive materials from regulatory control. To address this need the Commission is expanding upon its existing policy for protection of the public from radiation, currently expressed in existing regulations (Title 10, Code of Federal Regulations) and policy statements (30 FR 3462, Use of Byproduct Material and Source Material, dated March 16, 1965; 47 FR 57446, Licensing Requirements for Land Disposal of Radioactive Waste, dated December 27, 1982; and 51 FR 30839, General Statement of Policy and Procedures Concerning Petitions Pursuant to § 2.802 for Disposal of Radioactive Waste Streams Below Regulatory Concern, dated August 29, 1986). The expansion includes the provision of an explicit policy on the exemption from regulatory control of practices whose public health and safety impacts are below regulatory concern. A practice is defined in this policy as a set or combination of a number of similar sets of coordinated and continuing activities aimed at a given purpose which involve the potential for radiation exposure.

The purpose of this policy statement is to establish the basis upon which the Commission may initiate the development of appropriate regulations to exempt from regulatory control persons who receive, possess, use, transfer, own, or acquire certain radioactive material. This policy is directed specifically toward rulemaking activities involving the release of licensed radioactive material either to the environment or to persons who would be exempt from Commission regulations.

The concept of regulatory exemptions is not new. For example, tables of exempt quantities and concentrations for radioactive material were defined in 1965 and 1970 which a person could receive, possess, use, transfer, own, or acquire without a requirement for a license (30 FR 8185 and 35 FR 6427). Other exemptions allowing distribution of consumer products or other devices to the general public, or allowing releases of radioactive material to the environment, have been embodied in the Commission's regulations for some time. More recently, the Low Level Waste Policy Amendments Act of 1985 directed the Commission to develop standards and procedures for expeditious handling of petitions to exempt from regulation the disposal of slightly contaminated radioactive waste material that the Commission determined to be below regulatory concern. The Commission responded to this legislation by issuing a policy statement in August 1986 (51 FR 30839). That statement contained criteria which, if satisfactorily addressed in a petition for rulemaking, would allow the Commission to act expeditiously in proposing appropriate regulatory relief on a "practice-specific" basis consistent with the merits of the petition.

The Commission believes that these "practice-specific" exemptions should be encompassed within a broader NRC policy which defines levels of radiation risk below which specified practices would not require NRC regulation based on public health and safety interests. For such exempted practices, the Commission's regulatory involvement could therefore be essentially limited to licensing, inspection, and compliance activities associated with the transfer of the radioactive material from a controlled to an exempt status.

The Commission recognizes that, if a national policy on exemptions from regulatory control is to be effective, Agreement States will play an important implementation role. In the past, States have been encouraging findings that certain wastes are below regulatory concern and the Commission believes that States will support an expansion of these views to all practices involving exempt distribution or release of radioactive material. The Commission intends that rulemakings codifying regulatory control exemptions will be made a matter of compatibility for Agreement States. Consequently, any rulemakings that evolve from this policy will be coordinated with the States.

II. RADIATION PROTECTION PRINCIPLES

The Commission subscribes to three fundamental principles of radiation protection in formulating its policies and regulations to protect workers and the public from the harmful effects of radiation. They are (1) justification of the practice, which requires that there be some net benefit resulting from the use of radiation or radioactive materials, (2) dose limits, which define the upper boundary of individual dose which must not be exceeded in the conduct of nuclear activities, and (3) ALARA, which requires that radiation dose be as low as is reasonably achievable, economic and social factors being taken into account. The term, ALARA, is an acronym for As Low As is Reasonably Achievable.

For the purpose of establishing the stochastic health risk associated with its radiation protection policies, the Commission also subscribes to the linear model for dose and effect at the dose levels over which these policies apply. The hypothesis upon which the linear model is based assumes that the risk of radiation induced effects (principally cancer) is linearly proportional to dose, regardless of the size of the dose. In subscribing to this model, the Commission recognizes that it is a model based upon data collected at relatively high doses and dose rates which is then extrapolated to the low dose and dose rate region where there are no statistically reliable epidemiological data available. It is believed that the use of the linear model provides a conservative basis for defining exemption policy.

Collective dose provides a useful way to express the impact (i.e., detriments) of a nuclear activity on the health of the population subject to radiation exposure. Collective dose is the sum of the individual doses resulting from a practice or source of radiation exposure. By assigning collective dose a monetary value, it can be used in cost benefit and other quantitative analysis techniques. It is also an important factor to consider in balancing benefits and societal detriments for practice justification and ALARA determinations.

III. APPLICATION OF RADIATION PROTECTION PRINCIPLES TO EXEMPTIONS FROM REGULATORY CONTROL

The following sets forth guidelines about how the Commission will apply the fundamental principles of radiation protection in consideration of practices which are proposed to be exempt from regulatory control. These practices, if approved, would result in products being distributed to the general public and effluents and solid waste being released to areas of the environment other than licensed disposal sites.

- Justification - Exposures resulting from any practice should be justified; thus, even at trivial levels of dose, the practice considered for exemption should continue to be justified. However, as lower levels of radiation exposure are projected, the lower levels of benefit needed for justification open the possibility of simpler, less rigorous evaluation. This reduction in rigor of justification, in due proportion to the lower level of exposure envisioned, is entirely consistent with the ALARA concept.

- Dose Limits - Individual doses from all exempt practices should not be allowed to exceed 100 mrem per year. This 100 mrem per year value is equivalent to the dose limit for members of the public specified in proposed 10 CFR Part 20, Standards for Protection Against Radiation. The dose limits in proposed 10 CFR Part 20 apply to all sources of radiation exposure under a licensee's control (i.e., natural background and medical exposures are excluded). Although it is possible to reasonably project what the dose will be from a practice, and then take this information into account in controlling regulated practices so that the dose limits are not exceeded, exemptions imply ~~some degree of~~ loss of control. Therefore, in order to provide reasonable assurance that regulatory decisions regarding exemptions, combined with other sources of radiation, will not cause members of the public to exceed the dose limit, candidates for exemptions should typically not result in dose, on the average, to members of the critical group (the group defined as the individuals expected to receive the greatest exposure from the practice) in excess of a small fraction of the dose limit.

The Commission has concluded that, for currently licensed activities and activities which may be licensed in the near future, 100 mrem per year total effective dose equivalent for members of the public is not likely to be exceeded as a result of individual exposures to multiple practices involving use or release of radioactive material. This conclusion is supported by the existence of current EPA and NRC effluent and environmental regulations which impose "secondary" limits on classes of activities or practices that are fractions of the adequate protection limit; information supplied concerning annual releases from certain classes of licensed facilities; and independent environmental survey data collected in recent years for certain classes of byproduct material users. The Commission believes that the dose limit for members of the public will not be exceeded if the dose to a member of the critical group, as a result of typical exempted practices, does not exceed a few millirem total effective dose equivalent per year.

fewer than 20? 25 practices exempted?

- ALARA - The ALARA principle applies to exemptions in the same manner as it is applied to other practices which are subject to regulation. However, as in the case with justification, the level of effort to achieve, or to demonstrate achievement of ALARA, will be proportional to the individual and collective dose.

IV. PRINCIPLES OF EXEMPTION

Once a practice is established as justified, i.e., there is a positive net benefit to the introduction or use of radioactive material, the decision of whether or not the entire practice, or some defined subset of the practice, is a candidate for exemption from regulatory control hinges on the general question of whether or not application or continuation of regulatory controls are necessary and cost effective in reducing dose. To determine if exemption is appropriate, the Commission must determine if one of the following conditions is met:

1. The application or continuation of regulatory controls on the practice does not result in any significant reduction, in the individual or collective dose to the exposed population or;

2. The costs of the regulatory controls that could be imposed to reduce the individual and collective dose are not balanced by the benefits of dose reduction that could be realized.

For purposes of implementing its policy, the Commission recognizes that only under unusual circumstances would practices which cause radiation exposures approaching existing limits be considered as candidates for exemption. The Commission will consider such circumstances on a case specific basis using the general principles outlined in this policy statement. However, as the doses to members of the critical group decrease, the need for regulatory controls decreases and the analysis needed to support a proposal for exemption can become less rigorous. In essence, the complexity of the basis for decision-making for exemptions is a continuum ranging down from that required at the established limits of acceptability, namely the dose limits.

If the doses from practices under consideration for exemption are sufficiently small, the attendant risks are small compared with other societal risks. For example, the annual individual risk of radiation induced cancer associated with an exposure level of 10 mrem per year is of the order of 0.1 percent of the overall risk of cancer death.

The Commission believes that below an annual individual fatality risk of 10^{-5}, many in society would consider it reasonable to considered some relaxation of efforts to further reduce risks. Providing for some margin below this level, the Commission proposes a dose of 10 mrem[1] as the level of annual individual exposure below which the sophistication of cost benefit analysis could be somewhat reduced compared to the analysis expected at higher dose levels. A practice meeting this criterion, for which there would be no significant impact on the environment, and which complies with existing environmental regulations would be granted an exemption on the basis of a straightforward and relatively simple cost-benefit or ALARA analysis.

10% increase in budget

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1 Annual individual and collective dose when used in this policy, unless otherwise defined, refers to total effective dose equivalent.

The Commission further believes that annual individual fatality risks of approximately 10^{-6} to 10^{-7} are of little concern to most members of society. This order of magnitude of risk or dose has been termed by the National Council on Radiation Protection and Measurements (NCRP) as the Negligible Individual Risk Level (NIRL). On this basis, an annual individual dose threshold of 1 mrem is adopted where simple demonstrations of justification and ALARA for a specific practice may be warranted. In defining the scope of these practices to which the 1 mrem annual dose threshold applies, a test of significance of collective dose on the order of 100 person-rem is established. If the collective dose fails below this level, then the risk from a justified practice is considered to be ALARA without further analysis. The Commission does not consider that adoption of a test of significance on the collective dose is a limitation on what is acceptable but rather an opportunity for expediting approval of exemption. Practices not meeting this test of significance for collective dose may, nevertheless, be granted exemption on other bases for simple demonstrations of justificaiton and ALARA. For example, the collective dose will be proportional to both the extent to which an exempt practice is utilized and the resulting benefits. For example, the use of smoke detectors containing radioactive sources in houses is known to save lives. Both the number of lives saved and the collective dose will increase proportionally to the number of smoke detectors used. As indicated above, the establishment of a "simple demonstration" threshold on the order of 1 mrem per year below which only simple or minimal demonstration of justification and ALARA would be required should not be construed as a decision that doses below this level are necessary before a practice can be exempted while doses above the level would preclude exemptions. On the contrary, this level simply represents a range of risk which the Commission believes is sufficiently small compared to societal risks such that a rigorous analysis may not be required in order to make a decision regarding the acceptability of an exemption.

Establishment of an exemption for a particular practice does not necessarily imply that the individual and collective doses would be perceived as trivial by the particular individuals and population involved, even if the individual

doses to members of the critical group were within or below the range of 1 mrem per year. However, the Commission believes that promulgation of an exemption would still be appropriate because either the degree of risk reduction does not justify the burden of regulatory controls, or because there would be little gain in risk reduction by additional controls.

V. EXCLUSIONS FROM EXEMPTIONS

There are some types of practices involving radiation or radioactive materials which are, prima facie, socially unacceptable regardless of how trivial the resulting dose might be and, therefore, should be excluded from exemption. Excluded practices would include, but not be limited to, the intentional introduction of radioactive material into toys and products intended for ingestion, inhalation or direct application to the skin (such as cosmetics). Exclusions would also include the purposeful [illegible] distribution or release of radioactive materials where there are clear, economical alternatives to such use and the practice is not justified because there are no unique benefits from using the radioactive materials.

VI. PROPOSALS FOR EXEMPTION

A proposal for exemption must provide a basis upon which the Commission can determine if the basic conditions described above have been satisfied. In general, this means that the proposal should address the individual and collective doses resulting from the expected activities under the exemption, including the uses of the radioactive materials, the pathways of exposure, the levels of activity, and the methods and constraints for assuring that the assumptions used to define a practice remain appropriate as the radioactive materials move from regulatory control to an exempt status.

If a petition for exemption results in a rule containing generic requirements, a person applying to utilize the exemption would not need to address justification or ALARA. The Commission decision on such proposals will be based on the licensee's meeting the conditions specified in the rule. The promulgation of the rule would, under these circumstances, constitute a finding that the exempted practice is justified, and that ALARA considerations have

been dealt with. This approach is consistent with past practice, e.g., consumer product rules in 10 CFR Part 30.

If, after a practice is determined to be justified and a simple assessment indicates that the likely consequences of exemption are individual and collective doses approximately equal to or less than the "simple determination" thresholds, there would be high likelihood that the application would be accepted by the Commission.

There may be cases, however, where simplified assessments, which typically use conservative assumptions for bounding conditions, will indicate the potential for higher individual or collective doses. In these cases, a more detailed analysis will be required to make a determination on whether the basic conditions for an exemption have been met.

In addition to considerations of expected activities and pathways, the Commission recognizes that consideration must also be given to the potential for accidents and misuse of the radioactive materials involved in the practice. A proposal for exemption of a defined practice must therefore also address the potentials for accidents or misuse, and the consequences of these exceptional conditions in terms of individual and collective dose.

VII. CALCULATION AND USE OF COLLECTIVE DOSE ASSESSMENT

The collective dose can serve as both a measure of the impact (i.e., detriment) of a practice on the exposed population and a mechanism for assessing the benefits of regulatory constraints on the practice being exempted from regulatory control. In the latter case, a monetary value can be assigned to the collective dose so that cost-benefit assessments can be made with respect to the usefulness of controls or constraints on a practice to further reduce collective dose.

The Commission believes the assessment of the components of total collective dose must be made to satisfy National Environmental Policy Act requirements. However, when used for cost-benefit analyses, several alternative approaches can allow truncations or weighting factors to be applied. For example, the

collective dose is often used to discriminate between alternatives or options. The collective dose in such cases should be calculated to the point where a choice between options is clear. Complying with this requirement will often allow the truncation of the collective dose assessment in time and/or space. Also, large uncertainties associated with dose, particularly at very low dose or dose rates may render certain components of the assessment non-useful in the comparison of alternatives. In such cases, an individual dose cutoff could also be considered on the basis that small individual doses (e.g., less than 0.1 mrem per year) represent an insignificant risk and that the collective dose ignored will be very small in the absolute sense and in comparison to the collective dose from the exempted practice or from other causes.. Finally, varying monetary values could be assigned to components of collective dose; e.g., $1000 per person-rem for collective dose composed of individual doses in excess of 1 mrem per year and $100 per person-rem for individual doses of 1 mrem per year or ~~less.~~ 0.1 The Commission believes that the use of any of the above approaches could be appropriate depending on the practice under consideration for exemption from regulatory control.

VIII. VERIFICATION OF EXEMPTION CONDITIONS

The Commission believes that the implementation of an exemption under this broad policy guidance must be accompanied by a suitable program to monitor and verify that the basic considerations under which an exemption was issued remain valid. In most cases, the products or materials comprising an exempted practice will move from regulatory control to the exempt status under a defined set of conditions and criteria. The monitoring and verification program must therefore be capable of providing the Commission with the appropriate assurance that the conditions for the exemption remain valid, and that they are being observed. The Commission will determine compliance with the specific conditions of an exemption through its established licensing and inspection program and will, from time to time, conduct studies as appropriate to assess the impact of an exempted practice or combinations of exempted practices.

ENCLOSURE 3

Options For Numerical Values Within The Proposed Exemption Policy

The proposed exemption policy is broadly based on the principle that, if adequate public protection is provided, exemptions for a particular practice or class of practices can be based on justification of practice and a supporting cost-benefit analysis or determination. Numerical values are proposed for individual and collective dose which, because of the small risks involved, would allow the merits of exempting a practice from regulatory control to be based on simple analyses or judgments. These exemptions would involve practices resulting in individual doses of less than about 1 mrem per year and collective dose less than about 100 person-rem per year.

(1) The 1 mrem per year individual dose value [1]

Selection in the policy statement of the 1 mrem per year value as the threshold below which only simple justification and ALARA are needed is based on the premise that an individual risk approximating 10^{-7} per year is a level of risk considered trivial by many regulatory bodies and one which is widely held to be of no concern to the individual. The National Council on Radiation Protection and Measurements (NCRP) has recommended this value as an exposure level which, if resulting from a specific practice, could be dismissed from regulatory consideration. The IAEA and several national regulatory bodies have made similar determinations. This individual dose benchmark is one-hundreth (1/100) of the 100 mrem per year dose limit applicable to members of the public in the proposed 10 CFR Part 20. This value can also be compared to other exposures received by members of the public as indicated in Table 1.

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1 Dose when used in this enclosure refers to annual effective dose equivalent commitment

Alternative values below this individual dose level would add little to arguments supporting the selection of this value for defining conditions of minimal individual radiological risk. A 0.5 mrem per year value would translate into an individual risk at the low end of the range of values commonly identified by several regulatory bodies as being trivial to individuals. The National Radiological Protection Board (NRPB) has recommended this value as a de minimis individual dose rate when associated with exposure from a single practice.

Alternatives greater than 1 mrem per year could be selected and are in fact considered viable for selected situations. The Atomic Energy Board of Canada (AECB) is considering adopting 5 mrem per year as a de minimis dose rate for exempting specific sources and practices from licensing. This value of dose is stated as corresponding to the upper end of the range of risks considered insignificant by individuals in their personal decision-making. However, the AECB states that this value will be used to decide upon exemptions provided that the radiological impact is localized and the potential for exposures of large populations is small. Further, the AECB will take into account in exempting any new practice, the dose received by individuals within the critical group from all license-exempt practices. Selection of 5 mrem per year as a threshold value to indicate the need for only simple demonstrations of justification and ALARA would require addressing the AECB constraints as well as the considerations discussed below. A second alternative would be 4 mrem per year - a limiting value used by the EPA in drinking water standards, and being proposed by EPA as a BRC level for land disposal of low level waste. The 4 mrem per year value was discarded principally because its selection could imply a degree of precision inconsistent with the value-judgment aspects of the proposed policy. The 4 mrem per year value would also exceed the 3 mrem design objective guide for liquid effluent release proposed in 10 CFR Part 50, Appendix I. Given that the 1 mrem per year dose value is a threshold established for allowing the use of simple demonstrations of justification and ALARA, and that an existing BRC statement of policy and procedures regarding petitions for waste disposal refers to a range of doses (i.e., a few millirem per year), the

significance of choosing between a 1 or 4 mrem per year value is diminished.

(2) The 100 person-rem per practice per year collective dose value

This collective dose value is selected as a "test of significance" for simple demonstrations of justification and ALARA. This constraint also limits the number of hypothetical individual exposures at 1 mrem per year (i.e., the threshold dose level) to one hundred thousand people or ~ 0.04 percent of the U.S. population. Using the linear relationship between dose and effect, this collective dose constraint would provide high assurance that, for the exempt practices to which it is applied, no statistical fatalities would be predicted per year of practice. The 100 person-rem value has been used internationally to represent a de minimis collective dose on the basis that there would be no potential for reducing collective dose below this value at reasonable regulatory cost.

An alternative collective dose value of 500 person-rem could be selected. This value would retain the advantages of the 100 person-rem value (with the exception that a non-order-of-magnitude value could imply a certainty of knowledge not commensurate with the value judgments incorporated in the proposed policy). The 500 person-rem value would be consistent, although not truly comparable, with the Commission's societal risk safety goal if the societal risk goal was applied to the average 57 thousand people estimated (based on 1979 data) to be within 10 miles of nuclear power plants.

TABLE 1

COMPARISON OF INDIVIDUAL DOSE VALUES TO REFERENCE EXPOSURES RECEIVED BY MEMBERS OF THE PUBLIC

DOSE OF EQUIVALENT VALUES	Fraction or Multiple of Reference Value		
	10 mrem/yr.	1 mrem/yr	0.1 mrem/yr
Natural Background (excluding radon) ~ 100 mrem/yr	0.1	0.01	0.001
Cosmic Radiation (U.S.Average) ~ 28 mrem/yr	0.4	0.04	0.004
U.S. Variation in Cosmic Radiation - Washington,D.C. vs Denver, CO ~ 24 mrem/yr (26-50)	0.5	0.05	0.005
Terrestrial Gamma Radiation ~ 28 mrem/yr	0.4	0.04	0.004
U.S. Variation in Terrestrial Gamma Radiation - Atlantic/Gulf Coast vs. Rockies East Slope ~ 47 mrem/yr (16-63)	0.25	0.025	0.0025
One Hour of Air Travel at 39,000 feet - Enhanced Cosmic Exposure ~ 0.5 mrem	20	2	0.2

ENCLOSURE 4

MAJOR POLICY CONSIDERATIONS

CONSIDERATION 1 - THE ROLE FOR "JUSTIFICATION OF PRACTICE" IN THE COMMISSION'S PROPOSED EXEMPTION POLICY

In the SRM of March 30, 1988, the Commission requested that the staff should "... discuss the approach for implementing such a [generic BRC] number for multiple sources or licensed activities which does not require justification by individual licenses." Justification of practice has been a basic principle of radiation protection both nationally and internationally. The principle, recommended by the ICRP, has been reflected in existing Commission regulations and is included in basic radiation protection documents such as IAEA Safety Series No. 9.

The staff has attempted to respond to the Commission's direction in two ways. First, the staff is proposing a regulatory exemption policy with a threshold on individual dose and a test of significance on collective dose to define a basis for exemptions in which only simple demonstrations of justification and ALARA would be required. A practice would be considered a strong candidate for exemption if the average individual exposure to members of the critical population group is less than a value of about 1 mrem per year and the collective dose to the general public is less than about 100 person-rem per year. This decision process recognizes that the small individual and collective risks associated with certain practices should require little balancing in terms of compensating benefits. Second, the staff has provided in the policy statement an explicit recognition that rulemakings would constitute a finding by the Commission that the exempted practice was justified. Therefore, a person applying to utilize the exemption would not need to address justification or ALARA.

On the issue of multiple sources, the staff's recommendation that all practices be justified precludes a plethora of unjustified practices which would contribute to the problem of exposures to multiple sources. If a practice involves limited individual and collective risk as defined, the determination on whether the specific practice should be exempt from regulatory control would only hinge on the to proper assessment of the individual exposures within the critical population group and the collective exposure of the general public.

If the Commission should decide that "justification of practice" is not required for certain activities, based solely on the fact that the consequent doses are below certain levels, the staff believes that the Commission is essentially opting for definition of a de minimis or negligible risk policy. The staff and the ACRS Subcommittee on Nuclear Waste (now the ACNW) are both in agreement with the Commission's decision (made in the March 30, 1988 Staff Requirements Memorandum) to focus a proposed Commission exemption policy on below regulatory concern rather than de minimis considerations. A BRC policy is much more likely to have a positive impact in assuring reasonable and proper expenditure of resources to control small radiological risks. Since a BRC policy implies an acceptable trade-off between benefits and cost of regulatory control, the staff believes that the concept of justification of practice must be retained, although the rigor used to evaluate justification can be reduced, to allow simple or straight-forward judgments if radiological risks are sufficiently small.

CONSIDERATION 2 - SPECIFICATION OF PRACTICES EXCLUDED FROM THE EXEMPTION POLICY

The proposed policy includes a section which describes practices which would be excluded from the exemption policy. Excluded practices would include, but not be limited to, radioactive material introduction into toys and products intended for ingestion, inhalation, or direct application to the skin (such as cosmetics). The staff believes that these classes of practice would be considered socially unacceptable regardless of how trivial the resulting dose might be.

The need to identify practices excluded from exemption policy is closely tied to the role defined by the Commission for the "justification of practice" principle. If the Commission should decide to reduce the role played by "justification of practice" as currently described in the proposed policy, the staff believes the need for identification of excluded practices would be accentuated. As currently proposed, the section on practices excluded from exemption policy provides guidance on the types of practices for which the Commission believes that use of radioactive material is not justified.

CONSIDERATION 3 - CALCULATION AND USE OF COLLECTIVE DOSE ASSESSMENTS

The collective dose can serve as both a measure of the impact of a practice on the exposed population and a mechanism for assessing the benefits of any regulatory constraints on the practice being exempted from regulatory control. The assessment or description of the components of total collective dose must be made to satisfy NEPA requirements. However, in performing cost-benefit analyses, several approaches can allow truncation or weighting factors to be applied. Use of these truncations or weighting factors can be supported if the purpose of the collective dose assessment is to discriminate between options or if large uncertainties are associated with dose assessments, particularly at very low doses or dose rates, so that assessment of certain components of collective dose serves little purpose. Three approaches are described below which could be acceptable for use in decision-making regarding practices which are candidates for exemption from regulatory control.

Individual Dose Cutoff in Collective Dose Calculations

In the background discussion accompanying the publication of the proposed 10 CFR Part 20 revision (51 FR 1113) dated January 9, 1986, application of a de minimis individual dose level cutoff was considered which would be applicable to the calculation of collective dose. The proposed application of this de minimis concept was recognized as having an influence on the evaluation of situations where very large numbers of people could be subjected to very low doses. This provision was excluded from the final Part 20 rule in deference to the formulation of the policy proposed in this statement.

In essence, the individual dose cutoff approach would disregard extremely low annual individual doses (<0.1 mrem per year) from the collective dose impacts associated with a practice being considered for exemption from regulatory control. The recommended value for the individual dose cutoff in this approach is 0.1 mrem per year which represents an individual lifetime risk of about 10^{-6}. This risk level is used by other Federal and State agencies to make judgements on the risk of chemical carcinogens both in the environment and as residual contamination in food products. In these situations, substantial numbers of people can be exposed at these individual risk levels. Typically, no actions are taken when individual lifetime risk is less than 10^{-6}, even when significant populations could be affected. Exposures of about 50 million people would have to occur at the 0.1 mrem per year level before use of the linear hypothesis would predict a societal health effect. Where collective doses to a population are evaluated, the acceptability of the associated potential risks can also be compared to the sum of the potential risks from background radiation experienced by the same population over the same time interval. Consequently, even though some practices could result in very small but finite doses to very large numbers of people, the comparative collective risk to which these people are routinely subjected is also very substantial and proportional to the number of people considered.

It should be pointed out that although the NCRP supports the cutoff concept neither the ICRP nor NRPB has accepted the use of an individual dose cutoff for collective dose calculations. The NRC's Office of General Counsel has also expressed their concern about the implications of a collective dose cutoff on past regulatory positions (e.g. mill tailings).

Assignment of Varying Monetary Values to Collective Dose Components

In assigning values to collective dose, a value of $1,000 per person-rem has been used previously by the Commission. It was first used in 10 CFR Part 50, Appendix I for determination of ALARA. However, it has been recognized that the more universal application of the $1,000 per person-rem, when applied to summation of doses representing individual risks less than 10^{-6} to 10^{-7} per year, for purposes of determining ALARA, can in some instances result in undue expenditure of resources which might better be applied to other uses.

Numerous regulatory bodies have determined that a dose on the order of 1 mrem per year represents a range of risk in which individuals are unlikely to take any actions to further reduce their risk. This level serves, in the proposed Commission Policy Statement, as a threshold for determining if a simple analysis is required for approval of an exemption, or if a more detailed analysis is necessary before approval. This level may also be an appropriate value at which to reduce the valuation applied to collective doses for purposes of ALARA or cost-benefit analysis. For example, collective dose assessments for purposes of exemption policy may be assigned monetary values as follows:

- $1,000 per person-rem for collective dose composed of individual doses in excess of 1 mrem per year.

- $100 per person-rem for collective dose composed of individual doses at or below 1 mrem per year.

The valuation of collective dose at $100 per person-rem for individual doses at or below 1 mrem per year reflects the belief that the individual risk associated with these small levels of dose does not warrant the same level of consideration as larger doses. This is not meant to imply, however, that these doses can be dismissed entirely. In keeping with the linear hypothesis for radiation protection planning, these small levels of dose should be considered when establishing that the overall detriment of the practice is adequately balanced by the benefits of the practice.

TRUNCATIONS IN TIME AND SPACE

Truncations of collective dose in either time or space have been used in the past. These truncations could continue to be used in situations where a choice between alternatives is not clarified by unbounded collective dose assessments.

Enclosure 5

Responses to Commission Questions
Regarding Basis for Prior BRC Actions
and Discussion of Uncertainty in Dose-Response Coefficients

Question:

In 1981, the Commission revised Part 20 to permit disposal of scintillation cocktails and animal carcasses containing trace concentrations of ^{14}C or ^{3}H without regard for their radioactivity. Also, specified curie amounts of both isotopes may be released annually into the sewerage system. Some regulatory control remains (e.g. recordkeeping and limitation on use of contaminated carcasses) but in effect, once released to the environment, NRC exerts no further control, thereby setting a floor to ALARA for these specific isotopes and applications. What calculations of societal and/or individual risk were employed in determination of these exempted levels? Were the models and assumptions the same as those used to arrive at tables of exempt quantities elsewhere in NRC regs?

Answer

The analysis provided with SECY-81-77, Final Amendments to 10 CFR Part 20 on Disposal of Certain H-3 and C-14 Wastes, included calculations of individual and societal risks associated with the disposal of trace concentrations of H-3 and C-14 without regard to their radioactivity. In the preamble to that final rule, estimates were provided that total quantities of radioactive material affected by the rule would be 28 Ci of H-3 and 6 Ci of C-14 annually. The unrestricted disposal of these materials (except as to their non-radioactive hazardous properties) could result in a maximum radiation dose to exposed individuals of less than 1 millirem per year, and less than 1 societal health effect over the next 1000 generations. These impacts result from one years practice under the exemption at present levels of use. Doses were derived using incineration as the disposal method, Regulatory Guide

1.109 as the basis for breathing rate assumptions and for inhalation dose conversion factors, and ORNL-4992, A Methodology for Calculating Radiation Doses from Radioactivity Released to the Environment, for dose calculational methods and associated conversion factors. Doses associated with disposal of H-3 and C-14 using the sanitary sewage system were calculated to be much lower than doses from incineration.

The exempt quantities rule was issued much earlier, in the 1960's. The modeling and criteria used in that case were much simpler; if an exempt quantity was inhaled or ingested, the critical organ would not receive a dose commitment in excess of 500 mrem.

Question:

For purposes of enforcing the many de facto BRC limits, what explicit allowance is made for instrument and measurement uncertainties?

Answer:

There are instrument and measurement uncertainties associated with manufacturing consumer products, and with NRC activities aimed at assuring compliance with regulatory restrictions placed on the manufacturer. These uncertainties, as applied to the manufacture of products for exempt distribution, are not so different from measurement uncertainties applicable to other activities involving use or release of radioactivity. Applicants for licenses to manufacture products containing byproduct material for exempt distribution are selectively required to submit "quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards that the product will be required to meet" (10 CFR 32.26(b)(15)).

With a reasonable quality assurance program, measurement and instrument inaccuracies are not a major source of uncertainty in the dose analyses for exempt products. For decommissioning and some waste forms, difficulties in fully assessing the contamination present unique problems which must be carefully considered in rulemaking or licensing actions in these areas. Assessing residual radioactivity for the purposes of license termination involves the use of historical information to "look for" potential areas of significant contamination and application of statistical analyses to estimate doses since it is impractical to sample every inch of a facility or site where there is potential for contamination. The keeping of appropriate records to assist in decommissioning planning and in termination survey design has been addressed in the recently published decommissioning rule (June 27, 1988; 53FR24018). The verification process is being considered in an ongoing Battelle PNL contract which is providing input to the development of a policy or rulemaking on residual radioactivity criteria for license termination. In

addition, some waste streams, such as dry active waste, present a particularly difficult assessment problem which must be considered in any waste stream specific BRC waste rulemaking.

Question:

What is the origin of the DOT value of 2 nanocuries per gram used to define radioactive material for purposes of transportation?

Answer:

The Department of Transportation regulations in Title 49 of the Code of Federal Regulations contain a definition of "radioactive material" which excludes materials having a specific activity not greater than 0.002 microcuries per gram. This definition was taken from the Transportation Safety Act of 1974 (P.L. 93-633), Section 108, where its applicability was limited to transportation of radioactive materials by passenger aircraft. Prior to that, the definition has had broad applicability and for many years has been included in the Regulations for the Safe Transport of Radioactive Material (Safety Series No. 6) of the International Atomic Energy Agency (IAEA).

The IAEA explanation (IAEA Safety Series No. 7) of the reason for its definition of "radioactive material" including a lower cutoff of 70kBq/kg (0.002 μci/g) is "to avoid bringing within the scope of the regulations many substances, often naturally occurring, which contain insignificant amounts of radioactivity, and which, if transported, pose no significant hazard."

As to the origin of the limit, the French CEA, following its 1968 examination of the IAEA Transport regulations, offered the following explanation to the European Atomic Energy Community-Euratom:

> Working downwards, there necessarily comes a time when the specific activity of a material is so low that it no longer presents any external or internal radiation hazards; this limit has been fixed conventionally at 0.002 μCi/g. It is a limit relating to each gram of material and not a limit relating to the nuclide itself contained in this material. Below and up to this limit, the Regulations do not apply.
>
> This value probably originated as follows: Plutonium 239 was selected as being the most representative nuclide commonly met in transport. The MPC

(air) was, according to the ICRP recommendations at that time, 6×10^{-7} $\mu Ci/m^3$ for continuous 168 hour per week exposure. Taking 0.3 mg/m^3, i.e. $3 \times 10^{-4} g/m^3$, as the dust content of polluted air, the radioactive concentration of this air which could reach the above MPC was a maximum of

$$\frac{6 \times 10^{-7}}{3 \times 10^{-4}} = 0.002 \ \mu Ci/g.$$

Today's equivalent of this number, taking the internationally recommended derived air concentration (DAC) for Pu-239 of 2×10^{-1} Bq/m^3 (5×10^{-6} $\mu Ci/m^3$) for occupational exposure at 40 hr/wk and converting for continuous exposure of the general public would be 0.0004 $\mu Ci/g$.

It is not immediately clear if this limit on the definition of radioactive material derived through consideration of the inhalation pathway would have applicability to the wide range of practices for which "below regulatory concern" determinations could justify exemptions from regulatory control.

Question:

Acceptable levels of residual surface contamination are designated in Reg. Guide 1.86. Facilities with surface contamination levels below those specified may be released for unrestricted use. How many and what types of licensee facilities have been decommissioned using these criteria?

Answer:

The "Acceptable levels of residual surface contamination" of Regulatory Guide 1.86 have been used since June of 1974 for releases of reactor facilities to unrestricted access following decommissioning. The same set of numbers was used in the decommissioning of reactors prior to issuance of Regulatory Guide 1.86 and since at least 1970. At that time these numbers were specified in a draft position from the Division of Materials Licensing dated April 22, 1970 (Attachment 1). Since April of 1970 NRR has terminated reactor licenses for 31 non-power reactors (including critical facilities) under the above surface contamination criteria.

Since 1981, NRR has added a requirement for specific gamma emitting radionuclides (Co-60, Eu-152, and Cs-137) that are not surface contamination. These radionuclides must be removed such that the radiation level from them is less than 5 microroentgens per hour above natural background as measured at one meter from the surface. Alternatively, since 1982, a licensee is permitted to demonstrate that reasonable occupancy of an area would be such that the potential exposure from these gamma-emitting radionuclides would be less than 10 mrem per year. Examples of these criteria are provided in Attachment 2.

The following summarizes the status, as of March 8, 1988, of reactors (including critical facilities) that have been shutdown with continued license or decommissioned:

Type of Licensee Facility	Number Shutdown or Decommissioned
Power, Test, and Nuclear Ship Reactors	17
Research Reactors and Critical Facilities with Continued Possession License	8
Dismantled Research Reactors	33
Dismantled Critical Facilities	17
Decommissioned Demonstration Nuclear Power Plants (DOE Owned)	4

The criteria generally used by NMSS for releasing facilities for unrestricted use are contained in two documents. These documents are (1) "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Material", (Attachment 3) and (2) Disposal or Onsite Storage of Residual Thorium or Uranium (Either as Natural Ores or Without Daughters Present) From Past Operations Provided to the Commission in SECY-81-576 dated October 5, 1981. The guidelines have been used to release on the order of 20 facilities or buildings that processed natural U or Th, Pu, enriched U or depleted U. There are also on the order of 10 facilities or buildings where release is pending the confirmatory survey or the removal of residual contamination. The criteria in the second document has been used to release land or soil on the order of 10 times. In addition, over 19 requests for release using those criteria are pending. Occasionally, site specific criteria are established. These numbers do not include facilities that may have been released by the regions.

ATTACHMENT 3

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GUIDELINES FOR DECONTAMINATION OF FACILITIES AND EQUIPMENT PRIOR TO RELEASE FOR UNRESTRICTED USE OR TERMINATION OF LICENSES FOR BYPRODUCT, SOURCE, OR SPECIAL NUCLEAR MATERIAL

U. S. Atomic Energy Commission
Division of Materials Licensing
Washington, D. C. 20545

APRIL 22, 1970

The instructions in this guide in conjunction with Tables I and II specify the radioactivity and radiation exposure rate limits which should be used in accomplishing the decontamination and survey of surfaces of premises and equipment prior to abandonment or release for unrestricted use. The limits in Tables I and II do not apply to premises, equipment, or scrap containing induced radioactivity for which the radiological considerations pertinent to their use may be different. The release of such facilities or items from regulatory control will be considered on a case-by-case basis.

1. The licensee shall make a reasonable effort to eliminate residual contamination.

2. Radioactivity on equipment or surfaces shall not be covered by paint, plating, or other covering material unless contamination levels, as determined by a survey and documented, are below the limits specified in Tables I or II prior to applying the covering. A reasonable effort must be made to minimize the contamination prior to use of any covering.

3. The radioactivity on the interior surfaces of pipes, drain lines, or ductwork shall be determined by making measurements at all traps, and other appropriate access points, provided that contamination at these locations is likely to be representative of contamination on the interior of the pipes, drain lines, or ductwork. Surfaces of premises, equipment, or scrap which are likely to be contaminated but are of such size, construction, or location as to make the surface inaccessible for purposes of measurement shall be presumed to be contaminated in excess of the limits.

4. Upon request, the Commission may authorize a licensee to relinquish possession or control of premises, equipment, or scrap having surfaces contaminated with materials in excess of the limits specified. This may include, but would not be limited to, special circumstances such as razing of buildings, transfer of premises to another organization continuing work with radioactive materials, or conversion of facilities to a long-term storage or standby status. Such requests must:

   a. Provide detailed, specific information describing the premises, equipment or scrap, radioactive contaminants, and the nature, extent, and degree of residual surface contamination.

   b. Provide a detailed health and safety analysis which reflects that the residual amounts of materials on surface areas, together with other considerations such as prospective use of the premises, equipment or scrap, are unlikely to result in an unreasonable risk to the health and safety of the public.

5. Prior to release of premises for unrestricted use, the licensee shall make a comprehensive radiation survey which establishes that contamination is within the limits specified in Tables I or II. A copy of the survey report shall be filed with the Director, Division of Materials Licensing, US/EC, Washington, D. C. 20545, and also the Director of the Regional Division of Compliance Office having jurisdiction. The report should be filed at least 30 days prior to the planned date of abandonment. The survey report shall:

   a. Identify the premises.

   b. Show that reasonable effort has been made to eliminate residual contamination.

   c. Describe the scope of the survey and general procedures followed.

   d. State the findings of the survey in units specified in the instruction.

   Following review of the report, the AEC will consider visiting the facilities to confirm the survey.

SURFACE CONTAMINATION LEVELS[1]

ISOTOPE[2]	TABLE I TOTAL[3]	TABLE I REMOVABLE[3] [4]	TABLE II TOTAL[3]	TABLE II REMOVABLE[3] [4]
U-nat, U-235, U-238, Th-nat, Th-232, and associated decay products	10,000 dpm α/100 cm^2	1,000 dpm α/100 cm^2	Average[6] 5,000 dpm α/100 cm^2 Maximum 25,000 dpm α/100 cm^2	1,000 dpm α/100
Other isotopes which decay by alpha emission or by spontaneous fission	1,000 dpm α/100 cm^2	100 dpm α/100 cm^2	Average[5] 500 dpm α/100 cm^2 Maximum 2,500 dpm α/100 cm^2	100 dpm α/100
Beta-gamma emitters (isotopes with decay modes other than alpha emission or spontaneous fission)	0.4 mrad/hr at 1 cm[5]	1,000 dpm β-γ/100 cm^2	Average[5] 0.2 mrad/hr at 1 cm[5] Maximum 1.0 mrad/hr at 1 cm[5]	1,000 dpm β-γ/10

(1) Either Table I or Table II may be used. For example, if all beta-gamma readings were less than 0.4 mrad/hr at 1 c Table I could be used; but if the maximum reading were 0.8 mrad/hr, material could be released under Table II pro- viding the average was less than 0.2 mrad/hr.

(2) Where surface contamination by both alpha and beta-gamma emitting isotopes exists, the limits established for alp and beta-gamma emitting isotopes shall apply independently.

(3) As used in this table, dpm (disintegrations per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector and count rate meter for back- ground, efficiency, and geometric factors associated with the instrumentation.

(4) The amount of removable radioactive material per 100 cm^2 of surface area shall be determined by wiping that area, with dry filter or soft absorbent paper and with the application of moderate pressure, and assessing the amount o radioactive material on the wipe with an appropriate instrument of known efficiency. In determining removable co tamination on objects of lesser surface area, the pertinent levels shall be reduced proportionally, and the entire surface shall be wiped.

(5) Measured through not more than 7 milligrams per square centimeter of total absorber.

(6) Measurements of total contaminant shall not be averaged over more than 10 square meters. For objects of lesser

Attachment 2

APR 21 1982

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Docket No. 50-141

Dr. Roland A. Finston, Director
Health Physics and Biosafety
Stanford University
67 Encina Hall
Stanford, California 94305

Dear Dr. Finston:

By letter dated March 17, 1981, we provided radiation criteria for release of the dismantled Stanford Research Reactor to unrestricted access. That criteria specified Reg. Guide 1.86 for surface contamination and 5 micro Rem per hour at one meter for reactor generated, gamma emitting isotopes.

Since March 17, 1981, we have refined further our position with respect to release criteria and have determined that radiation from gamma emitting isotopes is also acceptable if the potential exposure to individuals is less than 10 mRem per year with reasonable occupancy assumptions. If you wish to justify gamma exposure rates from reactor generated isotopes that are greater than 5 micro Rem per hour, you should show that reasonable occupancy of that area would be sufficiently less than 2000 hours per year, which would result in exposures of less than 10 mRem per year.

Sincerely,

James R. Miller, Chief
Standardization and Special
Projects Branch
Division of Licensing

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

March 17, 1981

Enclosure 2

(15)

Docket No. 50-141

Dr. Roland A. Finston
Director, Health Physics and Biosafety
Stanford University
67 Encina Hall.
Stanford, California 94305

Dear Dr. Finston:

By letters dated December 9, 1977 and June 3, 1980 you provided data on the residual activity at the dismantled Stanford Research Reactor. You further requested termination of reactor License No. R-60.

As discussed with you, we have now determined the levels of radiation that would be acceptable for release of the Stanford reactor facility to unrestricted access. Enclosure No. 1 provides that criteria. Enclosure No. 2 (Regulatory Guide 1.86) is also provided for your information.

Therefore, we can terminate License No. R-60 when our independent surveys confirm that you have removed sufficient residual radioactivity to meet the criteria of Enclosure No. 1.

By copy of this letter to the NRC Region V Office, we request that they complete a confirmatory survey when you notify the NRC that your facility is in compliance with Enclosure No. 1 criteria.

Sincerely,

John F. Stolz, Chief
Operating Reactors Branch #4
Division of Licensing

Enclosures:
1. Radiation Levels for Release to Unrestricted Access
2. Regulatory Guide 1.86

cc w/enclosure 1 only:
See next page

Enclosure 1

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RADIATION LEVELS FOR RELEASE OF REACTOR FACILITY TO UNRESTRICTED ACCESS

Surface Contamination

Surfaces must be decontaminated to levels consistent with Table 1 of Reg. Guide 1.86.

Radioactive Material Other Than Surface Contamination (Co 60, Eu 152, Cs 137)

Co 60, Eu 152 and Cs 137 that may exist in concrete, components, structures, and soil must be removed such that the radiation level from these isotopes is less than 5 µR/hr above natural background[1] as measured at one meter from surface.

General

Site survey procedures acceptable to the NRC must be used.

1) Radiation from naturally occurring radioisotopes as measured at a compareble uncontaminated structure or exterior soil surface.

ATTACHMENT 3

~~154~~ 152

GUIDELINES FOR DECONTAMINATION OF FACILITIES AND EQUIPMENT PRIOR TO RELEASE FOR UNRESTRICTED USE OR TERMINATION OF LICENSES FOR BYPRODUCT, SOURCE, OR SPECIAL NUCLEAR MATERIAL

U.S. Nuclear Regulatory Commission
Division of Industrial and
Medical Nuclear Safety
Washington, DC 20555

August 1987

The instructions in this guide, in conjunction with Table 1, specify the radionuclides and radiation exposure rate limits which should be used in decontamination and survey of surfaces or premises and equipment prior to abandonment or release for unrestricted use. The limits in Table 1 do not apply to premises, equipment, or scrap containing induced radioactivity for which the radiological considerations pertinent to their use may be different. The release of such facilities or items from regulatory control is considered on a case-by-case basis.

1. The licensee shall make a reasonable effort to eliminate residual contamination.

2. Radioactivity on equipment or surfaces shall not be covered by paint, plating, or other covering material unless contamination levels, as determined by a survey and documented, are below the limits specified in Table 1 prior to the application of the covering. A reasonable effort must be made to minimize the contamination prior to use of any covering.

3. The radioactivity on the interior surfaces of pipes, drain lines, or ductwork shall be determined by making measurements at all traps, and other appropriate access points, provided that contamination at these locations is likely to be representative of contamination on the interior of the pipes, drain lines, or ductwork. Surfaces of premises, equipment, or scrap which are likely to be contaminated but are of such size, construction, or location as to make the surface inaccessible for purposes of measurement shall be presumed to be contaminated in excess of the limits.

4. Upon request, the Commission may authorize a licensee to relinquish possession or control of premises, equipment, or scrap having surfaces contaminated with materials in excess of the limits specified. This may include, but would not be limited to, special circumstances such as razing of buildings, transfer of premises to another organization continuing work with radioactive materials, or conversion of facilities to a long-term storage or standby status. Such requests must:

   a. Provide detailed, specific information describing the premises, equipment or scrap, radioactive contaminants, and the nature, extent, and degree of residual surface contamination.

   b. Provide a detailed health and safety analysis which reflects that the residual amounts of materials on surface areas, together with other considerations such as prospective use of the premises, equipment, or scrap, are unlikely to result in an unreasonable risk to the health and safety of the public.

5. Prior to release of premises for unrestricted use, the licensee shall make a comprehensive radiation survey which establishes that contamination is within the limits specified in Table 1. A copy of the survey report shall be filed with the Division of Industrial and Medical Nuclear Safety, U. S. Nuclear Regulatory Commission, Washington, DC 20555, and also the Administrator of the NRC Regional Office having jurisdiction. The report should be filed at least 30 days prior to the planned date of abandonment. The survey report shall:

   a. Identify the premises

   b. Show that reasonable effort has been made to eliminate residual contamination.

   c. Describe the scope of the survey and general procedures followed.

   d. State the findings of the survey in units specified in the instruction.

   Following review of the report, the NRC will consider visiting the facilities to confirm the survey.

TABLE 1

ACCEPTABLE SURFACE CONTAMINATION LEVELS

NUCLIDES[a]	AVERAGE[b c f]	MAXIMUM[b d f]	REMOVABLE[b e f]
U-nat, U-235, U-238, and associated decay products	5,000 dpm α/100 cm^2	15,000 dpm α/100 cm^2	1,000 dpm α/100 cm^2
Transuranics, Ra-226, Ra-228, Th-230, Th-228, Pa-231, Ac-227, I-125, I-129	100 dpm/100 cm^2	300 dpm/100 cm^2	20 dpm/100 cm^2
Th-nat, Th-232, Sr-90, Ra-223, Ra-224, U-232, I-126, I-131, I-133	1000 dpm/100 cm^2	3000 dpm/100 cm^2	200 dpm/100 cm^2
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	5000 dpm $\beta\gamma$/100 cm^2	15,000 dpm $\beta\gamma$/100 cm^2	1000 dpm $\beta\gamma$/100 cm^2

[a] Where surface contamination by both alpha- and beta-gamma-emitting nuclides exists, the limits established for alpha- and beta-gamma-emitting nuclides should apply independently.

[b] As used in this table, dpm (disintegrations per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

[c] Measurements of average contaminant should not be averaged over more than 1 square meter. For objects of less surface area, the average should be derived for each such object.

[d] The maximum contamination level applies to an area of not more than 100 cm^2.

[e] The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with dry filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of less surface area is determined, the pertinent levels should be reduced proportionally and the entire surface should be wiped.

[f] The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 mrad/hr at 1 cm and 1.0 mrad/hr at 1 cm, respectively, measured through not more than 7 milligrams per square centimeter of total absorber.

Question:

The Commission was recently made aware of some of the history behind the licensing of 3M static eliminator devices. The general license for these devices allowed up to 5 nCi of removal activity without any action being required on the part of the general licensees. Do similar provisions exist in other licenses? What is the origin of the 5 nCi allowable leakage rate? What assumptions of risk were made to justify this number?

Answer:

The 3M static eliminator devices are used under a general license provided in §31.5 of 10 CFR Part 31, "General Domestic Licenses for Byproduct Material." Users of devices under that general license are required, with certain exceptions (set out in §31.5(c) (2)). to test the device for leakage of radioactive material at intervals no longer than six months or at such other intervals as are specified in the label on the device. Section 32.51(b) of 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material," states the information which a manufacturer must submit in an application for approval of a label which provides a test interval greater than six months.

If the test for leakage results in detection of 0.005 microcurie (5 nCi) or more removable radioactive material, the general licensee is required to immediately suspend operation of the device until it has been repaired or shall dispose of the device by transfer to a specific licensee. The general licensee also must submit to the NRC a report containing a description of the event and the remedial action taken.

Similar provisions for "leak testing," suspension of operations, remedial action, and reporting are routinely set out in specific licenses which authorize the use of licensed material in the form of a sealed source.

Radiation safety programs for the use of licensed material as a sealed source are structured on the presumption that the radioactive material will not leak from the sealed source and contaminate the environment or expose individuals to radiation. The leak test is a check on the validity of that presumption.

The 5 nCi quantity is not an allowable leakage rate. It is a point at which certain regulatory actions are to be taken. The detection of 5 nCi or more is considered as a flag or signal that safety problems may exist.

The 5 nCi quantity has been used for about 30 to 35 years in the NRC (AEC) regulatory program and in industry standards. During early use, the 5 nCi quantity applied to alpha emitting radionuclides and a 50 nCi quantity applied to beta-gamma emitters. A primary consideration in early use of these quantities was the general availability and use of instruments which could measure the quantities. In about 1960, for administrative convenience in the regulatory program and with better instruments available, use of the 50 nCi quantity was largely discontinued and a single quantity, 5 nCi, has since been used.

The 5 nCi quantity, which serves as an initiator for further actions, historically has not been justified on specific assumptions of risk. It has generally been considered a sufficiently small quantity that, by itself, presents very low levels of radiation but is readily measured. It is not used in the regulatory program or by industry as an allowable leakage rate. Further, although termed a "leak test," the usual test performed by users of sealed sources and devices containing sealed sources is a "contamination test" and a positive indication does not always indicate leakage. A positive indication does show a need for further evaluation.

UNCERTAINTY IN DOSE-RESPONSE COEFFICIENTS

The principal data base for estimating the biological effects of ionizing radiation comes from the epidemiological study of Japanese atomic bomb survivors. Pertinent details of this study through 1982 are summarized in the following table.

LIFE SPAN SAMPLE STUDY
(1950 - 1982)

Number of survivors include	91,231
Number receiving absorbed doses greater than 1 rad (to 600)	54,058
Number receiving less than 1 rad (control group)	37,173
Total deaths from all causes	31,043
Total deaths from cancer	6,270
Cancer deaths in exposed group	3,832
Cancer deaths in control group	2,438
Cancer deaths in exposed group, not bomb related, inferred	3,514
Cancer deaths in exposed group, bomb related, inferred	318

Standard Mortality Ratio: 1.09

Statistical procedures were used to infer, from control group data, the number of cancer deaths that would have occurred among the exposed group if the bomb explosions had not occurred, viz., 3,514. Subtraction of this number from 3,832, the total cancer deaths recorded for the exposed group, provides an inferred number of cancer deaths caused by atomic bomb radiation.

The Standard Mortality Ratio (SMR) shown in the table is the ratio of cancer deaths among the exposed group to those among the control group. As indicated, the SMR for this study is 1.09. To the extent that the control group experience does not match that of the exposed group had no exposure occurred, an error is introduced. Since such errors can be large, epidemiologists usually express concern only when the SMR is considerably greater than 1.09. An SMR of 1.09 implies a 9% mortality increase if the estimate of deaths that would have occurred without the radiation is without error. If this error exceeds 9%, the study results do not provide overall evidence as to whether atomic-bomb radiation-induced cancers occurred. However, more conclusive evidence can be obtained by focusing attention on specific cancer sites receiving very large absorbed doses, and these data clearly demonstrate risks in the greater than 10 rads dose region.

In the 1980-BEIR Report information is provided as to the relationship between absorbed dose and the epidemiology study sample size required to test a small absolute cancer excess, assuming that excess is actually proportional to the dose. An approximate sample size of 50,000 exposed subjects was accepted by a majority of the BEIR-III Committee for doses of 10 rads or more.

The BEIR-III Committee did not provide radiation risk coefficients for populations in which absorbed doses of less than 10 rads are received. Their report does not state that there are no risks below 10 rads; the indication is that the data base is insufficient for useful risk estimates for lower doses. This data base provides single-exposure information. The Committee provided similar coefficients for use with large irradiated populations subjected to

lifetime dose rates of 1 rad/year or more. The Committee indicated that the data could not demonstrate whether doses of about 100 mrad/year or less are detrimental, since the effects at these dose rates would be masked by environmental or other factors that produce the same types of health effects as does ionizing radiation.

For the purpose of the development of radiation protection standards, conservative assumptions have been used in order to allow progress without compromising safety. Thus, risk coefficients for doses less than 10 rads and dose rates less than 1 rad/year have been used by many regulatory programs. Such an approach has been taken by both national and international regulatory bodies and advisory groups such as NCRP, ICRP, IRPA, and IAEA. Note, it is only necessary to extrapolate one order of magnitude from the dose response coefficients provided by BEIR. If one assumes a linear dose response curve down to 100 mrem/year, the risk coefficients apply equally to any exposures no matter how small since these exposures will always be incremental doses added to the exposures that people already encounter (background, indoor radon, medical x-ray, etc.) since all people are exposed to radiation (generally in the few 100 mrem/year range).

ENCLOSURE 6

Staff Response to ACNW Comments

On July 21, 1988, the Advisory Committee on Nuclear Waste reviewed an earlier draft of the Commission paper with the proposed policy statement and other enclosures. The Committee's comments were transmitted to the Commission on August 9, 1988 and several areas of consensus have been identified in the body of the Commission paper.

The ACNW has stated that exemptions should be granted for practices whose annual and lifetime individual risks are less than 10^{-7} and 10^{-5}, respectively, and that, under these conditions, any restriction on collective dose is unnecessary. The staff agrees that risks at these levels should allow simple demonstrations of "justification of practice" and ALARA. The staff however, believes that a test of significance regarding collective dose is necessary, especially in light of the fact that the proposed policy is all-encompassing in the type and number of practices to which it can apply and that the risk levels stated are not regarded as de minimis. Furthermore the ACNW (and the staff's proposed policy) support the possibility of granting exemptions for practices involving individual doses greater than those associated with the aforementioned risk levels. These exemptions are to be based on a cost-benefit analysis (which implies a role for collective dose). Other Federal and State agency decisions on cleanup of carcingenic chemicals infer a role for

collective dose even down to implied de minimis risk levels (10^{-6} to 10^{-7} lifetime risk).

The ACNW has also recommended that the policy statement should require all past NRC exemptions to be reviewed for compatibility with the proposed policy. The staff could support this position and could develop a plan and estimate the resources needed for such an undertaking. The staff believes that committing to such an undertaking in the policy statement is premature. Similarly, the ACNW suggests that prior methodologies for performing cost-benefit analyses should be carefully reexamined. Again the staff could support this position but believes the issue does not need to be resolved prior to issuance of the policy statement or discussion of the issues at the forthcoming international workshop.

Finally, the staff believes that it has logically presented a policy addressing the entire complex issue of exemptions from regulatory control. The staff recognizes that its recommendation goes beyond the Commission's desire for a single generic number for exposures that are below regulatory concern. However, the staff believes that a policy along the lines proposed (including definition of an individual dose threshold for simple demonstration of "justification of practice" and ALARA) will have a more meaningful impact on the granting of exemptions which will assure public health and safety while fostering a more logical expenditure of resources to control levels of risk below basic standards of adequacy.

ENCLOSURE 3

(15)

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

July 23, 1983

MEMORANDUM FOR: William Lahs, Office of Research

FROM: Robert L. Fonner, Deputy Assistant General Counsel, Rulemaking and Fuel Cycle

SUBJECT: BELOW REGULATORY CONCERN POLICY STATEMENT

The policy statement, forwarded to us on July 15th, on the basis for granting exemptions from regulations for sources and practices below regulatory concern has been reviewed in OGC. I reported to you orally on the nature of OGC concerns on July 19th. I believe that it would be useful to you to have the views of OGC (at least of those who have reviewed the paper, Martin Malsch, Leo Slaggie, and myself) in writing. In sum, we believe that the approach in the paper to collective dose needs more thought to be legally defensible.

We appreciate that the Commission has requested such a statement from the staff and understand the difficulty of arriving at a consensus of views on how the issue of BRC and the related issue of " de minimis" doses should be addressed. Having attended the meetings at which the policy statement was critiqued and rewritten, I do not believe it represents a solid consensus even within the NRC. It is really the approach that seemed to elicit the least strenuous objection.

On a substantive level, we have assumed that the staff accepts the 100 mrem public dose maximum in proposed Part 20 as presenting the value at which the public is afforded adequate protection. We had discussed this matter on an earlier draft and had arrived at an understanding that exemptions of practices below this level, that did not in the aggregate exceed it, could include considerations of cost. The second principle on page 6 of enclosure 2 implies this conclusion, but it might be well to state it explicitly. Our concern flows from the litigation on the backfit rule and the Commission's subsequent affirmation of the court's position that measures needed to provide adequate protection of the public may not take into account the cost of providing the protection.

The cutoff of 0.1 mrem for collective dose consideration is troubling from at least two perspectives. First, the rationale is not clearly stated. One could imply a rejection of the linear nonthreshhold hypothesis at very low levels of individual dose and a rejection of the potential for stochastic effects at such levels. But the concept accepts stochastic effects at only a slightly higher individual dose level. No clear cut scientific rationale is discernable for the cutoff. Alternatively we could try to show that certain

collective dose health effects are not of regulatory concern. It's hard to see how one could accomplish this without expressing the cutoff in terms of a BRC collective dose rather than an individual dose cut off, and without, perhaps, being forced to adopt the unappealing proposition that one or a few deaths are BRC.

Further, by cutting off the need to consider collective dose for individual doses below 0.1 mrem a cost-benefit analysis will be skewed to the benefit side in favor of the exemption. If used in a NEPA assessment such a skewed cost-benefit analysis may be vulnerable to challenge on its adequacy. For example, if the individual doses from a candidate exempt practice or source were normally distributed and had a mean value of 0.1 mrem, close to half of the cost due to collective dose would be ignored. If collective dose calculations were to be performed for all future NEPA statements and appraisals without regard for the policy statement, then there is no legal vulnerability associated with the policy statement. But if the policy statement signals a new way of doing NEPA reviews, then the collective dose cut off will need to be justified case by case. To do this we will need a more persuasive analysis than those proposed in this paper.

OGC reviewers are also concerned about the implications of the collective dose cutoff for past regulatory positions. The prime example is in the area of mill tailings where the GEIS integrated collective dose over the population of the North American continent to arrive at a calculated annual cancer mortality of six persons from uncovered tailings. The data in the GEIS suggests that somewhere beyond 50 to 60 miles from the tailings area the individual dose from tailings would be less than 0.1 mrem per year. If a collective dose cut off had been applied the calculated mortality would have been less than six and correspondingly have reduced the benefit of the regulations in relationship to the cost of compliance.

In retrospect the approach of scaling collective doses derived from different individual doses with a dollar value may have considerable merit, so long as a zero value is never assigned. Such an approach would retain collective doses at all levels of individual dose and provide a uniform and rational means of doing cost-benefit assessments for NEPA and regulatory analysis purposes. A table of such collective dose values (xx dollars per person rem) related to levels of individual doses could even be incorporated by rulemaking into Part 51 and serve for BRC NEPA assessments the same functions that tables S-3 and S-4 serve for reactor licensing.

Robert L. Fonner

Robert L. Fonner
Deputy Assistant General Counsel

ENCLOSURE 2

UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON NUCLEAR WASTE
WASHINGTON, D.C. 20555

August 9, 1988

The Honorable Lando W. Zech, Jr.
Chairman
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Chairman Zech:

SUBJECT: ACNW COMMENTS ON PROPOSED COMMISSION POLICY STATEMENT ON REGULATORY CONTROL EXEMPTIONS FOR PRACTICES WHOSE PUBLIC HEALTH AND SAFETY IMPACTS ARE BELOW REGULATORY CONCERN (BRC)

During the second meeting of the Advisory Committee on Nuclear Waste, July 21-22, 1988, we met with the NRC staff to discuss the referenced draft report. This meeting represented a continuation of earlier discussions on this subject by the Waste Management Subcommittee of the Advisory Committee on Reactor Safeguards. As a result of these reviews, we offer the following additional comments, which were affirmed on August 4, 1988 during the third meeting of the ACNW.

We believe that the proposed Policy Statement is not presented in a logical manner, and it fails to address certain questions raised by you and your fellow Commissioners. We believe that the Policy Statement should be revised to include the following comments and suggestions:

1. Exemptions should be based on an acceptable individual annual, as well as lifetime, risk. The values proposed (10^{-7}/year and 10^{-5}/lifetime) appear reasonable. Once this guidance has been presented and justified, comparable annual and lifetime dose limits should be given. At this level of risk, we believe that the limitation on individual risk will be sufficient; we see no need to provide a limit on the collective popu...on dose.

2. We agree with the NRC staff that, in all cases, each proposed exemption should be justified. In this regard, applications involving radiation exposures to members of the public which have no offsetting benefits should not be approved. However, considerable care should be exercised in describing practices that would be termed as frivolous.

3. In those cases where an apparently useful application of radiation would result in individual risks slightly greater than the limits cited above, a cost-benefit analysis should be made to determine if the application should be designated as BRC. Prior to undertaking such efforts, however, we believe that the methodology for conducting such analyses should be carefully reexamined. Specific items needing attention include the monetary value assigned per unit of

collective dose averted. In this regard, we suggest the development of a system in which higher monetary values are used as the annual risk increases above the level considered to be BRC.

4. Finally, the Policy Statement should require that, as a part of its implementation, all existing NRC exemptions be reviewed to ensure that they are commensurate with this approach.

If these comments and suggestions are incorporated, the revised Policy Statement should be satisfactory for presentation at the upcoming International Workshop on Rules for Exemption from Regulatory Control.

Sincerely,

Dade W. Moeller

Dade W. Moeller
Chairman

Reference:
U. S. Nuclear Regulatory Commission, draft Commission paper (Predecisional) for The Commissioners from Victor Stello, Jr., EDO, Subject: Proposed Commission Policy Statement on Regulatory Control Exemptions for Practices Whose Public Health and Safety Impacts are Below Regulatory Concern (BRC), transmitted by memorandum from B. M. Morris, Director, Division of Regulatory Applications, RES, to R. F. Fraley, Executive Director, ACNW, dated July 14, 1988.