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

November 14, 1989

The Honorable Carl Levin
United States Senate
Washington, DC 20510

Dear Senator Levin:

I am responding to your two letters of October 16, 1989, which requested our views on the matters pertaining to low-level radioactive waste disposals raised by Wesley Bullock and Jennifer Simkins-Bullock and Ms. Charlotte Runnells. Although the U.S. Environmental Protection Agency is developing generally applicable environmental standards which address low level radioactive waste disposals, we, at the Nuclear Regulatory Commission, are deeply involved with the issues raised by Ms. Runnells. These two letters, in fact, raise concerns common to several letters which the NRC has recently received from citizens of Michigan (re: the letter from Mr. Ken Russell which you forwarded to us on April 3, 1989).

As the Bullocks indicate, they had previously sent a letter to us in which they requested and were provided with further information on this subject. At the request of another Grand Rapids citizen, Mrs. Corinne Carey, we have also recently sent similar information to Mr. Marvin Hiddema, a Kent County Commissioner.

In responding to these citizens' concerns, I would point out that the Commission has neither evaluated nor published any proposed regulations that would allow disposal of low-level waste as mandated under the below regulatory concern (BRC) provisions of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (P.L. 99-240, Section 10). Thus, the Bullocks have incorrectly presumed a schedule for a Commission action on this subject. In 1986, in compliance with the Act, the Commission did adopt a final policy that established the standards and procedures that will permit us to act upon any BRC rulemaking petitions that we might receive. On December 2, 1986, we also published an Advanced Notice of Proposed Rulemaking that solicited public comments on the issue of BRC waste disposal. Most recently, the Commission has been developing a broadly applicable policy statement that would establish the principles and criteria that would govern Commission decisions related to the exemption of radioactive materials from some or all regulatory control. The policy is intended to provide the public health and safety framework that would be applied to the development of appropriate regulations on issues such as BRC waste disposal. As a key step in this initiative, the Commission issued for public comment the enclosed Federal Register Notice on December 12, 1988. You may recognize this notice as the one transmitted in our May 2, 1989 letter to you, which responded to the concerns of Mr. Russell. We have received, and continue to receive, responses to this notice which now total approximately 250 letters. The issues raised in these letters are being considered by the Commission, and we anticipate that the statement will be issued later this year or in early 1990.

CCS2
1/1

With respect to the specific points raised by the Bullocks, the NRC is aware that the nation's nuclear utilities are funding research to determine, in the industry's view, what low-level radioactive waste could be potentially classified as "below regulatory concern." The industry's preliminary estimates indicate that thirty percent (by volume) of low-level radioactive waste originating at nuclear power plants sites may be considered "BRC." However, the total amount of radioactivity in this waste is only about 0.01 percent of that contained in all low-level waste generated at these sites.

The Bullocks also stated that, ". . . there is a growing evidence that exposure to low-levels of ionizing radiation have much greater negative health effects than previously assumed . . . ." The Bullocks may be referring to estimates recently made by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR). These estimates were made primarily based upon the Japanese atomic bomb survivors, and pertain to the high doses and dose rates associated with those exposures. The dose levels, which would be associated with practices such as BRC waste disposal, are significantly smaller than those received by the bomb survivors. In fact, because these doses are a small fraction of natural background exposures, there is no direct evidence upon which risk estimates at such doses may be based. As a result, the Commission has used advice from various scientific committees, including UNSCEAR and the National Council on Radiation Protection and Measurements, to extrapolate the risk estimates applicable to the bomb survivors to the values used at low doses and dose rates as a cautious assumption for establishing exposure limits to the public. The Commission is using these estimates and other relevant information in formulating its exemption policy.

In closing, I want to assure you that we take our mandate to protect the health and safety of the public very seriously. As a result, the issues raised by the Bullocks, Ms. Runnells, and other concerned citizens are being carefully considered.

Sincerely,

James M. Taylor
Acting Executive Director
for Operations

Enclosure:
As stated

November 14, 1989

The Honorable Carl Levin
United States Senate
Washington, DC 20510

Dear Senator Levin:

I am responding to your two letters of October 16, 1989, which requested our views on the matters pertaining to low-level radioactive waste disposals raised by Wesley Bullock and Jennifer Simkins-Bullock and Ms. Charlotte Runnells. Although the U.S. Environmental Protection Agency is developing generally applicable environmental standards which address low level radioactive waste disposals, we, at the Nuclear Regulatory Commission, are deeply involved with the issues raised by Ms. Runnells. These two letters, in fact, raise concerns common to several letters which the NRC has recently received from citizens of Michigan (re: the letter from Mr. Ken Russell which you forwarded to us on April 3, 1989).

As the Bullocks indicate, they had previously sent a letter to us in which they requested and were provided with further information on this subject. At the request of another Grand Rapids citizen, Mrs. Corinne Carey, we have also recently sent similar information to Mr. Marvin Hiddema, a Kent County Commissioner.

In responding to these citizens' concerns, I would point out that the Commission has neither evaluated nor published any proposed regulations that would allow disposal of low-level waste as mandated under the below regulatory concern (BRC) provisions of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (P.L. 99-240, Section 10). Thus, the Bullocks have incorrectly presumed a schedule for a Commission action on this subject. In 1986, in compliance with the Act, the Commission did adopt a final policy that established the standards and procedures that will permit us to act upon any BRC rulemaking petitions that we might receive. On December 2, 1986, we also published an Advanced Notice of Proposed Rulemaking that solicited public comments on the issue of BRC waste disposal. Most recently, the Commission has been developing

for Operations

Enclosure:
As stated

See next page for Distribution

*See previous concurrences

OFFC	RPHEB:DRA*	RPHEB:DRA*	DD:DRA *	D:DRA*	DD/GI:RES*	D:RES*	AE[illegible]	OGC
NAME	WLahs:	DCool	ZRosztoczy	BMorris	TSpeis	EBeckjord	JATaylor	
DATE	11/02/89	11/02/89	11/02/89	11/02/89	11/3/89	11/3/89	11/13/89	11/14/89

OFFICIAL RECORD COPY

NUCLEAR REGULATORY COMMISSION

10 CFR Ch. I

Policy Statement on Exemptions From Regulatory Control

AGENCY: Nuclear Regulatory Commission.

ACTIONS: Advance notice of proposed statement and meeting.

SUMMARY: The NRC is in the process of developing a broad policy on exemptions from regulatory control for practices whose health and safety impacts could be considered below regulatory concern. This policy statement would provide for more efficient and consistent regulatory actions in connection with exemptions from various specific Commission requirements. The Commission, in formulating this Advance Notice, is seeking public input on some specific

questions which are key considerations in developing such a policy. The NRC staff will conduct a meeting to inform the public of its intentions, specifically to clarify and answer questions concerning the advance notice, and to hear preliminary views concerning a policy for exemptions with emphasis on the specific questions raised by the Commission.

DATES: Meeting to be held on January 12, 1989. Written comments should be submitted by January 30, 1989. Comments received after this date will be considered if it is practical to do so, but assurance of consideration can only be given as to comments received on or before this date.

ADDRESSES: Meeting will be held at the Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD 20814 (4 blocks north of the Bethesda Metro Station). Telephone: (301) 652-2000, 1-800-465-4329. Mail written comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC, 20555, Attention: Docketing and Service Branch. Comments may be delivered to 11555 Rockville Pike, Rockville, MD between 7:30 a.m. and 4:15 p.m. weekdays. Copies of the comments received may be examined and copied for a fee at the NRC Public Document Room at 2120 L Street, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Catherine R. Mattsen, telephone (301) 492-3638, or William R. Lahs, telephone (301) 492-3774, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC, 20555.

SUPPLEMENTARY INFORMATION:

International Workshop

In addition to conducting this public meeting, the Commission has sought input from the international regulatory community through an international workshop on exemptions from regulatory control which was held October 17-19, 1988 in Washington, DC. The importance of such interaction stems from the fact that many existing and potential exemptions involve radioactive materials purposefully used in consumer products or introduced into various products or materials through the recycling of contaminated scrap, either of which may enter international trade. Even effluents and waste disposal can involve exposures to people in countries other than those from which the effluent or waste originated. This aspect is a significant issue in the European community. Thus, some degree of consistency internationally is desirable, since exemption decisions can affect populations outside each country's border. It is hoped that exchanges of ideas and information such as occurred at the international workshop will, besides providing one avenue of input to the Commission's actions, lead toward a greater degree of consistancy in such exemptions worldwide. At the international workshop, the "Advance Notice of the Development of a Commission Policy on Exemptions from Regulatory Control for Practices Whose Public Health and Safety Impacts are Below Regulatory Concern", presented in this notice, was made available for discussion. The transcript of the international workshop which includes all the papers presented at the meeting may be examined and copied for a fee at the NRC Public Document Room at 2120 L Street, NW., Washington, DC.

Advance Notice of the Development of a Commission Policy

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 development 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 an activity or 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. Under this policy, the definition of "practice" is a critical feature which will assure that the formulation of exemptions from regulatory control will not allow deliberate dilution of material or fractionation of a practice for the purpose of circumventing controls that would otherwise be applicable.

The purpose of this policy statement is to establish the basis upon which the Commission may initiate the development of appropriate regulations or make licensing decisions to exempt from regulatory control persons who receive, possess, use, transfer, own, or acquire certain radioactive material. This policy is directed principally toward rulemaking activities, but may be applied to license amendments or license applications involving the release of licensed radioactive material either to the environment or to persons who would be exempt from Commission regulations. It is important to emphasize that this policy does not assert an absence or threshold of risk but rather establishes a baseline where further government regulations to reduce risks is unwarranted.

The concept of regulatory exemptions is now new. For example, in 1960 and 1970, the Commission promulgated tables of exempt quantities and concentrations for radioactive material which a person, under certain circumstances, could recieve, possess, use, transfer, own, or acquire without a requirement for a license (25 FR 7875, August 17, 1960 and 35 FR 6426, April 22, 1970). 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 Radioactive Waste Policy Amendments Act of 1985 directed the Commission to develop standards and procedures for expeditious handling of petititons 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 on August 29, 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 exemption 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 pay 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.

Advisory and scientific bodies have offered diverse views to the Commission in anticipation of this Policy Statement. There is not clear consensus based on existing scientific evidence or research regarding the selection of numerical criteria for use in this Policy Statement. Further, the Commission is aware that there are differing views within the NRC staff on the selection of numerical criteria for BRC.

In the absence of a scientific consensus, it is the Commission's task to assess the diversity of views in establishing a responsible BRC policy. The authority and responsibility to make the final selection of criteria rests with the Commission. Criteria selected must: (1) Provide reasonable assurance that public health and safety will be protected, and (2) consistent with such assurance, permit practices in the public domain which involve the use of radioisotopes for which society perceives a demand.

It is recognized that there is a delicate balance here. Criteria can be set sufficiently restrictive such that there is absolute assurance that health and safety will always be protected, no matter what events might transpire. However, in doing so, the regulator may then place undue and unnecessary restrictions on practices which should be permitted because of otherwise reasonable social, economic, or industrial considerations. There is always the danger of over-regulation which results in effects that are felt in areas where the NRC does not have authority and responsibility. Moreover, the Atomic Energy Act does not require absolute assurances of safety in the use of radioactive material and licensed facilities.

The numerical criteria ultimately selected will have significant impact on nuclear regulation here in the United States and potentially in the international community. The values under consideration in this Policy Statement do not necessarily agree with those selected or under consideration by other countries. The Commission has carefully reviewed these alternate criteria, and does not find significant scientific evidence that would dictate preferential selection of any of those views over what is proposed in this Policy Statement.

Radiation Protection Principles

The Commission recognizes that three fundamental principles of radiation protection have historically guided the formulation of a system of dose limitation to protect workers and the public from the potentially 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 adequate protection for a member of the public which should 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. The Commission is interested in assessing how these principles should be applied in establishing appropriate criteria for release of radioactive materials from regulatory control.

Because of the absence of observed health effects below 5 rem/year (50 mSv/year), scientific experts including the International Commission on Radiological Protection (ICRP) and the National Council on Radiation Protection and Measurements (NCRP) make the assumption that the frequency of occurrence of health effects per unit does at low dose levels is the same as at high doses (10 RAD (0.1 Gy)) where health effects have been observed and studied in humans and animals. This linear non-threshold hypothesis assumes that the risk of radiation induced effects (principally cancer) is linearly proportional to dose, no matter how small the dose might be. The coefficient used in the model as a basis for estimating statistical health risk is on the order of 2×10^{-4} risk of fatal cancer per person-rem of radiation dose (2×10^{-2} per SV). The Commission recognizes that it is a conservative 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. Alternative hypotheses have been proposed and reevaluations of the data base at higher doses continue. The Commission believes that use of the linear non-threshold hypothesis allows the theoretical establishment of upper limits on the numbers of health effects that might occur at very low doses which are the subject of the exemption policy.

The risk of death to an individual, as calculated using the linear model is shown in Table 1 for various defined levels of individual dose. A radiation exposure of 10 mrem per year (0.1 mSv per year) for a lifetime corresponds theoretically to an increase of 0.1% of the individual's annual risk of cancer death. The lifetime risk is based upon the further assumption that the exposure level is the same for each year of a 70-year lifetime.

In estimating the dose rates to members of the public that might arise through the use of various practices for which exemptions are being considered, the Commission has decided to apply the concept of the "effective dose equivalent." This concept, which is based on a comparison of the delayed mortality effects of ionizing radiation exposures, permits through use of weighting factors, the calculation of the whole body dose equivalent of partial body exposures. This approach was originally developed by the International Commission on Radiological Protection and was first expressed in its Publication 26 issued in 1977. Since that time, the concept has been reviewed and evaluated by radiation protection organizations throughout the world and has gained wide acceptance.

TABLE 1 [1]

Incremental annual dose	Incremental annual risk	Lifetime risk from continuing annual dose
100 mrem [2]	2×10^{-2}	1×10^{-1}
10 mrem [2]	2×10^{-3}	1×10^{-2}
1 mrem	2×10^{-4}	1×10^{-3}
0.1 mrem	2×10^{-5}	1×10^{-4}

[1] Risk coefficient of 2×10^{-4} per rem (2×10^{-2} per Sv) based upon publications of the ICRP.

[2] For purposes of comparison, the annual risk to an individual of dying from cancer from all sources in the U.S. is 1 in 500. The additional risk to an individual of dying from cancer when exposed to 10 mrem (0.1 mSv) is 2 in one million.

[3] Unless otherwise indicated, the expression of dose in mrem refers to the Total Effective Dose Equivalent. This term is the sum of the deep dose equivalent for sources external to the body and the committed effective dose equivalent for sources internal to the body.

The Commission recognizes that it is impossible to measure risk to individuals or populations directly, and,

that in most situations, it is impractical to measure annual doses to individuals at the low levels implied by exemption decisions. Typically, radioisotope concentrations or radiation levels from the material to be exempted are the actual measurements that can be made, and doses are then estimated by exposure pathway analysis combined with other types of assumptions related to the ways in which people might become exposed. Under such conditions, conservative assumptions are frequently used in modeling so that the actual dose is on the low side of the calculated dose. The Commission believes that this is the appropriate approach to be taken when determining if an exemption from regulatory controls is warranted.

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 a factor to consider in balancing benefits and societal impact.

Considerations in Granting Exemptions From Regulatory Control

The following elements are being considered by the Commission as a basis for evaluating practices which are proposed to be exempt from regulatory control. These practices, if approved, would result in products containing low levels of radioactive material being distributed to the general public and radioactive effluents and solid waste being released to areas of the publicly-accessible environment.

• Justification—The Commission seeks comment on the extent to which exposures resulting from any practice should be justified. As lower levels of radiation exposure are projected, should lower levels of benefit be required for practice justification? In establishing its exemption policy, should the Commission exclude certain practices for which there appears to be no reasonable justification? In considering proposals for exemptions, should the Commission evaluate the social acceptability of practices? Should the Commission determine a practice to be unjustified if nonradioactive economical alternatives exist?

• Dose Limits and Criterion—Individual doses from practices exempted under this policy should not be allowed to exceed 100 mrem per year (1 mSv per year). This is the dose limit for members of the public specified in the final revision of 10 CFR Part 20, Standards for Protection Against Radiation. The dose limits in the final revision of 10 CFR Part 20 apply to all sources of radiation exposure under a licensee's control (natural background and medical exposures are excluded). Because of the small risks involved, a 10 mrem (0.1 mSv) individual dose criterion is proposed as the basis for exemption decisions based on simple analysis and judgements. The Commission specifically seeks comment on the need for establishing a collective dose limit in addition to an individual dose criterion. If such a collective dose criterion is needed, what is the basis for this need? If the Commission decides that a collective dose criterion is needed, what approaches allowing truncation of individual dose in calculation of collective dose or weighting factors for components of collective dose would be appropriate? What alternatives should be considered for assessing societal impact?

• ALARA—The ALARA principle generally applies to determining dose levels below which exemptions may be granted on a cost-benefit basis. However, it is the purpose of this policy to establish criteria which would, in effect, delineate achievement of ALARA without cost-benefit analysis.

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. The Commission believes that a key consideration in establishing a policy for exemptions, and subsequently in specific rulemaking or licensing decisions, is the question of whether individuals may experience radiation exposure approaching the limiting values through the cumulative effects of more than one practice, even though the exposures from each practice are only small fractions of the limit. The Commission specifically seeks comment on the issue. By appropriate choices of exemption criteria and through its evaluations of specific exemption proposals in implementing the policy, the Commission intends to assure that it is unlikely that any individual will experience exposures which exceed the 100 mrem per year (1 mSv per year) limit.

Principles of Exemption

A major consideration in exempting any practice 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 dose received by individuals within the critical group and by the exposed population or;

2. The costs of the regulatory controls that could be imposed for dose reduction are not balanced by the commensurate reduction in risk 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 the 100 mrem per year (1 mSv per year) limit 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 and attendant risks to members of the exposed population decrease, the need for regulatory controls decreases and the analysis needed to support a proposal for exemption can reasonably be somewhat simplified.

The Commission is evaluating the use of two numerical criteria in defining the region where ALARA has been achieved. They are: (a) A criterion for the maximum individual annual dose reasonably expected to be received as a result of the practice and (b) a measure of societal impact to the exposed population. These criteria are being considered to assure that, for a given exempted practice, no individual will be exposed to a significant risk and that the population as a whole does not suffer a significant impact.

If the individual doses from a practice under consideration for exemption are sufficiently small, the attendant risks will be small compared with other societal risks. The Commission believes that annual individual fatality risks below approximately 10^{-6} (one in 100,000) are of little concern to most members of society. Providing for some margin below this level, the Commission proposes 10 mrem (0.1 mSv) as the level of annual individual exposure. The incremental annual individual cancer fatality risk associated with an exposure level of 10 mrem per year (0.1 mSv per year) is about 2×10^{-6} (two in one million) as indicated in Table 1 and of the order of 0.1 percent (one in one thousand) of the overall risk of cancer death.

In evaluating the need for a collective dose criterion, the Commission recognizes that this criterion could be the limiting consideration for practices involving very small individual doses to very large numbers of people. It is also

recognized that in such cases the collective dose criterion would, in effect, apply the ALARA concept to individual doses less than the below regulatory concern level of 10 mrem per year to the individual. Conversely, where the collective dose criterion would not be limiting, it would serve no purpose. The Commission requests comments on this issue, including comments on what the magnitude of the collective dose criterion, if any, should be.

If the dose is less than the below regulatory concern criteria, then the risk from a practice would be considered to be ALARA without further analysis. The Commission stresses that adoption of the criteria should not be construed as a decision that smaller doses are necessary before a practice can be exempted, while doses above the criteria would preclude exemptions. On the contrary, the criteria simply represent a range of risk which the Commission believes is sufficiently small compared to other individual and societal risks that a cost benefit analysis is not required in order to make a decision regarding the acceptability of an exemption. Practices not meeting these criteria may be granted exemptions on a case-by-case basis in accordance with the principles embodied within this policy. To further emphasize the Commission's recognition that a rigid limitation on collective dose would be inappropriate, it notes that for some practices, such as use of smoke detectors, appreciable benefits can only be attained through extensive utilization and, hence, with a commensurate collective dose.

The Commission is aware that existing regulations of the Environmental Protection Agency establish criteria more restrictive than exemptions which could otherwise be granted under this proposed policy. With regard to its own regulations, the Commission will evaluate whether there are exemption criteria embodied therein for which modification, according to the principles of this policy, would be beneficial.

Exclusions From Exemptions

The Commission's March 18, 1965, notice on the Use of Byproduct Material and Source Material-Products Intended for use by General Public (Consumer Products) (30 FR 3462) provides the basis for the Commission's approval of the use of these materials in consumer products without regulatory control on the consumer-user. This is accomplished by case-by-case exemption of the possession and use of approved items from applicable licensing requirements. Approval of a proposed consumer product depends upon an assessment of exposures of persons to radiation as well as an evaluation of the usefulness of the product.

Certain practices involving radiation or radioactive materials have been judged by NRC to be socially unacceptable regardless of how trivial the resulting dose might be and, therefore, have been excluded from exemption. Excluded practices include, but are not 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).

In addition to socially unacceptable uses of radioactive materials, a question also arises regarding uses where there are clear economical alternatives, and no unique benefits exist from using radioactive material. Where risks are trivial, the regulatory prohibition of such uses could pose an unnecessary regulatory burden by interfering with the conduct of business.

The Commission seeks comments on whether practices should be categorically excluded based on the Commission's judgement regarding social acceptability or the existance of alternatives. An alternative to categorical exclusion could be a case specific determination based on a safety analysis.

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 dose and societal impact resulting from the expected activities under the exemption, including the use 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 proposal 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.

In evaluating proposals for exemption under this policy, the projected exposures to different components of the exposed population will be considered with regard to the potential that some individuals may receive doses near the 100 mrem per year (1 mSv per year) limit when doses from other practices are also taken into consideration. If exposures from multiple practices can occur which are significantly beyond the individual dose criterion (10 mrem per year (0.1 mSv per year)), the exemption will not be granted without further analysis. As experience is gained, this policy and its implementation will be reevaluated with regard to this issue to assure that the exposures to the public remain well below 100 mrem per year (1 mSv per year).

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 individuals and collective dose.

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.

Tentative Meeting Agenda

I. Introduction and Summary NRC Staff

II. Discussion of Specific Questions-Brief NRC Staff summary and presentations or questions from scheduled participants.

A. Application of principle of justification including the questions:

1. As lower levels of radiation exposures are projected, should lower levels of benefit be required for justification of a practice which is a candidate for exemption?
2. In establishing exemption policy, should the Commission exclude certain practices for which there appears to be no reasonable justification?
3. In considering proposals for exemption, should the Commission evaluate social acceptability of the practice?
4. Should the Commission determine a practice to be unjustified if non-radiological economical alternatives exist?

B. Individual dose criterion for determining achievement of the "as low as reasonably achievable" (ALARA) principle in exemption decision-making:

1. Is the 10 mrem/year criterion proposed by the Commission appropriate?
2. Is the appropriateness of this number affected by the decision regarding whether a collective dose criterion should be used with the individual dose criterion?
3. Should the individual dose criterion be chosen on the basis of negligible risk as is done internationally (i.e., IAEA Safety Series No. 89) or can a somewhat higher number be used based on a Commission policy decision regarding a level of individual risk for which expenditure of resources is not warranted?
4. How important is international consistency in choosing an individual dose criterion?

C. Use of a collective dose criterion for determining achievement of the ALARA principle in exemption decision-making:

1. Is a collective dose criterion needed in addition to an individual dose criterion?
2. If so, what is the basis of that need?
3. If the Commission decides a collective dose criterion should be used, what should its magnitude be?
4. What alternative to a collective dose criterion should be considered for assessing societal impact?
5. In calculating collective dose, what approaches allowing truncation of individual doses or the use of weighting factors for components of collective dose are appropriate?

D. Approaches for assuring total exposures of individuals from multiple practices will not exceed the 100 mrem/year limit.

1. Is the approach of generally limiting individuals doses from each source or practice to a fraction of the overall limit appropriate?
2. Although most exempted sources would be expected to involve individual doses which are a small fraction of the overall limit, should flexibility be maintained by considering exemptions on a cost-benefit basis above 10 mrem/year?
3. Is the evaluation of collective dose important in considering the multiple exposure issue?
4. Will the application of justification of practice help to maintain a smaller number of sources making it easier to control overall exposures?
5. How important is monitoring to maintaining assurance that individual exposures do not exceed to the overall limit?

III. General Discussion/Question Period-Comments or questions by scheduled participants. Open to the floor as time permits.

Those members of the public who wish to participate by speaking at the meeting should notify one of the contacts listed above, so that they can be scheduled in the agenda.

Dated in Rockville, Maryland, this 2d day of December 1988.

Victor Stello, Jr.,

Executive Director for Operations.

[FR Doc. 88-28491 Filed 12-6-88; 8:45 am]

BILLING CODE 7590-01-M