CG/RESP.?

Amy Gesler
East Fairchild
1855 Sheridan Road
Evanston, IL 60201

DEC 6 1989

Dear Ms. Gesler:

I am writing in response to your October 31, 1989 letter concerning the disposal of slightly contaminated low-level radioactive waste in sanitary landfills. The Nuclear Regulatory Commission (NRC) published an advanced notice on this subject for public comment on December 12, 1988 (enclosed). A final policy statement is now under development and is expected to be published before the end of the year. Your letter has been docketed with other public comments on this matter.

Your letter expressed concern with any policy that would relax restrictions on the disposal of certain low-level radioactive wastes. Please be assured that, if this policy is made final, the kinds of radioactive materials that could eventually be disposed of at landfills would be precisely specified. The levels of radioactivity would be controlled so that radiation exposure would be within the approved safety limits for which the available scientific evidence indicates no significant health effects. Under the proposed policy, before acting to exempt a specific type of waste from regulatory control, the Commission would provide opportunity for public comment and would make available for public scrutiny the analyses supporting its proposed decision. Your views on any such future exemption action would be welcomed and taken into consideration prior to a final NRC decision.

Thank you for your interest in this matter.

Sincerely,

Michael J. Bell, Chief
Regulatory Branch
Division of Low-Level Waste Management
and Decommissioning
Office of Nuclear Material Safety
and Safeguards

Enclosure: As Stated

Distribution:	LLWM 89-138	Central File# 214.5	NMSS r/f	LLRB r/f
CGlenn	RBoyle	MBell	RBangart	PLohaus
JSurmeier	BLahs/RES	JLepre	LLRB t/f	
PDR YES X	NO ___	Category: Proprietary	___ or CF Only	___
ACNW YES ___	NO X			

SUBJECT ABSTRACT: RESPONSE TO STUDENT ON BRC

OFC	:LLRB	:LLRB	:LLRB	:
NAME	:CGlenn/es	:RBoyle	:MBell	:
DATE	:12/6/89	:12/6/89	:12/6/89	:

OFFICIAL RECORD COPY

8912200004 891206
PDR WASTE
WM-3 PDC

delete ACNW 4 11.4 WM-3 NL141

Administration (13 CFR 121.2) has defined small agricultural producers as those having annual gross revenue for the last three years of less than $500,000, and small agricultural service firms are defined as those whose gross annual receipts are less than $3,500,000. The majority of handlers and producers of South Texas lettuce may be classified as small entities.

As of October 14, 1988, estimated South Texas lettuce acreage planted was 1,086 acres compared to 476 acres at the same time in 1987. Total plantings for the 1988–89 season are expected to approximate 2,500 acres, which is up considerably from last year's total of 1,629 acres. Total shipments of South Texas lettuce for the 1987–88 crop were approximately 738,000 cartons. Total shipments for the 1988–89 crop are projected by the committee at 750,000 cartons. The majority of the crop is shipped to the fresh markets, with only a small volume utilized by processors.

The handling requirements for South Texas lettuce are specified in § 971.322 (51 FR 2, January 2, 1986). The current requirements for South Texas lettuce specify the inside dimensions of the four containers that may be used to pack lettuce and the number of heads that may be packed per container. Additionally, inspection is required and packaging lettuce on any Sunday or on Christmas Day is prohibited.

This proposed rule would authorize a new container for shipping South Texas lettuce and change the beginning of the effective period for the handling regulation for December 1 to November 15. These changes were unanimously recommended by the South Texas Lettuce Committee.

The four containers currently authorized under the handling regulation do not have the correct dimensions necessary to be properly stacked on pallets. The recommended new container, with inside dimensions of 23¼ inches (length) × 15¼ inches (width) × 10⅜ inches (depth), is of proper size to be palletized. The dimensions of a standard pallet are 48 inches (length) × 40 inches (width). The recommended container would be stacked in layers of five on the pallet and 100 percent pallet utilization would be possible when using such container.

The majority of lettuce shipped from California and Arizona, the top two lettuce producing States, is shipped on pallets. The use of pallets reduces the handling of individual containers, which in turn reduces damage caused by excessive handling and reduces handling costs. Palletized loads are preferred by produce warehouses and retail outlets because of the ease of loading and unloading palletized merchandise by fork lifts and pallet jacks. Authorizing a container of the correct size to be palletized should facilitate the efficient movement of lettuce from the packinghouse to the consumer.

The use of this container would enable lettuce shippers to take advantage of the benefits derived by the use of pallets. Texas lettuce shippers would also be able to fill orders for palletized loads and compete with California and Arizona shippers for this market. The proposed container is designated as carrier container No. 79–47, which is consistent with the manufacturers identification number. In addition, the proposed regulation would require that only 18, 24, or 30 heads of wrapped and unwrapped lettuce may be packed in this container. Packing 24 or 30 heads of lettuce in the proposed container is the industry norm. However, the committee believes it is necessary to include the 18-count limit to allow for packing larger heads of lettuce.

In recent years, the shipping season for South Texas lettuce has begun in late November rather than early December. This shift has been caused by changes in cultural practices, such as the use of black plastic and the transplanting of seedlings. The committee has recommended that the beginning of the effective period for the handling regulation be changed from December 1 to November 15 wo that it will coincide with the shipping season. This action will ensure the uniform application of marketing order requirements to all shipments of South Texas lettuce.

Based on the above, the Administrator of AMS has determined that this action would not have a significant economic impact on a substantial number of small entities.

A 30-day comment period is provided to allow interested persons sufficient time to respond to this proposal. All written comments timely received will be considered before a final determination is made on this matter.

List of Subjects in 7 CFR Part 971

Marketing agreements and orders, Lettuce, South Texas.

For the reasons set forth in the preamble, it is proposed that 7 CFR Part 971 be amended as follows:

PART 971—LETTUCE GROWN IN LOWER RIO GRANDE VALLEY IN SOUTH TEXAS

1. The authority citation for 7 CFR Part 971 continues to read as follows:

Authority: Secs. 1–19, 48 Stat. 31 as amended; 7 U.S.C. 601–674.

2. Section 971.322 is amended by revising the introductory text, redesignating paragraphs (a)(4) and (a)(5) as (a)(5) and (a)(6), respectively, and adding new paragraphs (a)(4) and (b)(3) to read as follows:

§ 971.322 Handling regulation.

During the period beginning November 15 and ending March 31 each season, no person shall handle any lot of lettuce grown in the production area unless such lettuce meets the requirements of paragraphs (a), (b), and (c) of this section, or unless such lettuce is handled in accordance with paragraph (d) or (e) of this section. Further, no person may package lettuce during the above period on any Sunday, or on Christmas Day unless approved in accordance with paragraph (f) of this section.

(a) • • •

(4) Cartons with inside dimensions of 10⅜ inches × 15¼ inches × 23¼ inches (designated as carrier container No. 79–47), or

• • • • •

(b) • • •

(3) Lettuce heads in carrier container No. 79–47 may be packed only 18, 24, or 30 heads per container.

Dated: December 7, 1988.

Robert C. Keeney,

Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 88–28450 Filed 12–8–88; 8:45 am]

BILLING CODE 3410–02–M

NUCLEAR REGULATORY COMMISSION

10 CFR Ch. I

Policy Statement on Exemptions From Regulatory Control

AGENCY: Nuclear Regulatory Commission.

ACTION: 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 to 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 consistency 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 6428; 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 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 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 these 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 dose 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 number 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^{-3}
10 mrem [2]	2×10^{-3}	1×10^{-4}
1 mrem	2×10^{-4}	1×10^{-5}
0.1 mrem	2×10^{-5}	1×10^{-6}

[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 26, 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 [illegible] need?
3. If the Commission decides [illegible] 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 ensuring that 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 constrain a sizable number of sources making it easier to control overall exposures?
5. How important is maintaining to maintaining assurance that individual exposures do not exceed to the overall limit?

III. General Discussion/Questions Period-Comments or questions by scheduled participants. Open to the floor at this point.

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. 88-28001 Filed 12-9-88; 8:45 am]

BILLING CODE 7590-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 88-ASW-48]

Airworthiness Directives; Sikorsky Aircraft Model S-76 Series Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This notice proposes to adopt a new airworthiness directive (AD) that would require a service life limit on the tail rotor horn on Sikorsky Model S-76 series helicopters. The proposed AD is needed to prevent a fatigue failure of the tail rotor horn which could result in loss of directional control of the helicopter and subsequent loss of the helicopter.

DATE: Comments must be received on or before January 31, 1989.

ADDRESSES: Comments on this proposal may be mailed in duplicate to: Rules Docket, Office of the Assistant Chief Counsel, FAA, Fort Worth, Texas 76101-0007, or delivered in duplicate to: Office of the Assistant Chief Counsel, Room 154, Building SB, 4400 Blue Mound Road, Fort Worth, Texas. Comments must be marked: Docket No. 88-ASW-48. Comments may be inspected at the above location between the hours of 8 a.m. and 4 p.m. weekdays, except Federal holidays.

A copy of the applicable service bulletin may be obtained from Sikorsky Aircraft, 600 Main Street, Stratford, Connecticut 06601-1381, or may be examined in the Regional Rules Docket, Office of the Assistant Chief Counsel, FAA, 4400 Blue Mound Road, Fort Worth, Texas.

FOR FURTHER INFORMATION CONTACT: Donald P. Thompson, Aircraft Certification Branch, ANE-152, Boston Aircraft Certification Office, New England Region, FAA, 12 New England Executive Park, Burlington, Massachusetts 01803, telephone (617) 273-7115.

SUPPLEMENTARY INFORMATION: Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments will be considered by the FAA before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket, Office of the Assistant Chief Counsel, FAA, 4400 Blue Mound Road, Forth Worth, Texas, for examination by interested persons. A report summarizing each FAA-public contact, concerned with the substance of the proposed AD, will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: Comments to Docket No. 88-ASW-48. The postcard will be date/time stamped and returned to the commenter.