

9441.1990(23)

MUNITIONS REGULATED AS HAZARDOUS WASTES

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 21 1990

MEMORANDUM

SUBJECT: RCRA Applicability to Military Munitions

TO: James Reidy, P.E., Chief
Caribbean Facilities Section (2AWM-HWF)

FROM: Sonya M. Sasseville, Chief
Alternative Technology and Support Section (OS-343)

Thank you for your memo of July 11, 1990 in which you elaborate upon the previous conversation between Chester Oszman of my staff and Mr. Jean of your staff regarding the point when munitions become hazardous waste and are regulated under the RCRA program. The Naval Ammunition Facility (NAF) at Vieques Island, Puerto Rico does not, as you point out, conduct a regulatable activity when storing "unserviceable" military munitions (e.g., damaged, outdated or possibly defective munitions) which have not been designated for demilitarization.

EPA supports Dept. of Defense's (DOD) definition of the point at which a munition or ordnance becomes a hazardous waste since that is DOD's responsibility as a generator. Unserviceable military munitions become hazardous waste normally at the point the transfer record (e.g. DD form 1348-1, DA Form 4508, or equivalent) is signed by the last approval authority acknowledging receipt of the munition or ordnance at a demilitarization facility. This happens when the U.S. Atlantic Fleet Weapons Training Area receives unserviceable munitions sent by NAF to be demilitarized.

In your letter, you mention that NAF stores ignitable, corrosive and reactive (other than serviceable or unserviceable munitions) wastes. These waste streams are waste when there is an intent to discard and are, in that case, fully regulated in the RCRA system. All applicable requirements of 40 CFR parts 260-272 apply.

I agree with your strategy that interim status for the facility should not be terminated immediately even though the NAF is withdrawing its part B permit application. Before the facility at NAF can become a less than 90 day

accumulator, all units that operated under interim status must be properly closed.

If you have any questions or would like to discuss the situation at NAF further, please feel free to call me, or Chester Oszman at 382-4499.

cc: Chester Oszman

NUCLEAR REGULATORY COMMISSION

Below Regulatory Concern; Policy Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Policy statement.

SUMMARY: This policy statement establishes the framework within which the Commission will formulate rules or make licensing decisions to exempt from some or all regulatory controls certain practices involving small quantities of radioactive material. Opportunity for public comment will be provided with each rulemaking and each licensing action where generic exemption provisions have not already been established. The exemptions may involve the release of licensee-controlled radioactive material either to the generally accessible environment or to persons who would be exempt from Commission regulations. Practices for which exemptions may be granted include, but are not limited to, (1) the release for unrestricted public use of lands and structures containing residual radioactivity; (2) the distribution of consumer products containing small amounts of radioactive material; (3) the disposal of very low-level radioactive waste at other than licensed disposal sites; and (4) the recycling of slightly contaminated equipment and materials. As described in this policy statement, NRC intends to continue exempting specific practices from regulatory control if the application or continuation of regulatory controls is not necessary to protect the public health and safety and the environment, and is not cost effective in further reducing risk. The policy statement defines the dose criteria and other considerations that will be used by NRC in making exemption decisions. The policy establishes individual dose criteria (1 and 10 mrem per year [0.01 and 0.1 millisievert per year]) and a collective dose criterion (1000 person-rem per year [10 personsievert per year]). These criteria, coupled with other considerations enumerated in the policy statement, will be major factors in the Commission's determination on whether exemptions from regulatory controls will be granted.

The policy statement establishes a consistent risk framework for regulatory exemption decisions, ensures an adequate and consistent level of protection of the public in their use of radioactive materials, and focuses the Nation's resources on reducing the most significant radiological risks from practices under NRC's jurisdiction. The average U.S. citizen should benefit from implementation of the BRC policy through (1) enhanced ability of NRC, Agreement States, and licensees to focus resources on more significant risks posed by nuclear materials; (2) timely and consistent decisions on the need for cleanup of contaminated sites; (3) increased assurance that funds available to decommission operating nuclear facilities will be adequate; (4) reduced costs and overall risks to the public from managing certain types of slightly radioactive

waste in a manner commensurate with their low radiological risk; and (5) increased assurance of a consistent level of safety for consumer products containing radioactive material under the Commission's jurisdiction.

EFFECTIVE DATE: July 3, 1990

ADDRESSES: Documents referenced in this policy statement are available for inspection in the NRC Public Document Room, 2120 L Street, N. W. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT:

The appropriate NRC Regional Office:

Region I - Dr. Malcom Knapp, King of Prussia, Pennsylvania;
telephone (215) 337-5000

Region II - Mr. J. Philip Stohr, Atlanta, Georgia;
telephone (404) 331-4503

Region III - Mr. Charles E. Norelius, Glen Ellyn, Illinois;
telephone (708) 790-5500

Region IV - Mr. Arthur B. Beach, Arlington, Texas;
telephone (817) 860-8100

Region V - Mr. Ross A. Scarano, Walnut Creek, California;
telephone (415) 943-3700

Federal and State Government Officials may contact: Mr. Frederick Combs, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Office of Governmental and Public Affairs, telephone (301) 492-0325.

Questions may also be directed to the following individuals at the U.S. Nuclear Regulatory Commission, Washington, DC 20555.

Dr. Donald A. Cool, Office of Nuclear Regulatory Research;
telephone (301) 492-3785

Mr. John W.N. Hickey, Office of Nuclear Material Safety and Safeguards;
telephone (301) 492-3332

Mr. L.J. Cunningham, Office of Nuclear Reactor Regulation;
telephone (301) 492-1086

SUPPLEMENTARY INFORMATION:

Statement of Policy

I. Introduction.

Ionizing radiation is a fact of life. From the day we are born until the day we die, our bodies are exposed to sensing, inspection, and enforcement programs. For example, the Commission may promulgate regulations that would require some type of labeling so that consumers could make informed decisions about purchasing a product containing exempted materials. Such labeling is presently required by the Commission for smoke detectors containing radioactive material (see 10 CFR 32.26). The NRC ensures that manufacturers label the detectors in compliance with the labeling requirement through licensing reviews and inspections. Specific source controls and exemption conditions are not discussed further in this policy because they will be more appropriately addressed in developing the exemption requirements for specific exemption proposals.

The concept of regulatory exemptions is not new. The Atomic Energy Act of 1954, as amended, authorizes the Commission to exempt certain classes, quantities, or uses of radioactive material when it finds that such exemptions will not constitute an unreasonable risk to common defense and security and to the health and safety of the public. In the 1960s and 1970s, the Atomic Energy Commission used this authority to promulgate tables of exempt quantities and concentrations for radioactive material. These exemptions allow a person or licensee, under certain circumstances, to receive, possess, use, transfer, own, or acquire radioactive material without a requirement for a license (30 FR 8185; June 26, 1965 and 35 FR 6425; April 22, 1970). The Commission currently allows distribution of consumer products or devices to the general public and allows releases of radioactive material to the environment consistent with established regulations. For example, regulations currently specify the conditions under which licensees are allowed to dispose of small quantities of radioactive material into sanitary sewer systems (see 10 CFR 20.303). These existing regulations specify requirements, conditions, and constraints that a licensee must meet if radioactive material is to be "transferred" from a regulated to an exempt or unregulated status.

More recently, Section 10 of the Low-Level Radioactive Waste Policy Amendments Act (LLRWPA) of 1985 directed the Commission to develop standards and procedures and act upon petitions "to exempt specific radioactive wastestreams from regulation ... due to the presence of radionuclides in sufficiently low concentrations or quantities as to be below regulatory concern." The Commission responded to this legislation by issuing a policy statement on

August 29, 1986 (51 FR 30839). That policy statement contained criteria that, if satisfactorily addressed in a petition for rulemaking, would allow the Commission to act expeditiously in proposing appropriate relief in its regulations on a "practice-specific" basis consistent with the merits of the petition.

Federal and State agencies have also developed and implemented similar exemptions based on evaluations of their risks to the public and the environment. The Food and Drug Administration (FDA), for example, has applied sensitivity-of-method, risk-based guidelines in connection with the regulation of animal drugs, food contaminants, and trace constituents in some food additives. Similarly, the Environmental Protection Agency (EPA) established exemption or threshold levels based on individual risks in the regulation of pesticides and other toxic and carcinogenic chemicals. For example, EPA employs such a concept in defining hazardous waste through the new Toxicity Characteristic rule in 40 CFR Part 261 [55 FR 11798; March 29, 1990].

The Commission believes that the Below Regulatory Concern policy is needed to establish a consistent, risk-based framework for making exemption decisions. Specifically, this framework is needed to (1) focus the resources of NRC, Agreement States, and licensees on addressing more significant risks posed by nuclear materials; (2) ensure that beyond the adequate protection threshold potential benefits from additional regulation outweigh the associated burdens; (3) establish residual radioactivity criteria and requirements for decommissioning and cleanup of radioactive contamination at licensed and formerly-licensed facilities; (4) ensure that licensee decommissioning funding plans provide adequate funds to cover the costs of cleanup of these facilities to protect people and the environment; (5) ensure that the public is consistently protected against undue risk from consumer products that contain radioactive materials under the Commission's jurisdiction; (6) provide decision criteria for reviewing petitions to exempt very low-level radioactive wastes in accordance with the Low-Level Radioactive Waste Policy Amendments Act of 1985; and (7) ensure that existing exemptions involving radioactive materials are consistent and adequate to protect the public.

The Commission's BRC policy establishes an explicit and uniform risk framework for making regulatory exemption decisions. This policy will also be used by the Commission as a basis for reevaluating existing NRC exemptions to ensure that they are consistent with the criteria defined herein. In lieu of such a policy, the Commission could continue the current practice of evaluating exemptions on a case-specific basis. Such an approach, however, does not ensure consistent evaluation and control of risks associated with exempted practices. For this reason and the reasons discussed above, the Commission has established the

BRC Policy Statement. This policy supersedes the Atomic Energy Commission's policy statement on this subject [30 FR 3462; March 16, 1965].

The Commission recognizes that Agreement States will play an important role in the implementation of the Below Regulatory Concern policy, specifically in the areas of developing and enforcing compatible State regulations, regulating cleanup and decommissioning of certain types of contaminated nuclear facilities, and exempting processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition.

"Collective dose" is the sum of the individual doses (total effective dose equivalents) received in a given period of time by a specified population from exposure to a specified source of radiation (or practice involving the use of radioactive material). Note: The calculated collective dose used to determine compliance with the criterion of this policy need not include individual dose contributions received at a rate of less than 0.1 mrem per year (0.001 mSv/year).

"Committed effective dose equivalent" is the sum of the products of weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to those organs or tissues.

"Deep dose equivalent" is the dose equivalent at a tissue depth of 1 cm.

"Dose" or "radiation dose" in this policy is the total effective dose equivalent.

"Exemption from regulatory control" refers to a decision process that may allow radioactive material to be transferred from a regulated status to an unregulated status, in which the material will no longer be subject to NRC requirements. Decisions to grant exemptions will be based upon findings by reason of quantity or concentration that the radioactive material poses a small risk to public health and safety and the environment and that the small magnitude of the risk does not warrant expenditure of additional resources of regulatory agencies and the regulated community in attempting to further reduce the risk.

"Exposure" means being exposed to ionizing radiation or to radioactive material.

"Licensed material" means source material, special nuclear material, or byproduct material that is received, possessed, used, transferred, or disposed of under a general or specific license issued by the Commission or an Agreement State.

"Licensee" means the holder of an NRC or Agreement State license.

"Linear, no-threshold hypothesis" refers to the theory that there is a proportional relationship between a given dose of radiation and the statistical probability of the occurrence of a health effect (such as latent cancers and genetic effects), and that there is no dose level below which there is no risk from exposure to radiation.

"Natural background dose" means the dose received from naturally occurring cosmic and terrestrial radiation and radioactive material but not from source, byproduct, or special nuclear material.

"Practice" is a defined activity or a set or combination of a number of similar coordinated and continuing activities aimed at a given purpose that involves the potential for radiation exposure. Disposal of specified types of very low-level radioactive waste; the release for unrestricted public use of lands and structures with residual levels of radioactivity; the distribution, use, and disposal of specific consumer products containing small amounts of radioactive material; and the recycle and reuse of specific types of residually contaminated materials and equipment are examples of practices for which this policy will have potential applicability. (See Section III for further discussion of practice).

"Rem" is the special unit of dose equivalent (1 rem = 0.01 sievert).

"Risk," for purposes of this policy, means the annual or lifetime probability of the development of fatal cancer from exposure to ionizing radiation and is taken as the product of the dose received by an exposed individual and a conversion factor based upon the linear, no-threshold hypothesis. The conversion factor for dose to risk is taken to be 5×10^{-4} fatal cancers per rem of radiation dose. The fatal cancer risk is considered, in general, to be more likely than other radiation induced health effects and to be the most severe outcome to an individual. While the Commission recognizes that the risks from exposure to radiation are greater for children than adults and that there are increased risks from exposure to the embryo/fetus, the estimate of fatal cancer risk for all ages and both sexes is considered to be an appropriate measure of risk from practices being considered for exemption in accordance with this policy statement (see Appendix).

"Source material" means -

- (1) Uranium or thorium, or any combination of uranium and thorium in any physical or chemical form; or
- (2) Ores which contain, by weight, one-twentieth of one percent (0.05 percent), or more, of uranium, thorium, or any combination of uranium and thorium. Source material does not include special nuclear material.

"Special nuclear material" means -

(1) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the Commission, pursuant to the provisions of Section 51 of the Act, requirements for further dose reductions or licensee resources to comply with such requirements is no longer warranted. These specific criteria include (1) values for the individual annual dose reasonably expected to be received as a result of the practice (e.g., an average dose to individuals in a critical group) and (2) a measure of radiological impact to the exposed population. In combination, these criteria are chosen to ensure that, for the average dose to members of the critical population group from a given exempted practice, individuals will not be exposed to a significant radiological risk and that the population as a whole does not suffer a significant radiological impact.

It is important to emphasize that, in this policy, the Commission does not assert an absence or threshold of risk at low radiation dose levels but rather establishes a baseline level of risk beyond which further government regulation to reduce risks is unwarranted. As described in the Appendix to this policy statement, the technical rationale for the Commission's BRC criteria is explicitly based on the hypothesis that the risk from exposure to radiation is linearly proportional to the dose to an individual. However, the presence of natural background radiation and variations in the levels of this background have been used to provide a perspective from which to judge the relative significance of the radiological risks involved in the exemption decision-making process.

The Commission notes that adoption of the individual and collective dose criteria does not indicate a decision that doses above the criteria would necessarily preclude exemptions. The criteria simply represent a range of risk that the Commission believes is sufficiently small compared to other individual and societal risks that further cost-risk reduction analyses are not required in order to make a decision regarding the acceptability of an exemption. Practices not meeting these criteria may nevertheless be granted exemptions from regulatory control on a case-by-case basis in accordance with the principles embodied within this policy, if (1) the potential doses to individual members of the public are sufficiently small or unlikely; (2) further reductions in the doses are neither readily achievable nor significant in terms of protecting the public health and safety and the environment; and (3) the collective dose from the exempted practice is ALARA.

B. The Individual Dose Criterion.

The Commission has noted that, although there is significant uncertainty in calculations of risk from low-level radiation, in general these risks are better

understood than the risks from other hazards such as toxic chemicals. Moreover, radiation from natural background poses involuntary risks (primarily cancers), which must be accepted as a fact of life and are identical to the kinds of risks posed by radiation from nuclear materials under NRC jurisdiction. These facts provide a context in which to compare quantitatively the radiation risks from various practices and make radiation risk especially amenable to the use of the approach described below to define an acceptable BRC level.

The Commission believes that if the risk from doses to individuals from a practice under consideration for exemption is comparable to other voluntary and involuntary risks which are commonly accepted by those same individuals without significant efforts to reduce them, then the level of protection from that practice should be adequate. Furthermore, for risks at or below these levels there would be little merit in expending resources to reduce this risk further. The Commission believes the definition of a BRC dose level can be developed from this perspective.

Variations in natural background radiation apparently play no role in individuals' decisions on common matters such as places to live or work (e.g., the 60-70 mrem differences between average annual doses received in Denver, Colorado versus Washington, DC). In addition, individuals generally do not seem to be concerned about the difference in doses between living in a brick versus a frame house, the 5 mrem dose received during a typical roundtrip coast-to-coast flight, or incremental doses from other activities that fall well within common variations in natural background radiation. These factors lead to the conclusion that differential risks corresponding to doses on the order of 5-10 mrem (0.05-0.1 mSv) are well within the range of doses that are commonly accepted by members of the public, and that this is an appropriate order of magnitude for the Commission's BRC individual dose criterion.

Although the uncertainties in risk estimates at such low doses are large, the risk to an individual as calculated using the linear, no-threshold hypothesis is shown in Table 1 for various defined levels of annual individual dose. The values in the hypothetical lifetime risk column are based on the further assumption that the annual dose is continuously received during each year of a 70-year lifetime. To provide further perspective, a radiation dose of 10 mrem per year (0.1 mSv per year) received continuously over a lifetime corresponds to a risk of about 4 chances in 10,000 (3.5×10^{-4}) or a hypothetical increase of about 0.25 % in an individual's lifetime risk of fatal cancer. The Commission prefers to use factors of ten to describe such low individual doses because of the large uncertainties associated with the dose estimates. The Appendix to the policy statement provides a more complete discussion of the risks and uncertainties associated with low doses and dose rates.

should exclude consideration of those individuals whose annual effective dose equivalent is less than or equal to 1 mrem per year (0.01 mSv per year). In the sensitivity-of-measure, risk-based guidelines used by EPA and FDA, a 10^{-6} lifetime risk of cancer has been used as a quantitative criterion of insignificance. Using an annual risk coefficient of 5×10^{-4} health effects per rem (5×10^{-2} per sievert), as discussed in the Appendix, the 10^{-6} lifetime risk value would approximate the calculated risk that an individual would incur from a continuous lifetime dose rate in the range of 0.01 to 0.1 mrem (0.0001 to 0.001 mSv) per year.

As a practical matter, consideration of dose rates in the microrem per year range and large numbers of hypothetical individuals potentially exposed to an exempted practice may unduly complicate the dose calculations that will be used to support demonstrations that proposed exemptions comport with the criteria in this policy. The Commission believes that inclusion of individual doses below 0.1 mrem per year (0.001 mSv per year) introduces unnecessary complexity into collective dose assessments and could impute an unrealistic sense of the significance and certainty of such dose levels. For all of these reasons, the Commission concludes that 0.1 mrem (0.001 mSv) per year is an appropriate truncation value to be applied in the assessment of collective doses for the purposes of this policy.

IV. Implementation.

The Commission's BRC policy will be implemented principally through rulemakings; however, exemption decisions could also be implemented through specific licensing actions.

In the first case, a proposal for exemption, whether initiated by the NRC or requested by outside parties in a petition for rulemaking, must provide a basis upon which the Commission can determine if the basic policy criteria have been satisfied. The Commission intends to initiate a number of rulemakings on its own (e.g., to establish a dose criterion for decommissioning) and may initiate others as a result of NRC's review of existing codified exemptions (e.g., consumer product exemptions in 10 CFR Parts 30 and 40). Rulemakings may also be initiated in response to petitions for rulemaking submitted by outside parties, such as a BRC waste petition submitted in accordance with Section 10 of the Low-Level Radioactive Waste Policy Amendment Act of 1985. In general, rulemaking exemption proposals should assess the potential health and safety impacts that could result if the exemption were to be granted.

The proposal should consider the uses of the radioactive materials, the pathways of exposure, the levels of radioactivity, and the methods and constraints for

ensuring that the assumptions used to define a practice remain appropriate as the radioactive materials move from a regulated to an unregulated status. Any such rulemaking action would follow the Administrative Procedure Act, which requires publication of a proposed rule in order to solicit public comment on the rulemaking action under consideration. The rulemaking action would include an appropriate level of environmental review in accordance with the Commission's regulations in 10 CFR Part 51, which implement the National Environmental Policy Act.

If a proposal for exemption results in a Commission regulation containing specific requirements for a particular exemption, a licensee using the exemption would no longer be required to apply the ALARA principle to reduce doses further for the exempted practice provided that it meets the conditions specified in the regulation. The promulgation of the regulation would, under these circumstances, constitute a finding that the practice is exempted in accordance with the provisions of the regulation and that ALARA considerations have been adequately addressed from a regulatory standpoint. The Commission in no way wishes to discourage the voluntary application of additional health physics practices which may, in fact, reduce actual doses significantly below the BRC criteria or the development of new technologies to enhance protection to the public and the environment. This is particularly pertinent in the area of decontamination and decommissioning, where the Commission anticipates that emerging technologies over the next several decades should enhance existing technical capabilities and further reduce doses to workers and the public and where other Federal agencies are in the process of developing standards which may affect those receiving exemptions.

The second means of policy implementation could involve exemptions that would be granted through licensing actions, such as determinations that a specific site has been sufficiently decontaminated to be released for unrestricted public use. The NRC intends to develop guidance regarding the implementation of the BRC criteria to ensure that such site-specific actions adhere to the criteria and principles of this policy statement. New licensing actions that transfer radioactive material to an unregulated status will be noticed in the Federal Register if they differ from previous generic exemption decisions.

One of the principal benefits of the policy is that it provides a framework to evaluate and ensure the consistency of past exemption decisions by the Commission. With the adoption of this BRC policy, the NRC will initiate a systematic assessment of exemptions currently existing in NRC's regulations to ensure that the public is adequately and consistently protected from the risks associated with exempted practices. In addition, the NRC will, on a periodic basis, review the exemptions granted under information may be useful in characterizing a practice on a national basis.

3. As low as is reasonably achievable (ALARA). An analysis should be provided that demonstrates that radiation exposure and radionuclide releases associated with the exempted practice overall will be ALARA consistent with the criteria in this policy. The ALARA principle referred to in 10 CFR Part 20 applies to efforts by licensees to maintain radiation exposures and releases of radioactive materials to unrestricted areas as low as is reasonably achievable. Appendix I to 10 CFR Part 50 describes ALARA for radioactive material releases from light water reactors (nuclear power plants). Exemption proposals should describe how ALARA considerations have been applied in the design, development, and implementation of controls for the proposed practice. Licensee compliance with the ALARA principle must remain in effect up to and including the point at which the materials are transferred to an unregulated status in accordance with an exemption granted under this policy.

D. Impact Analyses.

To support and justify a request for exemption, each petitioner or licensee should assess the radiological and nonradiological impacts of the proposed exemption. The analyses should be based on the characterizations described previously and should cover all aspects of the proposed exempt practice, including possession, use, transfer, ownership, and disposal of the material. NRC consideration of the exemption proposal and any environmental assessments and regulatory analyses required to implement the exemption will be based on the impact analyses and supporting characterizations.

1. Radiological impacts. The evaluation of radiological impacts should clearly address the policy's individual and collective dose criteria or provide a sufficient ALARA evaluation supporting the exemption. In either case, the following impacts should be assessed.

- Average doses to the critical population group;
- Collective doses to the critical population group and the total exposed population (under conditions defined in Section III); and
- The potential for and magnitude of doses associated with accidents, misuses, and reconcentration of radionuclides.

The collective doses should be estimated and summed in two parts: total dose to the critical population group and total dose to the exposed population. The critical group is the relatively homogeneous group of individuals whose exposures are likely to be the greatest and for whom the assessment of doses is likely to be the most accurate. Average doses to this group are the controlling

factors limiting individual doses and risk, and should be compared with the individual dose criteria, as appropriate. The critical group should be the segment of the population most highly exposed to radiation or radioactive materials associated with the use of radioactive material under unregulated conditions. The second part of the population exposure is the general population exposure, exclusive of critical group exposure. For this group, the individual exposures should be smaller, and the assessment will often be less precise. The impacts analysis should present an estimate of the distribution of doses within the general population. In situations where truncation of the collective dose calculation is done under the provisions of this policy, the basis for applying the truncation provision should be provided.

The evaluation of radiological impacts should distinguish between expected and potential exposures and events. The analysis of potential exposures in accident or misuse scenarios should include all of the assumptions, data, and results used in the analysis in order to facilitate review. The evaluation should provide sufficient information to allow a reviewer to independently confirm the results. The potential for reasonable interactions between the exempted radioactive material and the public should be assessed.

2. Other impacts. The analysis of other radiological impacts such as those from transportation, handling processing, and disposal of exempted materials should be evaluated. Nonradiological impacts on humans and the environment should also be evaluated in accordance with NRC requirements in 10 CFR Part 51. The analysis should also consider any adverse impact of the measures taken to provide nonradiological protection on radiation exposure and releases of radioactive material. Any NRC action to exempt a practice from further regulatory control would not relieve persons using, handling, processing, owning, or disposing of the radioactive material from other requirements applicable to the nonradiological properties of the material.

E. Cost-Benefit Considerations (as required).

A cost/benefit analysis is an essential part of both environmental and regulatory impact considerations. The analysis should focus on expected exposures and realistic concentrations or quantities of radionuclides. The cost/benefit analysis should compare the exposures and economic costs associated with the regulated practice and alternatives not subject to regulation. Benefits and costs should be considered in both quantitative and qualitative terms. Costs of surveys and compliance verification discussed under Item V.G. should also be covered. Any legal or regulatory constraints that might affect an exemption decision should be identified. For example, one such constraint might stem from Department of Transportation BRC Policy Statement

APPENDIX-DOSE AND HEALTH EFFECTS ESTIMATION

I. Dose Estimation

In estimating the dose rates to members of the public that might arise through various practices for which exemptions are being considered, the Commission has decided to apply the concept of the "total effective dose equivalent." This concept, which is based on a comparison of the delayed health effects of ionizing radiation exposures, permits and calculation of the whole body dose equivalent of partial body and organ exposures through use of weighting factors. The concept was proposed by the International Commission on Radiological Protection (ICRP) in its Publication 26 issued in 1977. Since that time, the concept has been reviewed, evaluated, and adopted by radiation protection organizations throughout the world and has gained wide acceptance. The "total effective dose equivalent" concept is incorporated in "Radiation Protection Guidance to Federal Agencies for Occupational Exposure-Recommendations Approved by the President," that was signed by the President and published in the Federal Register on January 27, 1987 (52 FR 2822). The Commission recognizes that, in considering specific exemption proposals, the total effective dose equivalent must be taken into account.

II. Estimating Health Effects From Radiation Exposure

A. Individual Risks.

In the establishment of its radiation protection policies, the Commission has considered the three major types of stochastic (i.e., random) health effects that can be caused by relatively low doses of radiation: cancer, genetic effects, and developmental anomalies in fetuses. The NRC principally focuses on the risk of fatal cancer development because (1) the mortality risk represents a more severe outcome than the nonfatal cancer risk, and (2) the mortality risk is thought to be higher than the risk associated with genetic effects and developmental effects on fetuses.¹ However, even though radiation has been shown to be carcinogenic, the development of a risk factor applicable to continuing radiation exposures at levels equal to natural background² requires a significant extrapolation from the

¹ Further discussion of these topics is provided in "Sources, Effects and Risks of Ionizing Radiation," United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), 1988 Report to the General Assembly with Annexes

² Natural background radiation can vary with time and location. In Washington, D.C., natural background radiation (excluding radon) results in individual doses of about 90 mrem per year (0.9 mSv/yr), while in Denver, Colorado, the value is about 160 mrem per year (1.6 mSv/yr). In both cases, naturally occurring radioactive material in the human body contributes approximately 40 mrem per year. Radiation from inhalation of the daughter products of radon contributes an average additional dose of 200 mrem per year (2 mSv/yr) to members of the U.S.

observed effects at much higher doses and dose rates.⁴³ This results in significant uncertainty in risk estimates as reflected by the views of experts in the field. For example, the Committee on the Biological Effects of Ionizing Radiation (BEIR III) of the National Academy of Science cautioned that the risk values are "...based on incomplete data and involve a large degree of uncertainty, especially in the low dose region." This Committee also stated that it "...does not know whether dose rates of gamma or x-rays (low LET; low linear energy transfer radiation) of about 100 mrad/year (1 mGy/year) are detrimental to man." More recently, the BEIR V Committee of the National Academy of Science/National Research Council stated that it "recognizes that its risk estimates become more uncertain when applied to very low doses. Departures from a linear model at low doses, however, could either increase or decrease the [estimation of] risk per unit dose." The commission understands that the Committees' statements reflect the uncertainties involved in estimating the risks of radiation exposure and do not imply either the absence or presence of detrimental effects at such low dose levels.

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) stated in their 1988 Report to the General Assembly that "...there was a need for a reduction factor to modify the risks (derived at high doses and dose rates)...for low doses and dose rates...[A]n appropriate range (for this factor) to be applied to total risk for low dose and dose rate should be between 2 and 10." This factor would lead to a risk coefficient value between 7×10^{-4} per rad (7×10^{-3} and 3.5×10^{-2} per Gy) based on an UNSCEAR risk coefficient of 7.1×10^{-4} per rad (7.1×10^{-2} per gray) for 100 rad (1 gray) organ absorbed doses at high dose rates. The report also stated, "The product of the risk coefficient appropriate for individual risk and the relevant collective dose will give the expected number of cancer deaths in the exposed population, provided that the collective dose is at least of the order of 100 person-Sv (10,000 person-rem). If the collective dose is only a few person-Sv (a few hundred person-rem), the most likely outcome is zero deaths."

In December 1989, the BEIR V committee published a report entitled "Health Effects of Exposure to Low Levels of Ionizing Radiation," which contained risk estimates that are, in general, similar to the findings of BRC Policy Statement

population (NCRP Report No. 93, "Ionizing Radiation Exposure of the Population of the United States").

³ The health effects clearly attributable to radiation have occurred principally among early radiation workers, survivors of the atomic bomb explosions at Hiroshima and Nagasaki, individuals exposed for medical purposes, and laboratory animals. Natural background radiation causes an annual dose that is at least two orders of magnitude less than the dose received by human populations from which the cancer risks are derived. Experiments at the cellular level, however, provide similar indications of biological effects at low doses.

Table 1

Risk	Hypothetical		
	Incremental Annual Dose*	Hypothetical Lifetime Annual Risk**	From Continuing Annual Dose**
100 mrem (1.0 mSv)	5 x 10 ⁻⁵	3.5 x 10 ⁻³	
10 mrem (0.1 mSv)	5 x 10 ⁻⁶	3.5 x 10 ⁻⁴	
1 mrem (0.01 mSv)	5 x 10 ⁻⁷	3.5 x 10 ⁻⁵	
0.1 mrem (0.001 mSv)	5 x 10 ⁻⁸	3.5 x 10 ⁻⁶	

* The expression of dose refers to the Total Effective Dose Equivalent. This term is the sum of the deep [whole body] dose equivalent for sources external to the body and the committed effective [whole body] dose equivalent for sources internal to the body.

** Risk coefficient of 5 x 10⁻⁴ per rem (5 x 10⁻² per Sv) for low linear energy transfer radiation has been conservatively based on the results reported in UNSCEAR 1988 (Footnote 2) and BEIR V (see also NUREG/CR-4214, Rev. 1).

III. Dose and Risk Estimation

The Commission recognizes that it is frequently not possible to measure risk to individuals or populations directly and, in most situations, it is impractical to measure annual doses to individuals at the low levels associated with potential exemption decisions. Typically, radionuclide concentrations or radiation dose rates can only be measured before the radioactive material is released from regulatory control. Estimates of doses to members of the public from the types of practices that the Commission would consider exempting from regulatory control must be based on input of these measurements onto exposure pathway models, using assumptions related to the ways in which people might become exposed. These assumptions incorporate sufficient conservatism to account for uncertainties so that any actual doses would be expected to be lower than the calculated doses. The Commission believes that this is an appropriate approach to be taken when determining if an exemption from some or all regulatory controls is warranted.

The additional views of Commissioner Curtiss and Chairman Carr's comments are attached.

Dated at Rockville, Maryland, this 22nd day of June 1990.

For the Nuclear Regulatory Commission.

Original Document signed
Samuel J. Chils
Secretary of the Commission.

the individual and collective dose criteria can be designated below regulatory concern, it is unclear why the Commission would then go on to say that it expects additional steps to be taken to keep exposures ALARA. As a general matter, I do not object to the ALARA concept. Indeed, I support the notion that collective dose and ALARA analyses should be performed in a manner that is consistent with basic national and international radiation protection principles. But in the context of a Policy Statement on Below Regulatory Concern, for the Commission to say on the one hand that the individual and collective dose criteria reflect levels below which no regulatory resources should be expended, while at the same time encouraging voluntary ALARA efforts to achieve lower doses, sends a confusing regulatory message.⁴ For the sake of regulatory clarity, I would explicitly identify the individual and collective dose criteria as floors to ALARA.

Justification of Practice

On the issue of justification of practice, the Policy Statement is unclear as to when and under what circumstances the justification of practice principle would be applied. At one point, the Policy Statement provides that:

The Commission believes that justification decisions involving social and cultural value judgments should be made by affected elements of society and not the regulatory agency. Consequently, the Commission will not consider whether a practice is justified in terms of net societal benefit.

At another point, the Policy Statement indicates that:

⁴ I am also concerned that the approach to ALARA set forth in the Policy Statement appears to be motivated, in part, by a concern that the Environmental Protection Agency may at some future point set more stringent criteria for BRC. Of particular note is the statement that-

This [approach to ALARA] is particularly pertinent in the area of decontamination and decommissioning...where other federal agencies are in the process of developing standards which may affect those receiving exemptions.

In my view, the ALARA issue should be approached with the objective of formulating a sound and defensible policy, rather than with an eye towards trying to anticipate what policy EPA might establish in the future.

The Commission may determine on the basis of risk estimates and associated uncertainties that certain practices should not be considered candidates for exemption, such as the introduction of radioactive materials into products to be consumed or used primarily by children.

This bifurcated approach to justification of practice, which appears to distinguish practices involving children from all other practices, will inevitably lead to confusion. Moreover, this approach poses the very real potential that the Commission could, on the one hand, reject a practice involving children (e.g., baby food, pacifiers, and the like) on the ground that the risk posed by such a practice is too high, yet authorize a practice directed at the general public that could, coincidentally, expose an even greater number of children, even though the practice itself is not specifically directed at children.

In my view, this ambiguity should be resolved in favor of a clear and unequivocal statement endorsing the principle of justification of practice. While I acknowledge that the principle of justification of practice calls upon the Commission to make decisions involving so-called questions of "societal value," that is an insufficient reason, in my view, to step back from this widely accepted health-physics principle. Indeed, the Commission already takes such considerations into account, either explicitly or implicitly, in many of the decisions that it renders.

Accordingly, in view of the central role that the justification of practice principle has played in health physics practice, as well as the complexity and confusion that will invariably result from the approach set forth in the Policy Statement, I would state explicitly in this Policy Statement that the Commission retains the prerogative to determine that specific practices may be unsuitable for exemption, regardless of risk, documenting such determinations on a case-by-case basis.

Agreement State Compatibility

With one exception, I concur in the general approach that this Policy Statement takes on the issue of Agreement State compatibility. The one area where I disagree involves the treatment of matters involving low-level radioactive waste disposal.

As I understand the position of the majority, the approach established in this Policy Statement, and to be implemented in the context of subsequent rulemaking initiatives, will be considered a matter of strict compatibility for Agreement State programs. As a consequence, the approach taken by individual Agreement States on BRC issues must be identical to the approach taken by the Commission. I disagree with this approach for the following reasons:

When Congress enacted the Low Level Radioactive Waste Policy Amendments Act of 1985 (LLRWPA), it vested in the States the responsibility for developing new low-level radioactive waste disposal capacity. Indeed, the Congress recognized at the time that the States were uniquely equipped to handle this important responsibility. Accordingly, the States were given a great deal of latitude in deciding how best to proceed with the development, construction, and operation of new low-level waste disposal facilities. To take one example, Congress

Chairman Carr's Response to Commissioner Curtiss' Views on the BRC Policy Statement

I am proud of the Commission's accomplishment in completing a comprehensive Below Regulatory Concern policy statement. I appreciate Commissioner Curtiss' enthusiasm and strong support for the policy. Commission deliberation of such views has helped to forge a comprehensive risk framework for ensuring that the public is protected at a consistent level of safety from existing and future exemptions and releases of radioactive materials to the general environment. The framework should also be helpful in allowing NRC, States, and the public to focus resources on reducing the more significant risks under NRC's jurisdiction. I offer the following response to Commissioner Curtiss' thoughtful views in the spirit of the constructive process that has culminated in the BRC policy.

As with many of the issues that the Commission deals with, there were very few right and wrong solutions to the issues associated with the BRC policy. The Commission reached its decisions on the policy by selecting preferred solutions from among a spectrum of possible policy options. These decisions were made based on the Commission's technical analysis of the issues associated with regulatory exemptions, legal interpretation of governing legislation, and regulatory experience in approving exemptions since the birth of civilian uses of nuclear materials in the 1950's. I believe Commissioner Curtiss' views on selected issues constitute part of the continuous spectrum of policy options. However, for the reasons articulated below, I affirm the Commission's decision to approve the policy statement in its present form and reject the differing views put forth by Commissioner Curtiss.

Commissioner Curtiss clearly endorses the policy and the concept of establishing a comprehensive framework for making decisions on regulatory exemptions. However, he takes issue with five elements of the policy: (1) the interim nature of the 1-millirem-per-year criterion for practices with widespread distribution, (2) selection of the 1000-person-rem-per-year criterion for collective dose, (3) the manner in which the Commission views the BRC criteria as a "floor" to ALARA, (4) omission of the principle of justification of practice, and (5) making BRC

rules an item of compatibility for Agreement State programs. These issues were fully considered by the Commission and the NRC staff in the course of developing the BRC policy. Indeed, Commissioner Curtiss vetoed in September 1989 to approve the BRC policy, the essence of which is preserved in the final BRC policy in today's notice.

Interim Individual Dose Criterion

On the first issue, Commissioner Curtiss would prefer to establish the 1-millirem-per-year criterion as a final criterion, rather than an interim value.

As stated in the BRC policy, the Commission is establishing the 1-millirem-per-year criterion as an interim value until after it develops more experience with the potential for individual exposures from multiple licensed and exempted practices. The widespread practices to which this criterion applies are primarily consumer products, which could involve very small doses to large numbers of people. The 1-millirem criterion was selected specifically to address the possibility that members of the public may be exposed to several exempted practices.

Simply put, exposure of an individual to a handful of exempted practices could result in annual doses close to 100 millirem if each practice were allotted individual doses up to 10 millirem per year. This is highly improbable given the Commission's plans to closely monitor any overlap of exposed populations from exempted practices as well as the aggregate dose to the public from exemptions. Nevertheless, NRC does not presently know how many exemption requests will be submitted by the public, how many will be approved, and what types of doses will be associated with the exemptions. If fewer exemptions are requested and granted, the probability of multiple exposures from exempted and licensed practices exceeding a substantial fraction of 100 millirem per year is considerably reduced. Therefore, the 1-millirem-per-year criterion may be too restrictive and the regulatory resources associated with its implementation may be better spent to control more significant risks. Consequently, the 1-millirem-per-year criterion was selected as an interim individual dose criterion to ensure that the sum of all exposures to an individual from exempted practices does not exceed a substantial fraction of 100 millirem per year. This criterion will remain an interim value until after the Commission gains experience with the potential for multiple exposures to exempted and licensed activities.

The initial rulemakings to implement the policy, particularly in the area of consumer product exemptions, should provide valuable insights into the validity and appropriateness of the 1-millirem criterion in terms of its need to protect the public against multiple exposures to nuclear materials. Although I agree with Commissioner Curtiss that a final criterion would be desirable from the

standpoint of "administrative finality," it would be premature to establish the 1-millirem criterion as a final criterion until after the Commission gains more experience cleanup for contaminated sites. Specifically, does the collective dose criterion apply generally to the practice of decommissioning or would it be applied on a site-specific basis? Similarly, how should the collective dose criterion be applied in cases where nuclear operations have contaminated groundwater resources that could potentially supply municipal drinking water systems? Resolution of these and other issues could cause the Commission to revise its selection of the magnitude of the collective dose criterion through future rulemakings and development of generic guidance. However, based on the technical information and recommendations currently before the Commission, 1000 person-rem/year appears to be an appropriate magnitude for the collective dose criterion.

For all of these reasons, the commission established a collective dose criterion of 1000 person-rem/year for each practice.

For all of these reasons, the Commission established a collective dose criterion of 1000 person-rem/year for each practice.

ALARA

Commissioner Curtiss would prefer to define the individual and collective dose criteria as "floors" to ALARA, that is, that the regulated community and NRC are relieved from the regulatory obligation to perform further ALARA analyses below these levels if individual doses are 1 millirem/10 millirem and the collective dose is 100 person-rem. Specifically, Commissioner Curtiss believes that the BRC policy sends a confusing message by encouraging voluntary efforts to achieve doses below the BRC criteria.

In responding to Commissioner Curtiss' view on this issue, it is important to begin from the definition of the term ALARA. ALARA is the regulatory concept that radiation exposures and effluents should be reduced as low as is reasonably achievable taking into account the state of technology, and the economics of improvements in relation to the benefits to public health and safety and other societal and socioeconomic considerations, and in relation to the utilization of atomic energy in the public interest (10 CFR 20.1(c)). The ALARA concept is one of the fundamental tenets of radiation protection and has been a keystone in NRC's regulatory framework. Public comments on the proposed BRC policy statement and on proposed revisions to 10 CFR Part 20 urged the Commission to define "floors" to ALARA or thresholds below which NRC would not require further reductions in doses or effluents.

The Commission responded to these comments in the policy by stating that "...a licensee using the exemption would no longer be required to apply the ALARA principle to reduce doses further for the exempted practice provided that it meets the conditions specified in the regulation" established for a particular exemption. In other words, the BRC criteria and implementing regulations will provide "floors" to ALARA for the exempted practice. In this regard, I agree with Commissioner Curtiss because the truncation of further efforts to reduce doses is one of the principal regulatory motivations for establishing the BRC policy.

However, I disagree with the rest of Commissioner Curtiss' view on this issue. It would be inappropriate to tell the regulated community that they cannot reduce doses below the BRC criteria. In short, although we will not require licensees to reduce doses further, we do not want discourage their efforts to do so either. This would be tantamount to telling a licensee how to operate his or her business regardless of whether any health or safety issues are involved. Such a direction would be inappropriate because it clearly falls outside of the health and safety focus of the NRC.

In formulating the BRC policy, the Commission recognized that new technologies being developed today promise to reduce doses, and therefore risks, at lower costs than at present technologies. Indeed, technological and cost considerations are explicitly recognized in the definition and application of the term "ALARA." Thus, I believe it would not be inappropriate to tell licensees that they cannot implement new technologies and health physics practices to further reduce doses if they want to.

Justification of Practice

Commissioner Curtiss would prefer to endorse the principle of justification of practice (i.e., whether the potential impacts of a practice are justified in terms of net societal benefits) and retain the prerogative to reject applications for exemptions regardless of the risk they pose.

I disagree with the Commissioner Curtis' view on this matter because it puts the Commission in a position of making decisions in areas outside the normal area of its expertise, where the agency would be especially vulnerable, perhaps justifiably so, to criticism. Consistent with the mission of the NRC, the Commission should base its judgements on an explicit, objective, and rational consideration of the health, safety, and environmental risks associated with practices, rather than on what many would perceive as personal preferences of the Commissioners. Such an approach fosters long-term stability in regulatory decisionmaking on potential exemptions.

Decisions on justification of practice involves social and cultural considerations that fall outside the Commission's primary focus and expertise for ensuring adequate protection of the public health and safety from the use of nuclear materials. Such decisions should be made by affected elements of society, such as residents near a contaminated site, potential customers, suppliers, and other members of the general public, rather than NRC. I believe that this position is consistent with regulatory practices of other Government agencies that generally do not regulate on the basis of whether a particular practice is

Atomic Energy Act of 1954, as amended. Absent the execution of a Section 274b Agreement with the NRC, a State is preempted by Federal law from exercising regulatory authority over the radiological hazards of these materials. The Commission is authorized to enter into an agreement with a State only upon a finding that the State program is compatible with the Commission's program for regulation of radioactive materials and adequate to protect the public health and safety. Section 274d.(2). The legislative history of Section 274 stresses throughout the importance of and the need for continuing compatibility between Federal and State regulatory programs. In comments on the legislation, the Joint committee on Atomic Energy (JCAE) stated that

5. The Joint Committee believes it important to emphasize that the radiation standards adopted by States under the agreements of this bill should either be identical or compatible with those of the Federal Government. For this reason the committee removed the language 'to the extent feasible' in subsection g. of the original AEC bill considered at hearings from May 19 to 22, 1959. The committee recognizes the importance of the testimony before it by numerous witnesses of the dangers of conflicting, overlapping and inconsistent standards in different jurisdictions, to the hindrance of industry and jeopardy of public safety.

Sen. Rept. No. 870, September 1, 1959, 86th Cong., 1st Sess.

The potential problems from conflicting standards identified by the JCAE in 1959 are fully apparent in the context of BRC and demonstrate why the scope of compatibility findings to be made by the NRC cannot be drawn to exclude low-level radioactive waste disposal. For instance, the Commission intends to use the risk criteria identified in the policy statement to establish decommissioning criteria, that is, the level at which a formerly licensed site may be released for unrestricted use. If the States are permitted to require that low-level waste streams designated BRC by the Commission be disposed of in a low-level waste facility, it could result in a site in one state being released for unrestricted use, while soil or materials in an adjacent State at that level would be required to be confined in a low-level waste facility. If a patchwork of disposal criteria were to develop, it would be virtually impossible to establish decommissioning funding

requirements that would be adequate to assure that all licensed facilities will set aside sufficient funds over the life of a facility to pay for decommissioning. The resulting confusion from these conflicting standards could well result in delays in adequate decommissioning of contaminated sites and certainly in unnecessary concern on the part of the public. I continue to believe that reserving to the NRC the authority to establish basic radiation protection standards, including designating which waste streams are below regulatory concern, is fully justified to ensure an adequate, uniform and consistent level of protection of the public health, safety and the environment.