6888, dated February 15, 1989). This standard, which is contained in Chapter 88 of the Code of Iowa (1983), was published as a Notice Of Intended Action in the Iowa Administrative Bulletin on April 5, 1989, as ARC 9788. In compliance with Iowa Code § 88.5(1)"b", a public hearing was scheduled for April 27, 1989. No comments were presented and no written comments were received. This resolution was adopted by the Division of Labor Services on May 25, 1989, pursuant to Chapter 17a, Iowa Code. The standard was effective July 20, 1989, and notice of its adoption was published by the State on June 14, 1989. Iowa also has promulgated Right to Know Rules which are broader than the State's Hazard Communication Standard. These rules establish requirements for Community Right to Know (Chapter 130) and Public Safety/Emergency Response Right to Know (Chapter 140) in addition to the Worker Right to Know requirements (Chapter 120). However, these additional provisions are administered separately from the State's OSHA program.

The State also submitted State standards comparable to: Hazardous Waste Operations and Emergency Response; Final Rule, 29 CFR 1910.120, as published in the **Federal Register** (54 FR 9317, dated March 6, 1989). This standard, which is contained in Chapter 88 of the Code of Iowa (1983), was published as a Notice Of Intended Action in the Iowa Administrative Bulletin on April 5, 1989, as ARC 9788. In compliance with Iowa Code section 88.5(1)"b", a public hearing was scheduled for April 27, 1989. No comments were presented and no written comments were received. This resolution was adopted by the Division of Labor Services on May 25, 1989, pursuant to Chapter 17a, Iowa Code. The standard was effective July 20, 1989, and notice of its adoption was published by the State on June 14, 1989.

The State also submitted State standards comparable to: Asbestos Collection of Information Requirements, 29 CFR 1910.1001, as published in the **Federal Register** (54 FR 29546, dated July 13, 1989). This standard, which is contained in Chapter 88 of the Code of Iowa (1983), was published as a Notice Of Intended Action in the Iowa Administrative Bulletin on September 6, 1989, as ARC 189A. In compliance with Iowa Code section 88.5(1)"b", a public hearing was scheduled for September 28, 1989. No comments were received. This resolution was adopted by the Division of Labor Services on October 26, 1989, pursuant to Chapter 17a, Iowa Code. The standard was effective December 20, 1989, and notice of its adoption was published by the State on November 15, 1989.

2. *Decision.* Having reviewed the State submission in comparison with the Federal standards, it has been determined that the State standards are identical to the comparable Federal standards and should therefore be approved.

3. *Location of Supplement for Inspection and Copying.* A copy of the standard supplement, along with the approved plan, may be inspected and copied during normal business hours at the following locations: Directorate of Federal/State Operations, Office of State Programs, Room N3700, 200 Constitution Avenue NW., Washington, DC 20210; Office of the Regional Administrator, Occupational Safety and Health Administration, 406 Federal Office Building, 911 Walnut Street, Kansas City, Missouri 64106; and Division of Labor Services, 1000 East Grand Avenue, Des Moines, Iowa 50319.

4. *Public Participation.* Under 29 CFR 1953.2(c) of this Chapter, the Assistant Secretary may prescribe alternative procedures to expedite the review process or for other good cause which may be consistent with applicable laws. The Assistant Secretary finds that good cause exists for not publishing the supplement to the Iowa State Plan as a proposed change and the procedural requirements of State law and further public participation and notice would be unnecessary.

This decision is effective July 3, 1990.

(Section 18, Public Law 91-596, 84 Stat. 1608 (29 U.S.C. 667)).

Signed at Kansas City, Missouri, this 2nd day of May, 1990.

Thomas H. Seymour, P.E.

Acting Regional Administrator.

[FR Doc. 90-15426 Filed 7-2-90; 8:45 am]

BILLING CODE 4510-26-M

NUCLEAR REGULATORY COMMISSION

Documents Containing Reporting or Recordkeeping Requirements; Office of Management and Budget Review

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of the Office of Management and Budget review of information collection.

SUMMARY: The Nuclear Regulatory Commission (NRC) has recently submitted to the Office of Management and Budget (OMB) for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

1. Type of submission, new, revision, or extension: Extension.

2. The title of the information collection: Medical Quality Assurance Assessment.

3. The form number if applicable: Not applicable.

4. How often the collection is required: The assessment will be conducted one time for each medical licensee.

5. Who will be required or asked to report: Persons holding NRC licenses under 10 CFR part 35 for the medical use of byproduct material.

6. An estimate of the number of responses: An average of 725 annually.

7. An estimate of the total number of hours needed to complete the requirement or request: Approximately two hours per response, for an average annual industry total of 1450 hours.

8. An indication of whether section 3504(h), Public Law 96-511 applies: Not applicable.

9. Abstract: As part of an effort to modify the regulatory framework concerning medical quality assurance, the NRC plans to continue its one-time assessment of QA programs and procedures at all NRC medical licensees' facilities. The assessment, conducted through a questionnaire that will be completed by NRC inspectors during scheduled safety inspections of medical licensees, will provide specific information on the QA programs and procedures that are in use at licensees' medical institutions. Results of the assessment will guide NRC's QA rulemaking effort by providing information about QA practices which should be addressed in NRC regulations.

Copies of the submittal may be inspected or obtained for a fee from the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

Comments and questions may be directed by mail to the OMB reviewer: Ronald Minsk, Paperwork Reduction Project (3150-0148), Office of Information and Regulatory Affairs, NEOB-3019, Office of Management and Budget, Washington, DC 20503.

Comments may also be communicated by telephone at (202) 395-3084.

The NRC Clearance Officer is Brenda Jo Shelton, (301) 492-8132.

Dated at Bethesda, Maryland, this 26th day of June 1990.

For the Nuclear Regulatory Commission.

Patricia G. Norry,

Designated Senior Official for Information Resources Management.

[FR Doc. 90-15406 Filed 7-2-90; 8:45 am]

BILLING CODE 7590-01-M

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 person-Sievert 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, NW. (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:

Dr. Donald A. Cool, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555; 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 low levels of radiation emitted from a variety of natural and man-made sources, including the cosmos, earth, building materials, industrial facilities, clothing, medicine, food, air, and our own bodies. All materials exhibit some degree of radioactivity. The consensus among scientists is that even low levels of radiation typical of the natural environment pose some correspondingly low risk of adverse health effects to humans. Recognition of the risk due to radiation exposure from natural sources provides perspective on the risks associated with human uses of radioactive materials.

Natural and man-made radionuclides are used in today's society in many forms for a variety of purposes, such as medical therapy and diagnosis, materials analysis, and power generation. In general, the existing regulatory framework ensures that radioactive materials are controlled consistent with the degree of risk posed to the public and the environment. Some products such as smoke detectors contain small quantities of radioactive materials that pose such a low risk that they have been widely distributed without continuing regulatory controls. To require that all radioactive materials be controlled in the same strict manner regardless of the risks they pose would not be a sound use of limited National resources. Such strict control could also deprive society of the benefits already derived from appropriate uses of radioactive materials and radiation. In addition, such control would not significantly reduce the risks associated with radiation exposure from controlled sources compared with risks associated with natural background radiation. Therefore, responsible decisions need to be made on how radioactive materials are controlled based on a judgement about the levels of risk they pose and the effectiveness of regulatory control to reduce those risks.

Over the last several years, the Commission has pursued development of a risk threshold to distinguish those radioactive materials that do not require the same stringent level of regulatory control as that imposed on potentially more hazardous materials. The Commission recognized throughout this process that the threshold would need to be low enough to continue to ensure adequate protection of the public. The Commission also recognized that the

threshold should be compatible with technological and measurement capabilities so it could be readily used in NRC's regulatory program for nuclear materials. In addition, the Commission identified the need to balance incremental reductions in risk below the safety threshold with the attendant expenditure of private and public resources.

In today's notice, the Commission establishes a policy to guide its decisions on which radioactive materials are "below regulatory concern" (BRC) because the low levels of risk they pose do not warrant regulation to the same degree as other radioactive materials to ensure adequate protection of the public and the environment. This policy translates the Commission's judgement on acceptable risk into explicit and practical criteria on which to base decisions to exempt practices from the full scope of NRC's regulatory program. The BRC criteria are necessary to ensure adequate and consistent decisions on acceptable risks posed by decontaminated and decommissioned nuclear facilities, consumer products containing radioactive materials, and very low activity radioactive wastes. These decisions will be implemented by the Commission through rulemakings and licensing decisions based on careful and thorough analyses of the risks associated with specific practices to ensure that the public is adequately protected.

Under the regulatory approach used by the U.S. Nuclear Regulatory Commission (NRC), the use of radioactive materials is subject to limits and conditions that ensure the protection of the health and safety of both workers and members of the general public, and the environment. For example, radioactive material is controlled by NRC- and Agreement State-licensees to ensure that dose limits are not exceeded. In addition, sources of radiation are designed, used and disposed of in a manner that ensures that exposures to radiation or radioactive material are as low as is reasonably achievable (ALARA), economic and social factors being taken into account. NRC has endorsed the ALARA provision in regulatory practice for a number of years (10 CFR part 20). However, NRC has not yet provided criteria that would establish the basis for defining the level of residual risk at which further regulatory control is no longer warranted.

The policy statement in today's notice provides a unifying risk framework for making decisions about which practices can be exempted from the full scope of NRC's comprehensive regulatory controls. Under the criteria and principles of this policy statement, exemptions of radioactive materials from regulatory controls would involve the transfer of very small quantities of the materials from a regulated to an unregulated status. NRC will analyze each proposed exemption to ensure that doses resulting from the proposed transfer will be sufficiently low that the public health and safety and the environment will remain adequately protected. A licensed activity producing an exempt material would continue to be subject to the full range of regulatory oversight, inspection, and enforcement actions up to and including the point of transfer to an exempt status. The Commission also intends to conduct research periodically to evaluate the effectiveness of this policy and to confirm the safety bases that support the exemption decisions.

Through appropriate rulemaking actions or licensing decisions, the Commission will establish constraints, requirements, and conditions applicable to specific exemptions of radioactive materials from NRC's regulations. The NRC will verify that licensees adhere to these exemption constraints and conditions through NRC's licensing, 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 a 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 (LLRWPAA) of 1985 directed the Commission to develop standards and procedures and act upon petitions "to exempt specific radioactive waste streams 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.

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 certain low-level radioactive wastes from requirements for disposal in licensed low-level waste disposal facilities. The Atomic Energy Act of 1954, as amended, gives to the Federal government the exclusive authority to regulate source, special nuclear, and byproduct materials to ensure protection of the public health and safety. While Congress subsequently provided for Federal-State agreements under Section 274b of the Atomic Energy Act through which States could assume regulatory responsibilities in lieu of Federal regulation for certain classes of nuclear materials, it required that State radiation protection standards be coordinated and compatible with the Federal standards for radiation protection.

NRC regulations exempting BRC wastes will not affect the authority of State or local agencies to regulate BRC wastes for purposes other than radiation protection in accordance with Section 274b of the Atomic Energy Act. Under the Atomic Energy Act, Congress intended that there be uniformity between the NRC and Agreement States on basic radiation protection standards. Future BRC Rulemakings will establish basic radiation protection standards below which regulatory oversight is not needed. The Commission will address compatibility issues in future rulemakings. In initiating proceedings to implement NRC's BRC policy, the Commission will continue to consult with and seek the advice of the States.

Some States have expressed concerns that economic and institutional impacts of actions resulting from the Commission's BRC policy may undermine their efforts to develop new disposal facilities for low-level radioactive waste in accordance with the Low-Level Radioactive Waste Policy Amendments Act of 1985. These States would prefer to establish their own standards for determining which wastes should be exempted from regulatory control rather than adopting standards that are compatible with uniform Federal standards. The Commission has developed the BRC policy to provide a uniform and consistent health and safety framework for exemption decisions. In so doing, the Commission recognized the concerns expressed by Congress when it enacted the Low-Level Radioactive Waste Policy Amendments Act of 1985 that health, safety, and environmental considerations should take precedence over economic or institutional concerns (see Senate Report 99-199 that accompanied S. 1517, Senate Committee on Energy and Natural Resources, November 22, 1985, 99th Congress, 1st Session at page 9).

The Commission is confident that waste exemption decisions made in accordance with requirements that implement its BRC policy will be adequate to ensure protection of the public health and safety. The Commission is concerned that inconsistent regulation of BRC wastes could result in differing levels of risks to the public and the environment through the application of different residual radioactive criteria in the cleanup of contaminated sites. The Commission is also concerned that inconsistent regulation of BRC waste could in fact undermine State and Federal efforts to manage low level waste safely. A uniform framework for exemption decisions is needed now to avoid disrupting State and compact development of new disposal facilities close to Congressional milestones in 1993 and 1996. Such a framework may also facilitate the resolution of the mixed waste issues for these BRC wastes.

The policy described in this document is intended to provide the public health and safety protection framework that would apply to a wide spectrum of Commission exemption decisions. As such, it provides individual and collective dose criteria, and discusses other important elements of the exemption decision-making process. Section II provides definitions of key terms and concepts used in the policy statement. Section III presents the basic elements of the policy, while Section IV discusses how the policy will be implemented through rulemakings and licensing actions and describes how the public will have an opportunity to comment on the Commission's exemption decisions. This section also notes NRC plans to review past exemption decisions to ensure consistency with the risk framework described in the BRC policy. Section V describes, in general terms, the information needed to support the exemption decision-making process.

II. Definitions.

ALARA (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain radiation exposures as far below applicable dose limits as is practical, consistent with the purpose for which the licensed activity is undertaken taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations and in relation to utilization of nuclear energy and licensed materials in the public interest.

"Agreement State" means may State with which the Commission has entered into an effective agreement under

subsection 274(b) of the Atomic Energy Act of 1954, as amended.

Byproduct material means—

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or utilizing special nuclear material; and

(2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition.

Collective doses 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 specifed 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, determines to be special nuclear material, but does not include source material; or

(2) Any material artificially enriched by any of the foregoing but does not include source material.

Total effective dose equivalent means the sum of the deep dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures) expressed in rem or sievert.

III. Policy Elements

The purpose of this policy statement is to establish the risk framework within which the Commission will initiate the development of appropriate regulations or make licensing decisions to exempt certain practices from some or all regulatory controls. 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. In either case, opportunity for public comment will be provided with each rulemaking and each licensing action where generic exemptions provisions have not already been established.

It is the Commission's intent to broadly define specific practices so that the effect of an exemption decision on any individual or population will be evaluated in its entirety and not in a piecemeal fashion. At the same time, the practice must be identified and described in terms that will facilitate reasonable impact analyses and allow imposition of appropriate constraints, requirements, and conditions as the radioactive material passes from a regulated to an unregulated status (i.e., the material is no longer required to be under the control of a licensee). Under this policy, the definition of a "practice" in any specific decision (rulemaking or licensing action) is a critical feature. The NRC will ensure that formulation of exemptions from regulatory control will not allow deliberate dilution of material

or fractionation of the radiation or radioactive material for the purpose of circumventing controls that would otherwise be applicable. The definition of the practice in any specific exemption decision will also provide the framework for taking into account the potential effects of aggregated exposure from that practice together with other exempted practices, as well as the possible consequences of accidents or misuse or the potential for other nonstochastic radiological impacts associated with the exemption.

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. Such practices should be specifically evaluated to determine if they could result in greater risk levels to exposed members of the public than the levels found acceptable by the Commission in formulating this policy. These decisions clearly fall within the Commission's purview to protect the health and safety of the public.

In formulating this policy statement, the Commission deliberated at length on the need to consider whether practices must be rigorously justified in terms of societal benefit regardless of the level of risk thay pose. Justification of practice is recognized by health physics professionals and national and international organizations as one of the three fundamental tenets of radiation protection (justification, dose limits, and ALARA). The Commission has prepared this policy statement in conformance with these basic tenets as appropriate for exemption decisions. Consistent with the position of the International Atomic Energy Agency in its Safety Series Report No. 89, the Commission believes that justification decisions usually derive from considerations that are much broader than radiation protection alone. 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.

A. Principles of Exemption

The principal consideration in exempting any practice from some or all regulatory controls hinges on the general question of whether the application or continuation of regulatory controls is necessary to protect the public health and safety and the environment. To decide if exemption is appropriate, the Commission must determine if adequate protection is provided and 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 dose received by individuals within a critical group (i.e., the group expected to receive the highest exposure) and by the exposed population; or

2. The costs of the controls that could be imposed for further dose reduction are not balanced by the potential commensurate reduction in risk.

At a sufficiently low level of risk, the Commission believes the decision-making process for granting specific exemptions from some or all regulatory controls can be essentially reduced to an evaluation of whether the overall individual and collective risks from each particular practice are sufficiently small. The Commission believes that individual and collective dose criteria should be basic features of its overall policy to define the region where the expenditure of Commission resources to enforce 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 risks 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, D.C.). 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.

TABLE 1

Incremental annual dose*	Hypothetical incremental annual risk**	Hypothetical lifetime risk from continuing annual dose**
100 mrem (1.0 mSv)	5×10^{-3}	3.5×10^{-3}
10 mrem (0.1 mSv)	5×10^{-4}	3.5×10^{-4}
1 mrem (0.01 mSv)	5×10^{-7}	3.5×10^{-5}
0.1 mrem (0.001 mSv)	5×10^{-6}	3.5×10^{-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.

** Calculated using a conservative risk coefficient of 5×10^{-4} per rem (5×10^{-2} per Sv) for low linear energy transfer radiation based on the results reported 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 and "Health Effects of Exposures to Low Levels of Ionizing Radiation, BEIR V," 1990, Committee on Biological Effects of Ionizing Radiation, National Research Council (see also NUREG/CR-4214, Rev. 1).

In view of the uncertainties involved in risk assessment at low doses and taking into account the aforementioned risk and dose perspectives, the Commission finds that the average dose to individuals in the critical group should be less than 10 mrem per year (0.1 mSv per year) for each exempted practice. In addition, an interim dose criterion of 1 mrem per year (0.01 mSv per year) average dose to individuals in the critical group will be applied to those practices involving widespread distribution of radioactive material in such items as consumer products or recycled material and equipment, until the Commission gains more experience with the potential for individual exposures from multiple licensed and exempted practices. These criteria provide individual dose thresholds below which continued regulatory controls are unnecessary and unwarranted to require further reductions in individual doses. The Commission considers these criteria to be appropriate given the uncertainties involved in estimating doses and risks, and notes that these criteria should facilitate straightforward implementation of this policy in future rulemakings or licensing decisions.

The Commission believes that, notwithstanding exemption of practices from regulatory control under these criteria, it still has reasonable assurance that exposures to individual members of the public from all licensed activities and exempted practices will not exceed 100 mrem per year (1 mSv per year) given the Commission's intent (1) to define practices broadly; (2) to evaluate potential exposures over the lifetime of the practice; (3) to evaluate the potential for aggregated exposures from multiple exempted practices; (4) to impose both individual and collective dose criteria; (5) to monitor and verify how exemptions are implemented under this policy; (6) to verify dose calculations through licensing reviews and rulemakings with full benefit of public review and comment; and (7) to inspect and enforce licensee adherence to specific constraints and conditions imposed by the Commission on exempted practices.

The Commission intends that only under unusual circumstances would exemptions be considered for practices that could cause continuing radiation exposure to individuals exceeding a small fraction of 100 mrem per year (1 mSv per year). In rare cases, exemptions of such practices may be granted if, after conducting a thorough analysis of the proposed exemption, the Commission determines that doses to members of the public are ALARA and that additional regulatory control is not warranted by further reductions in individual and collective doses.

C. The Collective Dose Criterion

The Commission believes that the collective dose (i.e., the sum of individual total effective dose equivalents) resulting from exposure to an exempt practice should be ALARA. However, if the collective dose resulting from an exempted practice is less than an expected value of 1000 person-rem per year (10 person-Sv per year), the resources of the Commission and its licensees could be better spent by addressing more significant health and safety issues than by requiring further analysis, reduction, and confirmation of the magnitude of the collective dose. The Commission notes that, at this level of collective dose, the number of hypothetical health effects calculated for an exempted practice on an annual basis would be less than one.

The National Council on Radiation Protection and Measurements recommends in its Report No. 91[1] that collective dose assessments for a particular practice 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

[1] Recommendations on Limits for Exposure to Ionizing Radiation, NCRP Report No. 91, National Council on Radiation Protection and Measurements, June 1, 1987. Available for purchase from NCRP Publications, 7910 Woodmont Ave., Suite 1016, Bethesda, MD 20814.

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 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 this policy to ensure that the public health and safety continue to be protected adequately.

V. Information To Support Exemption Decisions

A. General

The information required to support an exemption decision in a rulemaking or licensing action should provide the basis for the proposed exemption in accordance with Section III of this policy. In addressing the radiological health and safety impacts, potential individual and collective doses attributed to the practice under consideration should either meet the policy's dose criteria or otherwise be demonstrated to be low enough to ensure protection of the public health and safety and ALARA. In addition to the impacts of routine exposures, realistic impacts resulting from potential misuse or accident scenarios should also be evaluated and demonstrated to be insignificant. The NRC may reject proposals for exemptions if they do not provide a sufficient technical basis to support analysis of the potential exemption.

Practices should be defined with respect to the geographic and demographic areas to which the exemption will apply. In some cases, an exemption will be limited to one particular locality or area. However, many practices will have national applicability and should be characterized accordingly. Information on these issues will be necessary for determinations regarding which individual dose criterion should be applied.

The Commission believes that the implementation guidance provided with its "General Statement of Policy and Procedures Concerning Petitions Pursuant to § 2.802 for Disposal of Radioactive Waste Streams Below Regulatory Concern," published August 29, 1986, 51 FR 30839, generally defines the types of information needed to support an exemption decision. However, not all of the information may be applicable to the broader range of practices considered for exemption under this policy. Applicants should examine potentially relevant guidance available at the time the exemption proposal is being prepared and provide the information which is relevant to the particular type of exemption decision being requested.

B. Material Characterization

1. *Radiological properties.* The radiological properties of the materials to be exempted should be described, including, as appropriate, the concentration or contamination levels and the half-lives, total quantities, and identities of the radionuclides associated with the exempted practice. The chemical and physical form of the radionuclides should be specified. All radionuclides present or potentially present should be specified. The distribution of the radionuclides should be noted (e.g., surface or volume distribution). Mass- and volume-averaged concentrations should also be presented. The variability of

radionuclide concentration, distribution, or type as a function of process variation or variations among licensees should be addressed and bounded, as appropriate.

2. *Nonradiological properties.* The nonradiological properties of the materials to be exempted should be described to ensure complete characterization of the properties of the material and consideration of any adverse impacts associated with these properties. An NRC exemption, based on radiological impacts, would not relieve licensees from compliance with applicable rules of other agencies which cover nonradiological properties. A description of the materials, including their origin, chemical composition, physical state, volume, and mass should be provided. The variability and potential changes in the materials as a function of process variation should be addressed. The variation among licensees should be described and bounded, as applicable.

C. Practice Characterization

1. *Total impact.* A regulatory action taken under this policy is likely to be generic and may be nationwide in scale. Therefore, to the extent possible, an estimate of the number of NRC and Agreement State licensees that possess the radioactive material considered for exemption, the annual volumes and masses, and the total quantities of each radionuclide that would be a part of the exempted practice should be given. The estimates should include the current situation and the likely variability over the reasonably foreseeable future. A geographical description would be a helpful tool in characterizing the distribution of radioactive material involved in the exemption decision. Such distribution, submitted as part of the practice characterization, should be used to assess realistic impacts of the practice, in addition to conservative bounding estimates that tend to overestimate human exposures and doses. In any case, the typical quantities produced per practice (e.g., number of units of a particular consumer product) and an estimate of the geographic description of the practice should be described. The potential for short- and long-term recycle or reuse of the product containing the exempted radioactive material should also be addressed. Both the resource value (e.g., salvageable metals) and the functional usefulness (e.g., usable tools) should be examined.

2. *Basis for assessment.* A description of bases for the materials and practice characterizations should be provided. Monitoring and analytical data and calculations should be specified and provided in support of the characterization. Actual measurements or values that can be related to measurements to confirm calculations are important and should be provided. The description should address the quality assurance program used in data collection and analysis and supporting information. If any surveys were conducted, they should be described. Market 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 analsyis 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 (DOT) requirements for labeling, placarding, and manifesting radioactive materials in 49 CFR part 173.

F. Constraints, Requirements, or Conditions on Exemptions

In most cases, the characterizations of the material and the assessment of impacts will be based on either explicit or implicit constraints, such as limitations on the amount of radioactive material in a consumer product. In order for an exemption decision to take credit for these constraints, the exemption proposal should specifically identify appropriate constraints, such as quantity limits, concentration limits, and physical form characteristics. The bases on which these constraints are to be ensured should also be discussed. In general, constraints should be verifiable in order to provide the basis for an exemption decision.

G. Quality Assurance and Reporting

This portion of the exemption proposal should be tailored to either a generic petition for rulemaking or specific proposal for a license amendment. For generic petitions for rulemaking, the proposal should provide and justify generic requirements for Quality Assurance/Quality Control and Reporting. Such proposals should include example requirements and show their effectiveness and feasibility. For site-specific license amendments, the exemption proposal should provide specific requirements for Quality Assurance/Quality Control and Reporting that have been tailored to the licensee's program.

1. Quality assurance/quality control. The program to ensure compliance with specific exemption constraints, requirements, or conditions should be defined. The records of inventory, tests, surveys, and calculations used to demonstrate compliance with the exemption constraints should be maintained for inspection. Such programs are necessary to provide the NRC and the public reasonable assurance of conformance with the constraints and of adequate protection of human health and the environment.

2. Reports. Reports may be required from licensees who, by rule or license, are permitted to release materials exempted from regulatory control. Associated recordkeeping to generate the reports should be defined. Minimum information in the reports could include volume, isotope and curie content. More detailed recordkeeping and reporting requirements may be imposed to address uncertainties in projecting future volumes or amounts of exempted materials and to consider the cumulative impacts of multiple exemptions.

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 the 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.[2] 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 background [3] requires a significant extrapolation from the observed effects at much higher doses and dose rates.[4] 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

[2] 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.

[3] Natural background radiation can vary with time and location. In Washington, DC, 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. population (NCRP Report No. 93, "Ionizing Radiation Exposure of the Population of the United States").

[4] 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.

(low LET; low linear energy transfer radiation) of about 100 mrads/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^{-5} and 3.5×10^{-4} per rad (7×10^{-3} 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 the 1988 UNSCEAR report. The BEIR V report's estimate of lifetime excess risk of death from cancer following an acute dose of 10 rem (0.1 Sv) of low-LET radiation was 8×10^{-3}. Taking into account a dose rate effectiveness factor for doses occurring over an extended period of time, the risk coefficient is on the order of 5×10^{-4} per rem, consistent with the upper level of risk estimated by UNSCEAR.

In view of this type of information, the NRC, the Environmental Protection Agency, and other national and international radiation protection authorities have established radiation protection standards defining recommended dose limits for radiation workers and individual members of the public. As a matter of regulatory prudence, all these bodies have derived the value presumed to apply at lower doses and dose rates associated with the radiation protection standards by a linear extrapolation from values derived at higher doses and dose rates. This model is frequently referred to as the linear, no-threshold hypothesis, in which the risk factor at low doses reflects the straight-line (linear) dose-effect relationship at much higher doses and dose rates. In this respect, the BEIR V report notes that "in spite of evidence that the molecular lesions which give rise to somatic and genetic damage can be repaired to a considerable degree, the new data do not contradict the hypothesis, at least with respect to cancer induction and hereditary genetic effects, that the frequency of such effects increases with low-level radiation as a linear, non-threshold function of the dose."

The Commission, in the development of the BRC policy, is faced with the issue of how to characterize the individual and population risks associated with low doses and dose rates. Although the uncertainties are large, useful perspective on the bounding risk associated with very low levels of radiation can be provided by the linear, no-threshold hypothesis. Consequently, such risk estimates have been a primary factor in establishing individual and collective dose criteria associated with this policy. The estimations of the low risk from potentially exempted practices can be compared to the relatively higher potential risks associated with other activities or decisions over which the NRC has regulatory responsibility. Through such comparisons, the Commission can ensure that its radiation protection resources and those of its licensees are expended in an optimal manner to accomplish its public health and safety mission.

In this context, 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 hypothetical increase of about 0.25% in an individual's lifetime risk of cancer death. Ten millirem per year (0.1 mSv per year) is also a dose rate that is a small fraction of naturally occurring background radiation and comparable to the temporal variations in natural background radiation due to fluctuations that occur at any specific location.

TABLE 1

Incremental annual dose [1]	Hypothetical incremental annual risk [2]	Hypothetical lifetime risk from continuing annual dose [2]
100 mrem (1.0 mSv)	5×10^{-3}	3.5×10^{-2}
10 mrem (0.1 mSv)	5×10^{-4}	3.5×10^{-3}
1 mrem (0.01 mSv)	5×10^{-7}	3.5×10^{-5}
0.1 mrem (0.001 mSv)	5×10^{-6}	3.5×10^{-6}

[1] 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.

[2] Risk coefficient of 5×10^{-4} per rem (5×10^{-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).

The Commission prefers to use factors of ten to describe such low individual doses because of the large uncertainties associated with the dose estimates. Use of values such as 0.7 or 12 imputes a significance and sense of certainty that is not justified considering the levels of uncertainty in the dose and risk estimates at these low levels. Thus, order of magnitude values such as 1 and 10 are preferable to avoid providing analysts and the public with a sense of certainty and significance that is not commensurate with the actual precision and certainty of the estimates.

B. Collective or Population Risk

In the application of the fundamental principles of radiation protection, collective dose provides a useful way to express the radiological impact (i.e., potential detriments) of a practice on the health of the exposed population. Because of the stochastic nature of risk, analysis of exposures of large groups of people to very small doses may result in calculated health effects in the population at large. Collective dose is the sum of the individual total effective dose equivalents resulting from a practice or source of radiation exposure. It is used in comparative cost-benefit and other quantitative analytical techniques and, therefore, is an important factor to consider in balancing benefits and societal detriments in applying the ALARA principle. For purposes of this policy, individual total effective dose

equivalents less than 0.1 mrem per year (0.001 mSv per year) do not need to be considered in the estimation of collective doses. The Commission believes consideration of individual doses below 0.1 mrem per year imputes a sense of significance and certainty of their magnitude that is not justified considering the inherent uncertainties in dose and risk estimates associated with potentially exempted practices. The Commission also notes that doses in the range of 0.01 to 0.1 mrem per year correspond approximately to lifetime risks on the order of one in a million. The NRC has used collective dose, including rationales for its truncation, in a number of rulemaking decisions and in resolving a variety of generic safety issues.

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 into 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 response are attached.

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

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

Additional Views of Commissioner Curtiss

I strongly endorse going forward with a comprehensive policy that will establish a disciplined and consistent framework within which the Commission can define those practices that, from the standpoint of radiological risk, we consider to be below regulatory concern (BRC). The principal advantage of such a policy, in my view, is that it will bring much-needed discipline and technical coherence to the patchwork of BRC regulatory decisions that have been rendered to date, providing a clearly-articulated, risk-based approach for reaching decisions on matters such as—(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; and (4) the recycling of slightly contaminated equipment and materials. A coherent, risk-based policy is urgently needed to provide the foundation for future regulatory actions in each of these areas. Accordingly, I strongly support this initiative.

There are certain aspects of this policy, however, with which I must reluctantly disagree. My views on these matters follow:

Individual Dose Criteria

I support the individual dose criteria of 10 millirem per year for practices involving potential exposures to limited numbers of the public and 1 millirem per year for widespread practices that involve potential exposures to large numbers of the public. In view of the potential for multiple exposures from widespread practices, however, and in the interest of administrative finality, I believe that the Commission should establish the 1 millirem criterion as a final criterion, rather than an interim value.

Collective Dose Criterion

I do not support the establishment of a collective dose criterion at a level of 1000 person-rem. This level is an order of magnitude higher than the level recommended in IAEA Series No. 89, as well as the level recommended by most other international groups. Furthermore, it is an order of magnitude higher than the 1986 collective dose to members of the public due to effluents from all operating reactors, the most recent year for which figures are available.

A collective dose criterion of 1000 person-rem would mean, for example, that if, pursuant to this Policy Statement, the Commission were to exempt on the order of fifteen separate practices with collective doses at or near the exemption level of 1000 person-rem—not an unreasonable expectation, given previous practice—we would project somewhere between 5 and 10 excess health effects annually. I consider this level to be unacceptably high, when viewed in the context of other risks that we regulate and in view of the fact that the purpose of this Policy Statement is to establish a framework for identifying those practices that the Commission considers to be below regulatory concern.

Beyond this, if the collective dose criterion is to be defined as the floor to ALARA (as I would propose below), a more conservative approach to establishing a collective dose criterion is warranted in view of the fact that doses may be truncated in the calculation of collective dose and the collective dose criterion may be applied to single licensing actions.

For these reasons, I do not support a collective dose criterion of 1000 person-rem. Instead, in view of what appears to be the prevailing technical view on this matter, I would endorse a collective dose criterion of 100 person-rem.[1]

ALARA

I would define the individual and collective dose criteria as floors to ALARA.[2] Unfortunately, the Policy Statement is equivocal on this issue, suggesting at one point that the individual and collective dose criteria should be construed as floors to ALARA—

[A] licensee * * * 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.

but then going on to send what I consider to be a conflicting and confusing message about what the Commission expects—

The Commission in no way wishes to discourage the voluntary application of additional health physics practices which may, in fact reduce actual doses below the BRC criteria or the development of new technologies to enhance protection to public and the environment. (emphasis added)

If the Commission intends to say, as I believe it does in this Policy Statement, that those practices that fall within the individual and collective dose critera can be designated below regulatory

[1] I would point out that the Policy Statement allows higher collective doses if analyses show that the collective dose is ALARA for a given practice. Therefore, adoption of the lower IAEA value of 100 person-rem based on dollar estimates of resources to do detailed ALARA analyses would not eliminate the option to approve practices such as smoke detectors that involve large numbers of potentially exposed members of the public.

[2] By "floor to ALARA", I mean that the petitioner and the staff 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.

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.[3] 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:

> 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 ambigutiy 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 (LLRWPAA), 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 recognized that some states may decide to construct facilities that, from a technical standpoint, go beyond the requirements established in 10 CFR Part 61 for shallow land burial facilities; for this reason, Congress directed the NRC to develop guidance on alternatives to the shallow land burial approach reflected in Part 61 (see section 8 of P.L. 99-240). Similarly, should a State decide to require radioactive wastes beyond those defined by the NRC as Class A, B, and C wastes to be disposed of in a regional disposal facility, the Act permits the states that option as well (see section 3(a)(2) of P.L. 99-240).[4] In short, the LLRWPAA grants states a great deal of latitude in deciding what kind of facility to build and what types of waste will be disposed of in that facility, so long as—(1) the facility complies with the requirements of 10 CFR Part 61; and (2) the State provides disposal capacity for Class A, B, and C wastes.

If one interprets the LLRWPAA in this manner, as I do, then in my judgment it is consistent with this general approach to conclude that this Policy Statement (and the subsequent rulemaking initiatives implementing the Policy Statement) should not be considered matters of compatibility. The result of such an approach would be that individual states would be allowed the option of deciding whether low-level wastes designated BRC by the Commission under this Policy Statement should nevertheless be disposed of in a licensed low-level radioactive waste disposal facility.

The argument, as I understand it, that is advanced in support of the approach taken in the Policy Statement—that the Commission's position on BRC should be a matter of compatibility—is that states should be foreclosed from departing in any way from the approach established by the Commission. To take the most visible and controversial example that has arisen to date, this would lead to the result that a State could not require that low-level waste streams designated BRC by the Commission nevertheless be disposed of in a licensed low-level radioactive waste disposal facility.

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[3] 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.

[4] Indeed, the Commission did not object when the Rocky Mountain compact proposed to dispose of radium waste in the Rocky Mountain compact site.

I am not aware of any public health and safety rationale involving low-level waste disposal that has been advanced as a basis for the NRC to insist that the Commission's position on BRC should be a matter of compatibility for Agreement States. One hears the anecdotal information about reducing exposures to truck drivers by allowing BRC waste streams to be disposed of in local landfills, rather than requiring such waste to be transported across the country to a licensed low-level waste disposal facility. If examples such as this constitute the basis for declaring that a health and safety concern exists such that the Commission should, in turn, prohibit a State from requiring such waste to be disposed of in a licensed low-level waste disposal facility, then a more disciplined and persuasive presentation of the argument is needed. To date, I have yet to see such a case.[5] In the absence of a health and safety concern, it is incongruous, in my judgment, to say that the risk from a particular waste stream can be so insignificant as to be "below [NRC's] regulatory concern", but at the same time insist that we nevertheless have a sufficient interest to dictate how a State might otherwise wish to handle that waste stream.[6]

For the foregoing reasons, I would not treat the federal policy on below regulatory concern, as set forth in this Policy Statement and subsequent rulemakings, as a matter of compatibility for Agreement States when it comes to issues involving commercial low-level radioactive waste disposal.

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 voted 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 allocated 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 few 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

[5] This kind of information may well be a part of the waste stream petition that the nuclear utilities are reportedly preparing for submission. If so, I would hold open the option of revisiting this question if and when the petition is filed. But at this point, I have yet to see a health and safety justification that would support a decision on the Commission's part that states should be preempted from the option of requiring waste streams designated BRC under this Policy Statement to be disposed of in licensed low-level radioactive waste disposal facilities.

[6] The argument has been made that permitting states the option of requiring BRC waste streams to be disposed of in licensed low-level waste disposal facilities would use up scarce disposal capacity and otherwise have an adverse impact on the compacting process. Indeed, this appears to have been one of the principal concerns advanced in the Commission's 1986 Policy Statement on BRC, wherein the Commission expressed the view that low-level waste generators would "be competing for space in the existing [LLW disposal] sites and the [BRC] concept should be applicable nationwide" in order to ensure "that the system works on a national basis and that it remains equitable." It was in part for this reason that the Commission declared in the 1986 Policy Statement that future "[r]ulemakings granting petitions [on BRC] will be made a matter of compatibility for Agreement States." (Policy Statement, 51 FR 30839, 30840 (August 29, 1986)). Whatever merit that approach might have had at the time, I disagree with it for two reasons: (1) Congress has vested states with the responsibility for developing and managing disposal capacity for low-level waste and, in view of this, decisions about how best to proceed, including decisions about whether states prefer to require BRC waste streams to be disposed of in licensed low-level waste sites rather than sanitary landfills, are best left to the individual states. (2) There is an abundance of disposal capacity under development at the present time and, for this reason, the concern about husbanding limited disposal capacity no longer appears to be relevant. Indeed, the decision to permit the Rocky Mountain compact to dispose of radium waste in it regional disposal facility seems to suggest that the objective of preserving limited disposal capacity for the disposal of low-level radioactive waste is not the driving consideration.

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 with exemptions of practices with widespread distribution.

Collective Dose Criterion

Commissioner Curtiss would have preferred to adopt a collective dose criterion of 100 person-rem/year because of his view that this value is more consistent with the prevalent technical view on this matter.

For the reasons discussed below, I believe that a collective dose criterion of 1000 person-rem/year is more consistent with the prevalent technical view on this matter and provides a sounder regulatory basis for making exemption decisions. The Commission considered two fundamental questions associated with the collective dose criterion: (1) Is there a need for a collective dose criterion and, if so, (2) what should the value of that criterion be?

The Commission initially questioned the very need for a collective dose criterion for the types of practices that would be considered as potential candidates for exemption. This questioning was based on a number of factors that indicated that the Commission may not need to consider collective dose in making exemption decisions. These factors included:

1. There is considerable uncertainty associated with the validity of risk estimates based on projections of collective doses composed of small to very small doses to large numbers of people.

2. The individual dose criteria of 1 and 10 millirem per year, coupled with the other provisions of the policy (e.g., broad definition of practice), should ensure a consistent and adequate level of protection of members of the public from all exempted and licensed practices.

3. Although collective dose has been considered in evaluating environmental impacts and in assessing the effectiveness of licensee ALARA programs, NRC's regulatory program has not traditionally placed specific constraints on collective doses associated with regulated activities.

4. Based on comments submitted to the Commission on its proposed BRC policy, including comments presented by the Health Physics Society, the prevailing technical view opposed adoption of a collective dose criterion in the BRC policy.

Despite these considerations, the Commission also recognized the benefit of a collective dose criterion in limiting the total population dose associated with exempted practices and in evaluating environmental impacts and the effectiveness of ALARA programs. Consequently, the Commission decided to establish a collective dose criterion as a part of the BRC policy, provided that it was based on valid scientific analysis and that it did not constrain decisions on exemptions without an adequate health and safety or environmental basis.

Based on these provisions, the Commission selected the value of 1000 person-rem/year as a level of collective does that ensures less than one health effect per practice. In selecting this value, the Commission relied on contemporary recommendations of expert national and international bodies. These included the 1988 conclusions of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) that collective dose calculations only provide reasonable estimates of health risks if the collective dose is at least of the order of 10,000 person-rem. This value is an order of magnitude greater than the value of the collective dose criterion selected by the Commission. UNSCEAR also stated that the most likely outcome of collective doses on the order of a few hundred person-rem is zero deaths.

The Commission also considered the magnitudes of collective doses associated with practices, primarily consumer products, that have already been exempted by the Commission. This was done to provide a benchmark for the value of the collective dose criterion based on historical decisions that the public found acceptable. The Commission found that the magnitudes of the collective doses for these exempted practices fell in the range of the 1000 person-rem/year dose. Specific examples include 1200 person-rem/year from watches whose dials are adorned with paint containing tritium, 800 person-rem/year from smoke detectors containing radioactive materials, and 8600 person-rem/year from gas mantles for lanterns that contain thorium (NCRP Report No. 95).

In addition, the Commission considered the magnitude of collective doses associated with licensed activities, such as discharge of effluents from nuclear power plants. The Commission established ALARA design objectives for effluent treatment systems for power plants in Appendix I to 10 CFR Part 50. The Commission noted that the dose values established in the design objectives are generally consistent with a collective dose criterion with a magnitude of 1000 person-rem/year. However, the Commission also recognized that licensees have performed better than required in accordance with Appendix I by reducing estimated collective doses from reactor plant effluents to 110 person-rem per year in 1986, which is the most recent year for which the data have been completely assessed (see NUREG/CR-2850, Vol. 8).

Finally, the Commission and its staff are only beginning to evaluate specific details of how the BRC policy will be implemented through subsequent rulemakings and licensing decisions. Even at this preliminary stage, the Commission has identified substantive implementation issues pertaining to the application of the collective dose criterion. For example, an issue has been identified regarding how the collective dose criterion would be applied in making decisions about appropriate levels of cleanup for contaminated sites. Specifically, does the collective dose criterion apply generically to the practice of decommissioning or would it be applied on a site-specific basis? Similarly, how should the collective dose criterion by 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.

ALARA

Commissioner Curtiss would prefer to define the individual and collective dose criteria as "floors" to ALARA, i.e., 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 veiw on this issue, it is important to begin from the defintion of the term ALARA. ALARA is the regulatory concept that radiation exposures and effluents should be reduced as low as 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 to 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 and 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 present technologies. Indeed, technological and cost considerations are explicitly recognized in the definition and application of the term "ALARA." Thus, I believe it would 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 Commissioner Curtiss' view on this matter because it puts the Commission in a position of making decisions in areas outside the normal arena 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 judgments 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 involve social and cultural considerations that fall outside of 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 justified in terms of net societal benefit. For example, to the best of my knowledge, the Environmental Protection Agency does not question whether the generation of hazardous wastes is justified in terms of net societal benefit, even though the agency promotes the minimization and elimination of such wastes to reduce risks.

I believe that Commissioner Curtiss misinterprets the BRC policy when he claims that it embodies a bifurcated approach on the principle of justification of practice. As clearly indicated in the policy, the Commission may determine that certain practices should not be considered candidates for exemption on the basis of risk estimates or associated uncertainties. Rejection of such an application should be based on the risks posed by the practice, rather than whether the practice is justified in terms of net societal benefit. The types of concerns he rasises about risks to children and the general public would be critically evaluated by the Commission in rulemakings to determine whether particular practices should be exempted. Therefore, I believe that the Commission has established an appropriate BRC policy that does not consider whether a proposed practice is justified in terms of societal benefit.

Agreement State Compatibility

Commissioner Curtiss also disagrees with the Commission majority view on the need for uniformity between basic radiation protection standards established by NRC and Agreement States. He indicates that he would not treat the Commission's policy on below regulatory concern as a matter of compatibility for Agreement States with respect to disposal of commercial low-level radioactive waste. He reaches this conclusion in part because he reads the Low-Level Radioactive Waste Policy Amendments Act of 1985 as giving states a great deal of latitude in deciding how to proceed with the development, construction and operation of new low-level waste disposal facilities. Drawing upon this interpretation, he concludes that individual states should be allowed the option of deciding whether low-level waste designated BRC should be disposed of in a licensed low-level radioactive waste disposal facility.

This policy statement in and of itself does not make any compatibility determinations; as indicated in the statement, compatibility issues will be addressed in the context of individual rulemakings as they occur. But I believe it is important to respond to Commissioner Curtiss on this issue in two respects. First, I do not read the Low-Level Radioactive Waste Policy

Amendments Act as giving the States particular latitude let alone specific authority in the area of waste to establish radiation standards different than those of the Commission. Second, I do not believe that the issue of BRC for waste disposal can easily be divorced from BRC in other areas such as decommissioning.

The Low-Level Radioactive Waste Policy Amendments Act did not change the regulatory framework applicable to Atomic Energy Act materials. On the contrary, the Act specifically recognized the importance of that framework by including provisions such as the following:

Sec. 4(b) * * * (3) EFFECT OF COMPACTS ON FEDERAL LAW.—Noting contained in this Act or any compact may be construed to confer any new authority on any compact commission or State—

(A) to regulate the packaging, generation, treatment, storage, disposal, or transportation of low-level radioactive waste in a manner incompatible with the regulations of the Nuclear Regulatory Commission * * *;

(B) to regulate health, safety, or environmental hazards from source material, byproduct material, or special nuclear material;

* * * * *

(4) FEDERAL AUTHORITY.—Except as expressly provided in this Act nothing contained in this Act or any compact may be construed to limit the applicability of any Federal law or to diminish or otherwise impair the jurisdiction of any Federal agency, * * *

Unlike the Uranium Mill Tailings Radiation Control Act of 1978, as amended, the Low-Level Radioactive Waste Policy Act, as amended, does not authorize States to establish more stringent standards. The Act also specifically directed the Commission to establish standards for exempting specific radioactive waste streams from regulation due to the presence of radionuclides in such waste streams in sufficiently low concentrations or quantities as to below regulatory concern. If, in response to a request to exempt a specific waste stream, the Commission determines that regulation of a radioactive waste stream is not necessary to protect the public health and safety, the Commission is directed to take necesary steps to exempt the disposal of such radioactive material from regulation by the Commission. Thus, the Act did not, in my view, grant any particular latitude to the States to determine which waste streams were of regulatory concern. Rather, it reaffirmed the existing roles of the NRC and the States in determining regulatory standards for low-level waste and specifically defined the Commission's authority in this regard as including designating waste streams which are below regulatory concern.

The respective roles of the Commission and the States with respect to the licensing and regulation of Atomic Energy Act materials, including the disposal of low-level radioactive waste received from other persons, are governed by the provisions of section 274 of the 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, i.e., 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.

[FR Doc. 90–15309 Filed 7–2–90; 8:45 am]
BILLING CODE 7590-01-M

RAILROAD RETIREMENT BOARD

Agency Forms Submitted for OMB Review

AGENCY: Railroad Board

ACTION: In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C chapter 35), the Board has submitted the following proposal(s) for the collection of information to the Office of Management and Budget for review and approval.

SUMMARY OF PROPOSAL(S): .

(1) Collection title: Notices of Intent to Offset Federal Income Tax Refund.

(2) Form(s) submitted: G–49A, G–49B.

(3) OMB Number: New Collection.

(4) Expiration date of current OMB clearance: Three years from date of approval.

(5) Type of request: New Collection.

(6) Frequency of response: Annually.

(7) Respondents: Individuals or households.

(8) Estimated annual number of respondents: 300.

(9) Total annual responses: 300.

(10) Average time per response: .166 hours.

(11) Total annual reporting hours: 50.

(12) Collection description: Under section 3720A ot title 31, U.S.Code, the Railroad Retirement Board (RRB) is authorized to refer to the Internal Revenue Service legally enforceable debts for collection by offset against tax refunds owed to individuals by the Government. The collection obtains information from overpaid beneficiaries under the Railroad Retirement Act or