Kile Zahn

(84)

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

MAR 01 1990

Mr. Andrew Maier, President
Save Our Mountains
Chairman, Summers County
Solid Waste Authority
P.O. Box 1286
Hinton, WV 25951

Dear Mr. Maier:

Your November 1, 1989, letter to Senator Rockefeller was forwarded to this office for response to the issues and questions you raised regarding potential "below regulatory concern" (BRC) waste disposal practices.

As your enclosed information indicates, the Low-Level Radioactive Waste Policy Amendments Act of 1985 (Pub. L. 99-240) directed the Nuclear Regulatory Commission (NRC) to ". . . establish standards and procedures . . . and develop the technical capability for considering and acting upon petitions to exempt specific radioactive waste streams from regulation . . . due to the presence of radionuclides in such waste streams in sufficiently low concentrations or quantities as to be below regulatory concern." In response to the legislation, NRC developed and published in 1986, a Statement of Policy and Procedures which outlines the criteria for considering such petitions. A copy of the statement is enclosed for your information (Enclosure 1). To date, no petition has qualified for consideration under this 1986 policy; however, we are aware that the nation's nuclear power utilities are preparing such a petition which may be submitted to us in the near future.

Besides this 1986 policy, the Commission is currently in the process of developing a policy that would identify the principles and criteria that govern Commission decisions which could exempt radioactive material from some or all regulatory controls. This policy, the subject of the enclosed advance notice (Enclosure 2), would apply not only to BRC waste disposals but also to other decisions which would allow licensed radioactive material to be released to the environment or to the general public. The Commission's proposed exemption policy is intended to provide a consistent basis for all our decisions that allow radioactive material to be exempt from regulatory control. Thus, the policy, although applicable to BRC waste disposal, would also provide the basis for decommissioning decisions involving the release of lands, structures, or recycled materials for unrestricted use as well as decisions regarding consumer product exemptions. We believe the nation's best interests are served by a policy that establishes a consistent risk framework within which exemption decisions can be made with assurance that human health and the environment are protected. Such a policy will also contribute to focusing limited national resources on those risks with greatest potential impact on public health and safety.

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The Commission has attached considerable importance to its rationale for selecting the numerical dose values within its exemption policy (e.g., the 10 millirem per year individual dose criterion) and intends to develop these values on a unifying risk basis. In this endeavor, the relationship between risk and dose is derived from cautious extrapolations of the most recent data available from studies of the Japanese atomic bomb survivors and other individuals that have received large doses of radiation. You will note that the individual dose criterion is also compared to variations in background exposures received by individuals in the United States and the increased exposures received from commonplace activities, such as cross-country airplane flights. The individual dose criterion, however, does not stand alone, but is coupled with a collective dose criterion and other constraints that, taken together, establish a sound basis for specifying a reasonable lower threshold for the "as low as reasonably achievable" (ALARA) principle.

With regard to the information attached to your letter, I believe several points need to be made. As you may be aware, virtually all materials contain radioactivity to some extent, such as carbon-14 or potassium-40. Therefore, it is obviously impractical to treat all wastes containing radioactive material as radioactive waste. However, a goal worth pursuing is to define the boundary of materials that should be considered as radioactive waste. The low-level waste that could be considered for exemption under Pub. L. 99-240 would only involve materials with the lowest levels of radioactivity content -- materials such as clothing, rags, paper, wood, or plastic which have been used in radiation areas within nuclear facilities. In fact, for some of these materials, the level of radioactivity may be such a small fraction of natural background radiation that it may not be readily detectable. As your information indicates, the nuclear power industry has estimated that 30 percent by volume of its low-level radioactive waste could qualify for BRC consideration. However, this material would contain only about 0.01 percent of the radioactivity contained in all the industry's low-level radioactive waste.

Second, I think it is important to understand that any BRC waste disposal activities conducted in accordance with the 1986 Policy Statement would be the subject of NRC rulemaking action. The NRC would establish regulations for determining which wastes are "below regulatory concern" and, under its normal inspection procedures, could monitor its licensees' activities to assure compliance with the requirements for transfer of such wastes from the licensees' control. One element that must be assured as part of the review is that the disposal form of the "below regulatory concern" waste must have negligible potential for recycling. You will note that this is one of the criteria in the 1986 policy. Because of this process and the expected "makeup" of BRC wastes, I do not believe that any solid waste disposal facility, much less the thousands you claim, would become future superfund sites because of BRC disposals.

Finally, I would point out that, while it is true that radiation protection policies have conservatively presumed that any level of radiation exposure involves risk, the most recent authoritative study, "Health Effects of Exposure to Low-Levels of Ionizing Radiation," issued by the National Research Council, points out that ". . . the possibility that there may be no risks from exposures comparable to external natural background radiation cannot be ruled out." As

you know, all of us routinely receive exposures from a variety of sources of radiation, including radiation naturally occurring within our own bodies. These exposures occur from radiation that is natural in origin as well as from sources which involve man-made uses of radioactive material. In total, as estimated by the National Council of Radiation Protection and Measurements (NCRP Report No. 93), the effective dose equivalent received by the United States population averages about 360 millirem per year. Of this total, about 300 millirem per year (or over 80 percent of the total) is a result of natural sources, including radon and its decay products, while medical exposures such as x-rays, when averaged over the U. S. population, contribute an estimated 53 millirem per year. Other man-made sources contribute the remaining 1 to 2 percent of the total exposure, including nuclear fallout and nuclear power plant effluents. I am presenting this total exposure "picture" to provide a perspective on the hypothetical risks which may be associated with potential BRC waste disposal practices since any exposures from such practices would be a small fraction of the total received annually by any individual. The Commission believes this relative risk perspective is relevant to its decisions to appropriately allocate its regulatory resources to control the potential radiological risks associated with the use of radioactive materials. I also believe this perspective indicates the unreasonable conservatisms you have used in stating that 100 West Virginians can expect to get fatal cancer during their lifetimes if BRC is implemented, and attributing this conclusion to the U.S. Environmental Protection Agency.

In the broadest sense, our goal is to use our resources in a manner that provides the greatest assurance that no member of the public is likely to receive an exposure from exempt and licensed practices that approaches a significant fraction of the existing public dose limits. We therefore, believe an NRC exemption policy has considerable merit in enhancing protection of the public.

In conclusion, I want to assure you that we take our mandate to protect the health and safety of the public very seriously. As a result, we will continue to do our best in carefully and clearly responding to issues and questions raised by you and other concerned citizens.

Sincerely,

Original Signed By
Themis P. Speis

Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

Enclosures:
As stated

cc: Senator John D. Rockefeller, IV

*See previous concurrences SEE NEXT PAGE FOR DISTRIBUTION

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hazardous waste treatment, phase 1 (1995); machinery manufacturing and rebuilding (1995); coastal oil and gas extraction (1995). Guidelines for the following categories will be revised by the following dates: organic chemicals, plastics and synthetic fibers (1993); pharmaceutical manufacturing (1994); and pulp, paper and paperboard (1995). In the future, EPA will expand the list of categories when it issues mandatory biennial plans. The plans, required under section 304(m), designate industry categories EPA plans to issue guidelines for and lays out the agency's schedule. The plan issued this week is the first of the agency's biennial 304(m) plans.

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Recommended public comment

OGC SAID TO BE TROUBLED BY LEGAL VULNERABILITY ON EPA WETLANDS AGREEMENT

EPA's Office of General Counsel is concerned about a series of suits recently filed challenging a major new wetlands agreement, and is worried that the agency failed to circulate the policy for public comment, say sources privy to negotiations. OGC attorneys are reportedly troubled that EPA has set itself up for myriad lawsuits by not opening the policy up for public comment. Though the wetlands agreement setting out EPA and the Army Corps of Engineers' policy for approving wetlands permits is not considered by OGC to be a "rule" subject to public comment, the office initially felt that since the policy was of great public interest, it would be prudent to gain public input. But that suggestion was rejected by the Office of Water, which argued that public comment was unnecessary and would hold up the document, which had already been deliberated on for five years.

EPA's issuance of the wetlands memorandum of agreement on Nov. 14, 1989 (Inside EPA, Nov. 24, 1989, p3) has been fraught with controversy, generated by other government agencies and the state of Alaska. These groups argue that the agreement represents a major departure from EPA's existing policy and will significantly deter growth. The opposition has caused EPA to temporarily postpone the policy's effective date, so that it may gain input from other agencies (Inside EPA, Dec. 22, 1989, p1). Since that date, EPA has been sued by several groups in Alaska *(see related story)*. Sources from the Alaska congressional delegation have argued that the policy constitutes a "rule" subject to public comment under the Administrative Procedure Act.

The issue has caused the White House to ask the Justice Dept. for its input, asking DOJ to provide an opinion on the need for public comment, hoping to settle differences among various government agencies. DOJ was asked "to take an independent view of whether notice and comment was required," says a Water Office source.

The lawsuits reportedly have troubled the Office of General Counsel, which had recommended that in light of great public interest in the policy, EPA should have issued it for public comment. One source says that OGC is concerned by recent court rulings finding that if an issue triggers sufficient public interest, it should be reviewed by the public before going final. OGC reportedly clarified that since the policy was not a rule, the agency was not technically required to issue it for public comment -- but still felt that this would be a wiser approach. OGC staff reportedly disagree with the ruling that the government is required to issue for public comment any policy commanding sufficient public interest. Nonetheless, allowing for public comment "would [have been] a good option," in this instance, says one source.

OGC emphasized that public comment was not required, says a Water Office source. "We typically don't publish interpretative rules" for the public, adds this source, who points out that the rule had been subject to five years of public discussions. This source argues that putting policies like the wetlands agreement out for public comment will significantly hamstring the agency and "make everything grind to a halt." Sources in the Water Office are confident that they had a well-reasoned process and did not violate any requirements of the Administrative Procedure Act. They are optimistic that the policy will survive the lawsuits.

CANCER RISK STUDY BOLSTERS EPA ARGUMENT FOR TOUGH RADIATION STANDARDS

EPA is pointing to new findings -- indicating that the risk of developing cancer from exposure to low-level radiation may be higher than previously estimated -- as indicating a need for stringent EPA radiation exposure standards that have been challenged by other federal agencies as unnecessarily restrictive, agency sources say. A National Research Council committee, in *Health effects of exposure to low levels of ionizing radiation*, states that the cancer risks from exposure to radiation such as X-rays and gamma rays may be three to four times higher than those contained in a 1980 Research Council report. As a result of the report, EPA sources say, the agency is better equipped to counter assertions made by the Nuclear

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Regulatory Commission that EPA's radiation-exposure standards are too strict.

The panel that prepared BEIR V, the fifth in a series of reports on the biological effects of ionizing radiations, found higher risks than did the 1980 BEIR III committee because of new risk models, revised dose estimates for survivors of the Hiroshima and Nagasaki atomic bombings, and additional data on health effects experienced by both atomic bomb survivors and people exposed to radiation for medical purposes.

EPA sources say the agency was aware of the data that served as the basis for the BEIR V report and that it used the information in developing its own standards for radiation exposure.

EPA and the Nuclear Regulatory Commission have disagreed on what constitutes "acceptable levels" of exposure. For example, EPA proposes stricter groundwater contamination standards than does the Commission and the two agencies are at odds over a standard for radionuclide air emissions. EPA sources assert that the Commission has relied on outdated BEIR III data and therefore has failed to seek radiation exposure standards that reflect the increased cancer risks indicated in BEIR V. "Some of the pot shots [the Nuclear Regulatory Commission] has taken will now have to cease," says an EPA staffer.

A Nuclear Regulatory Commission source responds that the Commission has already revised risk estimates as a result of a 1988 report of the United Nations Scientific Committee on the Effect of Atomic Radiation, which contains findings similar to those in the BEIR V report, the source says. The Commission will review BEIR V and, if warranted, recommend "appropriate changes" in rulemaking or regulatory guidance, says this source. However, the Commission's interpretation of the BEIR V data may differ from EPA's interpretation and therefore result in differing views among the agencies as to what, if any, action should be taken in response.

The Commission is represented on a federal panel that also will examine BEIR V, the source says. The panel is part of the Committee on Interagency Radiation Research and Policy Coordination, established by the White House.

Although some of the BEIR V cancer risk figures are higher than EPA had projected, they are not so high as to require EPA to modify its standards, say agency sources. However, EPA is conducting its own review of the BEIR V findings and will be prepared to make modifications in low-level radiation exposure standards if necessary, an agency source says.

To force EPA action on visibility

HOUSE MEMBER TO PUSH TIGHTER POWER PLANT REGS IN CAA TO PROTECT U.S PARKS

House Energy & Commerce Committee member Ron Wyden (D-OR) plans to offer a Clean Air Act amendment in the House to strengthen protection of national parks by more tightly regulating nearby power plants. The development comes as EPA is under fire by environmentalists for failing to promulgate regulations mandated in the 1977 clean air amendments that would require tighter power plant controls to protect against decreased park visibility. Visibility problems result when a regional haze caused by power plant pollution clouds vistas that would otherwise be clear. The issue has reportedly captured the attention of health & the environment subcommittee chairman Henry Waxman (D-CA) and some committee members. But the issue is not likely to gain support in the Senate, where western senators have opposed stringent control of power plants. And opponents of tighter regulation say it will only complicate the clean air debate, bogging it down. They point to a similar effort in the House in 1982 as one of the reasons clean air reauthorization failed that year.

In a Dec. 20 briefing, Wyden -- together with several national environmental organizations -- called for new regulations that would require EPA to identify emission sources impairing visibility in parks and publish state guidelines to establish reasonably available control technology (RACT) for these sources. The proposed new law would provide that a state could require more or less RACT of a source, based on its contribution to the problem and the feasibility of control. It would also provide for federal implementation in instances where a state does not act and require EPA to review national progress toward visibility goals every five years -- considering further action if necessary.

EPA sources at presstime had not yet formulated a response to Wyden's plan, which is sponsored by the Sierra Club, the Environmental Defense Fund, the National Clean Air Coalition and the National Parks & Conservation Assn.

Wyden's plan would also seek to broaden the classification of pristine areas -- referred to as class I areas -- by considering means to upgrade areas to class I. Under the current law, all areas meeting national ambient air quality standards are in the Prevention of Significant Deterioration (PSD) program. Air quality in these areas is not allowed to degrade to national standards, but such areas are allowed an "increment" of degradation to permit new growth. Class I areas have the smallest increment, while class III have the largest. Wyden's proposed new law would broaden the categories of federal lands classed as II or

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MEMORANDUM FOR: Chairman Carr
Commissioner Roberts
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick

FROM: James M. Taylor, Executive Director for Operations

SUBJECT: PRELIMINARY REVIEW OF BEIR V REPORT

BEIR III ? Thought LR was on radon

On December 19, 1989, the National Academy of Science, National Research Council, Committee on the Biological Effects of Ionizing Radiation released a report entitled, "Health Effects of Exposure to Low Levels of Ionizing Radiation: BEIR V." This report is the latest in a series of reports prepared to advise the U.S. Government on the health consequence of radiation exposures, and update the findings of the BEIR IV report in 1980. The report contains information related to a number of topics, including risk estimates for cancer induction (solid tumors and leukemia), genetic effects and risks from prenatal exposure.

The staff noted in SECY-89-360, "Commission Policy Statement on Exemptions from Regulatory Control," that the BEIR V report would be available in December , 1989, and that it might be appropriate to acknowledge the report in the policy statement. The staff has begun a detailed analysis of the BEIR V report, and plans to provide further information in the subject. However, a preliminary examination of the BEIR V report has been made to determine if it contains information directly affecting the Policy Statement on Exemptions From Regulatory Control.

The Commission paper (SECY-89-360) contains a discussion of the information currently available to the staff on the health effects of radiation in Appendix A of the Policy Statement - "Dose and Health Effects Estimation." In that discussion, the staff calculated hypothesized incremental annual risk and hypothesized

lifetime risk from continuing annual dose using a risk coefficient of 5×10^{-4} per rem. The BEIR V report indicates that the risk from an acute dose of 10 rem is approximately 8×10^{-4}, and that a dose rate effectiveness factor of 2 or more should be applied when the same dose is accumulated weeks or months. Thus, the risk estimate from the BEIR V report is approximately 4×10^{-4} per rem. Other values of risk were calculated for situations where there is continuous exposure at a rate of 0.1 rem per year, and continuous exposure at a rate of 1 rem per year between the ages of 18 and 65. Table 4-2 from the BEIR V report summarizes the findings (see enclosure). In each case, taking into account a dose rate effectivenesses factor of 2, the estimates of risk are smaller than the 5×10^{-4} value assumed by the staff.

The BEIR V report also contains other information which is relevant to the considerations of exemptions from regulatory control. In particular, the BEIR committee estimated that the risks from exposure to radiation are similar for males and females, and that the risk from exposure during childhood is estimated to be about twice as large as the risks for adults. The BEIR committee recognized that its risk estimates become more uncertain when applied to very low doses, but noted that departures from a linear model at low doses could, however, either increase or decrease the risk per unit dose. The committee concluded that the new data upon which the report is based "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, nonthreshold function of the dose."

Based upon its preliminary examination, the staff believes that the statements and risk estimates in the policy statement are consistent with, and in fact are higher than those in the BEIR V report. The staff therefore, recommends that the following paragraph be added to the policy statement, Appendix A, page 30, after the paragraph discussing the 1988 UNSCEAR report.

"In December 1989, the National Academy of Sciences/National Research Council's Committee on the Biological Effects of Ionizing Radiation published a report entitled, "Health Effects of Exposure to Low-Levels of Ionizing Radiation: BEIR V." This report contained risk estimates that are in general similar to the findings in 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 was 0.8 percent. Taking into account a dose rate effectiveness factor of 2, the risk estimates is thus on the order of 4×10^{-4}, consistent with the upper level of risk estimated by UNSCEAR."

James M. Taylor
Executive Director
for Operations

Eclosure:
As stated

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CLEAN AIR ACT AMENDMENTS OF 1989

REPORT

OF THE

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS UNITED STATES SENATE

together with

ADDITIONAL AND MINORITY VIEWS

TO ACCOMPANY

S. 1630

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by the Agency), compliance data is kept at the regional level and is not aggregated to determine progress at meeting the environmental goals established by law. Stringent standards included in regulations and permit limits do not achieve their purpose, if they are frequently violated and no enforcement action is taken. The permit provisions of this section require the owners and operators of facilities violating standards to "self-monitor" and provide notice of such violations. The annual report is to include a careful accounting of these reported violations and other information which can be reasonably collected by the Administrator and which is indicative of the level of compliance with the requirements imposed here.

Information in the report on compliance shall also include specific costs to regulated entities as the result of standards issued under section 112 or section 129. These costs should be reported by industrial category and should include projections of compliance costs for each industry expected in future years to the extent possible. The cost estimate may also report the benefits associated with control requirements including the reduction in cancer incidence, reductions in risk for maximally exposed individuals, environmental and welfare impacts and benefits associated with other aspects of the air pollution control program including reductions in emissions of ozone and particulate matter precursors attributable to the standards established here.

Third, the report is to include an update on the development of the national urban air toxics program established by subsection (k).

The report is to include a listing of the recommendations made by the Chemical Safety Board established under section 129 and the actions which the Administrator has taken in response to any such recommendations. The report may also include recommendations of the Administrator with respect to changes in law which would further the purposes of section 112 or section 129.

The report may also include an estimate of the expenditures made by EPA and State and local air pollution control agencies to implement the requirements of this sections 112 and 129.

Authorization.—Subsection (u) of section 112, as added by the bill, authorizes the appropriation of such sums as are necessary to carry out each of the provisions described above. The authorization is without fiscal year limitation.

Marine Manufacturing (Section 302)

SUMMARY

Section 302 is a free-standing provision (not an amendment to the Clean Air Act) which requires the Administrator to list boat manufacturing as a separate subcategory of sources when establishing emissions standards under section 112 for styrene, unless the Administrator finds that such listing is inconsistent with requirements of the Act.

DISCUSSION

This provision is designed to recognize that there are differences relevant to standard-setting between the manufacturing process for recreational boat building and for other industries that use styrene. Emissions from the recreational boat building industry are far greater in air volume and lower in styrene content than similar emissions from other segments of the reinforced plastics industry which use different manufacturing processes. Citing this difference is not to suggest any conclusion in terms of risk to public health from styrene any conclusion in terms of risk to public health from styrene emissions of any industry; but rather is only to indicate that requiring the same technology-based emissions standards for boat manufacturing as are mandated for other segments of the reinforced plastics industry may impose disproportionate costs on boat builders. Therefore, the provisions establishes a separate subcategory for recreational boat manufacturing.

If the Administrator demonstrates that the costs of achieving compliance and any non-air quality health and environmental impacts or energy requirements will not be borne disproportionately by the recreational boat building industry, then the Administrator may find that a separate listing for recreational boat builders would be inconsistent with the goals and requirements of the Clean Air Act and would not be required to establish such a subcategory when regulating styrene emissions.

Dual Regulation of Radionuclides (Section 303)

SUMMARY

This section of the bill amends Section 302(g) of the Clean Air Act to exclude radioactive materials regulated by the Nuclear Regulatory Commission (NRC) or an Agreement State under the Atomic Energy Act from the definition of "air pollutant." Thus, in the future, such materials will be regulated solely under the Atomic Energy Act.

DISCUSSION

Under existing law, emissions of radionuclides from facilities licensed by the NRC are regulated under both the Atomic Energy Act and the Clean Air Act. The Atomic Energy Act of 1954, as amended, and the Reorganization Plan No. 3 of 1970 provide EPA with the authority to establish generally applicable environmental standards for the release of radioactive materials regulated under the Atomic Energy Act. The standards established by EPA under this authority must be adequate to protect the public health and safety and are not to consider cost.

Using this authority, EPA has promulgated environmental standards for the operation of uranium fuel cycle activities which include nuclear power plants, uranium mills, and nuclear fuel fabrication facilities. EPA also has established generally applicable environmental standards for high-level and transuranic waste storage and disposal facilities.

NRC enforces these standards at NRC-licensed facilities by promulgating regulations governing the operation of those facilities. Additionally, NRC requires that radionuclide emissions from facilities under their jurisdiction be "as low as reasonably achievable."

At present, these same radionuclide emissions also are regulated under the Clean Air Act. In 1979, EPA listed radionuclides as a

"hazardous air pollutant" under Section 112 of the Clean Air Act. After considerable litigation over several years concerning the scope of the EPA's resulting obligation under the Clean Air Act to issue National Emission Standards for Hazardous Air Pollutants (NESHAP) for radionuclides, the EPA issued, on November 1, 1989, final emission standards for radionuclides. In promulgating the rule, EPA stated that the decisions in *Natural Resources Defense Council* v. *EPA*, 824 F. 2d at 1146 (D.C. Cir. 1987) (the *Vinyl Chloride* case), and *Sierra Club* v. *Ruckelshaus*, 602 F. Supp. 892 (N.D.Cal. 1984), compelled EPA to issue a NESHAP for radionuclides.

The section 112 standards cover various sources of radionuclides, including all NRC licensees. In addition to establishing numerical standards for air emissions of radionuclides at these facilities, EPA has imposed various recordkeeping, monitoring, and reporting requirements for the sources covered.

During the legal controversy over the EPA's obligation to issue a NESHAP for radionuclides, EPA stated on several occasions that the regulation of radionuclide emissions from sources regulated by NRC under the Atomic Energy Act already provided adequate protection to the public health and safety. For example, in 1984, EPA stated that to issue an emission standard for uranium fuel cycle facilities in addition to the Atomic Energy Act standard "would be duplicative and . . . would not offer any additional public health protection." 50 Fed. Reg. at 5191.

Similarly, with respect to other NRC licensees, EPA stated that:

> EPA continues to believe existing emissions from these sources are already so low that the public health is already protected with an ample margin of safety, even without regulations. . . . Since the beginning of regulation under section 112, EPA has interpreted this section as not requiring regulation in cases where the risks from a category of sources do not exceed a certain minimum threshold. Indeed, contrary interpretations lead to results that are hard to defend from any logical or policy perspective. *Id.*

Despite its objections, EPA nonetheless proceeded to issue a radionuclide NESHAP for these licensees as required under the Clean Air Act pursuant to the order of the U.S. District Court in *Sierra Club* v. *Ruckelshaus*, *supra*. The radionuclide NESHAP issued by the EPA for these licensees under the Clean Air Act was approximately equivalent to the environmental standard for uranium fuel cycle facilities issued by EPA under the Atomic Energy Act, and reflected existing control technologies, operating practices, and emission levels of the non-fuel cycle licensees.

NRC objected to the inclusion of NRC licensees in the EPA radionuclide NESHAP issued on November 1, 1989. During the EPA rulemaking, NRC commented that "the proposed rule is not necessary as a matter of health risk, regulatory policy, or law." NRC stated that the existing regulatory structure already "provide[s] a very high degree of protection of public health and safety."

Although both EPA and NRC have stated that regulation of radionuclides under the Clean Air Act will not provide significant

public health benefits, such regulation will entail additional and significant costs. Methods for demonstrating compliance with the Atomic Energy Act differ from the methods for demonstrating compliance with the Clean Air Act standards. The compliance criteria also are different. Monitoring, recordkeeping, and reporting requirements impose significant costs upon the regulated entity under both statutes. These costs are not justified in the absence of a significant public health benefit.

Dual regulation is expensive not only for the regulated entity but also for the regulating agencies. If regulation were to continue under two separate statutes, both EPA and NRC would need to devote substantial resources to enforcing duplicative regulations. Considering the shortage of funds available for the enforcement of environmental laws, it is important to make scarce resources available for non-duplicative activities.

Both EPA and NRC support an amendment to the Clean Air Act to eliminate dual regulation of NRC licensees under both the Atomic Energy Act and the Clean Air Act.

Accordingly, section 303 eliminates regulation under the Clean Air Act of radionuclides already regulated by NRC under the Atomic Energy Act. Section 303 deletes from the definition of "air pollutant" in section 302 of the Clean Air Act radionuclides which are emitted from a facility licensed by NRC or by a State which has an agreement with the Commission pursuant to section 274 of the Atomic Energy Act (i.e., an "Agreement State"). Other conforming amendments to section 122 are made as well.

In addition, the savings clause (section 112(r), as amended by the Clean Air Act Amendments of 1989) excludes sources subject to licensing by NRC from the radionuclide emission standard preserved by that provision. Thus, the radionuclide emission standards issued by EPA on November 1, 1989, for facilities licensed by the NRC or Agreement States are nullified.

Because DOE facilities are not licensed by NRC, radionuclide emissions from those facilities would continue to be regulated by EPA under the Clean Air Act. Radionuclide emissions from other non-NRC sources also are not affected by this section, and would continue to be regulated by EPA under the Clean Air Act. In addition, EPA's regulatory authority to set generally applicable environmental standards for radionuclides under the Atomic Energy Act is not affected by this section.

Prevention of Sudden, Accidental Releases (Section 304)

SUMMARY

Section 304 of the bill adds a new section 129 to the Clean Air Act to establish programs and requirements to prevent catastrophic chemical accidents and to mitigate the consequences of such accidents when they do occur. These authorities are to be coordinated with other accident prevention and response authorities assigned to the Environmental Protection Agency including the programs established by the Emergency Planning and Community Right-to-Know Act of 1986.

The new section 129 addresses substances which, when released into the air in significant quantities, may, even in periods of limit-

ADDITIONAL VIEWS OF SENATOR MITCHELL

I support the Clean Air Act Amendments of 1989, as reported by the Environment and Public Works Committee. The Committee has labored long and hard since 1982 on the public health crisis of air pollution. The Clean Air Act has not been amended since 1977—longer than any of our other environmental statutes. The Act needs modification to keep it current.

The bill is comprehensive. It addresses the problems of acid rain, urban smog and failure of areas to meet national air quality standards, air toxics, municipal incinerators, global warming and chlorofluorocarbon emissions that deplete the earth's protective ozone layer.

The Committee has held 65 days of hearings and 45 days of markup on clean air since 1980. There is a full record of the history of the Committee's clean air activities. After a decade of deliberation, the time has come to act.

The bill reflects the decision of the Committee members to directly address our air pollution problems. This bill makes many tough choices. A timit approach will continue the litigation and delay that occurs under the existing Act, while children and the elderly continue to suffer the adverse health impacts of air pollution.

There is no perfect solution to our air pollution problems. But the quest for perfection has too often been used to justify no action at all. Further delay is not acceptable. According to a draft report, "The Health Costs of Air Pollution", by the American Lung Association, health care costs associated with mobile source emissions may range as high as $93 billion per year. According to that draft report: "The highest overall estimate from any of the studies reviewed predicted $432 billion in annual health costs from exposure to sulfate pollution, assuming "worst case" dose-response correlations between sulfate pollution and premature deaths." These are at the upper limits of the cost estimates, but it is significant that any cost estimate would be this high. This legislation, if enacted, would dramatically reduce these health cost estimates.

There is one issue on which I must express my concern. During Committee markup, an amendment to the radionuclide section of the air toxics title was offered and accepted. The authors of that provision states they intended only to avoid dual regulation of the same sources of radionuclides by both Environmental Protection Agency and the Nuclear Regulatory Commission. Both the EPA and the NRC supported this change.

However, one consequence of this change may have been to preeempt States from exercising the jurisdiction they had under the Clean Air Act to adopt radionuclide standards that are more protective than those required by the Federal Government. This is because EPA's authority to regulate radionuclides under the Clean

Air Act was eliminated. The Clean Air Act is not preemptive in this regard, as the legislative history clearly demonstrates.

Due to the amendment adopted during Committee markup, EPA only has authority to regulate radionuclides under the Atomic Energy Act. Unfortunately, that Act is preemptive. The effect of this change is to preempt States from establishing their own standards for radionuclide emissions.

Now is not the time to make such a change. For example, it was reported on December 20, 1989, that a panel of the National Research Council concluded that the risks from low levels of radiation exposure may be three to fourteen times greater than previously estimated. If the panel's analysis is correct, then cancer deaths from the Chernobyl nuclear explosion in the Soviet Union in 1986 would produce 70,000 cancer deaths, rather than the 17,400 previously estimated.

Members of the research panel indicated that this new data may cause government standards for radiation exposure to be tightened. If the Federal government fails to take this step, I do not believe that States should be barred from adopting standards that they believe are needed to protect the public health.

My position on preemption has been clear and consistent. I do not belcive that the Federal government should deny States the authority to protect the public health and the environment beyond the level of protection required by the Federal Government.

GEORGE J. MITCHELL.

1/12/90
C.S.M.

ECONOMIC IMPACT STATEMENT - EPA REGS

We have endeavored to produce a realistic economic impact study to ascertain the cost of complying with this duplicative EPA regulatory proposal. In order to do so, we obtained a copy of the COMPLY program and the Compliance Guide and performed sample calculations for several types of hospitals. While it appears to be the case that small community hospitals with limited nuclear medicine services will be exempt from having to report at all, this will not be the case for many hospitals of several hundred beds and greater, not to mention medical centers with research activities. Most medical licensees will not be required to measure airborne contamination on line, but use of I-131, Tc-99m, and Xe-133 is of sufficient quantity in many institutions to warrant formal yearly reporting and informing EPA of any plans to alter institutional structures that impact on radionuclide use. Although this will not be an insurmountable burden for most institutions, the costs in many cases will not be negligible.

For example, one way to cope with EPA's I-131 limits is to switch from using NaI-131 in solution to NaI-131 in capsules, because the COMPLY program treats capsules as solids and permits 1000 times more activity to be used per year in this form relative to liquids. However, NaI-131 capsules are approximately twice the cost of NaI-131 in solution, and this cost will have to be borne by the patient or the patient's health insurer. Use of capsules is very popular despite cost because most users are exempt from thyroid bioassay measurements if capsules are used instead of liquid. About 75% of NaI-131 doses are in capsule form already. To go to 100% capsules will therefore result in an added cost of about 12.5% on the average. Another way to cope with EPA's I-131 limits is to use a charcoal filter, which gives the institution an extra factor of 10 in activity limits. It costs several thousand dollars to upgrade an existing hood to one using activated charcoal.

In addition to costs such as those itemized above, it will take the Radiation Safety Officer several person days, or about 1-2% of his yearly activity to comply with EPA reporting. Although it does not take very long to run the COMPLY program, it takes time to add up the total activity of each radionuclide used at the institution that year, and note the form, and review all the hoods in use, and check which have filters, and report intended construction and renovation plans, and study this perverse scheme in the first place and all the revisions and upgrades and downgrades and proposed rulemakings that, sure as death and taxes, will be coming down the pike forever in exponentially increasing quantities.

It will take additional RSO time for preparation of the EPA equivalent of NRC license amendments in order to demonstrate compliance with EPA standards, especially since the EPA standards are often oversimplistic or unreal and not compatible with hospital practice. For example, let us take the use of Xe-133. Used primarily for ventilation imaging in the past, it is seeing increased use for measuring absolute values of brain blood flow in conjunction with the newer SPECT brain agents such as Tc-99m-HMPAO and the anticipated Tc-99m-ECD. The Compliance Guide does not list any filter system for Xe-133 that gives higher than a 50% decrease in Xe-133 concentration, yet systems with activated charcoal are available that trap virtually 100% of the gas. RSO's will have to make measurements to prove this and seek waivers from the listed Xe-133 limits. One 500 bed hospital included in this survey that has an active brain imaging service uses 2.9 times the maximum listed quantity of Xe-133 per year. It does not even use this radiopharmaceutical for ventilation studies. An EPA license amendment based on documentation of filter effectiveness will be necessary to continue this activity.

Another example of problem standards involves Tc-99m, the radiopharmaceutical responsible for about 7.5 million nuclear medicine imaging procedures per year in the United States. This is our primary "workhorse" radionuclide, and surely great care should have been given to the setting of its standards. The same 500-bed hospital mentioned above uses 75% of the maximum listed activity, which gives precious little room for the other 17 radionuclides and forms used this year. The problem is a very high estimate of aerosolization of $NaTcO_4$, about $1x10^{-5}$. This "guestimate" was made using data from one paper published 10 years ago from a laboratory in Scotland that used generators not in use in the United States at present.[1] It is most probably several orders of magnitude too conservative, thus launching many medical institutions into the need to report and to quite possibly write license amendments to justify their workloads.

The RSO will also spend his valuable time obtaining the latest wind rose data, hoping for a few more degrees of reprieve, and vigilantly watching for that most dastardly of deeds, the establishment of a much-feared farm significantly closer to the hospital than he had last entered into the COMPLY program.

[1]Eadie AS, Horton PW, and Hilditch TE: Monitoring of airborne contamination during the handling of technetium-99m and radioiodine. Phys.Med.Biol.25:1079-1087, 1980.

1/12/90

C.S.M.

Indeed, the terrifying discovery of a small strawberry farm a full order of magnitude closer to that 500 bed hospital mentioned above has led physicians there to contemplate that if this EPA scheme becomes a reality, it might turn out to be economically advantageous to have "bought the farm".

It appears reasonable to suppose that the costs of having to report to EPA, including hood filters, increased radiopharmaceutical costs, RSO base time and extra time and equipment for license amendments would cost on the order of $20,000-$50,000 per reporting medical institution. This is not an expense of monumental proportion, but it is significant and it is not justifiable. There would be no advance in public health and safety. EPA would merely be regulating paper. Perhaps the Sierra Club, so quick to sue to establish additional and unnecessary radiation standards, should consider how many trees would be lost to make the paper that this regulatory maze would require. We would rather save the trees. NRC is already saving the people.

BELOW REGULATORY CONCERN (BRC) POLICY

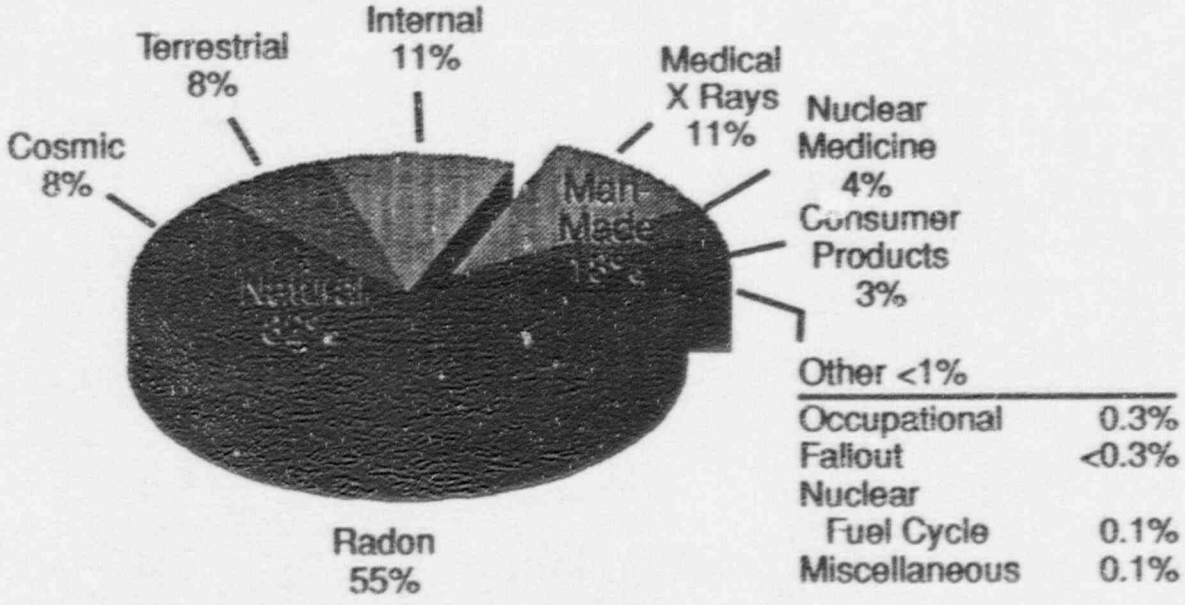
- Defines a level of radiation so small that further efforts to reduce exposures below this level are not warranted.
- Establishes a framework for future decisions on whether to exempt certain products and activities from regulatory control.

BRC CRITERIA

- Individual dose
  - 10 mR/year -- if affects limited number of people
  - 1 mR/year -- if affects large number of people (e.g., consumer products or recycled equipment)

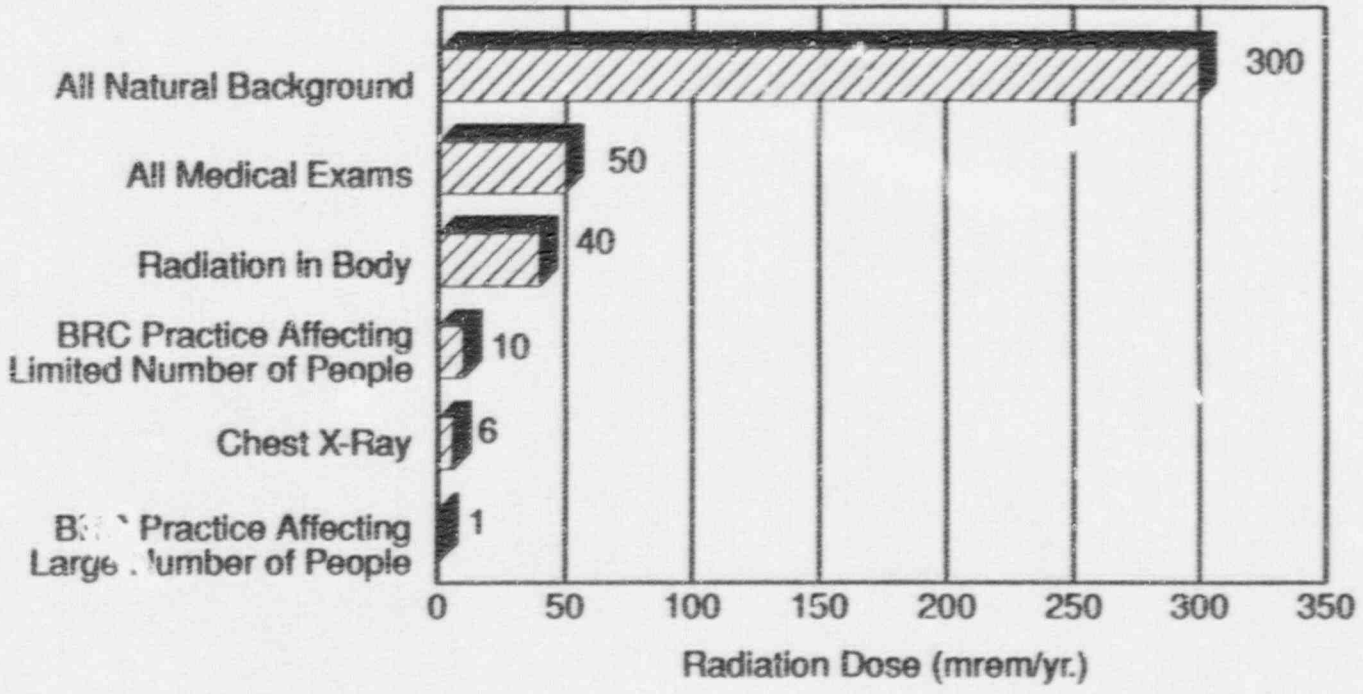
- Collective dose (sum of all individual doses)
  - 1000 person-rems/year
  - If individual dose below 0.1 mR/year, need not be considered in calculating collective dose

CONTRIBUTION OF VARIOUS RADIATION SOURCES TO THE AVERAGE RADIATION DOSE IN THE U.S. POPULATION*

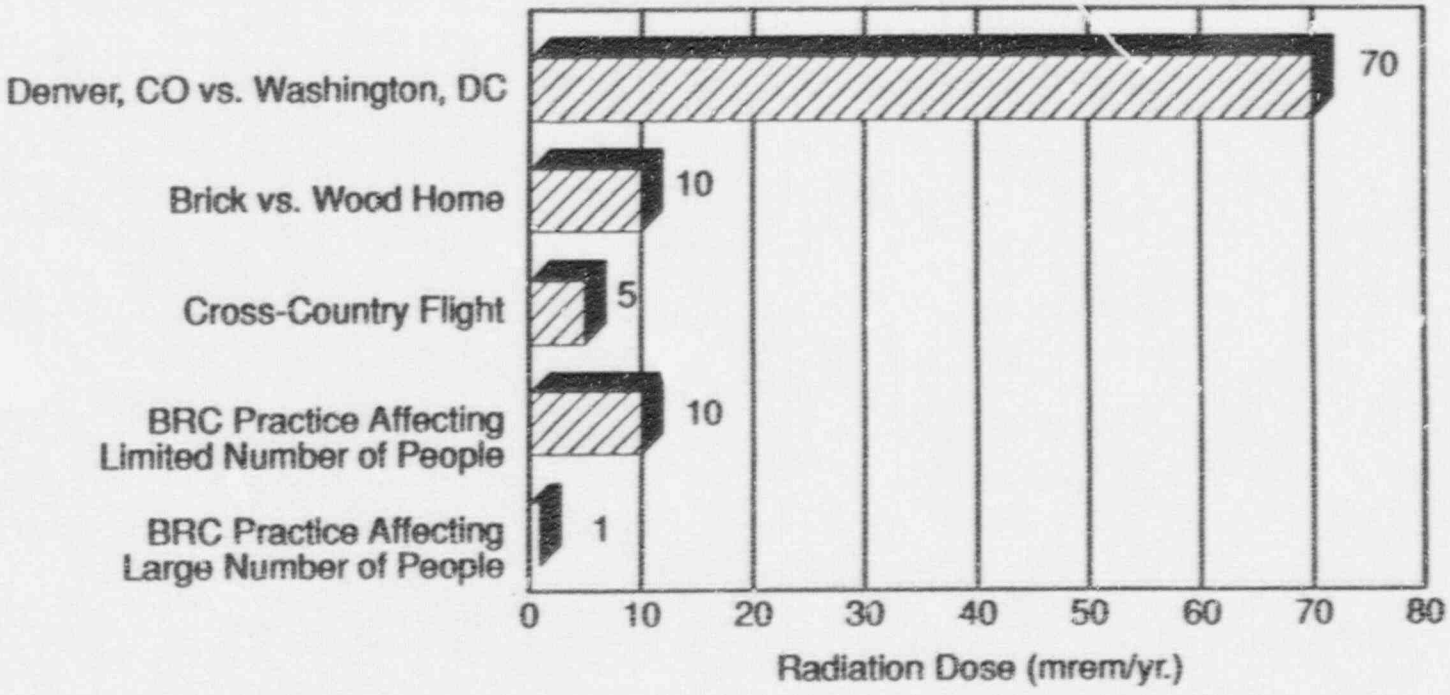


*Used with permission of the National Council on Radiation Protection and Measurements.

COMPARISON OF BELOW REGULATORY CONCERN DOSES TO DOSES FROM NATURAL BACKGROUND AND MEDICAL EXPOSURES



COMPARISON OF BELOW REGULATORY CONCERN DOSES TO DOSES FROM SELECTED OTHER RADIATION SOURCES

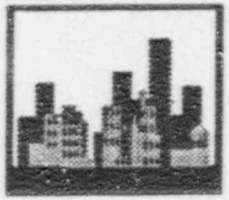


EXAMPLES OF NATURAL RADIATION EXPOSURE

FROM THE SKY - About 30 millirems per year.
About 100,000 cosmic ray neutrons and 400,000 secondary cosmic rays penetrate the average individual every hour.

FROM THE AIR THAT WE BREATHE - About 200 millirems per year.
About 30,000 atoms disintegrate each hour in the lungs and give off alpha or beta particles and some gamma rays.

FROM OUR FOOD AND DRINK - About 40 millirems per year.
About 15 million potassium-40 atoms and about 7,000 natural uranium atoms disintegrate inside every person each hour.



FROM SOILS AND BUILDING MATERIALS - About 30 millirems per year.
Over 200 million gamma rays pass through the average individual each hour.

Below Regulatory Concern Policy

Objective

- ✓ To establish the framework within which the the Commission will make decisions to exempt from some or all regulatory controls certain products and activities involving radioactive material that are below regulatory concern

Below Regulatory Concern Policy

Potential Applications

- ✓ Release for unrestricted public use of lands and structures containing residual radioactivity
- ✓ Distribution of Consumer Products containing small amounts of radioactive material
- ✓ Disposal of very low-level radioactive waste at other than licensed disposal sites
- ✓ Recycle or Reuse of slightly contaminated equipment and materials

Below Regulatory Concern Policy

Potential Benefits to Public

- ✓ Timely cleanup of contaminated sites
- ✓ Increased assurance that adequate funds are availiable to decommission operating nuclear facilities
- ✓ Enhanced low-level radioactive waste management practices commensurate with potential risks
- ✓ Increased assurance of a consistent level of safety for consumer products

Below Regulatory Concern Policy

Rationale for Policy

- ✓ The low levels of risk posed by some uses of radioactive material do not warrant the same degree of regulation as other radioactive materials
- ✓ Criteria are necessary to ensure adequate and consistent decisions on acceptable risks
- ✓ Policy will provide a unifying risk framework for decisions about which practices can be exempted from the full scope of NRC's comprehensive regulatory controls
- ✓ Criteria will allow NRC to focus attention on those practices where continued regulation in necessary or appropriate to ensure that the public and the environment is adequately protected

Below Regulatory Concern Policy

Reasons for Policy

- ✓Establish residual radioactivity criteria and requirements for decommissioning and cleanup of contamination to licensed and formerly-licensed facilities
- ✓Ensure that licensee decommissioning funding plans provide adequate funds to cover the costs of cleanup of these facilities
- ✓Ensure that the public is protected against undue risk from consumer products that contain radioactive materials
- ✓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

Below Regulatory Concern Policy
Reasons for Policy

- ✓ Focus the resources of NRC, Agreement States, and licensee on addressing more significant risks posed by nuclear materials
- ✓ Establish a risk-based threshold to ensure that the potential benefits of additional reductions in risk are commensurate with the costs of attaining the reductions
- ✓ Review NRC's regulatory framework to ensure that existing exemptions involving radioactive materials are consistent and adequate to protect the public

(Continued)

Below Regulatory Concern Policy
AEA Exemption Authority

✓ 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

✓ Numerous exemptions currently promulgated in regulations:
- exempt quantities and concentrations
- consumer products and devices
- certain waste streams

Below Regulatory Concern Policy
LLRWPAA Exemption Authority

✓ Section 10 of the Low-Level Radioactive Waste Policy Amendments Act of 1985 directed the Commission to develop standards and procedures and to act upon petitions to:

> "exempt specific radioactive waste streams from regulation ... due to the presence of radionuclides ... in sufficiently low concentrations or quantities to be below regulatory concern"

Below Regulatory Concern Policy
Conditions for Exemption

- ✓ The application or continuation of regulatory controls on the practice does not result in any significant reduction in dose received by individuals within critical groups and by the exposed population.
- ✓ The costs of the regulatory controls that could be imposed for further dose reduction are not balanced by the commensurate reduction in risk that could be realized.

Below Regulatory Concern Policy

Risk Basis for Criteria

- ✓ The Commission assumes that the radiation dose to fatal cancer risk response is linear, without threshold
- ✓ The conversion factor for dose to fatal cancer risk is taken to be 5×10^{-4} per rem
- ✓ The Commission believes that most members of society will not expend resources to reduce an annual individual risk of fatality below approximately 1 chance in 100,000 (1×10^{-6})

Below Regulatory Concern Policy
Criteria for Exemption

✓ Individual Dose Criterion
- 10 mrem/yr (0.1 mSv/yr)
- 1 mrem/yr (0.01 mSv/yr) for practices involving widespread distribution of radioactive materials such as consumer products or recycled materials or equipment

✓ Collective Dose Criterion
- 1000 person-rem
- 0.1 mrem/yr individual doses need not be considered in collective dose

✓ Consideration of accidents and misuse

Below Regulatory Concern Policy
Exceptions to Criteria

- ✓ Practices which do not meet the criteria for exemption may nevertheless be granted exemptions from regulatory control on a case-by-case basis in accordance with the principles of the policy if:
  - ✓✓ The potential doses to individual members of the public are sufficiently small or unlikely
  - ✓✓ further reductions in the doses are neither readily achievable or significant in terms of protecting the public health and safety and the environment
  - ✓✓ the collective dose from the exempted practice is ALARA

Below Regulatory Concern Policy
Final Policy Outline

✓ Introduction

✓ Definitions

✓ Policy Elements
- Principles of Exemption
- Individual Dose Criterion
- Population Dose Criterion

✓ Implementation

✓ Information To Support Exemption Decisions

Below Regulatory Concern Policy
Implementation

- ✓ Exemption will result in the transfer of very small quantities of materials from a regulated to an unregulated status under the criteria and principles of the Policy

- ✓ The Commission will establish constraints, requirements and conditions applicable to specific exemptions through appropriate rulemaking or licensing actions, with the opportunity for public comment

- ✓ A licensed activity producing an exempt material would continue to be subject to the full range of regulatory oversight, inspection, and enforcement up to and including the point of transfer

Below Regulatory Concern Policy
Contents of Petitions

✓ A petition for rulemaking to exempt a practice must provide a basis upon which the Commission can determine if the basic policy criteria have been satisfied.

✓ Petitions should include:
- potential individual and societal impacts.
- uses of radioactive materials.
- pathways of exposure.
- levels of radioactivity.
- potential for accidents and misuse.
- quality assurance and reporting requirements.
- constraints and conditions necessary to ensure the assumptions used to grant the exemption remain valid.

Below Regulatory Concern Policy
Agreement State Compatibility

- ✓ Decisions on below regulatory concern are viewed as establishing basic radiation protection standards
- ✓ Future rulemakings will be assessed for compatibility
- ✓ NRC regulations exemption 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

PRESENTATION ON

THE NUCLEAR REGULATORY COMMISSION'S

BELOW REGULATORY CONCERN

POLICY STATEMENT

Below Regulatory Concern Policy
Outline of Presentation

- ✓ Introduction/Background/Objective/Public Participation
- ✓ Potential Applications/Benefits to Public
- ✓ Basic Elements of Policy/BRC Dose Criteria
- ✓ Perspective of Exposures to Radiation from Various Sources Including Natural Background
- ✓ Quantitative Risk Perspective for 10 Millirem Criterion
- ✓ 1 Millirem and Collective Dose Criteria
- ✓ Interaction with State/Local Government
- ✓ Information Required for Rulemaking
- ✓ Actions Planned to Implement Policy

Below Regulatory Concern Policy
Introduction

- ✓ The NRC is publishing a policy statement defining levels of exposure to radioactivity under its jurisdiction which are "below regulatory concern"
- ✓ The Policy will be applicable to future exemption decisions by the Agency
- ✓ This reflects the Commission's belief that there is a need to establish a broadly applicable and consistent risk basis for exemption decisions

Below Regulatory Concern Policy
Background

- ✓ Atomic Energy Act authorizes Exemptions when they do not constitute an unreasonable risk to public health and safety
- ✓ Past exemptions include
  - Release of consumer products such as smoke detectors
  - Decommissioning of commercial power reactors
  - Disposal of waste generated for medical treatment
- ✓ Past decisions were made on a case-by-case basis guided primarily by the principle that exposures should be reduced to a level as low as reasonably achievable (ALARA)
- ✓ There was no Commission policy which provided a broadly applicable and consistent risk basis for exemption decisions

Below Regulatory Concern Policy
Background (continued)

- ✓ Section 10 of the Low-Level Radioactive Waste Policy Amendments Act of 1985 directed the Commission to develop standards and procedures and to act upon petitions to:
  > "exempt specific radioactive waste streams from regulation ... due to the presence of radionuclides ... in sufficiently low concentrations or quantities to be below regulatory concern"
- ✓ Commission Policy Statement of August 29, 1986, provided criteria for expeditious resolution of petitions to dispose of such wastes
- ✓ This new Policy Statement applies the concept of "below regulatory concern" to a broader range of exemption decisions than low level waste disposal

Below Regulatory Concern Policy
Objectives

- ✓ To establish a broadly applicable risk based framework to ensure consistency in future rulemaking and licensing decisions and for review of existing exemptions.
- ✓ To allow the NRC, Agreement States and licensees to focus their resources on reducing the most significant radiological risks under NRC jurisdiction

Below Regulatory Concern Policy
Public Participation in Decisions

- ✓ Policy itself does not authorize BRC activities
- ✓ Opportunity will be provided for the public to comment on each regulation proposed by the Commission to implement the BRC Policy
- ✓ Licensing actions that implement the BRC policy will be noticed in the Federal Register

Below Regulatory Concern Policy

Framework to Develop Regulations & Guidance on ...

- ✓ Release for unrestricted public use of lands and structures containing residual radioactivity
- ✓ Distribution of Consumer Products containing small amounts of radioactive material
- ✓ Disposal of very low-level radioactive waste at other than licensed disposal sites
- ✓ Recycle or Reuse of slightly contaminated equipment and materials

Below Regulatory Concern Policy
Benefits to Public

- ✓ Timely cleanup of contaminated sites
- ✓ Increased assurance that adequate funds are available to decommission operating nuclear facilities
- ✓ Low-level radioactive waste management practices commensurate with potential risks
- ✓ Assurance of a consistent level of safety for consumer products

Below Regulatory Concern Policy
Basic Elements of Policy Framework

- ✓ Risk-based thresholds expressed in the form of individual and collective dose criteria
- ✓ The BRC dose criteria correspond to individual and societal risks sufficiently small that expenditure of resources to reduce them further is unwarranted

Below Regulatory Concern Policy
BRC Dose Criteria

✓ Individual Dose Criteria
- 10 millirem/yr (0.1 milliSievert/yr)
- 1 millirem/yr (0.01 milliSievert/yr) interim criterion for practices involving widespread distribution of radioactive materials such as consumer products or recycled materials or equipment

✓ Collective Dose Criterion
- 1000 person-rem/yr
- Doses less than 0.1 millirem/yr excluded

EXAMPLES OF NATURAL RADIATION EXPOSURE

FROM THE SKY - About 30 millirems per year.
About 100,000 cosmic ray neutrons and 400,000
secondary cosmic rays penetrate the average
individual every hour.

FROM THE AIR THAT WE BREATHE - About 200 millirems per year.
About 30,000 atoms disintegrate each hour in
the lungs and give off alpha or beta particles
and some gamma rays.

FROM OUR FOOD AND DRINK - About 40 millirems per year.
About 15 million potassium-40 atoms and about
7,000 natural uranium atoms disintegrate inside
every person each hour.

FROM SOILS AND BUILDING MATERIALS - About 30 millirems per year.
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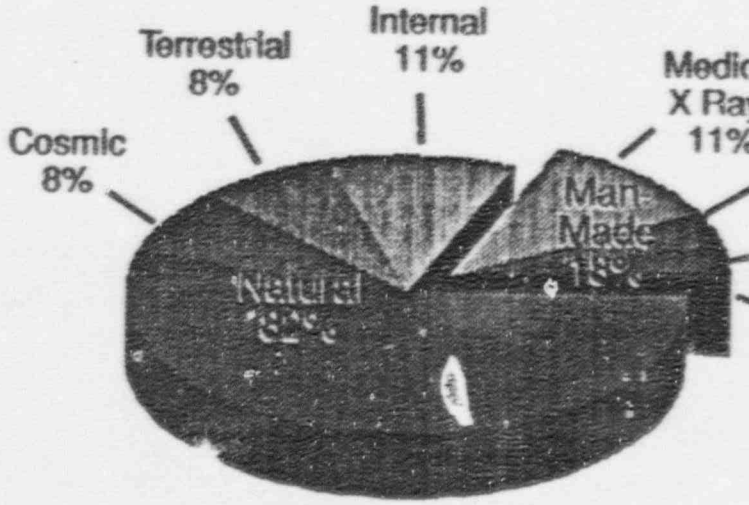
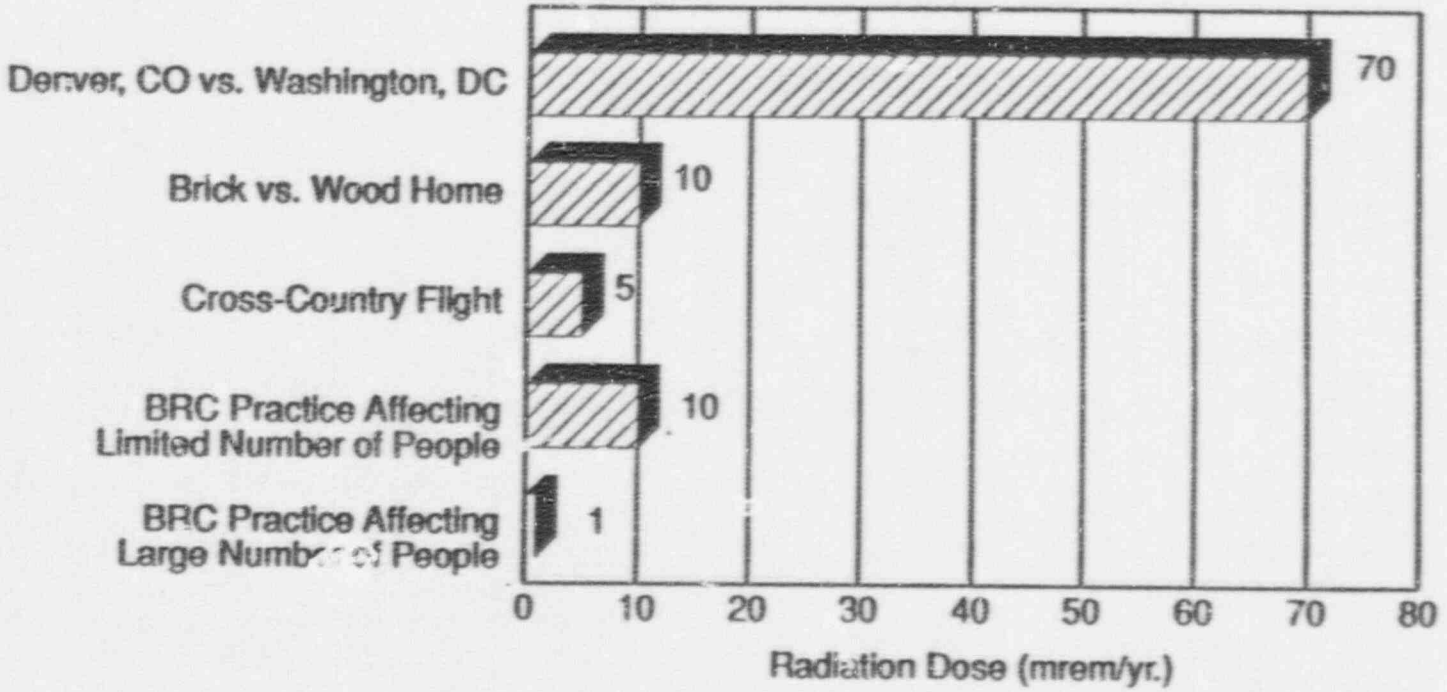
CONTRIBUTION OF VARIOUS RADIATION SOURCES TO THE AVERAGE RADIATION DOSE IN THE U.S. POPULATION*



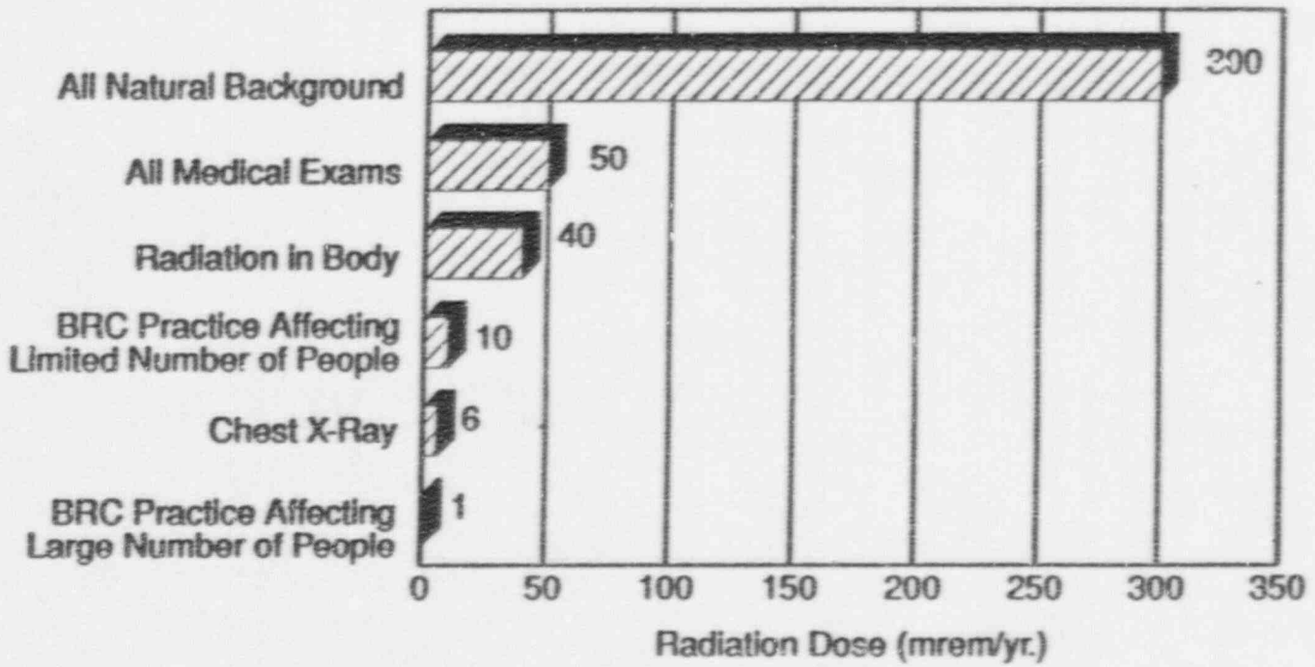
Other <1%	
Occupational	0.3%
Fallout	<0.3%
Nuclear Fuel Cycle	0.1%
Miscellaneous	0.1%

*Used with permission of the National Council on Radiation Protection and Measurements.

COMPARISON OF BELOW REGULATORY CONCERN DOSES TO DOSES FROM SELECTED OTHER RADIATION SOURCES



COMPARISON OF BELOW REGULATORY CONCERN DOSES TO DOSES FROM NATURAL BACKGROUND AND MEDICAL EXPOSURES



Below Regulatory Concern Policy
Basis for Individual Dose Criteria

- ✓ Ionizing radiation is a part of our natural environment
- ✓ Average individual in U.S. is exposed to 300 millirem/yr from natural environmental radiation
- ✓ Significant variations in these exposures are experienced by members of society without apparent concern
- ✓ Examples - 70 millirem/yr difference between Denver and Washington; 10 millirem/yr difference between brick and wood home
- ✓ Practicality of confirming exposures and consistency with technological capabilities
- ✓ Based on this perspective, the NRC considers individual exposures on the order of 10 millirem, a level that poses a very low level of risk, to be BRC

Below Regulatory Concern Policy
Quantitative Risk Perspective

- ✓ The Commission used risk assessments for low-level radiation by the United Nations (UNSCEAR 1988) and by the National Academy of Sciences (BEIR V)
- ✓ The 10 millirem annual individual dose criterion corresponds to an annual risk of fatality from cancer for an individual of 1 in 200,000
- ✓ This corresponds to less than one-half of 1 percent of the annual risk of fatality from all causes of cancer

Below Regulatory Concern Policy

Basis for 1 millirem Criterion

- ✓ An interim criterion while more experience is gained with exemptions involving widespread distribution of radioactive material
- ✓ Examples include consumer products and recycled material and equipment
- ✓ The interim criterion provides added assurance that individual exposures to multiple licensed and exempted practice will be well below radiation dose limits
- ✓ The annual risk of cancer fatality from an exposure of 1 millirem is estimated to be 1 in 2 million

Below Regulatory Concern Policy
Collective Dose Criterion

- ✓ The Commission believes that sum of the individual doses from an exempted practice should be ALARA
- ✓ However, if this collective dose from exempted practice is no more than 1000 person-rem/yr, a level where no fatality on annual basis is expected, no further effort is needed to analyze and reduce collective dose
- ✓ Not necessary to include individual dose below 0.1 millirem (annual risk of 1 in 20 million) in calculating collective dose

Below Regulatory Concern Policy

Interaction With State and Local Governments

- ✓ Consistent with Federal law, there should be uniformity between NRC and Agreement State Basic Radiation Protection Standards
- ✓ The NRC will develop regulations, including basic radiation protection standards, to implement the BRC policy
- ✓ Agreement States will play an important role in developing and enforcing regulations compatible with NRC's basic radiation protection standards
- ✓ NRC will be assessing future regulations for compatibility
- ✓ 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

Below Regulatory Concern Policy
Information Required for Rulemaking

✓ A proposal for rulemaking to exempt a practice, either from petitioners or the NRC staff, must be supported by an adequate technical analysis.

✓ On this basis, the Commission will consider whether the basic policy criteria have been satisfied in making its decisions.

✓ Technical basis should include:
- Individual and societal impacts.
- uses of radioactive materials.
- pathways of exposure.
- levels of radioactivity.
- potential for accidents and misuse.
- quality assurance and reporting requirements.
- constraints and conditions necessary to ensure the assumptions used to grant the exemption remain valid.

Below Regulatory Concern Policy

Specific Actions Planned to Implement the Policy

- ✓ Development of proposed amendments to regulations and supporting regulatory guide defining residual radionuclide concentrations for decommissioned lands and structures
- ✓ Systematic assessment of current NRC regulations against criteria in policy to identify and initiate needed changes
- ✓ Resolution of petitions to provide greater flexibility and economy in disposal of BRC low level wastes from medical research
- ✓ Publication of proposals in Federal Register over next few years

Below Regulatory Concern Policy

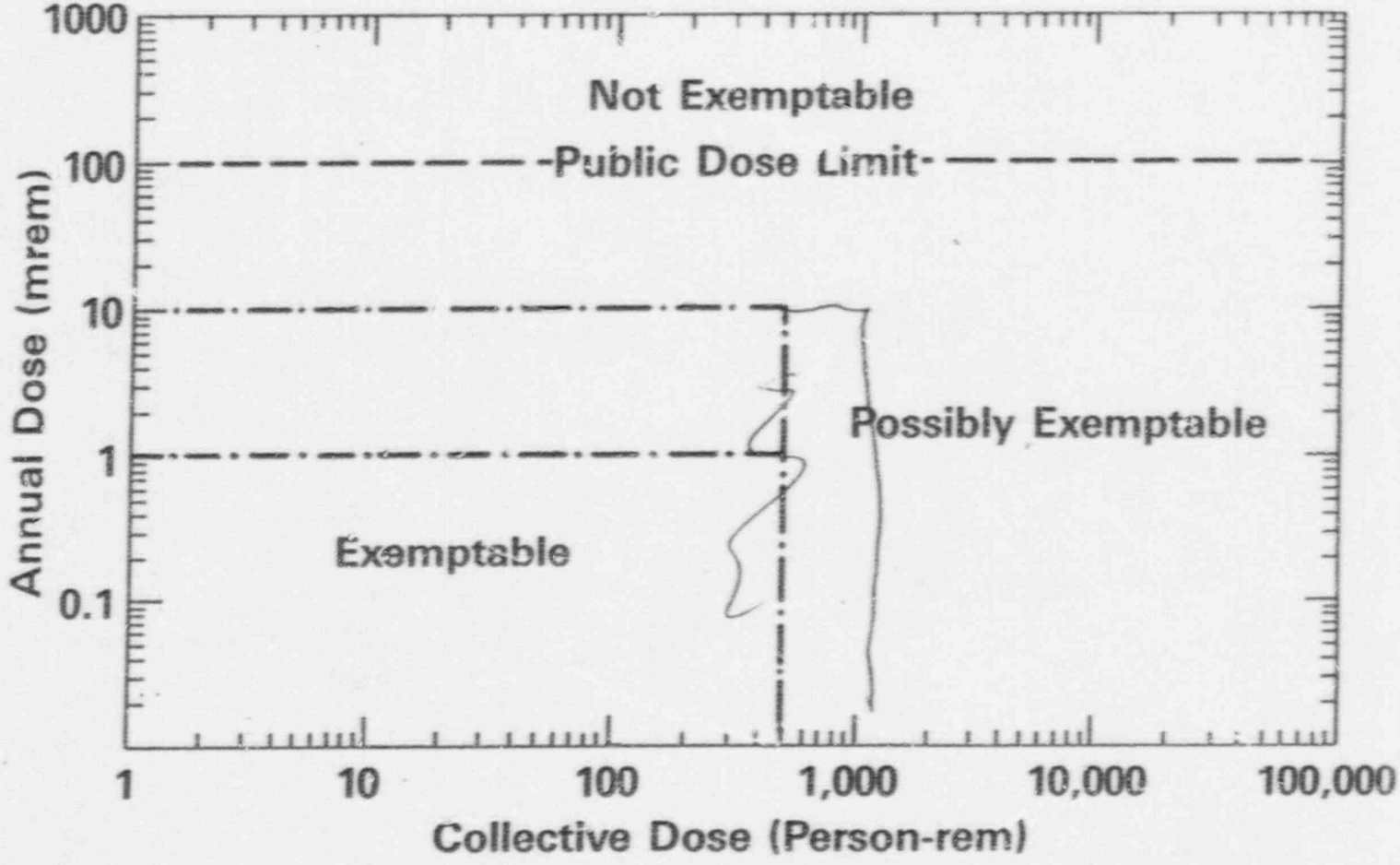
Uses of Radioactive Material

- ✓ Generation of electrical power
- ✓ Medical diagnosis, therapy and research
- ✓ Consumer products such as smoke detectors
- ✓ Industrial applications such as radiography of structures to detect flaws

Common Risks Faced By People in U.S.

Cause	Annual Risk of Fatality (Chances in a million)
Heart Disease	3200
Cancer	1900
Stroke	620
All Accidents	390
Motor Vehicle Accidents	200
~~Accidents in The Home~~	90
Falls	50
Accidental Poisoning	25
Drowning	20
Fire, Burns	20
Ingestion of Food or other Objects	15
Firearms Accidents	6
Suicide	130
Homicide	90
10 Mrem	5

Below Regulatory Concern Policy



Consumer Product Doses

Current Exemptions

Product	Max Ind Dose (mr/yr)	Coll Dose (p-r/yr)
Tritiated Watches	0.06 (avg)	5700
Radium Watches	--	16675
Static Eliminators	<0.1	--
False Teeth (gamma)	<0.001 (per tooth)	6.8 (full denture)
False Teeth (a+b)	1000 (buccal cavity)	--
Thorium Mantles	15 (warehouse wkr)	1282
Welding Rods	88	2800
Ophthalmic lenses	0.018	950
Ceramics/Glassware	4	--
Electron Tubes	14	2300
Lamp Starters	<0.001	0.45
Smoke Detectors	<0.08	1100
Biomed Waste	3.1	--

INVALID NEED NEW LIST FROM NMSS

NUREG/CR-1775 and NUREG-0456

Below Regulatory Concern Policy
Application of ALARA

- ✓ A fundamental principle of NRC radiation protection policy
- ✓ The ALARA principle applies to efforts by licensees to maintain radiation exposures and releases of material As Low As Reasonably Achievable
- ✓ Radiation exposures and releases of material associated with an exempted practice should be ALARA
- ✓ A practice will be considered ALARA by the Commission if the individual and collective dose criteria of the policy are met

Below Regulatory Concern Policy
Justification of Practice

- ✓ The Commission affirms its acceptance of the basic tenets of radiation protection (justification, optimization, dose limits) as appropriate.
- ✓ However, at low levels of risk, the Commission will not consider whether a practice is justified in terms of societal net benefit.
- ✓ The Commission may determine, on the basis of risk estimate and associated uncertainties, that certain practices should not be considered candidates for exemption, such as the introduction of radioactive materials into products to be used or consumed primarily by children.

Below Regulatory Concern Policy
Exceptions to Criteria

✓ Practices which do not meet the criteria for exemption may nevertheless be granted exemptions from regulatory control on a case-by-case basis in accordance with the principles of the policy if:

✓✓ The potential doses to individual members of the public are sufficiently small or unlikely

✓✓ further reductions in the doses are neither readily achievable or significant in terms of protecting the public health and safety and the environment

✓✓ the collective dose from the exempted practice is ALARA

Below Regulatory Concern Policy

Conditions for Exemption

- ✓ The application or continuation of regulatory controls on the practice does not result in any significant reduction in dose received by individuals within critical groups and by the exposed population.
- ✓ The costs of the regulatory controls that could be imposed for further dose reduction are not balanced by the commensurate reduction in risk that could be realized.

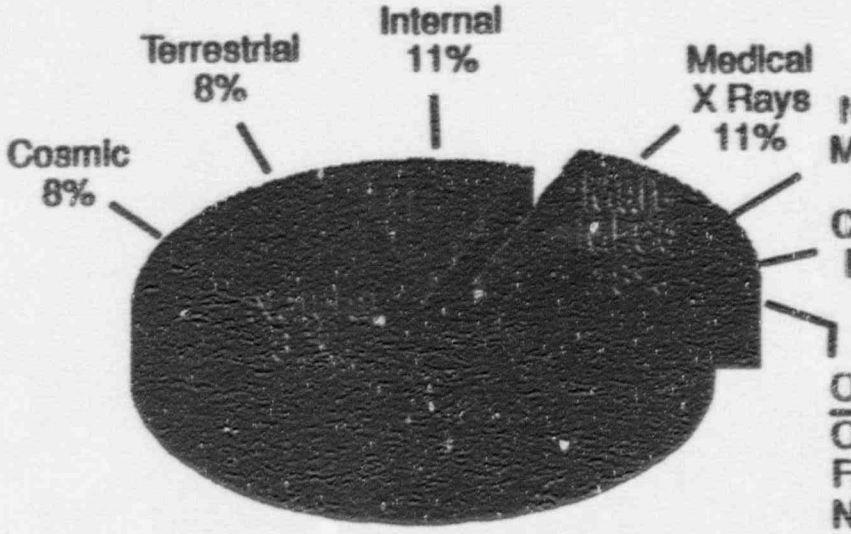
Below Regulatory Concern Policy

Rationale for Policy

- ✓ The low levels of risk posed by some uses of radioactive material do not warrant the same degree of regulation as other radioactive materials
- ✓ Criteria are necessary to ensure adequate and consistent decisions on acceptable risks
- ✓ Policy will provide a unifying risk framework for decisions about which practices can be exempted from the full scope of NRC's comprehensive regulatory controls
- ✓ Criteria will allow NRC to focus attention on those practices where continued regulation in necessary or appropriate to ensure that the public and the environment is adequately protected

(~360 mrem/year)

CONTRIBUTION OF VARIOUS RADIATION SOURCES TO THE AVERAGE RADIATION DOSE IN THE U.S. POPULATION*



Occupational	0.3%
Fallout	<0.3%
Nuclear Fuel Cycle	0.1%
Miscellaneous	0.1%

*Used with permission of the National Council on Radiation Protection and Measurements

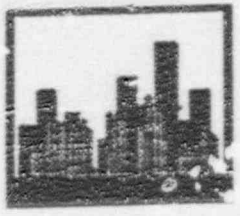
1990

EXAMPLES OF NATURAL RADIATION EXPOSURE

FROM THE SKY - About 30 millirems per year, from cosmic radiation
~~About 100,000 cosmic ray neutrons and 400,000 secondary cosmic rays penetrate the average individual every hour.~~

FROM THE AIR THAT WE BREATHE - About 200 millirems per year, including radon
~~About 30,000 atoms disintegrate each hour in the lungs and give off alpha or beta particles and some gamma rays.~~

FROM OUR FOOD AND DRINK - About 40 millirems per year, from natural radioactive materials such as potassium-40
~~About 15 million potassium-40 atoms and about 7,000 natural uranium atoms disintegrate inside every person each hour.~~



FROM SOILS AND BUILDING MATERIALS - About 30 millirems per year, from natural radionuclides such as uranium.
~~Over 200 million gamma rays pass through the average individual each hour.~~

TOTAL = 300 mrem/year

Client 2

COMPARISON OF BELOW REGULATORY CONCERN DOSES TO DOSES FROM SELECTED OTHER RADIATION SOURCES

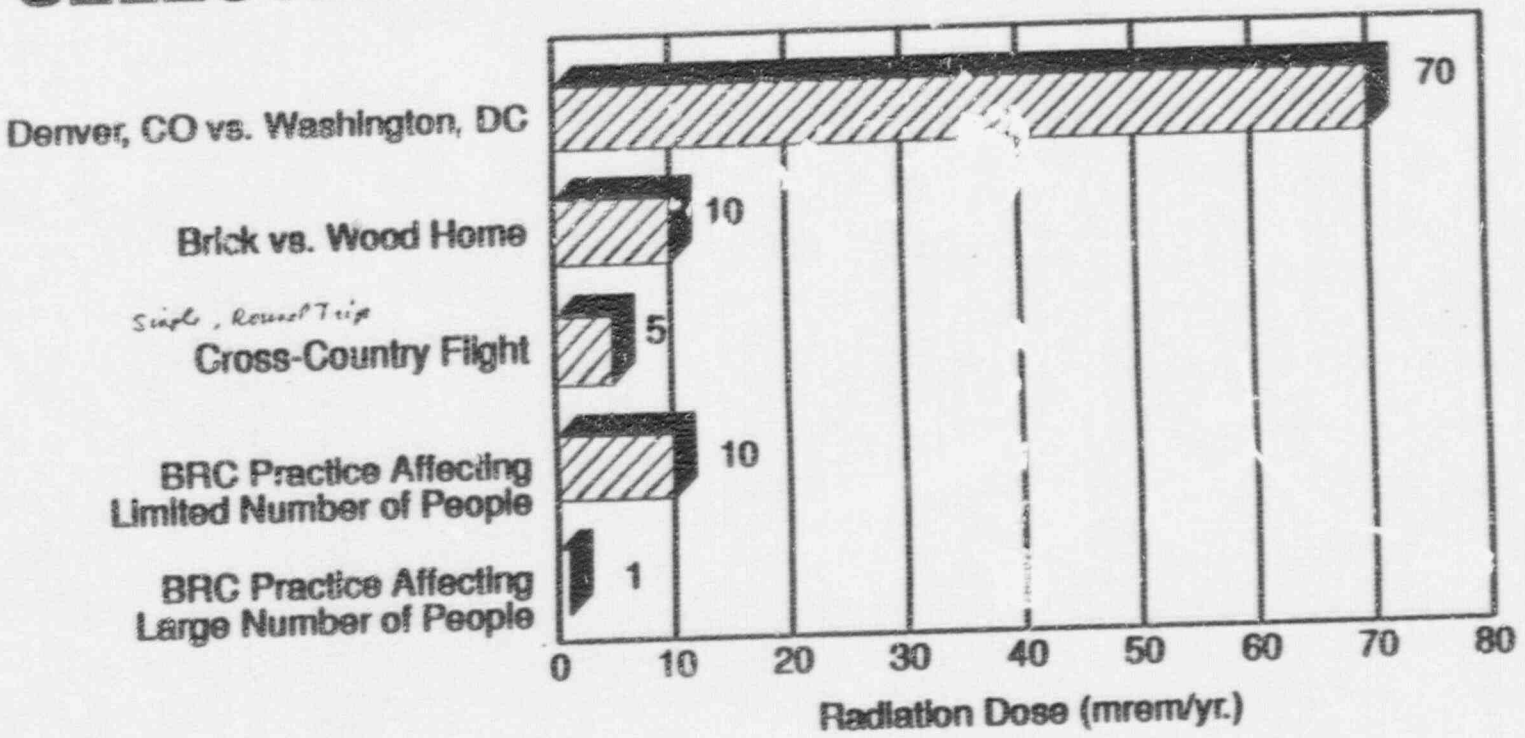
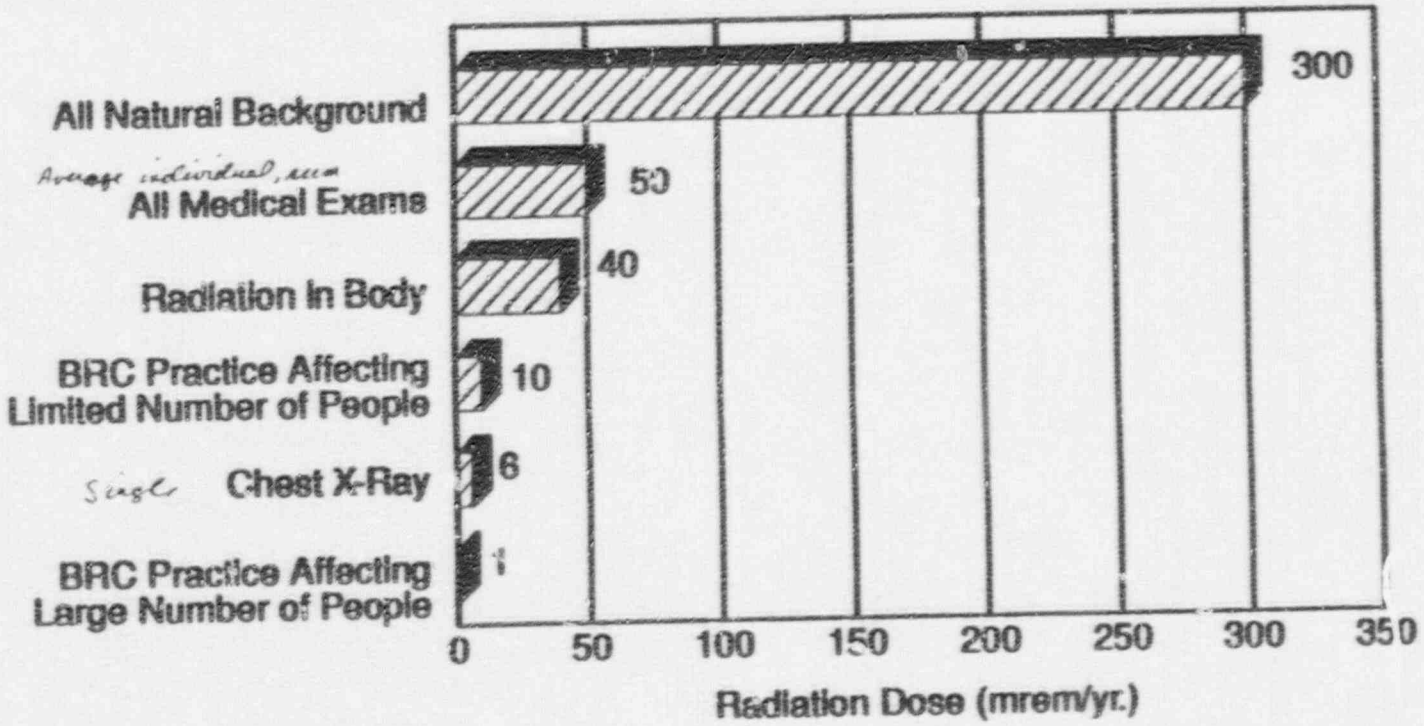


Chart 3

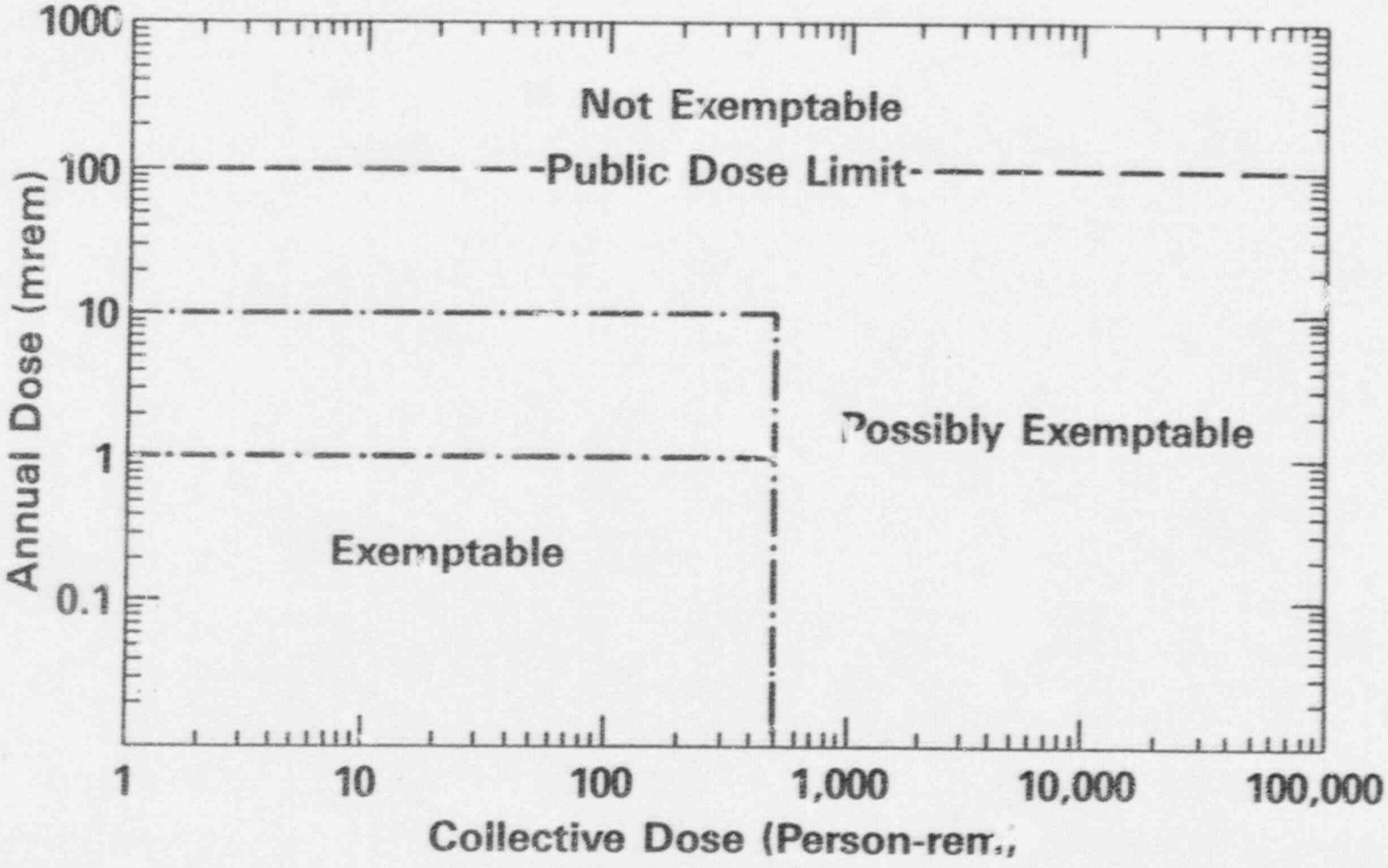
COMPARISON OF BELOW REGULATORY CONCERN DOSES TO DOSES FROM NATURAL BACKGROUND AND MEDICAL EXPOSURES



Below Regulatory Concern Policy
Application of ALARA

- ✓ The ALARA principle applies to efforts by licensees to maintain radiation exposures and releases of material As Low As Reasonably Achievable
- ✓ Radiation exposures and releases of material associated with an exempted practice should be ALARA, consistent with the individual and collective dose criteria
- ✓ The individual and collective dose criteria constitute a threshold below which further efforts to reduce exposures in keeping with the ALARA principle are not necessary
- ✓ ALARA remains in effect up to and including the point at which exempted radioactive materials are transferred to an unregulated status

Below Regulatory Concern Policy



Below Regulatory Concern Policy
LLRWPAA Exemption Authority

✓ Section 10 of the Low-Level Radioactive Waste Policy Amendments Act of 1985 directed the Commission to develop standards and procedures and to act upon petitions to:

> "exempt specific radioactive waste streams from regulation ... due to the presence of radionuclides ... in sufficiently low concentrations or quantities to be below regulatory concern"

✓ Commission Policy Statement of August 29, 1986 provided criteria for expeditious resolution of petitions to dispose of such wastes

Below Regulatory Concern Policy

Exemptions by Other Agencies

- ✓ FDA - Has applied risk based guidelines for animal drugs, food contaminants, and trace constituents in food additives
- ✓ EPA - Has applied risk based exemption OR vs. threshold levels for pesticides and toxic and carcinogenic chemicals

Becker

Below Regulatory Concern Policy
LLRWPAA Exemption Authority

✓ Section 10 of the Low-Level Radioactive Waste Policy Amendments Act of 1985 directed the Commission to develop standards and procedures and to act upon petitions to:

> "exempt specific radioactive waste streams from regulation ... due to the presence of radionuclides ... in sufficiently low concentrations or quantities to be below regulatory concern"

✓ 1986 ~~Policy Statement Criteria~~ August 29, Commission Policy Statement of 1986, Provided Criteria For Expeditious Resolution of Petitions To Dispose of Such Waste

Below Regulatory Concern Policy
Objectives

- ✓ To establish a framework for future rulemaking and licensing decisions exempting certain activities involving radioactive material from regulatory control on the basis that the risks are so small that further efforts to reduce them are not warranted
- ✓ To focus the resources of the NRC, Agreement States and licensees toward addressing more significant risks from radioactive materials under NRC jurisdiction

Below Regulatory Concern Policy
Potential Applications

- ✓Release for unrestricted public use of lands and structures containing residual radioactivity
- ✓Distribution of Consumer Products containing small amounts of radioactive material
- ✓Disposal of very low-level radioactive waste at other than licensed disposal sites
- ✓Recycle or Reuse of slightly contaminated equipment and materials

Below Regulatory Concern Policy
Benefits to Public

- ✓ Timely cleanup of contaminated sites
- ✓ Increased assurance that adequate funds are availiable to decommission operating nuclear facilities
- ✓ Enhanced low-level radioactive waste management practices commensurate with potential risks
- ✓ Assurance of a consistent level of safety for consumer products

Below Regulatory Concern Policy
Public Participation in Decisions

- ✓ Through publication in the Federal Register an opportunity will be provided for the public to comment on each generic regulation proposed by the Commission to implement the BRC Policy
- ✓ Significant licensing actions involving individual licensees or sites will be noticed in the Federal Register and may involve public hearings

Below Regulatory Concern Policy
Impact of Policy

- ✓ The Policy Statement is not a regulation
- ✓ It does not constitute a decision on any specific exemption from regulatory control
- ✓ Before any regulations or licensing amendments are finalized, a complete analysis of the details and particular circumstances will be performed

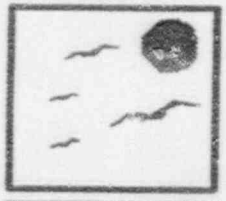
Below Regulatory Concern Policy
Basic Elements of Framework

- ✓ Risk-based thresholds in the form of residual radiation exposure or dose criteria
- ✓ The BRC dose criteria are selected to correspond to individual and societal risks sufficiently small that expenditure of resources to reduce them further is unwarranted

Below Regulatory Concern Policy
BRC Dose Criteria

- ✓ Individual Dose Criterion
  - 10 mrem/yr (0.1 mSv/yr)
  - 1 mrem/yr (0.01 mSv/yr) for practices involving widespread distribution of radioactive materials such as consumer products or recycled materials or equipment
- ✓ Collective Dose Criterion
  - 1000 person-rem

EXAMPLES OF NATURAL RADIATION EXPOSURE



FROM THE SKY - About 30 millirems per year.
About 100,000 cosmic ray neutrons and 400,000 secondary cosmic rays penetrate the average individual every hour.

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About 30,000 atoms disintegrate each hour in the lungs and give off alpha or beta particles and some gamma rays.

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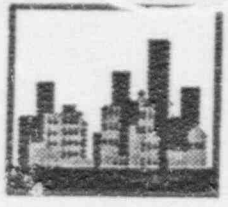
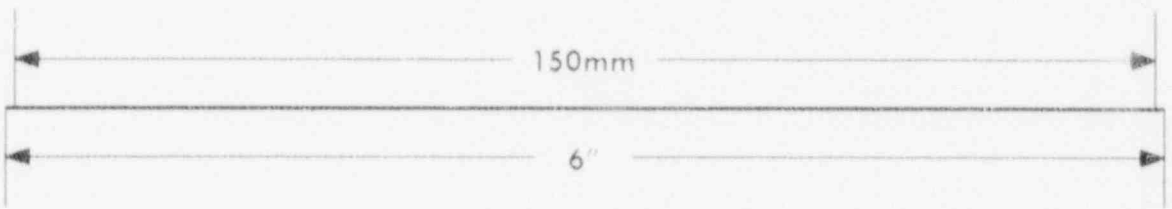


FROM SOILS AND BUILDING MATERIALS - About 30 millirems per year.
Over 200 million gamma rays pass through the average individual each hour.

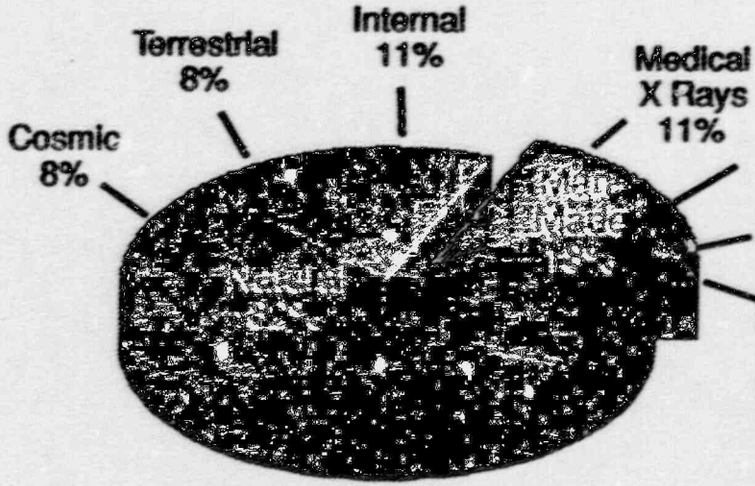
2

IMAGE EVALUATION TEST TARGET (MT-3)



PHOTOGRAPHIC SCIENCES CORPORATION
770 BASKET ROAD
P.O. BOX 338
WEBSTER, NEW YORK 14580
(716) 265-1600

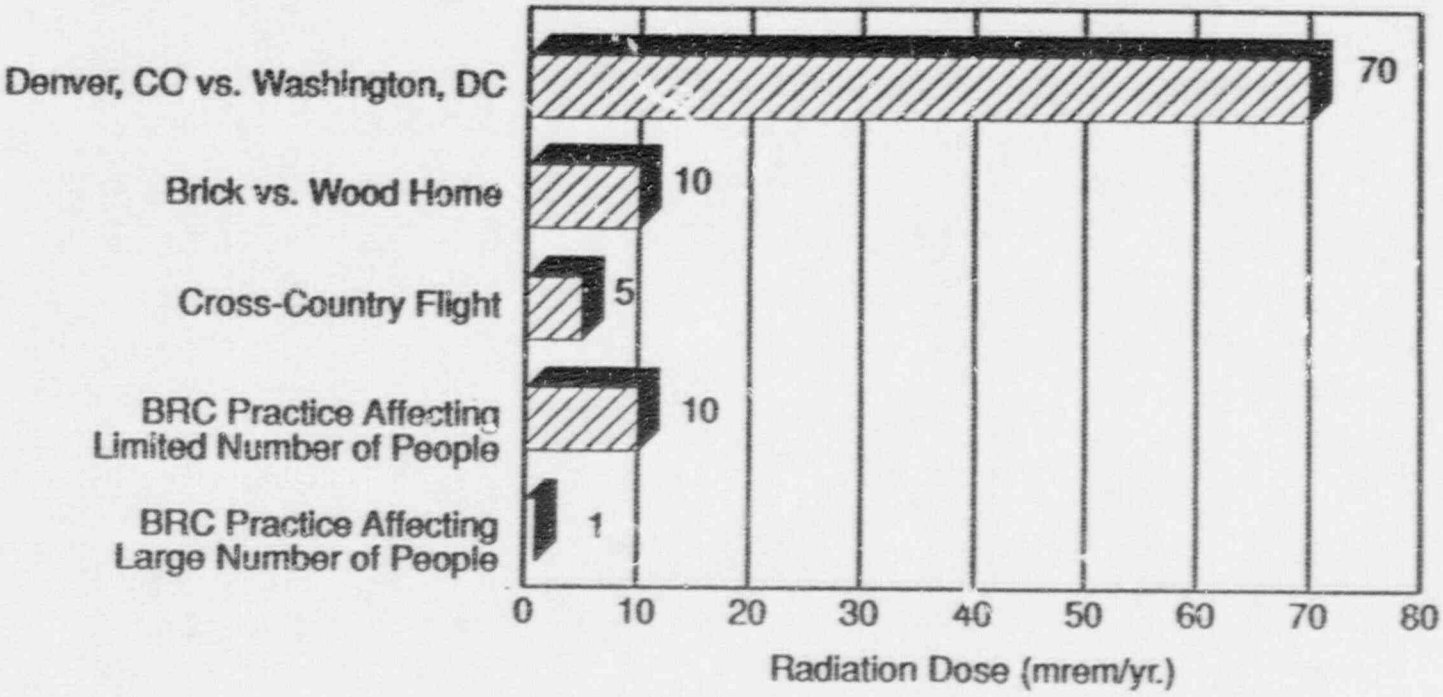
CONTRIBUTION OF VARIOUS RADIATION SOURCES TO THE AVERAGE RADIATION DOSE IN THE U.S. POPULATION*



Other <1%	
Occupational	0.3%
Fallout	<0.3%
Nuclear Fuel Cycle	0.1%
Miscellaneous	0.1%

*Used with permission of the National Council on Radiation Protection and Measurements.

COMPARISON OF BELOW REGULATORY CONCERN DOSES TO DOSES FROM SELECTED OTHER RADIATION SOURCES



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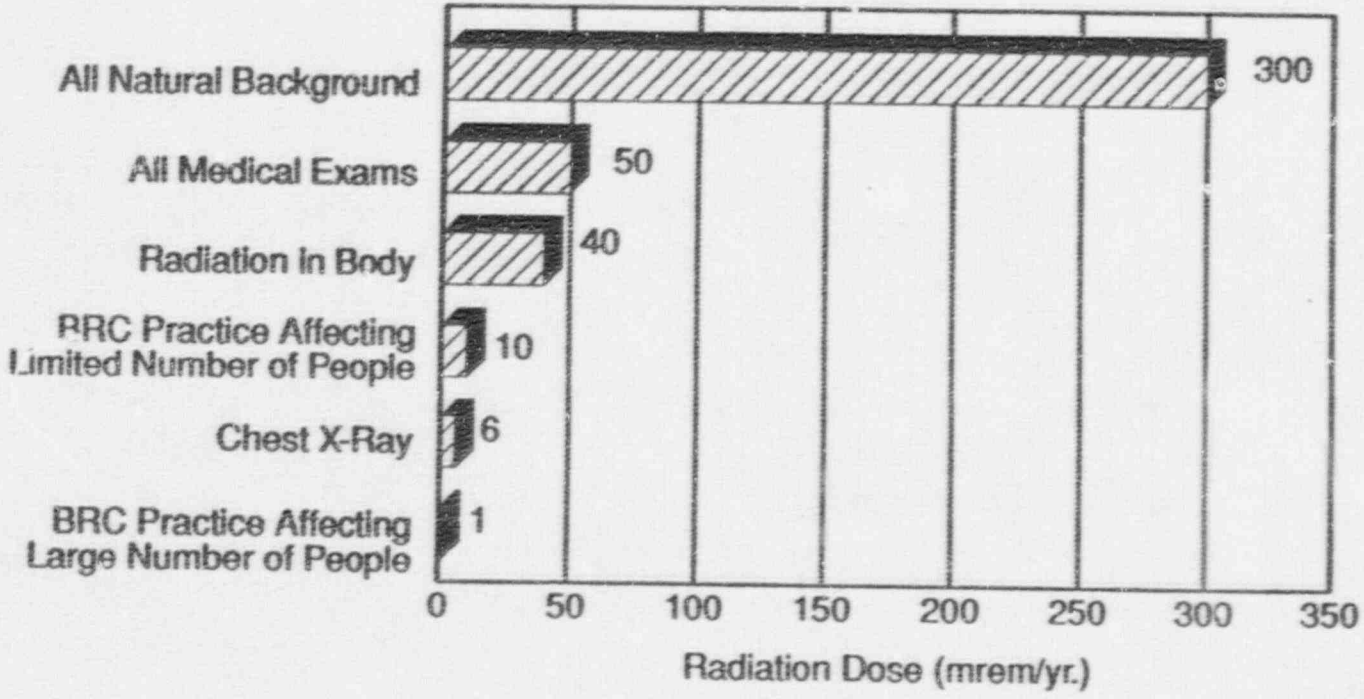

Below Regulatory Concern Policy

Perspective of Exposures to Natural Environment

- ✓ Ionizing radiation is a part of our natural environment
- ✓ Individuals are routinely exposed to about 300 mrem per year from this natural environmental radiation
- ✓ Significant variations in these exposures because of lifestyle or place of residence are experienced by people without apparent concern
- ✓ For example, the difference in exposure between living in Denver, Colorado, and Washington, D.C., is about 70 mrem, that between living in a brick versus a wood home is about 10 mrem, and the exposure from a round-trip cross country airplane flight is about 5 mrem
- ✓ Based on this perspective, the NRC considers individual exposures of up to 10 mrem to be BRC

Below Regulatory Concern Policy

Quantitative risk perspective

- ✓ The Commission has used two risk assessments, one sponsored by the United Nations (UNSCEAR 1988) and another performed by the National Academy of Sciences (BEIR V), in estimating the risks from low levels of radiation
- ✓ The 10 mrem individual dose criterion corresponds to an annual risk of fatality from cancer for an individual of 1 in 200,000
- ✓ For perspective, these risks correspond to less than one-half of 1 percent of the annual risk of fatality from all causes of cancer

Below Regulatory Concern Policy
Basis for 1 mrem Criterion

- ✓ An interim criterion while more experience is gained with exemptions involving widespread distribution of radioactive material
- ✓ Examples include consumer products and recycled material and equipment
- ✓ The interim criterion provides added assurance that individual exposures to multiple licensed and exempted practice will be well below radiation dose limits
- ✓ The annual risk of cancer fatality from an exposure of 1 mrem is estimated to be 1 in 2 million

Below Regulatory Concern Policy
Collective Dose Criterion

- ✓ The Commission believes that sum of the individual doses from an exempted practice should be ALARA
- ✓ However, if this collective dose from exempted practice is no more than 1000 person-rer a level where no fatality on annual basis is expected, the Commission believes that no further effort is needed to analyze and reduce collective dose

Below Regulatory Concern Policy

Interaction With State and Local Governments

- ✓ The NRC views BRC regulations issued to implement the Policy as establishing basic radiation protection standards
- ✓ NRC will be developing regulatons to implement the Policy Statement, and Agreement States will play an important role by developing and enforcing compatible regulations
- ✓ Consistent with Federal law that there be uniformity between NRC and Agreement States on Basic Radiation Protection Standards, the NRC will be assessing its future rulemaking for compatibility
- ✓ 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 274 of the Atomic Energy Act

Below Regulatory Concern Policy
Information Required for Rulemaking

✓ A proposal for rulemaking to exempt a practice, either from petitioners or the NRC staff, must provide a technical basis upon which the Commission can determine if the basic policy criteria have been satisfied.

✓ Technical basis should include:
- potential individual and societal impacts.
- uses of radioactive materials.
- pathways of exposure.
- levels of radioactivity.
- potential for accidents and misuse.
- quality assurance and reporting requirements.
- constraints and conditions necessary to ensure the assumptions used to grant the exemption remain valid.

Below Regulatory Concern Policy

Specific Actions Planned to Implement the Policy

- ✓ Development of proposed amendments to regulations and supporting regulatory guide defining residual radionuclide concentrations for decommissioned lands and structures
- ✓ Systematic assessment of current NRC regulations against criteria in policy to identify and initiate needed changes
- ✓ Resolution of petitions to provide greater flexibility and economy in disposal of BRC low level wastes from medical research
- ✓ Publication of proposals in Federal Register over next few years

Mack

Below Regulatory Concern Policy
Objectives

3 thoughts

- ✓ To establish a framework for future rulemaking and licensing decisions (2) exempting certain activities involving radioactive material from regulatory control (3) on the basis that the risks are so small that further efforts to reduce them are not warranted

- ✓ To focus the resources of the NRC, Agreement States and licensees toward addressing more significant risks from radioactive materials under NRC jurisdiction

(1) Who is the audience – regulatory in background, technical, or lay person?

(2) What are these significant risks that the NRC & States need more resources to address? Does this imply that (1) public health & safety will be better protected? or (2) that NRC could then afford to reduce its staff and expenditures?

Below Regulatory Concern Policy
Potential Applications

- ✓ Release for unrestricted public use of lands and structures containing residual radioactivity } examples of Δ
- ✓ Distribution of Consumer Products containing small amounts of radioactive material } examples of Δ
- ✓ Disposal of very low-level radioactive waste at other than licensed disposal sites } example of Δ
- ✓ Recycle or Reuse of slightly contaminated equipment and materials } example of Δ

Below Regulatory Concern Policy
Benefits to Public

- ✓ Timely cleanup of contaminated sites — How is this a benefit
- ✓ Increased assurance that adequate funds are available to decommission operating nuclear facilities — ok
- ✓ Enhanced low-level radioactive waste management practices commensurate with potential risks — maybe ok
- ✓ Assurance of a consistent level of safety for consumer products — OK

Below Regulatory Concern Policy
Public Participation in Decisions

- ✓ Through publication in the Federal Register an opportunity will be provided for the public to comment on each generic regulation proposed by the Commission to implement the BRC Policy

- ✓ Significant licensing actions involving individual licensees or sites will be noticed in the Federal Register and may involve public hearings

— Will this be a de facto sham job on the process?

Below Regulatory Concern Policy
Impact of Policy

- ✓ The Policy Statement is not a regulation
- ✓ It does not constitute a decision on any specific exemption from regulatory control
- ✓ Before any regulations or licensing amendments are finalized, a complete analysis of the details and particular circumstances will be performed

Below Regulatory Concern Policy
Basic Elements of Framework

- ✓ Risk-based thresholds in the form of residual radiation exposure or dose criteria ok
- ✓ The BRC dose criteria are selected to correspond to individual and societal risks sufficiently small that expenditure of resources to reduce them further is unwarranted ok

Below Regulatory Concern Policy
BRC Dose Criteria

- ✓ Individual Dose Criterion
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  - 1 mrem/yr (0.01 mSv/yr) for practices involving widespread distribution of radioactive materials such as consumer products or recycled materials or equipment
- ✓ Collective Dose Criterion
  - 1000 person-rem

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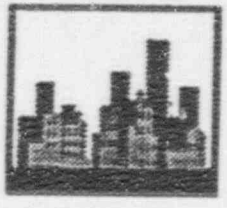

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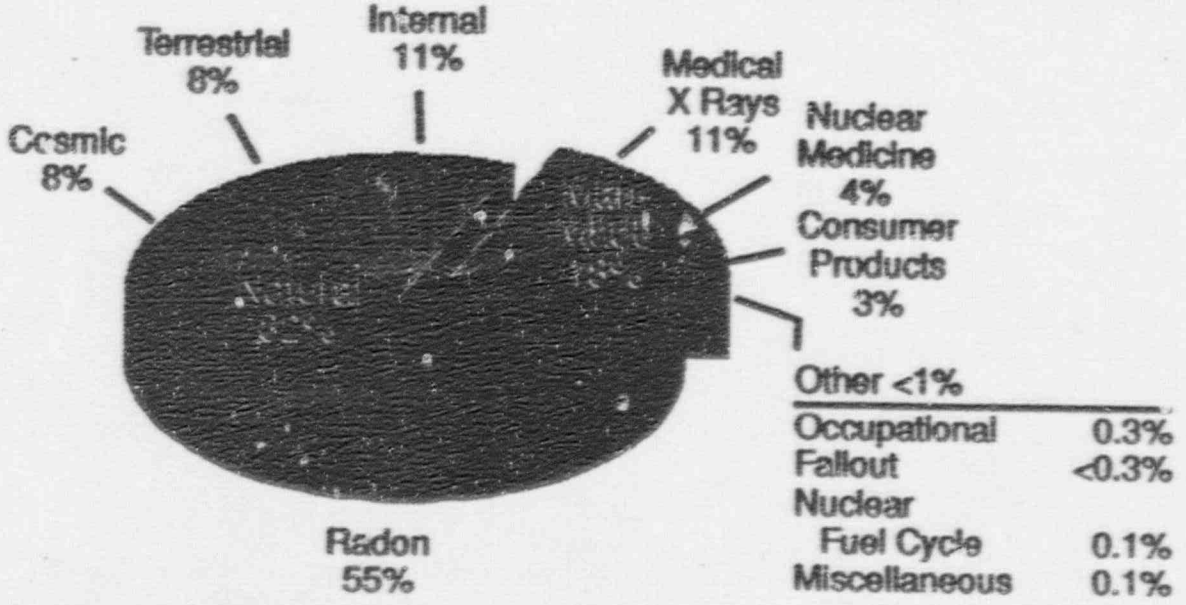

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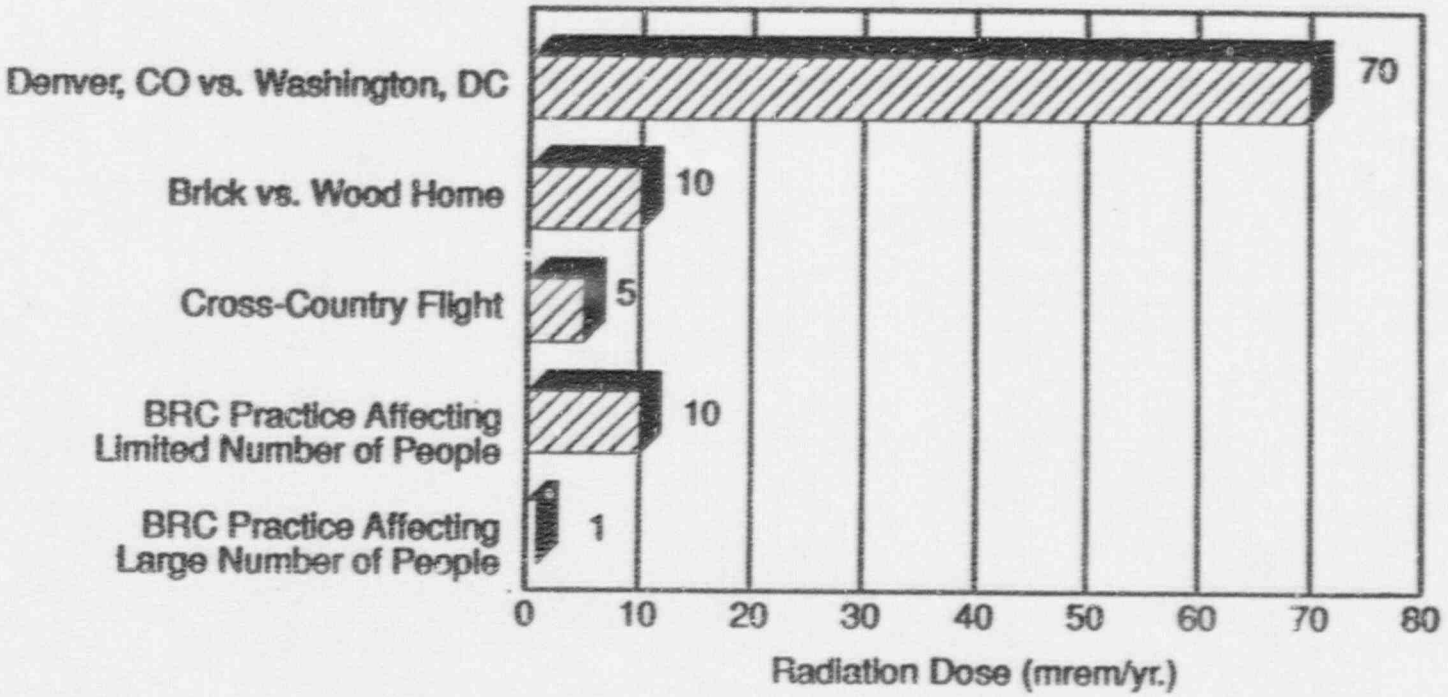

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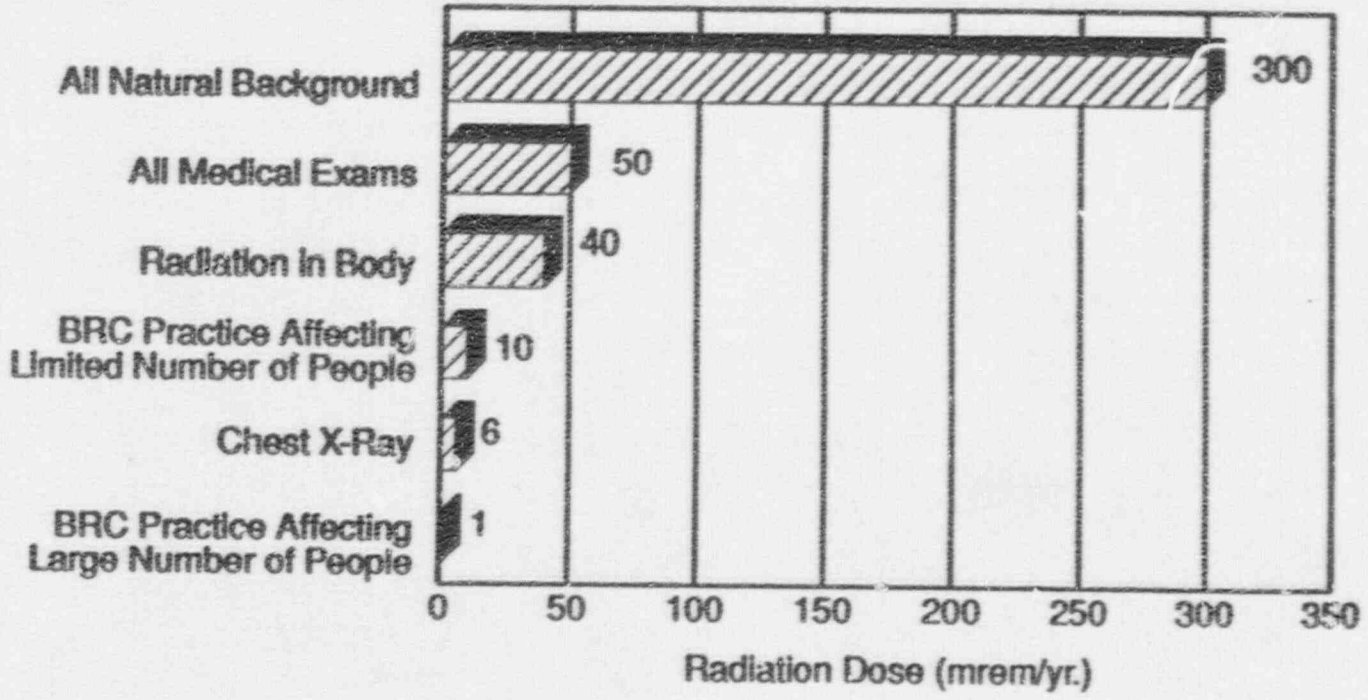

Below Regulatory Concern Policy

Perspective of Exposures to Natural Environment

- ✓ Ionizing radiation is a part of our natural environment
- ✓ Individuals are routinely exposed to about 300 mrem per year from this natural environmental radiation
- ✓ Significant variations in these exposures because of lifestyle or place of residence are experienced by people without apparent concern

Very important point! Can we quantitate?

- ✓ For example, the difference in exposure between living in Denver, Colorado, and Washington, D.C., is about 70 mrem, that between living in a brick versus a wood home is about 10 mrem, and the exposure from a round-trip cross country airplane flight is about 5 mrem
- ✓ Based on this perspective, the NRC considers individual exposures of up to 10 mrem to be BRC

Below Regulatory Concern Policy
Quantitative risk perspective

- ✓ The Commission has used two risk assessments, one sponsored by the United Nations (UNSCEAR 1988) and another performed by the National Academy of Sciences (BEIR V), in estimating the risks from low levels of radiation
- ✓ The 10 mrem individual dose criterion corresponds to an annual risk of fatality from cancer for an individual of 1 in 2[illegible]0
- ✓ For perspective, these risks correspond to less than one-half of 1 percent of the annual risk of fatality from all causes of cancer

Below Regulatory Concern Policy
Basis for 1 mrem Criterion

- ✓ An interim criterion while more experience is gained with exemptions involving widespread distribution of radioactive material *It could be too high?*
- ✓ Examples include consumer products and recycled material and equipment *such as?*
- ✓ The interim criterion provides added assurance that individual exposures to multiple licensed and exempted practice will be well below radiation dose limits *of 100 mrem/yr*
- ✓ The annual risk of cancer fatality from an exposure of 1 mrem is estimated to be 1 in 2 million

Below Regulatory Concern Policy

Collective Dose Criterion

? "the sum" or "some"

- ✓ The Commission believes that sum of the individual doses from an exempted practice should be ALARA
- ✓ However, if this collective dose from exempted practice is no more than 1000 person-rem, a level where no fatality on an annual basis is expected, the Commission believes that no further effort is needed to analyze and reduce collective dose

? ridiculous!

If simple approaches can result in significant decontamination then they should be applied.

Below Regulatory Concern Policy

Interaction With State and Local Governments

- ✓ The NRC views BRC regulations issued to implement the Policy as establishing basic radiation protection standards
- ✓ NRC will be developing regulatons to implement the Policy Statement, and Agreement States will play an important role by developing and enforcing compatible regulations
- ✓ Consistent with Federal law that there be uniformity between NRC and Agreement States on Basic Radiation Protection Standards, the NRC will be assessing its future rulemaking for compatibility
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Below Regulatory Concern Policy
Information Required for Rulemaking

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- uses of radioactive materials.
- pathways of exposure.
- levels of radioactivity.
- potential for accidents and misuse.
- quality assurance and reporting requirements.
- constraints and conditions necessary to ensure the assumptions used to grant the exemption remain valid.

SRP has not been developed to review such petitions (except for waste streams)

Below Regulatory Concern Policy

Specific Actions Planned to Implement the Policy

- ✓ Development of proposed amendments to regulations and supporting regulatory guide defining residual radionuclide concentrations for decommissioned lands and structures
- ✓ Systematic assessment of current NRC regulations against criteria in policy to identify and initiate needed changes
- ✓ Resolution of petitions to provide greater flexibility and economy in disposal of BRC low level wastes from medical research
- ✓ Publication of proposals in Federal Register over next few years

Below Regulatory Concern Policy
Final Policy Outline

✓ Introduction

✓ Definitions

✓ Policy Elements
- Principles of Exemption
- Individual Dose Criterion
- Population Dose Criterion

✓ Implementation

✓ Information to Support Exemption Decisions

PRESENTATION ON
THE NUCLEAR REGULATORY COMMISSION'S
BELOW REGULATORY CONCERN
POLICY STATEMENT

1990

BELOW REGULATORY CONCERN (BRC) POLICY

- Defines a level of radiation so small that further efforts to reduce exposures below this level are not warranted.
- Establishes a framework for future decisions on whether to exempt certain products and activities from regulatory control.

Congressional Directive

- ✓ Section 10 of the Low-Level Radioactive Waste Policy Amendments Act of 1985 directed the Commission to develop standards and procedures and to 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"
- ✓ A Commission Policy Statement of August 29, 1986, provided procedures for expeditious resolution of petitions to dispose of such wastes

Below Regulatory Concern

- ✓ The NRC is now publishing a policy statement to set a basis for radiation protection standards and to expand the concept of "below regulatory concern" to a broad range of activities
- ✓ The term "below regulatory concern," as used in the new Policy Statement, means that for certain uses of radioactive materials, the risks are so low that to require expenditure of resources to reduce them further or to impose regulatory controls is not necessary

Past Practices

✓ Past exemptions under the Atomic Energy Act include:
- Release of consumer products such as smoke detectors
- Release of decommissioned sites
- Disposal of waste generated by medical treatment

✓ Past exemption decisions were made on a case-by-case basis

✓ There was no Commission policy which provided a broadly applicable and consistent risk basis for exemption decisions

Objectives

✓ The overriding objective of the Commission continues to be to assure that there is adequate protection of the health and safety of all members of the public

✓ The objectives of the policy are:

- To establish a broadly applicable risk-based framework to ensure consistency in future rulemaking and licensing decisions and for review of existing exemptions

- To allow the NRC, Agreement States, and licensees to focus their resources on reducing the most significant radiological risks under NRC jurisdiction

Framework to Develop Regulations & Guidance on ...

- ✓ Cleanup of contaminated sites
- ✓ Consumer Products containing small amounts of radioactive material
- ✓ Disposal of very low-level radioactive waste
- ✓ Recycle or reuse of equipment and materials

Public Participation

- ✓ Policy itself does not authorize BRC activities
- ✓ Opportunity will be provided for the public to comment on each regulation proposed by the Commission to implement the BRC Policy
- ✓ Licensing actions that implement the BRC policy will be noticed in the Federal Register when they deviate from existing provisions

Conditions for Exemption

- ✓ Adequate protection of public health and safety must be provided.
- ✓ The application or continuation of regulatory controls on the practice does not result in any significant reduction in dose received by individuals within critical groups and by the exposed population.
- ✓ The costs of the regulatory controls that could be imposed for further dose reduction are not balanced by the commensurate reduction in risk that could be realized.

Basis for Dose Criteria

- ✓ Ionizing radiation is a part of our natural environment
- ✓ Significant variations in these exposures are experienced by members of society without apparent concern
- ✓ Ability to measure exposures
- ✓ Commission risk assessments consistent with the National Academy of Sciences (BEIR V)

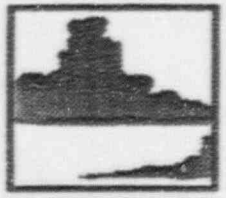
BRC Dose Criteria

✓ Individual Dose Criteria
- 10 millirem/yr
- 1 millirem/yr interim criterion when widespread distribution of radioactive materials such as consumer products is involved.

✓ Collective Dose Criterion
- 1000 person-rem/yr
- Doses less than 0.1 millirem/yr excluded

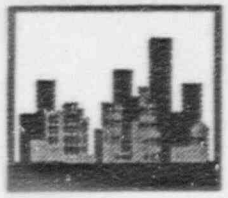
EXAMPLES OF NATURAL RADIATION EXPOSURE

FROM THE SKY - About 30 millirems per year from cosmic radiation.



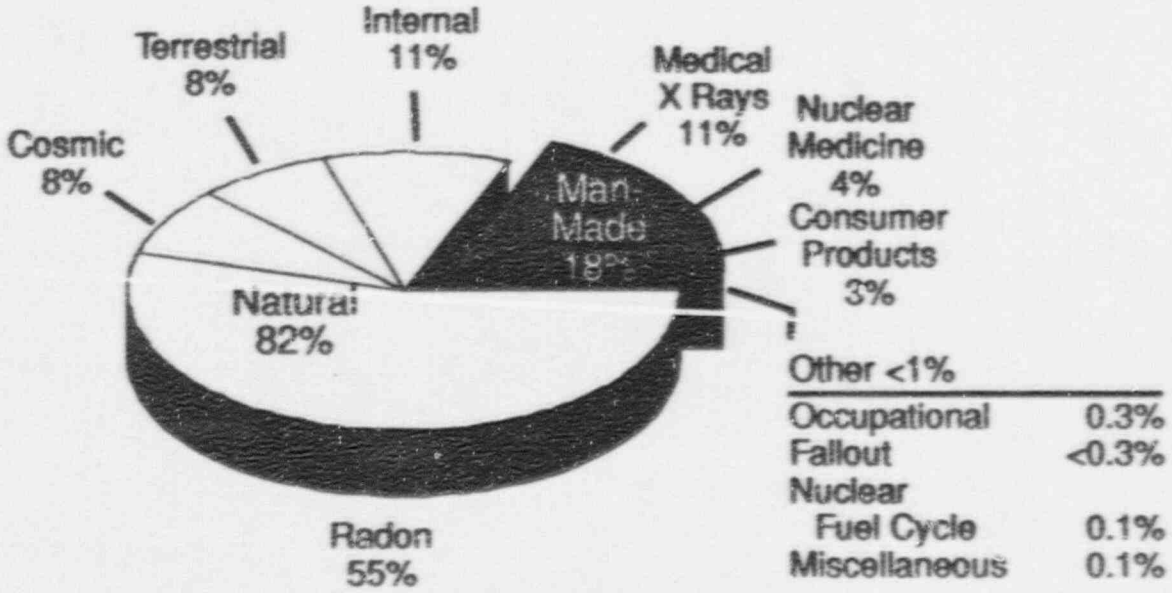
FROM THE AIR THAT WE BREATHE - About 200 millirems per year, including radon.

FROM OUR FOOD AND DRINK - About 40 millirems per year from natural radioactive materials such as potassium-40.



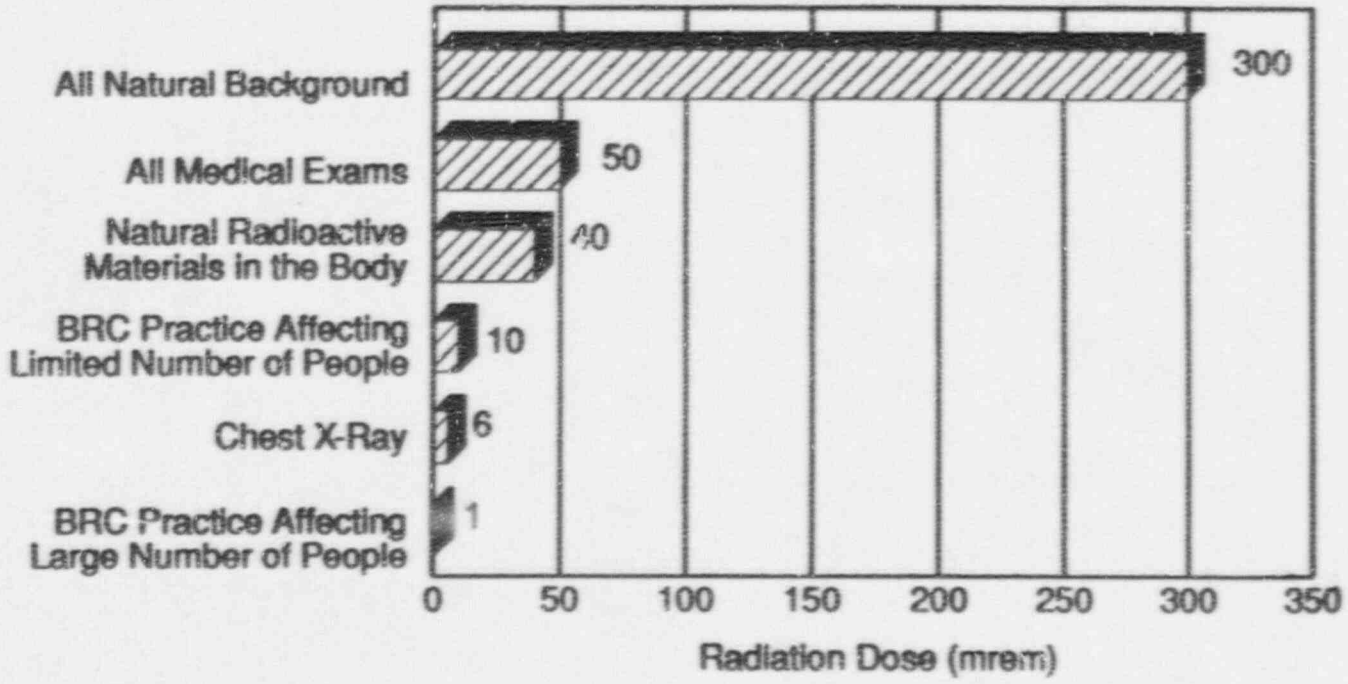
FROM SOILS AND BUILDING MATERIALS - About 30 millirems per year from natural radionuclides such as uranium.

CONTRIBUTION OF VARIOUS RADIATION SOURCES TO THE AVERAGE RADIATION DOSE IN THE U.S. POPULATION*

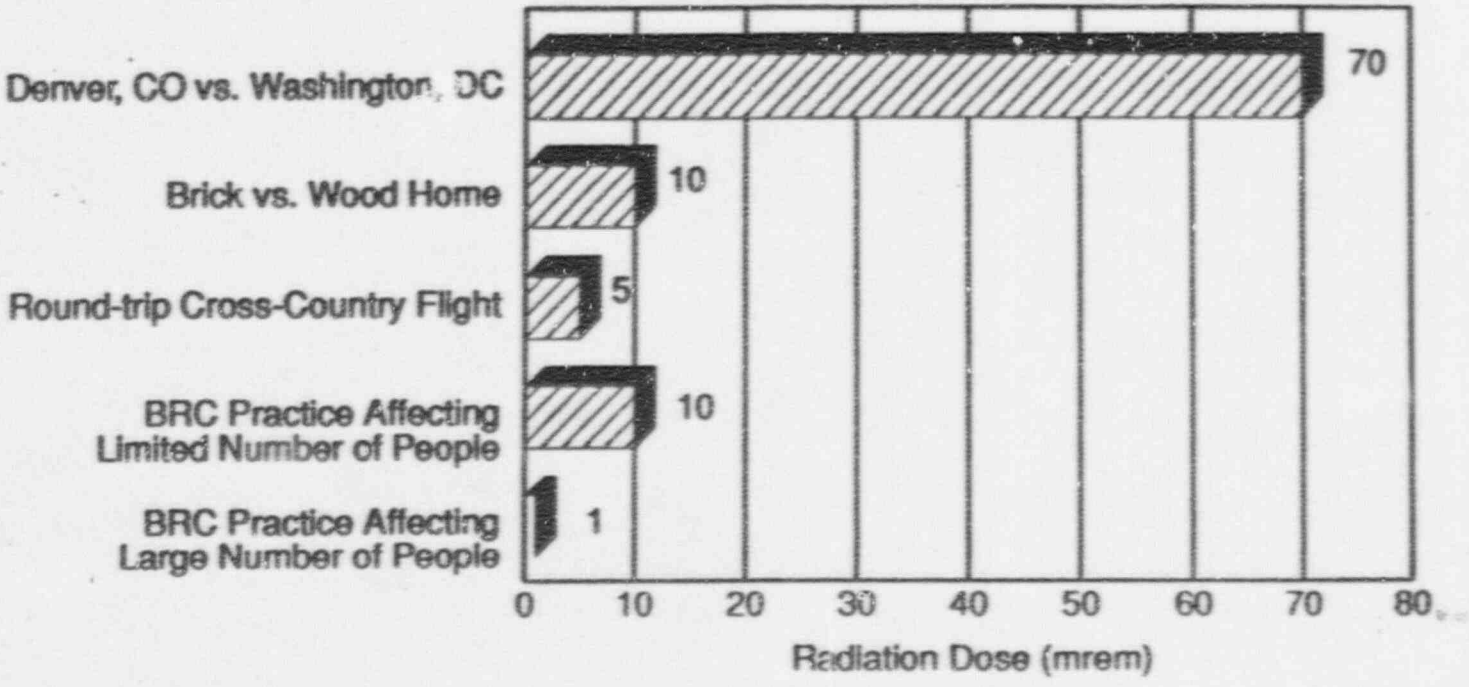


Occupational	0.3%
Fallout	<0.3%
Nuclear Fuel Cycle	0.1%
Miscellaneous	0.1%

COMPARISON OF BELOW REGULATORY CONCERN DOSES TO DOSES FROM NATURAL BACKGROUND AND MEDICAL EXPOSURES



COMPARISON OF BELOW REGULATORY CONCERN DOSES TO DOSES FROM SELECTED OTHER RADIATION SOURCES



Quantitative Risk Perspective

- ✓ The Commission used risk assessments for low-level radiation by the United Nations (UNSCEAR 1988) and by the National Research Council (BEIR V)
- ✓ The 10 millirem annual individual dose criterion corresponds to an annual risk of fatality from cancer for an individual of 1 in 200,000
- ✓ The annual risk from fatal cancer from all causes is about 400 in 200,000
- ✓ Effect is not measurable within the variation of background radiation

Implementation

- ✓ The BRC policy is not self implementing
- ✓ Using the policy as a basis, NRC staff shall:
  - Establish residual radioactivity criteria for decommissioning
  - Reevaluate all existing exemptions
  - Deal with new practices or petitions
  - Ensure substantial public involvement

What will NRC Do Under The Policy

✓ Analyze proposals for exemption

✓ Determine that the risks from the proposal are acceptable

✓ Establish the conditions, constraints, or requirements under which the proposal meets acceptance criteria

✓ Inspect and enforce to verify that the conditions, constraints, or requirements of the exemption are met

✓ Review the exemptions granted to ensure that the public health and safety continue to be protected adequately

Information Required for Rulemaking

✓ A proposal for rulemaking to exempt a practice, either from petitioners or the NRC staff, must be supported by an adequate technical analysis.

✓ On this basis, the Commission will consider whether the basic policy criteria have been satisfied in making its decisions.

✓ Technical basis should include:
- Individual and societal impacts.
- uses of radioactive materials.
- pathways of exposure.
- levels of radioactivity.
- potential for accidents and misuse.
- quality assurance and reporting requirements.
- constraints and conditions necessary to ensure the assumptions used to grant the exemption remain valid.

Interaction With State and Local Governments

- ✓ Consistent with Federal law, there should be uniformity between NRC and Agreement State basic radiation protection standards
- ✓ The NRC will implement the BRC policy by developing regulations, including basic radiation protection standards
- ✓ Agreement States will play an important role in developing and enforcing regulations compatible with NRC's basic radiation protection standards
- ✓ NRC will be assessing future regulations on a case-by-case basis to determine which should be compatible
- ✓ 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

Conclusion

The BRC policy will ...

- Assure that there is adequate protection of the health and safety of all members of the public
- Establish a broadly applicable risk based framework to ensure consistency in future rulemaking and licensing decisions and for review of existing exemptions.
- Allow the NRC, Agreement States and licensees to focus their resources on reducing the most significant radiological risks under NRC jurisdiction

Revision of 10 CFR 20

- ✓ Commission is finalizing a major revision of its standards for radiation protection
- ✓ Adopts scientific basis for calculating radiation dose endorsed in Federal Guidance on Occupational Radiation Protection signed by the President in 1987
- ✓ Lowers the radiation dose limit for members of the public from 500 millirem to 100 millirem
- ✓ The BRC Policy is compatible with these provisions

Outline of Presentation

- ✓Congressional Direction
- ✓Below Regulatory Concern
- ✓Past Practices
- ✓Objectives
- ✓Revision of 10 CFR 20
- ✓Applications
- ✓Public Participation
- ✓Benefits
- ✓BRC Dose Criteria
- ✓Comparison to Other Sources of Radiation
- ✓Basis for Dose Criteria
- ✓Implementation
- ✓Conclusion

BACKUPS

BRC

Uses of Radioactive Material

- ✓ Generation of electrical power
- ✓ Medical diagnosis, therapy and research
- ✓ Consumer products such as smoke detectors
- ✓ Industrial applications such as radiography of structures to detect flaws

Current Exempt Consumer Products

Product	Individual Dose (mrem/yr)	Collective Dose (person-rem/yr)
Smoke Detectors	0.008	800
Tritiated Watches	0.1	1200
Lamp Mantles	0.2	8600
Electron Tubes	0.004	1000
Welding Rods	16.	5000

Source: NCRP Report
No. 95, 1987

Application of ALARA

- ✓ A fundamental principle of NRC radiation protection policy
- ✓ The ALARA principle applies to efforts by licensees to maintain radiation exposures and releases of material As Low As Reasonably Achievable
- ✓ Radiation exposures and releases of material associated with an exempted practice should be ALARA
- ✓ A practice will be considered ALARA by the Commission if the individual and collective dose criteria of the policy are met

Rationale for Policy

- ✓ The low levels of risk posed by some uses of radioactive material do not warrant the same degree of regulation as other radioactive materials
- ✓ Criteria are necessary to ensure adequate and consistent decisions on acceptable risks
- ✓ Policy will provide a unifying risk framework for decisions about which practices can be exempted from the full scope of NRC's comprehensive regulatory controls
- ✓ Criteria will allow NRC to focus attention on those practices where regulation is necessary and appropriate to ensure that the public and the environment are adequately protected

Justification of Practice

- ✓ The Commission affirms the basic tenets of radiation protection (justification, optimization, dose limits) as appropriate.
- ✓ Justification decisions are based on more than health and safety considerations
- ✓ Justification should be determined by the general public and the proponent of the practice

Basis for 1 millirem Criterion

- ✓ An interim criterion while more experience is gained with exemptions involving widespread distribution of radioactive material
- ✓ Examples include consumer products and recycled material and equipment
- ✓ The interim criterion provides added assurance that individual exposures to multiple licensed and exempted practices will be well below radiation dose limits
- ✓ The annual risk of cancer fatality from an exposure of 1 millirem is estimated to be 1 in 2 million

Collective Dose Criterion

- ✓ Collective dose is the sum of the individual doses from an exemption
- ✓ This criterion has the effect of limiting the total number of people exposed at or near the individual dose criterion
- ✓ Added assurance that significant exposures to multiple exemptions will be unlikely
- ✓ Not necessary to include individual doses below 0.1 millirem (annual risk of 1 in 20 million) in calculating collective dose

Specific Actions Planned to Implement the Policy

- ✓ Development of proposed amendments to regulations and supporting regulatory guide defining residual radionuclide concentrations for decommissioned lands and structures
- ✓ Systematic assessment of current NRC regulations against criteria in policy to identify and initiate needed changes
- ✓ Resolution of petitions to provide greater flexibility and economy in disposal of BRC low level wastes from medical research
- ✓ Publication of proposals in Federal Register over next few years

ESTIMATED DEATH RATE FOR SELECTED CAUSES (1988)

(per 100,000 population; based on 10% sample)

All causes	883.0
Some Selected Causes:	
Cardiovascular diseases	395.5
Malignancies	198.0
Accidents (Vehicular)	39.7
Suicides	12.3
Homicides	9.0

Exceptions to Criteria

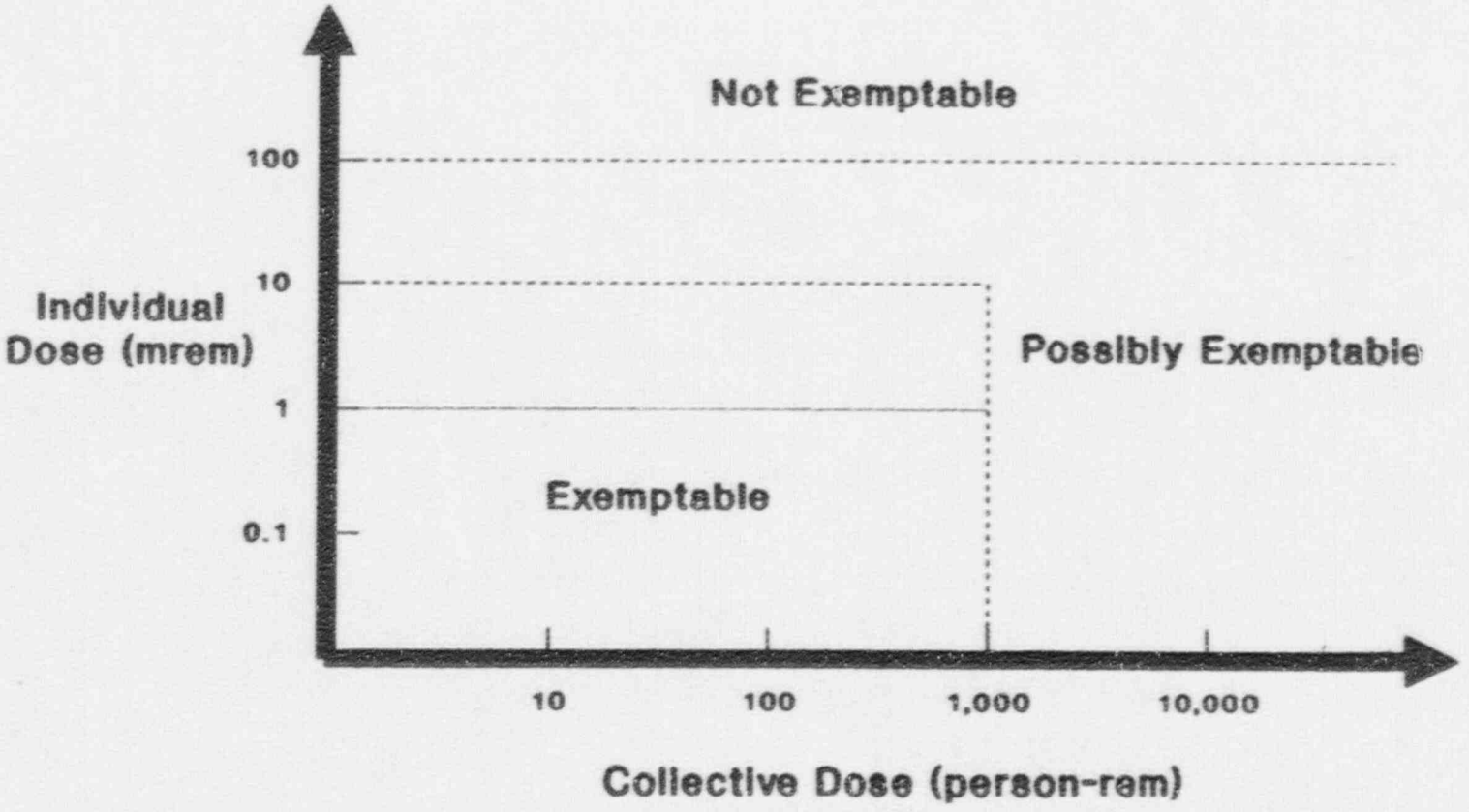
✓ Practices which do not meet the criteria for exemption may nevertheless be granted exemptions from regulatory control on a case-by-case basis in accordance with the principles of the policy if:

✓✓ The potential doses to individual members of the public are sufficiently small or unlikely

✓✓ further reductions in the doses are neither readily achievable or significant in terms of protecting the public health and safety and the environment

✓✓ the collective dose from the exempted practice is ALARA

POLICY DOSE CRITERIA



AEA Exemption Authority

✓ 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

✓ Numerous exemptions currently promulgated in regulations:
- exempt quantities and concentrations
- consumer products and devices
- certain waste streams

Comparison of Risks from BRC Exposures with Other Risks

Cause	Annual Risk of Fatality (Chances in a Million)
Motor Vehicle Accident	300
Drowning	30
Smoking Pack of Cigarettes	14
Falling Objects	6
10 mrem	5
Lightning	0.5
Tornado	0.4
1 mrem	0.5

PICTORIALS

BRC