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REGULATORY REQUIREMENTS FOR RADIATION PROTECTION

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ABSTRACT

Regulatory requirements for protecting man from radiation have evolved and matured over several decades. Due to the wide adoption of recommendations of the International Commission on Radiation Protection (ICRP), there is international consistency in the principles followed for radiation protection. This foundation will be increasingly important due to the growing need for international agreements and standards for radiation protection and radioactive materials management as the nuclear industry develops.

During the early years of the commercial nuclear industry, primary reliance was placed on the protection of the individual, both in the work force and as a member of the public. With the growth of nuclear power in the 1960's and 1970's, environmental impact assessments and expert reviews of bio-effects data have focused attention on statistical risks to large population groups and the use of the collective dose commitment concept to estimate potential effects.

The potential release of long-lived radionuclides from the nuclear fuel cycle requires further consideration of radionuclide accumulation in the biosphere and calls for controls conceived and implemented at the international level. The initial development efforts for addressing these concerns already have been instituted by the ICRP and the IAEA. However, formal international agreement and a unified set of international standards may be required to implement the recommendations of these groups. Further international efforts in the field of radiation protection are also called for in developing waste management practices and radioactive effluent control technology, in site selection for fuel reprocessing plants and waste disposal facilities, and for ensuring safe transport of high-level wastes in various forms. Since very low doses and dose rates will be involved, it will be useful to reexamine dose-effect relationships and to develop explicit societal goals for health protection. Improved criteria and methodologies for "as low as readily achievable" will also be required.

INTRODUCTION

The application of nuclear energy as an important source of electric power is becoming a reality. With increased world-wide utilization, health and safety concerns no longer are restricted to a few localized developmental facilities but are international in scope. This scope is particularly appropriate for discussions of the nuclear fuel cycle.

Some of the radioactive materials associated with nuclear fuel cycle operations tend to be longer lived than the radionuclides of primary concern at power reactors (short-lived noble gases and radioiodines) and several of them can be truly global pollutants. The increasing growth of nuclear power and its associated fuel cycle and waste disposal operations requires consideration of the cumulative and additive nature of releases from multiple source locations. Effluents can move beyond national boundaries so that international cooperation and planning are required for the protection of resources such as rivers and other large bodies of water which cross national boundaries.

These two factors, the release of global pollutants, and the potentially cumulative and additive nature of releases from a multiplicity of sources, suggest that further international cooperation and agreement are needed on the principles for setting regulatory requirements for restricting effluents from nuclear fuel cycle facilities and for the siting of reprocessing and waste disposal facilities. This need is further strengthened by the need for attention to the statistical effects of radiation on large population groups.

The development of standards for radiation protection traditionally has evolved through international consensus. This consensus has been achieved through multinational groups of experts such as the International Commission on Radiological Protection (ICRP) and through the exchange of technical information at conferences sponsored by the IAEA and other organizations, such as the International Radiation Protection Association. The fundamental approaches and recommendations issued by the ICRP have been employed in the development of national standards, such as the recommendations of the U.S. National Council on Radiation Protection and Measurements (NCRP), and for regulations issued by governmental agencies, such as the U.S. Nuclear Regulatory Commission. The traceability of most national radiation protection regulations to the recommendations of the ICRP has resulted in a beneficial international uniformity in the basic principles for radiation protection. This uniformity can become the foundation for further international agreements for radiation control.

THE EVOLUTION OF THE BIOLOGICAL BASIS FOR RADIATION PROTECTION

The earliest radiation standards were based upon acute observable injury, such as the recommendation of A. Mutscheller in 1925 [1] for a maximum dose level based upon a fraction of the erythema dose. As long as the exposed population was limited to only a few researchers, this appeared to be a satisfactory basis for protection. However, as more use was made of X-rays and radium in medical treatment, research, and industrial applications, the size of the exposed population grew and, consequently, the association between radiation exposure and long-term chronic injury was manifested and became of concern for radiation protection.

The confirmation of the mutagenic properties of radiation by R. H. Muller [2] in 1927 added concern for protection against the production of mutations in the gene pool as a basis for the development of radiation standards. This resulted in eventual limitations on exposures to the general population in order to limit the damage to future generations.

Epidemiological studies have given emphasis to the importance of the statistical risks from radiation which, although small from the standpoint of any individual, may result in potential health effects if large population groups are exposed. The work of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the British Medical Research Council, and the Advisory Committee on the Biological Effects of Ionizing Radiation (BEIR) of the U.S. National Academy of Sciences - National Research Council have been particularly valuable adjuncts to the work of the ICRP in evaluating these effects.

The growing body of information on radiation bioeffects continues to confirm that the current ICRP recommendations [3] provide a satisfactory basis for protection of the individual. Despite the fact that the hazards of radiation and radioactive materials are known with greater certainty than for any other toxic agent or pollutant, there still is uncertainty regarding the risk at low doses and its dependence upon dose-rate. Recent assessments [4,5] have cast doubt on the validity of linear extrapolations of the dose-effect relationships observed at high doses. However, in the absence of unequivocal evidence that a threshold dose exists below which there is no biological damage, these low-level, low-dose-rate exposures still must be considered in setting regulatory requirements for radioactive material releases into the environment if large population groups would be exposed. Global physical dispersion processes produce extremely low radionuclide concentrations and, consequently, this will result in small individual doses delivered at very low dose rates to large population groups. Thus, consideration of low-level doses is particularly important for those impacts of the nuclear fuel cycle which transcend national boundaries. This, however, is not to say that the assumption of dose-effect linearity should be used to obtain realistic estimates of the potential biological damage to large population groups.

RECENT U.S. EXPERIENCE IN DEVELOPING REGULATORY REQUIREMENTS FOR RADIONUCLIDE DISCHARGES TO THE ENVIRONMENT

Concurrent with the growing body of knowledge on radiation bioeffects, there has been a corresponding evolution of the methodology for setting radiation protection criteria. Traditionally, basic radiation protection standards have been expressed in terms of "maximum permissible doses"[1] to individuals or "maximum permissible concentrations." Although we in the United States prefer the terminology "Radiation Protection Guides" (as these dose levels are not always permissible nor are they "maximum" doses for all circumstances), we do agree with the concept of setting upper exposure levels for the protection of individuals which should not be exceeded without compelling reasons for doing so. The basic foundation for regulatory requirements specifying the upper bounds for individual exposures would, of course, be the recommendations of the ICRP [3] and those of related national bodies such as the U.S. National Council on Radiation Protection and Measurements (NCRP) [6].

Methodology is evolving for implementing the ICRP guidance that exposures be kept as low as is readily achievable. The conceptual framework set forth in ICRP Report No. 22 [7] entails the application of a cost-effectiveness analysis for further reductions in radiation dose below the ICRP recommended limits. As noted, both in ICRP Report No. 9 [3] and by the NCRP [8], there is considerable difficulty in applying this approach in practice because of the uncertainties inherent in attempting to quantify the risks and benefits. Considerable further development is required in this area and should entail international efforts by experts in scientific and social disciplines.

The concept of keeping radiation exposures "as low as readily achievable", ALARA, (or "as low as practicable", ALAP) has been in the regulations of the

[1] Note: In the precise terminology of ICRP Report No. 9, the term "maximum permissible dose" is reserved for application of limits for occupationally exposed individuals and the term "dose limit" would be applied to recommendations covering routine exposures of individual members of the public and populations.

U.S. Nuclear Regulatory Commission and its predecessor agency, the U.S. Atomic Energy Commission, since 1970. The incorporation of this concept followed guidance issued by the former Federal Radiation Council [9] (whose functions are now carried out by the U.S. Environmental Protection Agency) and recommendations of the NCRP. Initially, the implementation of this condition was performed on a case-by-case basis. Specific design and operating requirements for meeting the criterion "as low as practicable" for effluents from light-water-reactors were initially published on December 3, 1970 [10]. These requirements did not specify numerical criteria defining ALAP.

The development of generic numerical criteria for levels of radioactive material in light-water reactor effluents was initiated in response to comments from the nuclear industry, local and state agencies, and from environmental and conservation groups that favored more definitive quantitative criteria. The development of these guidelines entailed a lengthy rule making proceeding starting with the publication of a proposed rule on July 9, 1971 [11], progressing through public hearings in 1972 and 1973, and concluding in the issuance of a final regulation in the Spring of 1975 [12], which, incidentally, was one of the first major decisions of the new Nuclear Regulatory Commission following its formation on January 19, 1975.

The proposed criteria changed several times in the course of the rule making proceeding as shown in Table I. The initial criteria included limitations on radionuclide concentrations in air and water which were later dropped as being unnecessary for the implementation of individual dose restrictions. Similarly, restrictions on the total quantity of radioactive materials in liquid effluents and the total quantity of radioiodine in airborne effluents were dropped in favor of a cost-benefit analysis of the need for additional controls to reduce population doses beyond the controls required for the individual dose limitations. This analysis requires the sequential augmentation of effluent controls until the incremental cost per unit reduction in the collective dose to the population within 50 miles (80 km) exceeds $1,000 per man-rem or $1,000 per man-thyroid-rem. The value used in adjudging the cost-benefit balance point is an interim value which is believed to be conservative and is slightly higher than previously published values for the worth of radiation exposure reductions. The use of the $1,000 value for the collective thyroid dose is also an interim measure as biological data would suggest a lower value for the worth of reductions in the thyroid dose than for whole body exposures. At present, we are attempting to define better the monetary benefits of reducing radiation exposures in order to provide a better decision criterion than the somewhat arbitrary $1,000 per man-rem value presently used.

We have gained useful experience in the course of developing and implementing these ALARA guidelines. The changes in the individual dose limitations point out the need for definitive data from operating experience both for length of operation and replication at different facilities. What is "as low as practicable" cannot be determined without practice. As major effluent release pathways are reduced, minor releases and release points become significant contributors to the estimated dose. These release points generally have not been monitored so that their contributions cannot be well characterized.

Table I. Evolution of NRC Guidelines for "As Low As is Reasonably Achievable" Levels of Radioactive materials in Light-Water-Cooled Nuclear Power Reactor Effluents.

Publication Date	Proposed Rule June 9, 1971 [11]	Staff Concluding Statement February 20, 1974 [13]	Commission Decision and Effective Rule May 5, 1975 [12]
Annual Design Objectives			
Total Activity Released per reactor liquids (exclusive of tritium)	5 curies per year	5 curies per year	deleted in lieu of requirement for cost-benefit evaluation
radioiodine - 131 (airborne)	No restriction	1 curie per year	"
Concentrations of Radionuclides in water (total less ^{3}H)	20 pCi per liter	deleted	"
(tritium)	5,000 pCi per liter	"	"
Air: radioiodines and particulates	10^{-5} of 10 CFR Part 20 Appendix B, Table II, Column I concentrations	"	"
noble gases	10 millirem per year	see below	see below

(Continued)

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Publication Date	Proposed Rule June 9, 1971 [11]	Staff Concluding Statement February 20, 1974 [13]	Commission Decision and Effective Rule May 5, 1975 [12]
Annual Design Objectives			
Individual Doses from Liquid Effluents (total body)	5 millirem per year (site)	5 millirem per year (site)	3 millirem per reactor-year
(organ)	5 millirem per year	5 millirem per year (site)	10 millirem per reactor-year
Noble gases (gamma air dose)	-	10 millirad per year (site)	10 millirad per reactor-year
(beta air dose)	-	20 millirad per year (site)	20 millirad per reactor-year
(total body dose)	5 millirem per year (site)	5 millirem per year (site)	5 millirem per reactor-year
(skin dose)	-	15 millirem per year (site)	15 millirem per reactor-year
Radioiodines & Particulates (organ dose)	5 millirem per year (site)	15 millirem per year (site)	15 millirem per reactor-year
Limiting Conditions for Operation			
Licensee Action	2 times annual Design objective (one-half of the annual design objective in any calendar quarter)	one-half of the annual design objective in any calendar quarter	one-half of the annual design objective in any calendar quarter
NRC Action	4-8 times annual design objective	4 times annual design objective	not specified

There are numerous other sources of uncertainties in the cost and performance of unproven effluent treatment systems; in the radionuclide composition, magnitude, and physiochemical form of the effluents; in the environmental transport models; and in the parameters for predicting dose that must be allowed for in establishing regulatory requirements based upon cost-effectiveness analyses.

Several approaches have been employed in recent U.S. regulations to allow for the uncertainties in the theoretical cost-effectiveness analyses of radioactive waste treatment systems. In the NRC's development of ALARA effluent limitations, we have specified the numerical guidelines as design objectives and permit operating flexibility above the annual dose design objectives so that corrective action by licensees is not required until projected doses reach one-half of the annual design objective in a calendar quarter.

The cost-effectiveness of radioactive effluent control systems was also considered during the development of the generally applicable environmental radiation standards for uranium fuel cycle operations which were issued recently by the U.S. Environmental Protection Agency [14]. The EPA standards set forth environmentally acceptable dose limits for individuals, in contrast to the design objectives of Appendix I of 10 CFR Part 50. The annual dose limits established are 25 millirem to the whole body, 75 millirem to the thyroid gland, and 25 millirem to any other organ from all operations (except mining, transportation, and waste disposal) in the light-water-reactor uranium fuel cycle. Departures from theoretical predictions of effluent control system effectiveness and unexpected operational difficulties in reaching or maintaining the required levels are accounted for by a variance provision which permits the regulatory agency (NRC) to issue a temporary variance to operate above the standards for limited periods of time necessary to correct the deficiencies in system operation.

We have had approximately two years experience in the implementation of the design objectives of Appendix I to 10 CFR Part 50. Compliance is assessed by effluent measurements combined with environmental dispersion and dose calculation models. This calculational approach is used because the radionuclide concentrations in the environment which correspond to the design objective doses are so low that measurements are difficult. A series of guides has been developed that describe the NRC staff's models for predicting radionuclide releases, atmospheric and hydrological dispersion, biological reconcentration and human intake, and equipment costs [15-19]. License applicants may use other models which incorporate unique features or account for specific site-related conditions if they realistically depict actual physical processes.

The requirement for a case-by-case cost-benefit analysis generally has not resulted in major equipment additions beyond the radioactive waste treatment systems required to meet the individual dose design objectives. This is despite the presumably conservative value of $1,000 per man-rem, or man-thyroid-rem used as the balancing criterion. This was not totally expected but it can be explained. The cost-benefit analysis is based upon population dose and, therefore, the value of effluent reductions is related to the population density. Population densities are generally low in the vicinity of reactor sites. Sites are rare that have a sufficient population density to warrant additional effluent limitations and that do not have any individual or farm within a few miles

of the facility. Thus, for most situations, the design objectives based upon individual dose limitations will be the governing restriction.

Our experience in formulating and implementing regulatory requirements based on the principle of "as low as readily achievable" shows that such requirements can be successfully employed. The primary lesson that we have learned from the Appendix I rule making proceeding is that sufficient allowance must be made for departures from the predicted operation of unproven effluent treatment systems. Therefore, some operating flexibility must be permitted between the theoretical cost-benefit optimum and the control level set forth in regulations.

CONSIDERATIONS FOR FUTURE STANDARDS DEVELOPMENT EFFORTS

Adoption of the ICRP dose limits for individual protection and the ALARA concept for monitoring unnecessary radiation exposure provides a foundation for the development of future international agreements. In the introduction of this paper, several areas were identified where further international standards development efforts are desirable. These areas were:

1. limitation of global radioactive contaminants;
2. protection of communal natural resources;
3. development of consistent principles and procedures for risk estimation and regulation; and
4. development of consistent siting policies for nuclear fuel cycle facilities.

It is appropriate at this point to elaborate on these concerns and provide examples of ongoing efforts to resolve them.

Of primary concern is the need for uniform control over the long-lived radioactive emissions from nuclear fuel cycle operations that are potential global pollutants. Several radionuclides can be identified which, by nature of their persistence and mobility, have this potential. Krypton-85, tritium (hydrogen-3), and carbon-14 are of primary interest because of their dispersibility, production yields, and half-lives. Radionuclides such as iodine-129 and plutonium-239 presently are more of local and regional concern than global, but because of their extremely long half-lives they might become dispersed more widely over thousands of years. The uncertainty in the long-term behavior of such radionuclides in itself suggests that precautions should be taken to prevent the accumulation of such materials in the environment.

In the United States, we have made a national commitment to the institution of further controls on releases of krypton-85, iodine-129 and alpha-emitting transuranic elements. General environmental radiation standards for uranium fuel cycle operations were issued in the beginning of this year by the U.S. Environmental Protection Agency [14]. These standards will require the limitation of discharges of these materials to 50,000 curies of krypton-85, 5 millicuries of iodine-129, and 0.5 millicuries of alpha-emitting transuranic elements per gigawatt-year of electrical energy production. The standard for the transuranic emissions will be applied in 1979, and the additional retention of

krypton-85 and iodine-129 will be required for the reprocessing of all fuel irradiated on or after January 1, 1983 if a decision is made to reprocess fuel in the U.S. These lead times are required to develop and permit full scale testing of the required advanced effluent control systems. Studies are also underway to develop and assess technology for the control of carbon-14 and tritium.

The concern for the restriction of global radioactive pollutants is by no means unique to the United States. Many other countries are instituting controls on these emissions or are formulating standards which contain restrictions on the global collective dose commitment, such as the Nordic Radiation Protection Standards recommended by the Radiation Protection Institutes of Denmark, Finland, Iceland, Norway and Sweden [20]. However, more extensive agreement is needed to broaden the international institution of uniform controls over these emissions.

A second area where further international standards development efforts are warranted is the protection of communal natural resources. The limitation of radioactive material levels in bodies of water that are shared between nations is of principal interest in this regard, for example, the protection marine resources from ocean disposal of radioactive waste. Where rivers flow through several countries or large seas or lakes are located on national boundaries, the additive contributions from facilities in different countries must be controlled to insure that downstream facilities are not unnecessarily restricted by prior contamination. The protection of water quality in rivers and seas shared by several nations has, of course, been recognized and agreements have been or are being developed to deal with this general problem.

Examples of international cooperation to limit radionuclide concentrations in communal waters are the International Convention on the Prevention of Marine Pollution by Dumping Wastes and Other Matter [21] and the U.S. - Canadian 1972 Agreement on Great Lakes Water Quality [22]. The convention on Marine Pollution prohibits the dumping of high-level radioactive wastes and other toxic materials into the world oceans. A system of permits is set up for controlling the ocean disposal of low-level radioactive wastes. The convention parallels in many respects the provisions of U.S. law in the 1972 Amendments to the Federal Water Pollution Control Act and in the Marine Protection, Research, and Sanctuaries Act of 1972.

The U.S. - Canadian Agreement on Great Lakes Water Quality follows from a long-standing agreement on sharing common waters, the U.S. - Canadian Boundary Waters Treaty of 1909. The Water Quality Agreement provides for a Great Lakes Water Quality Board to establish objectives for the control and monitoring of pollution in the lakes. A subcommittee composed of U.S. and Canadian experts is in the process of developing water quality objectives for levels of radioactivity in water and a radioactivity surveillance plan for the Great Lakes.

The third area for future joint efforts is the development of consistent principles and approaches for regulating releases of radioactive materials to

the environment. There are on-going efforts by the ICRP through its Subcommittee Number 4 to provide additional guidance on implementation of the ICRP recommendations. The International Atomic Energy Agency has convened several Advisory Groups to prepare technical guidance for member states on developing regulations for radioactive effluent limitation. Draft reports have been prepared by IAEA Advisory Groups on the Monitoring of Airborne and Liquid Radioactive Discharges to the Environment from
Nuclear Facilities, on the Assessment of Collective Dose to Populations, and on the Principles of Establishing Limits for the Release of Radioactive Materials to the Environment. These and other efforts by the IAEA and the ICRP should provide valuable technical guidance on consistent methods which can be used in developing national regulations and international agreements for controlling radioactive pollutants.

International agreement would be beneficial in defining the geographic scope of consideration to be used for evaluating the costs and the benefits of nuclear power. It is difficult to argue against the position that the proper region of consideration should be the total biosphere and the world population. This scope of consideration is particularly appropriate for certain long-lived radioactive pollutants from the nuclear fuel cycle which are capable of worldwide dispersion. It is now U.S. policy that, for environmental impact assessments performed under the National Environmental Policy Act of 1969, the "human environment" is not to be restricted to U.S. territorial boundaries. A more limited region of consideration could be employed for certain applications where the impacts or costs are primarily confined to a small region. Our approach for power reactor licensing has been to require detailed data submissions for a limited area (50 miles) and to use upper bound estimates based on less precise calculations for the dose delivered to the U.S. and world populations for the environment impact assessment.

One additional area where a need for international consensus can be clearly seen is the development of radiation protection regulations which affect the siting of nuclear fuel cycle facilities and radioactive waste disposal sites. Experience with Eurochemic shows that multinational spent fuel reprocessing centers are feasible. Both the IAEA Regional Nuclear Fuel Cycle Center Study [23] and NRC's Nuclear Energy Center Site Survey [24] show that energy "parks" or centers containing nuclear power plants and reprocessing facilities and, perhaps, fuel fabrication plants, are viable from the standpoint of public health and safety considerations. The localized concentration of several nuclear fuel cycle facilities with possible inequities in the distribution of potential environmental impacts and benefits requires that common agreements for effluent limitation be developed.

CONCLUSIONS

Prototypical international agreements already exist which can be used as a cornerstone for the development of further international controls on radioactive pollutants. The international standards for the transportation of radioactive materials developed by the IAEA provide a well recognized and widely adopted basis for uniform international regulation that aids in ensuring safety of

international shipments and thereby promotes international trade. Similar agreements for the control of pollutants from nuclear fuel cycle facilities also should be beneficial.

We believe that there is a need for reaching international agreement on the development of requirements for controlling radioactive emissions from nuclear fuel cycle operations. The principles and recommendations for radiation protection set forth by the ICRP provide a foundation for such agreement. In order to accomplish this objective, the U.S. Nuclear Regulatory Commission, together with the Energy Research and Development Administration, the Environmental Protection Agency, the Department of State, and the Department of Transportation have agreed to undertake the following actions:

1. intensify U.S. efforts and participation in international efforts to develop codes and standards for environmental protection and to assess the environmental impact of alternative energy sources;
2. advocate futher international cooperative efforts along these lines;
3. continue support of IAEA and NEA activities to develop uniform standards for the transportation of radioactive materials and guidance to IAEA member states on the procedures for developing regulatory requirements for radioactive emissions; and
4. encourage adoption of the provisions of the Convention on the Prevention of Marine Pollution as an international standard for the control of ocean disposal of radioactive wastes.

We urge that others intensify their efforts in support and refinement of these objectives.

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