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A REGULATORY PERSPECTIVE

ON RADIATION PROTECTION:

NUCLEAR LAW AND RADIATION SCIENCE -

DOES THIS COMBINATION WORK?

By

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ABSTRACT

The need for lawyers and administrators to address the issues surrounding atomic energy was identified more than forty years ago. It can be argued that today the issue is not the lack of laws and regulatory programs, but whether existing laws and programs meet societal needs in ways that incorporate current scientific knowledge, are cost effective, and provide for consistency in application. The National Council on Radiation Protection and Measurements (NCRP) has historically provided recommendations for radiation protection to various U.S. regulatory bodies. NCRP recommendations are similar to those issued by the International Committee on Radiological Protection (ICRP). ICRP recommendations are largely adopted worldwide. U.S. governmental programs for radiation protection are carried out by many Federal and State agencies under various statutes. The Federal statutes have been enacted in different times to address different issues, have been amended, and have been subjected to court decisions. Interagency efforts have been mounted to coordinate the Federal radiation protection regulations but these efforts are constrained by existing statutes, agency policy determinations, and court decisions. The result is that U.S. radiation protection regulations are often redundant, are sometimes in conflict with each other, and are not in harmony with radiation protection programs in the rest of the world. Recent controversies over the use of the linear, non-threshold (LNT) theory when setting standards and the costs associated with meeting the standards have further fueled discussions about U.S. radiation protection standards. The coming millennium represents an opportunity to reconsider what nuclear laws should be required in the 21st century to protect workers, the public, and the environment from radiation hazards.

INTRODUCTION

Good morning ladies and gentlemen, I am pleased to be able to be with you today for the Nuclear Inter Jura ‘99.

Your theme for this meeting -- Nuclear Law in the 21st Century is both a natural one given that the new millennium is really here and a vitally important one in light of the controversy over what model best represents the effects of low-level radiation on health and the implications of that controversy on the setting of radiation protection standards. So this morning I would like to explore with you the question of what the role of lawmaking with respect to setting such standards should be. The coming millennium provides an incentive for taking a fresh look at this issue.

As I prepared for this meeting, I happened across a reference to a conference similar to this one held nearly forty years ago, in San Juan, Puerto Rico. It was entitled, “Atomic Energy and Law” and was described as an “Interamerican Symposium on Legal and Administrative Problems Connected with Peaceful Atomic Energy Programs.” In his preface to the book on the symposium, the editor recalled the social and political dislocations caused by the industrial revolution and noted that the problems of the nuclear age seemed even more numerous and difficult. He went on to say,

The main idea behind this symposium was to spotlight these problems and prepare ways for their intelligent discussion. Lawyers and administrators, the "architects of social order," should not be caught unprepared again.

The subsequent forty years have seen a remarkable development of laws and regulatory programs directed at atomic energy and related sources of radiation. The issue today is not the lack of laws and regulatory programs but whether the U.S. has a consistent approach to applying existing laws and programs. I believe the answer to that question is "no," and that at least part of the reason is the way the U.S. regulatory program has evolved over time.

Historically, in the United States, the U.S. Nuclear Regulatory Commission (NRC) and its predecessor, the U.S. Atomic Energy Agency (AEC) have adopted recommendations for radiation protection developed by the International Committee on Radiological Protection (ICRP) and the National Council on Radiation Protection and Measurements (NCRP). As we look to years past, in 1959, President Eisenhower established the Federal Radiation Council (FRC) to advise the President and the Federal agencies on radiation safety; in 1970, President Nixon established the U.S. Environmental Protection Agency (EPA) and transferred the FRC's functions to it; and, in 1980, the NRC, recognizing the revisions to the radiation protection system recommended by the ICRP in its Publication 26, initiated a process to revise comprehensively its radiation protection regulatory standards, universally referred to as "10 CFR Part 20." The EPA, which has responsibility for developing generally applicable radiation protection standards, likewise initiated work to develop updated Federal guidance for occupational exposure. The two agencies worked together toward this end, and the NRC participated in a series of public meetings sponsored by the EPA. The result was the publication for public comment by the NRC in 1987 of a proposed rulemaking that would revise Part 20 consistent with ICRP Publication 26 (ICRP 26) recommendations and with the EPA's guidance on occupational exposure then being finalized and subsequently issued in 1987. The NRC received more than 900 comments, and issued a final rule, which became effective in 1991.

In its final rulemaking, the NRC also took note of the ICRP comments and recommendations issued after ICRP 26, including the ICRP's 1990 recommendations in its Publication 60. The NRC noted that with respect to worker radiation protection standards, 97% of U.S. nuclear workers received occupational doses within the dose limit recommended in ICRP 60, a testimony to the vigorous application of the principle of keeping exposures "As Low As Reasonably Achievable" (ALARA). Similarly, application of ALARA to releases from nuclear facilities resulted in public doses well within the one millisievert (mSv) [100 millirem (mrem)] per year standard. Given this, the Commission concluded it should proceed with finalizing the rule without further consideration of ICRP 60. For the future, the NRC will continue to consider carefully the recommendations of the ICRP and the NCRP and continue to work with the EPA in development of future revisions to U.S. standards for radiation protection.

Not surprisingly, EPA and other Federal agencies, including the NRC, have taken different approaches in establishing radiation protection standards. These different approaches to standard setting issues are a significant contribution to the apparent lack of consistency in U.S. radiation protection standards.

Many of EPA's standard setting authorities for radiation protection are part of umbrella statutes for environmental protection that address specific pathways for potential environmental pollution (e.g., the Clean Air Act and the Safe Drinking Water Act). EPA regulations issued under these statutes for pollutants, including radionuclides, as a general rule, set standards to be met and also allow the standards to be exceeded if certain criteria are met. EPA's preference is to set standards for individual pathways, which is, in part, based upon its statutes. However, consistent with ICRP and NCRP recommendations, NRC's approach to radiation protection standards is to establish radiological protection regulations based on an all-pathway approach and to incorporate the application of ALARA.

EPA standards setting has been influenced by court decisions. In particular, the Vinyl Chloride decision affected EPA's authority under the Clean Air Act. That decision addressed a problem that is also embedded in the current radiation protection standards framework - what level can be considered "safe" if there is no risk-free level, or, to use radiation protection parlance, "a threshold for health effects?" The court found that the Congressional mandate under the Clean Air Act to "provide an ample margin of safety" and "to protect the public health" requires the EPA Administrator to determine what is "safe." The court also stated that a finding of "safe" does not have to mean "risk free." The Vinyl Chloride decision forced EPA to consider whether a risk is acceptable without considering (at the same time) the potential benefits of the activity causing risk, feasibility of control, or other factors.

EPA's general policy is to define acceptable risk for all of its regulatory programs as lying within a range of 10^{-4} to 10^{-6}. Further, to maintain consistency, similar risk ranges are applied to both chemical and radiological carcinogens. Under the Atomic Energy Act, EPA has typically applied the 10^{-4} lifetime risk to all radioactive contaminants except radon. For fatal cancers, a 10^{-4} lifetime risk translates over a 70-year period to an annual dose of about 0.03 mSv (3 mrem), a level well below natural background radiation levels which, in the U.S., average about 1 mSv (100 mrem) per year excluding radon. Radon contributes an average 2 mSv (200 mrem) per year additional dose. Total U.S. annual background doses can vary from 1 to 3 mSv (100 to 300 mrem) per year.

Additionally, EPA established a separate requirement for use of "maximum contaminant levels" (MCLs) for radioactivity under the Safe Drinking Water Act. Except for tritium and strontium-90, EPA requires that the concentration of man-made radionuclides in groundwater must cause less than 0.04 mSv (4 mrem) total body or organ dose equivalent per year. The MCLs are isotope-specific, and on average, result in doses from 0.002 to 0.4 mSv (0.2 to 40 mrem) per year, do not use current risk methodology, and are not set at consistent risk levels.

INTERAGENCY COORDINATION ON SETTING RADIATION PROTECTION STANDARDS

Recognizing the different approaches the two agencies have, EPA and the NRC have taken steps to coordinate radiation protection regulatory activities, the most significant of which is an umbrella Memorandum of Understanding (MOU) between the two agencies, signed in 1992, that establishes "...principles and procedures for avoiding unnecessary duplication of regulatory requirements and focusing priorities on the most significant safety and environmental problems."

The record shows that despite the significant differences in the legislation underlying the two agencies' regulatory activities, NRC and EPA has had some successes in meeting these objectives. An excellent example of this was the 1997 NRC rule establishing a constraint on air emissions of radioactive materials to the environment of a Total Effective Dose Equivalent to a member of the public of 0.10 mSv (10 mrem) per year. NRC's rulemaking allowed the EPA to rescind its rule and thus avoid dual regulation of airborne effluents of radioactive materials under the Atomic Energy Act and the Clean Air Act. Another example, previously discussed, was NRC's comprehensive revision of its radiation protection regulations.

Under direction from Congress, NRC, EPA, the U.S. Department of Energy (DOE) and other Federal agencies established an Interagency Steering Committee on Radiation Standards (ISCORS) which provides a mechanism for the participating agencies and the States to exchange views and coordinate agency actions on radiation protection standards. ISCORS has proven to be a useful means of identifying agency differences in standards and provides a mechanism for harmonizing standards.

However, NRC and EPA were not successful in meeting the objectives of the MOU in the NRC's recently enacted rule entitled "Radiological Criteria for License Termination." In July 1997, NRC approved a rule that establishes an individual, all-pathways release criterion of 0.25 mSv (25 mrem) per year plus ALARA for unrestricted release of contaminated facilities and termination of licenses (*see* 62 FR 39058). This rule is consistent with the recommendations of the ICRP and NCRP. Another Federal statute, the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) allows EPA to apply its authority to establish generally applicable standards for remediation of sites including those contaminated by radioactive materials. In the context of CERCLA, EPA uses an individual risk of premature death of $1x10^{-4}$ as an acceptable level of risk. In this same context, EPA has determined that the NRC dose limit of 0.25 mSv (25 mrem) per year results in a cancer incidence (not fatality) risk of $5x10^{-4}$ and is unacceptable, but has also determined that the cancer incidence risk resulting from a dose limit of 0.15 mSv (15 mrem) per year (at $3x10^{-4}$) "is essentially equivalent to the presumptively safe level of $1x10^{-4}$."

A similar controversy exists with respect to the radiation protection standards that will be applicable to the proposed high-level radioactive waste geologic repository. NRC has again proposed an individual all-pathways 0.25 mSv (25 mrem) per year limit while EPA proposes a 0.15 mSv (15 mrem) per year standard plus a separate, much lower standard for groundwater that would become the *de facto* standard.

In my view, NRC radiation protection standards are based upon good science and are consistent with NCRP and ICRP recommendations. EPA, given its different statutory authorities, its policies and other limitations, does not agree that our regulations are protective of the public's health and safety.

Recognizing that this disagreement results in a lack of finality for licensees seeking to decommission sites, the NRC is seeking remedies through the Congress, specifically to amend CERCLA to recognize NRC's license termination rule for decommissioning as the Federal standard. Bills have also been introduced in the Congress to resolve the differences between the NRC and the EPA standards for the proposed high-level waste geologic repository.

However, this approach raises questions, too. Under the Atomic Energy Act, as amended, the Commission, after considering all of the scientific evidence and policy issues, makes the determination of permissible radiation doses to workers and the public. The dose limits are surrogates for acceptable risk levels. In doing this, the Commission carefully considers the recommendations of the ICRP and the NCRP. However, some of the bills introduced into the Congress to address the conflicts between the EPA and NRC would set the acceptable level of risk for the public or, more directly, the radiation protection standard for specific purposes such as decommissioning or high-level waste disposal. Under the Atomic Energy Act, the Commission has the flexibility to revise its standards in light of new knowledge or recommendations of the ICRP and NCRP and does so through a rulemaking process that provides for public participation. In my view, this is a desirable process. In contrast, setting standards by statute, while satisfying a limited, short term need, may have the long term disadvantage of losing the flexibility to revise standards on a timely basis when needed.

THE LINEAR, NO-THRESHOLD CONTROVERSY

Inherent in the differences between the NRC and the EPA, as well as in the Vinyl Chloride decision, is the challenge of dealing with a pollutant for which there is not a demonstrable “risk-free” level or threshold for health effects. Current knowledge about radiation health effects is based in large part on information gathered on populations exposed to high doses of radiation at high dose rates (e.g., the atomic bomb survivors and radiotherapy patients), and extrapolating that knowledge to the low radiation doses and low dose rates that are the subject of nuclear laws and regulations. In doing so, the ICRP and the NCRP conservatively assume, absent contrary information, that there is no threshold for radiation health effects. This is known as the linear, non threshold theory. In fact, the shape of the line may not be linear, but the important feature is that all national and international recommendations conservatively assume that there is no threshold dose below which there are no health effects.

Radiation is a weak carcinogen. As a result, radiation health effects at low doses and dose rates are not measurable with any scientific certainty. To gain the necessary statistical confidence in studies of populations to determine whether these effects exist at low doses and dose rates require very large populations to be studied over a period of time, a costly, if not impractical proposition. The consequence is that epidemiological studies are unlikely to shed light on the question. Nonetheless, claims have been made that some population studies have shown a threshold and that some cellular studies even show beneficial effects of low doses of radiation, called hormesis. With this information, ICRP and NCRP have found their LNT assumption under attack along with regulatory agencies whose standard setting processes incorporate it.

ECONOMICS

It is unfortunate and unavoidable, but there are costs associated with compliance with radiation protection standards, and, the compliance costs rise as the numerical standards are lowered. Worse, the costs rise at a non-linear, and some say exponential, rate.

Attaining an acceptable degree of statistical uncertainty in compliance measurements at near background levels requires extensive, complex sampling and analyses - with attendant costs. Demonstrating compliance means distinguishing within an acceptable degree of statistical uncertainty the radiation from the residual activity from background radiation. The lower the standards, then the smaller is the standard relative to background levels of radiation. Worse, as we know, background radiation itself, is not constant because it varies with location and with time.

Add to the cost of demonstrating compliance the costs for procedural and operational activities such as decontamination, to meet the standards. To paraphrase Senator Everett Dirksen, ". . . a few million here for the design and operations to meet the standard, a few million there to demonstrate compliance, and after a while, we're talking about real money. . ."

But whose money is it? Ultimately, it's yours and mine - the public's - whether we pay for it as electric ratepayers for the decommissioning of nuclear power plants or as taxpayers to fund the cleanup of DOE sites.

There is no uncertainty that these costs exist and there is no uncertainty about who pays for them.

A NEED FOR INTERNATIONAL CONSISTENCY

In my view, there is a need for the U.S. to follow more closely the radiation protection systems recommended by the ICRP and the NCRP. Their recommendations, while predicated on the LNT concept, constitute a coherent system. It includes appropriate guidance and admonitions that help guard against slavish application of radiation protection recommendations independent of the origin and purpose of the radiation source and the costs to mitigate the assumed risks. Many parts of the world are implementing the ICRP 60 system. For example, in the European Union, member countries are required to implement the IAEA Basic Safety Standards, which are based upon the ICRP 60 recommendations, by May 13, 2000.

In the United States, no plan currently exists to implement the revisions of ICRP 60. In fact, as I have indicated, existing statutes and court decisions prevent us, in part, from doing this. Present U.S. radiation protection requirements are derived only in part from ICRP and NCRP recommendations because Federal statutes, some of which are not specific to radiation protection, and court decisions, influence the development of U.S. radiation protection standards. While adopting the ICRP system will not necessarily address all of the present controversies, it will provide a more efficient, cost-effective government regulation of radiation hazards by eliminating the redundances and conflicts caused by existing statutes, agency policy determinations, and court decisions.

SUMMARY

Roger Clarke, Director of the UK National Radiological Protection Board and Chairman of the ICRP, in a recent opinion letter to a scientific journal, offered the following observation about risk, but the same can be said for the regulatory framework:

> The real issue to be decided between scientists, regulators and the public is not a threshold for risk but the acceptability of risk. They should join forces to determine acceptability in different circumstances - in work and public environments and under normal and accident conditions.

The coming millennium represents an opportunity to reconsider what nuclear laws should be required in the 21st century to protect workers, the public, and the environment from radiation hazards. Absent persuasive evidence that the science of the NCRP and ICRP systems are faulty, the U.S. should move toward harmonizing its regulatory program with their recommendations. Doing so will, in my opinion, go a long way toward resolving some of the current controversies in the U.S. about radiation protection standards with the desirable end result of increasing public confidence in our regulatory programs. Nuclear Laws as enacted by Congress should only provide the framework within which agencies can use good science to establish radiation protection standards. In so doing, the combination of nuclear law and radiation science can work today and into the 21st century.