TRANSLATING
RADIATION HEALTH EFFECTS SCIENCE
INTO REGULATIONS

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U. S. NUCLEAR REGULATORY COMMISSION

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LOW-LEVEL RADIATION HEALTH EFFECTS: REGULATION & SCIENCE

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INTRODUCTION

I am very pleased to participate in this annual meeting of the American Nuclear Society and, particularly in this Special Session jointly sponsored by the Presidents of the American Nuclear Society and the Health Physics Society.

This is unique occasion for the societies and for me. I am pleased that the societies have agreed to allow its members to attend the annual meetings. I believe that this will be of great benefit to both societies and its members. This session is an example of the positive benefits of closer collaboration between the two. I am also pleased to participate for the first time in an annual meeting of the American Nuclear Society.

The relationship between the science of health effects due to exposure to low levels of radiation or low dose rates and regulation is receiving heightened attention from many quarters. The public is concerned about radiation health effects but scientists are not in agreement about those effects at low doses and dose rates. Are the costs that are incurred by the regulated community when complying with implementing regulatory standards for radiation protection justified?

And, why do regulatory standards vary in spite of the common scientific basis that underlie them?

As part of this panel discussion, I'd like to briefly speak to these issues.

UNCERTAINTY - THE UNDERLYING ISSUE

Regulatory agencies are faced with the challenge of how to translate our current knowledge of radiation health effects into regulatory frameworks that are protective of workers, the public and the environment and, at the same time, take appropriate account of the uncertainties in that knowledge. These uncertainties have lead to a controversy over whether the present approach of using the linear non-threshold model to describe radiation health effects at low doses and dose rates is appropriate for establishing regulatory standards for radiological protection.

In the long term, the controversy underlying radiation protection standards can only be addressed by reducing the uncertainties in our knowledge of radiation health effects. To do this requires further research into the radiation health effects of ionizing radiation. Thus, strong international and national support of radiation health effects research will continue to be needed.

The National Research Council was asked recently whether sufficient new data exist to warrant a reassessment of health risks resulting from exposure to low levels of radiation. On January 21, 1998, Dr. Richard B. Setlow, Chairman of the Committee on Health Effects of Exposure to Low Levels of Ionizing Radiation (otherwise known as BIER VII, Phase 1) responded to this request in a letter to the U.S. Environmental Protection Agency. In that letter, he stated:

> "In the Committee's judgment, information that has come available since publication of the 1990 *Health Effects of Exposure to Low Levels of ionizing Radiation (BIER V)* makes this an opportune time to proceed with...a comprehensive reanalysis of health risks associated with low levels of ionizing radiations. Such a study should begin as soon as possible and is expected to take about 36 months to complete."

This is a significant development which will be followed closely by everyone with an interest in radiation protection.

THE CHALLENGE -TRANSLATING KNOWLEDGE INTO REGULATIONS

Such studies are essential to address the problem facing the regulators and the regulated community on how to translate our knowledge of radiation health effects into an appropriate, effective and efficient radiation protection system. The problem is further

complicated by the fact that many of the recommended dose limits and constraint levels that are thus derived are comparable to or smaller than background radiation levels. This takes on special importance in the context of developing standards for decontamination and decommissioning of licensed facilities, including those for waste disposal.

The NRC is pledged to move towards a risk-informed, performance based regulatory approach. The challenge facing the NRC when it applies this approach to the setting of radiation protection standards for the public and environment is to find assurance that (1) the standards *will* be protective and (2) the costs for complying with those standards *are* justified by the risks that would result if the standards were not met.

COSTS - WHO PAYS?

Although there are some in the radiation protection community who will argue that present radiation protection standards are not sufficiently protective, this is a minority view and it is not the source of the present controversy. Most radiation protection professionals will agree that the present standards *are* protective. However, it is a plain economic fact that 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.

There is no mystery about why this occurs. For example, examine what it means to demonstrate compliance of a decontaminated site with license termination standards. 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, background radiation, itself, is not constant because it varies with location and with time. Therefore, attaining an acceptable degree of statistical uncertainty in compliance measurements at near background levels requires extensive, complex sampling and analyses - with attendant costs.

Then, add to the costs 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 cleanup of DOE sites.

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

SCIENCE - WHOSE IS IT?

Knowledge and uncertainty about radiation health effects are not exclusively the domain of any individual country. Radiation health effects is an international science. The ICRP, an international body of experts, develops recommendations for a radiation protection system that are based upon international knowledge about radiation health effects and take into account the uncertainties about that knowledge.

Despite the fact that the underlying science is common to all, the present U.S. radiation protection regulatory system is neither uniform internally nor consistent with internationally accepted recommendations. Why?

RESTRAINTS - STATUTES & COURT DECISIONS

Many factors influence decisions on the setting of regulatory standards for radiation protection. These are policy decisions. In the final analysis, the flexibility and direction that agencies have in making these policy decisions are dictated by the underlying legislation for regulatory agencies and, in some cases, by court decisions on the implementation of the legislation. In the U.S., different statutory approaches to enable governmental programs to protect workers, the public and the environment combined with court decisions have resulted in a patchwork quilt of radiological protection requirements that often conflict with each other despite the common science basis.

This situation does not engender public and political confidence in our scientists and in our policy makers.

FUTURE DIRECTION - A RECOMMENDATION

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

We have not done so in the United States nor are there any plans to do so. In my opinion we should. 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 National Council on Radiation Protection and Measurements (NCRP) ICRP system recommendations will not necessarily address all of the present controversies, it will provide a more coherent framework for radiation protection requirements in the U.S. which would also be consistent with international recommendations and with regulatory frameworks elsewhere in the world. Adopting the NCRP and ICRP recommendations also, in my opinion, would enable the U.S. to maintain a radiation protection approach that will be in balance with knowledge of radiation health effects.

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:

> "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."

In my view, absent persuasive evidence that the science or the ICRP system is faulty, the U.S. should move towards harmonizing its regulatory program with NCRP and ICRP recommendations. Doing so coupled with continuing support of radiation health effects research will, in my opinion, go a long way towards 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.

In November, 1997, an international conference was held in Seville, Spain that was devoted to the issue of translating our present knowledge of and uncertainties about radiation health effects into regulatory frameworks. Speaking about the current LNT controversy, Dr. Abel Gonzalez of the IAEA said, rather succinctly:

> "Don't fix the biology; fix the implementation of the ICRP's recommendations."

I couldn't agree more.

Now, I look forward to this panel's discussion.