WHY WE NEED TO HARMONIZE RADIATION PROTECTION REGULATIONS

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INTRODUCTION

I am delighted to participate in the 1998 WIN Global Annual Meeting. My reasons are several. First, this meeting provides an opportunity to visit Taiwan whose nuclear power program is a key component in its energy program, and perhaps most important, it is an opportunity to meet old friends and to make new ones.

This morning, I would like to share with you some thoughts on a challenge facing regulators who are responsible for establishing radiological protection standards and implementing radiological protection programs. The challenge is 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. To date, in my opinion, we have not successfully responded to this challenge. How this challenge is resolved and its ultimate outcomes are matters that will affect virtually everyone working in the nuclear field and how nuclear resources may be used in the future.

THE SCIENTIFIC CONTROVERSY

The bulk of our knowledge about human radiation health effects that forms the basis for radiation protection standards is derived from studies of the survivors of the atomic bombs that struck Hiroshima and Nagasaki. Other human population groups that have provided significant data on radiation health effects are certain medical patient groups. It is largely the result of these human studies coupled with research on radiation effects on animals and at the cellular level that have led to the adoption on the

linear, non-threshold (LNT) theory to describe radiation health effects at the low doses and dose rates normally encountered by radiation workers and the public. The strict application of that theory at these low levels of exposure is being challenged. The reasons for the challenge are complex. In the opinion of some, the strict application of the LNT theory has lead to unnecessarily conservative radiation protection standards particularly for specific purposes such as the decontamination and decommissioning of licensed facilities. One way of obtaining relief from radiation protection standards that are viewed as unnecessarily restrictive or overly conservative is to challenge the theory underlying the standards.

In response to this growing controversy, the International Atomic Energy Agency (IAEA) and the World Health Organization (WHO) sponsored an international conference which was held last November in Seville, Spain. The conference title was, "Low Doses of Ionizing Radiation: Biological Effects and Regulatory Control." More than 600 persons registered for this meeting. It was the first time that scientists and regulators had met to jointly discuss the issue.

The conference was also held in cooperation with the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR). The conference was opened by Dr. Hans Blix, IAEA Director General and by Dr. Hiroshi Nakajima, WHO Director General.

There are uncertainties about the radiation health effects that are associated with the radiation dose and dose rate levels that we regulate because, with the possible exception of fetal radiation effects, radiation health effects in humans at these low levels have not been clearly demonstrated. As a result, an assumption must be made for the extrapolation from radiation health effects observed at high radiation levels to radiation health effects that may occur at low radiation levels in order to formulate a radiological protection system. This assumption is that there is a linear, non-threshold relationship between radiation and health effects at low doses and dose rates.

There is some evidence of a threshold and possibly for an hormesis effect for selected biological media and selected radiation effects at low levels of radiation. But such evidence, frankly, must become overwhelming and be demonstrated in humans before there will be serious consideration to moving away from the current LNT assumptions that underlie the present radiation protection framework. Further, while their views are not widely accepted, there are also scientists who believe that there is evidence that radiation health effects at low doses and dose rates are underestimated by the LNT assumption.

A variety of views were expressed during the course of this conference but the discussions did not lead to resolution of the current controversies over the appropriateness of using the linear, non-threshold (LNT) model that underlies present ICRP recommendations and regulatory radiation protection programs. While no consensus was reached at the end of the Seville conference, the prevailing view was probably best expressed by Dr. Sheldon Wolff of the Radiation Effects Research

Foundation who said in the closing session that data on hormesis effects must be convincingly positive before changes to theories underlying radiation protection recommendations could be made, otherwise, “we are dealing with religion, not science.”

Nonetheless, the conference discussions were useful because they showed why it has proven to be very challenging to translate our knowledge of radiation health effects into a regulatory framework that is protective of workers, the public and the environment and, at the same time, takes into account the uncertainties about that knowledge and the resulting need to make assumptions to construct a radiation protection system. The challenge is 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.

It should, therefore, not be surprising that policy makers responsible for establishing ionizing radiation protection regulations have not always followed international standards recommended by scientific expert bodies such as the ICRP and those recommended by national scientific expert bodies such as the NCRP in the United States. The unfortunate result in some cases is a patchwork quilt of radiation protection requirements that often conflict with each other. Most important, it is a situation that does not engender public confidence in our scientists and in our policy makers.

I cannot defend a framework that results in a failure to develop consistent radiological standards. For example, in the United States, not only have we not adopted the ICRP’s latest recommendations for standards as found in ICRP-60, to be consistent with international recommendations, but we are even inconsistent within our borders due to conflicting standards among our Federal agencies.

When seen in this light, it becomes apparent that what is lacking in the United States is an effective means of attaining and assuring harmonization of radiation protection standards at a National level.

THE NEED FOR HARMONIZATION OF RADIATION PROTECTION STANDARDS

I am personally in favor of a National commitment in the United States to more closely follow the recommendations of the ICRP. Such national commitments are not without precedent. Members of the European Union are expected to adopt radiological protection standards which follow those contained in the IAEA Basic Safety Standard (BSS) by May 13, 2000. The IAEA Basic Safety Standards, of course, is based upon ICRP recommendations.

The ICRP recommendations, in contrast to the fragmented, piecemeal statutory approach currently in place in the United States, constitutes a *coherent system* for radiological protection. It includes appropriate cautions and warnings that help guard

against slavish application of radiation protection recommendations independent of the origin and the purpose of the radiation source, the assumed risk of the radiation relative to that from background radiation and the costs to mediate the assumed risks. As Dr. Roger Clarke, ICRP Chairman, demonstrated in comments made at the Seville conference, it is flexible enough to address emerging challenges such as how to deal with standards applicable to decontamination and decommissioning of nuclear facilities.

With national and international harmonization of radiation protection standards will come, in due time, greater confidence of the public in our national regulatory programs.

While harmonization will help to address part of the challenge facing the current regulatory frameworks, the overriding issue of the LNT controversy needs attention. Let me suggest a possible path forward on this matter.

JOINT U.S. - RUSSIA RADIATION HEALTH EFFECTS RESEARCH

After becoming an NRC Commissioner, I was appointed as the NRC's representative to the Joint Coordinating Committee for Radiation Effects Research (JCCRER), a U.S. - Russian endeavor to coordinate joint government-sponsored radiation health effects research. While this research will include both U.S. and Russian populations, it is primarily focussed on workers and populations in the southern Urals area of Russia where the Russian nuclear weapons manufacturing center, Mayak is located. As a result of early operational practices and some accidents at Mayak, workers at the plant and populations around the site were exposed to unusually large amounts of radiation and radioactive materials. In many cases, the doses were comparable to those received by survivors of the Hiroshima and Nagasaki atomic bombings. A significant difference is that the exposures of the Mayak workers and populations were protracted - in many cases extending over many years - in contrast to the doses received by atom bomb survivors. Thus, there is a unique opportunity not only to gain additional insights into radiation health effects by studying the Mayak groups but to also learn more about radiation health effects at protracted exposure rates.

In addition, many of the workers and significant numbers of the surrounding population ingested radioactive materials in amounts large enough to result in significant internal doses and, in some cases, radiation health effects not seen in western radiation workers. For some workers, both internal and external doses were significant. The worker population, in contrast to US radiation worker populations, includes a large number of women as well as men. These are examples of other aspects that have the potential to provide further insights into radiation health effects in humans.

Underlying this are the extensive health records for the workers maintained by

the Russian government since the beginning of operations of the Mayak plant. Health records also exist for many members of the surrounding population who were exposed to radiation as a result of operations and accidents at the Mayak complex. While dose reconstruction will be a challenge, especially for the population, it is feasible.

As you can see, the research opportunity is a great one. It is for this reason that I am a strong supporter of the JCCRER research effort. In the United States, the Departments of Energy and Defense, the Environmental Protection Agency, the National Aeronautics and Space Administration and the NRC are joined in the JCCRER effort and work has begun. The unique research opportunities in the southern Urals area of Russia were repeatedly mentioned at the Seville conference.

Research is clearly needed to better describe radiation health effects particularly at the low radiation levels which are the subject of regulatory effort. In addition to human studies, molecular studies promise to shed further light on this subject. All such research deserves your strong support.

CONCLUSIONS

In summary, 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 LNT to model radiation health effects at low doses and dose rates is appropriate for establishing regulatory standards for radiological protection. At the legislative level, different statutory approaches to enable protection of workers, the public and the environment have resulted, in the United States, at least, in a patchwork quilt of radiological protection requirements that often conflict with each other. This is a situation that does not engender public and political confidence in our scientists and in our policy makers.

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.

However, even when reducing the uncertainties in our knowledge of radiation health effects becomes a reality and ICRP recommendations are refined accordingly, there must be national and international commitments to harmonize radiation protection regulatory standards with those of the ICRP.

I believe that these are attainable goals. Moreover, attaining these goals is essential to strengthen and retain public and political confidence in our science and in our regulatory frameworks.