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at the

Winter Meeting of the Low Level Waste Forum,
Panel on Radiation Health Effects

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INTRODUCTION

Let me start by expressing my appreciation for being invited to participate in this meeting. Low level radioactive waste disposal continues to be a major National issue and the Low Level Waste Forum provides an excellent vehicle for focussing attention on current issues.

As many of you are well aware, my experience includes serving first, as member of the Central Interstate Low Level Waste Compact Commission, and then as its Chairman. Thus, upon becoming an NRC Commissioner, I had the opportunity to view low level radioactive waste issues from the State and Compact perspective and now I view the issues from a National and even international perspective.

However, in my remarks today, I will not focus on specific waste issues but rather on an overarching issue with implications for decisions regarding waste generation, management and disposal. This overarching issue is the health effects of exposure to low doses of radiation or low dose rates and the associated concerns regarding standards setting and regulatory decisions.

Most discussions of radiation health effects will include comments about the basic model underlying most radiation protection standards - the linear, non-threshold (LNT) theory. More specifically, the comments may center on the controversy surrounding the theory.

So, this morning, in keeping with the overall purpose of this panel, I would like to speak briefly about the controversy over the linear, non-threshold theory for radiation health effects, in particular, why there is a controversy, and what could be done to help resolve the controversy.

As you know, the bulk of our knowledge about human radiation health effect 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 cells 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 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. As we will see, there is scientific uncertainty about radiation health effects at these low levels. Thus, 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.

IAEA INTERNATIONAL CONFERENCE ON LOW LEVEL RADIATION

This issue has attained international attention. 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 and I would like to share some observations from it that I believe you will find are relevant to this panel's topic. It was the first time that scientists and regulators have 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). In its first announcement of the meeting the sponsors stated:

> "The levels and biological effects resulting from exposure to ionizing radiation are continuously reviewed by [UNSCEAR]. Since its creation in 1928, the International Commission on Radiological Protection (ICRP) has published recommendations on protection against ionizing radiation. These recommendations have served as the basis for national, regional and international safety standards on this matter, including those developed by the IAEA and the WHO...
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> The biological estimates of health effects of low doses of ionizing radiation and the regulatory approach to the control of low level radiation exposure have both been much debated during recent times....The time therefore seems appropriate to take stock of these new advances [in knowledge] and to identify areas towards which new or greater research and development effort might best be directed."

The Seville conference featured two background sessions for reports on developments and findings in the radiation protection field and ten fora on specific aspects of radiation effects and control measures. A special session entitled, "From the Scientific Evidence to Radiation Protection" was interspersed in the fora and provided a transition from sessions on biological

effects to those addressing regulatory control. The schedule concluded with a round table on regulatory control and scientific research, a conference summary session and closing of the conference. The conference was opened by Hans Blix, IAEA Director General who noted that this was the last IAEA conference he would open prior to his retirement and by Dr. Hiroshi Nakajima, WHO Director General.

A variety of views were expressed during the course of this conference but the discussions did not lead to putting to bed the current controversies over the appropriateness of using the linear, non-threshold (LNT) model that underlies present ICRP recommendations and regulatory radiation protection programs. U.S. trade press articles, to a great degree, captured the spirit of the debates.[1]

In a nutshell, there are uncertainties about the radiation health effects that are associated with the radiation dose and dose rate levels that we regulate. With the possible exception of fetal radiation effects, radiation health effects in humans at these low levels have not been demonstrated. The critical assumption made for creating a radiation protection system 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 hormesis for selected biological media and radiation effects. 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.

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." The comment drew applause from many in the audience.

With Dr. Wolff's statement in mind, I would like to cite part of my introductory remarks for the conference summary session:

> "The effects of ionizing radiation on human health can be described as perhaps one of the most studied and better understood health effects relationships from a scientific point of view. Yet, there is still much more to be learned and there is some dispute about what we know in the scientific community. It has also proven to be very challenging to translate our knowledge into a regulatory framework to protect public and worker health and the environment. *This* is the main issue...Increasing our knowledge about radiation health effects through well designed and directed research is our most promising path to ultimately increase public and political confidence in our radiological protection standards and regulatory frameworks."

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[1] See *Nucleonic Week*, November 20 & 27 and December 4 1997 and *Inside NRC*, Nov. 24 1997.

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 to not only 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. In the U.S. the DOE, NRC, EPA, DOD and NASA 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.

It is for this reason that I am a strong supporter of the JCCRER research effort. Research is clearly needed to better describe radiation health effects particularly at the radiation levels subject to regulatory effort. In addition to human studies, molecular studies promise to shed further light.

FUTURE DIRECTIONS

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.

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 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 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.

As Roger Clarke, Director of the UK National Radiological Protection Board and Chairman of the ICRP put it in a recent opinion letter to a scientific journal:

> "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."

At the conference in Seville, Dr. Abel Gonzales, IAEA Deputy Director General was more succinct:

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

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. Federal statutes, some of which are not specific to

radiation protection, and court decisions have influenced the development of U.S. radiation protection requirements. While adopting the ICRP system 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 ICRP system also, in my opinion, would enable the U.S. to maintain a conservative radiation protection approach that will be more in balance with our knowledge of radiation health effects.

CONCLUSIONS

The issue that is increasingly confronting regulators, the regulated community and the public is whether National and State radiation protection standards properly take into account the scientific uncertainties about radiation health effects at the low levels of radiation exposure permitted by regulation.

Knowledge and uncertainty about radiation health effects are not exclusively the domains 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. The present U.S. radiation protection regulatory system is neither uniform nor consistent with internationally accepted recommendations. 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 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.