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Office of Public Affairs Telephone: 301/415-8200

Washington, DC 20555-001 E-mail: opa@nrc.gov

Web Site: http://www.nrc.gov/OPA

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WHY THE NRC BASES ITS REGULATIONS ON THE LINEAR NON-THRESHOLD THEORY

By

The Honorable Greta Joy Dicus
Commissioner
U.S. Nuclear Regulatory Commission

At the

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The Virginia Chapter of the Health Physics Society
And
The Virginia Section of the American Nuclear Society

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Introduction

Good morning, ladies and gentlemen. Let me start by expressing my appreciation for being invited to participate in this joint meeting of the Virginia Chapter of the Health Physics Society and the Virginia Section of the American Nuclear Society.

In keeping with the overall purpose of this meeting, I would like to speak briefly about why the Nuclear Regulatory Commission has based its regulations on the linear, non-threshold theory (LNT) for radiation health effects.

The LNT is Much Studied, But There Is More to Learn

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.

The LNT Is Based on High Dose/Dose Rate Studies

Current radiation protection standards are founded on the supposition that any radiation dose, no matter how small, can cause detrimental human health effects such as cancer. It is assumed that these effects are caused in direct proportion to the dose received such that doubling the radiation dose results in a doubling of the effect.

The bulk of our knowledge about these human radiation health effects 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. Most of these data were the result of high doses or dose rates. 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 of the LNT as the dose-response relationship which also describes radiation health effects at the low doses and dose rates normally encountered by radiation workers and the public.

Controversy of using the LNT at Low Doses and Dose Rates

The strict application of that theory at these low levels continues to be challenged. Controversies over the use of the LNT when setting standards and the costs associated with meeting the standards have further fueled discussions about the U.S. standards as well as international radiation protection standards. In the opinion of some, the strict application of the LNT has lead to unnecessarily conservative radiation protection standards, particularly for specific purposes such as the decontamination and decommissioning of licensed facilities. 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.

Uncertainties Related to the LNT; Other Theories

There are scientific uncertainties about the radiation health effects that are associated with the relatively low radiation dose and dose rate levels that we regulate. There is growing scientific evidence that the LNT may result in an overestimation of health risks at low doses because the theory does not account for such offsetting mechanisms as cellular repair of radiation injury. With the possible exception of fetal radiation effects, radiation health effects in humans at these low levels have not been demonstrated.

However, formulation of a radiological protection system has assumed an extrapolation from radiation health effects observed at high radiation levels to radiation health effects that may occur at low radiation levels. Notwithstanding the above, there is some evidence of a threshold and possibly for hormesis for selected biological media and radiation effects. But such evidence, frankly, must become convincingly positive [or 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.

Support for Current Use of the LNT

Several national and international committees, such as the ICRP and the National Council on Radiation Protection and Measurements (NCRP), continue to review the LNT model. Their general belief continues to be that using the model for regulatory purposes is a safe and conservative approach and, if there is error, it is on the side of enhanced protection. As a result of this consensus by these committees, Federal agencies including the NRC, DOE, and EPA have largely followed the model.

Dr. Roger Clarke, Director of the UK National Radiological Protection Board and Chairman of the ICRP, has recently stated that "because the sequence of events leading to cancer can start in the DNA of a single cell, and because the effectiveness of the repair mechanisms is unlikely to vary with small doses above those from natural radiation sources, it is likely that there is no threshold of dose below which there is no probability of stochastic effects. It is also likely that, for small incremental doses, the incremental probability of a stochastic effect will be proportional to the incremental dose."[1]

As recently as last fall, The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) concluded in its latest report that there is no scientific basis to discard the LNT model of radiation health effects. UNSCEAR Chairman Lars-Erik Holm stated that "ongoing and future studies in animal sciences and epidemiology will not solve the uncertainties surrounding the effects in humans of low-dose radiation. The statistical power is insufficient, and it is not scientifically valid to equate the absence of a statistically observable effect at low doses with the absence of risk."[2]

The Effect of Cell Repair[3]

There is abundant evidence that the capacity of irradiated cells to repair DNA damage acts to reduce cancer risk. Some have used this evidence to argue that the small amount of damage at low doses would be compensated by <u>complete</u> cellular repair. According to these proposals it is only at high doses where cellular repair capacity is saturated that cancer may occur. The proponents of this theory offer data showing that the ordinary, routine damage arising in DNA is very much greater than that induced by a low dose of radiation, even up to 20 rem.

However, there are other data that reveal a critical flaw in this argument. These latter data show clearly that routine DNA damage is chemically <u>simple</u>; whereas, DNA damage caused by radiation can take the form of <u>complex</u> breaks in both strands of the DNA molecule. Since this complex damage is very difficult to repair, mutation rates are very much higher than that associated with routine DNA damage. In accordance with these observations, dose-response relationships for gene and chromosomal mutations have been shown to be approximately linear down to doses of around 3 rem.

All of this is to say that although it appears that DNA damage repair in cells does act to significantly reduce the risk of radiation-induced cancer, there is no support for the concept that at low doses these repair functions can abolish such risk.

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[1] from Roger Clarke's draft report to the ICRP, "The New Recommendations: Options for Guidance on the Practical Applications," August 2000

[2] from Nucleonics Week, 6-1-00

[3] from Clarke, Roger, "Control of Low-level Radiation Exposure: Time for a Change?" J. Radiol. Prot. 1999 Vol 19 No 2

The Adaptive Response Argument

Another related argument used by those who oppose the LNT are indications of an "adaptive response" to radiation, whereby cells or animals given small doses are made more resistant to later, larger doses. The proponents of this theory argue that low-dose radiation therapy could be used to stimulate the human immune system for control of cancer. That is, low doses of radiation could be used to stimulate cell repair mechanisms such that the body adapts to the effects of radiation by developing protective responses. However, UNSCEAR, while acknowledging that the phenomenon has been observed in many systems, argues that the effect is not generally reproducible. The UNSCEAR report states, "Apparently, the range of priming doses is limited, the time for presenting the challenge dose is critical, and the challenge dose needs to be a reasonable magnitude. The response varies greatly [among individuals, as well]."

A Future Review Needed Based on Mayak Data

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 has included both U.S. and Russian populations, it is primarily focused 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 U.S. 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. Dose reconstruction is a challenge, especially for the population, but it is proving 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. It is for this reason that I support 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: Further Review Proposed by the ICRP

The National Research Council has been asked 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 BEIR 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 (BEIR V)* makes this an opportune time to proceed with...a comprehensive re-analysis 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 previous dosimetry study of the dominant Hiroshima data regarding the contribution of neutron dose has been and continues to be reviewed. The results on an additional analysis of this dosimetry data now underway should prove to be interesting.

The current Main Commission and committees of the ICRP had their final meetings in early October 2000 and new committees have been appointed for the four years beginning 2001. Committee 1 has been invited to provide a summary of the biological basis of the ICRP's policies, to prepare a new text on the health effects of radiation, and to develop a comprehensive report on the biological effects of radiation. In particular, the Committee will review risk factors and LNT.

I will note at this point that last fall I was elected to the 13-member governing body of the ICRP. My term is for four years and begins in July. In addition to my work as an NRC Commissioner, I intend to devote such time as is necessary to help further the ICRP's work in providing sound recommendations and guidance on this and all aspects concerning radiological protection.

Such studies as those of the ICRP 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 put it in an 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."

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. 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.