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THE ROLE OF RADIOLOGICAL PROTECTION RECOMMENDATIONS IN STRONG REGULATORY PROGRAMS

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Good morning, I want to extend my welcome and appreciation for your involvement in this Forum, the second of three regional Nuclear Energy Agency (NEA) Forums to discuss a new generation of draft International Commission on Radiological Protection (ICRP) recommendations. These Forums are a unique opportunity to discuss the content and possible implications of these draft recommendations that have been made available for public comment.

I want to offer a special welcome to our international attendees. I would like to particularly recognize Dr. Lars-Erik Holm, the Chairman of the ICRP, and Dr. Luis Echávarri, the Director General of the Nuclear Energy Agency. And since this is the North American workshop, I am pleased and honored to welcome the representatives from the Canadian Nuclear Safety Commission, Health Canada, and the Mexican National Commission on Nuclear Safety and Safeguards, as well as industry and professional society representatives from Canada and Mexico.

I am also pleased to welcome representatives from the United States government, including the Department of Energy, the Environmental Protection Agency, the Food and Drug Administration, and the Occupational Safety and Health Administration. In addition, I welcome U.S. State regulatory organizations, including the Organization of Agreement States and the Conference of Radiation Control Program Directors, industry representatives, and representatives from the Sierra Club and the Nuclear Information and Resource Service. All of you bring viewpoints that will contribute to the success of this Forum.

I understand that the first regional Forum, held in Tokyo in early July, was a great success, with significant feedback. In particular, I understand that during that meeting there was a growing

consensus on the meaning and use of constraints, a topic that has generated much discussion in the last few years. Following this Forum, the U. S. Nuclear Regulatory Commission (NRC) staff will be hosting a separate ad hoc NEA expert group meeting on Wednesday, and, if needed, Thursday, following this workshop to collect more specific comments.

The ICRP has, for some time, embarked on an effort to expand, revise and consolidate the current set of radiological protection recommendations. I commend them on the open process that is being used to gather feedback from the many interested groups, in particular this opportunity for stakeholders from North America to discuss how the ICRP draft recommendations can best meet the health and safety needs of their national radiological protection programs. The subject of this Forum is one of fundamental importance to the NRC, as an independent regulatory agency, in our responsibilities to establish and enforce safety and security standards for civilian applications of nuclear technologies while ensuring the right balance of public health and safety requirements and impact on the industry we regulate.

The development of radiation standards is also of great personal interest to me, particularly the application and implementation of the linear-no-threshold hypothesis, despite the lack of scientific data underpinning its validity at doses below 100 mSv. I understand the draft report's view that: " The Commission [emphasizes] that whilst the linear-no-threshold hypothesis remains a plausible element in its practical system of radiological protection, biological information that would unambiguously verify the hypothesis is unlikely to be forthcoming." Nevertheless, in my view, one goal of researchers in this field should be to provide that missing biological information.

In a time when scientific information is significantly increasing, it is critical that we carefully and continually evaluate the scientific basis for radiological protection recommendations. However, it is also critical that we are clear, constructive, consistent and predictable in dealing with both licensees and the public. Thus, it is important that we take an opportunity such as this to evaluate how best to move forward without unnecessarily changing processes that are working effectively.

The NRC appreciates the long-standing contributions of ICRP to improve the understanding and regulatory framework for low-dose radiation exposures. The ICRP has, for many years, provided recommendations that supported radiation protection practice and regulation, starting in 1928 with X-rays, and moving to increasingly sophisticated approaches to calculating doses to individuals. For example, the radiation protection regulations promulgated in 1956 were based, in part, on recommendations of genetics groups that observed a linear dose-response relationship between radiation exposure and mutations in Drosophila (fruit fly).

At that time, the ICRP also suspected that there was an increased incidence of leukemia amongst the early radiologists. But they didn't have any dose information for this group of occupational workers, so a 15 rem annual limit for individual organs was recommended, based in part on the genetic fruit fly work. ICRP recommendations have continued to evolve over time as better information and knowledge on exposures has been developed. During the middle of the 1970s, the ICRP recognized that information on risk was becoming available. For the first time, principles and recommended dose limits were based on a scientific approach to risk estimation. Thus, separate recommendations were made to prevent nonstochastic effects such as skin erythema, and new recommendations were made to minimize the risk of stochastic effects like cancer and hereditary disease. Today, our radiation protection standards limit occupational and public doses to levels well below those where any of these

effects can be observed, even in large populations.

This morning I would like to help set the stage for this Forum by discussing what I believe is an ongoing challenge to NRC and other regulators and the industry: the need for our regulatory programs to properly reflect the scientific evidence in an effective and efficient way. I believe that we face several challenges in this regard. First, do we have a solid, up-to-date, peer-reviewed basis for the recommendations? Second, do we have a set of recommendations that, while reflecting the science, is sufficiently pragmatic and practical to be efficient and effective in regulation and risk communications? And third, do these new ICRP draft recommendations suggest that changes are needed in our regulations, guidance, or licensees' radiation protection programs?

Let me start with the seemingly age-old question of the relationship of dose to risk. I agree with the ICRP that the so-called linear-no-threshold hypothesis is currently the most appropriate and conservative regulatory approach for managing risk from radiation exposure. Other recent reports are also evaluating this issue. This past year, the U.S. National Academies published their most recent report on Biological Effects of Ionizing Radiation (BEIR VII). Internationally, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) also is examining it. These reports have reaffirmed, for the present, that the linear-no-threshold hypothesis is an appropriate approach for radiation protection. But, by contrast, the French Academies published a report that argues in support of a practical threshold for radiation cancer risk. It is thus obvious that a great deal of work is being done in the area, but more work is needed to clarify the fundamental science.

In addition, even if we use this linear-no-threshold hypothesis, the issue of how and where to use this hypothesis deserves considerable discussion. I agree with ICRP that this hypothesis, if extended to calculate collective dose on large groups where population characteristics are poorly defined, is an inappropriate use of collective dose and is not a valid prediction of health effects from very small doses. I support ICRP's view that "Collective dose is mainly an instrument for optimization, for comparing radiological technologies and protection procedures. Collective dose is not intended as a tool for epidemiologic risk assessment and it is therefore inappropriate to use it in risk projections based on epidemiological studies." Other studies of this issue have reached similar conclusions. For example, the conference on Bridging Radiation Policy and Science concluded that "The concept of collective dose is often misapplied, e.g., to estimate health impacts of very low average radiation doses in large populations . . . Collective dose can be a useful comparative tool, for instance in the evaluation of protection options." In addition, the National Council on Radiation Protection and Measures (NCRP) Report No. 121, "Principles and Application of Collective Dose in Radiation Protection," covers many of the challenges of using collective dose.

Wildly varying estimates of risk can be derived by inappropriate use of collective dose. For example, the scientifically respected IAEA Chernobyl Forum estimated that there will be approximately 4,000 deaths associated with individuals who received the greatest radiation exposure from Chernobyl. This group of approximately 600,000 individuals includes the emergency workers, those individuals evacuated from their homes near Chernobyl and individuals living in very highly contaminated areas in Belarus, Ukraine and the Russian Federation. By contrast, some epidemiologists, in cooperation with the International Agency for Cancer Research, recently predicted that more than 40,000 cases of leukemia and solid cancer (including thyroid cancer) are expected among Europeans between 1986 and 2065 due to fallout from the 1986 accident. Finally, Greenpeace notes that "recently published figures

indicate that in Belarus, Russia and the Ukraine alone the accident resulted in an estimated 200,000 additional (cancer) deaths between 1990 and 2004.

In my view, such inappropriate uses of collective dose only serve to confuse and frighten the public. After all, the average radiation exposure from Chernobyl to the 570 million residents of Europe will be approximately 0.5 mSv during that time, or less than 10 microSievert per year. Such a small dose is four orders of magnitude below the lowest level of statistical sensitivity for epidemiological studies and is well below dose variations experienced by average citizens with slightly different daily experiences. While I certainly agree with the ICRP statement that such calculations are, as they stated, "inappropriate," I encourage the ICRP to provide stronger statements to further discourage misuse of this concept and to provide recommendations on applications where collective dose may be appropriate and more important, when it is not appropriate to use collective dose.

Another issue of concern to me has been the lack of sensitivity of scientific tools for examining low dose radiation effects. For example, epidemiological studies are insensitive below doses of about 100 mSv. But, much progress has been made examining radiation effects in cellular and molecular systems. Today, assay systems are able to detect radiation-induced changes following several centiGray exposures. This represents at least an order of magnitude improvement in the state of technology, but, the regulatory community is concerned about managing public exposures several orders of magnitude below these levels. As such, I challenge the scientific community to push the boundaries of our scientific knowledge of low dose radiation effects even further. Toward this goal, the U.S. Department of Energy (DOE) is managing a Low Dose Radiation Research Program, funding research projects at a number of laboratories to help establish risk assessment standards based on a strong scientific foundation. I'm personally proud that I had the opportunity during my years on Senate staff to assist in the creation of this program.

The DOE work is focused on understanding:

- how radiation damages DNA and how the cell responds by repairing this damage;
- how radiation-induced DNA damage differs from oxidative damage induced by cellular metabolism;
- how cells respond or adapt when repeatedly exposed to radiation;
- how irradiation of a single cell impacts those cells surrounding it (that is to say, bystander effects); and
- determining if there is a genetic basis for individual differences in sensitivity to radiation exposure.

To date, this program has demonstrated new techniques and instrumentation for measuring the biological and genetic changes induced by exposure to low doses of radiation, and I applaud the efforts of the principal investigators participating in this program.

Projects funded by DOE include activities where cells can be irradiated with a single alpha particle and the response of the irradiated cell and its neighbors can be monitored. Thus far, the results on topics such as bystander effects, repair mechanisms, and individual cellular responses to radiation exposure have not led to a single clear mechanism or model for radiation damage and repair. Not surprising, what is clear is that humans are very complex organisms, and that there is a great need for continuing research to more clearly understand how we react to various hazards. Congressional testimony describing this research has stated, with confidence, that the linear-no-threshold hypothesis model is

not an accurate prediction of risk at low doses, a conclusion also reached independently, as I noted previously, by the French Academies. It is my earnest hope that future work will quantify this qualitative assessment.

Nevertheless, as I mentioned earlier, the linear-no-threshold hypothesis is seen by both the BEIR VII report and the draft ICRP recommendations as providing a prudent basis for radiological protection. As a regulatory basis, it provides a consistent and predictable basis for establishing standards, and the implications and costs are fairly well known. Unfortunately, as pointed out in a report by the U. S. General Accounting Office in 2000, even with the same sets of data and the same underlying model, regulatory agencies can come to somewhat different conclusions on acceptable levels of protection, with very different public impacts.

For example, very large incremental public costs are entailed by selecting different low levels of residual dose for decommissioning projects. In a conference earlier this year held in Carlsbad, New Mexico, it was noted that cost estimates for remediation of sites such as Rocky Flats or the Brookhaven National Laboratory roughly double in going from a 25-millirem dose criterion to a 15-millirem dose criterion. With many billions of dollars of public funds being expended for such cleanups, and many workers and members of the public potentially exposed at some decommissioning sites, better understanding and consensus on such radiation dose levels is an issue of significant public impact.

The ICRP's draft recommendations also contain a number of other areas where it is critically important that we have a sound technical basis for our radiation protection standards. Changes are proposed in both the radiation weighting factors and tissue weighting factors, two key components in calculating the dose to an individual. As we discuss the recommendations over these next two days, I would encourage all of you to consider if the scientific basis has been adequately represented and justified. I would also suggest that one way to consider this issue is to ask if the report provides a sufficient and acceptable basis, within each of our legal and administrative systems, to decide if changes need to be made to our regulations and guidance.

When the ICRP embarked upon its current efforts to simplify, consolidate and update their recommendations, they had several key objectives. These objectives included: 1) to consider new biological and physical information and trends in the setting of radiation protection standards, 2) to improve and streamline the presentation of the recommendations, and 3) to maintain as much stability in the recommendations as is consistent with the new scientific information. I have already touched on the first point, that of accounting for new biological and physical information. Let me now briefly address the other two points.

Regulatory programs must provide for the protection of public health and safety. Adequate protection of public health and safety is my Agency's mandate under the law, applying to both workers and members of the public. We also have the obligation to develop a set of regulations that are predictable and stable so that the users of radioactive material know what to expect and how to function in their day-to-day activities. In the United States, licensees, such as the operators of power reactor facilities, have developed and maintained a systematic and structured approach to assure adequate protection. Their activities include a radiation protection program, administrative limits and levels, and the continuous application of the As Low As Reasonably Achievable concept, which internationally is known by the term "optimization." It is becoming increasingly apparent that the ICRP description on

constraints as a boundary of optimization is a description of what our licensees are doing each and every day.

As we consider these draft recommendations, I encourage you to consider the material in the ICRP draft recommendations from the standpoint of the extent to which the text of the draft does, or perhaps does not, contribute to continuing a sound regulatory program that is up to date scientifically and builds upon the current best practices of radiation protection without unnecessarily adding new burdens, impediments, or recommendations. The desired outcome for the NRC would be that we would be able to continue a performance-based approach to regulation which clearly articulates the basic requirements and provides each licensee with sufficient flexibility to best achieve protection.

I appreciate the significance of ICRP enabling each of us to contribute to the development of recommendations and encourage each of you to actively participate in open and frank discussion during this Forum. Such exchanges strengthen the development of the ICRP radiological protection recommendations, which in turn contribute to public health and safety and the consistency and effectiveness of our respective regulatory programs.

Thank you for giving me this opportunity today, and I look forward to excellent discussions and information exchanges during the course of this Forum.

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