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Current Experience With Risk-Informed Regulatory Inspections

by

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Commissioner
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at the

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Introduction

Good morning everyone.

I'm pleased to be given the opportunity to participate in this ALARA Symposium. To those of you who have been to previous Symposiums, welcome back. To those of you here for the first time, I hope you find the Symposium insightful and informative enough to see you again in coming years. Walt Disney, in referring to nearby EPCOT center, once said that "EPCOT will take its cue from the new ideas and new technologies that are now emerging from the creative centers of American industry. It will always be introducing and testing and demonstrating new materials and systems and will always be a showcase to the world for the ingenuity and imagination of American free enterprise." I think this symposium has many parallels to the vision Mr. Disney had for EPCOT and presents a unique opportunity for us to share ideas and information.

In my presentation today, I will first provide a brief overview of the NRC's current reactor oversight program, which has made extensive use of risk-informed regulatory inspection techniques. I will then discuss some recent experience regarding the release of radioactive materials which highlights the importance of using risk information in our inspection program. In addition, I will discuss how this

recent experience demonstrates the need to proceed cautiously in our attempts to develop a rule to control the release of such materials. Lastly, proving that "it's a small world after all," I'll be discussing some initiatives being proposed within the International Commission on Radiological Protection [ICRP]. The Chair of the ICRP, Professor Roger Clarke, whom I'm sure many of you know, was originally scheduled to discuss these initiatives. But as he was not able to attend, I was graciously offered the opportunity. I was told that this was because of my membership on the ICRP Main Commission, but I think the offer was because I was in the right time slot on the schedule!

Now, onto the **Reactor Oversight Program:**

The current reactor oversight program, which provided sweeping changes to our inspection, assessment, and enforcement processes, was implemented in April 2000. This program is, of course, anchored in the NRC's mission to ensure public health and safety in the operation of commercial power plants. That will always remain the agency's overarching responsibility. The objective of the program is to monitor performance in three broad areas -- reactor safety (avoiding accidents and reducing the consequences of accidents if they occur); radiation safety for both plant workers and the public during routine operations; and protection of the plant against sabotage or other security threats. To measure plant performance in these three areas, the program focuses on seven specific "cornerstones," including such things as the effectiveness of mitigating systems, emergency preparedness programs, and radiation protection programs for workers and the public.

In this process, the NRC evaluates plant performance by analyzing two distinct inputs: (1) inspection findings resulting from NRC's inspection program; and (2) performance indicators (PIs) reported by the licensee. The combined data provides a broad sample of information on licensee safety performance. However, it is not intended to cover every aspect of plant design and operation, but to provide an objective indication of the performance of plant systems and licensee programs in specific risk-significant areas. Both PIs and inspection findings are evaluated and given a color designation based on their safety significance, with "green" denoting the lowest safety significance, progressing through "white," "yellow," and finally "red" denoting the highest safety significance. The NRC uses this input to compare the PI data to risk thresholds and to assess plant performance within the cornerstone areas. As a whole, although improvements are something we are continuing to address, I believe that the revised oversight process has improved the efficiency and effectiveness of reactor regulation.

Now, some **Recent Experience Regarding the Release of Radioactive Materials:**

As you may be aware, one of our licensees was issued a "white" finding in the Public Radiation Safety Cornerstone last year. The Public Radiation Safety Cornerstone assesses the procedures and systems designed to minimize radioactive releases from a nuclear plant during normal operations and to keep those releases within Federal limits. Specifically, the licensee identified eleven examples in which radioactive material was inadvertently released from the radiologically controlled area because of improper surveys. The inspection finding was "white" because, although the public exposure associated with each item was small, there were multiple occurrences. The process used to determine the significance of findings in this area is one of the very few in the Reactor Oversight Program that consider the number of occurrences as a decision block. While this provides a simple methodology, it can hardly be called risk-informed because there is obviously little risk associated with these events.

Fortunately, we are taking steps to address this issue. The NRC staff has already undertaken a review of the Public Radiation Safety significance determination process, and public meetings have

been and will continue to be held to discuss stakeholder concerns. Many of these concerns stem directly from this recent experience and include; in addition to the obvious concern regarding the appropriateness of counting occurrences; (1) whether the process should be applied as soon as material is released from the radiologically controlled area versus some other boundary, and (2) whether some potential dose threshold should be applied to releases to determine their significance. To make this cornerstone truly risk-informed, I believe incorporation of this last concern is paramount.

Next, a potential solution to this concern, a **Clearance Rule:**

Recently, the NRC staff recommended to the Commission that we proceed with a rulemaking concerning the control of solid materials, that is, a Clearance rule. The staff made this recommendation after reviewing the report issued by the National Academy of Sciences (NAS) on the release of materials by NRC licensees[1].

The NAS report described some of the weaknesses in NRC's current approach of releasing solid material in a case-by-case fashion. One of the primary weaknesses is that the current approach is not based on potential health risk. Rather, the existing process is largely driven by the state-of-the-art of radiation measurement technology, allowing materials from reactors to be released if no radioactivity beyond background levels can be "detected." Other weaknesses include inconsistent application of the approach, a lack of transparency in the approval process, and concern as to whether the existing approach is sufficiently flexible to meet the demands arising from multiple requests for the release of large volumes of solid material that would come about with the eventual decommissioning of the current population of civilian nuclear reactors. The NAS recommends that, in considering release or conditional release, a standardized dose-based approach be applied. Such an approach could bring needed consistency, transparency, and predictability to the decision process -- factors that are in the best interests of both the NRC and all of its stakeholders.

Like the NAS and NRC staff, I believe that the weaknesses of the current approach warrant the consideration of alternative approaches to the control of solid material, even though the current efforts are protective of public health and safety. However, I believe we need to proceed cautiously. At the time of the staff's recommendation, I did not believe the time was right to move forward with rulemaking for several reasons. However, the Commission as a whole has supported moving forward with rulemaking, and I believe my original reasons for not moving forward will be informative to the rulemaking. These reasons include:

> The safety significance of the issues. As noted in the NAS report, the current approach for releasing this type of material is considered to provide a sufficient level of safety. The NAS report also notes that a criteria of 10 μSv/yr (1 mrem/yr) is a "reasonable starting point" regarding levels of risk when considering alternatives for controlling solid material. Both of these statements call into question whether significant resources should be devoted to an activity that might have minimal impact on maintaining health and safety, may not significantly reduce burden on our licensees because the proposed release levels are so low, and may erode public confidence in this time of increased attention on the security of radioactive materials.

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[1]National Academy of Sciences, Board on Energy and Environmental Systems, The Disposition Dilemma: Controlling the Release of Solid Materials from Nuclear Regulatory Commission-Licensed Facilities, issued March 21, 2002

More than 800 extensive and wide-ranging public comment letters were received from various stakeholders (including the metals and concrete industries, citizen groups and individuals, licensees and licensee representatives, and other organizations) in public meetings over the past few years. Despite NRC efforts to engage these stakeholders through various means including public workshops on the subject, there is significant distrust and lack of confidence in NRC and obtaining such confidence in a rulemaking effort on this subject would be difficult until we have thoroughly reviewed all of the underlying technical issues.

The National Council on Radiation Protection and Measurements (NCRP) is planning a symposium on this topic later this year. This symposium will have as participants interested members of the public and public interest groups, Federal agencies, State governments, professional associations, industrial groups, scientists, and representatives from national and international organizations. One goal of the symposium will be to develop an encompassing statement on this important issue. I believe that the NRC's understanding of the issues will benefit from such a product.

An NCRP report and an American Nuclear Society statement on clearance will be out this year with each of these organizations perspectives. Because these additional reports will only serve to provide more valuable information from another set of extremely knowledgeable stakeholders, I believe that we should explore the recommendations provided by these organizations before moving significantly forward on a Clearance Rule.

The U.S. Environmental Protection Agency (EPA) has the responsibility for setting generally-applicable environmental standards under the Atomic Energy Act and currently does not have a program to set standards on control of solids materials in the United States. Instead, EPA has decided to focus its efforts on **control** (versus **release**) of sources and radioactive materials. It will be beneficial to all of our stakeholders for the NRC to work with EPA, as well as other Federal and State agencies, on developing a standard before finalizing a Clearance Rule. Failure to do so, would be reminiscent of NRC's failure of the Below Regulatory Concern Policy of the 1990s.

The American National Standards Institute selected 10 μSv/yr (1 mrem/yr) as the primary dose standard for clearance. Under the Public Law 104-113, "National Technology and Transfer Act of 1995", and guidance from the Office of Management and Budget on the use of voluntary consensus standards, Federal agencies are required to use this type of technical standard unless its use is inconsistent with applicable law, or otherwise impractical. Before moving forward with a Clearance Rule, the NRC needs to weigh the pros and cons of either implementing or endorsing this standard as would be prudent in support of Public Law 104-113.

The NAS report states that relatively little solid materials will arise from nuclear power plant decommissioning over the next 20 years, so it may be prudent to wait and obtain a consensus from the international and national community before moving forward with a Clearance Rule.

Lastly, I note that several international organizations (the IAEA [International Atomic Energy Agency] and the European Commission) have selected 10 μSv/yr (1 mrem/yr) as a starting point for release of cleared materials. Since 1993, both NRC and EPA have participated with the IAEA Member States on the development of assumptions and parameters used to derive these clearance levels. Although there are still concerns amongst both national and international organizations regarding the accuracy of the parameters and modeling associated with the release

of solid materials, NRC's limited resources may be better spent in continuing this coordination process in order to be able to try to ensure a sound technical basis and approach in resolving this global issue before proceeding with a Clearance Rule.

Now that you've now heard my thoughts, I strongly encourage all of you to participate in the NRC's activities regarding the development of a Clearance Rule so as to ensure a thorough vetting of the multitude of issues in this area.

And lastly, **ICRP Initiatives:**

In 1990, the ICRP made major revisions to its basic radiation protection recommendations. Because of timing and other considerations, NRC adopted only a few of the ICRP 60 recommendations into 10 CFR Part 20. As an example, NRC adopted the ICRP recommendation to lower the annual dose limit for members of the public to 1 mSv (100 mrem) down from 5 mSv (500 mrem). However, with respect to the occupational exposures, NRC believed that a reduction to the ICRP-60 recommendation of 100 mSv (10 rem) in 5 years [with a 50 mSv (5 rem) maximum in any one year] was not necessary because in 1987 **over 98.7%** of individuals requiring radiation monitoring received doses less than 20 mSv (2 rem) per year (in 1999, this number had **increased to 99.6%**). In addition to these statistics, the NRC had also included the concept of maintaining radiation exposures As Low As Reasonably Achievable (ALARA) into its revised Part 20.

The ICRP system of radiological protection that has evolved over the years now covers many diverse topics. Subsequent to issuance of Part 20 in 1991, ICRP has issued publications 66 and 68-72 which contain updated models to reflect new biokinetic information and related parameters for calculation of exposure from radioactive materials. In general, emerging issues presented to the ICRP have been dealt with on an individual basis that results in an overall system, while very comprehensive, is also very complex. With such a complex system, it is not surprising that some perceived inconsistencies in the recommendations themselves may lead to concerns that radiation protection issues are not being adequately addressed. Different stakeholders in decisions involving radiation protection tend to focus on different elements of this incoherence.

In July 2001, I joined the Main Commission of the ICRP and in September attended my first meeting to discuss these and other additional changes. One area of particular interest to the NRC is the value selected for Doses for Protective Action, or Protective Action Levels to a member of the public. Current NRC regulations state an annual limit of 1 mSv (100 mrem) to any member of the public, which, as I mentioned before, was derived from ICRP 60. Internationally, there may be an interest to drop the public limit to a few tens of mSv, or about one-tenth of the limit from natural background. This equates to a source-related constraint of about 0.3 mSv (30 mrem) per year as the point of specifying whether or not a source (licensee) is appropriately controlling their material. This would be a factor of three reduction from an individual facility, if the ICRP were to adopt this recommendation. Of greatest concern, is the fact that the 1 to 0.3 mSv (100 to 30 mrem) reduction would have significant political ramifications not only for the regulated community, but especially for the public's perception of the reasons behind why this proposed change is being introduced, especially since any proposed decrease in regulatory limits would likely have no change in the actual doses received from licensed facilities by the public.

Another major shift considered by ICRP is going from a utilitarian ethical policy ("How much does it cost and how many lives are to be saved?" or "The greatest good for the greatest number"), to an egalitarian policy in which the doctrine of recognition of individual rights (dose constraints) and equal

treatment of individuals should be the guiding principle. Classical cost-benefit analysis when discussing collective dose is unable to consider the individual, and the ICRP attempted to correct this by the concept of the constraint. The constraint is an individual-related criterion, applied to a single source in order to ensure that the most exposed individuals are not subjected to excessive risk and to limit the inequity introduced by cost-benefit analysis.

In addition to the changes that the ICRP has under consideration, there are two other major efforts underway, both in the U.S. and internationally, to update dosimetric methods and reassess the health risk form low-levels of ionizing radiation. First, there are reviews underway by both the RERF and the U.S. Department of Energy (DOE) to revise the DS86 dosimetry system that was used in the health assessments of the A-Bomb survivors. More specifically, preliminary investigation indicates that there are discrepancies between the DS86 calculation of neutron flux at certain distances from the bomb hypocenter and the measured values from materials activated by thermal neutrons. Secondly, in 1998, the National Research Council was awarded a 3-year grant by several Federal Agencies to conduct a re-assessment of the health risks associated with exposures to low-levels of ionizing radiation (BEIR VII). This reassessment will include a review of the data that might affect the shape of the dose-response curve at low doses, and in particular, will investigate if a threshold in the dose-response relationship exists to provide a better understanding of the influence of adaptive response and radiation hormesis on radiation dose response.

Conclusions:

To conclude, I again refer to the words of Walt Disney when he said, “We keep moving forward, opening new doors, and doing new things, because we're curious and curiosity keeps leading us down new paths.” Thank you for your attention and I would be pleased to answer any questions you might have at this time.