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REGULATORY RISK COHERENCE

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Regulatory Risk Coherence

Ladies and gentlemen, it is a real pleasure to be here, and to share with you some thoughts about risk management, an area that has been of great interest to me since I was involved in the development of the Commission's Safety Goal Policy. I have had several opportunities to talk on this topic during the past year. Last month I spoke to a group representing the Franco-American Institute of Environmental Technology in Paris. One thing seems clear to me: The problem of how to refine regulatory programs to focus more accurately on achieving the appropriate level of protection of public health and safety is a problem that is being taken seriously by many governments, and has led to international efforts to better manage health and environmental problems.

Balancing the benefits of technology with the need to meet health and safety standards has, in the past, generally been a successful approach to regulation. And now that risk analysis has been developed into a sophisticated discipline, we can better determine how health and safety standards are being met. We are now better able to make sure our regulatory initiatives match the levels of safety we are trying to achieve. It is my contention that we should more aggressively apply what we have learned and the improved analytical tools we now have toward achieving greater coherence in our overall regulatory programs.

In the U.S., risk analysis is now being used to some extent in virtually every significant government program. The U.S. Environmental Protection Agency (EPA), the U.S. Consumer Products Safety Commission, the Food and Drug Administration, the Department of Energy, the U.S. Department of Agriculture, the Department of Defense, and OSHA, are but a few of the other agencies that utilize risk assessment. Additionally, Congress has created a Commission on Risk Assessment as part of the Clean Air Act Amendments of 1990.

The engineering risk assessments which provide the basis for regulatory decisions made by the NRC are different than the health risk assessments which provide the basis for regulatory decisions made by other agencies like the EPA. The methodologies and models are quite different. But the endpoints -- identification of incremental increases in cancer risk or prompt fatalities as a result of regulated activities -- can be the same. Many individuals representing both agencies believe that risk management is an effective tool for allocating resources for protecting the health and safety of the public and the environment. But, as you may already know, some controversy continues to surround the use of risk assessment for decision making in the U.S.

There are two national committees that have undertaken efforts to examine methods and consistency of use of risk assessment in government decision-making in the U.S. One committee within the National Academy of Sciences (NAS) is managing some of this work. I have participated as part of another committee, established by the White House's Office of Science and Technology Policy -- the Federal Coordinating Council for Science, Engineering and Technology's (FCCSET) Ad Hoc Working Group on Risk Assessment, which is examining consistency in application of risk assessment for decision-making, and looking for opportunities for collaboration on methods, research, and other issues of interest to agencies engaged in risk assessment. In order to solicit the views of others, this committee organized an intergovernmental public meeting which was held in Washington, D.C., on November 19, 1991.

Unfortunately, no specific goal has been set for the working group as a whole, other than to continue to serve as a springboard for interaction between the Federal and non-Federal science communities. The intentions of the group are good, but I think a more aggressive approach will be needed to respond to the need for an institutional framework that includes engineering risk assessment.

On March 16th of this year, the heads of both the NRC and the EPA signed a Memorandum of Understanding (MOU) which sets forth the principles and procedures for, among other things, avoiding unnecessary duplication of regulatory requirements and focusing priorities on the most significant safety and environmental problems. The MOU recognizes that risk assessment is an important tool for accomplishing this objective. It says that, in carrying out this MOU, the agencies will actively explore ways to "harmonize" risk goals, and will cooperate in developing a mutually agreeable approach to risk assessment methodologies for radionuclides.

I believe that the U.S. Nuclear Regulatory Commission and the licensed nuclear power industry have been the leaders in developing and establishing the use of PRAs in safety regulation and plant operation. Similar efforts are underway now in many nations with nuclear power programs. For example, during my recent trip to Indonesia, I was told that the Indonesians have performed a probabilistic risk assessment for one of their research reactors and are using it to determine priority among maintenance tasks. So the need for harmonization is international as well as national.

However, in the United States, there continues to be only limited and piecemeal application of risk assessment in establishing both limits and priorities for regulatory and managerial activities. Further, there is no common national public health and safety risk goal that guides the regulators and the regulated in determining whether a given public risk is acceptable in light of the public benefit of the activity.

It has become my personal belief, and I emphasize that these are my personal views, that regulatory activities which relate to the protection of public health and safety could be guided by a general public risk goal consisting simply of an annual individual risk goal. Such a national risk goal would guide regulators in establishing regulatory requirements for the protection of the public health and safety in their area of responsibility. In other words, the question of how much safety is enough safety for a variety of human activities involving public risk would have been answered on a common public risk basis. Industry then would be encouraged and well advised to set design and operation risk goals of their activities below the health and safety risk goals, in order to account for data and analytical uncertainties and for economic risk considerations.

For a number of industrial or other human activities, the most significant public risk to be considered is the risk of fatalities resulting from the activity. In this case, for purposes of discussion, one might establish an annual individual risk goal of between 10^{-5} to 10^{-6} per year. With important exceptions this risk goal could be applied to activities generally, even when they differ among themselves in the benefits they provide. One might then establish regulatory requirements to limit the annual individual risk to the public from these activities to no more than 10^{-5} per year, with the goal of achieving a lower risk of 10^{-6} per year, if cost-beneficial. To help put these numbers in perspective, I note that in the United States,^{1,4} and I believe in the United Kingdom, the annual individual risk of death from all causes is approximately 10^{-2} per year. Thus, in the United States, a particular activity which would pose an annual individual risk of 10^{-5} per year would only increase an individual's annual risk by approximately 0.1% (1/1000th) of the risk of death from all causes; a risk of 10^{-6} per year would increase an individual's annual risk by about 0.01% (1/10,000th) of the annual individual risk from all causes.

I appreciate the general reluctance to compare activities on the basis of the risk of death they might cause. I can also appreciate the tendency of some to argue that no goal should be established other than zero risk. However, we must face the reality that there are risks associated with almost any human activity. The statutory basis for the regulation of nuclear activities in the United States, the Atomic Energy Act of 1954, assumes, I believe, that the benefits of the use of

nuclear materials outweigh the recognized risks. The advantage of establishing a common risk goal is that it enables one to compare safety improvement alternatives for various activities resulting in public risk (e.g., energy production and use, transportation, food production and use, drugs, production and use of fertilizers and pesticides, etc.). The use of such a goal in conjunction with risk assessment techniques would help one gain a better perspective of the relative risks and thereby help set more realistic priorities for the use of national resources in mitigating the consequences of activities which affect public risk. The goal would be that one country, one agency, or one group would not expend resources on a risk which would be trivial when compared to other higher risks that are not being worked on.

To put an annual individual risk of 10^{-5} per year in perspective, consider the following from the literature:² An additional annual individual risk of death of 10^{-5} per year is approximately equivalent to the risk of death from:

- o Smoking 14 cigarettes per year (death from lung cancer/heart disease),
- o Drinking 2 1/2 liters of wine per year (sclerosis of the liver),
- o Living 20 days per year in New York or Boston (air pollution),
- o Riding in a canoe for 1 hr per year (accident),
- o Riding a bicycle for 100 miles per year (accident),
- o Riding 300 miles per year in a car in the U.S. (accident),
- o Being exposed to the average level of natural radioactivity in the United States for 24 days per year (cancer).

Also consider, for the sake of perspective, the position that the Health and Safety Executive of the U.K. has expressed on the matter of what constitutes tolerable and intolerable risk.³ I applaud the initiative of the British in expressing views on such matters, because there is general reluctance to discuss the subject of tolerable, acceptable and intolerable risk, how safe is safe enough, etc. I believe the Commission also deserves praise for its issuance of its Safety Goal Policy. The U.K. Health and Safety Executive states the following:

"Broadly, a risk of death of 1 in 1000 per annum (10^{-3} per year) is about the most that is ordinarily accepted under modern conditions for workers in the UK ... and it seems reasonable to adopt it as the dividing line between what is just tolerable and what is intolerable."

The Executive goes on to say that:

"If the maximum tolerable risk for any worker is set at around 1 in 1000 per annum, it seems right to suggest that the maximum level that we should be prepared to tolerate for any individual member of the public from any large-scale industrial hazard should be not less than ten times lower, i.e. 1 in 10,000 (1 in 10^4)."

The Executive then considers how safe is safe enough:

"Having considered what might be regarded as levels of risk that are **just tolerable** we must now consider what might be a **broadly acceptable** risk to an individual of dying from some particular cause, i.e., what is the level of risk below which, so long as precautions are maintained, it would not be reasonable to insist on expensive further improvements to standards. **This level might be taken to be 1 in a million (1 in 10^6) per annum** bearing in mind the very small addition this would involve to the ordinary risks of life An annual risk of 1 in a million is of course not altogether negligible; it is broadly the same as that of being electrocuted at home (and is about a hundred times less than the annual average risk of dying in a traffic accident). But it is a level of risk which, provided there is a benefit to be gained, and proper precautions are taken, does not worry us or cause us to alter our ordinary behavior in any way."

It is interesting to note that the annual individual occupational risk from work accidents across all industries in the U.S. in 1990 was approximately 10^{-4} per year,⁴ which is a factor of ten less than the U.K.-proposed dividing line between tolerable and intolerable occupational risk. Thus, an annual individual public risk goal of 10^{-5} to 10^{-6} per year would constitute one-tenth to one-hundredth the annual occupational risk in the U.S. As in the U.K., in the U.S. there has been a history of regulating activities in a manner that limits the public exposure to one-tenth of occupational exposures to adverse health effects. In sum, I believe that an annual individual public risk goal of 10^{-5} to 10^{-6} per year is consistent with past practices of maintaining public exposures to less than 10% of occupational exposures and is generally consistent with the views on tolerable and intolerable risk expressed by the Health and Safety Executive of the U.K.

Although a general philosophy of risk (i.e., an annual individual risk goal) has not guided us in setting our regulatory requirements or policies in the U.S., it is of interest to look at some of the dose criteria in existence in the NRC's regulations or policies to see how they might fit within such a general philosophy of acceptable risk.

NRC Safety Goals⁵

In 1986, the Commission adopted the following two qualitative safety goals that are supported by two quantitative health objectives.

Qualitative Safety Goals

- o Individual members of the public should be provided a level of protection from the consequences of nuclear power plant operation such that individuals bear no significant additional risk to life and health.
- o Societal risks to life and health from nuclear power plant operation should be comparable to or less than the risks of generating electricity by viable competing technologies and should not be a significant addition to other societal risks.

Quantitative Health Objectives

- o The risk to an average individual in the vicinity of a nuclear power plant (defined as within 1 mile of the plant site boundary) of prompt fatalities that might result from reactor accidents should not exceed one-tenth of one percent (0.1 percent) of the sum of prompt fatality risks resulting from other accidents to which members of the U.S. population are generally exposed.
- o The risk to the population in the area near a nuclear power plant (defined as within 10 miles of the plant site boundary) of cancer fatalities that might result from nuclear power plant operation should not exceed one-tenth of one percent (0.1 percent) of the sum of cancer fatality risks resulting from all other causes.

Approximately 5 persons out of 10,000 die annually as a result of all causes of accidents in the U.S., and roughly 19 persons per 10,000 population die annually in the U.S. as a result of cancer (these were the statistics at the time of development of the Safety Goals.⁶ Taking 0.1 percent of these annual individual risks of dying from the effects of an accident or from cancer (i.e., 5×10^{-4} and 2×10^{-3}) results in annual individual risks of approximately 10^{-6} per year. That is:

Prompt Fatality Risk Objective = 0.5×10^{-6} /yr. per reactor, and
Latent Fatality Risk Objective = 2×10^{-6} /yr. per reactor,

both of which fall near the lower end of an individual annual risk goal of 10^{-5} to 10^{-6} /yr, and thus are reasonably consistent with such a goal. But this consistency is fortuitous, at least in the sense that the Safety Goals were not established with the 10^{-5} to 10^{-6} risk goal in mind.

Below Regulatory Concern (BRC)

In 1990, the NRC published a policy statement, subsequently placed in moratorium in response to strong political opposition, establishing the process for how the NRC would make decisions on petitions to exempt from further regulatory control certain small quantities of radioactive materials in consumer products, waste streams, recycled materials, and decommissioned facilities or sites.⁷

For decommissioned facilities or sites, the NRC said that it would utilize a criterion of 10 mrem/yr (0.1 mSv/yr) for limiting radiation dose resulting from residual contamination of those facilities or sites. For widespread uses of radioactive materials, such as in consumer products, the NRC said that it would use a criterion of 1 mrem/yr (0.01 mSv/yr) for limiting individual doses. The NRC also said that it would use a collective dose criterion of 1,000 person-rem/yr (10 person-Sv/yr), and would truncate, or not include, in collective dose calculations individual doses below 0.1 mrem per year (0.001 mSv/yr).

If these proposed residual contamination and consumer product dose criteria are translated into fatality risks using the linear hypothesis and a cancer fatality risk coefficient of 5×10^{-4} /person-rem (5×10^{-2} /person-Sv), one obtains

$$\begin{aligned} 1 \text{ mrem/yr (0.01 mSv/yr)} &= 0.5 \times 10^{-6}/\text{yr individual risk, and} \\ 10 \text{ mrem/yr (0.1 mSv/yr)} &= 5 \times 10^{-6}/\text{yr individual risk.} \end{aligned}$$

Again, the annual individual risks associated with the 1 mrem/yr and 10 mrem/yr dose criteria in the NRC's moribund BRC policy fortuitously fall near the lower end of, or within the range of, an annual individual risk goal of 10^{-5} to 10^{-6} /yr.

Incidentally, the fact that a 10 mrem/yr dose equates to an estimated annual individual risk of 5×10^{-6} is a good reference number to help put radiation doses in perspective relative to other societal risks.

Reactor Site Criteria (10 CFR Part 100)

The NRC's Reactor Site Criteria prescribe an exclusion area and a low population zone of sizes such that in the case of an accident an individual would not receive a total radiation dose in excess of 25 rem (0.25 Sv) to the whole body. Utilizing a fatal cancer risk coefficient of 5×10^{-4} /person-rem and the linear hypothesis, a 25 rem whole body dose would result in the calculated consequence of 1.25×10^{-2} fatalities. To be within an annual individual risk of 10^{-6} /yr, the frequency of such an accident would need to be kept less than 8×10^{-5} /yr (i.e., $8 \times 10^{-5} \times 1.25 \times 10^{-2} = 10^{-6}$). Similarly, for an annual individual risk of 10^{-5} /yr, the frequency of such an accident would need to be kept less than 8×10^{-4} /yr. Therefore, an accident having a consequence of this magnitude should not occur more often than approximately every 1,000 to 10,000 years (i.e., 1,250 to 12,500 years). This seems reasonable, indicating that a risk goal of 10^{-5} to 10^{-6} /yr appears to be reasonable in this context also.

10 CFR Parts 50 and 100 Reorganization

The NRC has an effort underway to revise, update and reorganize 10 CFR Part 100. The purpose, in part, is to decouple plant siting requirements from plant design requirements; the latter requirements, including dose criteria, are to be moved to Part 50. I have been encouraging the staff to not only move the current dose criteria to Part 50, but to reanalyze those dose criteria from the standpoint of a coherent risk perspective. It is my personal view that the dose criteria, for example the 25 rem whole body and 300 rem thyroid dose criteria, should be evaluated from both a risk coherence standpoint as well as from the standpoint of their relative consistency with the organ dose weighting factors in the new Part 20. Further, I would like to see whether those dose criteria might be expressed as individual risk values, either in place of, or in addition to, deterministic values.

Disposal of Radioactive Waste (10 CFR Part 61)

Likewise, the NRC's criteria for protection of the general population from releases of radioactivity from a low-level radioactive waste disposal site to the water, air, soil, or through plants and animals must not result in an annual dose exceeding an equivalent of 25 mrem (0.25Sv) to the whole body. The requirements of 10 CFR Part 61 require that the ALARA concept be applied to the performance of the low-level waste disposal facility so the actual dose levels could be expected to be less than 25 mrem. Again, using a fatal cancer risk coefficient of 5×10^{-4} /person-rem and the linear hypothesis, a 25 mrem whole body dose would result in an annual individual risk of 1.25×10^{-5} /yr. If the ALARA principal were able to lower the annual dose level to the range of 2 to 20 mrem per year, a low-level radioactive waste facility would also fall within the risk goal of 10^{-5} to 10^{-6} /year.

Revised 10 CFR Part 20

The Commission recently revised its standards for protection against ionizing radiation in 10 CFR Part 20. The implementation date for these revised requirements for all licensees will be January 1, 1994. The revised Part 20 establishes two standards that are of interest for today. First, the revised Part 20 establishes a dose limit for individual members of the public of 100 mrem (1 mSv) per year. Secondly, the revised Part 20 requires that licensees control the occupational dose to individuals to an annual total effective dose of 5 rem (0.05 Sv). The occupational dose of 5 rem per year is the same as the level in the existing Part 20. However, the 100 mrem dose to individual members of the public in the revised Part 20 is a reduction by a factor of five from the existing Part 20 level of 500 mrem per year.

When one evaluates the individual risk posed by these levels, again using a risk coefficient of 5×10^{-4} per person-rem, the annual risk to members of the public is found to be 5×10^{-5} and the risk

to occupational workers is found to be 2.5×10^{-3} . One should note that ALARA practices generally keep these risks below these regulatory limits.

Clearly, our regulatory dose criteria were not developed consciously according to my proposed general risk goal. They were developed for different purposes at different times by different people. However, I find it of interest to note that there is a general, if somewhat fortuitous, consistency. (For a summary comparison of these dose criteria and the annual individual risks they imply, see the table at the end of this presentation.)

Earlier this year, I participated in a small international "Reflection Group" meeting on risk organized at the Nuclear Energy Agency of the OECD. The purpose was to determine, for events which might affect public health and safety, a risk level below which further detailed analysis or additional safety measures would not be warranted, or not possible. The group concluded that an event, or an individual contributing sequence to an event, which was found to contribute an annual individual public risk increment of 10^{-7} per year or less could be excluded from further consideration. The Reflection Group concluded that analyzing potential events which might contribute less than 10^{-7} per year to annual individual risk would generally suffer from a lack of scientific foundation due to inadequate knowledge of and data on equipment, system, or human behavior. Even assuming that probability numbers as low as 10^{-7} are not highly speculative, in many cases there will be a practical inability to reduce the risk below 10^{-7} . Except in unusual circumstances, trying to regulate risks this small will only waste resources and divert attention and resources away from more significant safety issues.

I believe that excluding events or truncating further analysis of events which contribute less than 10^{-7} per year to individual risk is consistent with the use of an annual individual risk goal of 10^{-5} to 10^{-6} per year.

Conclusion

Engineering and other forms of risk assessments have been developed and refined in recent years. They are being used more frequently by many agencies and in many parts of the world. They are far from perfect but can provide a rational and logical approach to estimating the potential risks from events of varying probability resulting from various human activities. We know that we cannot lock-in on the bottom-line numbers, but they can provide us with valuable insights into the potential risks of various events, and especially provide insights into the relative risks of the various events or the relative risks of design alternatives for preventing or mitigating the risks. In short, with their known weaknesses risk assessments have been demonstrated to be a valuable new tool for use in design, operation and regulation.

We are here to discuss "Risk Management - Expanding Horizons." The point I am trying to make today, the horizon that I believe ripe for expanding, is in the establishment and use of a general public risk goal consisting simply of an annual individual risk goal.

Such a general risk goal would provide us with a criterion to judge when our efforts at prevention and mitigation have been taken to reasonable and rational limits. Without such a goal, I'm afraid that regulators will continue to strive to reduce frequency numbers without knowledge of or a feeling for the relative risk significance of these efforts. Viewing such efforts from a relative risk perspective, we would be better able to concentrate on those events, or human activities, which represent the more significant risks to society. Further, the combined use of a general public risk goal with risk assessment tools would enhance communication amongst the various disciplines and amongst the various regulatory bodies involved in protecting the public health and safety.

It is my personal hypothesis presented to you today for your thought and discussion, that a general public risk goal in the form of an annual individual risk of, on the order of 10^{-5} to 10^{-6} per year, could be such a goal. It is a horizon I think ripe for expanding; it is one which I think would lead to a greater regulatory risk coherence.

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