Assessment of Latent Health Effects Attributable to Ionizing Radiation and Public Communication of Offsite Consequences

Opinions differ among the staff of the U.S. Nuclear Regulatory Commission (NRC) as well as within the external scientific community regarding the dose response relationship between latent cancer mortality and exposure to low dose radiation (less than 0.10 sievert (Sv)(10 rem)). Experts also disagree regarding the existence, or absence, of a threshold in the dose response model and the application of dose truncation in the state-of-the-art reactor consequence analyses (SOARCA). This makes it difficult to decide how SOARCA should evaluate latent cancer fatalities (LCFs) from low doses to large populations. Finally, the staff recognizes the challenges in communicating offsite health consequence results to external stakeholders.

Which Dose Response Relationship Should Be Used?

Experts generally agree that it is difficult to characterize cancer risk for some tissue sites because of the low statistical precision associated with relatively small numbers of excess cases. This can limit the ability to estimate trends in risk. From an epidemiological standpoint, in most if not all cases, the LCF attributable to radiation exposure from accidental releases from a severe accident would not be detectable above the normal rate of cancer fatalities in the exposed population (i.e., the excess cancer fatalities predicted are too few to allow the detection of a statistically significant difference in the cancer fatalities expected from other causes among the same population). For example, in 2006, the World Health Organization (WHO) estimated that 16,000 European cancer deaths will be attributable to radiation released from the 1986 Chernobyl nuclear power plant accident, but these predicted numbers are small relative to the several hundred million cancer cases that are expected in Europe through 2065 from other causes. Furthermore, WHO concluded that, “it is unlikely that the cancer burden from the largest radiological accident to date could be detected by monitoring national cancer statistics.”

New findings have been published from analyses of fractionated or chronic low dose exposure to low linear energy transfer (LET) radiation; in particular, a study of nuclear workers in 15 countries, studies of persons living in the vicinity of the Techa River in the Russian Federation who were exposed to radioactive waste discharges from the Mayak Production Association, a study of persons exposed to fallout from the Semipalatinsk nuclear test site in Kazakhstan, and studies in regions with high natural background levels of radiation. Cancer risk estimates in these studies are generally compatible with those derived from the Japanese atomic bomb data. Most recent results from analyzing these data are consistent with a linear or linear-quadratic dose response relationship of all solid cancers together and with a linear-quadratic dose response relationship for leukemia.

In the absence of additional information, the International Commission on Radiological Protection (ICRP), the U.S. National Academies, and the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) have each indicated that the current scientific evidence is consistent with the hypothesis that there is a linear, no threshold (LNT) dose response relationship between exposure to ionizing radiation and the development of cancer in humans.

Conversely, the French National Academy of Medicine, in "Dose-effect relationships and estimation of the carcinogenic effects of low doses of ionizing radiation," March 30, 2005, advocates the following:

> A linear no-threshold relationship (LNT) describes well the relation between the dose and the carcinogenic effect in this dose range (0.2 to 3 Sv) where it could be tested. However, the use of this relationship to assess by extrapolation the risk of low and very low doses deserves great caution. Recent radiobiological data undermine the validity of estimations based on LNT in the range of doses lower than a few dozen mSv which leads to the questioning of the hypotheses on which LNT is implicitly based.

While the French National Academy of Medicine raises doubts regarding the validity of using LNT for evaluating the carcinogenic risk of low doses (less than 100 millisieverts (mSv) (10 rem)) and even more so for very low doses (less than 10 mSv (1 rem)), it did not articulate what exact value should be ascribed to a dose threshold.

Is the Use of Collective Dose Appropriate for Predicting Latent Cancer Fatalities?

Ultimately, external and internal exposures to individual members of the public are converted from collective organ dose to LCFs using MACCS2. The LNT model raises the concern that the summation of trivial exposures may inappropriately attribute LCFs to individuals far from the site of the accident. While the possibility of LCF from very low doses cannot be ruled out, organizations such as ICRP and the Health Physics Society (HPS) consider it to be an inappropriate use of these exposures. While the National Council on Radiation Protection and Measurements (NCRP) supports the LNT model, it recommends binning exposures into ranges and considering those ranges separately. Furthermore, in situations involving trivial exposures to large populations, ICRP and NCRP have noted that the most likely number of excess health effects is most likely zero, when the collective dose to such populations is equivalent to the reciprocal of the risk coefficient (about 20 person-Sv (2000 person-rem)).

Nevertheless, issues remain related to assessing public exposure, estimating offsite consequences, and communicating these assessments to the public. Several organizations, such as ICRP, have addressed this issue. In its most recent recommendations (ICRP Report 103, "The 2007 Recommendations of the International Commission on Radiological Protection," approved March 2007), ICRP stated the following:

> (161) Collective effective dose is an instrument for optimisation, for comparing radiological technologies and protection procedures. Collective effective dose is not intended as a tool for epidemiological studies, and it is inappropriate to use it in risk projections. This is because the assumptions implicit in the calculation of collective effective dose (e.g., when applying the LNT model) conceal large biological and statistical uncertainties. Specifically, the computation of cancer deaths based on collective effective doses involving trivial exposures to large populations is not reasonable and should be avoided. Such computations based on collective effective dose were never intended, are biologically and statistically very uncertain, presuppose a number of caveats that tend not to be repeated

> when estimates are quoted out of context, and are an incorrect use of this protection quantity.

Although ICRP provided qualitative guidance regarding situations where collective dose should not be used, it did not provide guidance regarding when these concepts actually are, and are not, appropriate, nor did it clearly articulate the boundary conditions within which the calculations are valid, as well as the dose ranges for which epidemiological and cellular or molecular data provide information on the health effects associated with radiation exposure. ICRP did note, however, that when ranges of exposures are large, collective dose may aggregate information inappropriately and could be misleading for selecting protective actions.

How Should Low Dose Consequences Be Estimated?

The National Academies reported the following:

> The magnitude of estimated risk for total cancer mortality or leukemia has not changed greatly from estimates in past reports such as Biological Effects of Ionizing Radiation (BEIR) and recent reports of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and ICRP. New data and analyses have reduced sampling uncertainty, but uncertainties related to estimating risk for exposure to low doses and dose rates and to transporting risks from Japanese A-bomb survivors to the U.S. population remain large.

The National Academies go on to conclude that, "current scientific evidence is consistent with the hypothesis that there is a linear, no-threshold dose-response relationship between exposure to ionizing radiation and the development of cancer in humans."

Many groups acknowledge the uncertainties associated with estimating risk for exposure to low radiation doses. The question that remains is what offsite health consequences are attributable to very low radiation exposure. In its most recent recommendations (ICRP Report 103), described above, ICRP warned that the computation of cancer deaths based on collective effective doses involving trivial exposures is not reasonable and should be avoided, but it did not explicitly state which exposures should not be considered. However, in ICRP Report 104, "Scope of Radiological Protection Control Measures" (in press), ICRP concludes that the radiation dose that is of no significance to individuals should be in the range of 20–100 microsieverts (μSv) (2–10 millirem (mrem)) per year whole body dose. The International Atomic Energy Agency (IAEA) has stated that an individual dose is likely to be regarded as trivial if it is of the order of some several millirem per year. Although there is no scientific basis for defining a trivial dose, the ICRP and IAEA definitions of trivial dose may provide a basis to address truncation of offsite radiation exposure and attributable health consequences.

Alternatively, HPS developed a position paper, "Radiation Risk in Perspective," revised August 2004, to specifically address quantitative estimation of health risks. This position paper concludes that quantitative estimates of risk should be limited to individuals receiving a whole body dose of 0.05 Sv (5 rem) in 1 year or a lifetime dose of 0.1 Sv (10 rem), in addition to natural background. HPS also concluded that risk estimates should not be conducted below these doses. The position paper further states that low dose expressions of risk should only be

qualitative, discusses a range of possible outcomes, and emphasizes the inability to detect any increased health detriment. The difference between the HPS view and those expressed by ICRP and IAEA is the detectability of an offsite consequence versus exposure to trivial doses.

Are there Staff Concerns about Estimating Latent Cancer Fatalities?

As discussed above, the LNT model provides a viewpoint that is consistent with the regulatory approach of the agency. The NRC uses this model to calculate LCFs for regulatory purposes. Furthermore, past analyses using the MACCS2 code have assumed an LNT dose response model. In addition, past analyses calculated LCFs to 1,000 miles with forced deposition to account for all nonnoble gas radionuclides in the dose calculation. Therefore, if use of the dose response model of past analyses is desired, continued use of the LNT model without any dose truncation is necessary.

As a matter of policy, however, the NRC can use different approaches for different applications. The use of a truncation dose criterion would not necessarily impact the underpinnings of the agency's regulatory defense-in-depth approach to protect public health and safety, which is based on an LNT model. Any future SOARCA reports could emphasize that the NRC is not changing or contemplating changing radiation protection standards and policy as a result of an approach taken in this study to characterize offsite health consequences for low probability events. Regarding comparison with previous studies, the benefit gained by performing calculations using the LNT model without dose truncation, which would allow comparison on the same methodological basis, has to be weighed against the disadvantages of using such a collective dose model in what the agency intends to be a state-of-the-art model.

The SOARCA Steering Committee and some NRC staff expressed concern that the health consequence estimations conducted by MACCS2 are dominated by small exposures to large numbers of individuals where the health effects are statistically very uncertain. Furthermore, these staff members are concerned about their inability to present these offsite consequences in a context that compares SOARCA results with the existing rates of cancer mortality among the exposed resident population. To address these concerns, it was proposed that exposures to the public could be truncated to exclude all LCFs attributable to exposure less than some selected value (Figure 1).

On the other hand, other NRC staff are concerned that some NRC stakeholders will perceive the truncation of exposure, even exposures above a trivial dose, and the subsequent exclusion of offsite health consequences as disingenuous in that many individual exposures (and some future LCFs) will be arbitrarily, or deliberately, excluded from consideration and will not be reported as an offsite consequence. These staff members believe that this could significantly undermine public confidence in the NRC's ability to objectively evaluate and report offsite consequences and thus impartially regulate the civilian use of nuclear materials. Furthermore, the need to defend a truncation value may obscure the technically justified changes that have been made in the source term and offsite consequence model used in SOARCA.

What Is the Staff's Recommendation for Assessing Offsite Health Consequences?

National and international radiation protection organizations provide little or no policy guidance that addresses how individual effective dose and collective dose can be assessed and used to

estimate LCFs after low dose radiation exposure. In the absence of guidance, the NRC conducted a survey of staff health physics and radiation biology experts.

To aid the staff's evaluation of offsite health consequences, respondents evaluated a screened nuclear power plant accident for two power reactor sites. They assessed the potential occurrence of early fatality and LCFs. No early fatalities attributable to acute radiation sickness were predicted for either site. However, a number of LCFs might potentially occur depending on the dose truncation value selected. LCFs were estimated using truncation values ranging from 0 to 0.05 Sv (5 rem). For each truncation value, the LCFs were averaged and plotted as percent LCF versus dose (Figure 2). Selection of a 100 μSv (10 mrem) dose truncation reduced the number of estimated LCFs by approximately 40 percent. Truncation at 0.001 Sv (100 mrem) and 0.01 Sv (1 rem) reduced the number of estimated LCFs by 80 percent and 90 percent, respectfully. Virtually no LCFs are estimated with truncation at 0.05 Sv (5 rem) or more. Figure 2 illustrates that truncating doses even at very small values, for example 10 μSv (1 mrem), can reduce the aggregation of small doses to many individuals, thus reducing the estimated number of potential cancer deaths.

These experts considered the following five alternative methods for assessing offsite LCFs:

1. Use a range of dose truncation values, from 0 to 0.05 Sv (5 rem).

2. Use only an LNT model.

3. Estimate the number of LCFs using a single 0.05 Sv (5 rem) per year, 0.1 Sv (10 rem) lifetime dose truncation value.

4. Estimate LCF using a single 100 μSv (10 mrem) per year dose truncation value.

5. Estimate LCF using a linear dose response model with and without a single dose truncation value.

The respondents specified their recommended truncation values and provided their reasoning for their selection.

There was little expert support for assessing LCF using just an LNT dose response or truncating dose based on 0.05 Sv (5 rem) per year or 0.1 Sv (10 rem) lifetime. The expert group did not broadly endorse the 0 to 0.05 Sv (5 rem) range of dose truncation values proposed in SECY 05-0233, "Plan for Developing State-of-the-Art Reactor Consequence Analyses," dated December 22, 2005. The majority supported the alternative to estimate LCF using an LNT model and a linear model with a single truncation. The values suggested for truncation generally ranged from 10 μSv to 0.001 Sv (1 to 100 mrem). Half of these respondents favored values between 1 and 10 mrem because these most closely represent a trivial exposure. The other respondents favored values between 25 and 100 mrem because these most closely represent the public dose limit and source constraints on radiation exposure. The maximum value proposed for this alternative was 500 mrem. The central value was estimated to be approximately 10 mrem.

During a SOARCA Steering Committee meeting to discuss this issue, alternative (6) was suggested, using a different metric:

6. Estimate a population-weighted individual likelihood of LCF with and without a single dose truncation value for different distances from the plant. The calculation would include both LNT and 100 μSv (10 mrem) dose response models with results presented for three distances: (1) 0 to 16.1 km (10 miles); (2) 0 to 80.5 km (50 miles); and (3) 0 to 161 km (100 miles).

This metric is not new; past Environmental Impact Statements have used it (see, for instance, NUREC-0537, "Final Environmental Impact Statement Related to the Operation of Midland Plant, Units 1 and 2," issued July 1982). Furthermore, this approach is similar to the one The Commission used in establishing its Safety Goals. The metric has the advantage of facilitating public risk communication by providing a likelihood of consequences that could be compared with the occurrence of LCFs in the general population from causes other than a reactor accident. The staff's best estimate of offsite LCFs would be the assessment with the 100 μSv (10 mrem) truncation value because it would limit the overaggregation of very small exposures to many individuals. Comparison of this value with the nontruncated estimate will provide a general indication of how much small population doses impact the estimation of offsite consequences.

Conclusion

The staff recommends using alternative (6) for estimating LCF for screened nuclear power reactor severe accidents.

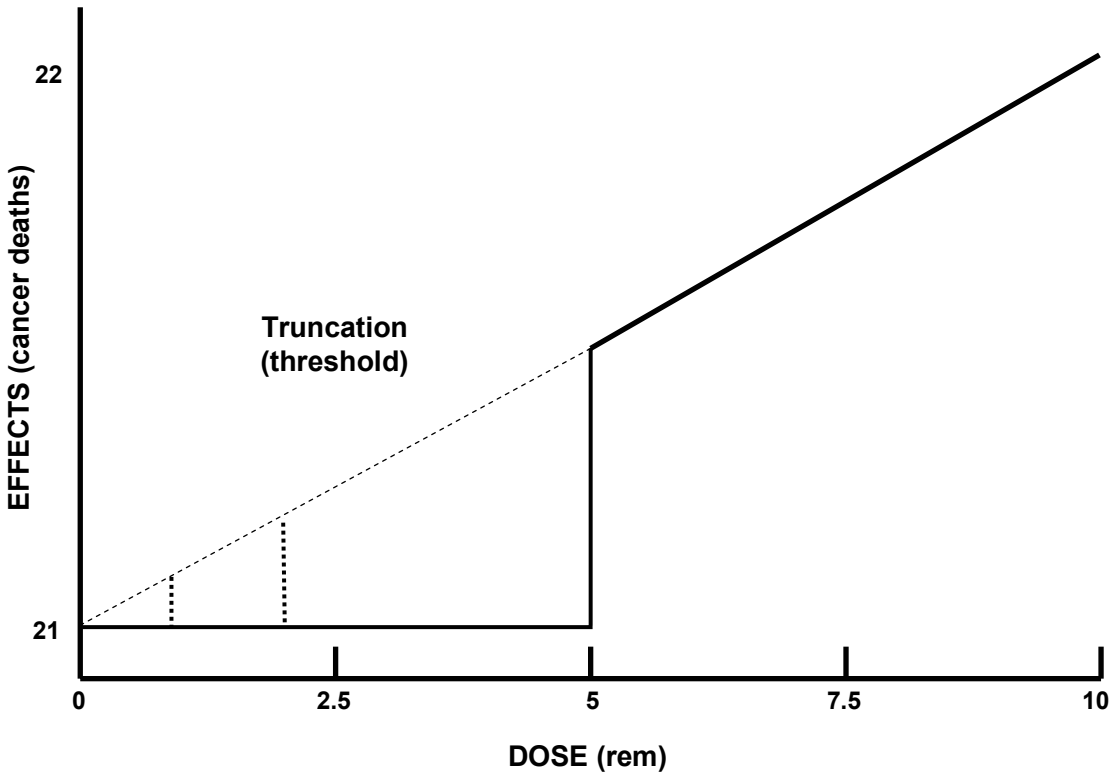

Figure 1 - Estimation of LCFs using a linear dose response model and dose truncation from 0 to 0.05 Sv (5 rem)

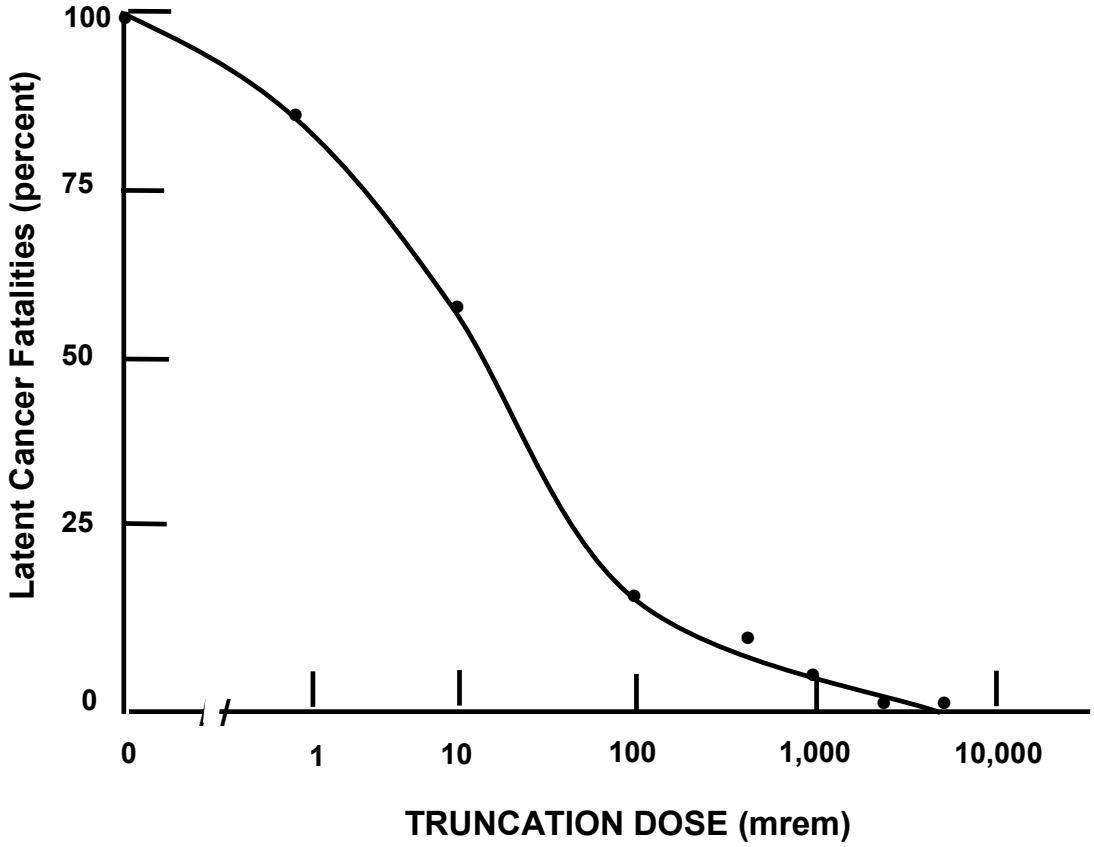

Figure 2 - Average sensitivity for LCF within 1000 miles of a nuclear power reactor