(15)

RES 13

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

There is a difference of opinion among the U.S. Nuclear Regulatory Commission (NRC) staff, and also within the external scientific community, regarding the dose response relationship between latent cancer mortality and exposure to low dose radiation (<10 rem, <0.10 Sv). There is also disagreement 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 Consequence Analysis (SOARCA). Finally, the staff recognizes there are challenges of communicating offsite health consequence results to external stakeholders.

Which dose response relationship should be used?

There is general agreement that it is difficult to characterize cancer risk for some tissue sites, owing to 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 latent cancer fatalities (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 there will be 16,000 European cancer deaths 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 up through 2065 due to 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-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 this 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 dose response relationship between exposure to ionizing radiation and the development of cancer in humans.

Conversely, the French National Academy of Medicine advocates that:

> "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

T/41

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 report raises doubts on the validity of using LNT for evaluating the carcinogenic risk of low doses (<10 rem, <100 mSv) and even more for very low doses (<1 rem, <10 mSv), it did not articulate what exact value should be ascribed to a dose threshold.

Is the use of collective dose appropriate for predicting LCF?

Ultimately, external and internal exposures to individual members of the public are converted from collective organ dose to latent cancer fatalities using MACSS2. For the LNT model, there is concern that the summation of trivial exposures may inappropriately attribute LCF to individuals far from the site of the accident. While the possibility of LCF from very low doses cannot be ruled out, it is considered by organizations such as, ICRP, National Council on Radiation Protection and Measurements and the Health Physics Society to be an inappropriate use of these exposures.

Nevertheless, there remain the issues of assessing public exposure, estimating offsite consequences, and communicating these assessments to the public. Several organizations, such as the ICRP, have addressed this issue. In its most recent 2007 recommendations (ICRP Report 103), the ICRP states:

(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 the ICRP provides qualitative guidance regarding the situation where collective dose should not be used, no guidance was provided with regard to when these concepts actually are, and are not, appropriate nor did they 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.

How should low dose consequences be estimated?

The U.S. National Academies reported that "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 and International Commission on Radiological

Protection. 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 which remains is what offsite health consequences are attributable to very low radiation exposure. The ICRP in their most recent recommendations (Report 103), as described above, warn that the computation of cancer deaths based on collective effective doses involving trivial exposures is not reasonable and should be avoided, but do not explicitly state which exposures should not be considered. However, in ICRP Report 104, Scope of Radiological Protection Control Measures (in press), the ICRP concludes that the radiation dose which is of no significance to individuals should be in the range of 2-10 mrem (20-100 μSv) 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 what a trivial dose might be, the ICRP and IAEA definitions of trivial dose may provide a basis in order to address truncation of offsite radiation exposure and attributable health consequences.

Alternatively, the Health Physics Society (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 5 rem (0.05 Sv) in one year or a lifetime dose of 10 rem (0.1Sv), in addition to natural background. They also conclude that below these doses risk estimates should not be conducted below these doses. The position paper further states that low dose expressions of risk should only be qualitative, discussing a range of possible outcomes, and emphasizing 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 LCF?

As discussed above, the LNT model provides a viewpoint that is consistent with the regulatory approach of the agency. This model is used by the agency to calculate LCF for regulatory purposes. That is to say, MACCS2 has used and continues to use the LNT dose response model to calculate LCF. If there is a desire to use the dose response model of past analyses, 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 our regulatory "defense-in-depth" approach to protect public health and safety, which is based on LNT. Any future SOARCA reports could emphasize that radiation protection standards and policy are not being changed or contemplated 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 we intend to be a "state-of-the-art" model.

The SOARCA steering committee and several SOARCA team members 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 the truncation of exposure, even exposures above a trivial dose, and subsequent exclusion of offsite health consequences, will be perceived by some NRC stakeholders as disingenuous in that many individual exposures (and some future latent cancer deaths) will be arbitrarily, or deliberately, excluded from consideration and will not be reported as an offsite consequence. These staff members believe that this will significantly undermine public confidence in NRC's ability to objectively evaluate and report offsite consequences and thus impartially regulate the civilian use of nuclear materials. Furthermore, the necessity 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?

There is little or no policy guidance from any of the national or international radiation protection organizations that address how individual effective dose and collective dose can be assessed and used to estimate LCF after low dose radiation exposure. In the absence of guidance, a survey of NRC health physics and radiation biology experts was conducted.

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

These experts were provided five alternative methods for assessing offsite LCF. These included:

(1) Use a range of dose truncation values, from 0 to 5 rem (0.05 Sv).
(2) Use only an LNT model.
(3) Estimate the number of LCF using a single 5 rem (0.05 Sv) per year, 10 rem (0.1 Sv) lifetime dose truncation value.
(4) Estimate LCF using a single 10 mrem (100 μSv) per year dose truncation value.
(5) Estimate LCF using both a linear dose response model with and without a single dose truncation value. The respondent was requested to specify what truncation value they would recommend and why.

There was little expert support for assessing LCF using just a LNT dose response or truncating dose based on 5 rem per year/10 rem lifetime. The 0 to 5 rem range of dose truncation values proposed in SECY 05-0233 was not broadly endorsed by the expert group. The alternative receiving majority support was to estimate LCF using a LNT model and a linear model with a single truncation. The values suggested for truncation generally ranged from 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. 500 mrem was the maximum value proposed for this alternative. The central value was estimated to be approximately 10 mrem.

Conclusion

If LCF is estimated for screened nuclear power reactor severe accidents, the staff recommends using both a linear dose response model with, and without, a 10 mrem truncation value. The staff's best estimate of offsite LCF would be the assessment with the 10 mrem truncation value because it would limit the over aggregation of very small exposures to many individuals. Comparison of this value with the non-truncated estimate will provide a general indication of how much the estimation of offsite consequences is impacted by small population doses.

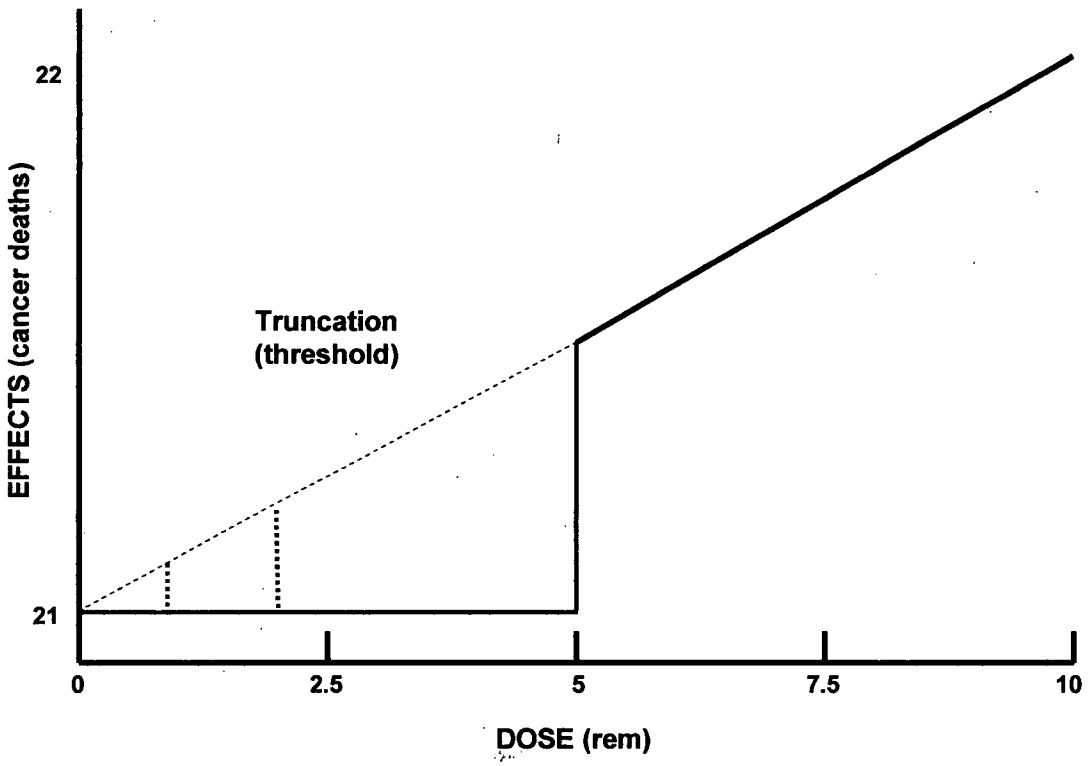

Figure 1. Estimation of latent cancer fatalities using a linear dose response model

and dose truncation from 0 to 5 rem (0.05 Sv).

Figure 2. Average sensitivity for latent cancer fatality (LCF) within 1,000 miles of a nuclear power reactor.