

**STANDARDIZED RADIOGENIC CANCER RISK COEFFICIENTS:
A REVIEW OF THE METHODOLOGY PRESENTED IN FEDERAL GUIDANCE
REPORT NO. 13**

Michael Boyd and Christopher Nelson, U.S. Environmental Protection,
Office of Radiation and Indoor Air, Washington, D.C.

ABSTRACT

The United States Environmental Protection Agency (EPA) published an interim version of Federal Guidance Report No. 13 - Part 1, "Health Risks from Low-level Environmental Exposure to Radionuclides," (FGR 13) in January of 1998. This version of FGR 13 employs state-of-the-art models and methods for estimating the risk of cancer from exposure to external and internal radiation from 100 important radionuclides. In contrast to previous EPA publications of risk coefficients, FGR 13 incorporates age and gender-specific dose models in estimating the lifetime risk of cancer from radiation exposure. Although the initial list was chosen based on available data from updated biokinetic models published by the International Commission on Radiological Protection (ICRP), the final version will include a much more comprehensive list of radionuclides.

Following publication of the interim version, EPA requested comments from the public and also asked its Science Advisory Board to review the document. This paper presents a brief discussion of the scientific basis for the risk coefficients presented in the interim report. Where appropriate, changes anticipated in the final version will also be discussed.

BACKGROUND

When the EPA was formed in 1970, the duties of the Federal Radiation Council were transferred to the EPA Administrator. Among these duties was the responsibility for issuing guidance to the Federal Agencies on matters related to radiation protection. Recommendations for protection of radiation workers and the general public are developed through consultation with the affected agencies and signed by the President. In addition, EPA also issues federal guidance technical reports that are designed to standardize the technical approaches to be used in determining compliance with these recommendations or related requirements. Most of the regulations for radiation protection that have been issued by EPA, the Nuclear Regulatory Commission (NRC), the Department of Energy (DOE), the States, and others have used some form of radiation dose as the metric for compliance. Some older regulations use the critical organ dose concept as defined in International Commission on Radiological Protection (ICRP) Publication 2. (1) More recent U.S. regulations have used effective dose equivalent as presented in ICRP Publications 26 (2) and 30 (3). Technical guidance for determining the dose from radionuclide concentrations in various media can be found in Federal Guidance Technical Reports 11 (4) and 12 (5). The purpose of the current Federal Guidance Technical Report, FGR13, is to provide Federal and State agencies and other organizations with consistent, technically sound methods for assessing cancer risks from exposure to radionuclides in the environment. The report describes methods and models for estimating cancer risk from internal or external environmental exposure to radionuclides. It also provides tabulations of cancer mortality and morbidity risk coefficients for assessing exposure to radionuclides in different environmental media. Given the amount of attention this document has

received in the press and among the regulated community, it is worth emphasizing that FGR13 does not affect any existing dose-based regulations.

Using risk as a compliance metric is not new. Under most of the environmental statutes, risk assessment is a common risk management tool. For example, it is used to determine cleanup levels at Superfund sites, to perform cost-benefit analyses in support of new rulemakings, and in preparing Environmental Impact Statements. EPA has been publishing radiation risk coefficients (called slope factors) for almost a decade in the Health Effects Assessment Summary Tables (HEAST) (6) which is updated about once a year. Risk and dose are linked since most dose limits are health- (or risk-) based and since any estimate of risk is derived from an underlying assessment of age- and organ-specific doses.

There has been some concern that the risk coefficients, when expressed in fundamental SI units of risk per becquerel (Bq^{-1}), will leave the casual reader with the impression that one decay event will lead to an excess cancer. Of course, using the linear no threshold theory, there is some risk assigned to each decay event. However, when the radiation dose associated with an acceptable risk limit of about one in ten thousand is calculated for a particular radionuclide of concern, one sees that the resulting acceptable dose is reasonably close to existing dose limits. This is not surprising, since dose based regulations, at least in recent years, have needed to use risk assessment tools to satisfy to the Office of Management and Budget that a new rule is cost effective. These calculations are usually presented in the Regulatory Impact Assessment for the new rule.

METHODOLOGY

What EPA has attempted to do in preparing FGR 13 is not to replace radiation dose assessments with risk assessments, but rather to standardize and update the risk coefficients that are already in use. The time is right for updating the methodology used to generate risk coefficients because our understanding of how radionuclides are metabolized and our ability to model age, gender, and organ-specific parameters have increased significantly in recent years. In particular, we make use of new biokinetic models published by the ICRP.

In the interim version of FGR13, tabulations are provided for cancer risk coefficients - mortality and morbidity risk per unit intake (Bq^{-1}) and per unit external exposure (e.g., per $\text{Bq}\cdot\text{s}\cdot\text{m}^{-2}$) - for about 100 radionuclides. The exposure modes include:

- Inhalation of radionuclides from air,
- Ingestion of radionuclides in food and water,
- Submersion exposure to radionuclides in air,
- External exposure to radionuclides on the ground surface, and
- External exposure to radionuclides uniformly distributed in soil.

In the final version of FGR 13, risk coefficients will be provided for approximately 800 radionuclides.

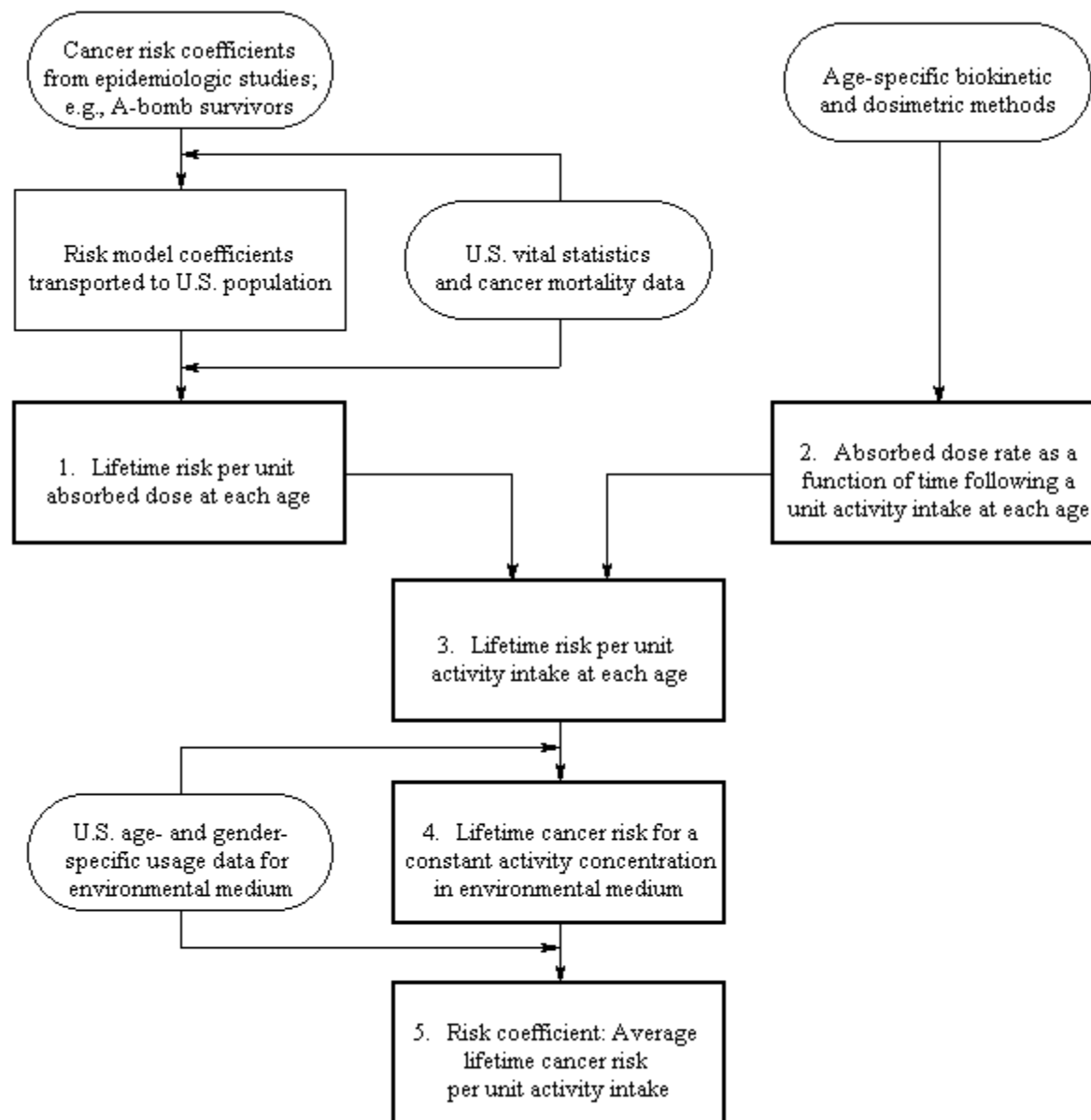


Figure 1 shows a flow chart description of how the risk coefficients are calculated. The numbered boxes in this diagram represent the following steps in the process:

1. Radiation risk methodology
2. Dosimetry Models
3. Age-specific risk calculation
4. Lifetime risk for a constant concentration
5. Cancer risk coefficient

Each of these steps is reviewed in the following sections.

Radiation risk methodology

The basic risk methodology relies on methods and models published in the 1994 EPA report, "Estimating Radiogenic Cancer Risk." (7) The risk coefficients are derived from epidemiological studies such as the Japanese atomic bomb survivors where risk as a function of dose has been estimated. The risk model coefficients are then transported to the US population. In this report, age- and gender-specific models for 14 cancer sites have been updated for the 1989-1991 US cancer mortality rates and life table data. (8) This information establishes the baseline cancer rates against which excess cancers are measured and also provides a means for accounting for competing causes of death at each age. By using this life table approach, the model reduces the population at risk for radiogenic cancer by those who would have died from other causes beforehand.

The model predicts that for a uniform dose to all organs and tissues, the average lifetime mortality risk is 5.75×10^{-2} per Gray (Gy). The corresponding cancer incidence risk (morbidity) is 8.46×10^{-2} per Gy. Using these models and data, lifetime cancer risks (mortality and morbidity) per unit absorbed dose (risk per Gy) are calculated for males and females at 1 year steps from age 0 (birth) to 120. (Of course, excess cancers predicted beyond age 100 are minimal since most of the population has expired.) Knowing the lifetime risk per dose brings us to the second piece of information required, the absorbed dose rate as a function of time following a unit activity intake at each age (box number 2 in Figure 1).

Dosimetry models

Absorbed dose rates (Gy/d) for each target site are calculated as a function of time following a unit activity intake. The age-specific biokinetic and dosimetric models used are from ICRP Publications 56, 67, 69, and 71, "Age-Dependent Doses to Members of the General Public from Intake of Radionuclides," Parts 1-4. (9) The age-specific inhalation models from ICRP Publication 66, "Human Respiratory Tract Model for Radiological Protection," (10) replace the Task Group lung model used previously. Dose rates per unit external exposure are from Federal Guidance Report 12. (5)

Age-specific risk calculation

Gender specific risks for each cancer site are calculated for a unit activity intake (risk per Bq) for persons at each age from 0 to 120. Risks are calculated for each site by integrating the product of

1. the absorbed dose rate as a function of time following the age of a unit activity intake,
2. the lifetime risk per unit absorbed dose as a function of time following the age of intake,
3. the fraction of survival following the age of intake

over time from the age of intake to age 120. Risks from low-LET radiation and high-LET radiation are calculated separately and combined.

Lifetime risk for a constant concentration

Gender specific cancer rates are calculated for a constant activity concentration in an intake medium. Activity intake rates are proportional to usage rates which are gender- and age-specific. Inhalation rates are from ICRP Publication 66. (10) Ingestion intake rates depend on the medium:

1. Tap water usage ($L\ d^{-1}$) includes drinking water and water added in preparing beverages and foods (Ershow and Cantor 1989). (11)
2. Food energy usage ($kcal\ d^{-1}$) use data from the Third National Health and Nutrition Examination Survey (NHANES III). (12)
3. Milk usage ($L\ d^{-1}$) data from EPA Exposure Factors Handbook.

Cancer risk coefficient

The cancer risk coefficient represents the lifetime cancer risk per unit activity (Bq^{-1}) averaged over age and gender. This is calculated as the lifetime risk for a constant concentration divided by the lifetime intake. This method retains the effect of relative age- and gender-specific usage rates. It allows assessments to be made using reference usages as per capita values and allows food concentrations and per capita usage to be in customary units (e.g., Bq/kg and kg/d , respectively).

APPLICATION

It is easy to use cancer risk coefficients. Once an exposure assessment has been completed, the user knows all the relevant data needed for the risk assessment and the final result becomes a matter of simple mathematics. For example, knowing the concentration of a radionuclide in air (Bq/m^3), a breathing rate (m^3/day), and a duration of exposure (days), one can find the total activity inhaled during the period of interest by multiplying these three values. The lifetime, age-averaged risk of excess cancer is then just the product of this value and the inhalation risk coefficient. In short, FGR13 risk coefficients represent all the data required for the radionuclide toxicity assessment. The user is only responsible for the exposure assessment and the experience needed to interpret the results.

REFERENCES

1. International Commission on Radiological Protection, "Report of Committee II on Permissible Dose for Internal Radiation," ICRP Publication 2, Pergamon Press, New York (1959)
2. International Commission on Radiological Protection, "Recommendations of the ICRP," ICRP Publication 26, Pergamon Press, Oxford (1977)
3. International Commission on Radiological Protection, "Limits for Intakes by Workers," ICRP Publication 30, Part 1, Pergamon Press, Oxford (1979)

4. K. F. ECKERMAN et al., "Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion - Federal Guidance Report No. 11," EPA 520/1-88-020, United States Environmental Protection Agency (September 1988)
5. K. F. ECKERMAN and J. C. RYMAN, "External Exposure to Radionuclides in Air, Water, and Soil - Federal Guidance Report No. 12," EPA 402-R-93-081, United States Environmental Protection Agency (September 1993)
6. "Health Effects Assessment Summary Tables, FY-1995 Supplement," EPA 540/R-95/142, United States Environmental Protection Agency (November 1995)
7. "Estimating Radiogenic Cancer Risks," EPA 402-R-93-076, United States Environmental Protection Agency (1994)
8. "U. S. Decennial Life Tables for 1989-91. Vol. 1, No. 1," DHHS, PHS-98-1150-1 (National Center for Health Statistics: United States Life Tables. Public Health Service, Washington, DC). (October, 1997)
9. International Commission on Radiological Protection, "Age-Dependent Doses to Members of the Public from Intake of Radionuclides, Parts 1 - 4" ICRP Publications 56, 67, 69, and 71 respectively, Pergamon Press, Oxford, (Part 1, 1989; Part 2, 1993; Parts 3 and 4, 1995)
10. International Commission on Radiological Protection, "Human Respiratory Tract Model for Radiological Protection." ICRP Publication 66, Pergamon Press, Oxford (1994)
11. A. G. ERSHOW and K. P. CANTOR," Order No. 263-MD-810264, National Cancer Institute, Bethesda, MD (1989)
12. M. A. McDOWELL, et al., "Energy and Macronutrient Intakes of Persons Ages 2 Months and Over in the United States: Third National Health and Nutrition Examination Survey, Phase 1, 1989-91," Advance Data 255, U. S. Dept. of Health and Human Services (1994)