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A PROPOSED FRAMEWORK FOR CONSISTENT REGULATION OF PUBLIC EXPOSURES TO RADIONUCLIDES AND OTHER CARCINOGENS*

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ABSTRACT

This paper discusses a proposed framework for consistent regulation of carcinogenic risks to the public based on establishing *de manifestis* (i.e., unacceptable) and *de minimis* (i.e., trivial) lifetime risks from exposure to any carcinogens at levels of about 10^{-1}-10^{-3} and 10^{-4}-10^{-6}, respectively, and reduction of risks above *de minimis* levels as low as reasonably achievable (ALARA). We then discuss certain differences in the way risks from exposure to radionuclides and other carcinogens currently are regulated or assessed which would need to be considered in implementing the proposed regulatory framework for all carcinogens.

INTRODUCTION

We believe there is a fundamental problem with current regulatory policies in the United States for limiting routine exposures of the public to radionuclides and other carcinogens - namely, a clear inconsistency in the levels of acceptable health risk associated with (a) standards for radionuclides only, as developed under authority of the Atomic Energy Act, and (b) standards for any carcinogens, including radionuclides, or for chemical carcinogens only, as developed under authority of other laws. We first describe the apparent inconsistency in the levels of acceptable risk associated with these two categories of standards and propose a set of principles, based on distinguishing unambiguously between unacceptable and trivial risks, which could provide more consistent regulation of carcinogenic risks to the public. The present inconsistency in acceptable risks and our proposed regulatory framework are discussed in more detail elsewhere [1]. We then discuss other differences in the way risks from exposure to radionuclides and other carcinogens currently are regulated or assessed which would need to be considered in implementing the proposed regulatory framework for all carcinogens.

INCONSISTENCY IN CURRENT REGULATORY APPROACHES

The current framework for regulating radiation exposures of the public under authority of the Atomic Energy Act may be referred to as a "top-down" approach. In this approach, a limit on radiation dose to individuals from all sources of exposure except natural background, corresponding to an upper bound on acceptable risk, is established in radiation protection standards. Then, doses are reduced below the limit by requiring that exposures be kept as low as reasonably achievable (ALARA), taking into account such factors as cost vs. benefit, technical feasibility, and societal concerns (e.g., perceptions of risk).

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The current dose limit in radiation protection standards for the public corresponds to a limit on acceptable lifetime risk of 5×10^{-3} [2]. However, the development in the United States of many standards for specific practices or sources, which represent an application of the ALARA principle, virtually assures that lifetime risks from routine exposures to all man-made radionuclides will not exceed 10^{-3}. The "top-down" approach also is applied to (a) regulation of exposures to naturally occurring radionuclides in mill tailings, (b) remedial action levels for exposure to natural background, principally radon decay products and external radiation, and (c) responses to radiation accidents. In these cases, the limit on acceptable lifetime risk is in the range 1×10^{-3} to 5×10^{-2}, and the ALARA principle is applied to reduction of public exposures.

The current framework for regulating exposures of the public to chemical carcinogens, and for regulating radiation exposures under authority of laws other than the Atomic Energy Act, is quite the opposite of that described above and may be referred to as a "bottom-up" approach. In this approach, there is no standard defining an upper bound on acceptable risk from all carcinogens and sources of exposure. Rather, for specific exposure situations only, a lower bound on acceptable risk is established as a goal, and this goal then may be increased to reflect risk levels that reasonably can be justified.

The "bottom-up" approach is exemplified by current laws and regulations for carcinogenic food additives (e.g., pesticides) and for radionuclides and chemical carcinogens in drinking water. In both cases, a carcinogenic risk of zero has been established as a goal, but this goal has been relaxed to permit lifetime risks up to 10^{-6} for pesticides and 10^{-4}-10^{-6} for carcinogens in drinking water. Acceptable risks in the range 10^{-4}-10^{-6} from exposure to radionuclides and other carcinogens also are embodied in standards for airborne emissions of hazardous substances and standards for cleanup of hazardous substances in the environment, e.g., at old waste disposal sites.

The "top-down" approach to regulating radiation exposures under authority of the Atomic Energy Act clearly is fundamentally different from the "bottom-up" approach to regulating exposures to radionuclides and other carcinogens under authority of other laws. Consequently, upper bounds on lifetime risks to the public regarded as "acceptable" clearly are inconsistent in the two cases - i.e., risks of 10^{-1}-10^{-3} in the former but 10^{-4}-10^{-6} in the latter.

PROPOSED FRAMEWORK FOR CONSISTENT REGULATION OF ALL CARCINOGENS

In order to reconcile the fundamental inconsistency in regulatory approaches described above and to provide more consistent regulation of carcinogenic risks to the public, we propose an explicit regulatory framework for all carcinogens which contains three basic elements:

[1] a *de manifestis* lifetime risk in the range 10^{-1}-10^{-3}, which would define an upper bound on acceptable risk from all carcinogens and sources of exposure and above which regulatory action would be taken to reduce risks regardless of cost;

[2] a *de minimis* lifetime risk in the range 10^{-4}-10^{-6}, which would define risks from any carcinogen and source of exposure so trivial that regulatory action to reduce risks would be unwarranted; and

[3] reduction of lifetime risks above *de minimis* levels based on application of the ALARA principle.

The key to our proposal is to recognize that the lifetime risks of 10^{-4}-10^{-6} embodied in some standards, as described previously, are *de minimis* rather than *de manifestis* levels. This interpretation is clearly supported by an analysis which showed that regulatory authorities in the United States usually have not acted to reduce risks from chemical carcinogens when the lifetime risk to a few individuals is below 10^{-4} and the average lifetime risk in large populations is below 10^{-6} [3].

The proposed use of ranges for the *de manifestis* and *de minimis* risks would permit taking into account the size of an exposed population in establishing these levels for particular situations [3] and would allow considerable flexibility in applying the ALARA principle. Therefore, complete uniformity of regulatory decisions in limiting carcinogenic risks to the public would not be required.

As indicated previously and discussed in more detail elsewhere [1], our proposed regulatory framework is consistent with virtually all current regulatory policies for limiting routine and accidental exposures of the public to radionuclides and other carcinogens, including proposed exemption levels for radiation exposure. Again, however, this consistency is achieved only if the lifetime risks of 10^{-4}-10^{-6} embodied in some standards are interpreted as *de minimis*.

We believe that our proposed regulatory framework would encourage consideration of risks from any carcinogen and source of exposure in the context of risks from all sources, as opposed to the rather piecemeal approach embodied in past regulatory decisions, particularly for chemical carcinogens [3]. Furthermore, the proposed *de minimis* levels would ensure that risks much less than largely unavoidable background risks, which average about 10^{-2} for radionuclides [2,4] and greater than 5×10^{-3} for chemical carcinogens [5], do not receive unwarranted attention.

ADDITIONAL CONSIDERATIONS IN IMPLEMENTING PROPOSAL

Implementation of our proposed regulatory framework for limiting risks to the public from all carcinogens would require additional considerations as a result of certain other differences in the way risks from radionuclides and chemical carcinogens are regulated or assessed.

First, the *de manifestis* and *de minimis* levels are expressed as lifetime rather than annual risks. Thus, for example, the common practice of apportioning an assumed limit on lifetime risk into equal annualized increments in setting dose limits in radiation protection standards is rather arbitrary for purposes of limiting stochastic risk to values below *de manifestis* levels. However, incremental apportionments of lifetime risk limits over relatively short time periods (e.g., annually) probably

are essential in applying the ALARA principle for either controlled or uncontrolled sources of exposure. Subsidiary limits on acute exposures to any carcinogens also would be needed if prevention of nonstochastic (i.e., deterministic) effects is of concern.

Second, there are inconsistencies in the factors for converting exposure to risk. In particular, radiation risk factors usually are best estimates [2], but upper 95th percentile confidence limits are used for other carcinogens [6]. In addition, radiation risk factors take into account risks from irradiation of all organs and tissues [2], but current risk factors for chemical carcinogens usually take into account only one organ or tissue at risk [6].

Third, the primary measure of risk from radiation exposure usually has been cancer fatalities [2], whereas the primary measure of risk for other carcinogens has been cancer incidence [6]. Risk factors for radiation exposure that include weighted nonfatal cancers as well as fatal cancers have been introduced [2], and a similar approach could be used in developing risk factors for chemical carcinogens.

Finally, in assessing radiation doses to maximally exposed individuals, the intent usually is to estimate average doses to members of critical population groups using reasonable assumptions for likely exposure scenarios and pathways. However, risk assessments for chemical carcinogens often emphasize unreasonably pessimistic assumptions [6], and the resulting estimates of risk may exceed values that could be experienced by any members of the public.

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