

PUBLIC HEALTH PERSPECTIVE

V. PUBLIC HEALTH PERSPECTIVE

In developing this document, NIOSH has been challenged to carefully consider all of the Institute's legislative, scientific, and moral responsibilities. Two legislative mandates are important in understanding NIOSH's responsibilities in developing this document and the recommendations it contains. First, the Occupational Safety and Health Act of 1970 [Public Law (PL) 91-596], which established NIOSH, requires safe and healthful working conditions for every working person. The Act further requires NIOSH to preserve our human resources by providing medical and other criteria that will ensure, insofar as practicable, that no worker will suffer diminished health, functional capacity, or life expectancy as a result of work experience [PL 91-956, Section 6(b)(5)]. The Act also authorizes NIOSH to develop new recommended criteria to further improve working conditions [PL 91-596, Sections 22(c) and (d)]. In addition, the Federal Coal Mine Health and Safety Act of 1969 [PL 91-173] and the Federal Mine Safety and Health Amendments Act of 1977 [PL 95-164] require NIOSH to develop and revise recommended occupational safety and health standards for mine workers. The Secretary of Health, Education, and Welfare (now the Secretary of Health and Human Services) shall consider, "in addition to the attainment of the highest degree of health protection for the miner . . . the latest available scientific data in the field, the technical feasibility of the standards, and experience gained under this and other health statutes" [PL 91-173, Title 1, Section 101(d)].

NIOSH has been required to review diverse scientific data that are subject to uncertainty and then, in keeping with its mandates, to recommend criteria that will attain the highest level of health protection and will at the same time account for other factors such as technical feasibility and insights gained through research and development.

To develop a public health perspective on the risk posed by occupational exposure to radon progeny, NIOSH must weigh a number of factors, as follows.

1. Human and animal data both clearly establish that exposure to radon progeny increases the risk of lung cancer. The human data consist of a number of positive epidemiologic studies, several of which demonstrate an exposure-related health risk that is not accounted for by smoking behavior. The animal studies demonstrate that lung cancer risk increases with exposure in the absence of smoking. It is important to note that smoking by miners appears to greatly exacerbate the risk of lung cancer posed by exposure to radon progeny alone.
2. The NIOSH risk assessment, based on a USPHS study of uranium miners [Lundin et al. 1971], demonstrated a significant exposure-response relationship. This analysis indicates that exposure to radon progeny at the current MSHA occupational exposure limit of 4 WLM over a working lifetime will result in 42 excess lung cancers per thousand miners. A miner's working lifetime has been defined as 30 years (MSHA uses 30 years as a miner's working lifetime). Risk declines substantially if a lower annual cumulative exposure is received over the working lifetime. Any risk assessment is subject to uncertainty because risk assessment

models may not reflect risk in a completely reliable way and because the data on which they are based are subject to uncertainties and limitations.

The Cox proportional hazards model, which was chosen for the NIOSH risk assessment, is considered one of the strongest analytical approaches for longitudinal epidemiologic data. But it is not clear how accurately the data can be extrapolated to predict risk below the levels of observed exposure. Current biological theory hypothesizes that carcinogenic processes involve an initiation stage that is followed by other stages before an actual malignancy is established. The essential characteristics of all of these stages remain to be delineated. The Cox proportional hazards model is very powerful in describing human risks based on epidemiologic data. Its strength is partly due to the model's ability to accommodate long follow-up periods during which changes occur in some of the risk factors, e.g., cumulative exposure. Nevertheless, it is not clear how accurately the Cox model or any other risk assessment model predicts the risk from a multistage cancer process when exposures are below levels that have been studied.

The USPHS study [Lundin et al. 1971] on which the NIOSH risk assessment was based is an extensive study, but the risk assessment is subject to uncertainties and limitations because of the nature of the data. For example, more uncertainty would be inherent in the risk estimates at the lower range of exposure because a relatively small proportion of this study population received the lowest cumulative exposures. Approximately 7% of the USPHS uranium miners (which included 7 lung cancers) had received cumulative occupational exposure levels of 30 WLM or less. At lower cumulative exposure levels, even smaller proportions of the cohort and fewer lung cancers were represented. Thus point estimates at these lower cumulative exposure levels would be more subject to the influence of chance occurrences. In addition, exposure levels are subject to measurement error. The uncertainty of exposures have been estimated to range from a relative standard deviation of 38% [Schaiger et al. 1981] to as high as 97% (see Appendix II).

3. Radon progeny and its associated risk are present in our ambient environment as well as in the mining environment and cannot be totally eliminated. Radon progeny are ubiquitous in that they emanate from all ore-bearing deposits containing elements that decay to produce radon gas. The national average exposure to radon progeny has been estimated to be 0.2 WLM [NCRP 1975]. Areas containing large amounts of ore-bearing deposits (e.g., the Colorado Plateau) are likely to have higher-than-average background levels of radon progeny [NCRP 1975]. The NIOSH risk assessment uses a fitted estimate of 0.4 WLM as the background exposure (the average annual cumulative exposure incurred in nonoccupational environments) in the Colorado Plateau. Although no adequate measurement data are available to characterize the level and variability of exposure in the homes of the general population and of miners, it is clear that everyone is exposed and that the degree of exposure depends on each individual's home and work environment. The limits of concentration detection and the accuracy of the measurement techniques become a potential problem when quantifying the very low

radon progeny exposure and concentration levels that may be found in the ambient environment (these levels are generally much lower than those found in underground mining environments). Extrapolation of risk to such low levels would become even more problematic than at higher levels because of the reduced accuracy of measuring such concentration levels. The elimination of radon progeny from the ambient and mining environments is not possible.

The primary engineering method for controlling radon progeny exposure is dilution ventilation. However, if radon progeny are ubiquitous in our ambient environment, no source of air is free of contamination. The only protective equipment that would eliminate exposure to radon progeny is the self-contained breathing apparatus (SCBA). SCBAs are unacceptable for wear in the ambient environment and represent a significant safety hazard if worn extensively in the mining environment.

4. It is valuable to compare the lung cancer risks associated with the miner's occupational and background exposures. No assessment has yet been made of the lung cancer risk associated with background exposures, either for the general U.S. population or for the population living in the Colorado Plateau. Until studies in homes are completed, it will be impossible to directly contrast the risks of occupational and background exposures.

Nonetheless, it is important to consider occupational risk in the context of the lung cancer risk experienced by the general population. On the basis of State vital statistics records, NIOSH estimates that the lifetime risk of lung cancer in the Colorado Plateau, uncorrected for smoking, is approximately 45 lung cancers per 1,000 white males. Unfortunately, accurate lung cancer rates are not available for nonsmokers in the Colorado Plateau.

Given this value for the lung cancer risk of background exposure, another question that must be considered is to what level it would be reasonable to control occupational risk. In its benzene decision, the U.S. Supreme Court gave the following example for the basis of evaluating occupational risk of chemically induced leukemia. The example indicated that an exposure associated with 1 excess death per 1 million exposed persons might pose an acceptable risk, whereas an exposure associated with 1 excess death per 1,000 exposed persons would pose a significant risk that should be reduced. This example is useful but it cannot be strictly applied in all cases, since it was offered as an illustration and not a fixed rule. In the specific case of lung cancer risk associated with radon progeny exposure, the example cannot be strictly applied because the risk of lung cancer is much greater than the risk of leukemia at background exposure levels and because cigarette smoking is known to create a confounding effect that greatly increases risk. An excess of 1 lung cancer death per 1,000 would probably not be detectable in a general population if the data were subject to considerable uncertainty, since it would necessitate differentiating between 46 and 45 deaths per 1,000.

5. The technical feasibility of achieving lower exposure levels is subject to the limitations of available technology. A report commissioned by the Bureau of Mines [Bloomster et al. 1984a, 1984b] has been the primary source for NIOSH's assessment of the technical feasibility of lower exposure levels. On the basis of an extensive engineering analysis of two uranium mines, these investigators indicated that it might be feasible to meet an operating standard of 1 WLM using the best available engineering controls. They expressed doubt about the technical feasibility of operating these uranium mines at a standard of 0.5 WLM. This analysis has been used by NIOSH to define exposure limits that are technically achievable with the best available technology.

These are some of the issues that have been considered by NIOSH in developing a recommended standard to prevent lung cancer associated with exposure to radon progeny. This process of weighing risk from a public health perspective parallels the philosophy of risk presented in the 1985 document entitled Risk Assessment and Risk Management of Toxic Substances: A Report to the Secretary [CCERP 1985]. In the process of developing this public health perspective, NIOSH has performed the following actions:

- NIOSH has identified a public health hazard posed by an occupational exposure. Exposure to radon progeny that occurs in underground mines and the ambient environment has been shown to cause a significant increase in lung cancer among uranium and other underground miners.
- NIOSH has developed recommendations in a manner that is prudent and in concert with the public need. This process was accomplished by complying with the Institute's legislative mandates to attain the highest level of health protection and at the same time consider other factors such as technical feasibility.
- NIOSH has sought appropriate public participation by eliciting external reviews. Reviews were requested from more than 60 individuals or groups, including industry, labor, academia, and government representatives. NIOSH has received and considered the comments from more than 30 of these reviewers.
- NIOSH has communicated risk understandably to both experts and lay persons. NIOSH has expressed risk as relative risk, which most epidemiologists and biostatisticians believe to be the most appropriate mode of expressing human cancer risk. NIOSH has also expressed risk as lifetime excess risk per 1,000 miners, an expression that can easily be interpreted by both experts and lay persons.
- NIOSH has used all currently available information and the most extensive pertinent set of human data to estimate risk. The USPHS study of uranium miners [Lundin et al. 1971] is the most extensive set of data available in the United States on the radon progeny exposure of underground miners. Unlike other analyses, this study used the entire qualifying cohort in the risk assessment, regardless of exposure level. These investigators felt this was the most valid way to analyze epidemiologic data using the selected model.

- NIOSH has considered alternative recommendations for risk control that are based on viable exposure limits and engineering controls. The considered options ranged from proposing no REL to prohibiting all occupational exposure to radon progeny. The REL presented in this document was chosen after a thorough weighing of the available data and Institute mandates.
- NIOSH has advanced the process of risk assessment and policy development by conducting the most thorough risk assessment possible on underground miners exposed to radon progeny. The NIOSH risk assessment permitted estimation of lung cancer risk at the lower range of the observed exposure levels. The assessment also suggested meaningful research areas such as lung cancer risks at low radon exposure levels, synergistic effects of other exposures such as cigarette smoke, effects of radon progeny on late versus early stage cancer, and the need for improved engineering control of exposure.

An extensive and complicated process has been used to develop the recommendations in this criteria document. After weighing the conclusions drawn from available data, the mandates of the Institute, and the public health issues, NIOSH recommends an annual cumulative exposure limit of no more than 1 WLM per year. However, as stated earlier, even this exposure poses a significant risk of lung cancer over a working lifetime. Thus NIOSH further recommends that mine operators regard this REL as an upper limit and that they make every effort to limit radon progeny to the lowest possible concentrations. In addition, NIOSH wishes to emphasize the fact that this standard contains many important provisions in addition to the annual exposure limit. These include recommendations for limited work shift concentrations of radon progeny, sampling and analytical methods, recordkeeping, medical surveillance, posting of hazardous information, respiratory protection, worker education and notification, and sanitation. All of these recommendations help minimize risk.

NIOSH recognizes its commitment to protect the health of the Nation's miners and will continue to reexamine this complex occupational health issue. Research on new and more effective methods for reducing occupational exposures will improve the available control technologies. Additional data on exposure levels and associated health risks will permit firmer estimates of risk and hence better recommendations. NIOSH will revise its recommended standard as important new data become available.

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