June 8, 2000

EPA-SAB-RAC-00-010

Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: An SAB Report: Assessment of Risks from Radon in Homes

Dear Ms. Browner:

At the request of Mr. Stephen B. Page, Director of the Office of Radiation and Indoor Air (ORIA), the Radiation Advisory Committee (RAC) of the Science Advisory Board (SAB) reviewed ORIA's draft document titled "Assessment of Risks from Radon in Homes" (October, 1999). The RAC previously reviewed ORIA's methodology described in an ORIA "White Paper". The RAC's recommendations were transmitted to ORIA in a July 1999 SAB Advisory: Assessing Risks from Indoor Radon (EPA-SAB-RAC-ADV-99-10).

The RAC held a public meeting in Washington DC on November 16-18, 1999 at which it was briefed by, and had technical discussions with, ORIA staff and conducted writing sessions, producing a draft report. The report addressed the charge questions as well as other issues beyond the charge identified during the public meetings.

The RAC found the ORIA draft document to be generally well-written and documented and was pleased to note that ORIA took into account the advice contained in its July 1999 Advisory. The RAC commends the authors of the draft ORIA document for applying and extending the risk assessment methodology contained in the National Academy of Sciences (NAS) Biological Effects of Ionizing Radiation Committee report (BEIR VI) to produce a credible model for use by the Environmental Protection Agency (EPA) in its efforts to inform and protect the public with regard to the harmful effects of radon decay products indoors.

The RAC responses to the specific charge questions posed by ORIA are as follows:

a) Question 1: Are the methodology and overall approach for assessing risks from radon in homes adequate?

The RAC found that, in general, the EPA's methodology and overall approach for assessing risk from radon in homes is adequate. The scaled concentration (SC) model derived by ORIA is a reasonable adaptation of the models developed by the BEIR VI Committee. However, the document does not adequately describe the method and justification for the method used in deriving the SC model. These methods need to be transparent in order to be credible to the potential model users.

b) Question 2: Are the assumptions behind the calculations appropriate?

In general, the assumptions used by ORIA in the calculations are appropriate. However, ORIA's discussion regarding the effect of smoking on radon risk should be clarified. ORIA should further consider the issues of changes in smoking prevalence and the impacts of other lung carcinogens on risk.

c) Question 3: Have the limitations and uncertainties in the assessment been adequately described?

The RAC was pleased that ORIA expanded the uncertainty analysis as was recommended in the "RAC White Paper" Advisory. However, the ORIA assessment did not adequately take into account the model uncertainties. In addition, the assessment should discuss biologically based models as well as other statistical methods that could be applied to the epidemiologic data to evaluate risks.

The RAC also addressed some issues beyond the charge, related primarily to enhancing the potential usefulness of the ORIA risk assessments for a wide variety of applications. The RAC continues to urge ORIA to make the model more accessible and transparent through an expanded discussion of the derivation of the SC model. A discussion of alternative models would improve the risk assessment document.

The RAC compliments ORIA for its efforts in adapting and enhancing the BEIR VI models for use in estimating risks from radon and its decay products. This is a very complex issue and EPA's methodology is likely to receive careful scrutiny particularly since the lung cancer risk estimates derived using the SC model are approximately double the previous estimates. The ORIA document is credible and, in general, well done.

The RAC appreciates the opportunity to provide this review to you and we hope that it will be helpful. We look forward to the response of the Assistant Administrator for Air and Radiation to the comments and recommendations in this report.

Sincerely,

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Dr. Morton Lippman, Interim Chair
Science Advisory Board

Dr. Janet A. Johnson, Chair
Radiation Advisory Committee
Science Advisory Board

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ABSTRACT

Since radon is the principal contributor to effective dose to members of the general public from background radiation, the U. S. Environmental Protection Agency (EPA) has devoted substantial consideration to quantifying the risks from radon in homes. EPA has commissioned several studies to develop models and risk estimates based on epidemiologic data from underground miners.

The Office of Radiation and Indoor Air (ORIA) derived a risk model for residential exposures based on the models developed by the National Academy of Sciences (NAS) Biological Effects of Ionizing Radiation (BEIR) Committee. The Radiation Advisory Committee (RAC) of the Science Advisory Board (SAB) reviewed the EPA model and the methods of estimating lung cancer risk from exposure to radon indoors.   The RAC agrees with ORIA's methodology in general. However, ORIA did not adequately address the uncertainties in the risk estimates, in particular, model uncertainty.

The RAC recommends that ORIA address, at least qualitatively, biologically-based models and models which would result from application of alternate statistical methodology to the miner data. In addition, since a wide variety of users will apply the ORIA point risk estimates to specific situations, ORIA needs to make sure its methodology, assumptions, and the limitations of the model used are transparent. Lack of understanding of the uncertainties in the assessment could result in misuse of the risk estimates.

KEYWORDS: Cancer Risks, Indoor Radon Exposures, Radon Models, Radon Risk

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1 Did not attend the meeting of November 14-16, 1999, but participated in the review.

2 Did not attend meeting of November 14-16, 1999, due to a schedule conflict.

3 Did not attend the meeting of November 14-16, 1999, due to illness.

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1. EXECUTIVE SUMMARY

Radon is the principal contributor to effective dose to members of the general public from background radiation. Therefore, EPA has devoted substantial consideration to the subject of risk from radon in homes. EPA commissioned a study by the National Academy of Sciences (NAS) National Research Council (NRC), Biological Effects of Ionizing Radiation (BEIR) Committee which resulted in publication of the BEIR IV Report, *Health Risks of Radon and Other Internally Deposited Alpha Emitters* (NAS 1988). In 1994, the EPA asked the NAS to revisit the risk assessment for indoor radon based on an expanded analysis of data on cancer risk to uranium miners and incorporation of the information available from indoor radon epidemiologic studies. The NAS published its revised risk models in early 1999 in its BEIR VI Report, *Health Effects of Exposure to Radon* (NAS, 1999).

EPA is now revising its assessment of risks of indoor radon in light of the BEIR VI Committee Report (NAS, 1999). The EPA Office of Radiation and Indoor Air (ORIA), in an extension of BEIR VI methodology, estimated specific risk coefficients and modified the estimate of the numbers of lung cancer deaths attributable to radon in its Draft Assessment of Risk from Radon in Homes (EPA, 1999).

ORIA requested that the Radiation Advisory Committee (RAC) of the Science Advisory Board (SAB) review its methodology for estimating cancer risks from exposure to radon in homes. In March 1999, the RAC engaged in an initial advisory on this subject. Although the RAC found the methodology to be acceptable in general, the RAC Advisory, finalized in July 1999 (SAB, 1999), included recommendations for some adjustments to the ORIA methodology. ORIA responded to those recommendations in its Draft Assessment of Risks from Radon in Homes (EPA, 1999).

The RAC met in Washington DC on November 16, 17, and 18, 1999 for a review of the revised ORIA radon risk assessment methodology. A draft RAC review report was prepared at the November meeting, with a technical editing session conducted by a telephone conference on December 10, 1999. The RAC's responses to the specific charge questions from the Agency are summarized below and discussed in detail in Section 3 of this report. The RAC also addressed issues beyond the charge, as presented in Section 4.

In general, the RAC found that ORIA has produced a credible risk assessment and has responded well to the recommendations provided by the RAC in its Advisory (SAB, 1999). The Draft ORIA document is, for the most part, well-written and documented and will be useful guidance for conducting radon risk assessments.

1.1 Question #1: Are the methodology and overall approach for assessing risks from radon in homes adequate?

The RAC found that, in general, ORIA's methodology and overall approach for assessing risk from radon in homes is adequate. Two models were derived by the BEIR VI Committee, one dependent on radon decay product concentration, and one dependent on duration of exposure. The BEIR VI Committee did not select a preferred model. The RAC, in its Advisory (SAB, 1999), recommended that ORIA derive a model intermediate between the two BEIR VI models. In response to that advice, ORIA scaled the BEIR VI concentration model (SC model) to give risk estimates intermediate between the estimates based on the BEIR VI concentration and duration models. The RAC agrees that the scaled (intermediate) model, while not the only choice, is reasonable; however, the draft ORIA document is not completely clear on how the intermediate model was derived and does not fully justify its use. Although ORIA's use of the BEIR VI model as a basis for the risk assessment is reasonable, the risk assessment should also include a discussion of biologically-based models as well as other credible models which could be applied to the epidemiologic data to assess risks. These additional models should be included in the characterization of model uncertainty.

The RAC supports the decisions by ORIA to derive estimates of etiologic risk, expand the treatment of smoking prevalence by age, and delete a proposed baseline adjustment.

1.2 Question #2: Are the assumptions behind the calculations appropriate?

The RAC found that, in general, the assumptions used by ORIA in the calculations are appropriate. ORIA's discussion of the assumptions about the effect of smoking on radon risk should be clarified and ORIA should further consider the issues of changes in smoking prevalence and the impacts of other lung carcinogens on risk. ORIA should also provide more focus on the factor, K, which relates the radiation dose per unit exposure in homes to the dose per unit exposure in mines. In particular, ORIA should consider how the K factor would change under specific exposure conditions. The BEIR VI Committee assumed that the K factor is equal to 1.

1.3 Question #3: Have the limitations and uncertainties in the assessment been adequately described?

The RAC was pleased with the expansion of the uncertainty analysis from the initial treatment in the White Paper. However, the RAC is concerned that EPA limited the analysis to the more easily quantifiable uncertainties and did not provide a strong sense of the overall uncertainties, which would include model uncertainty and other unquantified uncertainties. Specifically, model uncertainty is not adequately addressed in the draft risk assessment. The RAC recommends that model uncertainty be addressed in more detail in the risk assessment document and that ORIA include a discussion of uncertainties in radon risk estimates in any document based on the risk assessment.

1.4 Issues beyond the charge

The RAC has several recommendations related to the draft risk assessment document that do not strictly apply to the three main charge questions. These recommendations, related primarily to enhancing the potential usefulness of the ORIA risk assessments for a wide variety of applications, include the following:

a) The potential use of the document by various disparate groups (e.g., state regulators, home builders, educators, and public health officials) should be taken into account;

b) risks from ^{220}Rn should be given some additional consideration in the risk assessment;

c) while the RAC recognizes that the information available for the miners is limited to mortality data, for future risk assessments ORIA should use incidence data whenever possible, consistent with EPA's treatment of chemical carcinogens;

d) in the future, ORIA should seek further opportunities to validate its radon model against observations in residential populations; and

e) the document should be expanded to render the methodology more transparent by including complete derivations of equations and explaining terms in text as well as defining them in mathematical form.

The model should be readily adaptable to populations that do not match the characteristics of the stationary U.S. population used and the assumed constant lifetime exposure inherent in deriving the average risk coefficients and etiologic fractions that appear to be the principal outputs of the current effort.

2. INTRODUCTION

Radon, through its decay products, is effectively the largest contributor of natural background radiation exposure to humans. The effective radiation dose from this source generally exceeds the limits for radiation exposure for the general public from nonbackground sources. It is appropriate that the EPA give adequate consideration to the subject of risk from radon exposure in homes. *(Note: For clarity in this report, references to radon are assumed to include its short-lived decay products.)*

The Environmental Protection Agency's (EPA) Office of Radiation and Indoor Air (ORIA) has revised its methodology for estimating cancer risks from exposure to radon in homes in accordance with the recently published National Academy of Sciences (NAS) report, *Health Effects of Exposure to Radon: BEIR VI* (NAS, 1999). At the request of ORIA, the Radiation Advisory Committee (RAC) of the Science Advisory Board (SAB) reviewed ORIA's methodology as described in its Draft *Assessment of Risks from Radon in Homes* (EPA, 1999).

In March 1999, the RAC engaged in an initial advisory regarding ORIA's methodology for assessing risks of radon in homes, based on a white paper submitted to the RAC. In this Advisory, published in July 1999 (SAB, 1999), the RAC provided guidance during the development of the risk assessment methodology.

The RAC met in Washington DC on November 16, 17, and 18, 1999 for a briefing and discussion of ORIA's radon risk assessment methodology presented in the draft *Assessment of Risks from Radon in Homes* (EPA, 1999). A draft RAC review report was prepared at the November meeting based on face-to-face discussions and incorporating written comments submitted in advance of the meeting. The draft RAC report, *Review of Assessment of Risks from Radon in Homes*, was edited and distributed to the RAC on November 23, 1999. A second draft was prepared on December 5, 1999 and distributed to the RAC M/C for their review at the technical editing teleconference of December 10, 1999.

The RAC review focused on specific questions posed by ORIA in its charge to the RAC (Section 2.2), including the appropriateness of the models and assumptions used, as well as the adequacy of the evaluation of uncertainty in the assessment of risk. The RAC also addressed issues beyond the charge in its review.

In general, the RAC found that ORIA's Draft *Assessment of Risk from Radon in Homes* (EPA, 1999) is well done and is a very useful extension of the BEIR VI Committee Report (NAS, 1999). The subject is complex, but the ORIA staff has done an excellent job in dealing with this task. The RAC notes that ORIA took into account the recommendations provided in its Advisory (SAB, 1999).

It is likely that the ORIA document will be very carefully scrutinized, thus it must have a high degree of credibility, and the methods by which the risks are derived must be transparent. ORIA's risk assessment will provide a strong basis for estimating risks in support of rulemaking and public information programs. Some issues that remain to be addressed are presented in Section 3 in response to specific questions in the charge, and in Section 4, which deals with issues beyond the charge.

2.1 Background

EPA's guidance on risks associated with radon in homes has been developed based on the risk assessment models published in two National Academy of Sciences (NAS) reports. The first, *Health Effects of Exposure to Radon and Other Internally Deposited Alpha-Emitters: BEIR IV* (NAS, 1988), developed empirical models for estimating risk from inhalation of radon and its decay products based on four sets of underground miner epidemiological data; the second, *Comparative Dosimetry of Radon in Mines and Homes* (NAS, 1991), provided modifications to the BEIR IV models to account for differences between occupational and residential exposures. A third NAS report, published in 1994, *Health Effects of Exposure to Radon: Time for Reassessment?* (NAS, 1994), reviewed the new information available and suggested that the BEIR IV assessment be revisited and updated to take into account additional miner data and the data developed from residential studies. As a consequence, the NAS published a new, EPA-sponsored report on health risks associated with residential radon exposure, *Health Effects of Exposure to Radon: BEIR VI* (NAS, 1999). EPA is revising its assessment of risks from indoor radon based on the recommendations and models in the BEIR VI Report.

2.2 Charge

The specific charge to the RAC for this review was to respond to the following questions:

a) Are the methodology and the overall approach for assessing risks from radon in homes adequate?

b) Are the assumptions behind the calculations appropriate?

c) Have the limitations and uncertainties in the assessment been adequately described?

The RAC's response to the charge and a discussion of issues beyond the charge are contained in the following sections of this report.

3. RESPONSE TO THE CHARGE

In general, ORIA has produced a credible risk assessment and has responded well to RAC comments presented in its Advisory on Assessing Risks from Indoor Radon (SAB, 1999). The draft ORIA document is, with some exceptions described in detail below, well-written and documented and will be useful guidance for conducting radon risk assessments. The RAC recognizes additional areas where the document could be improved, as explained in the responses to the specific questions in the charge.

3.1 Charge Question #1

Are the methodology and overall approach for assessing risks from radon in homes adequate?

In general, ORIA's methodology and overall approach for assessing risks from radon in homes is adequate. ORIA's risk assessment is an extension of the methodology developed by the NAS BEIR VI Committee (NAS, 1999). The extension was necessary in order to produce a document that would be useful in assessing risks from residential radon for individuals and populations.

3.1.1 Modification of the BEIR VI Model

The BEIR VI Committee proposed two models for residential radon risks: one which included an "effect-modification factor" dependent on radon decay product concentration (concentration model) and a second model with an "effect-modification factor" dependent on exposure duration (duration model). These factors account for a dose-rate effect. The BEIR VI Committee did not select a preferred model stating only that the "models were equally preferred by the Committee" (NAS, 1999). ORIA's use of a model that is intermediate between the BEIR VI concentration and duration models is responsive to the advice contained in the RAC Advisory. However, the method and justification of the method of deriving the intermediate model should be clearer. The derivation should be more explicit in the text or should be included as an appendix to the document showing more detailed calculations.

The RAC supports ORIA's selection of a scaled BEIR VI concentration (SC) model as a practical choice, given the calculational difficulties of developing a model that is free from bias imposed by the selection of cut points for concentration or duration of exposure intervals. The RAC also supports the other adjustments made to the BEIR VI concentration model to derive estimates of the etiologic risk[1] and to expand the treatment of smoking prevalence by age. In addition, the RAC supports ORIA's decision to drop its previously proposed baseline adjustment, with a recommendation

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[1] Etiologic risk, as used in this Report, is defined as the probability of dying prematurely from a radon-induced lung cancer.

that the explanation of this decision given in Appendix B be strengthened. Finally, the RAC strongly supports the estimation of etiologic fraction[2] and average years of life lost per radon-induced lung cancer death as a supplement to the estimates of lifetime risk per working level month (WLM) and the estimation of the annual number of lung cancer deaths attributable to radon in homes. All of these estimates are useful for evaluating risks to subsets of the population, such as those in a particular geographic region or with a particular pattern of exposure.

ORIA's use of age-specific smoking prevalence data is a significant improvement over the BEIR VI analysis. This modification will allow the model to be adjusted as smoking patterns change in the general population. Even a small reduction in risk, due to a decrease in smoking prevalence, could be an incentive to promote the trend.

3.1.2 Alternative Models

The BEIR VI Committee estimated lung cancer risks from radon exposures in the home using empirical regression models based on uranium miner lung cancer mortality data. However, there are reports in the most recent literature and active research in the construction and application of biologically-based cancer models. Several researchers studying radon cancer risks have specifically applied the two-stage clonal expansion model of cancer that has been shown to describe, generally, both epidemiological and experimental cancer data (Luebeck et al., 1999; Leenhouts, 1999; Moolgavkar, 1993). This model considers the effect of the carcinogen on the initiation, transformation and proliferation of cells in the multistage development of cancer. As such it allows the interpretation of data in terms of relevant biological events in the cancer process.

In applications to the Colorado uranium miners, detailed modeling has incorporated data on both smoking rates and radon exposures (Leenhouts, 1999; Moolgavkar, 1993). The fitted two-stage model showed an inverse dose-rate effect at higher doses as well as sub-multiplicative effects of smoking and radon exposure. The risks, however, differed from those obtained by BEIR VI using empirical regression descriptions of the miner cohorts. ORIA should include a discussion of the biologically-based models and especially take into account model specification in its uncertainty analysis that may actually be the greatest source of uncertainty in risk estimation.

With the publication of Federal Guidance Report No. 11 (EPA, 1988) and the prior statement signed by President Reagan and published in the Federal Register, the Federal Radiation Council (EPA/FRC) had essentially endorsed the risk assessment and radiation protection concepts of the International Commission on Radiological Protection (ICRP). However, the ICRP, in its Publication 65 (ICRP, 1993) has adopted a quite different approach in its assessment of risk from radon. The

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[2] Etiologic fraction is defined as the fraction of lung cancer deaths in the exposed population in which radon played some causative role.

ORIA document should discuss how the application of these two approaches differs in terms of the result.

Developing scientifically valid risk estimates for cancer induction via residential radon exposure is a significant undertaking. ORIA is making good progress toward developing acceptable risk estimates for lung cancer induction based on the BEIR VI models. Significant challenges still remain, especially related to evaluating alternative models in the context of their associated uncertainties. ORIA's treatment of uncertainty is discussed in detail in Section 3.3 of this report.

3.2 Charge Question #2

Are the assumptions behind the calculations appropriate?

The assumptions ORIA used in the calculations are, in general, appropriate. Obviously, the assumptions made in applying the models are crucial in determining the risks from residential radon. In some cases, specific parameter values were determined by EPA risk assessment guidance. The RAC concerns regarding some of the assumptions used in the ORIA radon risk assessment are described below.

3.2.1 Smoking and Other Exposures

As suggested in the response to the first part of the charge, assumptions about the composition of the U.S. population and its patterns of exposure are necessary to estimate overall risk coefficients and etiologic fractions. ORIA’s choices are reasonable. However, ORIA’s discussion of the assumptions about the effects of smoking on radon risk needs to be clarified. The text is not clear about the difference between the relative risks of lung cancer deaths cited for ever smokers versus never smokers (p. 36) and the relative risks cited for current smokers versus nonsmokers (p. 35). The assumptions that underlie the relative risk model are unclear, specifically, regarding exposures other than radon and tobacco smoke. Agents that could affect lung cancer risk include asbestos, heavy metals, polyaromatic hydrocarbons (PAHs), crystalline silica, and radionuclides other than radon decay products.

Recent data show that smoking rates among young people are stable or increasing. ORIA should consider how this trend might affect the comparisons among never smokers, ever smokers, former smokers, and individuals exposed to second-hand smoke. The implications of changes in smoking rates for young people could be examined on the basis of gender, similarly to the discussion on pages 13-14 of the assessment about the male ever-smoking prevalence reaching 74 percent at age 70 years, compared to 58 percent for all adult males.

3.2.2 Comparisons Between Mine and Home Environments

The variability and uncertainty in the "K" factor that is key to the risk assessment should be addressed. K adjusts the dose of alpha energy per unit exposure for miners to a projected dose to other population groups (NAS, 1999), taking into account exposure factors such as

aerosol size distribution, bronchial morphometry, depositional pattern and clearance rate, and dose-response factors such as exposure rate, age at exposure and at risk, sex, and smoking.

$$K = [Dose(home)/Exposure(home)]/[Dose(mine)/Exposure(mine)]$$

The BEIR IV Committee initially assumed that the dose per working level month (WLM) is the same for occupational and environmental settings (NAS, 1988). In 1991, the NAS published a comparative assessment of radon in homes and mines (NAS, 1991) that proposed an adjustment factor, K, of 0.7; that is, radon was presumed to be less effective in producing lung cancer in residential exposure situations than in the mine environment. This resulted in a downward revision of the EPA risk estimates derived from the BEIR IV Report. However the BEIR VI Committee reviewed the data and determined that a value of 1 for K is reasonable (NAS, 1999).

The ORIA assessment should provide more focus on the components of K. If some of the considerations do or do not apply, depending on the situation, then a more situation-specific value of K might be appropriate. For example, ORIA should consider how K would be affected if breathing rates differ for various levels of activity, based on indoor vs. outdoor work, health profile, or even altitude or climate .

3.3 Charge Question #3

Have the limitations and uncertainties in the assessment been adequately described?

The Committee applauds the expansion of the uncertainty analysis from the initial treatment in the white paper and the addition of 90% uncertainty interval estimates on the estimates of risk per WLM, etiologic fraction, and years of life lost per radon-induced (cancer) death (Table 18, page 46). However, the RAC remains concerned that ORIA has limited the analysis to the more easily quantifiable uncertainties and has not afforded the reader a good sense of the overall uncertainties that include model uncertainty and other uncertainties mentioned but not quantified.

The RAC notes several specific issues in regard to the limitations and uncertainties in ORIA's risk assessment. In particular, model uncertainties are not adequately addressed. When ORIA issues guidance documents or other information on radon risks based on the draft risk assessment, it should be sure to include an appropriate discussion of the uncertainties in the risk estimates in addition to the point central risk estimates. The choice of the SC model, although responsive to the RAC's previous recommendations, could appear arbitrary without a comprehensive discussion of the other models. The RAC recognizes that a quantitative resolution of this issue could require substantial work by ORIA. An alternative approach would be to descriptively compare models rather than perform full-blown mathematical comparisons.

3.3.1 Model Uncertainty

ORIA has done commendable work in producing risk estimates that for the first time account for changes in smoking status with age, etiologic fraction, and average years of life lost per radon-induced lung cancer death. The uncertainties associated with various data sets and the quality and biases of their sources are adequately addressed although the choice of scaled concentration (SC) is not. This is important since that model is the basis for the Monte Carlo analyses used to quantify the uncertainties in the risk determinations. Standard statistical theory can be used to assess the various uncertainties associated with parameter values and sampling variations. However, the analysis using a single model does not capture the uncertainty in our state of knowledge of the problem. In addition to an overall assessment of the combined uncertainties from various data sources, uncertainties in the choice of a model need to be addressed.

The ORIA draft document makes the case for using the SC model in lieu of a Constant Relative Risk (CRR) model or other models proposed by the BEIR VI committee to describe risks from radon in homes. The RAC Advisory on the ORIA White Paper recommended that the EPA consider developing a model that would yield point risk estimates intermediate between those derived using the concentration and duration models. The RAC based that recommendation on several factors:

a) the concentration model produced point risk estimates 40 percent higher than those estimated using the duration model;

b) the risk estimates, cited in the initial ORIA assessment were between the estimates derived using the two BEIR models; and

c) the lack of agreement in risk estimates derived using the two BEIR VI models may have been caused by the choice of arbitrary cutpoints for concentration and duration intervals that are required when using Poisson regression to fit the Excess Relative Risk (ERR) models.

While the RAC recommended that ORIA consider an “intermediate” model , the choice of which methodology to be use was left to ORIA. In response, ORIA used the geometric mean of the estimated lung cancer fatality risks per working level month (WLM) calculated from the BEIR VI models to back-calculate the exposure-response parameter value, or excess relative risk coefficient ($), for its scaled concentration(SC) model. The SC model derived by ORIA was then used to calculate point risk estimates in the assessment of risk from radon in homes.

As expected, the excess lung cancer risk estimates derived using the SC model are intermediate between those derived from the concentration and duration models of BEIR VI. Although the choice of the SC model to derive the risk estimates is reasonable, it is still arbitrary. The real risk may, in fact be much closer to that derived using one of the original BEIR VI models, or may even be outside the range of risks defined by those models. Therefore, the basis on which ORIA dismissed the reduction in

the lower bound estimate of the risk, derived using the BEIR VI CRR approach (i.e., as a consequence of sampling error), was subjective and should be further justified.

3.3.1.1 Evaluation of Model Uncertainty

Model uncertainty represents a lack of confidence that a specified model is a valid formulation of a given assessment problem (NCRP, 1996). The term model is used to indicate a functional relationship for the assessment endpoint, in this case lung cancer risk, that may be empirical (e.g., BEIR VI concentration and duration models, ORIA's SC model) or mechanistic (e.g., multiple-mutation models, genomic-instability models, multistage models, etc.)

The degree to which model uncertainties can be determined depends on the field of interest and the availability of computational models available to that discipline. Ideally, the model user should address the following issues:

a) Are the models to be used in the risk assessment applicable and appropriate? Do the models capture all of the requirements needed to assess the risk?

b) What are the ranges in the results obtained using the models? This involves performing sensitivity analyses on each model using identical parameter and input data and boundary conditions. This is not always feasible as different models may require different inputs for the same problem. Logic and transparency of choice of inputs is critical to this analysis.

c) If certain models produce extreme results, is there any evidence that these models do not properly capture the basic factors involved in the assessment? Are the models outdated?

The best method for demonstrating model uncertainty is through model validation procedures. A model invalidated by data clearly has model uncertainty. For example, a model may predict a monotonic increasing trend when reliable data demonstrate a monotonic decreasing trend. Model validation requires that data not used to develop the model be used for model validation. Such data are not always available for model testing. In the case of lung cancer risk from indoor exposures, the results of epidemiological studies, recently completed and in progress, may, to some degree, provide that data. Additional comments on model uncertainties are provided in Appendix A.2

For more information about these quantitative methods and discussion of various Monte Carlo simulation tools, ORIA can refer to NCRP Commentary No. 14, *A Guide for Uncertainty Analysis in dose and Risk Assessments Related to Environmental Contamination* (NCRP, 1996) and NCRP Report No. 126, *Uncertainties in Fatal Cancer Risk Estimates Used in Radiation Protection* (NCRP, 1997).

3.3.1.2 Specific Recommendations for ORIA

The empirical BEIR VI models from which the ORIA SC model was derived are based on data from epidemiologic studies of miners. The primary issue of whether the extrapolation of the miner data to low doses and low dose rates is appropriate, has been the subject of considerable debate and affects the credibility of ORIA's lung cancer risk estimates. In general, this extrapolation is consistent with the majority of data on residential exposure, although the negative results reported by B. Cohen (1990; 1995) have received much attention. A note in the May 1999 issue of *Health Physics* by John Goldsmith (1999), in which he discusses the confounding effects of the known correlation of cancer incidence with population density, is an important addition to this debate. Goldsmith notes that this may explain the anomalous results reported by Cohen (1990; 1995) and concludes that counties are not appropriate population units for such a study. ORIA's discussion of the data reported by Cohen (1990; 1995) should refer to the conclusions of Goldsmith (1999).

Other computer simulations and/or analytical solutions should be used when possible to evaluate the preferred model results even if it is necessary to use less rigorous methods and subjective judgement. The RAC believes that comparison to other models would lend credibility to the ORIA risk estimates derived from the SC model. ORIA should consider fitting the BEIR VI model using Cox proportional hazards methodology which does not require categorization of exposure (WLM), duration, or concentration (WL) but can use individual exposure history or cumulative exposure. The Cox model and Poisson regression would yield essentially identical results if the intervals used in the Poisson regression were sufficiently small. Alternatively, ORIA could use Poisson regression, but with different, and smaller, exposure, duration, or concentration intervals. Either of these approaches would produce excess relative risk coefficients that should result in risk estimates intermediate between those derived using the concentration and duration BEIR VI models.

The data from on-going and recently completed epidemiologic studies of lung cancer incidence and indoor radon exposures should be used to validate ORIA's models. These data may provide a measure of model uncertainty and lend credibility to the analysis.

The RAC recognizes the time resource limitations on ORIA. However, quantitative and qualitative approaches to addressing model uncertainty, such as those described above, should be considered for ORIA's future modifications to the risk assessment. Any and all information that can be used in the evaluation of uncertainty in model choice should be presented, even if in a qualitative discussion.

3.3.2 Sensitivity Analysis

We commend ORIA for its use of model sensitivity analysis. ORIA employed the sensitivity analysis to estimate model robustness by exploring the effect of parameter uncertainty and/or variability on the Monte Carlo predictions. However, though convenient and easy to use, the Monte Carlo

methods need to be carefully monitored and baselined to ensure the integrity of the results and their connection to physical reality. Uncertainty does not reside solely in the degree of ignorance about the precise value of a particular parameter but also the degree of ignorance associated with the choice of a particular model used to describe the data and make extrapolated risk predictions. Even if it is not feasible to evaluate quantitatively the combined effects of all sources of uncertainty affecting radon risk estimates, a semiquantitative or, as a last resort, a qualitative evaluation of the model choice should be presented. This would help clarify the robustness of the proposed risk assessment.

Simulation exercises that employ algorithms which use error estimation inputs (e.g., K-factor) demonstrate that several acceptable solutions can be obtained without any bearing on "reality". For example, the K-factor can be used to account for differences in risk estimates due to varying environmental conditions, but an exact uncertainty cannot be assigned to a unique K value. As the mathematical formulation is undetermined, no degree of refinement can offset this result. Key uncertainties in the estimates and models could be reduced by considering a broader range of model simulations and their consequences for extrapolating radon-induced effects to lower dose rates.

More recent and ongoing epidemiologic and experimental research (e.g., in Germany and The Netherlands) could be considered for use in the evaluation of the BEIR VI predictions. There may also be advantages in using other more mechanistic models for comparison with the SC model (i.e., biologically-based models). Some discussion of *in vitro* and related studies showing inverse dose rate effects would be appropriate. References for such a discussion include Bettega et al. (1992), Elkind (1994), Hall et al. (1991), and Scott (1997).

3.3.3 Uncertainty in Estimates of Parameter Values

Quantitative risk estimates based on extrapolated epidemiological data require measures of uncertainty. Early on in the ORIA document, readers should be warned that use of point risk estimates without considering the associated uncertainties could result in misleading risk estimates.

One of the largest measures of uncertainty involves the estimation of the cohort member's exposure to the carcinogen of interest, i.e., radon decay products. This clearly is the case with the uranium miner cohorts and should be included in any formulation of total risk estimation precision involving the use of these radon exposed workers.

3.3.4 Impact of Background Radon Exposures on Risk Estimates

As requested by the RAC in its July 1999 Advisory (SAB, 1999), ORIA included a discussion of the impact of background radon exposure on the miner-based risk estimates. The method by which ORIA quantified this impact resulted in negative values for excess risk and the discussion of the impact was less than transparent. The problem may stem from a mis-specification of the model. For example,

an exponential model might have fewer specification problems than a linear model, and describe the impact of background radon exposure on risk estimates from empirical models more realistically.

ORIA should explain the implications of the negative risk numbers obtained when the baseline (or radon equal to zero case) is subtracted. Is it merely that there are so few cases of radon-induced lung cancer at the low end of the age spectrum that the uncertainty encompassing the baseline includes negative numbers, or is there a condition for which the model is not valid? This is not simply a matter of proper derivation. A clear verbal description of why the baseline does not need to be subtracted is needed.

3.4 Model and Parameter Uncertainty

Based on these observations regarding model uncertainty and parameter uncertainties, it is important that risk predictions include the uncertainty in the choice of model used to describe the data and quantify the predictive analysis as well as the uncertainty in the epidemiologic data and parameter values. For context, the assessment might discuss briefly uncertainties surrounding other causes of lung cancer (e.g., smoking alone or asbestos) compared to the uncertainties in radon-related lung cancer risk estimates.

4. COMMENTS BEYOND THE CHARGE

The RAC offers a few comments that do not strictly apply to the three main charge questions. The RAC's concerns are related primarily to enhancing the potential usefulness of the ORIA risk assessments for a wide variety of applications.

4.1 Potential Use of the Radon Risk Assessment Document

As noted by the RAC in its Advisory, the foremost potential use of the risk assessment document may be to revise national estimates of radon risk for risk communication purposes (e.g., as in the 1992 Citizens Guide to Radon). From the assessment narrative, it appears that the uncertainties related to the choice of the risk model (i.e., concentration, duration, or an intermediate models) do not allow for more exact risk estimates at this time. Any estimate of lung cancer risk related to residential radon exposure is likely to be associated with large errors. The net result may involve bracketing a risk range as was done previously.

The RAC continues to urge ORIA to make the model more accessible and transparent to those who wish to make risk calculations for defined populations and exposure patterns. In particular, the model should be readily adaptable to populations that do not match the characteristics of the stationary U.S. population and the assumed constant lifetime exposures that are inherent in deriving the average risk coefficients and etiologic fractions that appear to be the principal outputs of the current effort.

Although the section in the document on uncertainty is essential and (as discussed in Section 3.3) needs strengthening, to some audiences it may suggest that the evidence for the carcinogenicity of radon is poorer than for other environmental factors treated as carcinogens, which is not the case. However, failure to adequately discuss uncertainties could encourage users of the document to give more weight than can be justified to central risk estimates, leading to misuse of these estimates. Perhaps some of the details of the uncertainty analysis could be moved to an appendix, with the uncertainty section focusing on the overall reliability of the risk estimates.

While the purpose of ORIA's risk assessment document is to provide a scientific basis for policy decisions, the audience has to be very carefully considered. The types of audiences that are likely to use the document include:

a) radon testers and mitigators, as a tool to communicate risk to their clients,

b) real estate agents / attorneys involved in the sale of a home,

c) physicians,

d) public health officials, in setting priorities for their agencies,

e) federal and state regulators, in setting NEPPS goals,

f) Department of Energy, in determining appropriate clean-up levels for contaminated sites,

g) lawyers in dealing with compensation claims for uranium miners,

h) regulators, in setting Multimedia Mitigation (MMM) Program priorities to comply with the radon in water alternate maximum contaminant limit (AMCL), and

i) tobacco companies, to demonstrate that their stand alone product is safe for use.

ORIA should also consider how these audiences may misinterpret the document and what advice it can give these users about the model, its strengths and its limitations, and what would be a fair use of the model. This goes beyond uncertainty or sensitivity to what the model represents and how accurately it can be assumed to represent risks. ORIA should also consider how the model users can help improve the model, perhaps by data gathering and reporting. Although not necessarily a part of the ORIA mandate, the Agency should be encouraged to consider developing models that are user friendly and readily available, via the internet, to potential users in the field as well as in the general public.

It is difficult to know what decisions might be made differently at the state level based on the results of the assessment. For example, if EPA eventually develops a different basis for setting cleanup levels for radium in soils (p.2) using indoor radon risk pathways, numerous uranium-related soil cleanup decisions will be affected.

Some states have a constituency of concerned uranium miners. With the Senate Judiciary Committee having approved a bill to expand the Radiation Exposure Compensation Act to include uranium millers, there may be increased interest in affected areas in how EPA is comparing miner/miller risk to residential radon risk. This reinforces the RAC's suggestion in its Advisory that ORIA be clear about how the final risk model relates to situation-specific mixes of sex, age, and smoking behavior.

Some of the assumptions should be refined as new information becomes available from 2000 census data, from new smoking prevalence data, or from published indoor radon studies currently near completion. Rather than present a static model, ORIA should consider how the model can be modified or adapted to take advantage of the emergence of new data regarding factors such as equilibrium fractions or the impacts of radon mitigation in homes.

4.2 Consideration of ^{220}Rn

Nearly all of the draft ORIA document is devoted to ^{222}Rn with ^{220}Rn mentioned only briefly. Given the widespread distribution of ^{232}Th and its decay products and their substantially high concentrations in some locations, it would seem appropriate to devote some discussion to ^{220}Rn. The RAC recognizes that there are fewer available measurements and there are essentially no epidemiological studies of exposure to ^{220}Rn, however, it would be useful to summarize the existing information and to discuss, at least qualitatively, the potential risk from ^{220}Rn.

In justifying the exclusion of ^{220}Rn from consideration in its risk assessment, ORIA states that "...a lower fraction of the released alpha particle energy is absorbed within target cells in the bronchial epithelium than in the case of radon-222." While this statement, and a similar one made in ICRP Publication No. 50 (ICRP, 1987), may well be true, the reason is not obvious. ORIA should, at a minimum, consider a more comprehensive discussion of ^{220}Rn risks.

4.3 Use of Incidence Versus Mortality Data

There would be less uncertainty in the models and the derived risk estimates if lung cancer incidence data could be used in the analysis rather than lung cancer mortality. In general, a diagnosis of lung cancer (incidence) is more accurately counted than a lung cancer death that the death certificate might attribute to contributing factors rather than lung cancer. The EPA evaluates the risks for nearly all other environmental factors based on the incidence of adverse health effects rather than mortality. The RAC recognizes that the epidemiologic data available on the underground miners is limited to lung cancer mortality; thus estimation of radon risk in terms of lung cancer incidence, based on the miner data, is not practical. However, for future assessments where both incidence and mortality data are available, the RAC strongly supports use of incidence data in developing radiation risk estimates.

4.4 Validation of Radon Risk Models

The Committee notes that disagreements persist about the degree to which model extrapolations from observations in miners have been, or even can be, validated by comparison with available data on residential radon exposures and risks. Although ORIA should not be expected to resolve this issue in the current assessment, it should aggressively seek opportunities for model validation in the future. Otherwise, controversy among scientists will continue and public confidence in the models will suffer.

4.5 Exposition

Although the exposition is for the most part quite clear to those familiar with the radon risk literature, and although ORIA has added less technical text to help readers who are not experts, the Committee found several specific areas in which improvements in exposition would be valuable. The more important ones follow.

4.5.1 Derivation of Equations

A major concern with the ORIA draft risk assessment document is the difficulty in following the calculations. In several cases, the derivations are not included in the report. For example, the equations used to calculate the etiologic fraction and the average years of lost life expectancy per radon-induced lung cancer death are based on a quantity, *S'(a)*, which is defined somewhat ambiguously as the survival function adjusted for an incremental increase in radon exposure. No equations for calculating *S'(a)* are included. As a result, it is difficult to determine whether the methodology is reasonable. The adjustment in the survival function should be more clearly explained and the method of adjustment described either in the text or in an appendix.

The equation for determining the lung cancer death rates for never smokers is given without a derivation (page 13). The illustrations given (page 14) are also confusing in that a parameter value obtained in the first calculation is rounded to 2 significant figures but expressed using 3 significant figures in the second calculation:

0.00052= 0.0044/[0.42 + 14(0.58)]
0.0072 = 14 x **0.000515**

Adding to the confusion, is a typographical error in the second set of calculations: 0.00414 should be 0.000414.

In addition to including derivations of the equations in an appendix, all notation in the text should be defined in English as well as in mathematical form. For example:

w* = effective cumulative exposure
$* = effective dose response (or effective excess risk/WLM)

The ORIA risk assessment document will be read and critiqued by a large number of individuals with varying levels of experience with radon risk calculations and epidemiology. The methodology used must be transparent in order to minimize unwarranted criticism. It was helpful to include the derivation of the equations used in determining that the exclusion of miners' residential exposures would not significantly affect the calculated risks for indoor radon (Appendix B); however, even in this case, several steps were omitted in the derivation making it difficult to follow. The appendices should be expanded to include derivations of all unique equations used in the risk assessment. It will not be necessary to include derivations of equations obtained from BEIR VI; however, the methodology for adjusting the BEIR VI concentration model should be explicitly described in an appendix.

4.5.2 Specific Text Concerns

Specific substantive concerns with the text are given below.

Page 7, second paragraph under IVA: The inverse dose rate effect will seem counterintuitive to many people not familiar with the literature. Some discussion of mechanisms that might lead to such a behavior would be valuable.

Page 11, third paragraph: This draft continues to note the "biological implausibility" of the Cohen study. Although probably in the minority, a substantial number of credible scientists do not share this view. Moreover, no explanation is given for the speculation that radon levels might be inversely correlated with smoking, and it is certainly not an intuitively compelling conclusion. Although the meta-analysis of case-control studies does provide support for the extrapolation from the miner studies, it too can be criticized, and more explanation is required on why ORIA assigns essentially zero probability to the threshold/hormesis hypothesis.

The BEIR VI models are based on a linear-multiplicative relationship between radon exposure and risk with no threshold. That is, the risk per unit exposure is constant within specific smoking, exposure, and age categories, with a multiplier used to adjust risk among categories. However, the BEIR VI Committee also noted that "alternative exposure-risk relations, including relations with a threshold, may be operative at the lowest exposures" (NAS, 1999). The potential for a threshold for radon-induced lung cancer should be discussed in the ORIA uncertainty analysis.

Page 42, end of Section 1: The nominal value for the average residential radon concentration and the mean value for its distribution are different. ORIA should, at a minimum, better explain this difference and perhaps rethink its decision. The same is true for some of the other quantified uncertainties.

Page 50, Section 4: Because all of ORIA's quantitative estimates are for lifetime exposure to a constant concentration, it seems inappropriate to refer to the uncertainty due to age at first exposure. Moreover, even if ORIA is intending for the uncertainty to apply to age-specific risk estimates, if the Chinese tin miners showed a factor of two difference between children and adults, perhaps the median should be adjusted downward before applying a distribution with geometric standard deviation (gsd) of 2.

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APPENDIX A - EDITORIAL AND TECHNICAL COMMENTS

A.1 General Comments:

a. Should Systeme Internationale (SI) units be used? The risk coefficients given in Federal Guidance Report No. 13 (FGR-13) are in SI units. There are only a few places where traditional units would be appropriate, e.g., where reference is made to BEIR VI, it would be necessary to use pCi L^{-1}. Radon decay product concentrations are commonly expressed in units of working levels (WL) in the U.S. In the rest of the world, the quantity is potential alpha energy concentration (PAEC) expressed in joules per m^3 (J m^{-3}) of air.

b. Use negative exponents, e.g., Bq $^{-3}$ instead of Bq/m^3.

c. Should first person, which is used only seldom, be replaced by third person?

d. In the entire document there is no consistency concerning when an acronym is defined and then used, e.g., ever smoking (ES). Once it is defined the acronym should be used consistently.

e. Radon decay products should be referred to consistently throughout the document, i.e., either radon decay products (RDP), radon daughters, or radon progeny. Using these three terms interchangeably could cause confusion, particularly for individuals who have only a small degree of expertise in this field. The consistent use of the term radon decay products is preferred.

f. The term working level (WL) is defined as the concentration of radon decay products in air. It is not a unit of exposure rate. It only becomes a measure of exposure rate when the conditions of exposure are specified. Table 3 on page 8 was taken directly from Table A-4 of BEIR VI which does express exposure rate as WL. However, at the very least, Table 3 in the EPA risk document should include an explanatory footnote acknowledging that WL is not a **unit** of exposure rate, but under a specific condition, such as residential exposure, WL is a **measure** of exposure rate.

g. Equations should be numbered throughout the text as they are up to page 13.

h. Some of age axes of graphs extend to 100 y and some to 120 y. It would be desirable to be consistent to facilitate comparisons.

i. The axes in Figures 2 through 7 are hard to see. They should be redrawn.

A.2 Specific Comments on Model Uncertainty

Rarely, if ever, can alternative empirical models be considered to represent "true" models (NCRP, 1996). However, if among the alternative empirical models there is a preferred model (e.g., BEIR VI CM or ORIA SC model), then expert-based correction terms can be used on the model

output, thereby modifying the output to account for model uncertainty subjectively (NCRP, 1996). The quantification of the state of knowledge of the correction terms may be a function of the model output or its input. Generally, the set of alternative models is only an approximate characterization of the state of knowledge, since the selected set is only a small subset of the full set of all possible alternative models. However, no one ever attempts to find a full set of all possible alternatives for epidemiological models. One lifetime may be insufficient for such an adventure.

Occasionally, uncertainties about model structure are combined with uncertainties about model parameters. In such cases, two approaches can be used (NCRP, 1996).

1) In cases where the model uncertainty is not assumed to be the dominant uncertainty, the subjective probability distributions that are specified for the uncertain parameters can be modified by expert judgement and made sufficiently wide to include the effects of model uncertainty. When model uncertainty is dominant, it would be difficult to contain it within the uncertainty assigned to model parameters. An example of a case where the model uncertainty was not the dominant factor is described in the National Council on Radiation Protection and Measurements (NCRP) Report 126 (NCRP, 1997). For low doses of low-LET radiation, the uncertainty range for the dose and dose rate effectiveness factor (DDREF) was expanded to account (subjectively) for model uncertainty. The expanded uncertainty range was intended to account for all reasonable linear and sublinear models for atomic bomb survivor data. A threshold model was ruled out based on the data.

2) Subjective probability distributions that quantify uncertainty in model output can be obtained via expert judgement. These distributions can then be used to adjust the distribution for model parameters through model fitting procedures (Cooke and Vogt, 1990; NCRP 1996). In the past, this approach has been limited to relatively simple models (NCRP, 1996).

APPENDIX B - ACRONYMS

AMCL	Alternate Maximum Contamination Limit
BEIR IV	Biological Effects of Ionizing Radiation Committee Report IV, *Health Risks of Radon and other Internally Deposited Alpha-Emitters*
BEIR VI	Biological Effects of Ionizing Radiation Committee Report VI, *Health Effects of Exposure to Radon*
Bq	Becquerel [The special name for the SI (Systeme Internationale of units) unit of radioactivity (1 Bq = 1 disintegration per second)]
$*	Effective Dose Response (or effective excess risk/WLM)
Ci	Curies [Nuclear transformations (disintegrations). The special unit of activity: One curie equals $3.7X10^{10}$ disintegrations per second.]
CRR	Constant Relative Risk (model)
EPA	Environmental Protection Agency (U.S. EPA, or EPA)
ERAMS	Environmental Radiation Ambient Monitoring System
ERR	Excess Relative Risk
ES	Ever Smoker
FGR	Federal Guidance Report
GSD	Geometric Standard Deviation
ICRP	International Commission on Radiological Protection
K	The factor which relates the dose per unit exposure in homes to the dose per unit exposure in mines (BEIR VI assumed that the K factor is equal to 1)
L	Liter
m	Meter
m^3	Cubic Meter
MMM	Multimedia Mitigation Program

NAS	National Academy of Sciences
NEPPS	National Environmental Performance Partnership System
NRC	National Research Council
NS	Never Smoker
ORIA	Office of Radiation and Indoor Air (U.S. EPA/ORIA)
PAEC	Potential Alpha Energy Concentration (expressed on joules per m^3 of air)
p	pico [10^{-12}] in combination with specific units (e.g., pCi L^{-1} Pico Curie per Liter)
PAHs	Polynuclear Aeromatic Hydrocarbons
RAC	Radiation Advisory Committee (U.S. EPA/SAB/RAC)
RDP	Radon Decay Products
Rn	Radon, as an element, or as an isotope (e.g., ^{219}Rn, ^{220}Rn, ^{222}Rn)
SC	Scaled Concentration (Model)
SAB	Science Advisory Board (U.S. EPA/SAB)
SI	Systeme Internationale Units
Th	Thorium, as an element or as an isotope (e.g., ^{228}Th, ^{230}Th, ^{232}Th, ^{234}Th)
w*	Effective Cumulative Exposure
W	Exposures (expressed as W_1 and W_2, etc.)
WL	Working Level (radon decay product concentration)
WLM	Working Level Month (radon decay product exposure)