



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

August 17, 1984

OFFICE OF
THE ADMINISTRATOR

Honorable William D. Ruckelshaus
Administrator
U.S. Environmental Protection Agency
401 M Street, SW
Washington, D.C. 20460

Dear Mr. Ruckelshaus:

We are pleased to transmit to you the final "Report on the Scientific Basis of EPA's Proposed National Emission Standards for Hazardous Air Pollutants for Radionuclides." This report was prepared, in response to your request of December 6, 1983, by a Subcommittee of the Science Advisory Board (SAB). The report was reviewed and approved by the Board's Executive Committee.

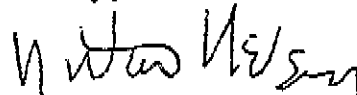
The Subcommittee concluded that the Office of Radiation Programs (ORP) has generally gathered the appropriate scientific information in a technically proficient manner for individual elements of an assessment of the risk of airborne radionuclides. However, the Subcommittee concluded that ORP has not assembled and integrated this information in the format of a risk assessment that provides a scientifically adequate basis for regulatory decisions on airborne radionuclides. On the other hand, the Subcommittee recognizes that the factors EPA must consider in the rulemaking process go beyond the scope of this review. Neither EPA nor the public should interpret these conclusions as representing a Subcommittee position in favor of or against the proposed radionuclide standards. The charge to the Subcommittee did not include consideration of the appropriateness of the standard. It strived to avoid such a consideration and focused, as you requested, on the scientific bases and procedures underlying the standard.

The report contains six recommendations which are directed toward enhancing the Agency's handling of radiation issues; two of them are highlighted here. It recommended preparation of an integrated risk assessment for airborne radioactivity as a basis for making any further risk management decisions on the airborne radionuclide emissions standard, including promulgation of a final standard. It also recommended the formation of a standing committee on radiation within the SAB, an action you endorsed at the last SAB Executive Committee meeting.

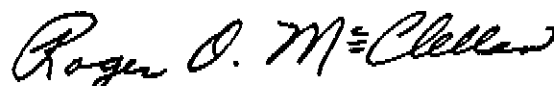
Preparation of this report on a very complex issue in a short time period required substantial effort and cooperation from many individuals. We take this opportunity to acknowledge the input of the many Agency personnel who contributed to the review process. It was a pleasure to interact with a number of individuals who demonstrated a high level of professional competence on radiation issues.

The Board and Subcommittee will be pleased to carry out any further review of this issue that you may request. We would appreciate receiving a formal response from the Agency on the recommendations and advice contained in the report.

Sincerely,



Norton Nelson, Chairman
Executive Committee



Roger O. McClellan, Chairman
Subcommittee on Risk Assessment
for Radionuclides

Enclosure

REPORT ON THE SCIENTIFIC BASIS OF
EPA'S PROPOSED NATIONAL EMISSION STANDARDS
FOR HAZARDOUS AIR POLLUTANTS FOR RADIONUCLIDES

SUBCOMMITTEE ON RISK ASSESSMENT FOR RADIONUCLIDES
SCIENCE ADVISORY BOARD
U.S. ENVIRONMENTAL PROTECTION AGENCY

AUGUST 1984

NOTICE

This report has been written as part of the activities of the Environmental Protection Agency's Congressionally established Science Advisory Board, a public group providing advice on scientific issues. The Board is structured to provide a balanced, independent, expert assessment of scientific issues it reviews, and hence, the contents of this report do not necessarily represent the views and policies of the Environmental Protection Agency nor of other agencies in the Executive Branch of the Federal government.

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I. EXECUTIVE SUMMARY

At the request of Administrator William D. Ruckelshaus, the EPA's Science Advisory Board (SAB) formed a Subcommittee on Risk Assessment for Radionuclides which has reviewed the methodology used by the Office of Radiation Programs (ORP) in assessing human health risks from airborne releases of radionuclides. In a distilled form, the Subcommittee's activities can be viewed as addressing two interrelated questions. First, did the Agency's staff collect the scientifically relevant data and use scientifically defensible approaches in modeling the transport of radionuclides through the environment from airborne releases, in calculating the doses received by persons inhaling or ingesting this radioactivity, and in estimating the potential cancer and genetic risks of the calculated doses? Second, are the individual facts, calculational operations, scientific judgments and estimates of uncertainty documented and integrated in a clear and logical manner to provide a risk assessment that can be used as a scientific basis for risk management purposes, i.e. standards setting?

With regard to the first question, the Subcommittee concludes that ORP has generally gathered the appropriate scientific information in a technically proficient manner for individual elements of a risk assessment. With regard to the second question, the Subcommittee concludes that ORP has not assembled and integrated this information in the format of a risk assessment that provides a scientifically adequate basis for regulatory decisions on airborne radionuclides. Neither EPA nor the public should interpret these conclusions as representing a Subcommittee position in favor of or against the proposed radionuclides standards. The charge to the Subcommittee did not include consideration of the appropriateness of the proposed levels in EPA's radionuclides emission standards, presumably because the standards embody not only risk assessment considerations but also risk management factors such as the legislative mandate and the cost of control technology to reduce emissions.

The document which most nearly represents such a risk assessment, but still stops far short, is the proposed rule for "National Emission Standards for Hazardous Air Pollutants: Standards for Radionuclides, "Federal Register Vol. 48, No. 67, April 6, 1983, pp. 15076-15091. The proposed rule is enclosed as Appendix C. By its very nature as a proposed standard, this document includes an interweaving of scientific facts and interpretation, economic considerations, and social and political value judgments. A second document, entitled the "Background Information Document; Proposed Standards for Radionuclides," EPA 520/1-83-001 is a useful supplement to the Federal Register notice. However, even when the proposed standards and the background document are considered together, they are not sufficiently complete nor organized to serve as a scientifically adequate statement of the health risks from emissions of radionuclides. Because of this deficiency, public debate on the scientific underpinnings of the standard has been blurred with discussion of social, economic and political considerations. Unfortunately, this blurring makes it difficult to reach agreement or effect changes even when they exclusively involve scientific issues.

For comparison with other scientific activities of the Agency, it is useful to consider the process used in developing National Ambient Air Quality Standards (NAAQS). In that process, it has been found appropriate to include preparation and Science Advisory Board (specifically, the Clean Air Scientific Advisory Committee) review of both a criteria document and a staff position paper. The position paper serves an intermediate step between the criteria document and the risk management functions of setting NAAQS. The staff paper has served to sharpen the analysis and presentation of the scientific basis of the standards.

The concept of a staff position paper is readily transferable to assessing radiation risks and to defining the use of scientific concepts and data for purposes of developing emission standards for radionuclides. Such a staff position paper should include the conceptual framework for assessing radiation risks starting with identifying sources of radionuclide emissions, analyzing the movement of radionuclides from a source through environmental pathways, calculating doses received by individuals or populations, estimating genetic and somatic health effects, and presenting a statement of uncertainty in the risk estimates. This uncertainty should be expressed as central estimates with lower and upper bounds for cancer and genetic endpoints. These estimates should then be compared to available information on incidence of cancer and genetic risks in the population that EPA attributes from other well-recognized environmental, social and occupational factors. It might also be appropriate for this position paper or a complementary document to identify various potential levels of a standard(s), noting for each level if compliance could be established by direct measurements or only indirectly by modeling. A presentation of this type would provide the scientific input needed by the risk manager to arrive at a reasonable and scientifically defensible standard(s).

In the case of the current proposed emissions standards for airborne radionuclides, a staff position paper was not prepared and the Subcommittee is uncertain as to how and to what extent the scientific data base was used to set the standard. It is also apparent that neither the scientific community in general nor the Science Advisory Board was asked to review thoroughly ORP's use of scientific data in early stages of the radionuclide standards development process.

To improve the scientific basis for regulatory decisions on radiation issues, the Subcommittee recommends a number of actions. These include:

- 1) that procedures be established to delineate more clearly the risk assessment and risk management aspects of the total radiation standards development process.
- 2) that for each regulatory action considered, the risk assessment process includes development of a risk assessment document which makes reference, as appropriate, to more detailed analyses found in the scientific literature.
- 3) that such a risk assessment document be prepared for airborne radioactivity as a basis for making any further risk management decisions on the airborne radionuclides emission standards, including promulgation of final standard(s).
- 4) that a standing committee be created as a part of the EPA Science Advisory Board to review risk assessments for radiation standards and to provide advice on the full range of scientific activities of the Office of Radiation Programs.
- 5) that procedures be developed for soliciting and receiving public comment and SAB review on radiation risk assessments before proposed standards are developed.
- 6) that steps be taken to enhance communication between the Office of Radiation Programs and other staff offices of the Agency and the scientific community on issues related to risk assessment.

The first five recommendations are consistent with procedures used by a number of offices within the Agency for assessing risks from other types of pollution and soliciting SAB and public input. The sixth recommendation is designed to ensure that maximum advantage is taken of the diverse kinds of expertise and experience that exist in the Agency and the scientific community which can be brought to bear on ORP activities. This recommendation is also developed to ensure that the expertise of ORP personnel can have a favorable impact on other offices within the Agency that prepare risk assessments in support of regulatory decisions.

II. INTRODUCTION

This is the final report of the EPA Science Advisory Board's Subcommittee on Risk Assessment for Radionuclides. The Subcommittee was established by the SAB Executive Committee on December 9, 1983, in response to an official request from Administrator William D. Ruckelshaus on December 6, 1983. The membership of the Subcommittee is presented in Appendix A.

The charge to the Subcommittee, as stated by Administrator Ruckelshaus, is to 1) "review the scientific basis of the risk assessments used to develop standards for protection from radionuclides in the environment." The Subcommittee interprets this activity as applying specifically to those source categories subject to EPA's rulemaking carried out under the authority of Section 112 of the Clean Air Act. 2) The Administrator also requested the Subcommittee to "critically review the process by which the Agency estimates human cancer and genetic risk due to radionuclides in the environment ... [including] examination of the methods used to estimate the transport of radionuclides in the environment due to emissions into air, the organ doses received by persons inhaling or ingesting this radioactivity, and finally, the cancer and genetic risks due to these organ doses." The objective of the review is to determine whether EPA "has proceeded in a reasonable and scientifically sound way" in developing risk estimates for radionuclides. A set of ten questions prepared by the Office of Radiation Programs accompanied the Administrator's request. A list of the questions and Mr. Ruckelshaus' letter are included in Appendix B.

A. Risk Assessment as a Basis for Regulatory Decision Making

The compilation and assessment of scientific data by regulatory agencies for the purpose of developing standards for the control of emissions from various source

categories to reduce human and environmental risk is a subject that has generated a great deal of discussion. Many proposals have evolved on how to present scientific data for use by policymakers in carrying out statutory mandates. Two recent attempts to define a framework for compiling and assessing scientific data in the rulemaking process were those articulated by the National Research Council in its March 1983 report entitled Risk Assessment in the Federal Government: Managing the Process,^{1*} and by EPA Administrator Ruckelshaus in speeches to the National Academy of Sciences in June 1983² and to the Alumni Society of Princeton University in March 1984.³

A common theme of these efforts is the need to separate issues related to the assessment of risk from those associated with the expression of social, economic, and political values which determine strategies for managing risk. An example of this distinction is the following: a technical assessment of the human health risk from radionuclides would address such issues as the relationships involving movement of radionuclides from a source through environmental pathways to a dose received by human populations to an estimation of the probability of a health effect occurring. This part of the process would also include a comparison of the calculated risks from other environmental, occupational and societal factors. A policy decision on how to manage the calculated risk would use the findings of this assessment effort in connection with a definition of acceptable risk (as established by the statute or by other means), consider the available methods of reducing exposures through, for example, control technologies and economic incentives, and compute the costs to society of regulating at various levels of residual risk.

As a general framework, the Subcommittee endorses the distinction between the scientific practice of assessing risk and the socio-political task of

*References in this report can be found in Appendix E.

choosing among regulatory options to manage risk. However, as the Subcommittee proceeded through its review of the ORP's documentation for assessing risks from radionuclide sources, it was obvious that the risk assessment/risk management framework is more of a continuum than a dichotomy.

This continuum exists for the airborne radionuclides rulemaking for at least five reasons. One is that the risk assessment phase of the regulatory process is not value free. This is the case because the facts required to develop a risk assessment are rarely incontrovertible. Thus, value judgments, albeit scientific, must be made as to which facts should be used in the risk assessment. Second, EPA does not currently have a program-specific, operational definition of the distinction between risk assessment and risk management. As a result, it is not clear that standardized terms of reference have been applied or that consistency of approach has been realized. Third, in the process of risk assessment, many assumptions must be made. Scientists may be swayed in their choice of assumptions by their underlying regulatory philosophy. The choice of a linear non-threshold dose-response relationship compared to a linear quadratic or other relationships is a good case in point. As evidenced by the National Academy of Science's third report on Biological Effects of Ionizing Radiation (BEIR III), knowledgeable scientists disagree on which dose-response relationship is best. Some of them favor the linear non-threshold relationship primarily because, in an area of uncertainty, they would prefer to choose the approach which yielded the higher calculations of risk. Others hold the opposite view.⁴ Fourth, and most importantly, the format in which the Subcommittee was asked to evaluate radionuclide risks commingled the risk assessment and risk management phases. At the time the Subcommittee was asked to begin its review of the scientific data base, the formal rule had already been proposed in the Federal Register on April 6, 1983.

This meant that the Agency had already completed its evaluation of human health risks from airborne radionuclides and had reached a tentative social/policy judgment on the amount of risk that was publicly acceptable. The Subcommittee was asked to separate and then evaluate, ex post facto, the technical basis and adequacy of risk assessment without commenting on the appropriateness of the social/policy decision. For reasons that are discussed in the body of the report, this is not an effective way to involve the Science Advisory Board nor the scientific community in EPA's rulemaking process. Finally, it should be noted that individual scientists are also citizens. Some scientists seek to express themselves not only on the objectives of science policy but also on public policy goals. When formulating judgments in regard to policy issues these scientists are frequently assisted by their knowledge of technical facts such as atmospheric emissions and their transport and the relative significance of radionuclide effects within the entire complex of environmental influences on the public health. The Subcommittee as a whole chose not to express an opinion on the policy objectives for this rulemaking activity. Individual Subcommittee members are, of course, free to provide their opinions on this issue and may choose to do so by other means.

B. Subcommittee Review Procedure

The Subcommittee held four meetings, three of them public, for a total of seven days. The fourth meeting consisted of a writing session which included Subcommittee members and no EPA staff except the Director of the Science Advisory Board. The Subcommittee evaluated past studies on radionuclides, and it reviewed a number of documents submitted by both the ORP and representatives of the public. Extensive briefings were provided by Agency staff on a number of issues including the mathematical procedures utilized for calculating environmental concentrations and dose to humans from airborne releases of radionuclides, the scientific

literature reviewed and/or developed by ORP staff, estimates of cancer deaths and genetic risks from radionuclide exposures, technical briefings provided to senior EPA decision-makers, and case studies of two source categories--the elemental phosphorus plant in Pocatello, Idaho, and the Y-12 facility at Oak Ridge National Laboratory--to illustrate the application of the methodology. The briefings were extremely helpful in enabling the Subcommittee to understand the technical issues under consideration and ORP's approach toward risk assessment. Agency staff were particularly cooperative in responding to the Subcommittee's questions and its requests for information. A list of Subcommittee meetings, briefings and public presentations is included in Appendix D.

C. Major Issues Addressed by the Subcommittee

As noted previously, the Office of Radiation Programs submitted ten questions for the Subcommittee's review. In general, the questions capture many of the components of the scientific analysis needed in a risk assessment, but they alone do not constitute a risk assessment. Therefore, this report includes not only the Subcommittee's response to ORP's questions, but it also presents the panel's judgment on the adequacy of the overall process utilized by ORP in evaluating scientific data and developing a risk assessment for this rulemaking activity.

A key assumption made by the Subcommittee throughout its review was the belief that EPA's risk management decisions should be based on the scientific evaluation by the ORP staff of the probable risk that would result from exposure to airborne radionuclides. Difficult as this assessment may be, it is believed to be

preferable to alternatives such as use of an ALARA* approach where the recommended standard is determined by the minimum exposure that may be reasonably achieved. It is the opinion of some, but not the majority of Subcommittee members that the ALARA concept should be vigorously applied as part of a strategy to minimize exposure and risk. However, the use of such a strategy must not be substituted for development of an integrated risk assessment that can be used as the cornerstone of development of the standards.

D. Outline of this Report

The body of this report consists of two major sections. Section III evaluates the approach employed by the Office of Radiation Programs in assessing human health risks from airborne radionuclides. The Subcommittee identifies the individual elements of a risk assessment for radionuclides, discusses the strengths and weaknesses of the ORP approach, evaluates the process for preparing health risk assessments for hazardous air pollutants within ORP compared with other EPA staff offices, and presents its key findings. The major conclusions and recommendations of the Subcommittee are presented in Section IV. These address the need for a scientific issues staff paper to identify and synthesize the scientific data base for an integrated health risk assessment used for standards development; establishment of a continuing scientific oversight mechanism to review ORP scientific activities, including the development of risk assessments for radiation standards; enhanced coordination

*ALARA is an acronym for As Low As Reasonably Achievable. It is a concept that is an outgrowth of the hypothesis that there is no threshold for the carcinogenic or genetic effects of ionizing radiation and that any dose, however small, increases the probability of such effects, which becomes small as the dose approaches the natural radiation background. An inherent problem with the ALARA concept lies in the subjectivity of the word "reasonably." No EPA policy has been formulated to define the word "reasonably" in this context. In this connection, the panel noted early in its deliberations, that the health impacts from radioactive emissions currently being discharged from all the U.S. facilities (other than coal-fired boilers) covered in the Background Information Document EPA 520/1-83-001 were calculated to be much less than one cancer per year for the entire country. This estimate should assist policy makers to judge whether ALARA is currently being achieved, and may also assist in deciding the relative priority that concerns about radioactive emissions should receive, relative to other matters that must be dealt with by EPA.

of risk assessment efforts between ORP and other offices within EPA, and some major research needs. An Executive Summary of the Subcommittee's major conclusions and recommendations is provided in Section I.

III. EVALUATION OF OFFICE OF RADIATION PROGRAMS APPROACH TO RISK ASSESSMENT FOR RADIONUCLIDES

A scientifically defensible risk assessment for radionuclides should address at least five major elements. These include 1) identification of the significant man-made or technologically enhanced sources of radionuclides; 2) a description of the movement of radionuclides from a source through environmental pathways to people; 3) calculation of the doses received by people; 4) estimation of genetic or somatic health effects; and 5) incorporation of estimates of uncertainty into elements 1-4 thereby enabling development of upper, central and lower estimates of health risks, for releases of small quantities of radionuclides. It is important that the uncertainty associated with the risk estimates consider all elements of the relationship from sources--> transport --> dose --> effects and not concentrate excessively on the relationship between dose and effects. It is quite likely that the scientific uncertainty associated with the relationship of sources --> transport --> dose are greater than those associated with the relationship between dose and effect.

The Subcommittee has evaluated the ORP approach to risk assessment for radionuclides using this conceptual framework presented above. Within each element of this framework, a statement of the strengths and weakness of ORP's efforts are presented. In addition, responses to the ten ORP questions listed in Appendix B are given in the following section of the report.

A. SUBCOMMITTEE EVALUATION OF INDIVIDUAL ELEMENTS OF A RISK ASSESSMENT FOR RADIONUCLIDES

1. Source term assessment

The identification of sources that are significant emitters of airborne radionuclides, and an estimation of the quantities of such emissions, is a major input parameter in the process of calculating probable human health effects.

To understand better how ORP assessed radionuclide emission sources and the relationship between airborne releases and human exposures, the Subcommittee requested briefings on specific source categories. Two briefings were presented. The first was for the Y-12 nuclear weapons facility at Oak Ridge National Laboratory and the other was for an elemental phosphorus plant in Pocatello, Idaho. The briefings aided the Subcommittee in understanding how ORP applied its AIRDOS-EPA air dispersion model to estimate radionuclide concentrations in the neighborhood of a source and dose rates to a population within a larger region. The release values for the Y-12 facility were provided to the EPA by the Department of Energy. Detailed information was not submitted as to how the release values were established nor their validity for projecting future releases. For the Pocatello site both site-specific monitoring data and calculated release values were available. Although the measured and estimated values were not in perfect agreement, the fact that they were within a factor of two to three did provide for greater confidence in the values than the case where only estimates were available. The Subcommittee concluded that ORP presented a clear statement of this element of the risk assessment chain. However, the Subcommittee felt there was a continuing need to further validate estimates when site specific data are not available and to establish the utility of data on past releases as predictors of future releases.

2. Dispersion and environmental transport models : source to individuals

ORP Question 9: Are the air dispersion models reasonable to estimate radionuclides concentrations 1) in the neighborhood of a source, and 2) to regional populations?

The basic model used by EPA for calculating the air dispersion of radionuclides is AIRDOS-EPA. This computer code includes a conventional, state-of-the art air dispersion model, developed for ORP by the Oak Ridge National Laboratory. It

incorporates standard meteorological observations together with parameters derived from the existing body of experimental atmospheric diffusion data by means of the widely accepted Gaussian plume assumption. It is a flexible, modular, and highly parameterized model, capable of addressing a wide range of air dispersion problems, from radionuclide concentrations in the neighborhood of a source to regional population exposures at greater distances. Details of the modeling methodology can be found in the handbooks by Turner⁵ Hanna, et al.,⁶ and in a brief summary by Gifford.⁷

The performance of AIRDOS-EPA in estimating air concentration levels has been found to compare well with that of other diffusion models of the Gaussian plume type. The level of uncertainty associated with this class of radionuclide transport and dispersion models was summarized by Crawford⁸ and Little and Miller.⁹ In the case of long-term average concentrations (a month or more) over flat terrain, and where strong plume buoyancy is not a significant influence, it ranges from a factor of about two for nearby receptors to a factor of four for more distant receptors. These factors can increase to an order of magnitude or more for short-term averages (an hour) and for strongly buoyant plumes such as those from a power-plant stack. Corresponding factors over rough terrain are essentially unknown but are certainly even larger.

How well AIRDOS-EPA performs in a particular modeling application--whether its actual performance level falls, for instance, within the above limits--depends primarily on the quality of the many data and parameter inputs that are required to operate the model, as well as on the correct resolution of various modeling details. For example, are the input meteorological data, which are often available only for a somewhat remote airport site, adequately representative of source area meteorological conditions? Is the AIRDOS-EPA plume-rise model, and related assumptions concerning mixing depth, correctly applied? How are calm winds to be dealt with, since wind speed occurs in the denominator of the air-concentration formula? Have conservative assumptions been cascaded to the point of unrealism?

These, and other, similar questions have formed the basis for criticisms of some of ORP's applications of AIRDOS-EPA. The Subcommittee believes that AIRDOS-EPA is a good, useful model, capable of addressing a wide range of air dispersion problems. It seems inevitable, however, that honest differences of opinion with the ORP staff related to various modeling details will continue to arise as the model is applied in regulatory proceedings. This natural tendency is exacerbated by the complicated structure of models like AIRDOS-EPA. The Subcommittee cannot, of course, resolve such differences during its current, limited review. The Subcommittee encourages ORP to present such models in as simple a documented format as possible with a view to their being understandable to those who would desire to critique the calculations made with the codes. The Subcommittee also sees the need for some form of continuing, technical review of modeling applications, on a case-by-case basis, until a better scientific consensus is reached.

ORP Question 10: Is the selection of transfer factors and other parameters in the food chain analysis reasonable?

The EPA methods in this area are appropriate and probably do not overestimate or underestimate the doses received beyond the inherent limits imposed by the current state of our knowledge of this complex area.

The portion of AIRDOS-EPA reviewed that addresses this question begins with a calculation of the deposition rate to the agricultural ecosystem from a computed ground-level air concentration and ends with a predicted ingestion rate for radionuclides by human receptors. These calculations are primarily embodied in the subroutine DOSEN. DOSEN is not a computationally large fraction of AIRDOS-EPA, but the rather significant inherent uncertainties within it account for a major portion of the overall uncertainty in the total risk assessment equation.

The mathematical routines within DOSEN are designed to yield steady-state, time averaged, deterministic predictions of radionuclide concentrations in animal forage and certain human foodstuffs per unit of deposition rate. The concentrations in foods are multiplied by food consumption rates to yield radionuclide ingestion rates by food type. These rates are summed over all food types to yield estimates of total ingestion rate for individual radionuclides. Corrections for the sources of the foods and radioactive decay during storage are included. The formulations were developed from those used in earlier models, especially the HERMES computer code¹⁰. They are essentially the same as those used in U. S. Nuclear Regulatory Guide 1.109.¹¹ The only readily apparent differences between AIRDOS-EPA and these earlier codes are in the choice of certain parameter values.

a. Apparent strengths of the environmental transport methodology

The deposition through ingestion sections of AIRDOS-EPA are based on relatively simple and straightforward formulae which are well documented. With some exceptions noted later, the formulations embodied in the relevant subroutines account for the major processes which normally affect the transport of radionuclides through terrestrial foodchains. They are generally accepted and used routinely by many groups throughout the world. They are designed to utilize a large body of experimental data which may be found in the open literature. The choices of parameter values generally appear to be reasonable and based on the relevant scientific literature. The model is generic in time and space, and thus, it should have broad applicability.

With the help of literature provided by Dr. Owen Hoffman of Oak Ridge National Laboratory, the Subcommittee made a comparison of AIRDOS-EPA with other models, with some limited observed data, as well as with a model called PATHWAY. This latter model has been tested extensively against real observations (see Table 1) but has not yet been published in the peer reviewed literature. However it has been presented

Table 1. Radionuclides Concentrations in Pasture and Foods: A Comparison Between AIRDOS-EPA and PATHWAY. Units Are Ci-day/kg Per Ci/sq m Deposited.*

Basis	pasture vegetables meat			milk		
	Cs-137	Sr-90	Cs-137	I-131	Cs-137	Sr-90
AIRDOS-EPA(p)	37	17	8	1.0	3.2	2.8
PATHWAY (p:a)	30	11	4	0.1	1.7	0.3
PATHWAY (px5:b)	150	28(c)	20	0.5	8.5	1.5
UNSCEAR (o)		2.4			2-16	1.4
PATHWAY (p/o)	0.93		0.54	1.2	2.7	2.0
#data sets	2		3	7	10	8
#data points	196		46	160	737	527
PATHWAY (p*o/p)	161		37	0.4	3.1	0.8
CONCLUSION,						
AIRDOS-EPA						
Overpredicts		x7		x2		x2-4
Underpredicts	x4		x5			

Note: p -prediction of model
o -real observations
a -time-averaged value
b -values multiplied by five to account for higher vegetation interception of small particles
c -value multiplied by 0.5 to account for washing loss

*See Appendix F for a detailed explanation of this table.

at scientific conferences and been published in conference proceedings. Based on these comparisons, it appears that concentrations of important radionuclides in basic foods as predicted by AIRDOS-EPA are likely well-within order of magnitude accuracy, and in most cases within a factor of two to five. This encourages the broad use of the EPA methodology for general assessment applications. There appears neither a general tendency for the foodchain portion of AIRDOS-EPA to be under-conservative or over-conservative.

b. Apparent weaknesses of the environmental transport methodology

The Subcommittee raises several questions about the basic structure of the food chain section of AIRDOS-EPA. For example, the processes of resuspension, rainsplash, absorption of surficial deposits into foliar tissues, and soil ingestion by beef and dairy cattle do not seem to be included in the code. Furthermore, several basic human food types are not explicitly modeled, such as fish, cheese, poultry, eggs, and red meats other than beef. These omissions do not appear to be offset by higher human consumption rates of similar foods modeled directly. The effects of neglecting these processes and specific food items are not clear in the absence of a sensitivity analysis designed to test for such effects. This raises the question of geographic and temporal differences wherein, for example, resuspension may only be important in arid or semi-arid regions during dry, windy periods.

AIRDOS-EPA appears to be structured to average across seasons since process parameters are held constant through time. This practice disregards the significant seasonal fluctuations in processes such as plant growth, cattle feeding, and sources of human foods. This simplification leads to wide fluctuations in the degree of conservatism in dose estimates obtained from AIRDOS-EPA, depending on the season of the year that releases might occur. This is potentially a greater problem for

short-lived radionuclides such as I-131 than for longer-lived substances such as Sr-90 or Cs-137. A further limitation of this constant-parameter, steady-state model becomes clear if it is applied to radionuclide releases which are short-term, time-variant, or sporadic.

Other weaknesses of the methodology include the failure to consider particle size dependency of the fraction of radionuclides intercepted by vegetation and the absence of documentation on either the scavenging rate or the geological removal rate.

Probably the greatest weakness of AIRDOS-EPA and similar computer codes is the lack of validation. The accuracy of prediction is not well-known, nor is the degree of uncertainty. Since such a large number of variable parameters are inherent in complex foodchain models, it does not seem productive to debate at length their individual values. It is the relative accuracy of the final result for the application intended by EPA which is the chief concern. The very limited comparison of AIRDOS-EPA to other models and to real data (see Table 1; see also Explanation of Table 1 and Figures 1-7 in Appendix F) suggests that the EPA methodology may be subject to slight (x5) underprediction in some cases (e.g., Cs-137 in pasture and meat). Superimposed on this situation is the likelihood, based on experience with the PATHWAY model, that such estimates carry uncertainties on the order of a factor of four in either direction (GSD=2). This suggests the small but real possibility of an underprediction by a factor of five x four which could lead to a significant error in the overall risk estimate. However, over-predictions of the same magnitude seem equally likely.

While AIRDOS-EPA appears reasonable for approximations of the dose under generic conditions, the methodology could possibly yield predictions for specific locales and scenarios of unacceptable accuracy and uncertainty. Thus, without

further testing and possible improvements in the structure of the computer code, any application of the EPA model to specific problems should be made with great care, and appropriate caveats should be stated.

3. Dose calculation models : dose to individuals in a population

ORP Question 8: In a few cases EPA has used organ transfer factors for a general population rather than those for occupational workers. Are these changes appropriate and justified in the documentation?

The uptake factors for the most part are taken from the International Council on Radiation Protection's (ICRP) estimates, and this is scientifically reasonable. However, for the transuranic radionuclides, other values were used that were based on ORP's "Proposed Guidance on Dose Limits for Persons Exposed to Transuranium Elements in the General Environment" (EPA 520/4-77-016, 1977). ORP apparently took specific values from a letter written by Bair and Thompson of the Battelle Pacific Northwest Laboratories (pp. 218-220 in "Response to Comments: Guidance on Dose Limits for Persons Exposed to Transuranium Elements in the General Environment", EPA 520/4-78-010, 1978). The draft document entitled "RADRISK/BEIR-3, Part II: Dosimetric Methods and Codes Used to Assess Radiation Risk" also notes that the new f_1 values adopted by the National Radiation Protection Board (NRPB) are closer to the EPA values than to those of the ICRP.¹² The ORP did not provide the NRPB or ICRP values, however.

The three sets of data are summarized in Table 2. The values shown under EPA are the Subcommittee's current understanding of what ORP used. At different times, in material received from different individuals within EPA, the Subcommittee received different values. This emphasizes the need for better documentation so it will

Table 2. Comparison of Values for the Gastrointestinal Absorption of Transuranic Radionuclides (fraction absorbed)

Element	Adult		
	ICRPa	NRPBb	EPA
Plutonium			
oxides, hydroxides	10^{-5}	10^{-5}	10^{-4} or 10^{-3}
other forms	10^{-4}	5×10^{-4}	10^{-3}
biologically incorporated	-		5×10^{-3}
Other transuranics ^c	5×10^{-4}	5×10^{-4}	10^{-3}
Child (0-12 mos)			
Plutonium			
oxides, hydroxides	-	5×10^{-4}	10^{-2}
other forms	-	5×10^{-3}	-
biologically incorporated	-	-	5×10^{-2}
Other transuranics ^c	-	5×10^{-3}	10^{-2}

^a For workers, from ICRP, Publication 30, Pt. 1. (1979).

^b For the public, from Harrison, Rad. Protect. Dosimetry 5, 19-35 (1983).

^c NRPB values are for americium and curium, only.

be clearer to all concerned as to what was actually done. The values adopted by EPA are very conservative and this was noted in the 1977 letter from Bair and Thompson. As the stated goal of the EPA is to provide a best estimate of dose, it would seem more reasonable to adopt the NRPB values that are based upon a more recent review and analysis of the literature.

ORP Question 7: Is the choice of ICRP dosimetric models scientifically adequate? Are there any alternatives?

The dosimetric models are basically those in general use by the scientific community and are scientifically adequate for the time being. However, EPA's choices of several inputs to the model are open to question or tend to yield conservative estimates of dose.

The program developed to estimate the absorbed dose and its effect on individuals exposed to radionuclides is called RADRISK. RADRISK and AIRDOS-EPA generate data to a program called DARTAB that provides estimates of genetic and somatic health impacts. These three programs - or sets of programs - are thus the basis for EPA's scientific evaluation of radionuclide exposure hazards.

RADRISK consists of a number of separate calculating procedures. The first step involves estimating the dose to each organ from internally absorbed radionuclides. The input data for the calculation are the metabolic model and physiological parameters for the element in question. In general, the output is expressed in terms of rads/microcurie-day for both low Linear Energy Transfer (LET) and high LET radiation. However, organ doses are calculated as lifetime doses, whereas genetic dose is calculated for the 0 - 30 year period. The models used are those recommended by the ICRP. A second step, called ADJUST 3, uses the above results, together with a life-table analysis and biological risk data derived principally from BEIR-III, to develop risk estimates for somatic and genetic effects for the radionuclide in question.

Latency period and RBE factors for low (1) and high (20) LET radiation are also included. The result for somatic effects is a RISK EQUIVALENT FACTOR (REF) which is essentially the fractional decrease in lifespan. A third step performs similar calculations for exposure to radionuclides in air or on the ground. The results are given in units of REF for exposures of 1 pCi/cm^3 and 1 pCi/cm^2 .

The methodology used in RADRISK appears to be scientifically sound, and the sample analyses that were presented express reasonable results. However, the program involves many assumptions and uses input data that must be continuously examined as new techniques and data evolve. In addition, the Subcommittee expresses strong concern about ORP's very poor method for documenting the calculating procedures and parameters for RADRISK. The Subcommittee eventually obtained the explanations it needed to understand the program but only after very laborious and time-consuming questioning of the staff. Any member of the public interested in attempting to verify the computation would have great difficulty. ORP needs to improve significantly its articulation of the conditions and the use of this program.

The Subcommittee has identified the following technical areas of AIRDOS-EPA, RADRISK and DARTAB where improvements may be required in the future:

1. There are several simplifications in the AIRDOS-EPA model that lead to the calculation of doses that are conservative by unknown amounts. In discussions with the ORP staff, it was stated that, in the calculation of external dose, it was assumed that the deposited radioactivity stays on the surface of the earth for one hundred years and never weathers into the soil. This assumption would seriously overestimate the dose from long lived radionuclides. However, it was stated that for the calculation of dose via the soil-root pathway, the assumption was made that deposited radionuclides are immediately mixed throughout the plow layer. This assumption leads to a significant overestimation of the dose via this pathway from shortlived radionuclides. Subsequently, ORP has stated that it used a ten percent annual removal constant for deposition in urban areas and two percent for rural areas. The confusion as to what was actually done emphasizes the need for improved documentation.

2. The documentation for AIRDOS-EPA also indicates that a constant absolute humidity value of 8 g/m^3 is used. As the tritium model uses the specific activity approach, the calculated dose is inversely related to absolute humidity. Since absolute humidity is typically much lower than 8 g/m^3 in much of the U.S., this assumption leads to an underestimation of dose. It would be more appropriate, and not difficult, to use site specific values for absolute humidity.

3. The physiological models and other input data required for the calculation of dose for internally absorbed radionuclides is equally important, and in many areas the data are incomplete. EPA should support work aimed at expanding the technical basis for many of the input parameters.

4. These three calculational programs do not now consider the important factor of uncertainty in each of the input parameters. The Subcommittee does not have specific suggestions as to how such data could be included, but believes that it is important for the EPA to develop methods that would indicate to the user the uncertainty or "noise" in the final values of REF. This uncertainty plays an important role in the setting of standards.

5. Although scientifically sound, the units of REF are difficult for the layperson, or even the scientist, to grasp. Alternatively, consideration might be given to developing and using a common unit of risk that could apply to all radiation hazards and be more readily understood.

4. Risk estimation models : individuals and populations

ORP Question 1: Has the EPA Office of Radiation Programs considered and interpreted in a scientifically adequate manner the appropriate literature on radiation risk assessment including data sources on radiation risks?

The ORP made available to the Subcommittee a voluminous body of data and literature related to health risks from radionuclides as well as a typical printout of DARTAB, the program that estimates population health effects. From its perusal of such information, the Subcommittee concludes that ORP staff identified the appropriate scientific basis in evaluating this form of radiation. It is also clear that, for some individual elements of the risk assessment (dose calculation models, for example), generally sound scientific judgment was utilized. The major shortcoming of ORP's analysis, however, was its failure to prepare a risk assessment that is readily understandable and integrates the five elements discussed earlier in Section III.

ORP Question 2: Are the assumptions made by ORP in estimating radiation risks reasonable, and are they justified in the supporting documentation?

There are a number of weaknesses in the ORP presentation. As noted in previous sections of this report, the assumptions and methodology utilized by ORP in assessing radiation risks are not presented and integrated with sufficient clarity in the supporting documentation. As a result, the Subcommittee was only able to clearly comprehend the approach being used after it requested and received a large number of briefings and supplemental written material. The public would experience great difficulty in attempting to understand the ORP analysis based on the documentation initially made available.

In estimating cancer risks the ORP approach was weakened by the use of a single dose-response model, the linear nonthreshold model. The use of only one model, which is generally viewed as conservative, in the risk assessment phase is scientifically inappropriate. A preferred approach would have been to present a range of models as discussed in BEIR III report so that the risk manager could be more fully informed as to the range of risk estimates that result from the use of different models.

An additional weakness is the variable degree to which attention is directed to details of the dose and risk calculations. This is especially notable with regard to age and time-dependent factors. ORP expended a great deal of effort, perhaps an excessive amount in view of the strength of the underlying data and the extrapolations, to use a life-table analysis approach to calculate how many people (or statistical fractions of individuals) die at specific ages. Yet, the calculations of dose per unit intake of radioactivity apparently do not use an age-dependent factor. It was not clear whether ORP did or did not use a special calculation to account for the increased absorption of transuranics by newborns. It was also not clear if, following radionuclide intake, the dose was assumed to be instantaneously delivered or protracted

in time. For the thyroid, it is well known that the dose to the infant can be ten times higher than to the adult. Also, the fetus is generally considered to be very radiosensitive, but no calculation of in utero dose is made. Thus, the great detail of the life-table approach is not matched by the details of the dose calculations.

ORP Question 3: Is ORP's selection of the National Academy of Sciences/Biological Effects of Ionizing Radiation III report as the basic guide to radiation risk estimates scientifically appropriate?

ORP appropriately selected the BEIR-III report as its basic guide to radiation risk assessment. However, the contents of the report have been used in an excessively selective manner. There appears to have been little recognition given to the caveats expressed by the BEIR-III panel or the limits in the applicability of the report to standard setting. Basically, ORP has used the BEIR-III risk coefficients presented for dose rates of 1 rad/yr (low LET radiation) to calculate the risks of small increments of dose added to background which is approximately 0.1 rad/yr.

The conclusions reached by the BEIR-III panel were by no means unanimous and may be subject to change in the future. Many Subcommittee members believe that the summed site approach, which was used by ORP for comparative purposes, gives values for total cancer incidence that are much higher than the amount of human data warrant.

Radiobiological data exist which indicate the likelihood that, at low doses and low dose rates, biological effects may be less than that suggested by a linear nonthreshold relationship. In this regard, the radiobiological literature developed from experimentation using many different biological systems are a useful supplement to the human data, and ORP should examine this information and make greater use of

it. The Subcommittee also believes that the use of the BEIR III report, which for cancer risks is based largely on human data at high doses and brief exposures, should be supplemented with other radiobiological data when extrapolations are made to very low doses accumulated over decades. This Subcommittee assertion is not intended as a criticism of the BEIR III panel's evaluation, for that report was not designed as a risk assessment for standard setting at very low levels of exposure.

ORP Question 4: Is the ORP analysis of potential lung cancer risks due to radon progeny scientifically defensible?

EPA uses human epidemiological data linked to exposures quantitated in Working Level Month (WLM) to assess the risk from radon daughters instead of using the dosimetric approach used for other radionuclides. Since the data are derived from mining populations, it is modified somewhat so as to apply to the general population, including children. Risk estimates are then compared with results analyzing other population groups. ORP again selected a single value, three percent lung cancer increase per WLM, as the relative risk coefficient. A range of values would have been more appropriate since the value of three percent lung cancer increase per WLM is open to challenge. Use of a range would not only address this criticism, but would ultimately provide the regulatory decision maker with a clearer picture of the uncertainties in this important area. This is one risk value which must meet real world criteria. The value should be consistent with predicting the incidence of lung cancer in non-smokers and their radiation exposures from naturally occurring radon, and its daughter products and other ecological factors implicated in lung cancer induction.

ORP Question 5: Is the wide range of uncertainty in estimates of human cancer and genetic risk clearly presented?

The Subcommittee is concerned that ORP uses the conservative or worst case linear extrapolation for carcinogenesis, i.e. extrapolation from acute high-dose exposures, while simultaneously using the chronic low-dose exposure extrapolation procedure for genetic effects. For genetic effects, the endpoint of concern is the nucleus. It is most likely that the nucleus is also the relevant target for important aspects of induction of somatic effects since scientists now recognize the role of oncogenes and chromosome re-arrangement in carcinogenesis. Thus, state-of-the art understanding of the mechanism of cancer induction can no longer justify ignoring "dose-rate effects" in favor of linear high-dose extrapolation. Scientific panels organized by the National Academy of Sciences, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the National Council on Radiation Protection (NCRP) and ICRP are in general agreement that some dose-rate effect occurs, and each of these groups uses this assumption in calculating best estimates. If ORP, in estimating somatic effects, continues to ignore this approach in favor of its conservative analysis, it should explicitly state its reasons for proceeding in this manner. At the same time, ORP should explain why it doesn't use similar assumptions to calculate genetic health risks. In addition, in cases where ORP proposes to use a years of life lost estimate per rad exposure for calculating the risk of somatic effects, a parallel approach should be applied to deriving a statement of genetic risk (see UNSCEAR 82). Finally, BEIR III estimates for genetic effects are low because the mouse female data are inappropriate for human extrapolation. The immature mouse oocyte cannot be used to detect mutations since an ionization

traversal through the cell membrane kills the cell (Dobson, 1983).¹³ Faced with this scientific uncertainty it would be judicious for ORP to also give an alternative estimate, assuming equivalent mutability for both sexes, until there is other evidence to the contrary.

ORP's selection of relative versus absolute risk models for estimating cancer risks is another instance where a more detailed analysis and presentation would have been useful. Both approaches have their strengths and weaknesses which should have been elaborated. If one approach was to be selected over the others then it would be appropriate to clearly document why it was selected and how it is reflected in the uncertainty of the final risk estimates.

In view of the above comments, the Subcommittee recommends that ORP continually review the scientific literature and modify its radiation risk estimates periodically, as additional information becomes available. This recommendation is especially appropriate at this time because exposure data from the Japanese A-Bomb experience are presently undergoing revision and will presumably, at some point in the near future, yield improved cancer risk estimates per rad of gamma radiation.

ORP Question 6: Is the ORP choice of the ICRP quality factor
of twenty for high LET radiation scientifically
reasonable or are there better alternatives?

The factor of twenty for high LET radiation appears appropriate when used by ICRP and inappropriate when used by ORP. This is not a paradox as will be illustrated for genetic risks. ICRP has a dose-rate factor for low LET radiation (chronic exposure) which is what it compares to high LET radiation. In contrast, ORP uses a high dose rate for low LET to compare with high LET. The factor of twenty is thus too great. An ORP handout provided to the Subcommittee (reproduced on the next page)

illustrates this point. The factor of twenty is clearly shown to apply only to low dose rate LET (a factor of 6.7 applied to high dose low LET without a dose rate factor). Unless there is some other justification, which ORD should document, this appears to be an example of compounding on error.

ORP Handout: "Serious Hereditary Disorders Per 10^6 Live borne/Per Rad of Parental Exposure/Per Generation"

<u>rg for</u>	<u>First Generation</u>	<u>Equilibrium</u>
Low Dose Rate Low-LET	20	260
High Dose Rate Low-LET	20x [60]	780
High-LET	[400] 6.7x	5200

B. USE OF RISK ASSESSMENT IN RULEMAKING UNDER SECTION 112 OF THE CLEAN AIR ACT

EPA, in general, has been a leading practitioner of risk assessment in the Federal government. At the same time, the use of risk assessment within EPA has a mixed record both in terms of the consistency of approach utilized among the regulatory offices within the Agency and the varied scientific quality of individual risk assessments. The former condition is, in part, the result of differing statutory direction provided to EPA, although it can also be attributed to the organization of the Agency's major offices around a specific environmental media or problem area. The different offices subject their risk assessments to varied degrees of peer review and have scientific staffs with differing skills.

The process of preparing risk assessments to evaluate candidate pollutants for regulation under Section 112 of the Clean Air Act is, with the exception of those prepared by ORP, managed by the Office of Health and Environmental Assessment

(OHEA) which is located within the Office of Research and Development. Risk assessments prepared by OHEA which have led to the regulation of hazardous air pollutants have consistently been reviewed by the Science Advisory Board. The process followed by OHEA in developing a risk assessment for a specific pollutant includes the following major sequential steps:

- compilation and interpretation of the scientific literature into a Health Assessment Document. The document includes a discussion of differing health endpoints (such as cancer, reproductive effects, and neurobehavioral effects) and has a chapter on quantitative risk assessment. This chapter presents the calculating procedures used in developing the risk assessment, evaluates several mathematical models or relationships to test the "goodness of fit" to the available scientific data, and compares the potency of the pollutant under study to other pollutants.
- solicitation of public comment on the scientific adequacy of the Health Assessment Document.
- Science Advisory Board review. To facilitate SAB review, OHEA staff prepare an issues paper to identify key issues for SAB consideration and present their own judgments about such key issues. The goal of this interaction between the OHEA staff and the SAB is an advisory report transmitted to the Administrator on the scientific adequacy of the Health Assessment Document. The process used to achieve this goal is iterative and frequently leads to the achievement of consensus regarding the interpretation of the scientific data for a particular pollutant.

There are several major advantages of the above described process. These include:

- 1) the separation of the risk assessment from risk management activities. The scientific evaluation of a pollutant is completed, both inhouse and externally, prior to any Agency decision on whether to regulate or at what level to regulate;
- 2) the scientific community and the public at large are involved early in the decision making process. Because scientists' participation in the review process occurs before the Agency has committed itself to a specific regulatory course of action, EPA is more able to respond to valid scientific criticisms by modifying a document while it is still in the risk assessment phase.

3) the scientific basis for the risk assessment is made more explicit. Scientific data are compiled and evaluated in the Health Assessment Document, and key assumptions are identified in the document for public and SAB review. The result is the development of an analytical bridge in the risk assessment that leads from the scientific studies to the set of risk estimates generated by the mathematical procedures employed.

The process followed by the Office of Radiation Programs in its development of regulatory proposals to control airborne radionuclides is a major exception to the approach outlined above. The ORP did not compile and interpret the available scientific evidence in a formal health risk assessment document. Neither was there ever a public or SAB review of the scientific basis upon which the Agency listed radionuclides as a hazardous air pollutant under Section 112 of the Clean Air Act.

C. SUBCOMMITTEE FINDINGS

1. The Subcommittee concludes that the Office of Radiation Programs' staff has gathered the appropriate scientific data for individual elements of a risk assessment for radionuclides emissions. Such information was used by the Agency to model the transport of airborne radionuclides through environmental pathways and to estimate the genetic and somatic health risks to humans from calculated doses.

2. In its proposed standards to control airborne radionuclides EPA stated that its objective was to "restrict emissions from each site to the amount that would cause an annual dose equivalent to 10 millirems (mrem) to the whole body and 30 mrem to any organ of any individual. This emission standard will keep the radiation doses relatively low both to nearby individuals and to populations living around the sites." (pp.15077-78 Federal Register, April 6, 1983).

The Subcommittee made numerous inquiries as to the scientific basis for the specific levels chosen in the proposed emission standards. ORP staff, on March 22, identified five factors which they and senior policy officials weighed in decision

making for the standard. These include: 1) the radiation dose and risk to nearby individuals; 2) the cumulative dose and risk to population groups; 3) the potential for emissions and risk to increase in the future; 4) the availability, practicability and cost of control technology to reduce emissions; and 5) the effect of current standards under the Act or other applicable legislative authorities.

The Subcommittee offers two observations about these decision criteria: 1) it is not clear what relative weights were assigned to these factors in selecting the levels for the proposed standards; and 2) most of the factors used to determine the proposed level of the standards do not result per se from an evaluation of scientific data in the preparation of a risk assessment.

Based upon the information it has received and reviewed, the Subcommittee concludes that ORP did not prepare a risk assessment in support of this rulemaking activity that integrated the available scientific data base. Of particular concern was the absence of a statement characterizing the degree of uncertainty embodied within the risk estimates for genetic or somatic effects. As discussed earlier, at several steps in the estimation of risk there is the opportunity to consider alternative models. It would have been useful to have the degree of uncertainty for the various alternatives documented. A related concern is the degree of selectivity in utilizing the existing health effects literature (such as the BEIR III report) and the lack of balance in the discussion of other scientifically plausible assumptions covered in this literature. In summary, the information ORP presented to the Subcommittee is not an adequate or balanced assessment of the scientific data pertaining to airborne radionuclides, and it cannot be judged as a scientifically adequate basis for regulatory decisions for this pollutant.

3. The Agency requested that the Science Advisory Board review scientific data associated with human health risk from radionuclides after it had formally proposed a risk management decision in the Federal Register. The Administrator has stated on numerous occasions that the major contribution of scientists to EPA's decision making process lies in peer reviewing the technical basis of standards. To achieve this result, scientists are increasingly asked to present their opinions before a risk management decision is proposed. By seeking SAB review of the radionuclide standards after their proposal, the Agency undermined the viability of the concept of separating risk assessment and risk management that it is seeking to implement. The worst possible time to ask the SAB and the scientific community to participate in the decision making process is following the proposal of a standard when the risk assessment and risk management components are blended together. As such, the approach used in this current rulemaking represents a major flaw in ORP's dialogue with the scientific community and its approach to risk assessment.

It has been noted that the SAB has the prerogative of reviewing the scientific basis of any of the Agency's proposed actions without waiting for a specific request from the Agency. It is important that this avenue be kept open to the Board. However, in the final analysis, it is the responsibility of the Agency to identify those issues that are of highest priority for SAB review. Such a course is warranted recognizing the limited size of the SAB and the myriad of issues it might potentially review.

4. Various offices within EPA are becoming increasingly sophisticated in their approach to characterizing and assessing human health risks. These efforts logically lead the Agency to present comparisons of risk estimates for different pollutants and to use risk assessment as a tool to define public health priorities to achieve more cost-effective environmental protection. It is not clear that the Office of Radiation Programs, in its approach to risk assessment, is greatly influenced by this trend. As such, ORP may not be taking sufficient advantage of these evolving

conceptual advances. At the same time, ORP, with its long experience in exposure assessment, may not be articulating to the Agency the benefits of its knowledge in this field. In short, the Subcommittee is concerned that ORP is not in the mainstream of EPA's continuing efforts to improve the practice of risk assessment.

IV. SUBCOMMITTEE CONCLUSIONS AND RECOMMENDATIONS

A. NEED FOR A SCIENTIFIC ISSUES STAFF PAPER TO IDENTIFY AND EVALUATE THE SCIENTIFIC BASIS FOR RADIATION RISK MANAGEMENT DECISIONS

The Subcommittee's major finding in its review of the scientific data associated with EPA's radionuclides rulemaking efforts is that the ORP has not assembled and presented a risk assessment that provides a clear and adequate statement of the scientific basis for developing standards to regulate airborne radionuclide emissions. What is needed is an intermediate step between the collection of the relevant scientific information, which ORP has carried out in a proficient manner in the current rulemaking, and the selection of regulatory options for purposes of risk management.

Such an intermediate step has already been developed in other program offices within EPA and is regarded as successful by both Agency staff and the general public, including the scientific community. For example, the Office of Air Quality Planning and Standards (OAQPS) has since 1979 prepared a scientific issues staff paper that provides an analytical bridge between a large number of scientific studies included in the air quality criteria document and the staff interpretation of how to use such studies as a basis for defining regulatory options. These staff papers are routinely reviewed by the public and the Science Advisory Board, and they have enhanced EPA's credibility in the setting of ambient air quality standards.

The Subcommittee strongly recommends that the preparation of a scientific issues staff paper incorporating an integrated risk assessment become a routine part of the ORP's regulation development process. The scope and complexity of an individual staff paper may vary in accordance with the rule under development, but certain generic characteristics of the staff paper concept are self evident. In the case of airborne radionuclides, for example, the staff paper should provide a conceptual framework that includes the state of knowledge to assess radiation risks beginning with 1) identification of radionuclides emissions sources; 2) evaluation of the transport of radionuclides through all relevant environmental media; 3) calculation of the dose received by a human population; 4) estimation of genetic or somatic health effects and (5) identification and characterization of the degree of uncertainty in the risk estimates. The latter should include a presentation of central estimates with lower and upper bounds for cancer and genetic endpoints. Such endpoints should then be compared to existing data on the incidence EPA attributes to various environmental, occupational and social factors. It might also be appropriate for this position paper, or a complementary document, to identify for various potential levels of a standard if compliance could be established by direct measurements or only indirectly by modeling. In summary, a staff paper can synthesize the scientific data base which the risk manager must utilize to propose reasonable and scientifically defensible standards.

B. ESTABLISHMENT OF CONTINUING SCIENTIFIC OVERSIGHT MECHANISM TO REVIEW

ASSESSMENTS FOR RADIATION STANDARDS AND OTHER ORP ACTIVITIES

The Subcommittee recommends the establishment of a continuing mechanism to provide scientific oversight and peer review of the scientific basis of ORP's regulatory proposals and its scientific activities. Such a mechanism could take the

form of a permanent standing committee within the EPA's Science Advisory Board. The Board is well suited to carry out this role for several reasons. These include 1) its statutory basis provides for both a continuous advisory relationship with the Agency and a clear delineation of its peer review role and authority; 2) it is able to attract highly qualified, independent and respected scientists and engineers to serve on its advisory panels; 3) a number of highly qualified scientists with expertise in radiation risk assessment currently serve on the Board; and 4) the establishment of a standing radiation committee within the Board is administratively simple and feasible from a budgetary point of view. A proposed charge for such a committee is given in Appendix G.

C. INTEGRATION OF RISK ASSESSMENT EFFORTS BETWEEN THE OFFICE OF RADIATION PROGRAMS AND OTHER STAFF OFFICES WITHIN EPA

ORP efforts in risk assessment are not sufficiently integrated with other staff offices that are working to refine the Agency's approach to risk assessment. This is a two-way street in that ORP could benefit by implementing some of the increasingly sophisticated efforts used in other parts of EPA to characterize and compare risks, while simultaneously the ORP staff could further educate their colleagues in areas, such as exposure assessment, where it possesses much expertise and experience. To achieve this result the Subcommittee recommends that ORP and the Office of Health and Environmental Assessment take more formal steps to integrate their preparation of risk assessments. A specific recommendation is that OHEA be represented on ORP work groups that prepare risk assessments for setting radiation standards. In addition, the ORP risk assessment effort is related to scientific modeling studies under way in the Office of Air Quality Planning and Standards, as well as related work in various other government and private agencies. The Subcommittee encourages ORP to continue to seek ways to improve its interaction with all such groups.

D. RESEARCH NEEDS

The Subcommittee believes that the identification of areas requiring additional research will provide useful input to those directing research programs in EPA and other Federal Agencies. The Subcommittee sees the need for additional research in the following areas:

1. The development air transport radioactivity models for situations other than emissions from tall stacks may become a topic of increasing importance for standard setting in future years.
2. The continuing assessment of the Japanese A-bomb data for improvement of the BEIR-III estimates of radiation hazard is needed to further refine estimates of health risks from current man-made sources of radionuclides.
3. The determination of the nature of dose-response relationships at low dose rates, as e.g. non-linearity in the linear-quadratic or quadratic relationships, could affect profoundly the estimates of radiation hazards at levels of great concern to the EPA.
4. There is a great need to validate radiation doses estimated with models and subsequent computer codes by means of measurement of radioactivity levels in air, on the ground and in plants, animals and humans in proximity to the radiation source(s).
5. The ultimate development of dynamic models having applicability to specific geographic regions is technically possible. Such models should provide the greater accuracy and credibility of assessments that is desired.
6. The development of more sensitive methods to determine genetic damage is an important research need. The advancing state-of-the-art is making it possible to plan DNA studies of children, for example.

APPENDIX A

U.S. Environmental Protection Agency Subcommittee on Risk Assessment for Radionuclides Science Advisory Board

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APPENDIX B



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 6 1983

THE ADMINISTRATOR

MEMORANDUM

SUBJECT: SAB Review of Risk Estimates Due to Radionuclides

TO: Chairman, Science Advisory Board

The Environmental Protection Agency's (EPA) responsibilities for protecting the public from exposure to radioactive materials requires that we conduct several regulatory programs. To make clear that these programs are based on analysis of the scientific information that is reasonable and rigorous, I request that the Science Advisory Board convene a special subcommittee to review the scientific basis of the risk assessments used to develop standards for protection from radionuclides in the environment.

This is an urgent task because of the Agency's statutory deadlines for completing ongoing regulatory programs, and the need to resolve public comments and other concerns expeditiously. I request that the subcommittee make every effort to complete its review and report its findings within three months.

I am requesting that the subcommittee critically review the process by which the Agency estimates human cancer and genetic risk due to radionuclides in the environment. This review should include examination of the methods used to estimate the transport of radionuclides in the environment due to emissions into air, the organ doses received by persons inhaling or ingesting this radioactivity, and finally, the cancer and genetic risks due to these organ doses. The subcommittee should render an opinion on whether EPA is using basic references on dosimetry models or risk estimates prepared by other expert committees such as the National Academy of Sciences' (NAS) Committee on the Biological Effects of Ionizing Radiation (BEIR), and the International Commission on Radiological Protection (ICRP) in a scientifically acceptable manner.

I believe it is particularly important that the subcommittee concentrate on whether the Agency has proceeded in a reasonable and scientifically sound way. In this vein, please look at procedures, information bases, and the reasonableness of the approach. I am seeking a review of the overall scientific bases used by the Agency in making radiation risk estimates.

The methodology that you will be reviewing is used to assess risks associated with source categories and specific facilities as part of the development of EPA's proposed standards. It would be helpful to me if the subcommittee concentrated on a few sample cases to ensure that the Agency's staff properly applied the general methodology.

I believe that risk assessment and risk management are distinct aspects of regulation development. Methodologies for risk assessment must be based on sound scientific information and principles, whereas risk management decisions need to take the results of the risk assessment and balance them with legal, economic, and other relevant factors. I believe the latter are policy decisions that are the responsibility of EPA staff and its senior managers after receiving appropriate comment through the rulemaking process. Examples of what I conceive as risk management issues are what constitutes an "ample margin of safety" and what constitutes acceptable risk levels.

Mr. Glen L. Sjoblom, Director of the Office of Radiation Programs and his staff stand ready to provide the subcommittee with appropriate briefings, background information, and necessary support so that your review can proceed as expeditiously as possible. I have attached a list of specific questions prepared by the Office of Radiation Programs for the subcommittee's review.

I am looking forward to the results of the review and plan to carefully consider it when making my decisions on the major risk management issues that involve exposure to radiation.



William D. Ruckelshaus

Attachment

Office of Radiation Programs: Questions for the SAB

1. Has the Office of Radiation Programs (ORP) considered and interpreted in a scientifically adequate manner the appropriate literature on radiation risk assessment including data sources on radiation risks? Please identify any important omissions.
2. Are the assumptions made by ORP in estimating radiation risks reasonable, and are they justified in the supporting documentation?
3. Is ORP's selection of the NAS-BEIR III report as the basic guide to radiation risk estimates scientifically appropriate?
4. Is the ORP analysis of potential lung cancer risks due to radon progeny scientifically defensible?
5. Is the wide range of uncertainty in estimates of human cancer and genetic risk clearly presented?
6. Is the ORP choice of the ICRP quality factor of twenty for high LET radiation scientifically reasonable or are there better alternatives?
7. Is the choice of ICRP dosimetric models scientifically adequate? Are there any alternatives?
8. In a few cases EPA has used organ transfer factors for a general population rather than those for occupational workers. Are these changes appropriate and justified in the documentation?
9. Are the air dispersion models reasonable to estimate radionuclide concentrations (1) in the neighborhood of a source? (2) to regional populations?
10. Is the selection of transfer factors and other parameters in the food chain analysis reasonable?

Wednesday
April 6, 1983

Part II

**Environmental
Protection Agency**

**National Emission Standards for
Hazardous Air Pollutants; Standards for
Radionuclides**

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 61

[AH-FRL 2324-3]

National Emission Standards for Hazardous Air Pollutants; Standards for Radionuclides

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Rule and Announcement of Public Hearing.

SUMMARY: On November 8, 1979, EPA listed radionuclides as a hazardous air pollutant under the provisions of Section 112 of the Clean Air Act. Pursuant to Section 112, EPA is proposing standards (including appropriate reporting requirements) for sources of emissions of radionuclides in four categories: (1) Department of Energy (DOE) Facilities, (2) Nuclear Regulatory Commission licensed facilities and non-DOE Federal facilities, (3) underground uranium mines, and (4) elemental phosphorous plants.

The Environmental Protection Agency (EPA) has identified several additional source categories that emit radionuclides and has determined there are good reasons for not proposing standards at this time for these categories. They are the following: (1) coal-fired boilers, (2) the phosphate industry, (3) other extraction industries, (4) uranium fuel cycle facilities, uranium mill tailings, management of high level waste, and (5) low energy accelerators.

DATES: Comments may be received on or before May 30, 1983.

Public Hearings. An informal public hearing will be held on April 28, 29, and 30, 1983 in Washington, D.C. The exact time and location of the hearing can be obtained by calling the Office of Radiation Programs at (703) 557-0704. Requests to participate in the informal hearing should be made by April 20, 1983. Written statements may be entered into the record before, during, or within 30 days after the hearing.

ADDRESSES: All written comments should be submitted to the Central Docket Section (A-130), U.S. Environmental Protection Agency, Washington, D.C. 20460. Attention: Docket No. A-79-11. This docket, containing information used by EPA in developing the proposed standards, is available for public inspection between 8:00 a.m. and 4:00 p.m., Monday through Friday at EPA's Central Docket Section, West Tower Lobby, Gallery One, Waterside Mall, 401 M Street SW., Washington, D.C. 20460.

Separate sections of the docket have been established for each category of radionuclide emissions to air. Comments specific to a proposed action should be addressed to the following docket sections:

- Section III A—Department of Energy Facilities
- Section III B—Nuclear Regulatory Commission Licensed Facilities and non-DOE Federal Facilities
- Section III C—Underground Uranium Mines
- Section III D—Elemental Phosphorous Plants
- Section III E—Coal-fired Boilers
- Section III F—Phosphate Industry
- Section III G—Other Extraction Industries
- Section III H—Uranium Fuel Cycle Facilities, Uranium Mill Tailings, and Management of High Level Waste
- Section III I—Low Energy Accelerators

Requests to participate in the informal hearing should be made in writing to Richard J. Guimond, Director, Criteria and Standards Division (ANR-460), U.S. Environmental Protection Agency, Washington, D.C. 20460. All requests for participation should include, at least, an outline of the topics to be addressed in the opening statements and the names of the participants. Presentations should be limited to 15 minutes each.

A Background Information Document has been prepared that contains, for each source category, projected doses and risks to nearby individuals and to populations, descriptions of current control technology, and descriptions and costs of emission control technologies. Single copies of the Background Information Document for the proposed standards may be requested in writing from the Program Management Office (ANR-458), U.S. Environmental Protection Agency, Washington, D.C. 20460, or by calling (703) 557-9351.

FOR FURTHER INFORMATION CONTACT: Terrence A. McLaughlin, Chief, Environmental Standards Branch (ANR-460), U.S. Environmental Protection Agency, Washington, D.C. 20460, (703) 557-8977.

SUPPLEMENTARY INFORMATION:

I. Overview of the Proposed Standards

A. Basic Terms Used in This Notice

All matter is made up of atoms; their nuclei contain protons and neutrons. The number of protons in an atom determines the identity of the element. For example, the element with 6 protons is called carbon. Atoms can contain different numbers of neutrons. The total number of protons and neutrons in an atom is called the atomic weight.

The nuclei of atoms of chemical elements with certain atomic weights are unstable by nature. Such nuclei can disintegrate spontaneously in

predictable ways and are said to be radioactive. Atoms with nuclei that disintegrate are called radionuclides. For example, carbon atoms with 8 neutrons disintegrate, whereas carbon atoms with 6 neutrons are stable. The number of disintegrations which will occur in a given amount of time is termed activity; the unit of activity is the curie. One curie equals 37,000,000,000 disintegrations per second.

Some radionuclides are found in nature; others are made in reactors and accelerators. This notice concerns facilities which handle or produce all types of naturally occurring and manmade radionuclides in a manner that results in their being released into the air.

B. Background

In 1977, Congress amended the Clean Air Act (the Act) to address airborne emissions of radioactive materials. Before 1977, these emissions had been either regulated under the Atomic Energy Act or unregulated. Section 122 of the Act required the Administrator of EPA, after providing public notice and opportunity for public hearings (provided by 44 FR 21704, April 11, 1979), to determine whether emissions of radioactive pollutants cause or contribute to air pollution that may reasonably be anticipated to endanger public health. On December 27, 1979, EPA published a Federal Register Notice listing radionuclides as hazardous air pollutants under Section 112 of the Act (44 FR 76738, December 27, 1979). To support this determination, EPA published the report titled *Radiological Impact Caused By Emissions of Radionuclides into Air in the United States—Preliminary Report* [EPA 520/7-79-006], Office of Radiation Programs, U.S. Environmental Protection Agency, Washington, D.C. (August 1979).

Section 122(c)(2) of the Act directed that, once EPA listed radionuclides to be regulated under the Act, EPA and the Nuclear Regulatory Commission (NRC) were to enter into an interagency agreement with respect to those facilities under NRC jurisdiction. Such a memorandum of understanding was effected on October 24, 1980, and was subsequently published in the *Federal Register* (45 FR 72980, November 3, 1980). When EPA began developing standards for Department of Energy (DOE) facilities, a similar memorandum of understanding was negotiated with DOE. This memorandum of understanding was signed in October 1982, and a copy has been placed in the Docket for public review.

On June 16, 1981, the Sierra Club filed suit in the U.S. District Court for the Northern District of California pursuant to the citizens' suit provision of the Act (Sierra Club v. Gorsuch, No. 81-2436 WTS). The suit alleged that EPA had a nondiscretionary duty to propose standards for radionuclides under Section 112 of the Act within 180 days after listing them. In March 1982, the Court granted the Sierra Club motion for partial summary judgment on the liability issue, and, on September 30, 1982, the Court ordered EPA to publish proposed regulations establishing emission standards for radionuclides, with a notice of hearing, within 180 days of the date of that order.

EPA is proposing standards for certain sources of radionuclide emissions to air and is proposing not to regulate other sources. To EPA's knowledge, these comprise all source categories that release potentially regulatable amounts of radionuclides to air. The deadline established by the Court for this rulemaking has required EPA to proceed with less information than it would like. As always, EPA invites comments and will consider them carefully to ensure that the Agency's decisions are the best possible ones.

C. Estimates of Health Risk

Agencies can never obtain perfect data but have to make regulatory decisions on the basis of the best information available. Although additional study may be suggested to clarify the health implications from exposure to radiation at relatively low levels, EPA is concerned about the potential detrimental effects to human health caused by radiation based on the best scientific information currently available. EPA believes its estimates of doses to humans and the potential human health risks constitute an adequate basis for decisionmaking.

The information used by the Agency in estimating the hazards to health due to exposure to radiation is summarized in the following reports: *The Effects on Populations of Exposure to Low Levels of Ionizing Radiation* (1972) and *Health Effects of Alpha Emitting Particles in the Respiratory Tract* (1976) by the BEIR Committee, the report of the United Nations Scientific Committee on the Effects of Atomic Radiation entitled *Sources and Effects of Ionizing Radiation* (1977), and *Publication 26* (1977) by the International Commission on Radiological Protection. These bodies agree that high levels of radiation cause cancer and mutations and that, when formulating radiation protection standards and guidance, it is reasonable to assume that the risks of cancer and

mutations are proportional to radiation dose. Background information on the risk associated with radon emissions can be found in an EPA report titled *Indoor Radiation Exposure Due to Radium-226 in Florida Phosphate Lands*, [EPA 520/4-78-013] (1978).

In concert with the recommendations of these reports, even for relatively low doses, EPA has assumed a linear, nonthreshold, dose-effect relationship as a reasonable basis for estimating the public health hazards due to exposure to radiation. This means that any radiation dose is assumed to pose some risk of damage to health and that the risk associated with low doses is directly proportional to the risk that has been demonstrated at higher doses. EPA believes this assumption is reasonable for public health protection in light of presently available information. However, EPA recognizes that the data available preclude neither a threshold for some types of damage below which there are no harmful effects nor the possibility that low doses of gamma radiation may be less harmful to people than the linear model implies.

As used in this notice, the term "dose to an individual" means an estimate of the dose rate in units of dose equivalent per year (rem/y) to the whole body or to a specified body organ due to exposure to radiation at a given level for the person's lifetime (70 years). These dose rates are a measure of, although not directly proportional to, the individual's risk of fatal cancer. The term "lifetime risk to an individual" means an estimate of the potential probability of premature death due to cancer caused by radiation exposure at a given level for the person's lifetime. There are also risks of nonfatal cancer and serious genetic effects, depending on which organs receive the exposure to radiation. The risks of nonfatal cancer and genetic effects cannot be accurately estimated, but neither risk is larger than the fatal cancer risk. EPA considers all these risks when it makes regulatory decisions on limiting emissions by restricting dose rates or exposures to radionuclide concentrations.

As used in this notice, the term "dose to population" means an estimate of the summed dose received by all persons in a population living within a given distance of the source, typically within 80 kilometers, due to a one year release of radionuclides (person-rem per year of operations). A person-rem is a total amount of exposure received by a large group equivalent to one person receiving an exposure of one rem. The term "risk to population" means an estimate of the number of potential fatal cancers that

might occur in the population living within a given distance of the emission source, typically within 80 kilometers. The risk is related to the amount of radionuclides that are emitted during a year of operation. Part of the population risk is likely to occur some time after the radionuclides are emitted because: (1) There is a delay between release and exposure as the radionuclides move through environmental pathways and (2) there is a latent period between exposure and the onset of the disease. The dose to populations for a specific organ is related to, although not directly proportional to, the risks of fatal cancer, nonfatal cancer, and serious genetic effects. EPA considers all fatal and nonfatal risks in making regulatory decisions on whether standards are needed to protect the general public. As used in this notice, the term "health effect" means potential fatal cancers. Additional information on risk can be found in the Draft Background Information Document.

EPA must make numerous assumptions when estimating the radiation dose to individuals and population groups and the likely risk this might present to health. The assumptions introduce uncertainties in the estimates of radiation doses and health risks. All individual risk calculations assume that individuals reside at a single location for a 70 year life and are exposed to a constant source of radionuclide emissions for the entire time. Factors such as radionuclide uptake by vegetation, consumption of locally produced crops and milk, and meteorology are quite site specific and can influence the actual risk to any given individual. Individual characteristics such as age, physiology, physical activity level, amount of time spent indoors, and eating habits can influence the rate and amount of radionuclides affecting the individual and, thus, the risk of that person.

EPA's risk estimates are "best estimates" considering the above factors. EPA believes that the estimates are within a factor of ten of the actual health risks to individuals if the assumptions are valid for the particular situation under consideration.

D. Summary of the Proposed Standards

EPA is proposing specific standards for sources in four categories: (1) DOE facilities, (2) NRC-licensed facilities and non-DOE Federal facilities, (3) underground uranium mines and (4) elemental phosphorous plants.

An indirect emission standard is proposed for all DOE facilities that will restrict emissions from each site to the

amount that would cause an annual dose equivalent to 10 millirem (mrem) to the whole body and 30 mrem to any organ of any individual. This emission standard will keep the radiation doses relatively low both to nearby individuals and to populations living around the sites. In addition, EPA expects these facilities to continue to comply with the current Federal Guidance requirement that emissions be limited to as low as practicable levels and has proposed a reporting requirement to describe emission control technology.

An indirect emission standard is proposed for NRC licensees and non-DOE Federal facilities that will restrict emissions from each site to the amount that would cause an annual dose equivalent of 10 mrem to any organ of any individual. This emission standard will keep radiation doses relatively low to nearby individuals and populations in the vicinity of the site. The term "NRC licensees" includes those facilities licensed by the NRC and by States under agreement with the NRC.

An indirect emission standard is proposed for underground uranium mines that will restrict the increase in annual average concentration of radon-222 at places people can live to 0.2 picocurie per liter (pCi/l). A person living in a house for a long time in an area exposed to this concentration might still be subject to a significant estimated level of risk. However, neither control technology nor other methods to reduce radon emissions from these mines are available at reasonable cost; thus, more restrictive controls are not reasonable. The proposed standard will reduce risk to people living closest to the mines; protection of the health of regional and more distant populations is of less concern because most mines are located in remote areas.

An emission standard is proposed for elemental phosphorous plants that will limit annual emissions of polonium-210 from each site to 1 curie. While other radionuclides are emitted from these plants, polonium-210 is the major contributor to the maximum individual risk. Limiting polonium-210 will control the others. Such a standard will keep radiation doses relatively low to both individuals and populations.

While one of the above standards limits stack emissions directly, the other three limit stack emissions indirectly by specifying dose or concentration limits to be achieved. EPA believes this is a reasonable approach, given the extreme diversity of DOE facilities and NRC licensees and the fact that radon-222 emissions from uranium mines are not amenable to controls. The form of the

proposed standards follows well developed and widely accepted practices in radiation protection. The use of procedures developed primarily to control chemicals would, in this context, be unworkable.

E. Basis for the Proposed Standards

In the Federal Register of May 18, 1960, President Eisenhower directed Federal agencies to follow the Radiation Protection Guidance of the Federal Radiation Council (FRC). When EPA was established, the Federal Radiation Council was abolished, and its responsibilities were transferred to EPA. EPA has considered this Guidance in establishing emission standards under Section 112 of the Clean Air Act, and the Agency's approach is compatible with it. For the purposes of this rulemaking, key elements of the Guidance are:

1. There should not be any man-made radiation exposure without the expectation of benefit resulting from such exposure.

2. The term "Radiation Protection Guide" should be adopted for Federal use. This term is defined as the radiation dose which should not be exceeded without careful consideration of the reasons for doing so; every effort should be made to encourage the maintenance of radiation doses as far below this guide as practicable.

3. For the individual in the population, the basic Radiation Protection Guide for annual whole body dose in 0.5 rem. This Guide applies when the individual whole body doses are known. As an operational technique, where the individual whole body doses are not known, a suitable sample of the exposed population should be developed whose Protection Guide for annual whole body dose will be 0.17 rem per capita per year.

4. There can be no single permissible or acceptable level of exposure without regard to the reason for permitting the exposure. It should be general practice to reduce exposure to radiation, and positive efforts should be carried out to fulfill the sense of these recommendations. It is basic that exposure to radiation should result from a real determination of its necessity.

5. There can be different Radiation Protection Guides with different numerical values, depending upon the circumstances.

6. The Federal agencies shall apply these Radiation Protection Guides with judgment and discretion to assure that reasonable probability is achieved in the attainment of the desired goal of protecting man from the undesirable effects of radiation. The Radiation Protection Guides provide a general

framework for the radiation protection requirements. It is expected that each Federal agency, by virtue of its immediate knowledge of its operating problems, will use these Guides as a basis upon which to develop detailed standards tailored to meet its particular requirements.

EPA believes that the following points in these guides are of particular importance: (1) There should be benefits from exposure to radiation; (2) Exposures should be kept as low as practicable; and (3) It is appropriate to have different standards with different values, depending on the circumstances.

These Guides apply to Federal agencies to the extent that they are not incompatible with more specific legislative directives. The Clean Air Act directs EPA to establish emission standards for hazardous pollutants and directs EPA to propose these standards at a level which, in the Administrator's judgment, will protect the public health with an ample margin of safety. Congress did not describe the degree of protection that provides an ample margin of safety, nor did it describe what factors the Administrator should consider in making these judgments. Therefore, EPA considers those factors it believes are necessary to make reasonable judgments on whether standards are needed and, if so, at what level they should be established.

If a hazardous pollutant under review has been shown to possess a threshold level below which no detrimental health effects are likely, it might be relatively easy to establish an emission standard. For example, the Agency might select an appropriate safety factor, divide the threshold level by this factor, and establish an emission standard that corresponds to the reduced level. This regulatory strategy would provide reasonable assurance that no detrimental effects would result from exposure to the hazardous pollutant.

This approach is not feasible or reasonable for radionuclides. This is because the risk of cancer from exposure to radiation has not been shown to have a threshold level. Consequently, if EPA applied the approach previously described, the Agency would likely conclude that the standard should be established at zero emissions. The only way to meet such a standard would be to close all facilities emitting radionuclides because it is impossible to reduce radionuclide emissions to zero through control technology. If this approach were adopted, society would be harmed greatly since it would have to forgo the

benefits of industries that emit radionuclides. Therefore, to allow society to continue to benefit from these activities, EPA must establish emission standards for radionuclides at a level that may present some human health risk. The Agency is not aware of any single level of risk that would be generally acceptable or constitute an ample margin of health protection. Some argue that an increase in cancer risk not exceeding one in 1000 due to a specific cause is acceptable, whereas others argue that an increase in risk of one in one million is unacceptable. EPA believes it should adopt an approach that will allow those various factors that influence society's health and well being to be weighed in assessing each source category. To accomplish this, EPA has decided to consider the following factors in making its judgments:

1. The radiation dose and risk to nearby individuals;
2. The cumulative radiation dose and risk to populations in the vicinity of the source;
3. The potential for radiation emissions and risk to increase in the future;
4. The availability, practicality, and cost of control technology to reduce emissions; and
5. The effect of current standards under the Act or other applicable legislative authorities.

By considering these factors, EPA will be able to provide public health protection that is consistent with the intent of the Federal Radiation Protection Guides and Clean Air Act.

The first three factors are used to assess the likely impact of emissions on the health of individuals and large populations and to estimate the potential for significant emissions in the future. The fourth factor enables EPA to assess whether state-of-the-art control technologies are currently in use and whether there are any practical means of reducing emissions through control technology or other control strategies. The last factor allows EPA to assess whether regulations or standards that have been established to control particulates or other pollutants are also minimizing releases of radionuclides.

The dose and risk to the individuals nearest a site are often the primary considerations when evaluating the need to control emissions of radionuclides. Controlling maximum individual dose assures that people living nearest a source are not subjected to unreasonably high risk. Further, protecting individuals usually provides an adequate level of protection to populations living further away from the source. Estimating the maximum

individual dose and risk allows a comparison of the potential impact of one source to other sources.

EPA believes that cumulative population dose and risk also need to be examined. The cumulative radiation dose and risk to surrounding populations are determined by adding together all of the individual doses and risks that everyone within a certain radius (usually 80 km) of an emission source receives. This factor can sometimes be more important than the maximum individual risk in deciding whether controls are needed, particularly if an extremely large population may be exposed. The aggregate dose and population risk can be of such magnitude that it would be reasonable to require a reduction in the total risk even though, if the maximum individual dose were considered alone, one might conclude that no further controls are needed.

In addition, EPA believes that the potential for emissions and risk to increase in the future needs to be considered even though the current projected maximum individual and population risks are very low. An emission standard might be appropriate because the facilities now, or may in the future, handle large quantities of radionuclides that could escape into the air if improperly controlled. Alternatively, when the amount handled by a facility is small or is decreasing, and there is no potential for large releases now or in the future, standards may not be needed.

The availability and practicality of control technology are important in judging how much control of emissions is warranted. For this rulemaking, EPA believes that the standard should be established at a level that will require best available technology with allowance for variation in emissions, once a determination is made that additional controls are necessary. Additional actions, such as requiring development of new technology, closure of a facility, or other extreme measures may be considered if significant emissions remain after best available technology is in place or if there are significant emissions and there is no applicable control technology. EPA is defining best available technology as that which, in the judgment of the Administrator, is the most advanced level of controls adequately demonstrated, considering economic, energy, and environmental impacts. The technological and economic impacts associated with retrofits are considered when determining best available technology for existing sources.

Finally, EPA believes it is reasonable to consider whether other EPA standards are achieving approximately the same goal as the Act, i.e., protecting public health with an ample margin of safety. In cases where other standards are providing comparable control for radionuclides, EPA believes it is appropriate not to propose redundant standards under the Act. There would be no benefits because the public health would already be protected with an ample margin of safety, but there could be unnecessary costs associated with implementing an additional standard.

EPA considered each of the relevant factors in making determinations for each source category that was reviewed. These factors were not quantitatively balanced through the use of formulas to derive emission limits. Rather, they were qualitatively weighed before deciding whether a standard was needed and, if so, what level of control was suitable. The consideration of these factors as they apply to each source category is detailed in the portion of this preamble devoted to that source category.

EPA requests comments on the appropriateness of the factors it has selected for consideration. Should some factors be added or deleted? Should more emphasis be placed on some factors than others? How should the cost-effectiveness, cost-benefits, or affordability of controls be considered when establishing appropriate emission standards to provide an ample margin of safety? EPA also requests comments on whether the factors were appropriately applied to the nine source categories that were reviewed.

It is the intent of the Act that control technology or operational practices be used to control emissions. Buying land to expand the size of the site or building higher stacks to reduce exposure to nearby individuals may not be used where other emission control devices or operational procedures are reasonably available. However, there are radionuclides, principally radon, which present significant risks and for which emission controls may not always be reasonably available. As a last resort in such cases, EPA has decided to propose standards achievable through dispersion techniques.

II. Department of Energy Facilities (DOE)

A. General Description

DOE administers many facilities that emit radionuclides to air. These facilities are Government owned but are managed and operated for DOE by private contractors. Operations at these

facilities include research and development, production and testing of nuclear weapons, enrichment of uranium and production of plutonium and other fissile materials for nuclear weapons, reactors, and other purposes, and processing, storing, and disposing of radioactive wastes. These facilities are on large sites, some of which cover hundreds of square miles in mostly remote locations, and are located in about 20 different states. Some of the smaller facilities resemble typical industrial sites and are located in suburban areas.

Each facility differs in emission rates, site size, nearby population densities, and other parameters that directly affect the dose from radionuclide emissions. Many different kinds of radionuclides are emitted to air. Six sites have multipurpose operations spread over very large areas. About a dozen sites are primarily research and development facilities, located in more populated areas. Reactor and accelerator operations at these sites may release radioactive noble gases and tritium; other operations may release small amounts of other radionuclides. Several facilities are primarily engaged in weapons development and production and may release small amounts of tritium and certain long-lived radionuclides. Finally, two sites are dedicated entirely to gaseous diffusion plants that enrich uranium for use in utility electric power reactors and for defense purposes. They primarily emit uranium.

B. Estimates of Dose and Risk

At 15 of the 25 DOE facilities, which are considered as a group in the Background Information Document because of their relatively small health impact, the doses to the nearby individuals are estimated to be considerably less than 1 millirem per year (mrem/y). The collective dose to the populations living around the sites is also low, no higher than about 10 person-rem as the result of 1 year of site operation. The health risk associated with this group is correspondingly low. The maximum lifetime risk to the most exposed individual is estimated to be less than 10 in 1,000,000 and the impact on the population is estimated to be less than 1 potential health effect per 100 years of operation. These estimates were developed using methods and assumptions discussed in Unit I.C. of this notice.

A second group of 13 facilities, those with the largest emissions of radionuclides, were studied in more detail. They included the following major sites: Argonne National

Laboratory, Brookhaven National Laboratory, Feed Materials Production Center, Fermi National Accelerator Laboratory, Hanford Reservation, Idaho National Engineering Laboratory, Lawrence Livermore Laboratory, Los Alamos National Laboratory, Oak Ridge Reservation, Paducah Gaseous Diffusion Plant, Portsmouth Gaseous Diffusion Plant, Rocky Flats Plant, and the Savannah River Plant.

The highest doses to individuals are projected for Los Alamos national Laboratory (about 9 mrem/y to all organs), Oak Ridge Reservation (about 50 mrem/y to lung and 8 mrem/y to the bone) the Paducah Gaseous Diffusion Plant (about 7 mrem/y to bone and 5 mrem/y to the lung), the Portsmouth Gaseous Diffusion Plant (about 11 mrem/y to bone, 7 mrem/y to lung and 2 mrem/y to thyroid), Feed Materials Production Center (about 88 mrem/y to lung and 26 mrem/y to bone), and Savannah River Plant (about 2 mrem/y to most organs and 5 mrem/y to the thyroid). The corresponding doses to large populations ranged up to about 200 person-rem to the lung per year of site operations. The corresponding maximum lifetime risk to the most exposed individual is estimated to be less than about 2 in 10,000, while the total risk to populations surrounding all 13 sites is estimated to be less than 1 potential health effect per 15 years of operation.

All risk estimates for DOE facilities were developed using methods and assumption discussed in Unit I.C. of this notice. It is important to recognize that the actual risk to specific individuals may differ greatly from these estimates because the circumstances involving the actual exposure may differ significantly from the assumptions used to make the estimates.

C. Emission Control Technology

Emissions from DOE facilities are, in general well controlled as part of a long-standing DOE program of systematically upgrading emission controls when practical. High-efficiency filters, usually in series when large amounts of radionuclides are processed, are used to control particulate emissions. At some facilities, there are processes that discharge radioactive noble gases and tritium mixed with large volumes of air. For these cases, control technologies to remove the noble gases and tritium are usually not feasible.

At the Oak Ridge site, the highest doses to nearby individuals are mostly caused by uranium-234 and uranium-238 emissions from the Y-12 plant, a facility that has fabrication operations using enriched uranium. Particulate emissions

from this facility are controlled by scrubbers, prefilters, cloth bag filters, or high-efficiency particulate filters. At the Feed Materials Production Center, the highest projected doses to nearby individuals are due to emissions of uranium-234 and uranium-238 from fabrication operations using uranium. There is also high exposure to radon decay products due to wastes containing radium-226 that are stored on this site. Particulate emissions are controlled by cloth bag filters or scrubbers but can be reduced further by additional high-efficiency filters or improved scrubbers. Waste tanks can be sealed to prevent the escape of radon.

D. The Proposed Standard

EPA is proposing that emissions of radionuclides from DOE facilities be restricted to the amount that would cause a dose equivalent rate of 10 mrem/y to the whole body and 30 mrem/y to any organ of any individual living nearby. For most practical purposes, compliance with this standard would be determined by calculating the doses to persons assumed to be living at the site boundary.

Consistent with the principles embodied in Federal Radiation Guidance to keep exposure to radiation as low as practical, it is EPA's intent that facilities subject to the DOE standard shall use best available technology even if compliance is possible with a lesser degree of control. This means that operators should periodically evaluate radionuclide emissions to air and reduce them to as low a level below the standard as is reasonably possible. This also means that the facilities now well controlled to levels considerably below the proposed standard should not relax their emission controls and that new facilities should use best available emission controls.

To determine if the standard is being implemented in a manner that keeps exposure as low as practicable, EPA is proposing a reporting requirement. DOE shall submit to EPA a concise annual report which includes the results of monitoring emissions, dose calculations, and discussions of DOE's programs for maintaining airborne releases of radionuclides as low as practicable. Much of this information is currently being collected; for example, emission data are reported by DOE's effluent information systems and annual site reports describe recent and planned improvements in emission controls. Therefore, EPA believes the burden of this reporting is reasonable. This information will be reviewed by EPA in

carrying out its compliance responsibilities.

The proposed emission standards of 10 mrem/y whole body and 30 mrem/y to any organ were selected by considering highest existing emissions from those major DOE facilities where best available technology is used and considering the level to which emissions would be reduced by applying additional controls to other facilities. Uniform standards for DOE facilities could not be set lower than these values because emissions from some major DOE facilities cannot, as a practical matter, be reduced further without closing major operations at the facilities. These DOE facilities provide substantial benefits in the areas of electrical power generation and national defense. The consequence of a more restrictive standard would be to eliminate some of these beneficial activities. Consequently, the risks associated with the proposed standard are not unreasonable. Those few DOE facilities, tending to have emissions greater than this proposed limit can, in EPA's judgment, reduce their emissions using available technology or work practices. EPA believes that the proposed standard would be met if the following plants upgraded their control technology: (1) Oak Ridge Y-12 plant (\$10 million capital costs) (2) Feed Materials Production Center (\$15 million capital costs).

The dose allowed by the proposed standard is a factor of 50 lower than the current upper limits now used by DOE. These current upper limits are based on the 1960 recommendations of the Federal Radiation Council, although the Federal Radiation Council admonished Federal agencies to establish standards that would reduce emissions to as low as practical below the upper limits. Actual public exposure to radiation due to releases from DOE facilities has been far below the 1960 Federal Guidance levels because of the DOE practice of limiting emissions to as low as practicable levels. Since the proposed standard is much more restrictive than the 1960 guidance, it will limit radiation doses to low levels. In practice, EPA expects that most DOE facilities will operate well below the proposed standard.

EPA estimates the actual lifetime individual risk associated with the proposed standard to be at the most about 2 in 50,000 when facilities are complying with the standard. EPA believes that the proposed standard and the reporting requirement will protect the public living around DOE facilities with an ample margin of safety. The

uncertainty associated with estimates of radiation does and risk is discussed in Unit I.C. and II.B of this notice.

EPA requests comments on the proposed values and the methodology used in arriving at them.

E. Alternatives to the Proposed Standard

EPA considered proposing emission limits in units of curies per year (Ci/y) for each radionuclide, with secondary corrections for particle size, lung clearance class, and other such factors. This approach was rejected because it would require very detailed and complex emission limits for each DOE facility to be as protective of public health as the proposed standard. In EPA's judgment, this would be so complex and difficult as to be infeasible.

The Agency considered proposing higher values than the proposed dose limit. We believe that many of these facilities are achieving the proposed standard at current operating levels. For the few cases where additional controls are needed to meet the standard, the technology appears available and effective and is not unreasonably expensive to purchase or operate. The protection offered by the proposed standard appears achievable, and we have not identified any good reason for accepting a lesser degree of protection.

Lower values were considered. Such limits, would be extremely costly or could force the closure of major operations of benefit to the country, possibly at several sites. The possible small additional reduction of dose and risk to a few individuals is not sufficient to justify such severe action.

Emission limits that would control dose to the general population rather than individuals were considered. In particular, EPA considered emission limits for long-half-life radionuclides such as tritium, carbon-14, krypton-85, and iodine-129. These kinds of radionuclides may cause population doses that are more significant than the doses these radionuclides cause to nearby individuals. EPA decided not to propose this kind of standard. For DOE facilities, population doses from these radionuclides are small; the highest of these small doses are caused by emissions of tritium for which control technologies are not effective. Consequently, proposing emission standards for long-half-life radionuclides at existing DOE facilities would not serve a useful purpose.

Different emission limits were considered for existing and new DOE facilities and for specific groups of DOE facilities, rather than setting uniform standards for all DOE facilities. Such a

strategy would permit more restrictive standards for certain DOE facilities, although not for all of them, at the cost of having to develop a much more complex standard. Rather than do this, EPA will rely on existing Federal Guidance to all Federal agencies to ensure that exposures are kept as far below the proposed standard as practicable and has added a reporting requirement to this end. This should provide, in practice, the same measure of emission control. EPA requests comments on the desirability of setting separate standards for different categories of DOE facilities.

EPA considered the alternative of proposing the standard in the form of a risk-equivalent, whole-body dose, using methodology similar to that recently recommended by the International Commission on Radiation Protection. The principal advantage is one of equity; that is, the emissions from each facility are limited on the basis of causing equivalent levels of risk. A disadvantage of this alternative is that the proposed standard would have to be reduced from 10 mrem/y to about 5 mrem/y to maintain a comparable degree of protection with the 30 mrem/y limit to any organ. Some sources could not meet such a standard using currently available technology. The Agency particularly requests comment on the use of the whole-body, risk-equivalent dose method as an approach to selecting emission standards.

EPA considered requiring the proposed standard to be met at a site boundary in all cases, even if there are good reasons why people are not likely to be at that location, but decided not to because this would be unrealistic. EPA requests comments on where the standard should apply.

F. Implementation of the Proposed Standards

The standards will be implemented by DOE pursuant to the Memorandum of Understanding between EPA and DOE. EPA will provide oversight to ensure that implementation procedures are appropriate. The standard should be implemented using pathway and dose calculations based on EPA's codes or, alternatively, on modeling techniques which, in EPA's judgment, are as suitable for particular applications as the EPA codes.

II. NRC Licensed Facilities and Non-DOE Federal Facilities

A. General Description

This category of facilities encompasses a wide range of activities

including research and test reactors, shipyards, the radiopharmaceutical industry, and other industrial facilities. For purposes of this proposed rule, EPA excludes facilities that are part of the uranium fuel cycle. The category includes both facilities licensed by NRC and facilities licensed by a State under an agreement with NRC. These facilities number in the tens of thousands and are located in all 50 states. The principal differences among these various types of activities are their emission characteristics and rates, their sizes, and the population densities of the surrounding areas. The following discussion provides illustrative examples.

There are a wide variety of designs of research and test reactors, and they operate over a range of power levels from near zero to approximately 10 megawatts. They emit primarily argon-41 and tritium at rates ranging from less than 1 Ci/y of each radionuclide up to several thousand Ci/y of argon-41 and several hundred Ci/y of tritium. They are most often located at or near universities.

The radiopharmaceutical industry currently produces about 65 different radionuclides for a variety of uses in hospitals and clinics. In most cases, emissions of iodine-125 and iodine-131 cause the highest organ (thyroid) doses to nearby individuals because: (1) They are emitted in the largest quantities, (2) environmental pathways bring them into contact with man, and (3) the thyroid concentrates iodine. Emissions occur at radiopharmaceutical manufacturing sites, hospitals, and sewage treatment plants receiving hospital wastewater.

There are many other industrial uses of a number of different radionuclides that result in emissions to air, including the manufacture of industrial gauges, static eliminators, radiographic devices, and certain commercial products (e.g., self-illuminating watches and smoke detectors). Most of the industrial uses of radionuclides involve production of sealed (encapsulated) sources. Once their manufacture is completed, these sealed sources do not emit radionuclides.

B. Estimates of Dose and Risk

The vast majority of NRC licensed facilities and non-DOE Federal facilities emit relatively small quantities of radionuclides, which cause correspondingly low doses to people living nearby. Most such facilities cause maximum radiation doses of less than 1 mrem/y; the total dose to the population living around a site rarely exceeds 1 or 2 person-rem per year of operations. The maximum corresponding lifetime risks

of such exposures are estimated to be less than 1 in 50,000 for the individuals receiving the highest doses, and the total risk to the population surrounding a typical facility should be less than about 1 health effect per 500 years of operation.

These estimates were developed by using methods and assumptions discussed in Unit I.C. of this notice. It is important to recognize that the actual risk to specific individuals may differ greatly from these estimates because the circumstances involving the actual exposure may differ significantly from the assumptions used to make the estimates.

C. Control Technology

Some NRC-licensed facilities emit argon-41 and tritium mixed with large volumes of air. For this type of facility, virtually all of the dose is caused by argon-41. Demonstrated treatment technology to reduce argon-41 emissions is not available because argon is a noble gas and cannot be filtered or easily trapped. However, design features, operating procedures, and equipment maintenance can be used to minimize formation of argon-41 in these reactors. For example, since air contains a small percentage of argon-40, areas in which air is exposed to neutrons generated by the reactor are sources of argon-41 when argon-40 absorbs a neutron during reactor operation. In some situations, these areas can be purged with an inert gas to reduce the amount of argon-40 available before starting up the reactor. In other cases, sealing air leaks will reduce the amount of argon-41 that would be produced.

Most facilities emitting dust to which radionuclides are attached use conventional particulate removal technology, such as fabric filters, electrostatic precipitators, scrubbers, or high-efficiency particulate air filters.

D. The Proposed Standards

EPA is proposing that emissions of radionuclides from NRC-licensed facilities and non-DOE Federal facilities be limited to that amount that would cause a dose equivalent of 10 mrem/y to any organ of any individual living nearby. Uranium fuel cycle facilities and all particle accelerators are specifically not covered by this standard for reasons discussed Unit VII of this notice.

In proposing this standard, EPA examined emission levels from facilities in this category and estimated the dose these emissions cause for people living nearby. The highest doses are caused by research and test reactors emitting principally argon-41. The dose associated with the operation of these

facilities is low and cannot be significantly reduced without major redesign and reengineering of these facilities. Therefore, EPA has decided to propose a standard at a level that can be met by existing facilities if they continue to use good management and operational controls to limit their emissions.

EPA believes that the proposed standard protects public health with an ample margin of safety. EPA estimates the risk associated with the proposed standard to be the same as for current practice for the individual receiving the highest dose. The uncertainty associated with estimates of risk is discussed in Units I.C. and III. B. of this notice.

EPA requests comments on the proposed standards and the methodology used in deriving it.

E. Alternatives to the Proposed Standard

The Agency considered higher and lower dose limits than the one being proposed. Higher values were rejected because the proposed standard is currently being met by all facilities in this group. A lower limit was rejected because the dose associated with these emissions is very low and EPA does not believe it is reasonable to set a lower standard and force these facilities to close or reduce their hours of operations.

EPA considered not proposing a standard for this category of facility because the dose from the operations is generally very low. The Agency rejected this alternative because of the potential impact of new facilities or modifications to existing facilities; a standard will ensure that no facilities will emit radionuclides at unreasonably high levels.

EPA also considered requiring that these facilities submit reports documenting that their emissions are as low as practicable, as is being proposed for DOE facilities. Such a requirement would impose a very large paperwork burden on government and industry. Facilities in this category number in the tens of thousands. For EPA to implement such a requirement for this category would require monitoring and reporting by thousands of facilities and a substantial effort on the part of NRC or EPA to review the reports. This considerable effort would help ensure that emissions remain very low. However, because the risk associated with the proposed standard is already low, EPA does not believe the paperwork burden on government and industry is justified. Furthermore, EPA expects that facilities in this category

will, in practice, keep emission levels as low as practicable, both to ensure compliance with the proposed standard and as a matter of good radiation protection principles when dealing with hazardous materials.

F. Implementation of the Proposed Standards

For NRC licensed facilities, NRC will implement the standards subject to EPA oversight to ensure there is compliance with the standard, as is specified in a Memorandum of Understanding between EPA and NRC (45 FR 72980). Implementation will follow the established NRC practice, which is based on a review of control measures used by licensees and their effectiveness as determined by generic assessments.

For non-DOE Federal facilities, EPA will ensure compliance with the standards. EPA's implementation will use the models AIRDOS-EPA and RADRISK to perform pathway analysis and to calculate dose equivalents.

IV. Underground Uranium Mines

A. General Description

Uranium mining involves the handling of large quantities of ore containing uranium-238 and its decay products. The concentrations of these radionuclides in ore may be up to 1,000 times their concentration in other rocks and soils. After mining, the ore is shipped to a uranium mill where the uranium is separated for subsequent use in nuclear power reactors.

Uranium mining is generally carried out by either surface (open pit) or underground mining methods, depending on the depth of the ore deposit. In 1981, there were 167 underground mines and 50 open pit mines in operation in the United States. These mines accounted for about 80 percent of the uranium produced in this country.

All uranium mining in the United States now takes place in western States. In general, the mines are located in relatively remote, low population areas. In 1981, about 70 percent of domestic uranium ore production took place in New Mexico, Wyoming, and Texas.

EPA has evaluated radionuclide emissions from uranium mining activities. These evaluations show that radon-222 is the most significant radionuclide emitted to air. Radon-222 is released to air from underground mines in relatively high concentration through a series of ventilation shafts installed at appropriate locations along the mine haulage ways. These ventilation shafts provide sufficient air exchange in the working areas of the mine to keep the

miners' exposures to radon decay products below the permissible limits. A recent study of 27 underground mines showed that radon-222 emissions to air from individual vents ranged from 2 to 9,000 Ci/y with an average of 900 Ci/y. The number of vents per mine ranged from 2 to 15 with an average of 6 vents per mine. The radon-222 released through these ventilation shafts can cause significant increases in the radon-222 concentration in ambient air in the vicinity of the mine vents.

EPA's evaluation of releases of radon-222 from uranium mines shows that radon-222 is released from surface mines in considerably smaller quantities and in more dilute concentrations than from underground mines. Therefore, radon-222 emissions from surface mines causes only small increases in the radon-222 concentrations in ambient air near the mines and concerns for the health of people near uranium mines is greatest for people living near underground mines.

B. Estimates of Exposure and Risk

Individuals living near underground uranium mines can be exposed to high levels of radon-222. This exposure generally occurs in structures built around the mines. Radon-222 enters the building and decays into other radionuclides which become attached to dust particles in the air. The concentration of these radionuclides build up in the air within the structures. EPA estimated the potential detriment to human health because of radon-222 emissions from uranium mines using the general assumptions discussed in Unit I.C. of this notice. It is important to recognize that the actual risk to individuals may differ greatly from these estimates because the circumstances involving the exposure may differ significantly from the assumptions used to make the estimates. Further, people need to be occupying a structure and not just standing outdoors for these estimates to be applicable.

It is estimated that an individual living 500 meters in the predominant wind direction from a large underground uranium mine will be exposed to a radon-222 concentration of 1 to 2 picocuries per liter (pCi/l) above background. Continuous exposure to indoor radon decay product concentrations (0.007-0.014 working level (WL)) produced by this radon-222 level might result in an increased lifetime risk of 1 to 2 in 100, although in areas where there are many mine vents clustered relatively close together, the risks could be as high as an order of magnitude greater. (A working level is a

unit used to measure exposure to radon decay products).

Collective exposures for populations living near uranium mines are relatively low because these mines generally are located in low population areas. For example, the population risk due to radon-222 emissions from a large underground mine is estimated to be extremely small (about 1 health effect per 30 years of operation of the mine). Consequently, for underground uranium mines, the exposure to the general population is of considerably less public health concern than the exposure for the people that live very close to the mine vents.

C. Control Technology

There are no radon-222 emission control systems now in use in underground uranium mines. However, several methods for reducing the radon-222 concentration in mine air are available and have been used or tested for controlling radon-222 decay product concentrations in the mine itself. These methods, which primarily involve preventing radon-222 from entering the mine air through the use of sealants on the mine walls, bulkheading or backfilling the mined-out stopes, and mine pressurization can also reduce the radon-222 emissions to the outside air. EPA has carried out engineering evaluations of the cost and effectiveness of some of these methods in a hypothetical mine. These evaluations showed that such control methods would be relatively costly and not very effective. The study predicted radon-222 emission reductions from 14 to 49 percent at costs from \$0.30 to \$4.70 dollars per ton of ore mined.

Based on available information, EPA has concluded that no practical technology now exists for achieving satisfactory reductions in radon-222 emissions to air from underground uranium mines. The most effective procedure for limiting exposure to individuals is to provide for greater dispersion of the released radon-222. The Act indicates a preference for avoiding this type of control action to reduce health risks. However, in this situation, traditional emission control methods do not appear to be sufficiently effective in reducing the human health risks posed by release of radon-222 from underground uranium mine vents.

D. The Proposed Standard

EPA is proposing a standard that will limit the annual average radon-222 concentration in air due to emissions from an underground mine to 0.2 pCi/l above background in any unrestricted

area. An unrestricted area is defined to be any area not under the control of the mine owner or a government agency. Under this proposed standard, for a typical, large underground mine using the modeling assumptions previously described, we estimate the lifetime risk to an individual will be on the order of about 1 in 500. For a case in which many mines are located close together, studies which estimate the hazard based on a lifetime exposure show that the potential risks would be higher. However, uranium mines have a limited useful lifetime, usually 5 to 15 years, which limits the period when radon-222 would be released. Further, several other assumptions used in these studies, such as the period of occupancy of the structure, are likely to be less severe in real cases. These factors are expected to make the actual remaining risk to individuals less than 1 in 500, possibly by one or two orders of magnitude, depending on the specific circumstances.

EPA chose a standard of 0.2 pCi/l because higher values did not provide sufficient protection of public health, particularly when many mines are located close together. Values lower than the proposed standard were judged to be impractical because of the cost and difficulty in controlling additional land and the expense associated with other control measures compared to their effectiveness. EPA believes that the risks associated with the proposed standard are not unreasonable in comparison to the cost of additional control.

The standard can be met by one of the following procedures: (1) Reducing the percentage of time the mine operates, (2) increasing the effective height of the release, and (3) controlling additional land. EPA expects that the least expensive way to meet the standard is for the mine operator to control the land around the mine so that people do not live in houses on the land. EPA believes that, on the average, compliance with the proposed standard can be achieved by controlling land within 2 kilometers of the mine vents. The cost to meet the standard by purchasing surrounding land and structures is estimated to be about 4 million dollars per year. This estimate was determined from an evaluation of the cost to control land within 2 kilometers of 29 large mines representing about 90% of the underground uranium mine or production.

Based on 1981 production values, this cost represents a \$0.30 per pound increase in the cost of producing

uranium. This represents a 1% increase in production costs. Although the costs for the smaller mines accounting for the remaining ore production are not included in the estimate, these costs will be relatively small because the radon-222 emissions from these mines are expected to be small.

Owners and operators of underground uranium mines will be required to keep records of radon-222 emissions and radon-222 concentration projections consistent with other actions under the Act.

EPA requests comments on the proposed concentration limit of 0.2 pCi/l. EPA believes that the proposed standard is the most practical and effective way to limit the potential risk to individuals due to radon-222 emissions from underground uranium mines.

E. Alternative Standards

The development of standards for uranium mines is more difficult and complicated than for other sources emitting radionuclides into air. Therefore, the Agency requests public comment on other possible options for standards. In particular, comments are requested on appropriate limits, cost, feasibility, and significance for public health for the following options:

Option 1: Land Control Standard. This type of standard would establish an exclusion area of fixed distance from a mine vent. This area would be under the control of the mine owner or a government agency to prevent excessive exposure to individuals.

Option 2: Work Practice Standard. This standard would include requirements for use of one or more of the following techniques to reduce radon emissions: bulkheading worked-out stopes (including the use of charcoal absorbers on bleeder pipes), backfilling worked-out stopes, and using sealants on mine walls.

Option 3: Emission Standard. This type of standard would establish an emission limit in curies per year of radon-222 from a mine vent as a function of the distance from the vent to the nearest unrestricted area. The emission limit would be set at a value that would keep the radon-222 concentration in ambient air in unrestricted areas below some predetermined value above background.

V. Elemental Phosphorus Plants

A. General Description

About 10 percent of the phosphate rock mined in the United States is used to produce elemental phosphorus. Elemental phosphorus is used primarily

for the production of high-grade phosphoric acid, phosphate based detergents, and organic chemicals. In 1977, approximately 285,000 metric tons of elemental phosphorus were produced from 4 million metric tons of phosphate rock.

Phosphate rock contains appreciable quantities of uranium and its decay products. The uranium concentration of phosphate rock ranges from about 20 to 200 parts per million (ppm), which is 10 to 100 times higher than the uranium concentration in most natural rocks and soil (2 ppm). The significant radionuclides present in phosphate rock are uranium-238, uranium-235, thorium-230, radium-226, radon-222, lead-210, and polonium-210. Because phosphate rock contains elevated concentrations of these radionuclides, handling and processing this material can, via dust particles, release radionuclides into the air. More importantly for elemental phosphorus plants, heating the phosphate rock to high temperatures in calciners and electric furnaces can volatilize lead-210 and polonium-210, resulting in the release of large quantities of these radionuclides into the air.

There are eight elemental phosphorus plants in the United States; these plants are located in Florida, Idaho, Montana, and Tennessee. EPA measurements at three of these plants show that polonium-210 and lead-210 are the radionuclides released from these plants in largest quantities. Most of these emissions occur in calciner stack exhausts. Based on these measurements, it is estimated that a large plant processing phosphate rock containing 25 picocuries per gram of uranium-238 and its decay products and using low energy scrubbers on its calciner exhausts would release about 4 curies of polonium-210 and 2 curies of lead-210 per year into the air. Several of the presently operating elemental phosphorus plants may be releasing comparable quantities of polonium-210 and lead-210, and these emissions would represent the largest quantity of alpha-emitting radionuclides released as particulates into the air by any type of facility in the United States.

B. Estimates of Dose and Risk

The most significant hazard associated with radionuclide emissions to air from elemental phosphorus plants is the radiation dose received by individuals living near those plants. EPA estimates that the radionuclide emissions, primarily polonium-210 and lead-210, from a large elemental phosphorus plant will cause radiation doses of 45 mrem/y to the kidney and 36

mrem/y to the lung of the most exposed individual living near the plant. The lifetime risk to the maximally exposed individual associated with these doses is estimated to be about 1 in 10,000.

The risks to the populations living near elemental phosphorus plants are relatively low. EPA estimates that the potential health risk to the population living around a large plant is about 1 health effect per 100 years of plant operation and that the total risk from radionuclide emissions from all elemental phosphorus plants is about 1 health effect per 20 years of operation.

These estimates were developed using methods and assumptions discussed in Unit I.C. of this notice. It is important to recognize that the actual risk to specific individuals may differ greatly from these estimates because the circumstances involving the exposure may differ significantly from the assumptions used to make the estimates.

C. Control Technology

Particulate emissions from calciner exhausts at elemental phosphorus plants are controlled through the use of wet scrubbers. Most plants use either spray towers or low-energy venturi scrubbers. Such systems are estimated to control particulate emissions to about 0.5 to 1.0 pound per ton of rock processed and are about 80 to 90 percent efficient for removal of polonium-210. One plant operates with two venturi-like scrubbers in series. Such a system should control particulate emissions to about 0.1 pound per ton of rock processed and is about 98 percent efficient for removal of polonium-210.

EPA has estimated the cost of installing high-energy venturi scrubbers on calciner stacks at large elemental phosphorus plants now operating with spray towers or low-energy scrubbers. The capital cost per plant for installing these scrubbers is about \$3 million, and the annual operating cost is \$1.5 million. A high-energy venturi scrubber is expected to be at least 98 percent efficient for polonium-210 removal and to reduce the emissions of this radionuclide for a large plant to less than 1 Ci/y. Lead-210 will be controlled at least as well because the scrubbers will remove lead with at least equal efficiency.

D. The Proposed Standard

EPA is proposing that the emissions of polonium-210 in the calciner off-gases at elemental phosphorus plants be limited to 1 Ci/y. EPA believes the use of best available technology at these facilities can achieve this standard. Limiting the polonium-210 emissions also effectively limits the lead-210 and other

radionuclide emissions in the calciner off-gases. This standard will keep the radiation doses to individuals living near these plants to less than 10 mrem/y to the lung and to less than 15 mrem/y to the kidney. The lifetime risk associated with these doses is less than 3 in 100,000. EPA believes this will protect the individuals living nearby with an ample margin of safety. The assumptions and uncertainties associated with estimates of risk are discussed in Units I.C. and V.E. of this notice.

Complete information is not available on the polonium-210 emissions from all elemental phosphorus plants. Therefore, some uncertainty exists regarding the number of plants that would need to retrofit emission control systems. However, based on presently available information, EPA estimates that no more than two plants would need to install additional control systems to meet the proposed standard. These would be the large-capacity plants processing high-radionuclide-content phosphate rock. Installation of high-energy venturi scrubbers on the calciner exhausts of two plants would result in a capital expenditure of about \$6 million and annual operating costs of \$3 million per year.

Under the proposed standard, owners or operators of elemental phosphorus plants will be required to (a) measure the polonium-210 emissions from their calciner stacks and to report the results of these tests to EPA and (b) continuously monitor the pressure drop across their calciner scrubbers and to maintain records of these measurements for a minimum of two years.

EPA requests comments on the proposed values and the methodology used in arriving at them.

E. Alternatives to the Proposed Standard

The Agency considered proposing higher or lower values than 1 Ci/y. Higher values did not seem justified because they would either not significantly reduce the radiation doses to individuals living near these plants or would cost just as much to implement as the proposed standard. Lower values were also considered, but available information indicates that additional control technology is not feasible to meet lower levels.

The Agency also considered a standard expressed as curies/metric ton of phosphate rock processed. However, this type of standard may require emission control retrofit by one or more additional plants even though their emissions of polonium-210 would be significantly less than 1 Ci/y. Since the

primary purpose of the standard is to limit the annual radiation doses to the most exposed individual living near these plants, the Agency concluded that an annual emission limit, rather than an emission limit per unit of rock processed, is the more appropriate form of the standard.

VI. Sources for Which Standards Are Not Proposed

EPA has identified several source categories that emit radionuclides to air for which standards are not being proposed. These emissions comprise radionuclides that occur naturally in the environment but are released to air due to industrial processes. In addition to these sources, EPA is not proposing emission standards for uranium fuel cycle facilities, uranium mill tailings, management of high level radioactive wastes, and low energy accelerators. The reasons for these decisions are discussed in the following paragraphs. Additional supporting information may be found in the Docket and in the Background Information Document.

Estimates of risk used in this analysis were developed using methods and assumptions discussed in Unit I.C. of this notice. It is important to recognize that the actual risk to specific individuals may differ greatly from the estimates because the circumstances involving the actual exposure may differ greatly from the assumptions used to make the estimates.

A. Coal-Fired Boilers

Large, coal-fired boilers are used by utilities and industry to generate electricity and by industry to make process steam and to heat water for space heaters and industrial processes. When these boilers are operating, trace amounts of uranium, radium, thorium, and decay products of these radionuclides that are present in coal become incorporated into the fly ash and are emitted along with the particulates into the air. Technology that removes particulates will, therefore, also limit radionuclide emissions.

Particulate emissions from new utility boilers are controlled under Section III of the Act (43 FR 42154, September 19, 1978, revised by 44 FR 33613, June 11, 1979). These New Source Performance Standards (NSPS) require utility boilers constructed after September 19, 1978, to have best available technology that limits particulate emissions to 13 nanograms per joule (ng/J) (0.03 pound/million Btu). To meet this emission standard, electrostatic precipitators (ESPs) or fabric filter systems are usually installed. Doses from utility

boiler radionuclide emissions under NSPS are low, less than 1 mrem/y to any organ, and there is no practical way to reduce them further since best available technology is already being used. Further reduction in emissions would require a second fabric filter or ESP in series with the first; this would be unreasonably expensive for the emission reduction achieved. Thus, radionuclide emission standards for new utility boilers would be either redundant or, if more restrictive, prohibitively expensive.

Particulate emissions from new large industrial boilers are controlled by NSPS that limit particulate matter to 43 ng/j (0.1 pound/million Btu). EPA plans to propose NSPS for smaller industrial boilers also; draft proposed limits have been circulated for comment. These standards should reduce particulate emissions to low levels and should correspondingly reduce doses to nearby individuals from radionuclide emissions to less than 1 mrem/y to any organ. With NSPS in place, radionuclide standards for industrial boilers would be redundant.

Existing utility and industrial boilers are regulated for particulate emissions by State Implementation Plans (SIPs) required by the Act. Limits vary for specific plants, but, in general, SIPs require large boilers located in populated areas to be well controlled with ESPs. Preliminary information indicates that retrofitting existing utility boilers to further reduce radionuclide emissions would cost approximately \$15 billion for capital improvements and \$3 billion a year to operate them. Total retrofitting of the industry with best available technology would reduce the estimated potential health effects by about 1 to 2 per year. For industrial boilers, the costs are about \$3 billion for capital improvements and \$0.7 billion to operate them. Total retrofitting of the industry with best available technology would reduce the estimated potential health effects by about 1 every three years. For both utility and industrial boilers, the costs are judged to be unreasonable in comparison to the reduction in dose and risk that would result.

The amount of radionuclides that could potentially be emitted by coal-fired boilers is strictly limited by the amount of uranium and thorium in the incoming coal. EPA has no reasons, therefore, to expect that massive releases of radionuclides will occur or that current emission rates will increase significantly. Under the current Federal and State regulatory programs,

emissions should slowly decrease as old boilers are replaced.

In summary, EPA is not proposing standards for coal-fired boilers because existing emission controls that limit particulate releases also limit radionuclide releases. The risks to nearby individuals and the total risks to populations after application of controls already required are not large when compared to the cost of additional control technology. There is no potential for emissions to increase due to the limited amounts of radionuclides within the coal; rather, overall emissions will decrease with time as old plants are replaced with new ones with improved emission controls as required by the NSPS for particulate emissions.

EPA did consider the possibility that boilers may be using coal with radionuclide content that is significantly above average or that existing boilers may be operating in a manner that causes elevated emissions of radionuclides. If this is the case, there could be a subcategory of coal-fired boilers for which it would be appropriate to issue an emission standard. EPA requests comments and information on whether these situations do exist, their causes, their significance to public health, whether emission standards are needed, and what emission levels would be appropriate.

B. Phosphate Industry

The phosphate industry processes phosphate rock to produce fertilizers, detergents, animal feeds and other products. The production of fertilizer uses approximately 80 percent of the phosphate rock mined in the United States. Diammonium phosphate and triple superphosphate are the phosphate fertilizers produced in the largest quantities. Phosphate deposits contain large quantities of natural radioactivity, principally uranium-238 and members of its decay series. Uranium concentrations in phosphate deposits range from 10 to 100 times the concentration of uranium in other natural rocks and soils.

The processing of phosphate rock in dryers, grinders, and fertilizer plants results in the release of radionuclides into the air. As with coal-fired boilers, control techniques that remove particulates will also control radionuclide emissions and risks. Particulate emissions from the process exhausts of these plants are already well controlled, and the doses to individuals and populations from the radionuclides contained in the particulates are less than 15 mrem/y to any organ.

Particulate emissions from new or modified phosphate rock dryer and

grinder facilities are already regulated by NSPS under Section 111 of the Act (47 FR 16582, April 16, 1982). To meet these standards, high-energy scrubbers of high-energy ESPs are usually installed on dryers, and fabric filters are installed on grinders. Particulate emissions from existing dryers and grinders are regulated under SIPs. About 20 percent of the existing dryers already have controls equivalent to NSPS; the remaining dryers either employ low-energy or medium-energy scrubbers. About 75 percent of the existing grinders already have controls equivalent to NSPS; the remaining grinders use the equivalent of medium-energy scrubbers.

To retrofit all existing phosphate rock dryers with best available technology would require a capital expenditure of \$44 million and an increase of \$3 million in annual operating costs. This would reduce the maximum individual bone dose from 15 mrem/y to 3 mrem/y and avoid 1 health effect in 50 years of operations. To retrofit all existing phosphate grinders with best available technology would require a capital expenditure of \$4 million but would not increase the annual operating cost. This would reduce the maximum individual bone dose from 1 mrem/y to 0.2 mrem/y and avoid 1 health effect in 500 years of operations.

Phosphate fertilizer plants use wet-scrubber systems on their process exhausts. These controls are needed to comply with NSPS (40 CFR Part 60, Subparts T through X) or SIPs for fluoride emissions. About 75 percent of the existing industry production capacity is controlled by both primary and secondary scrubbers. Scrubbers used to control fluoride emissions are also effective controls for particulate emissions.

To retrofit all existing fertilizer plants with secondary scrubbers on their diammonium phosphate and triple superphosphate process stacks would require capital costs of \$14 million and would result in an increase of \$1.5 million in annual operating costs. This would reduce the maximum individual bone dose from 2 mrem/y to 1 mrem/y and would avoid 1 health effect in 500 years of operations.

In summary, EPA is not proposing standards for phosphate rock dryers and grinders or phosphate fertilizer plants, because (1) the bone dose to individuals represent a small hazard to health compared to a similar dose to most other organs, (2) the potential for increased emissions is not present due to the limited amount of radionuclides in the phosphate rock, (3) other Clean Air Act standards require controls that also

reduce radionuclide emissions, and (4) the cost to further reduce radionuclide emissions is unreasonably large compared to the additional protection achieved.

About 25 percent of the phosphate rock used for fertilizer production is treated in calciners rather than dryers to remove organic matter prior to processing. Since calciners operate at significantly higher temperatures than dryers, this may result in the volatilization and release to air of significant quantities of polonium-210, similar to the emissions from elemental phosphorus plants. Radionuclide emission studies are being planned for phosphate rock calciner plants. However, no radionuclide emission data are available for calciners, and, therefore, EPA is unable to determine at this time that standards are needed for these facilities. EPA requests comments and information on these emissions, their significance to public health, whether emission standards are needed, and what limits would be appropriate.

C. Other Extraction Industries

Almost all industrial operations involving removal and processing of soils and rocks to recover valuable commodities release some radionuclides into the air. EPA has carried out studies of airborne radioactive emissions from such mining, milling, and smelting operations.

The industries studied include iron, copper, zinc, clay, limestone, fluorspar, and bauxite. These are relatively large industries and are, therefore, considered to have the greatest potential for emitting radioactive materials into the air.

Although the analysis of data from these studies is not complete, the information available to the Agency at the present time shows that the radiation doses to individuals and populations from radionuclide emissions from these types of facilities are small and would not be reduced at reasonable cost. Therefore, EPA is not proposing standards for these parts of the extraction industry.

D. Uranium Fuel Cycle Facilities, Uranium Mill Tailings, and Management of High Level Waste

The Uranium Fuel Cycle (UFC) consists of operations associated with production of electric power for public use by light-water-cooled reactors using uranium fuel. It includes light-water-cooled nuclear power plants and facilities that mill the uranium ore, enrich uranium, and fabricate and reprocess uranium fuel. EPA has promulgated emission standards for

normal operations of the UFC under the Atomic Energy Act (40 CFR Part 190). These standards limit the annual dose equivalent to body organs of nearby individuals to 25 mrem/y (75 mrem/y for the thyroid) and limit the emissions of krypton-85, iodine-129, and other long-half-life, alpha-emitting, transuranium radionuclides. As a practical matter, the EPA standards and their implementation by the NRC require the use of best available technology, which keeps doses to individuals and populations to low levels. The estimated individual risk associated with 25 mrem/y to all organs for a lifetime is about 1 in 2000.

Uranium mill tailings remain after uranium ore is processed to remove the uranium. Altogether, there are many thousands of acres of these tailings at both inactive and active uranium mill sites, mostly in the Southwest. Large amounts of radon-222 are emitted to air from the piles due to the radium-226 remaining in the tailings after the uranium is removed. Congress addressed this problem through the Uranium Mill Tailings Radiation Control Act of 1978 (Pub. L. 95-604). Under this authority, EPA has active programs to promulgate standards requiring remedial actions that will, among other objectives, prevent these tailings from being moved and prevent radon from escaping after the piles become inactive. Standards have been promulgated for inactive mill sites and will soon be proposed for active mill sites.

The highly radioactive liquid or solid wastes from reprocessing spent nuclear fuel, or the spent fuel elements themselves if they are disposed of without reprocessing, are called "high level wastes". Over the last several years, the Federal government has intensified its program to develop and demonstrate a permanent disposal method for high level waste. As part of this effort, EPA has proposed standards to limit radiation exposure of members of the public from management of this waste prior to disposal (47 FR 58196, December 29, 1982). These proposed standards would limit the annual dose equivalent to any member of the public to 25 mrem/y to the whole body, 75 mrem/y to the thyroid, or 25 mrem/y to any other organ. Waste management operations are also to be conducted so as to reduce exposures below these levels to the extent that this is reasonably achievable.

EPA is not proposing additional radionuclide standards for UFC facilities, uranium mill tailings, and high level wastes because the Agency believes that EPA standards established (or to be established) under other applicable authorities will protect public

health with an ample margin of safety in the same way as an emission standard established under Section 112 of the Act.

E. Low Energy Accelerators

Accelerators, which impart energy to charged particles such as electrons, alpha particles, and protons, are used for a wide variety of applications, including radiography, activation analysis, food sterilization and preservation, radiation therapy, and research. There are over 1,200 accelerators in use in the United States, not including accelerators owned by DOE. This number has been growing at a rate of approximately 65 machines per year.

Accelerators other than those owned by the DOE operate at low energy levels (i.e., less energy is imparted to the particles). These machines emit very small quantities of radionuclides (specifically, carbon-11, carbon-14, nitrogen-13, oxygen-15, and argon-41) because they operate at relatively low energies. In addition, those accelerators using tritium targets may emit a small quantity of tritium, typically less than 1 Ci/y. The quantity of radionuclides produced is so small that the doses and health risks associated with those emissions are extremely low, generally several orders of magnitude less than other sources discussed in the proposed rule. Further, there is no practical way to reduce them. EPA is not proposing standards for accelerators because of the low doses, less than 1 microrem/y to nearby individuals, and because there is no potential for the doses from existing or new facilities to exceed this level significantly.

F. Request for Comments

EPA requests comments on its proposed decisions not to issue standards for radionuclide emissions from the categories of sources just described. These decisions will be reconsidered if additional information becomes available indicating that doses and risks are significantly greater, costs are significantly lower, or controls are more available than those on which EPA based its decisions.

If the Administrator decides not to issue standards for particular source categories, such decisions are likely to be accompanied by determinations that these decisions are of nationwide scope and effect under the terms of section 307(b) of the Act.

VIII. Miscellaneous

A. Docket

The Docket is an organized and complete file of all information

considered by EPA in the development of these proposed standards. The Docket allows interested persons to identify and locate documents so that they can effectively participate in the rulemaking process. It also serves as the record for judicial review.

A transcript of the hearing and all written statements will be placed in the Docket and will be available for inspection and copying during normal working hours.

B. Executive Order 12291

Under Executive Order 12291, issued February 17, 1981, EPA must judge whether a rule is a "major rule" and, therefore, subject to the requirement that a Regulatory Impact Analysis be prepared. EPA has determined that this rule is not a major rule as that term is defined in Section 1(b) of the Executive Order.

EPA concluded that the rule is not major under the criteria of section 1(b) because the annual effect of the rule on the economy will be less than \$100 million. It will not cause a major increase in costs or prices for any sector of the economy or for any geographic region. Also, it will not result in any significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States enterprises to compete with foreign enterprises in domestic or foreign markets.

This proposed rule was submitted to the Office of Management and Budget (OMB) prior to publication, as required by the Executive Order.

List of Subjects in 40 CFR Part 61

Air pollution control. Asbestos. Beryllium. Hazardous materials. Mercury. Vinyl chloride. Radionuclides.

C. Paperwork Reduction Act

The Paperwork Reduction Act of 1980 (Pub. L. 96-511) (PRA) requires that the Office of Management and Budget review reporting and recordkeeping requirements that constitute "information collection" as defined. Assuming, without deciding, that some or all of the proposed reporting and recordkeeping requirements constitute information collection within the meaning of the PRA, the PRA requires the Office of Management and Budget to review information collection activities to determine whether they are "necessary for the proper performance of the functions of the Agency" (section 3508).

This proposal, if promulgated, would impose reporting and recordkeeping requirements for one Federal agency and on owners and operators of

elemental phosphorus plants and underground uranium mines.

EPA requests comments on the reasonableness of the information collection requirements and on the costs involved as compared to other means of compliance determinations.

D. Regulatory Flexibility Analysis

Section 603 of the Regulatory Flexibility Act, 5 U.S.C. 603, requires EPA to prepare and make available for comment an "initial regulatory flexibility analysis" in connection with any rulemaking for which there is a statutory requirement that a general notice of proposed rulemaking be published. The "initial regulatory analysis" describes the effect of the proposed rule on small business entities.

However, Section 604(b) of the Regulatory Flexibility Act provides that Section 603 "shall not apply to any proposed * * * rule if the head of the Agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities."

EPA believes that virtually all small businesses covered by this proposed rule are already meeting the proposed standards. Therefore, this rule will have little or no impact on small businesses.

For the preceding reasons, I certify that this rule, if promulgated, will not have significant economic impact on a substantial number of small entities.

Dated: March 29, 1983.

Lee Thomas,

Acting Administrator.

It is proposed to amend Part 61 of chapter I of title 40 of the Code of Federal Regulations as follows:

1. By adding to the table of sections the following items:

Subpart K—National Emission Standards for Radionuclide Emissions from Department of Energy Facilities

- Sec. 61.120 Designation of facilities.
- 61.121 Definitions.
- 61.122 Standard.
- 61.123 Emission monitoring and test procedures.
- 61.124 Compliance and reporting.

Subpart L—National Emission Standard for Radionuclide Emissions From Facilities Licensed by the Nuclear Regulatory Commission and Federal Facilities Not Covered by Subpart K

- 61.130 Applicability.
- 61.131 Definitions.
- 61.132 Standard.

Subpart M—National Emission Standard for Radionuclide Emissions From Underground Uranium Mines

- 61.140 Applicability.
- 61.141 Definitions.

- Sec. 61.142 Standard.
- 61.143 Emission tests.
- 61.144 Reporting.

Subpart N—National Emission Standard for Radionuclide Emissions From Elemental Phosphorous Plants

- 61.150 Applicability.
- 61.151 Definitions.
- 61.152 Standard.
- 61.153 Emission tests.
- 61.154 Test methods and procedures.
- 61.155 Monitoring of Operations.

Appendix B—Test Methods

Method 111—Determination of polonium-210 emissions from stationary sources.
Authority: Sec. 112 and 301(a), Clean Air Act, as amended [42 U.S.C. 7412, 7601(a)].

2. By adding the following Subpart K:

Subpart K—National Emission Standards for Radionuclide Emissions From Department of Energy Facilities

§ 61.120 Designation of facilities.

The provisions of this subpart apply to radiation dose equivalent values received by members of the public as the result of operations at facilities that are owned or operated by the Department of Energy and that emit radionuclides to air.

§ 61.121 Definitions.

(a) "Whole body" means all human organs, organ systems, and tissues exclusive of the integumentary system (skin) and cornea.

(b) "Organ" means any human organ or tissue exclusive of the integumentary system (skin) and the cornea.

(c) "Radionuclide" means any nuclide that emits radiation.

(d) "Dose equivalent" means the product of absorbed dose and appropriate factors to account for differences in biological effectiveness due to the quality of radiation and its distribution in the body. The unit of the dose equivalent is the rem.

§ 61.122 Standard.

Emissions of radionuclides to air from operations of Department of Energy facilities shall not exceed those amounts that cause a dose equivalent rate of 10 mrem/y to whole body or 30 mrem/y to any organ of any member of the public.

§ 61.123 Emission monitoring and test procedures.

To determine compliance with the standard, radionuclide emissions shall be determined and dose equivalent values to members of the public calculated using EPA approved sampling procedures, codes AIRDOSE-EPA and RADRISK, or other procedures

which EPA has determined to be suitable.

§ 61.124 Compliance and reporting.

DOE shall submit to EPA an annual report which includes the results of monitoring emissions from points subject to this standard and dose calculations for each site. The report shall also describe the DOE program for maintaining airborne radionuclide releases as low as practicable below the standard, including a discussion of - current controls, new control equipment installed during the year, and a discussion of new controls that are under consideration.

3. By adding the following Subpart L:

Subpart L—National Emission Standards for Radionuclide Emissions From facilities Licensed by the Nuclear Regulatory Commission and Federal Facilities Not Covered by Subpart K

§ 61.130 Applicability.

The provisions of this subpart apply to NRC-licensed facilities and to facilities owned or operated by any Federal agency other than the Department of Energy, except that this subpart does not apply to facilities regulated under 40 CFR Part 190 or to any accelerator.

§ 61.131 Definitions.

(a) "Agreement State" means and State with which the Atomic Energy Commission or the Nuclear Regulatory Commission has entered into an effective agreement under subsection 274(b) of the Atomic Energy Act of 1954, as amended.

(b) "Dose equivalent" means the product of absorbed dose and appropriate factors to account for differences in biological effectiveness due to the quality of radiation and its distribution in the body. The unit of the dose equivalent is the rem.

(c) "NRC/licensed facility" means any facility licensed by the Nuclear Regulatory Commission or any Agreement State to receive title to, receive, possess, use, transfer, or deliver any source, by-product, or special nuclear material.

(d) "Organ" means any human organ or tissue exclusive of the integumentary system (skin) and the cornea.

(e) "Radionuclide" means any nuclide that emits radiation.

§ 61.132 Standard.

(a) Emissions of radionuclides to air from facilities subject to this subpart shall not exceed those amounts that cause a dose equivalent rate of 10 mrem/y to any organ of any member of the public.

(b) This standard shall be implemented using pathway and dose equivalent calculations based on EPA's codes AIRDOSE-EPA and RADRISK or modeling techniques which, in EPA's judgment, are as suitable for particular applications as the EPA codes.

4. By adding the following Subpart M:

Subpart M—National Emission Standard for Radionuclide Emission From Underground Uranium Mines

§ 61.140 Applicability.

The provisions of this subpart are applicable to owners or operators of underground uranium mines.

§ 61.141 Definitions.

(a) "Unrestricted area," as used in this subpart, means an area not under the control of the mine owner or operator or a governmental agency for the purpose of restricting the use or establishment of structures for residential purposes.

(b) "Mine vent" means a shaft extending from the working areas of an underground uranium mine to the earth's surface for the purpose of discharging ventilation air from the mine to the earth's atmosphere.

(c) "Curie" is a unit of radioactivity equal to 37 billion nuclear transformations (decays) per second.

§ 61.142 Standard.

The radon-222 emissions to air from the mine vents of an underground uranium mine shall not result in an increase in the annual average radon-222 concentration in air in an unrestricted area in excess of 0.2 pCi/l.

§ 61.143 Emission tests.

(a) Unless a waiver of emission testing is obtained under 61.13, each mine owner or operator subject to 61.142 shall measure the radon-222 emissions from each of his mine vents:

(1) Within 90 days of the effective date of this rule, and annually thereafter, in the case of an existing source or a new source which has an initial startup date preceding the effective date of this rule; or

(2) Within 90 days of startup, and annually thereafter, in the case of a new source that did not have an initial startup date preceding the effective date.

(b) The Administrator shall be notified at least 30 days prior to an emission test so that EPA may, at its option, observe the test.

(c) Each emission test shall consist of three runs. The tests shall be conducted during normal operating and ventilation conditions. The average of all three runs shall apply in computing the emission rate.

(d) For use in calculating radon-222 concentrations in unrestricted areas under § 61.144, the annual emissions from each mine vent shall be determined by multiplying the radon-222 concentration measured in the air emitted from the mine vent by the total volume of air discharged through the vent over a one year period based on continuous operation of the ventilation system.

(e) Records of emission test results and other data needed to determine total emissions shall be retained at the source and made available for inspection by the Administrator for a minimum of 2 years.

§ 61.144 Reporting.

(a) Each owner or operator of a source subject to the requirements of § 61.142 shall calculate the average annual radon-222 concentration in air at the nearest unrestricted area to each of the mine vents from his mine using the following equation:

$$C_j = 0.1 \sum Q_i (X_{ij})^{-1.75}$$

Where

C_j = radon-222 concentration in picocuries per liter (pCi/l) at location j due to all vents from the mine.

Q_i = radon emission rate in kilocuries per year from vent i .

X_{ij} = distance in kilometers from mine vent i to location j .

(b) Rather than use the method prescribed in paragraph (a), an owner or operator of a mine may, subject to the approval of the Administrator, use dispersion factors based on site specific meteorology.

(c) The calculations performed under paragraph (a) or (b) shall be reported to the Administrator within 30 days of completion of the emission tests required under § 61.143.

5. By adding the following Subpart N:

Subpart N—National Emission Standard for Radionuclide Emission From Elemental Phosphorus Plants

§ 61.150 Applicability.

The provisions of this subpart are applicable to owners and operators of nodulizing kilns and electric furnaces at elemental phosphorus plants.

§ 61.151 Definitions.

(a) "Elemental phosphorus plant" means any facility that processes phosphate rock to produce elemental phosphorus using pyrometallurgical techniques.

(b) "Nodulizing kiln" means a unit in which phosphate rock is heated to convert it to a nodular form.

(c) "Electric furnace" means a unit in which the phosphate rock is heated with silica and coke to reduce the phosphate to elemental phosphorus.

(d) "Curie" is a unit of radioactivity equal to 37 billion nuclear transformations (decays) per second.

§ 61.152 Standard.

Emissions of polonium-210 to air from sources subject to this subpart shall not exceed 1 curie in a calendar year.

§ 61.153 Emission tests.

(a) Unless a waiver of emission testing is obtained under § 61.13, each owner or operator required to comply with § 61.152 shall test emissions from his source within the following time limits:

(1) Within 90 days of the effective date of this rule in the case of an existing source or a new source that has an initial startup date preceding the effective date of this rule; or

(2) Within 90 days of startup in the case of a new source that did not have an initial startup date preceding the effective date of this rule.

(b) The Administrator shall be notified at least 30 days prior to an emission test so that EPA may, at its option, observe the test.

(c) Each emission test shall consist of three runs. The phosphate rock processing rate during each test shall be recorded. The average of all three runs shall apply in computing the emission rate. For determining compliance with the emission standard of § 61.152, the annual polonium-210 emissions shall be determined by multiplying the polonium-210 emission rate in curies per metric ton of phosphate rock processed by the annual phosphate rock processing rate in metric tons. In determining the annual phosphate rock processing rate, the values used for operating hours and operating capacity shall be values that will maximize the expected production rate. If the owner or operator of a source subject to this subpart changes his operation in a way that could change his emissions of polonium-210, he may determine his compliance with the requirements of this subpart on the basis of calculations using data from previous emission tests.

(d) All samples shall be analyzed, and polonium-210 emissions shall be determined within 30 days after the source test. All determinations shall be reported to the Administrator by a registered letter dispatched before the close of the next business day following such determination.

(e) Records of emission test results and other data needed to determine total emissions shall be retained at the

source and made available for inspection by the Administrator for a minimum of 2 years.

§ 61.154 Test methods and procedures.

(a) Each owner or operator of a source required to test emissions under § 61.153, unless an equivalent or alternate method has been approved by the Administrator, shall use the following test methods:

1. Test Method 1 of Appendix A to Part 60 shall be used to determine sample and velocity traverses;

2. Test Method 2 of Appendix A to Part 60 shall be used to determine velocity and volumetric flow rate;

3. Test Method 5 of Appendix A to Part 60 shall be used to collect particulate matter containing the polonium-210;

4. Test Method 111 of Appendix B to this part shall be used to determine the polonium-210 emissions.

§ 61.155 Monitoring of operations.

(a) The owner or operator of any source subject to this subpart using a wet scrubbing emission control device shall install, calibrate, maintain, and operate a monitoring device for the continuous measurement of the pressure loss of the gas stream through the scrubber. The monitoring device must be certified by the manufacturer to be accurate within ± 250 pascals (± 1 inch of water). Records of these measurements shall be maintained at the source and made available for inspection by the Administrator for a minimum of two years.

(b) For the purpose of conducting an emission test under § 61.153, the owner or operator of any source subject to the provisions of this subpart shall install, calibrate, maintain, and operate a device for measuring the phosphate rock feed to any affected nodulizing kiln. The measuring device used must be accurate to within ± 5 percent of the mass rate over its operating range.

Appendix B—[Amended]

6. By adding the following test method of Appendix B:

Method 111—Determination of Polonium-210 Emissions From Stationary Sources

Performance of this method should not be attempted by persons unfamiliar with the use of equipment for measuring radioactive disintegration rates.

1.0 Applicability and Principle

1.1 *Applicability.* This method is applicable to the determination of polonium-210 emissions in particulate samples collected in stack gases.

1.2 *Principle.* A particulate sample is collected from stack gases as described in Method 5 of Appendix A to 40 CFR

Part 60. The polonium-210 in the sample is put in solution, deposited on a metal disc and the radioactive disintegration rate measured. Polonium in acid solution spontaneously deposits on surfaces of metals which are more electropositive than polonium. This principle is routinely used in the radiochemical analyses of polonium-210 (reference 1).

2.0 Apparatus

2.1 Alpha-counter photomultiplier tube, (5 cm), with associated electronics to record pulses.

2.2 Constant temperature bath at 85°C.

2.3 Polished nickel discs, 3.8 cm diameter, 0.6 mm thick.

2.4 Silver activated zinc sulfide screen.

2.5 Beakers, 400 ml, 150 ml.

2.6 Hot plate, electric.

2.7 Fume hood.

2.8 Teflon beakers, 150 ml.

Teflon is a registered trademark of DuPont Co.

3.0 Reagents

3.1 Analysis.

3.1.1 Ascorbic acid, reagent grade.

3.1.2 Distilled water.

3.1.3 Hydrochloric acid 12M, concentrated reagent grade.

3.1.4 Hydrofluoric acid 28M, reagent grade.

3.1.5 Nitric acid 16M, concentrated reagent grade.

3.1.6 Perchloric acid 12M, 72 percent reagent grade.

3.1.7 Sodium hydroxide 18M. Dissolve 720 g of sodium hydroxide pellets in distilled water and dilute to 1 liter.

3.1.8 Trichloroethylene.

3.2 *Standard solution.* Prepare calibrated solution of polonium-210 from supplier of this radionuclide. Known aliquots are to be used to establish efficiency of deposition.

4.0 Procedure

4.1 Sample Preparation.

4.1.1 Place filter collected by EPA Method 5 Part 60 in Teflon beaker, add 30 ml hydrofluoric acid and evaporate to dryness on hot plate in hood.

4.1.2 Repeat step 4.1.1 until glass fiber filter has been digested.

4.1.3 Add 100 ml 16M nitric acid to residue in Teflon beaker and evaporate to dryness. Do not overheat.

4.1.4 Add 50 ml 16M nitric acid to residue from step 4.1.3 and heat to 80°C.

4.1.5 Decant acid solution into glass beaker and add 10 ml 12M perchloric acid.

4.1.6 Heat acid mixture to perchloric acid fumes.

4.1.7 Adjust volume to 60 ml with distilled water and neutralize with 18M sodium hydroxide.

4.1.8 Dilute to 100 ml with distilled water and adjust solution to 0.5M in HCl by adding 4 ml 12M hydrochloric acid.

4.2 *Sample Analysis.* Analyze the solution for polonium-210 using any published method which involves the spontaneous electrodeposition of polonium-210, including the method described below:

4.2.1 Add 200 ml of ascorbic acid and heat solution to 85°C in constant temperature bath.

4.2.2 Melt a thin coating of polyethylene on the unpolished side of disc to prevent deposition. Adhesion of the polyethylene to the disc is enhanced by sanding the nickel surface with garnet paper.

4.2.3 Clean polished side with trichloroethylene, hydrochloric acid, and distilled water.

4.2.4 Suspended nickel disc in the solution using glass or plastic hook.

4.2.5 Maintain disc in solution for 3 hours while stirring the solution.

4.2.6 Remove nickel disc, rinse with distilled water and dry at room temperature.

4.3 *Measurement of Polonium-210.*

4.3.1 Position deposition side of nickel disc adjacent to zinc sulfide screen on photomultiplier tube and count pulses.

4.3.2 Establish background count rate by measuring counts over clean nickel discs.

4.3.3 Determine procedure efficiency by adding calibrated aliquots of polonium-210 to acid solution with clean filter and following procedure through radioassay step.

4.3.4 Determine counter efficiency by carefully evaporating known aliquots of polonium-210 on nickel disc and measuring count rate, comparing count rate to known disintegration rate as fraction.

5.0 *Calculations*

5.1 Calculate the curies of polonium-210 in the sample using the following equation:

$$A = \frac{C_T - C_B}{2.22 \times 10^{12} (E_p)(E_c)(T)(D)}$$

A = Curies of polonium-210 in sample.

C_T = total sample counts for counting period.

C_B = background counts for counting period.

E_p = procedure efficiency.

E_c = counting efficiency.

T = counting time in minutes.

D = decay correction.

5.1.1 *Decay Correction*

$$\text{Decay correction (D)} = e^{-\frac{0.693(T)}{t_{1/2}}}$$

T = time in days from midpoint of collection time to the counting time.
 $t_{1/2}$ = radiological half life of polonium-210, 138.4 days.

5.2 *Procedure for Calculating Emissions.*

Calculate the polonium-210 emission per metric ton of rock processed using the following equation:

$$E = \frac{AQ_s}{V_s M}$$

E = Curies of polonium-210 per metric ton of rock processed.

A = Curies of polonium-210 in sample from 5.1.

Q_s = Volumetric flow rate of effluent stream in m³/h.

V_s = Total volume of air sampled in m³.

M = Rock processing rate during sampling in metric tons/hr.

6.0 *References*

1. Blanchard, Richard L., Rapid Determination of Lead-210 and Polonium-210 in Environmental Samples by Deposition on Nickel. *Anal. Chem.* 38, 189 (1966).

(FR Doc. 83-8728 Filed 4-5-83; 8:43 am)
 BILLING CODE 6550-50-M

APPENDIX D

List of Subcommittee Meetings, Briefings and Public Presentations

The Subcommittee held four meetings in Washington, D.C., three of them public. The non-public meeting consisted of a writing session of Subcommittee members at which no EPA staff attended with the exception of the Director of the Science Advisory Board. Agendas for the three public meetings, which identify EPA staff briefings and public presentations, are included in this appendix. In addition, transcripts of these public meetings are on file at the Science Advisory Board offices.

Room 1112
Crystal Mall #2
1921 Jefferson Davis Hwy.
Arlington, Virginia

U.S. Environmental Protection Agency
Science Advisory Board
Subcommittee on Risk Assessment for Radionuclides
Open Meeting--January 16, 1984

9:30 a.m.	Opening Remarks	Dr. McClellan Dr. Yosie
9:45	Introduction of the Subcommittee	
10:00	Charge to the Subcommittee	Mr. Sjoblom Dr. Yosie
10:30	Risk Assessment and Risk Management in the Office of Radiation Programs	Mr. Sjoblom
11:15	Break	
11:30	Radionuclides Background Briefings	
	1. A Computerized Methodology for Estimating Environmental Concentra- tions and Dose to Man from Airborne Releases of Radionuclides (AIRDOS Model)	Mr. Nelson
12:30 p.m.	Lunch	
1:30	Background Briefings, continued	
	2. Life Table Methodology for Eval- uating Radiation Risks	Dr. Bunger
2:15	3. Basis for EPA Radiation Risk Assessments	Dr. Ellett
3:00	Break	
3:15	Committee Discussion and Development of Plans for Future Activities	
4:00	Adjourn	

Room 1112 Crystal Mall #2
1921 Jefferson Davis Hwy.
Crystal City, Virginia

U. S. Environmental Protection Agency
Science Advisory Board
Subcommittee on Risk Assessment for Radionuclides
February 21-22, 1984--Open Meeting

Tuesday, February 21

9:00 a.m.	Opening Remarks	Dr. R. McClellan Dr. T. Yosie
9:15	Recapitulation of the ORD Risk Issues and Process (From the Previous Meeting)	Dr. W. Ellett
9:45	Update on Transport/Modeling Briefing From the Previous Meeting -- Questions from the Subcommittee on the Transport Modeling (AIRDOS-EPA)	Dr. C. Nelson
10:15	Dose Models and Risk Assess- ment Models and Codes	Dr. B. Sullivan
11:00	Break	
11:15	Discussion of Dose and Risk Models, continued	
12:00	Lunch	
1:00	EPA Estimates of Cancer Fatal- ities	Dr. W. Ellett
2:00	EPA Estimates of Genetic Effects	Dr. N. Nelson
2:30	Statements From the Public	Mr. D. Scroggin, Idaho Mining Assoc. Dr. L. Hamilton, Dr. J. Harley and Dr. N. Harley Dr. I. White, NCRP
3:00	Break	
3:15	Case Study Briefing	
	1. Y-12 Facility	Mr. J. Hardin
5:00	Recess	
6:00	Subcommittee Dinner	

Wednesday, February 22

9:00 a.m.	Opening Remarks	Dr. McClellan
9:15	Case Study Briefing, Continued	Dr. P. Magno
	2. Phosphorus Plant	
11:00	Break	
11:15	Subcommittee Discussion and Future Agenda	
12:30	Adjourn	

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Arlington, Va.

U.S. Environmental Protection Agency
Science Advisory Board
Subcommittee on Risk Assessment for Radionuclides
March 22-23, 1983

Thursday, March 22

9:00 am	Opening Remarks	Dr. R. McClellan Dr. T. Yosie
9:15	Subcommittee Discussion of Issues To Be Included in a Draft Report and Development of Preliminary Position Papers	
12:00 pm	Lunch	
1:00	Follow-Up on Y-12 Case Study Briefing	Dr. C. Nelson
1:15	Supplementary Comments and Materials on Cancer Risk Estimates	Dr. W. Ellett
1:30	Application of Risk Assessment Decision-Making	Mr. R. Guimond
3:00	Break	
3:15	Statements From the Public	Dr. H. Whipple Utility Air Regulatory Group
3:30	Subcommittee Discussion	
4:30	Recess	
6:00-8:00	Subcommittee Dinner	

Friday, March 23

9:00 am	Opening Remarks	Dr. R. McClellan
9:10	Subcommittee Discussion of Issues To Be Included in a Draft Report and Development of Preliminary Position Papers	
12:00	Adjourn	

Appendix E

References

1. Risk Assessment in the Federal Government: Managing the Process, Committee on the Institutional Means for Assessment of Risks to Public Health, National Academy of Sciences/National Research Council, 1983.
2. William D. Ruckelshaus, "Science, Risk and Public Policy," Speech Delivered Before the National Academy of Sciences, June 22, 1983.
3. ----- "Managing Risk in a Free Society," Princeton Alumni Weekly, March 7, 1984, pp. 18-23.
4. The Effects on Populations of Exposure to Low Levels of Ionizing Radiation: 1980, Committee on the Biological Effects of Ionizing Radiation (BEIR III), National Academy of Sciences/National Research Council, (1980).
5. D. B. Turner, Workbook of Atmospheric Diffusion Estimates. U.S. Department of Health, Education and Welfare, 1969. Publication No. 995-AP-26.
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7. F. A. Gifford, "Estimating Ground-Level Concentration Patterns From Isolated Air-Pollution Sources; A Brief Summary," Environmental Research v. 25 (1981), pp. 126-138.
8. T. V. Crawford, Atmospheric Transport of Radionuclides. Report of the Working Group on Atmospheric Dispersion, Deposition and Resuspension. Proceedings of the Workshop on Evaluation of Models Used for the Environmental Assessment of Radionuclide Releases, Gatlinburg, TN., September 6-9, 1977. Oak Ridge National Laboratory Report No. CONF-770901 (Oak Ridge, TN).
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11. Calculation of Annual Doses to Man From Routine Releases of Reactor Effluent for the Purpose of Evaluating Compliance with 10 CFR Part 50, Appendix I, Regulatory Guide, 1.109 (Revision I). U.S. Nuclear Regulatory Commission (1977).
12. R. Sullivan and C. Nelson, RADRISK/BEIR-III, Part II: Dometric Methods and Codes Used to Assess Radiation Risk (January, 1984 Draft).
13. R. L. Dobson, J. Straume, J. S. Felton, and P. C. Kwan, "Mechanism of Radiation and Chemical Oocyte Killing in Mice and Possible Implications for Genetic Risk Estimation (Abstract)," Environmental Mutagen V. 5 (1983), pp. 498-499.

APPENDIX F: Comparison of AIRDOS-EPA Predictions With Those of Other Models
and Real Data: Explanation of Table 1 and Figures 1-7

EXPLANATION OF FIGS. 1-7 AND TABLE 1

Several internationally-recognized models for assessment of the transfer of radionuclides through terrestrial foodchains were compared by Hoffman and colleagues.^{1,2} Comparisons were made of the steady-state concentrations of Cs-137, Sr-90 and I-131 in milk, meat and vegetables, as predicted by the various models, per unit of chronic deposition rate. The units are $\mu\text{Ci}/\text{kg}$ per $\mu\text{Ci}/\text{M}^2\text{-day}$. Among the models compared are AIRDOS-EPA, International Atomic Energy Agency (IAEA), National Radiological Protection Board of the United Kingdom (NRPB), BIOPATH (Studsvik Energiteknik AB, Sweden) and U.S. Nuclear Regulatory Commission (NRC). For some radionuclides in some foods, observed data compiled by UNSCEAR were compared to model predictions. All the above models were run to produce time-independent estimates of steady state concentrations per unit deposition rate.

In this exercise, these models were compared to predictions by PATHWAY, a dynamic model developed to predict human ingestion of fallout-produced radionuclides in the vicinity of the Nevada Test Site during the 1950's.³ PATHWAY predicts time-integrated concentrations in foods per unit of acute deposition ($\mu\text{Ci-days}/\text{kg}$ per $\mu\text{Ci}/\text{M}^2$). It can be shown that this quantity is mathematically equivalent to the quantities predicted by the above models. The utility of using PATHWAY for comparison is that it illustrates time-dependencies in the various foodchain processes, and it has been rather carefully tested against real observations.⁴

In Figs 1-7, the results of PATHWAY are plotted by the calendar date of fallout deposition, and the values predicted by the other models or observed by UNSCEAR are also shown. The significant time-dependencies shown by the PATHWAY results mainly reflect dynamics in animal diets, harvest practices of feed crops, and plant growth patterns.

A major difference between PATHWAY and the other models is found in the mass interception of radionuclides by foliage. Whereas PATHWAY uses a value applicable to large fallout particles (50-300 μm), the other models use a value applicable to submicron particles and gases. The PATHWAY predictions may be multiplied by a factor of five to adjust for this particular difference. This has been done in Table I, for comparison to AIRDOS-EPA.

In Table I, PATHWAY predictions scaled to correspond to real data observations [PATHWAY (P*O/P)] are compared directly to AIRDOS-EPA predictions as a test of the latter model's accuracy. In the case of Sr-90 in vegetables, PATHWAY did not use a comparable category, so the UNSCEAR data were used as the basis of testing AIRDOS-EPA. For Cs-137 and Sr-90 in milk, both UNSCEAR and scaled PATHWAY results could be compared to the EPA model.

1. Hoffman, F.O., V. Bergstrom, C. Gyllander and A. Wilkens. 1983. The transfer of Co-60, Sr-90, I-131, and Cs-137 through terrestrial foodchains: A comparison of model predictions. STUDSVIK/NW-83/417, Studsvik Energiteknik AB, Sweden.
2. Hoffman, F.O., V. Bergstrom, C. Gyllander and A. Wilkens. A comparison of predictions from internationally recognized assessment models for the transfer of selected radionuclides through terrestrial foodchains. Nuclear Safety (In Press).
3. Kirchner, T.B., F.W. Whicker and M.D. Otis. 1983. PATHWAY: A simulation model of radionuclide transport through agricultural foodchains. pp. 959-968 In Lauenroth, W.K., G.V. Skogerboe and M. Flug (eds.). Analysis of Ecological systems: State-of-the Art in Ecological Modelling. Elsevier Sci. Publ. Co., Amsterdam.
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FIGURE 1

TIME-INTEGRAL OF I-131 CONCENTRATION IN MILK
PER UNIT DEPOSITION: MODEL COMPARISONS

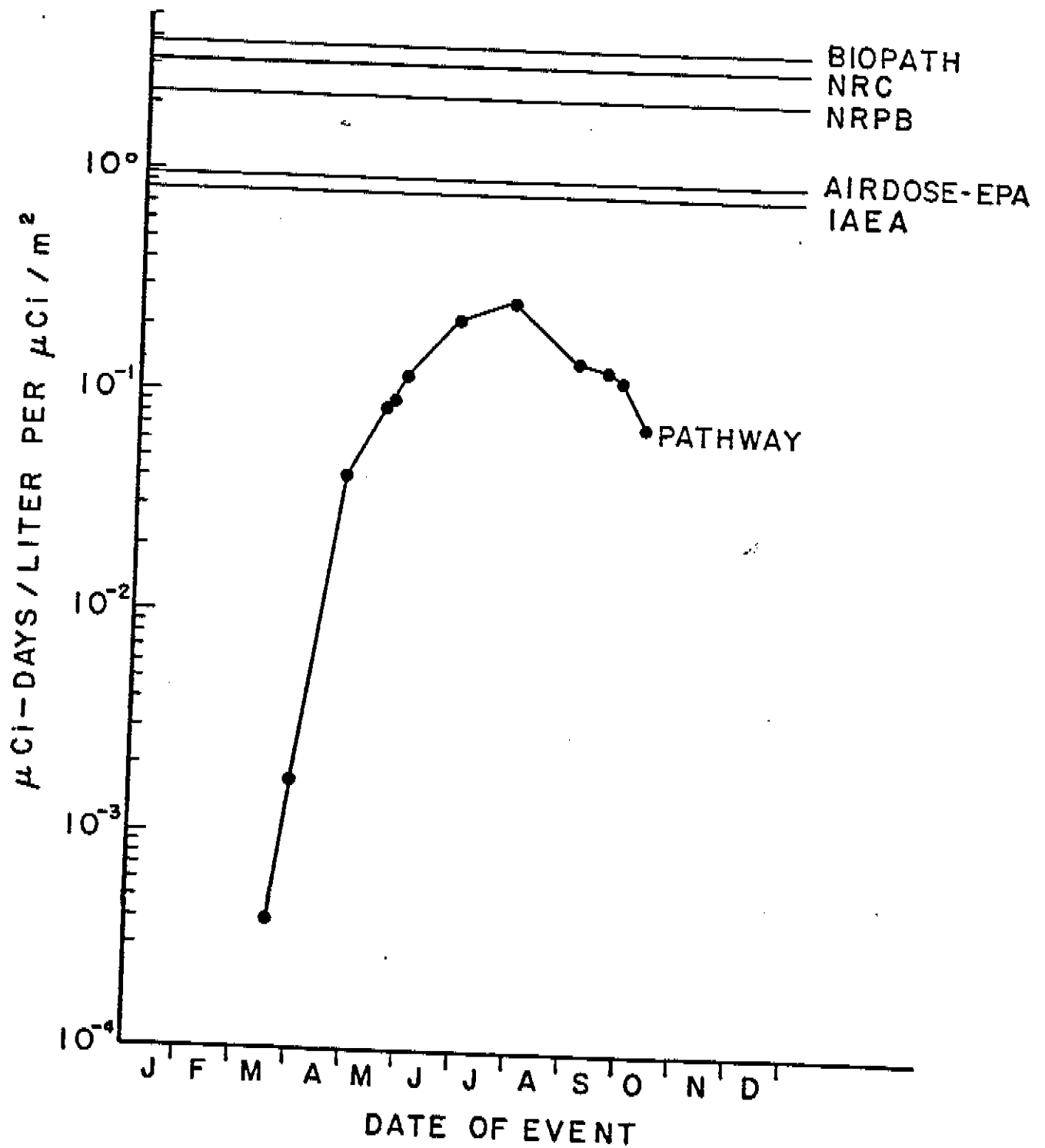


FIGURE 2

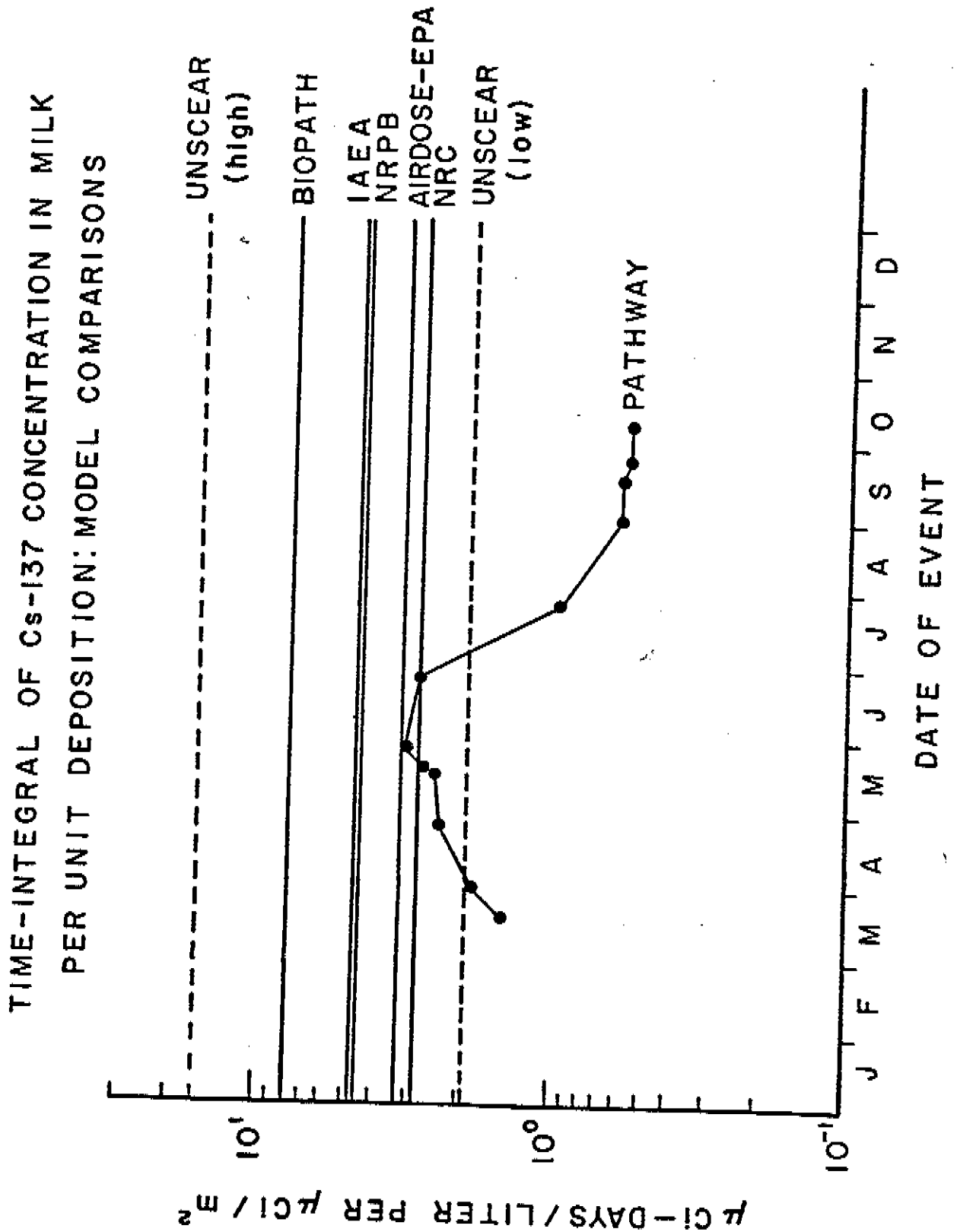


FIGURE 3

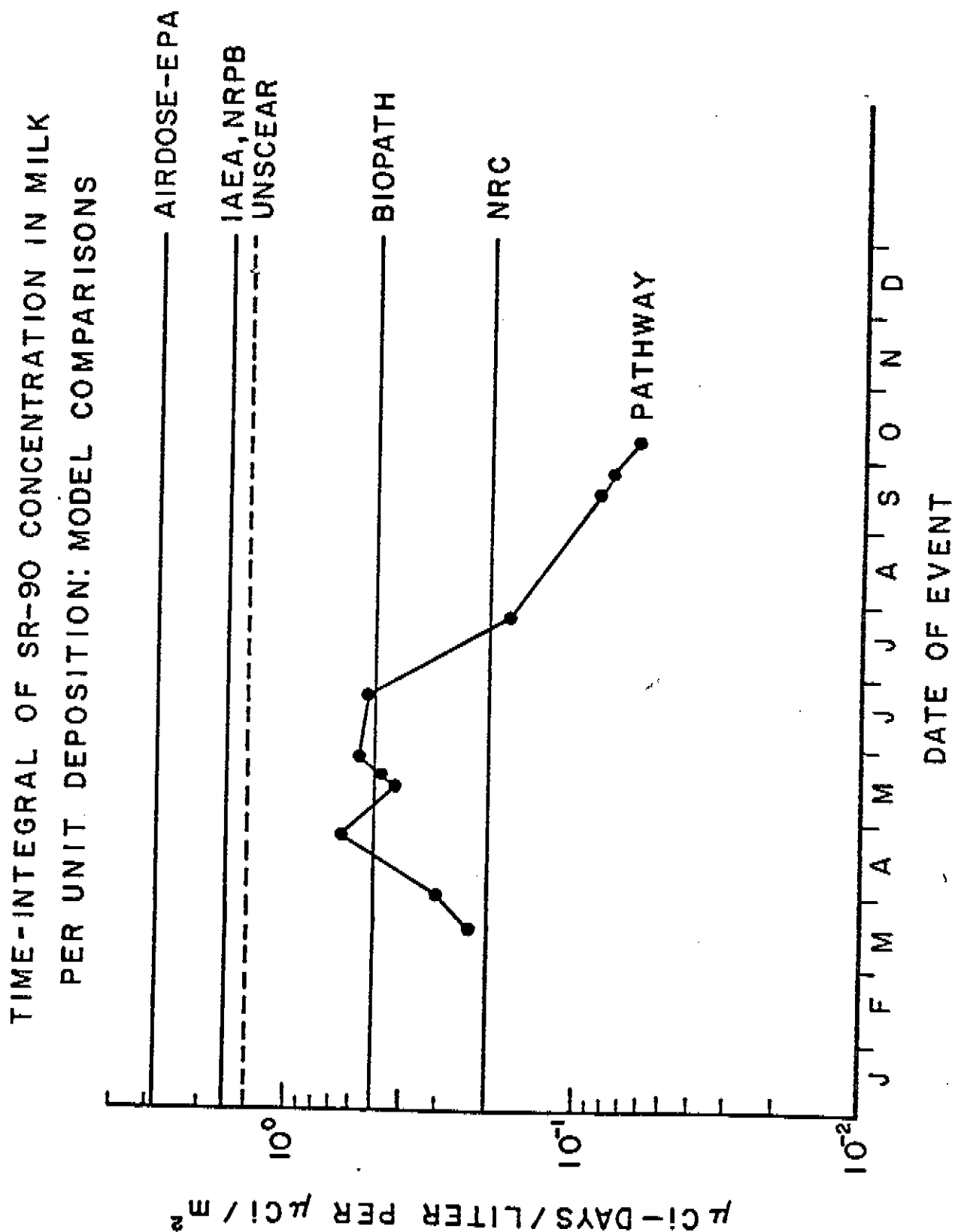


FIGURE 4

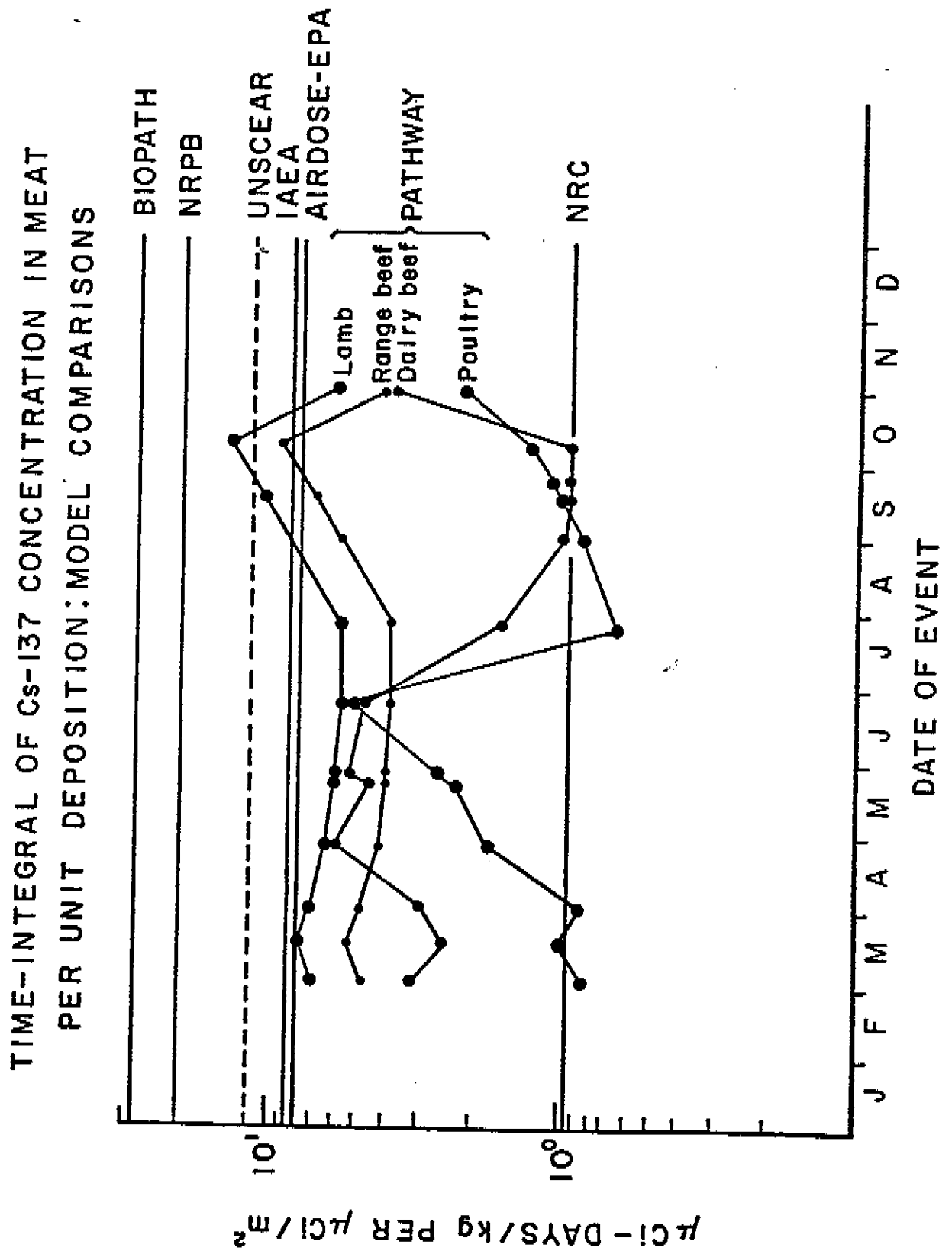


FIGURE 5

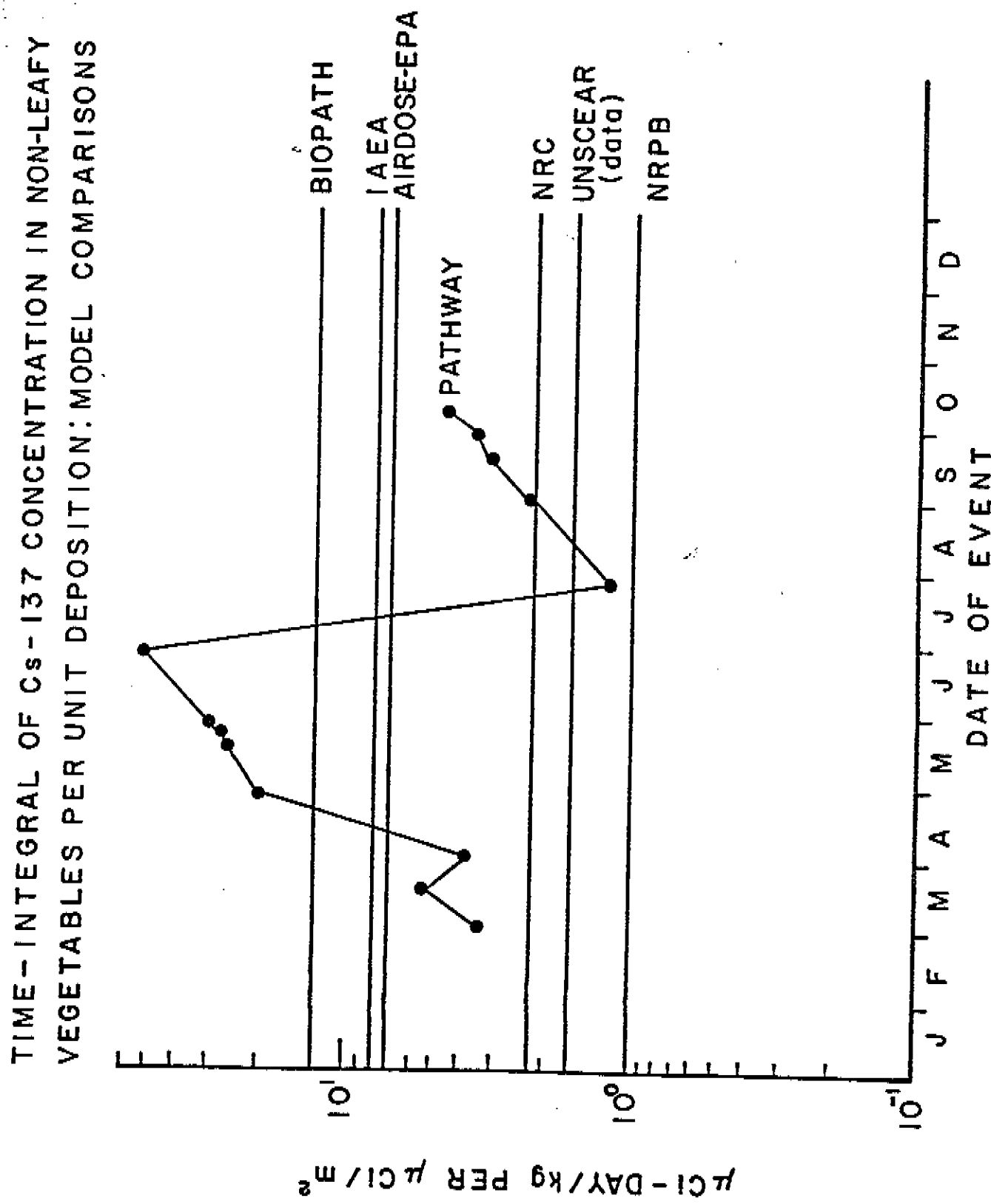


FIGURE 6

TIME-INTEGRAL OF SR-90 CONCENTRATION IN NON-LEAFY
VEGETABLES PER UNIT DEPOSITION: MODEL COMPARISONS

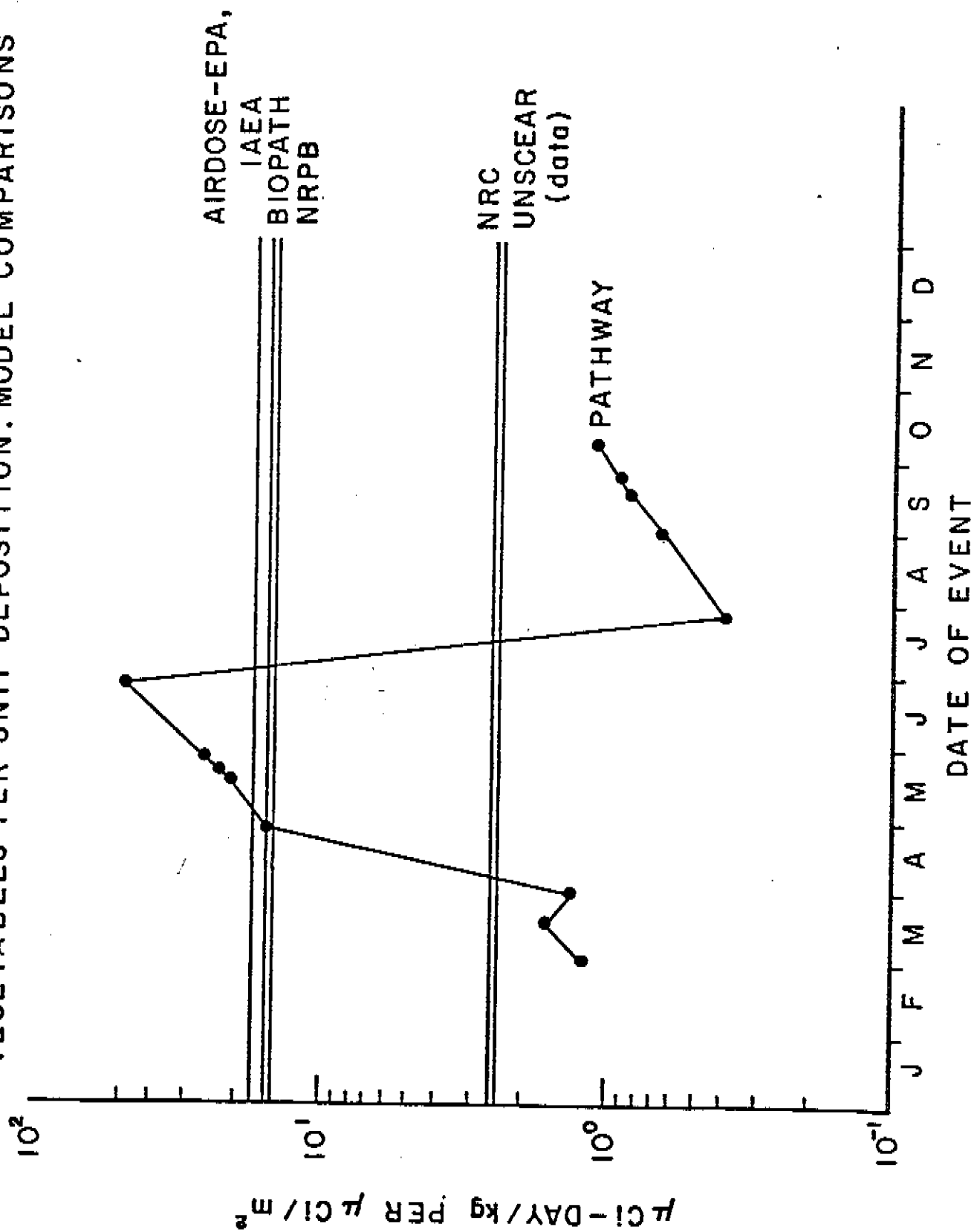
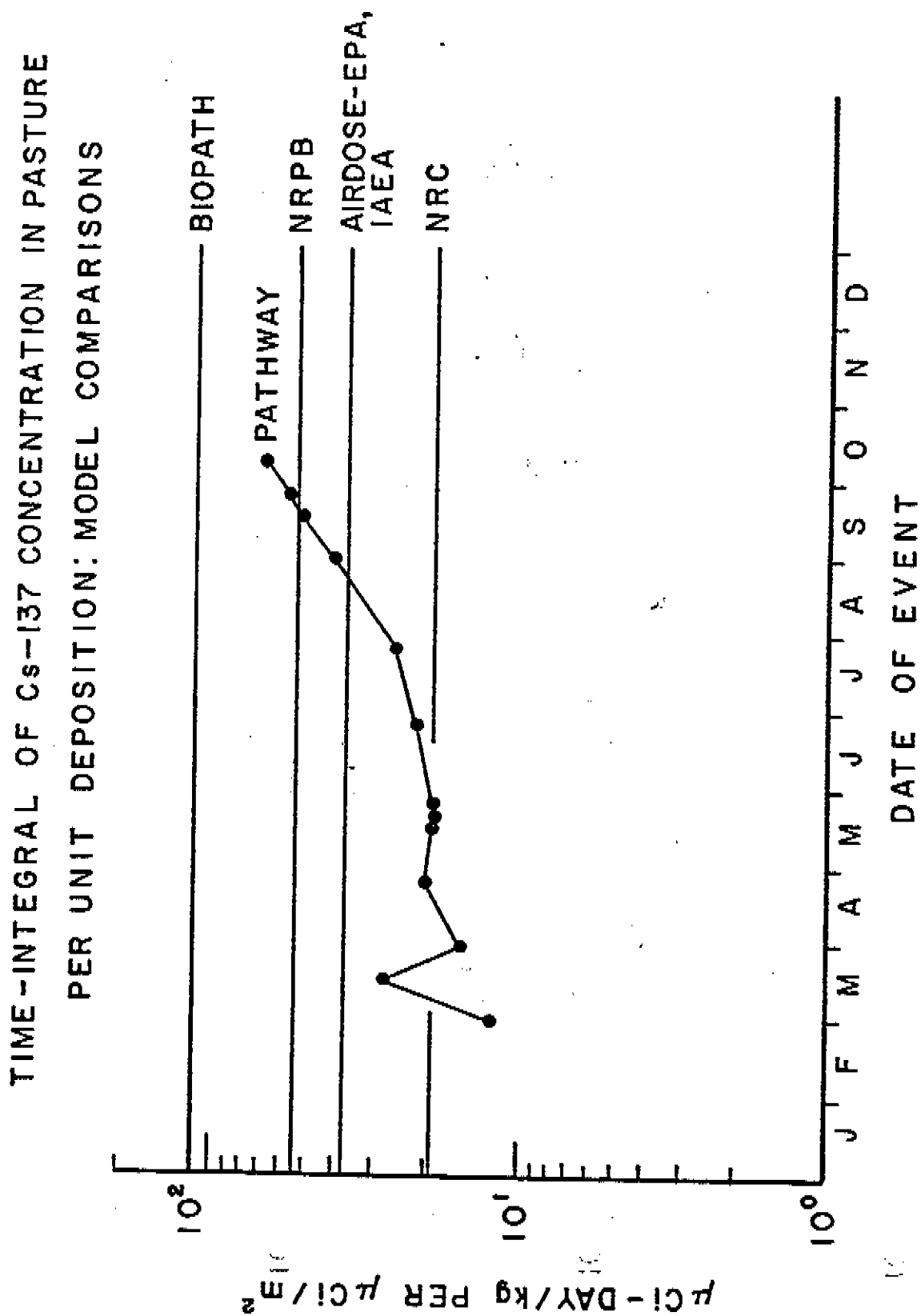


FIGURE 7



APPENDIX G

RADIATION ADVISORY COMMITTEE

Preamble

The Administrator of the Environmental Protection Agency has asked the Science Advisory Board (SAB) to establish a standing committee on environmental radiation. The formation of such a committee was recommended by the SAB Subcommittee on Risk Assessment for Radionuclides as part of its review of the scientific basis of EPA's proposed standards for airborne radionuclides. The newly created committee is expected to provide a continuing source of scientific advice to EPA's Office of Radiation Programs (ORP) and other elements of the Agency as they carry out their mandated activities.

OBJECTIVE: To review and evaluate the scientific basis and quality of the Agency's scientific assessments, research and other scientific activities related to environmental radiation.

CHARGE: To provide, on a continuing basis, a committee constituted of a group of scientists knowledgeable in matters related to the impact of radiation on the environment and human populations. The committee is expected to provide a review of the scientific quality of the Agency's radiation activities and to offer advice on how its scientific capabilities can be maintained at a high level. Further, the committee is expected to review and comment on the adequacy of scientific information and analyses used in developing risk assessments and other scientific documents the ORP and other Agency offices may prepare as a basis for risk management decisions on radiation matters.

SCOPE OF ACTIVITIES: Areas of current and planned committee activity include:

- 1) providing independent scientific review of scientific analyses used to estimate the importance of radiation on the environment and people for EPA's rule making and guidance development activities; 2) providing peer and scientific review and advice to the Agency on the development and maintenance of the state-of-the-art in the various scientific areas needed to discharge its responsibilities including sources of radiation exposures and radioactivity, movement of radionuclides through the environment, estimation of the dose received by people from both internally deposited and external radiation sources and estimation of the health and environmental risks of radiation exposure; and 3) identifying priority monitoring and other scientific information needs to support the Agency's regulatory activities for radiation.

PROCEDURE: The committee will meet at least twice annually, or more frequently if necessary to carry out its assigned responsibilities. It will hold public meetings to advise the Agency and solicit information from the public. The Committee will report to the Administrator through the Executive Committee of the Science Advisory Board.

