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Assessment of Capabilities and Research Needs in the Area of Health Effects of Low-Level Ionizing Radiation

A Joint Report to the Congress by the
U. S. Environmental Protection Agency and
the U. S. Nuclear Regulatory Commission

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PREFACE

This report was prepared jointly by the Environmental Protection Agency and the Nuclear Regulatory Commission to describe their needs, capabilities, and current research programs in the area of the health effects of low-level ionizing radiation. The report was prepared in response to a Congressional directive contained in Public Law 95-601 and has been transmitted to the Congress in fulfillment of that directive. This version of the report differs slightly from the version transmitted to the Congress in that funding levels of NRC research and technical assistance projects have been deleted.

I. INTRODUCTION

A. PURPOSE AND ORGANIZATION OF THIS REPORT

1. Purpose

The Congress of the United States directed[1] the Environmental Protection Agency and the Nuclear Regulatory Commission to prepare an assessment of their research needs and capabilities in the area of the health effects of low-level* ionizing radiation. This report, prepared jointly by the Environmental Protection Agency and the staff of Nuclear Regulatory Commission, represents the agencies' response to this directive.

2. Agency Responsibilities

The Environmental Protection Agency (EPA) and the Nuclear Regulatory Commission (NRC) have complementary responsibilities in protecting the public from radiation that might be emitted from the nuclear fuel cycle and from other peaceful uses of radioactive materials. Under Reorganization Plan No. 3 of 1970, EPA has the responsibility for setting generally applicable environmental radiation standards. The NRC has responsibility for developing and enforcing standards for occupational radiation protection and radioactive effluent limitations and for enforcing the EPA standards for activities it licenses under the authorities of the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended. Because of their respective responsibilities, both the EPA and NRC must assure that these generally applicable standards provide adequate protection of public health.

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*For the purposes of this report "low-level" radiation is considered to be radiation doses within current Federal guidance for occupational exposure.

(1)Sec. 5(c) of Public Law 95-601, Authorizing Appropriation to The Nuclear Regulatory Commission for FY 1979.

The Environmental Protection Agency has specific statutory authority for ensuring protection of public health and the environment under separate statutes for air and water pollution control, drinking water quality protection, ocean disposal, resource recovery, and hazardous material control. Several of these authorities also cover standard-setting and enforcement activities that relate to radioactive materials as described in Part II of this report. Because of these authorities and the authorities of the former Federal Radiation Council for preparing guidance to Federal agencies on the formulation of radiation protection standards, the Environmental Protection Agency's responsibilities are considerably broader than those of NRC. EPA's research needs will also be more diversified than those of NRC. For this reason, the specific needs and capabilities of the two agencies will be discussed in separate sections.

3. Organization

This report describes, in separate sections, the needs, capabilities, and current programs of the Environmental Protection Agency and the Nuclear Regulatory Commission for assessing the potential health effects associated with exposure of workers and the general public to low-level ionizing radiation. In addition to this information, the report also provides a general description of the methods used by both agencies to estimate these effects and a summary of the statutory authorities of the two agencies for conducting these assessments and research programs. These sections, and the section which describes other on-going Federal efforts to

improve the coordination of Federal radiation protection and radiation health research programs, should provide useful background information for evaluating the specific agency needs and programs.

The introductory portions of this report in this Section were prepared jointly. Section II, which deals exclusively with the needs and capabilities of the Environmental Protection Agency was prepared by EPA. Similarly, Section III which pertains solely to the activities of the Nuclear Regulatory Commission was prepared by the NRC.

B. RELATIONSHIP TO OTHER FEDERAL ACTIVITIES ON RADIATION PROTECTION AND RADIOLOGICAL HEALTH RESEARCH

This report is one of several on-going efforts to improve the coordination of Federal radiation protection activities and the conduct of health research on the effects of ionizing radiation. These efforts were initiated both by the Congress and the Executive Office of the President in response to increased public concern regarding the potential health consequences of exposure to low-level radiation.

One of these efforts is the Interagency Task Force on Ionizing Radiation. This Task Force was formed at the direction of the President of the United States[2] to provide a coordinated response to the growing Agency and Congressional concern about the effects of radiation exposure on participants in nuclear tests and workers in nuclear-related projects.

The objectives of the Interagency Task Force on Ionizing Radiation are to:[3]

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(2)Memorandum from Stuart Eizenstat and Zbigniew Brzezinski of the Executive Office of the President to the Secretaries of Defense, Health, Education, and Welfare, and Energy and The Administrator of Veterans Affairs, May 9, 1978.

(3)Department of Health, Education, and Welfare, Report of the Interagency Task Force on the Health Effects of Ionizing Radiation, June 1979, p. 4.

(1) Assess the dimensions of the health problem created by radiation exposure, conduct an inventory of federally-supported radiation research, and recommend a research program to resolve questions about the health effects of radiation;

(2) examine legal restrictions on health researchers' access to records necessary for epidemiological research and recommend appropriate changes;

(3) review present efforts to reduce the exposure to radiation and recommend additional measures, if needed;

(4) examine existing systems for providing care and benefits to persons possibly injured by radiation exposure and options for improving these systems and recommend changes if necessary;

(5) design and recommend a public information program;

(6) recommend institutional changes that would improve efficiency, responsiveness, and coordination within the Federal government.

The efforts of the Interagency Task Force have resulted in a series of seven reports[4] which have been published.

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(4)The separate portions of the Interagency Task Force on the Health Effects of Ionizing Radiation are: (1) Final Report of the Task Force, (2) Report of the Work Group on Science, (3) Report of the Work Group on Records and Privacy, (4) Report of the Work Group on Exposure Reduction, (5) Report of the Work Group on Public Information, (6) Report of the Work Group on Care and Benefits, and (7) Report on Institutional Arrangements.

The Biomedical Research and Research Training Amendments of 1978[5] provide an increased emphasis within the Department of Health, Education, and Welfare on the control of cancer and other health effects due to occupational and environmental causes. This statute specifically authorizes the Secretary of Health, Education, and Welfare to establish a comprehensive program of research into the biological effects of low-level ionizing radiation[6] and to conduct a comprehensive review of Federal research programs in this area.[7]

The Health Services Research, Health Statistics, and Health Care Technology Act of 1978[8] provides for expanded collection and analysis of health statistical and epidemiological data by the Department of Health, Education, and Welfare (Sections 5 and 8) and for a study of the costs of environmentally-caused diseases and other adverse effects on humans (Sec. 7). These activities, although they are not limited to radiation, will provide more complete and more uniform statistical data which could be used in epidemiological investigations of the biological effects of low-level ionizing radiation and in assessments of the societal costs of these effects.

(5)Title II to P.L. 95-622, 42 U.S.C. 201 et seq.

(6)Part E, Sec. 262 (b) of P.L. 95-622, paragraph (2)(A).

(7)Part E, Sec. 262 (b) of P.L. 95-622, paragraph (2)(B).

(8)P.L. 95-623, 42 U.S.C. 201 et seq.

In addition to this report on the health research needs and capabilities, Public Law 95-601 also directed the EPA and the NRC to undertake preliminary planning and design studies for epidemiological research on the health effects of low-level ionizing radiation[9] and, in consultation with the Secretary of Health, Education, and Welfare, to prepare, by September 30, 1979, a report to the Congress on the options and the feasibility of these options for Federal epidemiological research on the health effects of low-level ionizing radiation.[10] These two studies, and related efforts by the Department of Health, Education and Welfare, will provide a more comprehensive assessment of Federal research activities on the health effects of low-level ionizing radiation. The activities described in this report are limited to those of EPA and NRC.

(9)Sec. 5(a) of P.L. 95-601.

(10)Sec. 5(d) of P.L. 95-601.

C. GENERAL INFORMATION REQUIREMENTS FOR THE ESTIMATION OF POTENTIAL HEALTH EFFECTS FROM RADIATION EXPOSURE

The methods used by both the EPA and NRC staffs to prepare estimates of the potential health effects of ionizing radiation are generally similar and involve similar processes and information requirements. For this reason, a description of these information requirements can be presented in a general sense without reference to specific agency needs.

The information required to assess the health effects of ionizing radiation includes information on the radiation doses received by exposed population groups. The general process of estimating these doses and potential health effects is shown schematically in Figure 1. Radiation doses arise from two principle means of exposure: exposure to radiation emitted from sources outside of the body (external radiation exposure) and radiation emitted from radioactive materials which have been inhaled or ingested (internal radiation exposure). Those two pathways result in different information requirements as shown in Figure 1.

The general steps shown conceptually in Figure 1 would be the same for estimating the health effects to occupationally-exposed workers or to members of the general population who are exposed to radioactive materials in the environment. These steps also would be applicable for predictive calculations of potential radiation doses and estimating the health effects from a proposed operation or for evaluating exposures to radiation from ongoing operations. The primary difference between the predictive assessments and the operational evaluations is that for predictive assessments, estimates based on experience

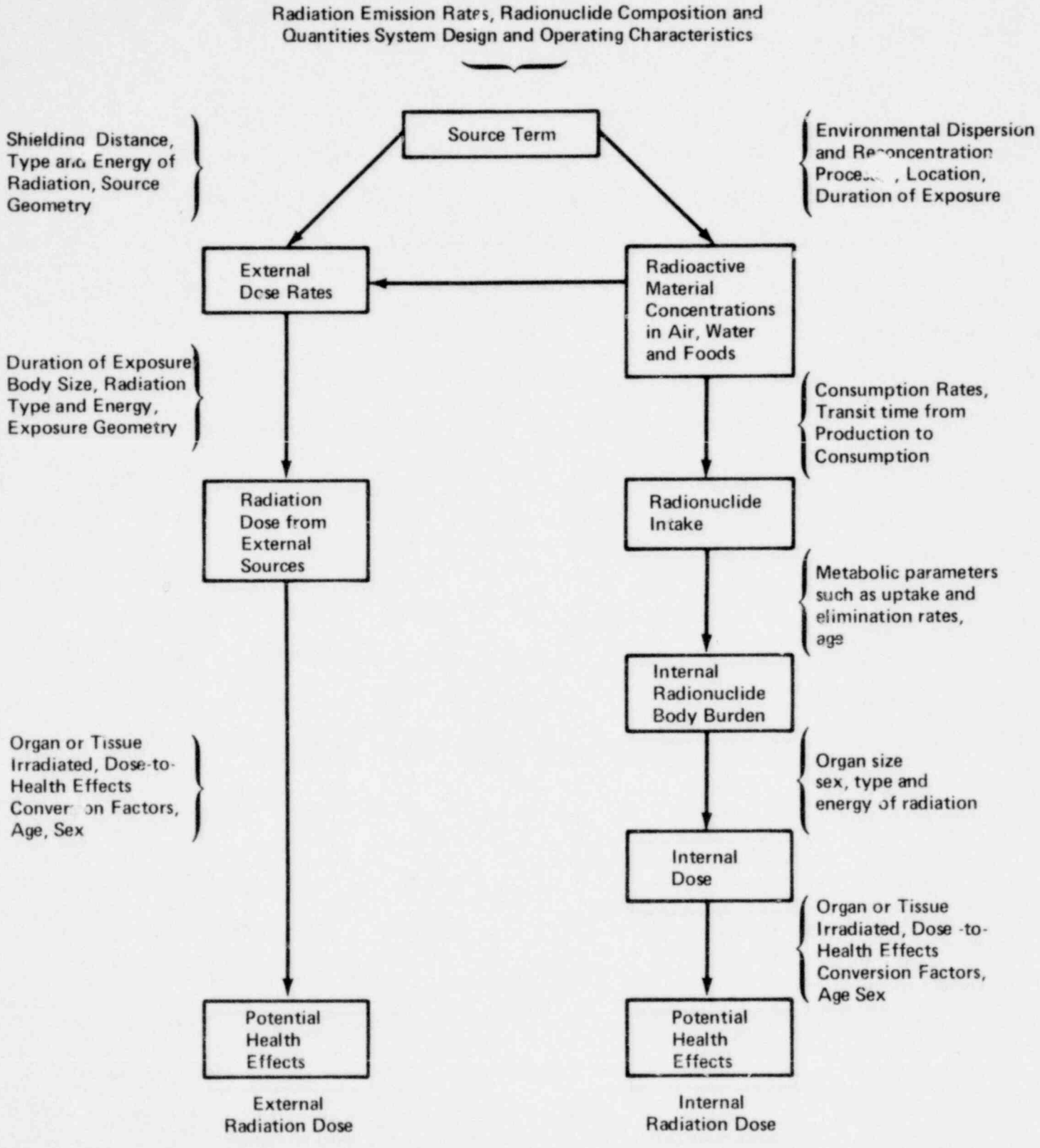

FIGURE 1. INFORMATION REQUIREMENTS FOR ESTIMATING POTENTIAL HEALTH EFFECTS FROM SOURCES OF RADIATION EXPOSURE

or calculations done with mathematical models must be used, whereas some reliance can be placed upon direct measurements of the parameters of interest in the operational evaluation.

1. Estimation of External Radiation Doses

The estimation of external radiation dose requires knowledge of the intensity of the radiation fields to which an individual is exposed, the duration of this exposure, and, for the purposes of estimating the health consequences, the distribution of the dose among the various organs of the body. For estimating external radiation fields, knowledge of the source of the radiation and its characteristics is required. Characteristics of the source which must be evaluated are: the type of radiation emitted, the energy of the radiation, and the rate at which it is emitted.

Evaluation of external radiation dose from operational sources is aided by area radiation monitoring and by personnel dosimeters. Area radiation monitors measure the intensity of the radiation field (exposure rate) at selected locations in a facility or in its environs. Personnel monitoring devices worn by radiation workers (such as film badges, ionization chambers, or thermoluminescent dosimeters) provide information which can be used to assess actual dose received by a specific individual.

Predictive assessments of proposed sources of radiation exposure rely primarily upon calculational models (and information gained from previous experience with similar sources) to provide predictions of potential exposures. In addition to the characteristics of the radiation source, these estimates require information on the parameters which can effect the intensity of the

radiation field such as shielding and distance from the source. Assessment of external radiation doses to members of the general population requires information on the sources or concentrations of radioactive materials in the environment and their radiological characteristics. Concentrations may be predicted from knowledge of the rate of release of radioactive materials from a particular source using models of atmospheric and hydrological dispersion processes. Radioactive materials can be concentrated by organisms that comprise ecological systems and food chains and these bioaccumulation processes must also be considered in predicting radionuclide concentrations in food and biota.

2. Estimation of Internal Radiation Doses

The estimation of internal radiation dose requires estimates of the concentration of different radioactive materials in various organs and tissues of the body (body or organ burdens). This, in turn, requires knowledge of the quantities of radioactive materials which might be (or have been) ingested with water or food or inhaled as airborne contaminants. The metabolic functions of the body which control the uptake, translocation, and elimination of these materials also must be known. In certain cases, the uptake and elimination rates may be directly assessed for specific individuals following ingestion or inhalation of radioactive materials by bioassay procedures such as whole-body gamma spectrometry measurements, exhalation sampling (for radon, tritium, or carbon-14), or analyses of urine and feces. However, these procedures are applicable only after an exposure has occurred and are used primarily to estimate internal radionuclide body burdens for occupationally-exposed individuals. For most situations, particularly for members of the general population where large numbers of individuals may be exposed to radioactive materials in almost undetectable amounts, the assessment of internal dose must

be based upon models of radionuclide uptake for a typical individual such as the reference models developed by the International Commission on Radiological Protection[11] and upon published anatomical dimensions for a reference individual.[12] These models are used together with estimates of the concentrations of individual radionuclides in air, water, or food items and intake rates for air, water, and foodstuffs to calculate the internal organ radiation doses which then form the basis for estimating the potential health consequences of these exposures.

The concentration of radioactive materials in air and water for occupational internal exposure and in air, water, and foodstuffs for exposure of the general population may be measured directly for operational evaluations. For predictive assessment of proposed operations, reliance is again placed on analytical models to predict these concentrations from knowledge of the source of the radioactive materials, projected release rates, and the mechanisms for dispersion and buildup in the environment or working place. These calculational models also are currently used for estimating radiation doses received from operating nuclear facility effluents where the radionuclide concentrations in the environment may be too low to measure accurately. In this situation, environmental surveillance programs are used primarily to confirm these projections and to provide assurance against significant underestimation (or overestimation) of predicted levels.

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(11) International Commission on Radiological Protection, Publication No. 19 - The Metabolism of Compounds of Plutonium and other Actinides and Publication No. 20 - Alkaline Earth Metabolism in Adult Man.

(12) International Commission on Radiological Protection, Report of the Task Group on Reference Man., ICRP Publication No. 23, Pergamon Press, Oxford, England (1975).

3. Estimation of the Health Consequences of Exposure to Radiation

Both the somatic and genetic effects of low-level ionizing radiation are stochastic or statistical in nature.* This means that although an individual may be exposed (even repeatedly) to radiation, these effects may or may not occur within his or her lifetime. For this reason, the health consequences of exposure to low-level radiation for a particular individual are expressed in terms of an increased risk** of incurring cancer or, in the case of future descendants of an irradiated individual, in terms of an increased risk of birth defects or other genetic disorders.

Because of the statistical nature of radiation-induced health effects and the similarity between low-level radiation-induced cancers and those arising from other causes, a direct cause-effect relationship cannot be proven by examination of a single individual. The magnitude of this risk can only be inferred from studies of populations of irradiated individuals where the increased risk per individual may result in a statistically significant increase in the number of cancers or other effects above the level which would be expected to occur in an "unirradiated"*** population of substantially identical composition (in terms of numbers, age, sex, and other factors bearing on health).

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*High-level radiation doses can produce observable early effects ranging from minor changes in blood-cell numbers (at 25-50 rems) to death (for single whole-body doses above approximately 500 rems). These early non-stochastic effects from high-dose are different from the late effects due to low-level radiation doses.

**The increased risk to an individual is derived from health consequences of exposure to a population.

***Because of naturally occurring "background" radiation from cosmic radiation and naturally-occurring radioactive materials such as uranium, thorium, radium, and potassium-40 and exposure to man-made radiation in medical applications, there are no truly "unirradiated" populations. This term is used to means populations which did not receive additional exposure from man-made sources of radiation.

Another consequence of the statistical nature of health effects from low-level radiation is the need to assess the total radiation dose delivered to population groups in addition to radiation doses received by individuals. The sum total of the individual doses received by members of a specified population group is termed the collective dose and is the basis for estimating the potential radiation health impact to that group from a particular source or from a collection of radiation-producing sources.

Quantitative extrapolation of data on radiation health effects obtained from one animal species to another species cannot be done with assurance. For this reason, up to the present time controlled animal experiments have not been generally used for quantitative estimates of the risk to humans.* These risks have been estimated primarily based upon studies of human populations which have been exposed to radiation. Such populations include the survivors of the atomic bomb attacks on Japan; persons exposed to radiation or radioactive materials from atomic weapon and nuclear device tests; uranium miners, radiologists, radium watch dial painters, persons with measurable body burdens of transuranic elements, and other radiation workers; and persons treated with radiation or radioactive materials for medical diagnosis or therapy.

Many follow-up studies have been undertaken to examine these populations in order to identify and attempt to quantify the health consequences of radiation exposure. Some of these studies have produced ambiguous or conflicting results. Detailed examination of the statistical and experimental design,

*Animal experiments can provide considerable insight into the basic mechanisms of radiation damage and the factors which modify the dose-effect relationship. Such studies are of considerable importance to a clear understanding of these basic processes.

dosimetry, and conclusions are required in order to arrive at meaningful consistent estimates of these risks. For this reason, both the EPA and NRC technical staffs rely to a considerable extent upon expert consensus based upon analysis of the existing technical literature for estimates of the health risks of radiation.

The primary sources of health risk estimates which are currently available are the 1972 report of the Advisory Committee on the Biological Effects of Ionizing Radiations (the "1972 BEIR Report")[13] and the reports of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR).[14] The 1972 BEIR Report is the principal source of most radiation health effects estimates currently used by Federal agencies. An update of this report has been prepared by the National Academy of Sciences under contract with EPA, and its issuance was announced by the Academy on May 2, 1979.

(13)Advisory Committee on the Biological Effects of Ionizing Radiations, The Effects on Populations of Exposure to Low-level Ionizing Radiation, National Academy of Sciences-National Research Council, Washington, D.C. 1972.

(14)The United Nations Scientific Committee on the Effects of Atomic Radiation was established in 1955 and has issued a series of reports since that time. The two most recent reports are Ionizing Radiation: Levels and Effects (2 vols.) (1972) and Sources and Effects of Ionizing Radiation (1977).

II. RESEARCH NEEDS AND CAPABILITIES OF THE U.S. ENVIRONMENTAL PROTECTION AGENCY IN THE AREA OF HEALTH EFFECTS OF LOW-LEVEL IONIZING RADIATION

A. INTRODUCTION

1. Agency Research Responsibilities

Serious questions have been raised concerning the adequacy of present standards to provide reasonable protection of the public from adverse somatic and genetic consequences of exposure to ionizing radiation. Although it has not been definitely shown that assumptions underlying the current standards are markedly in error, recent findings strongly indicate that further research should be conducted to develop more definitive information on risk from low-level exposure.

In terms of Agency responsibilities, the needs for research on ionizing radiation are quite similar to those needs in other Agency programs. The most precise standards for any pollutant are based on an understanding of the basic biological mechanisms leading to adverse health effects. Each step toward understanding the role of environmental pollutants in the etiology of specific somatic and genetic diseases allows the regulatory framework to become more meaningful in addressing real, rather than perceived risks. However, at present, risk assessments must depend almost entirely on the results of long-term animal studies and human epidemiology investigations, and their careful interpretation in terms of statistical modeling.

It should be noted that as valuable a source of information as epidemiological studies are, any excess risks identified in such studies are the result of past practices. Regulatory efforts based on such studies are by definition reactive. Anticipatory regulatory policies must be based on

sufficient knowledge to foresee the consequences before exposures occur. Fundamental research into the underlying biological mechanisms is one of the few Agency actions that can lead to regulation before health effects occur.

2. Summary of Findings and Conclusions

Under present legislative and administrative authorities the EPA has broad responsibilities in the area of radiation. The Agency must consider public health protection related not only to the environment, but also to the healing arts and to occupational exposures. Development of radiation protection guidelines to meet these responsibilities requires a wide range of scientific data pertaining to potential impacts on the health of exposed populations.

Most present radiation research activities and capabilities within EPA are devoted to operational and confirmatory objectives rather than fundamental research, and are conducted under the direction of the Office of Radiation Programs (ORP). EPA's Office of Research and Development (ORD) has significant capabilities for research in ionizing radiation exposure and effects. However, ORD conducts only a small intramural research effort in this area, with main attention on nonionizing radiation and toxic substances. Since 1975 EPA policy has resulted in heavy reliance on other Federal agencies for fundamental research information. Steps have been taken to establish mechanisms for coordination of EPA needs with those of the other Federal agencies conducting the majority of the ongoing research in this field.

This review provides a timely opportunity to evaluate the success of the coordination process and the current relevance of the EPA research policy.

From the assessment of EPA research needs and capabilities in the area of health effects of low-level ionizing radiation, an important finding has emerged:

- Communication of research needs to other agencies at the detailed scientific level has not been effective and attempts to influence research objectives in other agencies have been largely unsuccessful.

This finding supports the general conclusion that EPA must review and consider modifying its present Agency policy toward direct control of and participation in ionizing radiation research activities. This reassessment should take cognizance of the current Federal initiatives to coordinate research on low-level effects, the findings of the BEIR Committee, and the planned feasibility evaluation of potential epidemiologic studies.

B. EPA MANDATES IN RADIATION

1. Authorities

The U.S. Environmental Protection Agency (EPA) was created by Reorganization Plan Number 3 of 1970, which consolidated in one agency various Federal pollution abatement activities from other organizations. The principal components and functions which were incorporated into the EPA were: the Federal Water Quality Administration from the Department of Interior; the National Air Pollution Control Administration from the Department of Health, Education, and Welfare (DHEW); functions of the Environmental Control Administration, DHEW, carried out by the Bureau of Solid Waste Management, Bureau of Water Hygiene, and certain functions of the Bureau of Radiological Health which pertained to environmental radioactivity, research, and monitoring; functions of the Department of Agriculture, the Department of Interior, and the Food and Drug Administration related to pesticide registration and effects investigation; functions of the Atomic Energy Commission related to the establishment of generally applicable environmental radiation standards; and the functions of the Federal Radiation Council.

The Reorganization Plan transferred to EPA from the Atomic Energy Act of 1954, as amended, certain radiation authorities. One authority was that of providing overview guidance to all Federal agencies. Before EPA was created, the President had the Cabinet-level Federal Radiation Council, which was to "consult qualified scientists and experts in radiation matters . . . . and qualified experts in the field of biology and medicine and in the field of health physics . . . ," to ". . . advise the President with respect to

radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in formulation of radiation standards . . . ." In creating EPA, the President dissolved the Federal Radiation Council and transferred its authority to the new agency. This gave EPA the power to make recommendations to the President which, if approved, would be published as guidance to the appropriate Federal regulatory agencies.

The Departments of Health, Education and Welfare, Energy, Housing and Urban Development, and Labor, and the Nuclear Regulatory Commission (NRC), all have jurisdiction over various programs relating to radiation hazards and currently are enforcing existing radiation standards. Any new EPA guidance is to assure uniformity and eliminate diversity among Federal radiation standards. Although recommendations made by EPA in the exercise of this statutory authority are only advisory, once the President approves such recommendations, Federal agencies may not issue standards and regulations under their existing statutory authority which are inconsistent with EPA guidelines.

From the Atomic Energy Act which governs the development, use, and control of nuclear power, a second radiation authority given to EPA was to establish generally applicable standards for the protection of the general environment from radiation and radioactive materials. Standards inside nuclear facilities are established and implemented by NRC and the Department of Energy (DOE). NRC regulates nuclear facilities used in the manufacture of commercial electricity, while DOE has radiation jurisdiction over weapons

plants and for energy research and development. EPA's guidelines and environmental standards relating to these sources are enforced by the appropriate Federal regulatory agency.

Since 1970, EPA's radiation protection authority has been supplemented by the following legislation:

- Federal Water Pollution Control Act Amendments of 1972
- Toxic Substances Control Act of 1976
- Resource Conservation and Recovery Act of 1976
- Safe Drinking Water Act of 1974
- Clean Air Act of 1970 and Amendments of 1977
- Marine Protection, Research, and Sanctuaries Act of 1972
- Uranium Mill Tailings Control Act of 1978.

In 1978 the President issued Executive Order 12088 which requires that EPA provide leadership for prevention, control, and abatement of environmental pollution at Federal facilities in a nationwide effort to protect the general environment from the hazards of radiation.

The Clean Air Act Amendments of 1977, enacted on August 7, 1977, gave the EPA Administrator authority to establish standards to control emissions of radioactive pollutants into the ambient air. The amendments require determination within 2 years whether such pollutants will cause or contribute to air pollution that may endanger public health. This allows EPA to regulate radioactive pollutants under several options of the Clean Air Act Amendments.

EPA is also required to study the effect on the public health and welfare of radioactive pollutants in the ambient air.

The Uranium Mill Tailings Control Act calls for promulgation by EPA of standards to protect the public health, safety and the environment from radiological and nonradiological hazards associated with mill tailings. Such standards are to be enforced by NRC in their licensing and regulation of current and future sources and by DOE in their remedial program for inactive tailings piles and other contaminated sites.

2. Historical Perspective

To carry out the various mandates outlined above, the Agency must be able to make meaningful forecasts of the potential injury due to various classes of radiation sources and exposures. The approach used by the Agency to make such risk estimates is outlined in the its Policy Statement of March 3, 1975 (Federal Register, 41 FR 28402) on the relationship between radiation dose and effects.

The statement makes the following points. Even when levels of radiation in the environment can be measured directly, it is necessary to use various models of pathways and human metabolism to estimate dose, as outlined in Figure 1 in Chapter I. The policy statement recognizes that it is also necessary to formulate relationships between radiation dose and effects, relationships that are derived primarily from human epidemiological studies are also reflective of research utilizing animals and other biological systems.

In discussing the basis for assessing radiation risks, the policy statement points out that, "While the utilization of a linear, non-threshold relationship is useful as a generally applicable policy for assessment of radiation effects, it is also EPA's policy in specific situations to utilize the best available detailed scientific knowledge in estimating health impact when such information is available for specific types of radiation, conditions of exposure, and recipients of the exposure. In such situations, estimates may or may not be based on the assumptions of linearity and a nonthreshold dose. In any case, the assumptions will be stated explicitly in any EPA radiation protection actions."

Clearly, this policy presupposes an existing body of knowledge concerning radiation effects, the Agency's ability to investigate new situations as they develop, and a competent body of radiation experts to assess new information.

To place the conclusions and recommendations stemming from the present review in perspective, a discussion of the history of EPA research activities in ionizing radiation effects may be helpful. In addition to EPA's general authorities related to environmental research and monitoring, a number of specific responsibilities and authorities related to the establishment of standards for protection from ionizing radiation were transferred to the Agency in the early 1970s. Yet, research projects underway at the time these responsibilities were assumed by EPA were concluded and fundamental research on radiobiological effects was

gradually phased out, with a policy to rely on research conducted by other agencies formally established in 1975. This decision was based on two major considerations. First, the breadth of other environmental exposures requiring regulatory attention and the scale of responsibilities inherent in monitoring overall environmental quality necessitated the adoption of priorities for employment of EPA resources. Second, because the substantial body of ongoing effort in ionizing radiation research would continue in other agencies, it appeared desirable to concentrate research efforts in those agencies, particularly those activities that required expensive, long-term commitments.

Up to the present time, EPA's Office of Radiation Programs (ORP) has relied heavily on other Federal agencies to fulfill ORP's research needs. In his statements to the Congress in September 1977 and June 1978, Dr. Rowe, then Deputy Assistant Administrator for Radiation Programs, discussed this policy and the steps taken to coordinate EPA research needs with programs of other agencies in a cost-effective manner.[1] While the assumptions and approaches constituting EPA research policy in the area of ionizing radiation seemed prudent at the time, Dr. Rowe indicated that the Agency recognized the importance of review and modification of this policy as new information was forthcoming. Reassessment of dose-effect assumptions in the light of current research was being made by the National Academy of Sciences under EPA contract, with particular attention to the linear

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[1] Statements of Dr. W.D. Rowe, Deputy Assistant Administrator for Radiation Programs, Environmental Protection Agency, before the Subcommittee on Environment and the Atmosphere, Committee on Science and Technology, U.S. House of Representatives, September 27, 1977 and June 7, 1978.

hypothesis and effects at low doses.[2] He also pointed out certain possible limitations in reliance on other agencies to meet EPA research needs:

- Priorities and budget restrictions of other agencies might result in research that does not meet EPA requirements.
- EPA might not be able to influence the direction of the research in a satisfactory manner.
- Information generated by another agency might be used by EPA to regulate ongoing operations of the source agency, posing some unusual legal problems.

Dr. Rowe considered that the cooperative mechanism was in a test phase. Thus, EPA considers this current review and report a timely opportunity to reassess Agency research policy.

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[2] The report of the Academy's Committee on the Biological Effects of Ionizing Radiation will be available by April, 1979.

C. RESEARCH NEEDS

The EPA carried out a systematic analysis to develop a list of needs in research and operational studies in 1977 and 1978. Those needs have been recently updated and presented here as priority areas of research. Final prioritization will be dependent upon analysis of the state of knowledge in each research area.

Studies directly related to the subject of this report are grouped, under the heading "Bioeffects," into three major areas: Epidemiology, Comparative Biology, and Basic Biology. Less directly related studies are grouped under the heading "Human Exposure Pathways" into two major areas: Data Collection and Data Interpretation.

1. Bioeffects Research Needs

a. Epidemiology

(1) Followup of Earlier Work

Expand the current epidemiology studies of United States uranium miners to include other types of hard rock mining and more detailed studies such as cancer incidence, histological types of cancers, and exfoliative cytopathology and chromosome aberrations in peripheral lymphocytes.

Develop epidemiologic studies on the somatic and genetic effects of ionizing radiation in selected occupationally exposed persons, where such studies meet criteria for reasonable success.

Determine the applicability of risk estimates based on such groups as uranium miners and Japanese atomic bomb survivors to the general U.S. population.

(2) New Epidemiology and Epidemiological Support Studies

Evaluate the practicality and requirements of large-scale epidemiologic studies of the general public exposed to low levels of ionizing radiation.

Determine levels of ascertainment of cause of death due to malignancy, stratified for source (death certificate, autopsy), sample (biopsy, resection, autopsy), age, and histology.

b. Comparative Biology

(1) Human Biology

Determine whether somatic mutations in radiation workers are indicative of future clinical problems.

(2) Animal Biology

Subject a variety of animal species to acute and chronic whole-body exposures (X- or gamma rays, tritium, krypton) to determine the dose-effect response during several stages of life: namely, fetal, newborn, immature, mature, aged.

Conduct experiments for chronic exposure to internally deposited alpha particle emitters to determine the long-term effects of high linear energy transfer (LET) radiation on young populations of several species.

Determine response spectrum for continuous inhalation of low levels of actinides as compared to acute or divided exposures.

Explore comparative pathology of gamma radiation of the lung as compared to actinide or radon inhalation, particularly in larger laboratory animals.

Establish life tables and probabilities of dying for malignancy and other causes of death in common laboratory animals for testing models of lifetime risk due to radiation.

c. Basic Biology

(1) Metabolic and Dosimetry Studies (Human and Animal)

Compare genetic mutation rate due to alpha emitters incorporated into gonadal tissues with effects of external X-radiation.

(2) Effects Studies (Animal)

Determine effects of various chemical forms of americium and plutonium as found in contaminated soil, on uptake by plants and animals.

Design biological studies to test the validity of Martell's "Warm Particle" Hypothesis as it pertains to the temporal pattern of exposure.

(3) Mechanisms

Develop accurate models for the dose due to radon inhalation that account for nonuniform deposition. This should include morphometric studies and studies of cell number, histology, and distribution in the respiratory system.

Develop productive models that characterize the observed difference in relative biological efficiency between low and high LET radiations.

2. Human Exposure Pathways

a. Data Collection

(1) Instrumentation

Develop low-cost instrumentation to detect radon levels on the order of 0.001 working levels.

(2) Survey Design

Develop a data base to evaluate the radiological impact of in situ leaching of uranium deposits and heap leaching of uranium ore.

Characterize emissions from nonfuel cycle radioactive wastes.

Evaluate the radiological impact of a direct conversion fluid-bed fuel fabrication facility.

(3) Survey Protocol

Conduct emsission studies for radon from mill tailings and tritium from nuclear power plants.

Characterize low-level emissions from wastes generated by fuel fabrication plants.

Develop a protocol or code of practices for collecting, processing, and analyzing geologic, hydrologic, biologic, and engineering samples collected for environmental studies at low-level radioactive waste burial sites.

b. Data Interpretation

(1) Atmospheric Models

Develop refined environmental transport model for radon that takes into account local meteorology.

Develop exposure models for estimating population exposure from radon emanating from such natural sources as uranium mill tailings' piles, potable water, and inside structures.

(2) Aquatic Models

Investigate environmental impact and disposal problems involving radium wastes from drinking water treatment facilities.

(3) Soil Models

Develop appropriate environmental pathway-dose calculational model for radioactive materials released from radioactive waste repositories.

Investigate aerosol resuspension phenomena as they relate to the inhalation of deposited materials.

D. CURRENT RESEARCH ACTIVITIES RELATED TO THE HEALTH EFFECTS OF LOW-LEVELS OF IONIZING RADIATION

The present activities strongly reflect the present EPA policy of relying on other agencies for research on ionizing radiation. Agency efforts are concentrated on monitoring, support, and source identification. Recently, a few research contracts have been let to support specific objectives in the development of Clean Air Act standards.

1. Bioeffects

Currently, EPA has one ionizing radiation effects study under the Office of Research and Development (ORD):

The Effects of Krypton-85 Exposure on Rats and Guinea Pigs

These investigations initiated in 1973 have been maintained primarily by a Department of Energy (DOE) contract since 1977 and have shown leukemia can be associated with krypton-85 exposure. This finding cannot be accounted for on the basis of the dose received by bone marrow. Additional work is necessary to determine whether irradiation to peripheral or circulatory lymphocytes might be the cause.

In FY 1978 contract funds were provided to the Office of Radiation Programs (ORP) for studies to support the development of standards under the Clean Air Act as Amended in 1977. Contracts have been awarded in the areas of biological and environmental research. The resumes of these contracts, below, indicate the thrust of these 12-month efforts.

a. Epidemiology

Support to BEIR Committee

ORP commissioned the National Academy of Sciences-BEIR Committee to review new information and update the 1972 BEIR Report on the Effects of Low-Levels of Ionizing Radiation where necessary.

Cytologic Studies in Areas with Atypical Radon Concentrations

These studies will compare cytogenetic and sputum cytology findings for an area of high natural radon concentration to findings in an area with low natural radon. This is an attempt to assay radiation effects using a more sensitive biological effects indicator than cancer mortality statistics.

b. Comparative Biology

Age-specific Human Respiratory Morphometrics

The investigation will determine length, diameter, branching angle and number of airways in the human respiratory tract at several different ages. Comparative differences in age-related values will be used in prediction of respiratory deposition and dose from inhaled radionuclides.

c. Basic Biology (Metabolism and Dosimetry)

Technetium-99 Emission and Biological Uptake Studies

These studies will provide information on technetium-99 emissions, pathways and metabolism so that ORP can evaluate its current technetium-99 dosimetry level.

Dosimetry and Health Effects Analysis

The contractor will use his own dosimetric models and ORP health effects models to calculate the potential health effects resulting from unit exposure to specific airborne radioactive pollutants.

2. Human Exposure Pathways

a. Data Collection

Mines, Mills and Tailings (Non-Uranium)

Airborne effluents from these sources will be evaluated to determine whether there are radioactive components. ORP will then evaluate the potential hazard of these sources.

Coal Fuel Cycle Radionuclide Evaluations

The contractor will obtain samples from fossil fuels, charge, waste piles and emissions at coal-fueled facilities. The samples will be radio-assayed by ORP and the potential hazard evaluated.

Radon from Phosphate Industry Operations

This study will identify and quantify radon emissions associated with the phosphate industry for evaluation by ORP.

Study of Particle Accelerators and Their Airborne Effluents and Associated Control Technologies

This study will identify radioactive effluents and potential control technologies.

Exposure Conditions in Structures due to Radon in Water Supplies

This investigation will characterize the exposure conditions which will exist in structures from the release of radon-222 dissolved in water used in the structure as a result of human activity.

b. Data Interpretation

Environmental Pathway Model Analysis and Development for Radionuclides Released to the Atmosphere

Models for radionuclide transport from source to the point of human exposure will be analyzed and evaluated. The most valid models will be selected for EPA to use in its evaluation of the hazards of various sources of radioactive materials.

E. RESEARCH CAPABILITIES

1. General Capabilities

Capabilities for health effects and related research on low-level ionizing radiation exist in the Office of Research and Development (ORD) and the Office of Radiation Programs (ORP). ORD facilities are the Environmental Monitoring and Support Laboratory (EMSL) at Las Vegas and the Health Effects Research Laboratory (HERL) at Research Triangle Park. The ORD Health Effects Research Laboratory (HERL) at Cincinnati has done radiation research in the past, primarily on metabolism.

There is a good nucleus on which to develop a radiation research program in ORD. Experienced, senior radiation biologists are located at each of the ORD facilities, and many of the personnel at these laboratories have had experience in radiation research in either metabolism studies, bioeffects studies, or both.

ORP capabilities are located in the Criteria and Standards Division and the Environmental Analysis Division of ORP Headquarters, in the Office of Radiation Programs facility at Las Vegas (ORPLV), and in the Eastern Environmental Radiation Facility (EERF) at Mongomery, Alabama. The ORPLV and EERF facilities do no research; they are, however, engaged in monitoring and support operations, in source identification, and in the development of methodological applications. This work may be routine laboratory or field studies in support of standard-setting in response to Regional Office requests.

Research management capability for both inhouse and contractor studies exists at all the ORD and ORP locations mentioned.

2. Specific Additional Capabilities

a. Environmental Monitoring and Support Laboratory, Las Vegas

This Laboratory's program is primarily dedicated to providing radiological health monitoring support to the Department of Energy's nuclear weapons testing process. The Nuclear Radiation Assessment Division is comprised of 34 employees, the majority of whom are technical staff.

The EMSL has facilities for conducting small-animal exposures, large-animal (dairy and beef herds primarily) exposures and metabolic studies, radiochemistry and data support. The laboratory also has one of the best facilities in the country for performing whole-body counting of humans. Data accumulated over a period of approximately 15 years are being compiled and evaluated for use in the DOE retrospective dose study by DOE.

Specific facilities available in this laboratory include: whole body counter, small-animal exposure and handling rooms, a veterinary surgery room, a dairy farm, an experimental beef herd, and an animal investigation program (wildlife and range cattle).

b. Office of Radiation Programs, Las Vegas

ORP facilities at Las Vegas are not presently directed toward research but do represent potential capabilities in environmental radiation exposure analysis. The staff at Las Vegas is comprised of 14 technical personnel, 8 analytical support personnel and 6 clerical/program management staff.

c. Eastern Environmental Radiation Facility, Montgomery

The major research-related work at Montgomery relates to confirming data going into the standard-setting process and support for the Clean Air Act-mandated radiation studies. The laboratory supervises the Environmental Radiation Ambient Monitoring System (ERAMS), which is designed to provide direct assessment of population intake of significant radioactive pollutants.

This laboratory is scheduled to move into a new building in early 1981. This building will provide for potential expansion from the present staff of 47 to approximately 110.

d. Health Effects Research Laboratory, Research Triangle Park

The Experimental Biology Division of the Laboratory is headed by a radiation biologist with a staff nucleus of seven Ph.D. or D.V.M. radiation biologists, one radiochemist, one radiation physicist, and three radiation technicians. Many of the present staff have experience in ionizing radiation research with a variety of species

and in both metabolism and bioeffects studies. This staff conducted EPA's low-level ionizing radiation effects research on krypton-85 and tritium for 5 years. Present efforts are primarily directed to nonionizing radiation and toxic substances. In addition to staff resources, there are fairly comprehensive counting facilities and animal handling facilities for species p through primates.

Two epidemiologists in the Population Studies Division at the Health Effects Research Laboratory have a background in radiation effects research.

F. FINDINGS AND CONCLUSIONS

Under the Federal Radiation Council authorities, and other legislative and administrative authorities, the EPA provides a Federal overview of radiation protection philosophies, policies and controls. These broad responsibilities in the radiation area must consider public health protection related not only to the environment, but also to the healing arts and to occupational exposures. General authorities provide for conducting the research necessary to establish risk in the exposed populations.

In 1975 the Agency discontinued any substantial involvement of its Office of Research and Development in research on ionizing radiation. The Office of Radiation Programs, through which EPA regulatory responsibilities in this area are implemented, has continued to direct research-related activities which are limited to operational and confirmatory objectives. This policy places heavy reliance on other Federal agencies to meet ORP needs for fundamental scientific information.

At the time the present policy on ionizing radiation research was implemented the available information supported the premises on which it was based. Adoption of the seemingly conservative approach of no threshold, the apparent small incremental risk at low doses, and the difficulties in detecting radiation-induced illness in epidemiologic studies indicated that consolidation of efforts in the major research agencies would be most cost-effective. The mechanisms (initiated in 1977) for coordination of EPA needs

with these programs were considered to be in a test phase and subject to later review. Limitations in this approach were recognized at the time.

From the current assessment of EPA research needs and capabilities in the area of health effects of low-level ionizing radiation, an important finding has emerged.

It has been found that the steps taken by EPA to communicate priority research needs and influence research activities in other agencies toward meeting its needs have not proven satisfactory. It appears that there are two basic reasons for this. One of these is the essentially passive role that EPA must take in seeking to impact programs under control of other Federal agencies. Where EPA research needs lie outside the direct interests and priorities of the agencies engaged in basic research, EPA must rely on the general provisions of interagency agreements and persuasion to effect its goals, rather than a more active mechanism such as direct funding of a project. The other reason is less obvious. Coordination mechanisms have tended to involve higher-level agency representatives and transmittal of research needs phrased in aggregate, generalized terms. Details of the original specific issues become obscured. Furthermore, because EPA scientists are minimally engaged in radiation research, interchange among agencies at the detailed technical level is hindered. The result of these factors is that ORP must extrapolate from research that is designed by outside investigators and that may not directly pertain to Agency needs.

Current public concern has now put the linear hypothesis and the risk at low dose in the context of issues needing reassessment and, perhaps, extensive additional research, primarily but not exclusively epidemiologic research. Moreover, if feasible approaches can be identified in the current EPA-NRC study, the difficulty of detecting incremental radiation-induced illness no longer can be accepted as a justification for not implementing such research.

The preceding supports the general conclusion that EPA must review its policy in this area and consider more direct control of, and participation in, ionizing radiation research activities, where such efforts are pertinent to obtaining the required scientific information to meet Agency responsibilities. It is premature at this time to discuss the directions and substance of a revised program.

An expanded Agency research program which would provide a competent cadre of inhouse experts on ionizing radiation effects, could have several important advantages. New ideas could be incorporated into Agency decisionmaking. The soundness of extra-Agency assessments could be scrutinized to the same standards as inhouse work. Interagency research projects assessments could be more effectively designed. Finally, the presence of competent inhouse staff could be a buttress to public confidence in Agency guidelines.

EPA has contracted with the National Academy of Sciences to reassess the data and basic assumptions relevant to active pursuit of research needs identified by ORP. Also the feasibility/planning study of epidemiologic

investigations on low-dose effects authorized by Congress will directly address the potential for meeting priority research needs.

The policy review will be initiated from the findings and recommendations of the BEIR Committee report, which will be available by April 1979. Other important input to EPA policy decisions will be provided by the early results from the planned feasibility evaluation of potential epidemiologic approaches to study of low-dose effects and the ongoing reassessment of Federal radiation research programs being conducted by the National Institutes of Health under the authority of PL 95-662.

III. RESEARCH NEEDS AND CAPABILITIES OF THE NUCLEAR REGULATORY COMMISSION IN THE AREA OF THE HEALTH EFFECTS OF LOW-LEVEL IONIZING RADIATION

A. INTRODUCTION

The Nuclear Regulatory Commission (NRC) has responsibility for protecting public health and safety and the environment with regard to the peaceful applications of nuclear energy and source, byproduct, and special nuclear materials. The NRC was created in 1975 to assume the regulatory functions of the former Atomic Energy Commission (AEC) when these functions were separated from the developmental functions of the AEC.

In creating the Nuclear Regulatory Commission, the Congress provided for an Office of Nuclear Regulatory Research with authority to engage in or contract for research deemed necessary by the Commission to carry out its regulatory functions. It was the intent of the Congress* that this research be of a confirmatory nature to provide the Commission with an "independent capability for developing and analyzing technical information" necessary to support its licensing and regulatory functions rather than to develop basic scientific knowledge. For the results of basic research, the Commission was to rely upon the research conducted by other Federal agencies, but it would have an "independent capability" to evaluate such data submitted by license applicants or developed elsewhere.

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* House Conference Report No. 93-1445 (October 8, 1974), pp. 34-35 and Senate Conference Report No. 93-1252 (October 9, 1974), pp. 34-35.

To fulfill its licensing and regulatory functions, the Commission conducts a program of health and bioenvironmental research and technical support activities. The following sections will describe the responsibilities of the Nuclear Regulatory Commission, current activities to provide information necessary to assess the radiological impact and potential health consequences of NRC-licensed activities, and future information needs in these areas.

B. NRC'S LEGISLATIVE MANDATES CONCERNING PUBLIC HEALTH AND SAFETY AND THE ENVIRONMENT

1. Energy Reorganization Act of 1974, as amended

The Nuclear Regulatory Commission (NRC) was established by the Energy Reorganization Act of 1974, as amended[1] to assume the responsibilities of the former Atomic Energy Commission (AEC) for regulating source materials (natural uranium and thorium), byproduct materials (radioactive materials produced in conjunction with the use of special nuclear materials or in conjunction with the production or disposal of source materials), special nuclear materials (enriched uranium or plutonium), and production and utilization facilities (facilities, such as nuclear power reactors, creating or using significant quantities of special nuclear materials. The Act provides for cooperation between the Energy Research and Development Administration (ERDA), now part of the Department of Energy (DOE),[2] and the NRC in the conduct of reactor safety and related Commission research. The Act also provides for NRC licensing of and regulatory authority over demonstration reactors and high-level waste storage facilities operated by the Administration (DOE).[3]

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(1)Title II (42 U.S.C. 5841) of P.L. 93-438 (42 U.S.C. 5801).

(2)Department of Energy Organization Act, P.L. 95-91, 42 U.S.C. 7101 et seq., and Executive Order 12038 of February 26, 1978.

(3)Sec. 202 of the Energy Reorganization Act of 1974, describes the specific facilities under NRC regulatory authority.

2. Atomic Energy Act of 1954, as amended

The AEC's licensing and regulatory responsibilities were created by the Atomic Energy Act of 1954, as amended,4 essentially to provide for the common defense and security and to protect the health and safety of the public. As regards licensing, the Act provides NRC authority to establish rules and criteria which include consideration of public health and safety.5

In addition, section 161b. of the Act provides NRC authority to "[E]stablish by rule, regulation, or order, such standards and instructions to govern the possession and use of special nuclear material, source material, and byproduct material as the Commission may deem necessary or desirable to promote the common defense and security or to protect health or to minimize danger to life and property."

3. Reorganization Plan No. 3 of 1970

Reorganization Plan No. 3 of 1970, which created the Environmental Protection Agency (EPA), transferred to EPA certain functions of the former AEC related to setting generally applicable environmental radiation standards. As stated in the plan, "[S]tandards mean limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control

(4)P.L. 83-703, 42 U.S.C. 2011 et seq., The AEC was created by the Atomic Energy Act of 1946, P.L. 79-585, 42 U.S.C. 1801 et seq.

(5)Chapter 6, Special Nuclear Material (Sec. 53b.); Chapter 7, Source Material (Sec. 63b.); Chapter 8, Byproduct Material (Sec. 81); and Chapter 10, Atomic Energy Licenses (Sec. 103b).

of persons possessing or using radioactive material."[6] The responsibility for implementing these standards remained with AEC and was transferred to NRC by the Energy Reorganization Act of 1974.

4. Uranium Mill Tailings Radiation Control Act of 1978

The Uranium Mill Tailings Radiation Control Act of 1978[7] expanded NRC's authority over mill tailings. Title II of this Act provides authority for the Commission to establish requirements for ensuring adequate reclamation of uranium mill tailing deposits and for requiring bonds or other financial arrangements to ensure that stabilization and reclamation is carried out following cessation of licensed milling operations. The Act also requires the Commission to enforce standards developed by EPA for controlling the radiological and non-radiological impacts of these operations.

5. National Environmental Policy Act of 1969 and other statutes

NRC also has responsibility (with regard to the facilities, materials and operations it licenses) under the National Environmental Policy Act of 1969 (NEPA).[8] To comply with NEPA's requirements, the Commission staff evaluates the radiological and other environmental impacts associated with proposed licensing actions. These evaluations are issued in the form of

(6)Sec. 2(6) of Reorganization Plan No. 3 of 1970.

(7)P.L. 95-604, 42 U.S.C. 7901 et seq.

(8)P.L 91-190, 42 U.S.C. 4321 et seq.

environmental statements for each major licensing action or rulemaking proceeding and are made available to the public and to other Federal, State and local agencies.

In its regulatory and licensing actions, the Commission also considers other legislation, as appropriate, such as the Federal Water Pollution Control Act, as amended,[9] the Coastal Zone Management Act of 1972, as amended,[10] the Clean Air Act Amendments of 1977,[11] and the Resource Conservation and Recovery Act of 1976.[12]

(9)P.L. 80-845 and P.L. 91-224, 33 U.S.C. 466; in particular the Federal Water Pollution Control Act Amendments of 1972, P.L. 92-500, 33 U.S.C. 1151 et seq.

(10)P.L. 92-583 and P.L. 94-370, 16 U.S.C. 1451 et seq.

(11)P.L. 95-95, 42 U.S.C. 7401 et seq.

(12)P.L. 94-580, 42 U.S.C. 6901 et seq.

C. RESEARCH NEEDS OF THE NUCLEAR REGULATORY COMMISSION RELATED TO LOW-LEVEL IONIZING RADIATION

The health research requirements of the NRC pertain to needs for specific information required to make technically sound and effective regulatory decisions. These requirements arise out of needs to improve the technical bases for NRC standards and regulations, to confirm the adequacy of these standards, and to reduce the uncertainties in data used to assess the potential environmental impacts and health consequences of licensed activities. The NRC uses information on the health effects of radiation to perform three primary functions: (1) to assess the adequacy of current radiation protection standards, (2) to evaluate the potential radiological impact of proposed or licensed operations, and (3) to define areas where additional research is needed.

The needs of the Nuclear Regulatory Commission include information on the mechanisms of radiation injury and for improving the precision and accuracy of numerical estimates of the health risk from low-level ionizing radiation. This information is of importance to the radiation protection community, in general, as well as to Federal regulatory agencies. Continuing needs for improved scientific understanding of the fundamental mechanisms causing radiation injury are addressed by the basic research programs of the Departments of Energy and Health, Education, and Welfare. These programs are presently undergoing a major Federal review and, as directed by Congress in the Biomedical Research and Training Amendments of 1978, the Department of Health, Education, and Welfare is establishing a comprehensive program of research into the biological effects of low-level ionizing radiation. Because of these more extensive efforts to assess Federal research programs on the

health effects of low-level radiation, the focus of this report is on specific information needs of the Nuclear Regulatory Commission required to fulfill its regulatory functions. The NRC staff is participating in these other activities to ensure that the narrower needs of regulatory agencies are considered in these efforts.

Because the Commission has responsibility for ensuring and evaluating the safety of licensed activities, these needs are not restricted to the chronic effects of low-level radiation. They also include needs for information on the effects of high radiation doses for use in evaluating the consequences of low-probability large accidental releases of radioactive materials into the environment and occupational overexposures.

The types of information required to assess radiation exposures and to estimate the potential health effects from these exposures have been described generally in Section IC of this report. In order to fulfill its mandate for protecting public health and safety, the Commission carries out a confirmatory research program on the health effects of radiation and on the factors, processes, and parameters which affect the magnitude of radiation exposures which result from NRC-licensed activities. Current Commission research and technical support activities related to dose and health effects assessment are described in the following section to provide an overview of the scope of these activities.

Future Research Needs of the Nuclear Regulatory Commission

The uncertainty regarding the magnitude of the health risk from low-level radiation requires a conservative approach for controlling radiation exposures.

Current radiation standards are based upon an assumed linear, dose-rate-independent, non-threshold dose-effect relationship. This assumption presumes that there is no level, except zero dose, below which there is no risk (non-threshold theory), that chronic health risks resulting from high doses can be extrapolated in direct proportion to the magnitude of the dose to estimate the effects of low doses (linearity), and that the dose response is not affected by the rate at which the dose is delivered (dose-rate independence). Although these assumptions are generally regarded as conservative, a some recent analyses of data obtained from studies of human populations exposed to low doses have disputed the validity of the linear extrapolation and have suggested that the risk per unit dose at low levels may be even higher than that obtained using the linear model. On the other hand, animal studies suggest exactly the opposite; that for low-LET* radiation (e.g., beta particles, gamma radiation, and X-rays), the risk from low doses delivered at low dose rates is considerably less than predicted by linear extrapolations from high dose and high dose rates.

1. General Needs

a. Epidemiological Studies to Confirm Health Risks from Low-level Radiation Exposure

Because of the uncertainty of the validity of extrapolated values, there is a need for further epidemiological studies of human populations which

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* Low-LET radiation is radiation which has a low Linear Energy Transfer, and deposits small amounts of energy per unit pathlength. High-LET radiation deposits considerable energy per unit distance of material traversed.

have been exposed to low-level radiation. The joint EPA/NRC study to be performed to comply with the Congressional mandate in Public Law 95-601 is designed to evaluate the feasibility of conducting and designing future studies to meet this need. It is expected that the planning and feasibility study will identify which populations of exposed individuals, if any, are suitable for further investigation of the effect of low-level ionizing radiation. This joint EPA/NRC effort, together with on-going efforts by the Departments of Defense, Energy, and Health, Education, and Welfare, may provide a better basis for providing upper-bound estimates for the health risks of low-level radiation. If these studies confirm that the risks of somatic injury from low-level radiation are higher than currently believed, additional long-term epidemiological studies may be required to evaluate both the somatic injury to individuals exposed to radiation and the magnitude of genetic damage to their offspring. With respect to genetic effects, additional information is required on the occurrence of radiation-induced recessive mutations and how these mutations are expressed in terms of ill health or an increased susceptibility to disease.

b. Continued Animal Studies of Mechanisms of Radiation Injury

Animal studies* provide evidence of a quadratic dose-effect relationship of the form: $R = \alpha D + \beta D^2$ which indicates, for low-LET** radiation, that linear extrapolations of the effects observed at high doses and high dose rates would overestimate the effects for low doses and low dose rates by factors between 2 and 10. Recent experimental evidence for high-LET** radiation (e.g.,

*These studies are described in Annex G, Section ID; Annex H, Section IIF; and Annex I, Section V(D) of the United Nations Scientific Committee on the Effects of Atomic Radiation 1977 Report, Sources and Effects of Ionizing Radiation and in a forthcoming report of Scientific Committee 40 of the National Council on Radiation Protection and Measurements.

**These terms are defined in the footnote on page IIIC-3.

neutrons, protons, and alpha particles) indicates that this quadratic response is not observed for these radiations. Continued animal studies are required to assist in confirming the conservatism believed to be inherent in assuming a linear extrapolation model, and to better define the mechanisms of radiation injury and repair processes.

c. Studies to Determine Factors which may Modify Radiation Injury

Information is needed on the effect upon the dose-effect relationships of such factors as exposure pathway, sex, age, and health condition and genetic factors such as possible inherited susceptability to disease or hypersensitivity. Such information could help identify groups within the population that require special consideration for radiation protection purposes.

Improved information on the levels of individual and population exposure to all toxic materials is required to assess the magnitude of the total health risk to exposed populations. Expanded animal research efforts are also needed to examine possible interactions between exposure to other toxic agents and radiation exposure to define how dose-response relationships may be affected by these other exposures. Similar studies on the effect of radiation sensitivity of humans and animals of conditions caused by pathogens and pathogenic organisms should also be expanded.

d. Studies of Biological Indicators of Radiation Damage

Continued investigations are needed of possible biological indicators of radiation damage such as identification of chromosome aberrations in peripheral

lymphocytes (blood cells). Additional work is needed, particularly in the low-dose area, to determine whether these changes could provide biological indications of future health consequences.

2. Specific Needs of the Nuclear Regulatory Commission

In addition to health research studies needed to confirm the adequacy of existing radiation protection standards and radiation health effects estimates, the Commission will require additional research and technical assistance studies to improve its evaluations of the health impacts of licensed operations. Although future needs are dependent to some extent upon the results obtained from on-going studies, the Commission staff has identified the following areas where additional information is required:

a. Uranium Milling Operations

Preparation of a Generic Environmental Impact Statement on Uranium Milling has resulted in the identification of additional information needs required to update and supplement existing studies to better define the impacts of this class of operations:

Improved information will be needed on the metabolism and retention of the various chemical compounds of uranium which are generated in the milling, conversion, and fuel fabrication stages of the fuel cycle.

Further analysis of the data obtained from field measurements of emissions of radon and particulates from uranium mill tailings piles will be required in order to develop general models for predicting these emission rates.

Extensive information on the costs and effectiveness of various methods to stabilize and reclaim tailings piles and to limit releases of radon and particulates will be required to support NRC's expanded responsibilities under the Uranium Mill Tailings Radiation Control Act of 1978, Public Law 95-604.

A review of bioassay data from operating uranium mills, conversion and, fuel fabrication facilities should be performed to determine the need for additional requirements for worker protection.

b. Radioactive Waste Management

Extensive on-going NRC efforts to develop licensing criteria and to review procedures for high-level waste disposal facilities and for upgrading site selection requirements for low-level waste burial sites have identified needs for additional research in the following areas:

There is a need for development of improved models for predicting ground-water transport of radioactive materials.

Additional studies are needed of the mechanisms and parameters for estimating the retention characteristics of various soil types.

Additional studies are required of the interactions between high-level waste solidification matrices and the minerals that may exist in underground repositories.

c. Long-Term Impacts of Releases of Radioactive Materials into the Environment

Further studies are needed to improve environmental transport models for predicting the fate of long-lived radionuclides released into the environment. In particular, expanded research on the geochemical cycling of stable elements would be useful for estimating the global movement of long-lived radionuclides.

d. Occupational Exposure to Neutrons

Improved information on the neutron exposure received in nuclear power reactors is needed to assess the health implications of neutron exposure.

Experimental animal studies are required to confirm the biological effectiveness of neutron exposure.

e. Radiation Doses from Medical Devices and Radioisotope Applications

Further studies are needed to better document doses received by medical personnel (technicians, nurses, and physicians), patients, and patient families resulting from medical radiation applications of NRC-licensed materials and on techniques for reducing these exposures.

These needs will be addressed in future NRC research plans beyond FY 1981.

D. CURRENT NRC ACTIVITIES RELATED TO THE ASSESSMENT OF POTENTIAL HEALTH EFFECTS FROM COMMISSION-LICENSED ACTIVITIES

In addition to requirements imposed on NRC licensees to record and to report radiation exposures, in-plant radioactive material concentrations and releases of radioactive materials into the environment, the Commission conducts its own studies to obtain information on the radiation exposures and the potential health impacts from Commission-licensed activities, funds State assistance programs to confirm environmental radiation levels around nuclear power reactors, and makes occasional measurements of effluents to confirm reported data. The health-related studies fall into two general catagories: (1) technical assistance studies conducted by the principal licensing program offices (the Offices of Nuclear Reactor Regulation and the Nuclear Materials Safety and Safeguards) or the Office of Standards Development and (2) confirmatory research conducted by the Office of Nuclear Regulatory Research.

Technical assistance studies are generally short term studies to provide very specific information required in licensing actions or in standards-setting. Although these technical assistance studies may involve some laboratory experimental work or field measurements, they generally rely on reviews of the existing technical literature rather than producing new data. In many cases, these technical assistance studies are directed toward developing or improving calculational models to predict radiation exposures and potential health impacts from existing or proposed operations.

Confirmatory research encompasses longer term (usually multi-year) studies to provide information of broader application to NRC's regulatory

programs. These studies might entail considerable experimental work in laboratories or extensive field measurement programs. This research is undertaken in response to specific needs of the program offices rather than being broad fundamental research of a basic scientific nature. This research is generally undertaken only when the required information cannot be obtained from the larger basic research programs conducted by other agencies and where the existing information is either inadequate or contradictory.

In order to provide an understanding of the range of activities conducted by NRC to fulfill its regulatory mission, the following sections will provide short summaries of research and technical assistance studies currently being conducted in the areas of dose assessment and radiological health. The NRC office which has primary responsibility for carrying out individual studies is identified following the title of the study. Confirmatory research conducted by the Office of Nuclear Regulatory Research is identified by the acronym (RES) and the technical assistance studies conducted by the other program offices are identified by (NRR) for the Office of Nuclear Reactor Regulation, (NMSS) for the Office of Nuclear Materials Safety and Safeguards, and (SD) for the Office of Standards Development.

1. Studies Directly Related to the Assessment of Human Health Effects

a. Epidemiological Studies of Human Exposure

The following studies are epidemiological investigations of exposed human populations which are currently being carried out in order to provide information on the health effects of radiation exposure:

A Follow-Up Study of Patients Who Had I-131 and Other Diagnostic Procedures During Childhood (RES)

This study was begun in 1973 under the sponsorship of the U.S. Environmental Protection Agency. NRC has supported this work since FY 1976 in a joint effort with DHEW, Bureau of Radiological Health and the National Cancer Institute. The objective is to determine if exposure to diagnostic levels of I-131 in childhood is associated with an increased risk of developing benign and malignant thyroid neoplasia. This is an epidemiologic investigation of a study population of 6500 patients who received diagnostic I-131 before 16 years of age. Two control groups consisting of (1) patients who received other thyroid function tests and (2) siblings of the exposed patients will be studied. The study is expected to continue until 1982.

Health Effects of Industrial Exposure to Thorium (RES)

The objective is to evaluate the health effects in workers resulting from exposure to thorium in a thorium processing plant. A mortality study based on death certificates from former employees and a morbidity study based on medical records of a sub-population of workers most highly exposed to thorium are underway. Medical examinations and measurements of residual radioactivity are being conducted on individuals most highly exposed. Willed bodies are being autopsied and autopsy specimens are being analyzed to correlate pathology and radiological findings. Continued study of the thorium workers is planned.

Design and Feasibility Study for Epidemiologic Investigation of the Health Effects of Low-Level Ionizing Radiation (SD)

Pursuant to Public Law 95-601, this effort is to assess the feasibility of conducting a large-scale epidemiological study of populations exposed to low-levels of ionizing radiation. Although NRC is funding the study, EPA and NRC are sharing the project management responsibilities as mandated. The overall objectives are:

a) to define the statistical, technical, and administrative aspects and constraints which are inherent in the conduct of epidemiologic studies on subjects exposed to low-level ionizing radiation; and

b) to examine the merit of conducting such epidemiologic studies on the health effects of low-level ionizing radiation exposure in light of the strengths and constraints identified in (a) above, current knowledge of biological effects, and the characteristics of candidate populations.

Independent Evaluations of Hanford Mortality Data (SD)

The objective of this study is to obtain independent analyses of the Hanford Mortality Data as analyzed by Mancuso, Stewart, and Kneale. The specific objectives are to:

a) examine the relationship between radiation exposure of individuals and cancer deaths;

b) determine the dose-response relationships over the range of exposures; and

c) provide appropriate methods to deal with statistical variables of the data.

The results of these efforts will be available by June 1979.

Excess Cancer Incidence in Mesa County (SD)

This study was conducted to determine whether there is a relationship between an observed excess of cancer in Mesa County, Colorado, and chronic exposure to mill tailings used for residential and commercial construction purposes. The final report was received in November and is expected to be issued shortly. This work was performed by the Colorado State Department of Health.

b. Animal Studies on Radiation Health Effects

These studies on animals are conducted to produce specific information on the health effects of radiation to resolve conflicting information or to develop predictive models which can be applied to the estimation of the risks to man.

Early Effects of Inhaled Radionuclides (RES)

This topic grew out of a need identified in the preparation of the Reactor Safety Study (WASH-1400, NUREG-75/014) for quantitative information on the early effects arising from inhalation of radioactive aerosols. Two studies are directed primarily toward the high-dose consequences of potential accidents. Phase I is a comprehensive review of the published studies of early animal mortality from exposures to radioactive aerosols for developing quantitative models for predicting early mortality and morbidity.

Radiation Dose Estimates and Hazard Evaluations for Inhaled Airborne Radionuclides (RES)

The purpose is to study the sources, biological fate, and predicted health consequences of airborne radioactivity which may be released in the nuclear fuel cycle work environment. Extended dose pattern studies in rats, beagles, and monkeys are being conducted following an acute inhalation exposure to reaerosolized industrial radionuclide bearing materials. Dose-response studies in rats are being initiated this year.

Biodosimetric Confirmation of Dose-Rate Amelioration Factors (RES)

The objective of this research is to develop hematologic and immunological tests which can be used as biodosimeters for chronic irradiation. The development of late effects including leukemia is being studied in beagles exposed to whole body gamma radiation at 0.07 and 0.33 R/day.

The Influence of Genetic Immune Disorders and Anemia in Radiation Leukemogenesis (RES)

The objective is to determine if the genetic disorders producing immunological or hematological deficiencies enhance susceptibility to radiation-induced leukemia. The magnitude of these genetic factors on the latency period and total incidence of radiation-induced leukemia in mice will be studied. The normal mice and those with genetic disorders will be exposed to continuous whole body gamma irradiation.

2. Studies Indirectly Related to the Assessment of Human Health Effects

a. Studies of Radionuclide Retention and Excretion

These studies provide information on the behavior of radioactive materials in animals and humans for use in improving estimates of the internal dose delivered from radioactive materials which are inhaled or ingested.

Human Studies

Translocation of Yellowcake from the Human Respiratory Tract (RES)

The objective is to determine the biological half-life of uranium in yellowcake forms in the human lung. This will be done by collecting urine for radiochemical analysis and by whole-body counting workers exposed to high levels of airborne yellowcake in industrial exposure incidents. It is planned to follow ten cases or less if the findings are sufficiently conclusive to support a model useful to occupational exposure assessment.

Evaluation of the Thorium Content of Human Tissues from Grand Junction, Colorado (RES)

The objective is to measure and interpret the thorium content of human tissues obtained at autopsy from residents of Grand Junction, Colorado and from an area with no uranium mill tailings piles. The study will be completed by the end of 1979.

Animal Studies

Biological Characterization of Radiation exposure and Dose Estimates for Inhaled Uranium Milling Effluents (RES)

The primary objective is to define the metabolic behavior of inhaled yellowcake for use in dose estimation. A secondary objective is to relate the physical and chemical characteristics of the yellowcake samples to the observed biological behavior. Rats, beagles, and monkeys will be exposed to reaerosolized yellowcake collected from operating uranium mills. The study will continued for four to five years.

A Study of UF_6/UO_2F_2 in Experimental Animals (RES)

The objective is to determine the temporal and quantitative relationships which exist between controlled exposures to UF_6 or known body burdens of UO_2F_2 and the urinary elimination of uranium. A second objective is to determine the levels of exposure which cause kidney damage. Inhalation and instillation exposures are being conducted on rats and dogs.

In-vitro Studies

Solubility Classification of Airborne Products from LWR-Fuel Plants (SD)

The objective of this project is to classify the solubilities of airborne products from light-water-reactor fuel preparation plants for use in dose estimation. Representative samples of airborne dust and dust deposited on horizontal structural elements will be collected at three plants that fabricate this type of fuel. The specific surface areas and chemical compositions of the samples will be determined, and their dissolution half-times in simulated lung fluid at 37°C will be evaluated. These half-times will then be used as a basis for recommending solubility classifications for the samples.

b. Studies to Improve Internal and External Dosimetry

These studies provide improved models for dose assessment or evaluations of current techniques of measuring doses.

Development and Confirmation of Biotransport and Dosimetry Models to Implement 10 CFR Part 50 Appendix I Requirements (RES)

The objective is to provide improved dose conversion factors for all significant exposure modes from reactor effluents. This program has provided computer codes to calculate the dose equivalent to organs of man from an inhaled or ingested radionuclide. Dose-rate conversion factors for external exposure to gamma and beta-emitting radionuclides are being prepared. Work is currently concentrating on the environmental transport of radionuclides.

Methods in Dosimetry for Nuclear Regulation (RES)

The objective of this study is to provide an improved data base for internal exposure calculations. One aspect concerns the development of pediatric phantoms, which involves the mathematical design of organs corresponding to the newborn, 1, 5, 10, and 15-year old humans. Another task concerns the construction of metabolic models to estimate the time integrals of activity in source organs.

Neutron Dosimetry Programs (RES)

Two independent projects were funded in 1978 for a 15-month period to study the effectiveness of personnel neutron dosimetry programs at operating nuclear power plants. Neutron instrument and dosimeter data will be compared to the theoretical dose-rates calculated from the measured spectra and fluxes.

Internal Dosimetry and Methods of ICRP (SD)

The objective of this project is to provide NRC with a report on data and methodology used by the International Commission on Radiological Protection (ICRP) in formulating their forthcoming recommendations on permissible intakes of radionuclides for radiation workers. The report will provide a tabulation of the basic data, techniques, and programs used in calculating the recommended limits. These data will be presented in a format suitable to the NRC staff for use in the formulation of its own regulations and regulatory programs. The report will discuss the use of ICRP data and methods in calculating internal dose, evaluating exposures to airborne radioactive material, estimating the Derived Air Concentrations, and computing the annual intake limits.

Performance Testing of Personnel Dosimetry (SD)

The Office of Standards Development is currently considering an amendment to 10 CFR 20 to require performance testing of personnel dosimetry. This effort is to conduct pilot tests for dosimetry processors prior to the amendment of Part 20. The specific objectives are to develop operational and administrative procedures to be used later by a permanent testing laboratory, and to determine whether a new standard for accuracy provides an adequate and practical test of dosimetry performance. These studies will also provide information on the reliability of personnel dosimetry which will be of use in epidemiological studies.

Methods for Assessing Radiation Exposures from Products Containing Radioactive Material (SD)

The objectives of this project include:

a) development of a general methodology for estimating individual and population radiation doses that could be associated with distribution, use, and disposal of radionuclide-containing consumer products; and

b) application of the methodology to estimates of radiation doses associated with products that are exempt from licensing requirements.

The final version of the methodology will be suitable for estimating radiation doses to individuals and to population groups from a variety of radionuclide containing products.

c. Studies of the Transport of Radioactive Materials in the Environment.

These studies are conducted to provide improved information on the atmospheric, hydrological, and groundwater transport of radioactive materials which may be released from NRC-licensed activities and on the biological accumulation mechanisms in food chains and in ecological systems that affect the radiological impact to man and other species.

Evaluate Groundwater Transport of Uranium Mill Waste (RES)

The objective is to determine the interaction of mill tailings leachate with clay liner material and subsurface sediments at the Morton Ranch Mill Site. Information will be gained on the adequacy of the engineered barrier to retard deleterious migration and will identify the migration of potentially hazardous constituents through subsurface sediments if the liner fails. The latter task will aid in the assessment of long time environmental impacts. This work will result in the development of distribution coefficients and the extension of this technology for general use and application to uranium mill waste disposal problems. Finally, licensing factors will be developed and site surveys will be made at active and inactive sites to provide additional tests of methodology on current status.

Characterization, Resuspension and Transport of Radioactive Particles from Energy Fuels Extraction and Processing Plants (RES)

The objective is to investigate the nature, quantity and environmental significance of particles from uranium mills. Emphasis will center on particles originating in the tailings piles from active mills. The short range objectives will be the distribution of important radionuclides and heavy element constituents in the surface and windblown particles in the respirable range. The longer range objectives will include better definition of the sources of airborne waste, including chemical and physical properties, the relationship of airborne waste to surface contamination during seasonal changes, and the application of transport models to assess the radiological consequences of people in the vicinity.

Evaluation of Isotope Migration - Water Chemistry at Shallow-Land Burial Grounds (RES)

Define the source terms of radionuclides and other solutes in trench water from licensed low-level radionuclides disposal sites in cooperation with USGS and describe the physical, chemical, and biological properties that control the movement of radionuclides along the flow paths of ground water.

The Relationship of Soil Types and Soil Microflora to Transport of Waste Radionuclides through the Soil Profile (RES)

Investigate the movement and retention of radionuclides of nuclear waste origin by selected soil types including soils associated with existing radioactive waste treatment facilities. Evaluate correlations between the physical, chemical, mineralogical, and microfloral properties of soils and the degree of movement and retention of waste radionuclides. Evaluate sampling methods for sampling various soil matrices.

Survey of Radionuclide Distribution in Maxey Flats Environs (RES)

Identify, measure and map distribution of radionuclides on ground surface of Maxey Flats low-level waste burial site, and determine the depth distributions of gamma emitters along lengths of existing boreholes and test wells on Maxey Flats site.

Radionuclide Retention and Land Form Modification in Surface Pathways (RES)

Investigate the potential for radionuclide migration at the West Valley, New York burial site by considering surface water effects, determining source terms, and evaluating land form modification processes. Assess the onsite movement of dissolved radionuclides and the radionuclides sorbed on suspended and bed-load sediments to determine their capability of being released to offsite environment. Determine the general pattern of radionuclide migration in backfill material contributing to sediment load of site drainages.

Research Program - Uranium Mill Tailings (RES)

The purpose of this study is to obtain experimental data for the prediction of impacts of uranium milling operations on public health and the environment. This field study program at operating uranium mills will:

1. Provide measurements which can be used as a basis for estimating and characterizing the airborne effluent release rates (source terms) for uranium milling activities. This would include release rates of radioactive particulates and radon-222 from mill stacks and vents, ore piles and tailings piles;

2. Provide data which can be used to confirm predicted offsite environmental concentrations (based on source terms and dispersion calculations); or which can be used for revising estimates of release rates (particularly releases from area sources such as tailings piles and ore pads);

3. Provide data and evaluate the radiological significance of food ingestion pathways resulting from airborne effluent releases from uranium mills. This should primarily focus on ingestion exposures associated with grazing animals and locally raised food crops or garden produce; and

4. Test, demonstrate and evaluate environmental monitoring methods and techniques in order to provide information for developing guidance for these monitoring programs.

Nuclear Waste Management Criteria (NMSS)

The objective of this technical assistance program is to: (1) prepare a regulatory framework for management of high-level and transuranium contaminated wastes; (2) assess critically the Department of Energy (DOE) waste management program; and (3) develop tools with which to review an application for future licensing of a high-level waste (HLW) and transuranic repository. A portion of this program is devoted to development and validation of dose models for converting radionuclide concentrations releases to the biosphere into dose-to-man.

Radionuclide Transport in Agricultural Systems (RES)

Confirm the soil to plant pathways and transfer coefficients for radioisotopes which could be transported from nuclear wastes through food chains to man.

Critical Pathways of the Radionuclides to Man from Agro-Ecosystems (RES)

The objectives of this study are to determine whether uptake of selected radioactive elements increases as a function of the number of times a crop has been grown on a particular soil and to determine the effects of treatments such as lime and chelating agents on long term relationships between crops and radionuclide uptakes.

Evaluation of the Bioaccumulation Factor for P-32 in Fish (RES)

The objective is to determine the appropriate bioaccumulation factor for phosphorus-32 in fish and quantify the variables affecting transfer of P-32 from water to the edible portions of fish.

Environmental Behavior of Transuranics Discharged to Marine Environments from Nuclear Power Stations (RES)

Under normal operating conditions, nuclear power stations discharge very low concentrations of radioactive materials to the aqueous environment. This program will attempt to characterize the transuranics released from nuclear stations to marine waters and to establish their environmental behavior in the corresponding receiving water bodies.

Distribution Coefficients for Transuranic Elements in Aquatic Environments (RES)

Transuranic elements, in trace quantities, may be released into aquatic environments during fuel cycle operations and, in larger quantities, in

the event of a major nuclear reactor accident. Their fate in aquatic environments cannot be reliably predicted from present information obtained from laboratory experiments or field observations. The general objective is to obtain new or better information for predicting the fate of transuranic elements in freshwater and estuarine environments.

Mathematical Simulation of Sediment and Contaminant Transport in Surface Waters (RES)

This study will provide mathematical models for simulations of radionuclide transport in surface waters, including rivers (tidal and non-tidal), lakes, estuarines, and oceans, by considering the effects of radionuclide adsorption/desorption, sediment transport (including suspended sediments), and sediment deposition and resuspension.

Sediment and Radionuclide Transport in Rivers - Model Verification (RES)

This study will verify the time-dependent two-dimensional sediment and radionuclide transport model, SERATRA by application to Cattaraugus and Buttermilk Creeks near the West Valley radioactive waste burial site in New York.

d. Studies of Releases of Radioactive Materials into the Environment and In-Plant Radiation Levels and Radioactive Material Concentrations.

These studies are designed to provide improved data on the source terms used in predicting radiation doses and potential health impacts from Commission-licensed activities.

Shipping Cask Sabotage Term Assessment (RES)

The objective is to establish the magnitude and characteristics (i.e., the physical and chemical form) of the potential radiological source terms associated with specified explosive attacks on spent fuel shipping casks. The source terms derived from scale model tests will be used to develop meaningful and reliable consequence estimates. Collectively, the study results will provide a basis for staff review on the need for and formulation of additional safeguards measures for protection of spent fuel shipments.

Radon Exhalation from Uranium Mill Tailings Piles (RES)

The major source of radiation to the public associated with milling and mining operations results from radon which is emanated from tailings piles. A method has been proposed which would permit an absolute measurement of radon emission based on an analysis of the radon-to-radium concentration ratio as a function of depth within tailings piles. A short-term objective

will be to estimate actual release rates from the surface of active uranium tailings sites. The longer-range objectives will include effects of meteorological conditions and of tailings pile composition on these release rates.

Properties of Low-Level Radioactive Wastes and Containers (RES)

The objective of this program is to develop improved information on the physical and chemical characteristics of low-level wastes which can be used to assess the safety of land burial operations, interim storage and transportation of low specific activity materials.

Institutional Radioactive Wastes (RES)

This study will provide definitive data on the sources, characteristics, volumes and treatment methods for low level wastes arising in the medical/academic uses of radioisotopes.

Reactor Radwaste Generic Study (RES)

Revise and update existing information on the effectiveness of filtration, evaporation, ion exchange and solid waste treatment systems at operating reactors.

Burial Ground Site Survey - Kentucky (RES)

This study consists of extensive field sampling and laboratory radioassays conducted by the State of Kentucky around the Maxey Flats waste burial site.

The purpose of this study is to fully characterize the site, surface water runoff flows, and airborne and liquid-borne radioactive materials released from the burial site and associated operations.

Fuel Cycle Facility Consequence Analysis (SD)

The purpose of this study is twofold: first, by analysis of operating data, the study is intended to identify and categorize various characteristics, accidents, and incidents which can occur at certain fuel cycle facilities, to estimate the frequency of occurrence of such accidents, to identify possible initiating events and sequences for each accident, and to generate the source terms characterizing release the environment by types, quantity, and mode. Second, by the degree of completeness and level of detail of the results, this study should indicate whether a detailed risk assessment for any or each non-reactor fuel cycle facility is needed. Hence, this work is the first necessary part of an overall risk assessment study which would be carried out by the Probabilistic Analysis Staff of the Office of Nuclear Regulatory Research.

e. Studies Pertaining Specifically to the Requirements of the National Environmental Policy Act of 1969

These studies are designed to provide information to improve the quality of NRC's evaluations of the environmental impact from NRC licensed activities and from alternatives to those activities. Because of the requirements of NEPA to provide an assessment of alternatives to a proposed Federal action and to provide a complete assessment of the environmental impacts that may be associated with an activity, several of these studies deal with the impact of fossil-fueled power facilities and uranium mining operations, two activities which are not within NRC's regulatory authorities.

Technical Assistance in Updating the Environmental Survey of the Uranium Fuel Cycle (NMSS)

This task is designed for the preparation of supplement to WASH-1248, Environmental Survey of the Uranium Fuel Cycle, which will present the technical basis for rule making to provide a value in Table S-3 of 10 CFR 51.20 for radon released during uranium mining and milling operations, including radon emissions from stabilized mill tailings piles and from mines after cessation of operations. Calculations and ...e commitments and resulting health effects to the U.S. population associated with the radon release quantities developed for the Table S-3 will be estimated.

Projection Models for Health Effects Assessments in Populations Exposed to Radioactive and Non-Radioactive Pollutants (RES)

Develop models and computer codes which permit more realistic estimates of health effects (mortality and morbidity) and life-shortening from the coal and nuclear fuel cycles for future populations. These estimates are used in comparative cost-benefit analyses of nuclear power facilities and fossil-fueled alternative energy sources. These models will use existing data.

Impacts of the Coal Fuel Cycle (NRR)

The study, to be completed in FY 1979, will provide a technical basis for the detailed generic assessment of the environmental effects of using coal for generating electricity, and to provide for a comparison of these effects with those of using uranium. The impacts associated with each phase of the fuel cycle such as mining, transportation, storage, treatment, combustion,

and waste management and disposal will be identified and evaluated. The major impacts of concern include but are not limited to land use and reclamation, gaseous (including radon) and particulate emissions, point and nonpoint source liquid discharges, acid mine drainage, acid precipitation, toxic effects of effluents and solid wastes, effects of heavy metals and organic substances, solid waste disposal and management, effects on ambient air and water quality, effects on the integrity of natural habitats, effects of noise and vibration, impacts on transportation systems, and other impacts such as possible "green house effects." The study is based on a review and synthesis of existing literature. No new basic research is required.

NEPA Reviews of Accident Risks: Methodology for Assessment of the Consequences of Class 3-8 Accidents (NRR)

A consequence model is being developed for calculation of radiological exposure to the public, resulting health effects and economic losses due to Class 3-8 accidents in nuclear reactors. Radiological exposure to the public from release of radioactivity to the water and the atmosphere and from direct radiation from radioactivity contained in the buildings of the facility will be considered. An evacuation model will be incorporated. Expected completion date is September 30, 1980.

Phase I was funded in FY77 (SD). Work consisted of review of existing calculational models such as in NRC Regulatory Guides for routine operations and accidents, and in WASH-1400. Work was completed in September 1978 and resulted in publication of NUREG/CR-0545.

Phase II was funded in FY78 (NRR). Work consists of assembling the consequence model and the associated computer program. It is expected to be completed in September 1979.

Consequences using the computer program to specific sites, performing sensitivity analysis, and providing recommendations for analysis for NEPA review of accident risks.

Characterization and Environmental Significance of Gases and Particles in Exhaust Vent Air From Underground Uranium Mines (RES)

The objective is to provide the basic information for assessing the significance of pollutants in uranium mine ventilation air released to the atmosphere. The principal activity is to measure radon and radon daughter concentrations, total aerosol particle concentration, trace elements associated with blasting and diesel exhaust, NO_x and SO_x concentrations to determine the relationship of these pollutants to the output of the mines. Develop estimates of source terms for these effluents in terms of release per ton of U_3O_8 mined. Calculate long-term dose commitments for people in the region.

Radon and Aerosol Releases from Open Pit Uranium Mining (RES)

Task I. Measure radon release rates in the Wyoming uranium mining district's open pit uranium mines and in the associated overburden piles, ore storage piles and other areas disturbed by mining activities to determine a total radon release source term for open pit mining. Measure natural background radon emission rates at the mine site and correlate mine emissions of radon

with atmospheric concentrations. Calculate long term dose commitments for people in the region.

Task II. Measure the release rates of radon, aerosols and particulate material from an active open pit uranium mine under a range of meteorological conditions in the New Mexico mining district. Perform an environmental study at the site of a proposed open pit uranium mine to establish background radon emanation rates and atmospheric concentrations of radon and aerosols. Evaluate changes in the radon and aerosol levels during excavation, ore extraction, and refilling of the pit, and after final reclamation. Compare radon releases and factors affecting them in New Mexico with those in Wyoming.

f. Generic Issue Evaluations

These evaluations are performed to estimate radiation exposures and the potential health impact arising from a particular class of licensed operation. Although they do not provide new information on the health effects of radiation, such studies do provide an assessment of radiation dose and health impact which will be used as a basis for decisionmaking in individual licensing actions or in rulemaking.

Generic Environmental Impact Statement (GEIS) on Uranium Milling (NMSS)

This program is a major effort to qualitatively and quantitatively identify the typical environmental impacts of a uranium mill and assess the efficiency and costs of various operational controls, procedures, and mechanisms. Radiological impact analyses examine local, regional, and continental impacts of radioactive material releases during operations, post-operation, and post-reclamation. Other analyses include investigation of impacts of a single model mill, a highly localized cluster of mills, and the overall impact of the entire U.S. uranium milling industry. Results of these analyses are presented in terms of both dose commitments and resulting potential health effects as functions of various levels of effluent control.

Study of Consumer Products Containing Radioactive Material (NMSS)

Evaluate consumer products containing radioactive materials and develop information for the preparation of a generic environmental impact statement on the distribution of such consumer products. This study will provide estimated individual and collective population doses arising from licensing activities in this area.

"As Low As Reasonably Achievable" (ALARA) for Radiopharmaceutical Manufacturers (NMSS)

Radiopharmaceutical manufacturing firms are among the largest users of radioactive materials in unsealed form. The potential for both occupational exposures and release of radioactive materials to the environment exists. This program studies the current practices and procedures at the pharmaceutical manufacturing facilities to obtain information and data to assess: (1) throughput per year of each specific nuclide; (2) installed equipment, technology, and procedures for use and handling of radioactive materials; (3) occupational exposures, both external and internal, received as a result of processing and manufacturing operations; and (4) quantities of each radionuclide released per year as airborne and waterborne effluents.

Safeguards for High-Level Waste (HLW) Repositories (NMSS)

This study will provide a technical basis for NRC's determination of whether explicit safeguards measures are required for geologic repositories for HLW in addition to health and safety measures. As part of this study, the range of consequences that might be deliberately produced by malevolent activities will be examined, including health effects from the release and dispersal of radioactive materials.

Assessment of Radiation Doses Resulting from Uranium Mining and Milling (NMSS)

There are three main objectives for this study: (1) to review and recommend environmental transfer factors and dose conversion factors for two radionuclides (Pb210 and Ra226) that are major contributors to individual and population doses from uranium mills; (2) to estimate population exposures and doses due to radon releases from mills; (3) to compare radon releases from mills with natural and technologically enhanced sources of radon.

Safeguards Analysis for Byproduct Materials and Small Quantities of Special Nuclear Material (NMSS)

This study will provide a technical basis for NRC to evaluate the safeguards need, if any, to protect byproduct materials and small quantities of SNM. The effort involves screening these materials to determine whether any current articles of commerce would, if used malevolently, produce consequences of sufficient severity that the materials should be potential candidates for additional safeguards. The candidates will be investigated to identify those nuclear materials where the current conditions of possession, use, and/or shipment are such that further that evaluation of their safeguard needs is warranted.

Generic Environmental Assessment for Transportation of Radioactive Material Through Densely Populated Areas (SD)

The general objective of this study is the preparation of a generic environmental assessment of the possible radiologic, nonradiologic, and economic impacts on a densely populated urban area resulting from transportation of all radioactive material to and through such an area. As part of the environmental impact assessment, potential population dose commitments and health effects will be evaluated.

Revise WASH-1238 (SD)

WASH-1238 (Environmental Survey of Transportation of Radioactive Materials to and from Nuclear Power Plants) was published in 1972. This study assessed the environmental impact of radioactive material transportation associated with nuclear power plants including population dose and health impact assessment. The objective of the current study is to update WASH-1238 using the most current analysis techniques.

Preparation of a Generic Environmental Impact Statement on the Decommissioning of Nuclear Fuel Cycle Facilities (SD)

In accord with NRC's planning for future decommissioning rule making proceedings, OSD is undertaking development of a GEIS on decommissioning. This study will provide technical information costs, safety and environmental impacts, including occupational and public radiation exposure.

Impacts and Costs Related to Decommissioning Nuclear Fuel Cycle and Byproduct Material Facilities (SD)

The objective of these studies is to develop comprehensive engineering information on: anticipated levels of residual radioactivity in retired nuclear facilities; equipment, methods and techniques for decommissioning; potential decommissioning costs, and methods available for financing such costs; occupational and public radiation exposure; land usage; potential impact on public safety; and facility design changes that would benefit decommissioning.

Impacts and Costs Related to Decommissioning Light-Water Nuclear Power Reactors (SD)

Determine the levels of residual radioactivity associated with end-of-life decommissioning of light-water power reactors and evaluate alternative methods for decommissioning in terms of occupational and public radiation exposure, cost, time, land use requirements and safety.

E. CAPABILITIES OF THE NUCLEAR REGULATORY COMMISSION TO PERFORM RESEARCH ON THE HEALTH EFFECTS OF IONIZING RADIATION

As discussed above, the NRC requirements for technical information to support its regulatory program are satisfied to the extent possible by existing data and by the research programs of other agencies. The NRC relies upon expert consensus to interpret and integrate the results of research for application to its programs.

The Commission has no in-house capability, nor dedicated facilities, for conducting research on the health effects of ionizing radiation. Whenever the information necessary for the performance of its functions is not otherwise available, the NRC sponsors the necessary confirmatory research. For this purpose, the NRC has the professional staff and funds for contracting and managing a health-related research program.

Through an interagency agreement with the Department of Energy, the Commission has access to research capabilities of the DOE national laboratories. Through this mechanism, the Commission contracts with individual DOE laboratories to perform the technical support studies and confirmatory research necessary to meet its regulatory needs. A major portion of NRC's health-related research is conducted by the national laboratories. This arrangement provides NRC with access to extensive research capabilities which its own research needs alone would not be able to justify.

The Commission also contracts with private institutions such as universities and research institutes. By relying upon private contractors as well as the national laboratories, the Commission is assured of diversified sources of expertise to meet its research and technical assistance needs.

F. SUMMARY AND CONCLUSIONS

The Nuclear Regulatory Commission conducts confirmatory research to support its licensing and related regulatory functions. As part of this effort, the Commission maintains research and technical assistance programs to develop information on the radiological impact that results from or may potentially result from NRC-licensed activities. These programs provide information to document current radiation exposures, to predict potential future doses, and to estimate the potential health consequences of radiation exposures received by workers and members of the general population. The types of information needs which are met by these programs range from detailed data on the physical and chemical forms of radioactive materials generated in or released from NRC-licensed operations and studies of environmental transport mechanisms and dosimetry, to animal and human epidemiological studies of the health consequences of radiation exposure.

Although the Commission does not have in-house capability to perform this research, it funds studies to obtain the specific information required to carry out its regulatory and standard-setting functions. These studies are carried out through interagency agreements with other Federal agencies or by contracts with universities, research institutes, or private firms. This arrangement is consistent with the intent of the Congress and has provided adequate support to carry out the Commission's mandate to protect public health and safety.

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THE REPORT SUMMARIZES THE CAPABILITIES, RESEARCH NEEDS AND ON-GOING PROJECTS OF THE ENVIRONMENTAL PROTECTION AGENCY AND THE NUCLEAR REGULATORY COMMISSION RELATED TO THE HEALTH EFFECTS OF LOW-LEVEL IONIZING RADIATION. THE STATUTORY AUTHORITIES OF BOTH EPA AND NRC RELATED TO RADIATION PROTECTION AND RADIATION RESEARCH ARE ALSO BRIEFLY DESCRIBED. AN INTRODUCTORY GENERAL SECTION DESCRIBES CURRENT EFFORTS TO IMPROVE FEDERAL RADIATION RESEARCH AND GENERAL METHODS USED BY BOTH AGENCIES FOR RADIATION DOSE ASSESSMENT AND THE ESTIMATION OF THE POTENTIAL HEALTH EFFECTS OF LOW-LEVEL IONIZING RADIATION. SEPARATE SECTIONS DESCRIBE THE RESPECTIVE AUTHORITIES, NEEDS, CAPABILITIES, AND CURRENT RESEARCH PROGRAMS OF THE TWO AGENCIES. THE REPORT WAS PREPARED TO FULFILL A REQUIREMENT BY THE U.S. CONGRESS WHICH IS CONTAINED IN SECTION 5(c) OF PUBLIC LAW 95-601.

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