

**Oak Ridge
Associated
Universities**

**THE FEDERAL IONIZING
RADIATION RESEARCH AGENDA
RELATED TO LOW LEVEL
BIOLOGICAL EFFECTS: FY 1985**

March 1988

Submitted To:

**Committee on Interagency Radiation
Research and Policy Coordination**

Prepared By:

**K.L. Mossman, D.S. Flack, L.F. Geiger,
and W.A. Mills**

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The Committee on Interagency Radiation Research and Policy Coordination (CIRRPC) is chartered through the Federal Coordinating Council for Science, Engineering and Technology (FCCSET), Office of Science and Technology Policy, Executive Office of the President, Washington, DC 20506. The Medical and Health Sciences Division of Oak Ridge Associated Universities provides technical assistance to CIRRPC.*

This report is based on work performed primarily under contract number DE-AC05-76OR00033 between the U.S. Department of Energy and Oak Ridge Associated Universities.

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Printed in the United States of America. Copies available by referring to publication number ORAU 88/C-68 and writing:

National Technical Information Service
U.S. Department of Commerce
5285 Port Royal Road
Springfield, VA 22161

NTIS price codes: Printed copy, A:10; Microfiche copy, A:01.

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SUMMARY

The Committee on Interagency Radiation Research and Policy Coordination (CIRRPC) was established on April 9, 1984 and chartered under the Federal Coordinating Council for Science, Engineering and Technology, Office of Science and Technology Policy, Executive Office of the President. Its overall charge is to coordinate radiation matters among agencies, evaluate radiation research, and provide advice on the formulation of radiation policy. Technical assistance to the Committee is provided by Oak Ridge Associated Universities (ORAU).

This report is in response to the provision in CIRRPC's Charter that "... [the CIRRPC] Science Panel will assist the Committee in preparing an appropriate research agenda on selected radiation issues ..." Following Science Panel approval of recommendations on how to address an overview of the Federal research agenda related to low level radiation effects, ORAU was tasked to develop an overview report that compared the fiscal year 1985 research program with that of fiscal year 1981. Research data for these years were to be categorized according to the research needs identified in the Interagency Radiation Research Committee's 1981 report on Federal Strategy for Research into the Biological Effects of Ionizing Radiation ("Strategy Report"). The CIRRPC member agencies and National Science Foundation were requested to provide FY85 research program data (Appendix A). The FY81 data were extracted from the 1982 report of IRRC's Subcommittee on Radiation Research Strategy Implementation entitled Assessment of Radiation Research Strategy Implementation ("Implementation Report"), (Appendix B).

The present report is divided into four sections with two appendices, mentioned above. Section A is an introduction to the report and provides the specific charges from CIRRPC to ORAU to conduct the study.

Section B addresses how the Federal radiation research agenda for FY85 met the research needs specified in the 1981 Strategy Report. This section is divided into six chapters, the first four pertaining to the research categories in the Strategy Report: physics, chemistry, and related areas; biological sciences; epidemiology and the health sciences; and sources of exposure to ionizing radiation. Chapters I-IV include brief descriptions of how the needs in these categories were addressed

by the various Federal agencies, along with tabular data of numbers of projects and levels of FY85 funding. Chapter V addresses Federal agency funding of support services, which were not separately identified in the earlier reports. Chapter VI comments on how the FY85 Federal radiation research agenda satisfied the recommendations of the Strategy Report and the National Academy of Sciences' 1981 report on Federal Research on the Biological and Health Effects of Ionizing Radiation ("FREIR Report"). Chapter VII summarizes the findings on the FY85 radiation research agenda in the context of the comprehensive radiation research program supported by the Federal government. Appendix A of the report provides the complete FY85 data base, including project titles and dollars, used in the development of Section B.

Overall, there was no apparent overlap in projects in any of the research areas by the Federal agencies in FY85. When all the research data are considered collectively, the FY85 research agenda appeared to satisfy the needs identified in the Strategy Report and the recommendations of the Strategy and FREIR Reports. However, Section B identifies several areas which were not adequately addressed.

Section C of the report compares the Federal radiation research agendas for FY81 and FY85 in order to identify overall trends in Federal support of radiation research. The FY81 data were extracted from the Implementation Report (Appendix B); the FY85 data were extracted from Section B in the current report. The section is divided into three chapters: Chapter I is a comparison of how the two Federal radiation research agendas addressed the various research categories and needs identified in the Strategy Report; Chapter II is a comparison of the distribution of funding by the various Federal agencies; and Chapter III is a summary of the comparisons. The following points summarize the major findings of the comparison of the FY81 and FY85 Federal radiation research agendas, both with regard to emphasis in research categories and in the level of support:

- (1) There was an increased emphasis on radiation chemistry studies in FY85.
- (2) There was a shift toward greater support of molecular and cell biology studies, with a simultaneous decrease in support for animal radiobiology studies.
- (3) In epidemiology and health sciences studies, there was a substantial de-emphasis of human genetics and birth defects studies in FY85.
- (4) There was a decrease in the total support of studies to characterize sources of exposure to ionizing radiation, primarily due to decreased support of studies to determine

specific sources and routes of exposure in occupational settings.

- (5) DOE and NIH were the principal funding agencies in both the FY81 and FY85 radiation research agendas.
- (6) In terms of FY81 dollars, between FY81 and FY85 there was a 44% increase in support for radiation and physics, chemistry and related areas in FY85; an 18% increase in support for biological sciences studies; a 9% decrease in support for epidemiology and the health sciences; and a 21% decrease in support for studies to characterize radiation sources.
- (7) Two-thirds of the total budgets in both FY81 and FY85 were for support of biological sciences and epidemiology and health sciences research.

The last section of the report, Section D, offers the following recommendations with regard to future reports:

- (1) Within the next three years, a follow-up review should be made of the Federal radiation research program, including comparisons with the FY81 and FY85 Federal radiation research agendas.
- (2) To facilitate subsequent reviews of the Federal radiation research programs, it is recommended that, to the extent it is practical, a compatible information retrieval system be established in each Federal agency.
- (3) A report of the Federal radiation research effort in high dose radiation effects should be carried out since substantial Federal funding is used to support such research and since many studies are applicable to both the high and low dose radiation research agendas.

ACKNOWLEDGMENTS

The preparation of this report required the cooperation of numerous individuals in obtaining, compiling and categorizing the extensive Federal radiation research data base. The authors wish to express their appreciation to those scientists in the Federal agencies who not only provided ORAU with the data, but also reviewed and provided useful comments on the draft report. A special note of appreciation is extended to Elaine Doggett, Jamesette Hutchins, and Mei Lee Strom of the ORAU/CIRRPC Technical Assistance Office who devoted many hours and much patience to the careful preparation of the text and numerous tables in the report.

Dr. Kenneth L. Mossman, who worked on this effort under a personal services agreement with ORAU, is a Professor in the Department of Radiation Medicine at Georgetown University, Washington, D.C.

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SECTION A

INTRODUCTION

The Committee on Interagency Radiation Research and Policy Coordination (CIRRPC) was established on April 9, 1984 by Dr. George A. Keyworth II, Science Advisor to the President and Director of the Office of Science and Technology Policy (OSTP) and was chartered under the Federal Coordinating Council for Science, Engineering and Technology. CIRRPC replaced the Committee on Interagency Radiation Policy and was assigned the responsibilities of the former Interagency Radiation Research Committee (IRRC) and former Radiation Policy Council. Its overall charge is to coordinate radiation matters among agencies, evaluate radiation research, and provide advice on the formulation of radiation policy. At the present time, there are eighteen CIRRPC member agencies (Table 1), fourteen of which have members on the CIRRPC Science Panel. Each of these agencies has significant research, operation or policy functions in the area of radiation.

In 1985, an ad hoc subpanel of the Science Panel considered how to address the following provision set forth in CIRRPC's Charter: "... [the] Science Panel will assist the Committee in preparing an appropriate research agenda on selected radiation issues...." Recommendations were drafted by the subpanel on how best the CIRRPC Science Panel could address an overview of the Federal radiation research agenda. Following approval of these recommendations by the Science Panel, the Oak Ridge Associated Universities (ORAU)/CIRRPC Technical Assistance Office was requested by the CIRRPC Executive Committee to perform several tasks related to the subpanel's recommendation to develop an overview report of Federally supported radiation research.

Specifically, CIRRPC authorized and requested ORAU to perform the following:

I. The CIRRPC Secretariat Office [ORAU/CIRRPC Technical Assistance Office] is to prepare an overview of the radiation research conducted or supported by the Federal establishment for fiscal years 1981 and 1985, for research categories listed in the Interagency Radiation Research Committee's (IRRC) 1982 draft report. The data for 1981 should be extracted from the 1982 draft, and the data for 1985 is to be developed from current programs. The overview is to contain:

- a. A presentation of the dollars expended in the research categories listed in the IRRC 1982 draft report,

- b. A statement of the nature of the research in each category, with particular regard to changes from 1981, and;
 - c. Reference supplementary documents of relevant research abstracts.
- II. The CIRRPC Secretariat [ORAU/CIRRPC Technical Assistance Office] is to explore the desirability and feasibility of developing separate summaries of radiation research in categories excluded from or not considered in the 1982 report, but of sufficient interest to CIRRPC to merit development of a 1985 summary. Such additional research summaries are to be presented for approval to the Science Panel.

The present ORAU report, entitled "The Federal Radiation Research Agenda: FY85," is the result of the ORAU/CIRRPC Technical Assistance Office's efforts to fulfill this charge. The FY85 research program data were provided by the CIRRPC member agencies and the National Science Foundation. Other references used by ORAU were the IRRC's Federal Strategy for Research into the Biological Effects of Ionizing Radiation ("Strategy Report") (1); the National Research Council's Federal Research on the Biological and Health Effects of Ionizing Radiation ("FREIR Report") (2); and the Assessment of Radiation Research Strategy Implementation ("Implementation Report") (Appendix B). Because this task required extensive use of the Implementation Report, which was previously unpublished, permission was requested and granted by the National Institutes of Health (NIH) to publish that report as an appendix to the present report.

TABLE 1

COMMITTEE ON INTERAGENCY RADIATION RESEARCH AND POLICY
COORDINATION (CIRRPC): MEMBER AGENCIES

Department of Agriculture (USDA)
Department of Commerce (DOC) 1/2/
Department of Defense (DOD) 1/3/
Department of Energy (DOE) 1/
Department of Health and Human Services (HHS) 1/4/
Department of Housing and Urban Development (HUD)
Department of Interior (DOI) 1/
Department of Justice (DOJ)
Department of Labor (DOL)
Department of State (DOS)
Department of Transportation (DOT)
Environmental Protection Agency (EPA)
Federal Emergency Management Agency (FEMA)
National Aeronautics and Space Administration (NASA) 1/
Nuclear Regulatory Commission (NRC) 1/
Veterans Administration (VA) 1/
Office of Management and Budget (OMB)
National Security Council (NSC)

1/ Agencies providing research data for this report. The National Science Foundation (NSF) is not a member of CIRRPC, but was asked to provide research data for this report because the 1982 Implementation Report (Appendix B) contained NSF data.

2/ DOC has two agencies with radiation responsibilities: National Bureau of Standards (NBS) and National Oceanic and Atmospheric Administration (NOAA). Only NBS provided data for this report.

3/ DOD has four agencies with radiation responsibilities: Department of the Air Force, Department of the Army, Department of the Navy, and the Armed Forces Radiobiology Research Institute (AFRRI). All agencies except the Department of the Army provided data.

4/ HHS has three agencies with radiation responsibilities: National Institutes of Health (NIH), Center for Devices and Radiological Health (CDRH), and Centers for Disease Control (CDC). All agencies provided data.

SECTION B

THE FY85 FEDERAL RADIATION RESEARCH AGENDA

This section addresses how the FY85 Federal radiation research agenda related to low level effects met the research needs specified in the Strategy Report (1). This section is divided into six chapters, the first four pertaining to the research categories outlined in the Strategy Report: Physics, Chemistry, and Related Areas (Chapter I); Biological Sciences (Chapter II); Epidemiology and the Health Sciences (Chapter III); and Sources of Exposure to Ionizing Radiation (Chapter IV). Chapters I-IV include brief descriptions of how the needs were addressed by the various Federal agencies, along with tabular data of numbers of projects and levels of FY85 funding. Chapter V addresses Federal agency funding of support services, which was not considered as a separate category in either the Strategy Report or the Implementation Report (Appendix B). Chapter VI comments on how the FY85 Federal radiation research agenda addressed the recommendations of the Strategy Report (1) and the FREIR Report (2). Chapter VII summarizes the findings of Chapters I-VI and presents some basic conclusions on the FY85 agenda.

All CIRRPC member agencies (Table 1) with representation on the CIRRPC Science Panel and the National Science Foundation were requested to provide their agencies' FY85 research program data, including budgetary information and descriptions of the projects funded. These project descriptions were required to be of sufficient detail that the research could be categorized according to the research needs identified in the Strategy Report (1). In some cases, agencies themselves provided a categorization of their research projects; otherwise, the ORAU/CIRRPC Technical Assistance Office performed this task. All agencies responded to the CIRRPC request, but some reported that they did not support radiation research programs in FY85 which addressed the Strategy Report needs. Consequently, there are no data from the U.S. Department of Agriculture, Department of Housing and Urban Development, Department of Labor, Department of Transportation, Environmental Protection Agency and Federal Emergency Management Agency.

Appendix A is a listing of titles of 478 research projects comprising the FY85 Federal research agenda related to low level effects of ionizing radiation. This data base is organized by individual agency; within each agency project titles are grouped by research need. In Appendix A, a number of project titles have asterisks, which denote that the project fulfills more than one need and that the project title is repeated elsewhere. CDC,

CDRH, DOD, NASA, NBS, and NIH (especially in epidemiology and the health sciences) have a large number of projects fulfilling two or more needs. In cases where projects fulfilled multiple needs, the total funds for the project were divided equally among all the needs addressed, unless specific apportionments were provided by the agency.

Only research data related to low level effects of ionizing radiation were included in this report. For purposes of this report, low level radiation is defined as that which results in a radiation dose equivalent less than 10 cSv (10 rem). However, research projects which were conducted at dose equivalences higher than 10 cSv were included if they had obvious relevance to low level radiation effects, e.g., epidemiologic studies of human radiation carcinogenesis as a consequence of radiotherapy for benign diseases. High dose radiation effects studies as they pertain to military research (DOD) and biomedical research (NIH) (e.g., studies of the radiobiological basis of human cancer radiotherapy) were excluded. DOD supported high dose radiation research to a level of approximately \$19.5 million in FY85; and NIH funded such research to a level of approximately \$60 million in FY85 to support its radiotherapy development program. These criteria were used to maintain consistency between the present report and the Implementation Report in order to facilitate a comparison between the two reports (see Section C). Clearly, high dose radiation effects research is an important source of research data to understand the biological effects of radiation at any dose level. Such research can provide data to clarify our understanding of the physico-chemical and biochemical nature of the radiation lesions in living systems and contribute to our understanding of the major radiation effects which occur at low doses--carcinogenesis, mutagenesis, and in utero (developmental) effects.

Chapter I: Physics, Chemistry, and Related Areas

Chapter II of the 1981 Strategy Report (1) addresses needs in physics, chemistry, and related areas. The "related areas" refer primarily to measurement and monitoring activities that support studies on the biological effects of ionizing radiation. Table 2 lists the needs identified in the Strategy Report. Implementation of the research needs by the various Federal agencies is shown in Tables 3 and 4. Table 3 lists the number of projects funded by agency and need. Table 4 provides corresponding funding information and indicates that in FY85 DOE was the major funding agency for research needs in physics, chemistry, and related areas. Project numbers and funding for each need are combined for all agencies in Table 5.

Following is a brief description of the research efforts. Research needs have been grouped together according to the main categories of physics, chemistry, and related areas (radiation measurements).

Radiation Physics (Needs 2.1-2.5)

Studies in radiation physics, which are covered by Needs 2.1-2.5, were supported primarily by DOE, as shown in Tables 3 and 4. DOE provided greater than 50 percent of the total support of these needs, with DOD, NBS, NASA and NIH providing lesser amounts of support. DOE support covered all areas of radiation physics, except Need 2.2. The vast majority of research, however, supported Need 2.1 which pertains to studies of the primary transfer of energy from radiation to matter. Projects supported by DOE involve molecular radiation physics, interactions of slow electrons with high pressure gases, neutron interactions with biological tissues, microdosimetry, biological modelling and theoretical biophysics, and theory of relative biological effectiveness. Projects supported by other Federal agencies include basic physical data for neutron dosimetry, measurement of KERMA for high energy neutrons, radiation physics theory, and HZE reaction and transport.

Radiation Chemistry (Needs 2.6-2.13)

Research in radiation chemistry is covered by Needs 2.6-2.13. Four agencies, DOD, DOE, NBS, and NIH, provided funding for these studies, with DOE and NIH providing most of the support.

The research programs supported by the various Federal agencies in radiation chemistry range from studies of free radicals in aqueous solutions to radiation effects in macromolecules. Examples of studies in radiation chemistry included electron transfer reactions in microheterogeneous media, mechanisms of radiation damage in cells, lethal damage from oxygen and OH radicals in irradiated cells, oxidative and free radical mechanisms in the toxicity and carcinogenicity of radiation, energy transformation in molecular systems, mechanisms of radiation damage in DNA, solid state radiation chemistry of nucleic acid bases, and DNA damage and repair studies.

Each need in radiation chemistry was addressed by at least one research project, except Need 2.8 which is concerned with pulse radiolysis studies in complex systems. However, other needs (e.g., Need 2.11) are related to Need 2.8 and research projects in these other needs address, in part, Need 2.8.

Radiation Measurement (Needs 2.14-2.20)

Projects to improve current dosimetry techniques and equipment are addressed in Needs 2.14-2.20. These studies were supported primarily by DOE, but DOD and NBS also provided support. In FY85, DOE provided significant support for two important dosimetry reassessment projects, namely the dosimetry revision for the A-bomb survivors and the dose reassessment project for individuals exposed downwind from the Nevada Test Site. Among the various other studies supported by DOE were studies on internal radiation dosimetry standards and research on neutron dosimetry.

SUMMARY

Table 5 summarizes the number of research projects and total funding for all agencies in radiation physics, radiation chemistry, and radiation measurement. DOE provided greater than 50 percent of the research funding in this area; DOD, NBS, and NIH provided most of the remaining support. Of the three sub-areas, needs in radiation measurements and related areas were funded to the greatest extent. This is not surprising since research in radiation dosimetry and measurements has significant practical value, not only in supporting radiation physics and radiation chemistry studies, but also in supporting other areas of the radiation research agenda, particularly epidemiologic studies where it is necessary to correlate health effects with radiation exposures. Radiation chemistry studies in comparison

were supported to a much lesser extent. However, this does not mean that radiation chemistry research was not being done. On the contrary, radiation chemistry studies were conducted in every phase of radiation research and, in particular, in studies investigating the molecular basis of radiation injury. Except for Need 2.8, all needs in radiation physics, chemistry and related areas were covered by at least one research project.

TABLE 2

RESEARCH NEEDS IN PHYSICS, CHEMISTRY, ^{1/} AND RELATED AREAS,
INCLUDING DOSIMETRY

- 2.1 Continued studies on the primary transfer of energy from radiation to matter, especially condensed matter
- 2.2 Mapping of activation spectra for molecules of chemical and biological importance
- 2.3 Determination of the energy distribution spectrum for single collisions between specific charged particles and molecules
- 2.4 Research into the details of multiple collision processes
- 2.5 Research into the structure of radiation tracks--the time sequence and spectral distribution of secondary radiation-induced events
- 2.6 The application of steady-state radiolysis techniques to complex systems, with product analysis
- 2.7 The application of electron spin resonance methods to the study of radicals in irradiated complex systems, including living organisms
- 2.8 Pulse radiolysis studies for the investigation of events at very short times following irradiation of complex systems in both polar and nonpolar media
- 2.9 An expansion of studies of micellar systems and other synthetic models of biological structures
- 2.10 Studies of the mechanisms of radiation sensitization and desensitization, including the role of molecular oxygen
- 2.11 Studies on the chemistry of free radicals and excited states in irradiated biological systems
- 2.12 Investigations of energy transfer processes between molecules following irradiation

^{1/} Chapter II of Strategy Report(1)

- 2.13 Detailed radiation chemical studies relevant to specific biological effects (mutation, cell death, or cell transformation)
- 2.14 Improvement of the dosimetry system in current use, which is based primarily upon absorbed dose (usually in rads), by including the determination of additional physical parameters (e.g., differences in radiation quality) in order to provide the basis for estimating the biological effectiveness of a given dose
- 2.15 The development of improved instrumentation for accurate dosimetry for mixed radiation fields, which can yield some information on the type and energy spectrum of radiation
- 2.16 Studies to improve dose-distribution information in living tissue, particularly over dimensions less than one micrometer
- 2.17 Research to improve the dosimetry of radionuclides in the human body, including the precise location and quantity of each
- 2.18 The development of improved personnel monitors capable of giving all biologically relevant information quickly and accurately, especially for the measurement of low-energy neutrons, beta particles, low-energy photons, and mixtures of different types of radiation
- 2.19 The development of improved environmental monitors, which (1) are accurate at both ambient low doses and emergency doses, (2) respond to all radiations present (photons and beta rays), and (3) are highly reliable
- 2.20 Research into dosimetry methods for the dose reconstruction of past exposures to aid epidemiological studies

TABLE 3

NUMBER OF FY85 PROJECTS RELATED TO RESEARCH NEEDS
IN PHYSICS, CHEMISTRY, AND RELATED AREAS

Research Need	CDRH	DOD	DOE	DOI	NASA	NBS	NIH	NRC	VA
<u>Radiation Physics</u>									
2.1		5	10		1	3	2		
2.2		1			1		1		
2.3		3	2			1			
2.4		1	1			1			
2.5		1	3						
<u>Radiation Chemistry</u>									
2.6		1				1	1		
2.7		1	2				1		
2.8									
2.9			1				1		
2.10		1	1				2		
2.11		1	2			1	2		
2.12		1	3				1		
2.13		1	1				1		
<u>Related Areas</u>									
2.14		2	3		1	1			
2.15		4	7	1	1	6			1
2.16		2	3						
2.17			5					1	
2.18		2	5			3			
2.19			2						
2.20	1		7				2		
Total*	1	9	58	1	3	11	11	1	1

* Total number of projects. This total may be less than sum of columns because some projects may fulfill more than one need.

TABLE 4

FY85 FUNDING RELATED TO RESEARCH NEEDS
IN PHYSICS, CHEMISTRY, AND RELATED AREAS

(In Thousands of Dollars)

Research Need	CDRH	DOD	DOE	DOI	NASA	NBS	NIH	NRC	VA
<u>Radiation Physics</u>									
2.1		759	1974		50	295	104		
2.2		54			30		43		
2.3		406	540			100			
2.4		54	50			100			
2.5		178	291						
<u>Radiation Chemistry</u>									
2.6		54				129	397		
2.7		54	280				83		
2.8									
2.9			75				26		
2.10		121	29				296		
2.11		121	198			129	109		
2.12		53	225				26		
2.13		121	130				85		
<u>Related Areas</u>									
2.14		182	370		115	128			
2.15		568	1052	205	28	1078			25
2.16		230	450						
2.17			1633					150	
2.18		891	1795			700			
2.19			320						
2.20	240		1314				371		
Total	240	3846	10726	205	223	2659	1540	150	25

TABLE 5
NUMBER OF PROJECTS AND FUNDING IN
FY85 FOR RESEARCH NEEDS IN PHYSICS, CHEMISTRY,
AND RELATED AREAS FOR ALL AGENCIES COMBINED

Research Need	Number of Projects	FY85 Funding (In Thousands of Dollars)
<u>Radiation Physics</u>		
2.1	21	3182
2.2	3	127
2.3	6	1046
2.4	3	204
2.5	<u>4</u>	<u>469</u>
Subtotal	37	5028
<u>Radiation Chemistry</u>		
2.6	3	580
2.7	4	417
2.8	0	0
2.9	2	101
2.10	4	446
2.11	6	557
2.12	5	304
2.13	<u>3</u>	<u>336</u>
Subtotal	27	2741
<u>Radiation Measurement</u>		
2.14	7	795
2.15	20	2956
2.16	5	680
2.17	6	1783
2.18	10	3386
2.19	2	320
2.20	<u>10</u>	<u>1925</u>
Subtotal	60	11845
Total	96*	19614

* Total number of projects is less than sum of the column because some projects could be fit into more than one need.

Chapter II: Biological Sciences

In this chapter, research needs in the biological sciences are addressed. Biological studies, especially at the cellular level, offer the most probable means of obtaining information on the biologic effects of radiation at low levels of radiation exposure, the principal effects being cancer induction several years after exposure, genetic effects in future generations, and developmental effects as a result of exposure in utero. Studies in the biological sciences, in particular cellular radiobiology studies and studies in various whole animal systems, can provide important information about mechanisms of radiation effects that are necessary in evaluating radiation effects in humans where direct observations at low doses are limited. Table 6 summarizes the needs identified in the various areas of molecular and cell biology and animal radiobiology research described in Chapter 3 of the research Strategy Report (1). How these research needs were implemented by each of the Federal agencies in FY85 is addressed in Tables 7 and 8. Table 7 provides numbers of research projects by need and Table 8 provides funding by need for each of the Federal agencies. Table 9 provides a summary of project numbers and funding for all Federal agencies combined.

Needs 3.1 - 3.12 address molecular and cell biology studies; and Needs 3.13 - 3.18 address animal radiobiology studies. The molecular and cell biology studies may be further subdivided as follows: studies involving damage to biologically important molecules, especially DNA, and repair (Needs 3.1 - 3.4); mutagenesis (Needs 3.5 - 3.7); cell killing, mutations, and transformation (Need 3.8); cell transformation and carcinogenesis (Needs 3.9 - 3.11); and modification of radiation effects (Need 3.12). Animal radiobiology studies may be further subdivided into the following categories: radiation carcinogenesis, mutagenesis and teratogenesis (Needs 3.13 - 3.15, 3.17, 3.18) and fate of inhaled or ingested radionuclides (Need 3.16). The following is a brief description of the research projects in this area funded by the various Federal agencies. The subcategorizations of cellular and molecular radiobiology and animal radiobiology have been used to facilitate discussion.

Molecular and Cell Biology Studies (Needs 3.1-3.12)

Damage to Biologically Important Molecules (Especially DNA) and Repair (Needs 3.1-3.4)

DNA is generally recognized as the key macromolecular target in the cell resulting in radiation effects such as cell killing,

carcinogenesis (cellular transformation) and mutagenesis. A large number of FY85 studies, supported primarily by NIH and DOE, were concerned with the nature of radiation damage to DNA and other biologically important molecules and repair of DNA damage. Supported studies included radiation biochemistry of DNA base damage, DNA damage and repair assays, DNA damage and repair in irradiated tissues, cross-linking of nucleoproteins by radiation and repair in radiosensitive cells.

Mutagenesis (Needs 3.5-3.7)

Studies of mutation induction by radiation at the cellular level are important as a basis for understanding the mutagenesis process and for predicting the quantity and quality of genetic injury in irradiated populations. In FY85, DOE and NIH were almost solely responsible for studies in radiation genetics. Topics of supported studies included radiation mutagenesis in human cells, somatic mutagenesis by gamma rays, radiation damage to chromosome proteins, DNA repair processes, mechanisms of genotoxicity in vitro, genetic effects of high-LET radiation, and mutagenic effects of incorporated radionuclides.

Cell Killing, Mutations, and Transformation (Need 3.8)

Need 3.8 addresses the interrelationship of cell killing, mutations and transformation. In FY85, only NIH and DOE supported research in this area, including studies on membrane composition and radiation damage, UV-X ray interactions in mutagenesis and transformation, and inducible responses to carcinogenic DNA damage.

Cell Transformation and Carcinogenesis (Needs 3.9-3.11)

The principal somatic effect of ionizing radiation at low doses is cancer induction, and, consequently, studies at the cellular level are important to elucidate mechanisms of the carcinogenesis process. DOE and NIH were solely responsible for supporting research projects in this area. General areas of investigation included the role of oncogenes in transformation, high-LET radiations and transformation, interaction of radiations and chemicals, hormones and radiation, and effect of dose protraction and repair of radiation-induced carcinogenic damage.

Modification of Radiation Effects (Need 3.12)

Ionizing radiation exposure may be associated with exposure to other toxic agents (e.g., smoking), and such interactions between radiation and other noxious agents are often complex. Supported primarily by NIH, studies addressing this need investigated both the interaction of ionizing radiation with other radiation modalities and the interaction of radiation with various chemical agents.

Animal Radiobiology (Needs 3.13-3.18)

Radiation Carcinogenesis, Mutagenesis, and Teratogenesis (Needs 3.13-3.15, 3.17, and 3.18)

In addition to studies at the cellular level, animal radiobiology studies of carcinogenesis, mutagenesis and teratogenesis are important since the response of whole organisms (e.g., man) cannot be predicted solely on the basis of cell culture studies. For instance, animal studies can provide important information concerning the nature of the dose response relationship, the role of host factors in carcinogenesis, mechanisms of mutation induction in germ cells, and mechanisms of developmental effects following in utero radiation exposure.

In FY85, studies addressing these needs were primarily funded by NIH and DOE, with lesser support from CDRH and NASA. Areas of investigation which were supported included life shortening effects of high Z particles, teratogenic effects of radiation in mice, neoplasia in beagles after irradiation during pre- and postnatal development, late effects of protracted irradiation in dogs, effects of low-level or chronic exposure to toxic agents, cancer in dogs given whole body irradiation, carcinogenic interactions of radiation and chemicals, radiosensitivity of oocytes and other cells during development, and life shortening and tumor induction by low doses of neutrons or gamma rays.

Fate of Inhaled or Ingested Radionuclides (Need 3.16)

Unlike external radiation sources, exposure to some radionuclides pose special hazards when internalized. Depending on the chemical and physical characteristics, small quantities of inhaled or ingested radionuclides can concentrate in certain tissues delivering biologically significant radiation doses.

Research in this area was almost totally sponsored by DOE. Radionuclides of concern include plutonium and other actinides, radon and its daughter products, strontium and radium. Studies included investigations of dose response relationships for low- and high-LET radiation, gastrointestinal absorption, metabolism of radionuclides, bio-distribution of radionuclides, and radiation effects in specific tissues such as lung and bone.

SUMMARY

Table 9 summarizes the number of research projects and total funding for all agencies combined in the areas of molecular and cell biology and animal radiobiology. NIH and DOE provided the majority of support for biological sciences research in FY85. As shown in Table 9, the majority of research was directed toward molecular and cell biology studies. This is not surprising since molecular and cell biology studies are less expensive to conduct than animal studies and molecular and cell experimental systems are the most likely means by which mechanisms of carcinogenesis and mutagenesis may be elucidated.

All the needs identified in the Strategy Report for the biological sciences were addressed. Among the needs in molecular and cell biology research, interest was directed primarily at Needs 3.2 and 3.9 -- studies to elucidate the basic mechanisms of DNA replication and repair; and the basic mechanisms of cell transformation by radiation and other agents and its relationship to carcinogenesis. Emphasis in these areas reflects a general concern to clarify cellular mechanisms of cancer induction, the principal somatic effect of ionizing radiation exposure at low doses.

In animal radiobiology studies, primary interest was in Need 3.16--research on the fate of inhaled and/or ingested radionuclides and the biological effects which may be produced in specific tissues and organs. It is not surprising that emphasis was placed in this area since ingestion and inhalation of radionuclides is an important hazard for which basic laboratory animal studies are needed to elucidate bio-distribution, dosimetry and bioeffects mechanisms.

Large animal studies to evaluate the carcinogenic effects of ionizing radiations at low doses were also supported primarily by NIH, DOE, and CDRH. These studies included health effects evaluations of ionizing radiation exposure in the beagle dog; effects of inhaled plutonium nitrate in dogs; toxicity of plutonium and radium in juvenile and mature humans, beagles, and mice; and studies of late effects following protracted irradiations in dogs.

TABLE 6

RESEARCH NEEDS IN THE BIOLOGICAL SCIENCES ^{1/}

- 3.1 Studies to characterize and measure quantitatively the full spectrum of lesions produced in DNA, particularly when irradiated in vivo
- 3.2 Continued efforts to elucidate the basic mechanisms of DNA replication and repair
- 3.3 Research to identify those radiation-induced lesions in DNA and other structures which are repairable, and the extent to which each is repaired in human cells in vivo
- 3.4 Studies to correlate certain biological end-points with specific lesions in DNA or other structures
- 3.5 Studies of "single-hit" or linear dose effects, their possible dependence on dose rate, and how they are influenced by the rates of molecular and cellular repair processes
- 3.6 Studies on the underlying mechanisms of mutagenesis in microorganisms and cultured animal cells
- 3.7 Investigations on radiation-induced chromosome anomalies to determine the functional significance of such lesions
- 3.8 Studies of the relationship(s) between cell killing, mutation, and transformation
- 3.9 Increased efforts to elucidate the mechanisms of cell transformation, both by radiation and other agents, and its relationship to carcinogenesis
- 3.10 Research to clarify the role of "initiators," "promoters," and other agents which may influence the process of carcinogenesis
- 3.11 The development of new cellular systems for in vitro investigations of transformation, including diploid cells rather than polyploid cell "lines," from appropriate individuals with identifiable genetic diseases, cancer, etc.

^{1/} Chapter III of Strategy Report(1)

- 3.12 Studies to determine which agents are additive to, synergistic with, or antagonistic to the different effects of ionizing radiation, and how these act
- 3.13 Population studies to determine the dose-response characteristics of different types of radiation and for different time patterns of dose delivery for carcinogenesis, mutagenesis, and teratogenesis
- 3.14 Studies of the influence of host factors on radiation effects utilizing model animal systems, including radiation-sensitive, repair-deficient, and other specialized animal strains
- 3.15 Studies to characterize the interaction between radiation and toxic or carcinogenic chemical agents
- 3.16 Research on the fate of inhaled and/or ingested radionuclides and the biological effects which may be produced in specific tissues and organs
- 3.17 Studies on the long-term effects of fetal irradiation leading to cancer, birth defects, or other abnormalities
- 3.18 Studies of the mechanisms of the induction of radiation effects (cancer, birth defects, etc.), including the promoting and modifying conditions and the underlying bases for variations in susceptibility

TABLE 7
 NUMBER OF FY85 PROJECTS RELATED TO RESEARCH NEEDS
 IN THE BIOLOGICAL SCIENCES

Research Need	CDRH	DOD	DOE	NASA	NIH	NRC	NSF	VA
<u>Molecular & Cell Biology</u>								
3.1		2	3	1	5			
3.2		1	6	1	26			
3.3		1	2		7			
3.4		3	7		6			
3.5		2	6		11			
3.6	1		11		11		1	
3.7			5		5			1
3.8			3		6			
3.9			11		11			
3.10			3		4			
3.11					8			
3.12	1	2	2		10			
<u>Animal Radiobiology</u>								
3.13	2	1	7	1	8	1		
3.14	2		2	1	2			
3.15	1		1	1	5			
3.16			24	1	3	3		
3.17	3		4	1	9			
3.18			4		8			
<hr/>								
Total*	4	4	100	5	123	4	1	1

* Total number of projects. This total may be less than sum of columns because some projects may fulfill more than one need.

TABLE 8

FY85 FUNDING RELATED TO RESEARCH NEEDS
IN THE BIOLOGICAL SCIENCES

(In Thousands of Dollars)

Research Need	CDRH	DOD	DOE	NASA	NIH	NRC	NSF	VA
<u>Molecular & Cell Biology</u>								
3.1		174	1050	183	591			
3.2		121	774	15	2999			
3.3		14	252		615			
3.4		317	1392		1082			
3.5		208	1178		1679			
3.6	46		1602		969		90	
3.7			1736		487			12
3.8			420		729			
3.9			2537		1040			
3.10			670		274			
3.11					926			
3.12	46	174	179		1568			
<u>Animal Radiobiology</u>								
3.13	115	250	3280	182	2200	285		
3.14	90		675	60	286			
3.15	45		210	45	382			
3.16			9131	90	258	291		
3.17	123		1145	27	857			
3.18			695		1025			
Total	465	1258	26926	602	17967	576	90	12

TABLE 9

NUMBER OF PROJECTS AND FUNDING IN FY85
FOR RESEARCH NEEDS IN THE BIOLOGICAL
SCIENCES FOR ALL AGENCIES COMBINED

Research Need	Number of Projects	FY85 Funding (In Thousands of Dollars)
<u>Molecular and Cell Biology</u>		
3.1	11	1998
3.2	34	3909
3.3	10	881
3.4	16	2791
3.5	19	3065
3.6	24	2707
3.7	11	2235
3.8	9	1149
3.9	22	3577
3.10	7	944
3.11	8	926
3.12	<u>15</u>	<u>1967</u>
Subtotal	186	26149
<u>Animal Radiobiology</u>		
3.13	20	6312
3.14	7	1111
3.15	8	682
3.16	31	9770
3.17	17	2152
3.18	<u>12</u>	<u>1720</u>
Subtotal	95	21747
<hr/>		
Total	242*	47896

* Total number of projects is less than sum of the column because some projects could be fit into more than one need.

Chapter III: Epidemiology and the Health Sciences

In this chapter, research needs in epidemiology and the health sciences are addressed. Studies of human populations exposed to ionizing radiation from natural background and for military, occupational, or medical purposes provide the only opportunity to directly study the biological effects of radiation on humans. Historically, these studies have formed the primary basis for the development of human health risk estimates from exposure to radiation.

The primary purpose of epidemiologic research is to assess human health risks at radiation doses too low to cause immediate health effects. However, because dosimetry information, identification of appropriate control populations, and appropriate sample sizes are frequently lacking in epidemiologic studies, it is often difficult to draw valid conclusions about health effects in exposed populations.

In this chapter, a review is made of the extent to which FY85 Federal radiation research efforts attempted to fulfill needs in epidemiology and health sciences research. Table 10 is a listing of the research needs in epidemiology and the health sciences, as identified in the Strategy Report (1). How these research needs were implemented by the various Federal agencies is addressed in Tables 11 and 12: Table 11 provides numbers of research projects by need for each of the Federal agencies; and Table 12 provides funding by need for each of the Federal agencies. It should be noted that while the tables illustrate the major needs addressed by the studies, they do not show all the needs addressed by each project because almost all the epidemiology and health sciences studies address multiple needs. Table 13 is a summary of numbers of projects and funding for each need for all agencies combined.

The following is a brief description of research projects funded by the various Federal agencies in epidemiology and the health sciences. To facilitate discussion, the needs have been categorized as follows: human population genetics (Needs 4.1-4.2); human epidemiology (Needs 4.3-4.12); human birth defects (Needs 4.13-4.14); and other somatic effects (Needs 4.15-4.20).

Human Population Genetics (Needs 4.1 - 4.2)

Compared to our understanding of human radiation carcinogenesis, relatively little is known about the human genetic response to radiation exposure. Genetic injury may be highly variable and in some instances very difficult to detect. Research needs in human population genetics were primarily supported by DOE in FY85.

Studies were funded to evaluate the long-term effects of ionizing radiation on health in the Japanese atomic bomb survivors. These studies included evaluation of genetic injury in the first generation of children born to the exposed atomic bomb survivors.

Human Epidemiology (Needs 4.3 - 4.12)

Several agencies, notably CDC, CDRH, DOE, and NIH, funded studies in human cancer epidemiology, with the major support provided by DOE and NIH. Epidemiologic studies of radiation carcinogenesis can be placed in four general categories: studies following military, occupational, medical and environmental exposures to radiation.

The most important source of human data on radiation carcinogenesis continues to be the survivors of the atomic bombings at Hiroshima and Nagasaki. In FY85, DOE provided primary support for these follow-up studies of Japanese atomic bomb survivors through the Radiation Effects Research Foundation (RERF). The RERF program supports a wide variety of studies in addition to cancer epidemiology of the survivors. Other epidemiologic studies as a consequence of military activities included studies of nuclear test participants and studies of leukemia and other cancers in residents of Utah as a result of fallout from Nevada Test Site operations.

Support was also provided to evaluate the health consequences of environmental and occupational radiation exposures, including studies on lung cancer incidence in uranium miners, the health and mortality study of employees of the DOE Hanford facility, health effects studies in shipyard workers, and studies of cancer risks in x-ray technologists. These studies were primarily supported by DOE, with lesser support from NIH and CDC.

A large number of studies of individuals exposed to ionizing radiation for medical reasons also provides evidence of the association between radiation and cancer. Studies, primarily funded by NIH in FY85, included evaluation of cancer risk following multiple chest fluoroscopies, thyroid cancer risk following radiotherapy for benign conditions of the head and neck, thyroid cancer risk following diagnostic and therapeutic I-131 exposure, prenatal x-ray exposure and childhood cancer, cancer risks in patients irradiated for peptic ulcer, cancer risk in women irradiated for benign gynecological disorders, and cancer risk in populations of children and adults receiving radiotherapy for malignant conditions such as cervical cancer.

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Human Birth Defects (Needs 4.13-4.14)

Teratogenic effects of radiation, especially at low doses, are not well understood. Little information is available on dose response relationships for effects at different gestational ages, on the effects of radiation of different LETs, and on the fate of, or effect of, maternally ingested or inhaled radionuclides. Only one project, supported by NIH, was identified as addressing radiation effects on development.

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Other Somatic Effects (Needs 4.15-4.20)

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Although the principal somatic effect of ionizing radiation at low doses is cancer induction, other effects may also be produced. Depending on dose, temporary or permanent sterility, cataracts, and general susceptibility to disease can occur. NIH and DOE primarily supported studies in these areas, with CDC and CDRH providing lesser support. FY85 studies included evaluations of the health status of nuclear workers and studies of radiation induced chromosome damage in humans.

SUMMARY

Table 13 summarizes the number of research projects and the total funding for all agencies combined in epidemiology and the health sciences for FY85. DOE and NIH provided the greatest amount of support for research in these areas. The major focus of research was the determination of dose-response relationships, especially for cancer induction, characterization of the differential sensitivity of different tissues and organs to radiogenic cancer, and evaluation of time-response and risk projection models. In addition, DOE heavily supported research on the clinical consequences of radionuclide deposition in specific tissues.

Little or no research support was identified for studies to assess the placental transfer of radionuclides, for studies on the effect of radiation exposure on human fertility, or for impaired organ or tissue function studies, particularly cataractogenesis. However, human fertility is a topic covered by the NIH studies on cancer risks in women irradiated for benign gynecologic disorders. Many of these effects have practical thresholds which are observable only at high doses, as seen in radiotherapy settings.

TABLE 10

RESEARCH NEEDS IN EPIDEMIOLOGY AND THE HEALTH SCIENCES ^{1/}

- 4.1 The development of rapid screening techniques to detect missing or abnormal proteins
- 4.2 A study to determine the feasibility of the development of a program to obtain complete medical and family histories on patients with clinical genetic disorders, in order to facilitate the analysis of such data for correlations with parental exposure to radiation or mutagenic agents
- 4.3 The integration of animal data, cytogenetic data, and the knowledge of basic radiation mechanisms with epidemiological data in order to establish dose-response relationships for low levels of exposure, as a function of the type of radiation and site of tumor
- 4.4 Studies on human populations exposed to agents in addition to radiation, in order to assess possible synergistic or antagonistic effects
- 4.5 Investigation of the effects of age, diet, general health, genetic factors, etc., on sensitivity to radiogenic cancer
- 4.6 Studies to characterize the differential sensitivity of tissues and organs to radiogenic cancer
- 4.7 Research on the role of radiation quality in the carcinogenic response to ionizing radiation
- 4.8 Studies of the effect of dose-rate on the risk of cancer
- 4.9 Investigation of the patterns of appearance of radiogenic cancer with time and their relationship to the temporal patterns of spontaneous cancer
- 4.10 The refinement and development of epidemiological designs and biostatistical methods to improve the sensitivity of epidemiological studies by accurately correcting for extraneous variables

^{1/} Chapter IV of Strategy Report(1)

- 4.11 The development of procedures to facilitate the acquisition of medical, occupational, and exposure records for radiation and other toxic agents, possibly utilizing the Social Security record system
- 4.12 The preliminary screening of populations exposed to ionizing radiation to select those which may be suitable subjects for epidemiological studies
- 4.13 Efforts to construct dose-response relationships for teratogenic effects of fetal exposure at different developmental stages for different types of radiation and LETs, from both animal experiments and existing human data
- 4.14 Studies to assess the placental transfer of radionuclides
- 4.15 Further investigations of the mechanisms of impaired organ functions, such as radiation-induced eye cataracts in animals
- 4.16 Studies to improve quantitative estimates of the effect of radiation exposure on human fertility from existing human exposure data
- 4.17 Studies on human populations, animals, and cellular systems to determine the significance, if any, of radiation-induced chromosome anomalies
- 4.18 Studies to determine the dose-response relationships for the effects of radiation exposure on the increased susceptibility to disease, impaired organ function, reduced capacity of physiological systems, and a general lowering of health status
- 4.19 Studies on the clinical consequences of radionuclide deposition at specific internal sites (e.g., liver, lungs, and bone), including post-mortem pathology
- 4.20 The development of complete and easily accessible medical records which include radiation exposure data as well as exposure information on other toxic agents

TABLE 11

NUMBER OF FY85 PROJECTS RELATED TO RESEARCH NEEDS
IN EPIDEMIOLOGY AND THE HEALTH SCIENCES

Research Need	CDC	CDRH	DOE	NASA	NIH	NRC
4.1			3	1		
4.2		1		1		
4.3			2	1	6	
4.4	2		3			
4.5	1		1		12	
4.6	1	1	1		8	
4.7						
4.8	2				2	
4.9	1		1		5	
4.10	2		2		1	
4.11	1	1	3			
4.12	2	2	3			
4.13					1	
4.14						
4.15			1			
4.16						
4.17			1		3	
4.18	3	1	4			1
4.19			5		6	
4.20		2	3			
Total*	10	6	21	2	21	1

* Total number of projects. This total may be less than sum of columns because some projects may fulfill more than one need.

TABLE 12

FY85 FUNDING RELATED TO RESEARCH NEEDS
IN EPIDEMIOLOGY AND THE HEALTH SCIENCES

(In Thousands of Dollars)

Research Need	CDC	CDRH	DOE	NASA	NIH	NRC
4.1			1062	15		
4.2		33		80		
4.3			590	15	1877	
4.4	55		1041			
4.5	11		45		773	
4.6	5	52	218		1696	
4.7						
4.8	100				1277	
4.9	6		852		369	
4.10	20		2446		4	
4.11	6	65	795			
4.12	20	145	1173			
4.13					87	
4.14						
4.15			160			
4.16						
4.17			725		284	
4.18	30	52	6055			150
4.19			2628		404	
4.20		31	1041			
Total	253	378	18831	110	6771	150

Chapter IV: Sources of Exposure to Ionizing Radiation

Chapter V of the Strategy Report (1) focuses on the characterization of sources of exposure to ionizing radiation. Emphasis has been placed on the characterization of radionuclides in the terrestrial and aquatic environments, the transport of these radionuclides through various environmental pathways to man, sources of exposure in occupational settings, and the fate of ingested or inhaled radionuclides in man, including assessments of radiation doses to specific organs and tissues.

Table 14 lists the research needs concerning the characterization of sources of exposure which were identified in the Strategy Report (1). Implementation of these research needs by the various Federal agencies is shown in Tables 15 and 16. In FY85 DOE provided essentially all the support in these areas. Table 15 lists the number of projects funded by need. Table 16 provides corresponding funding information. Table 17 provides a summary of the number of research projects and total funding for all agencies combined for needs in this area. Following is a brief description of research efforts addressing these needs.

Transport of Radionuclides in the Environment (Need 5.1)

The characterization of the environmental behavior of radionuclides is important in order to map environmental distributions and to facilitate calculations of radiation doses to human populations. FY85 studies focused primarily on transuranic elements, radon and its daughter products, and fission products in the aquatic, terrestrial, and atmospheric environments.

Human Exposure to Radionuclides in the Environment (Need 5.2)

FY85 studies on the assessment of human exposures to radiation from radionuclides in the environment primarily focused on assessment of radon and radon daughters from uranium mill tailings and in homes and buildings and reconstruction of the radiation doses to populations downwind from the Nevada Test Site. Other studies in this area included environmental transport research on radon and plutonium.

Food Chain Pathways of Radionuclides (Need 5.3)

Food chain pathways are an important mode of radionuclide intake by humans. FY85 research projects addressing this need focused on the behavior of radionuclides in soils and plants, cycling of radionuclides, and transport of radionuclides through farm animals to food products.

Occupational Sources of Radiation Exposure (Need 5.4)

Only two projects were identified relating to studies of occupational sources of radiation exposure. In FY85, NASA supported one project on exposure to high atomic number, high energy (HZE) particles; and DOD supported one project on high energy astrophysics.

Organ Dosimetry (Need 5.5)

FY85 studies to elucidate the fate of radionuclides inhaled or ingested by humans and to assess the radiation doses received by specific organs and tissues included the following: assessment of plutonium contamination in occupationally exposed individuals (United States Transuranium Registry); comparative metabolism of actinides; and toxicology of thorium cycle nuclides.

SUMMARY

Table 17 summarizes the number of research projects and total funding for all agencies combined for needs characterizing sources of exposure to ionizing radiation. DOE provided most of the support in this area. The major focus of research was in the characterization of the environmental behavior of radionuclides. Relatively little support was identified for studies to determine specific sources and routes of exposure in occupational settings. However, other needs, particularly in Radiation Physics, Chemistry and Related Areas and in Epidemiology and the Health Sciences did address occupational exposure issues.

TABLE 14

RESEARCH NEEDS CONCERNING THE CHARACTERIZATION OF SOURCES OF EXPOSURE TO IONIZING RADIATION ^{1/}

- 5.1 Empirical and theoretical studies of the transport of radionuclides in the atmosphere, and in the terrestrial and aquatic environments
- 5.2 The assessment of human exposures to radiation from radionuclides in the surrounding environment, including water supplies, building materials, etc.
- 5.3 The uptake of radionuclides in the environment by living organisms, and the passage to human populations through the food chain
- 5.4 Studies to determine specific sources and routes of exposure in occupational settings
- 5.5 Research to elucidate the fate of radionuclides inhaled or ingested by humans, and to assess the radiation dosages received by specific organs and tissues

^{1/} Chapter V of Strategy Report(1)

TABLE 15

NUMBER OF FY85 PROJECTS RELATED TO RESEARCH NEEDS TO
CHARACTERIZE SOURCES OF EXPOSURE TO IONIZING RADIATION

Research Need	CDRH	DOD	DOE	NASA	NIH
<u>Environmental Sources</u>					
5.1			42		1
5.2			11		
5.3			8		1
<u>Occupational Sources</u>					
5.4		1		1	
5.5	1		8	1	
Total*	1	1	66	1	1

* Total number of projects. This total may be less than sum of columns because some projects may fulfill more than one need.

TABLE 16

FY85 FUNDING RELATED TO RESEARCH NEEDS
TO CHARACTERIZE SOURCES OF EXPOSURE
TO IONIZING RADIATION

(In Thousands of Dollars)

Research Need	CDRH	DOD	DOE	NASA	NIH
<u>Environmental Sources</u>					
5.1			9978		397
5.2			1490		
5.3			2739		397
<u>Occupational Sources</u>					
5.4		193		50	
5.5	5		1322	30	
Total	5	193	15529	80	794

TABLE 17

NUMBER OF PROJECTS AND FUNDING IN FY85
FOR RESEARCH NEEDS TO CHARACTERIZE SOURCES
OF EXPOSURE TO IONIZING RADIATION
FOR ALL AGENCIES COMBINED

Research Need	Number of Projects	FY85 Funding (In Thousands of Dollars)
<u>Environmental Sciences</u>		
5.1	43	10375
5.2	11	1490
5.3	<u>9</u>	<u>3136</u>
Subtotal	63	15001
<u>Occupational Sources</u>		
5.4	2	243
5.5	<u>10</u>	<u>1357</u>
Subtotal	12	1600
Total	70*	16601

* Total number of projects is less than sum of the column because some projects could be fit into more than one need.

Chapter V: Support Services

The Strategy Report (1) did not identify specific needs to provide indirect support for ongoing research programs. Likewise, the Implementation Report (Appendix B) did not contain separate data on either the number of projects or funding levels for support services in FY81, FY82, or FY83. However, the FY85 data submitted by the Federal agencies included abstracts of projects which were clearly identifiable as providing indirect support services for research programs, rather than providing funding for basic radiation research. Table 18 provides a summary of funding for support projects for each agency. Support services included operational support of radiation facilities, computer support, data banks and epidemiology support. Funding provided by the Federal agencies in support of various scientific groups (e.g., NCRP) and conferences was not included in this category because such support is not readily identifiable as either indirect or direct support of radiation research.

TABLE 18

NUMBER OF PROJECTS AND FUNDING IN FY85
RELATED TO SUPPORT SERVICES

Agency	Number of Projects	FY85 Funding (In Thousands of Dollars)
CDC		
CDRH		
DOE	6	910
DOI		
EPA		
FEMA		
NASA		
NBS		
NIH	3	574
NSF		
VA		
Total	9	1484

Chapter VI: FY85 Agenda Relative to Strategy Report and FREIR Report Recommendations

The Strategy Report (1) and FREIR Report (2) offer a number of recommendations concerning the Federal radiation research program, with emphasis on encouraging research in specific areas. Although these recommendations were written in the early 1980's they are still applicable to the Federal radiation research agenda. Below are the various recommendations from the Strategy Report and FREIR Report, with comments on how the FY85 radiation research agenda met these recommendations.

Radiation Physics

STRATEGY RECOMMENDATION. Research in radiation physics must be adequately supported if we are to improve our knowledge of radiation and of the interactions that occur in biological systems and if we are to decrease the physical uncertainties in radiation dosimetry. Of special interest is the improvement in dosimetry of high-LET radiation, dosimetry of internally deposited radionuclides, and microdosimetry.

In FY85, research in radiation physics was primarily addressed by Need 2.1 which is concerned with the primary transfer of radiation energy in matter. Federal support was provided to a lesser extent for research in dosimetry of high-LET radiations, particularly neutrons, and microdosimetry. Studies of internally deposited radionuclides are not addressed directly within needs identified in radiation physics, but were addressed within Need 5.5. Work in this area was supported primarily by DOE in FY85. NIH, by contract with Brookhaven National Laboratory, supported dosimetry studies for I-131 treated patients. In general, research in microdosimetry, high-LET dosimetry and dosimetry of internally deposited radionuclides appears not to have been adequately supported to the extent suggested in the Strategy Report recommendation or to the extent required by present needs for improved dosimetry. Since high dose studies are not addressed in this report, it should be noted that NIH does support high-LET radiation dosimetry in its high-LET radiotherapy development program.

Radiation Chemistry

STRATEGY RECOMMENDATION. Support should be expanded for radiation research to address the types and rates of chemical reactions that affect the biological function of cells, including studies which explore the use of chemical compounds to enhance or protect against radiation effects.

Although almost all the needs in radiation chemistry were supported by the Federal agencies in FY85, the level of support was minimal. In almost all cases, the chemistry needs were addressed by no more than two or three projects. No significant work in radiation protectors or radiation sensitizers was identified in the low level radiation effects research agenda. However, NIH, in its radiotherapy development program, and DOD, in its high dose radiation effects program, did support development and testing of radiation sensitizers and radioprotectors to a significant extent.

Radiation Measurements

STRATEGY RECOMMENDATION. High priority support is warranted for the development and application of new technologies and analytical techniques for improving the measurements of ionizing radiation. Such improvements are needed particularly for personnel dosimetry of high-LET radiation.

FREIR RECOMMENDATION (2). The committee recommends that emphasis be placed upon dosimetric research for neutrons and mixed radiations. Added emphasis should also be placed on the development of dosimetric instrumentation to be used in measurements of non-uniform field distributions of radionuclides. Particular attention should be directed toward measurements of doses to organs and tissues and to specific cells within these organs and tissues.

FREIR RECOMMENDATION (9). The committee, therefore, finds that practical methods to improve occupational dosimetry and to reduce radiation exposure require greater emphasis and urges attention to vulnerable occupational groups, especially in the mining industries.

The Strategy and FREIR Report's recommendations in radiation measurements and dosimetry are primarily addressed by Needs 2.14

- 2.20. In FY85, personnel dosimetry associated with high-LET radiation exposure was supported primarily by DOE, but was not supported to the same extent as low-LET dosimetry programs. FREIR Recommendation 2 is primarily addressed by research Needs 2.15, 2.16 and 2.17, which were also supported principally by DOE. FREIR Recommendation 9 is concerned primarily with occupational exposures in the mining industries. Of particular concern is lung exposure from inhalation of radon and its daughter products. Little research support was provided for radon dosimetry in FY85.

Molecular and Cell Biology

STRATEGY RECOMMENDATION. Physicochemical and biological studies at cellular and molecular levels are of high priority. Such studies offer the most likely means of obtaining information on the biological effects of ionizing radiation at levels of exposure at which the probability of observing such effects in animals (including humans) is very small. Of particular significance to establishing better dose-effect relationships for cancer induction and genetic effects are additional studies on repair of DNA damage.

FREIR RECOMMENDATION (4). The committee recommends that future studies in the field of radiation biology place increased emphasis on an understanding of the mechanisms of radiation carcinogenesis. This is particularly important with respect to carcinogenesis following low doses of low linear energy transfer (LET) radiation. This research should involve cellular and molecular experiments combined with selected studies of irradiated animals and appropriate observations of irradiated human populations. The committee encourages the design and conduct of experiments that test the current concepts in models of carcinogenesis in general and radiation carcinogenesis in particular.

FREIR RECOMMENDATION (5). The committee recommends that future research on radiation genetics place increasing emphasis on resolving the uncertainties surrounding the nature of genetic damage and its biological consequences whether or not radiation is used as a probe of the system. Such research should be directed toward observations not only on single cells from animals and plants but also of whole organisms.

These recommendations reflect the importance of molecular and cellular research, not only in improving the understanding of

mechanisms of DNA damage and repair, but also as a key to better quantitative understanding of effects having very low incidence, e.g., carcinogenesis following low doses of low LET irradiations. Review of the FY85 project abstracts from the various Federal agencies (particularly NIH and DOE) indicates that much research was supported in the cell biology field, in particular with regard to the understanding of DNA damage and repair, radiation mutagenesis, and carcinogenesis. However, an area which continues to be problematic is the identification of biologically relevant lesions in DNA and other biologically important molecules which are responsible for low dose radiation effects. Now, however, with the increased availability of DNA probes and the various new technologies introduced in molecular biology, the radiation biologist has the opportunity to study DNA damage and repair in ways that were heretofore not possible. Molecular biology approaches, therefore, will be important in making significant advances in further understanding the molecular basis of radiation mutagenesis and carcinogenesis.

Animal Radiobiology

STRATEGY RECOMMENDATION. Animal studies designed to derive risk estimates for cancer and genetic effects and to better define metabolic pathways and organ distributions of radionuclides require continued support. In order to obtain useful information from life span studies, long-term commitments of resources are necessary.

FREIR RECOMMENDATION (5). The committee recommends that future research on radiation genetics place increasing emphasis on resolving the uncertainties surrounding the nature of genetic damage and its biological consequences whether or not radiation is used as a probe of the system. Such research should be directed towards observations not only on single cells from animal and plants but also of whole organisms.

FREIR RECOMMENDATION (6). The committee recommends the continuance of research on radiation effects on whole organisms, especially studies evaluating these effects in appropriate subpopulations and the physiological and metabolic processes that determine dose distributions in both time and space from internal and external radiation sources.

These recommendations indicate the importance of continued support of animal radiobiology research. The response of a complex organism cannot be fully predicted on the basis of

molecular and cellular research. These data are necessary to complement the limited amount of human radiation response data that forms the basis for radiation risk estimates. However, animal studies continue to be very costly and the general trend has been to emphasize cellular radiobiology studies, primarily because of the lower economic costs. While the FY85 research agenda addressed all the animal radiobiology needs identified in the Strategy Report, a significant shift in emphasis occurred in the biological sciences since the 1982 Implementation Report. In FY81, 75 percent of funding in the biological sciences was in support of animal radiobiology studies; while in FY85 only 45 percent of the funding supported animal studies (See Section C).

Epidemiology and the Health Sciences

STRATEGY RECOMMENDATION. Current epidemiologic studies of atomic bomb survivors, uranium miners, radium-dial painters, and many of the various groups of people exposed to ionizing radiation for medical reasons warrant continued high-priority support. Other groups, such as workers in nuclear research and defense installations, in facilities for nuclear power generation, and medical patients, also warrant study if the exposures are sufficiently high and the populations large enough that the studies are scientifically sound and technically and economically feasible. These studies should be designed to provide the most information possible on the effects of age, sex, and confounding factors, such as smoking and exposure to nonradioactive toxic materials. To increase the value of all studies, it is important to develop standardized methods of obtaining radiation exposure and medical data. The support of further development of methods and techniques in biostatistics for use in human and laboratory studies is strongly recommended.

FREIR RECOMMENDATION (2). The committee recommends that currently supported, large-scale epidemiologic studies on the health effects of ionizing radiation be continued with periodic peer review until they have reached their logical conclusions. Meanwhile, Federal agencies supporting epidemiologic research in this field should reexamine their priorities and confine future scientific research to areas that are likely to yield statistically reliable data. The committee recognizes that social and political processes may require responses in the form of surveys and epidemiologic studies even when such efforts are

predictably unrewarding scientifically. In such cases, a clear distinction should be made between these studies and those that are scientifically justifiable.

In the FY85 Federal radiation research agenda, epidemiologic studies continued to be a high priority. Approximately one-fourth of all research dollars in the FY85 Federal radiation research agenda supported epidemiologic and health sciences research. The majority of epidemiologic studies focused on populations receiving medical exposures where careful dosimetry and clinical observations were available. The highest level of support was provided for studies of the atomic bomb survivors, which have been the primary source of human radiation risk data.

Occupational Sources

STRATEGY RECOMMENDATION. Efforts to characterize major sources of radiation exposure warrant continued support. Any gaps of information, necessary for assessing health risks from these sources, should be considered for study in the other areas described in this strategy. Research addressing the health risks from exposure to radon is of high priority in this context.

FREIR RECOMMENDATION (9). The committee, therefore, finds that practical methods to improve occupational dosimetry and to reduce radiation exposure require greater emphasis and urges attention to vulnerable occupational groups, especially in the mining industries.

Both the Strategy Report and the FREIR Report recommendations focus on the health risks from exposure to radon. Radon is the major source of human radiation exposure from naturally occurring radiation. It is necessary to understand radon dosimetry and health effects not only in the occupational setting, but also in the environmental settings as well where radon exposure and dosimetry parameters are different. Furthermore, interactions of carcinogens, such as cigarette smoking and radon, are not well understood and require further research. The FY85 Federal radiation research agenda inadequately addressed environmental dosimetry and health-related issues of concern for radon. Further research is necessary, especially in determining the health effects of various levels of radon in the environment.

Environmental Sources

STRATEGY RECOMMENDATION. Research on transport of radionuclides in the environment and the refinement of pathway models describing this transport is necessary. Environmental transport of radioactive wastes is of major interest, and research addressing this interest should receive high priority.

FREIR RECOMMENDATION (8). The committee recommends that long-term, broadly-focused research programs be undertaken to increase understanding of the complex transport systems used by radionuclides in a contaminated environment. Supportive research on dietary pathways is especially important. Adequate support should also be given to the continuing development and validation of models by which radionuclide levels within the ecological system may be predicted following radionuclide contamination of the environment.

These recommendations focus on support for environmental transport modeling, improved characterization of food chain pathways, and attention to the environmental transport of radioactive waste. These recommendations were not adequately addressed in the FY85 Federal radiation research agenda. At the present time, knowledge is limited on the transfer coefficients and concentration ratios for many radionuclides. Application of existing models to estimate the health effects of radionuclides released to the environment following the Chernobyl accident clearly reinforce the necessity to obtain more information on the numerous factors influencing the transport of radionuclides through the environment, e.g., chemical forms of radionuclides, environmental media, food plants, terrestrial and marine pathways, and bioavailability of radionuclides at different points in the food chain.

Chapter VII: Summary and Conclusions

Summary

Earlier chapters in this section analyzed the FY85 Federal radiation research agenda according to how it addressed the research needs and recommendations in the Strategy Report (1) and the recommendations in the FREIR Report (2). It should be noted that there was no apparent overlap in projects in any of the research areas by the Federal agencies in FY85. The purpose of this chapter is to summarize these findings in the context of the comprehensive radiation research program supported by the Federal government.

Table 19 provides a summary of FY85 funding by radiation research category for each agency. DOE supported approximately 65 percent of the research funding and NIH about 25 percent; all other agencies combined provided 10 percent of the funding. DOE placed major emphasis in the biological sciences, epidemiology and the health sciences, and sources of exposure. NIH primarily supported research in the biological sciences and epidemiology and the health sciences. It should be emphasized that in developing this report, relevant to the research needs stated in the Strategy Report (1), a substantial amount of radiation research conducted by Federal agencies for other purposes was excluded. This included all preclinical and clinical radiotherapy investigations supported by NIH and high energy physics research supported by NSF and DOE.

Table 20 provides a summary of FY85 project numbers and funding for each agency. Research categories in Table 20 are a condensed version of categories in Table 19. The Federal radiation research budget for FY85 was 112 million dollars-43 percent in the biological sciences; 24 percent in epidemiology and the health sciences; 17 percent in physics, chemistry, and related areas; 15 percent in sources of exposure; and 1 percent in support services. Thus, about 67 percent, or two-thirds of Federal support is in research directly investigating radiation effects in humans and other biological systems.

Conclusions

Overall, the FY85 Federal radiation research agenda was responsive to the needs identified in the Strategy Report and the recommendations of the Strategy and FREIR Reports. The Federal agencies' emphasis on the biological and health sciences

in the Federal radiation research agenda reflects the importance placed on elucidating mechanisms of the major health effects of radiation exposure at low doses and on determining the public health consequences of low dose radiation exposures. Although many issues are yet to be clarified in radiation physics and in the characterization of radiation sources, the reduced emphasis placed on these reflects the relative greater understanding associated with these research aims.

Although, when all Strategy Report needs are considered collectively, the FY85 Federal radiation research agenda appeared to satisfy these needs and the recommendations put forth in the Strategy Report and FREIR Report, there are several needs and recommendations which were not adequately addressed:

1. Research towards improvement in dosimetry of high-LET radiation, dosimetry of internally deposited radionuclides, and microdosimetry appear not to have been adequately supported to the extent suggested in the Strategy Report recommendation or to the extent required by present needs for improved dosimetry.

2. In FY85, little support was provided for studies concerned with exposure to radon and its daughter products, including research on radon dosimetry, effects of occupational exposures in the mining industries, public health consequences of environmental exposures to low levels of radon, and interaction of radon with other carcinogens in the environment, e.g. cigarette smoke.

3. Although much research was supported to add to our understanding of DNA damage and repair, there was still minimal progress in the identification of biologically relevant lesions in DNA and other biologically important molecules which are responsible for low dose radiation effects. This was primarily because of the lack of appropriate technology. Within the next several years, however, applications of existing and future technologies in molecular biology should greatly aid this endeavor.

4. Little research was identified with regard to radiation exposures during development (particularly with respect to the placental transfer of radionuclides as a consequence of maternal contamination), for studies on the effect of radiation exposure on human fertility, or for impaired organ or tissue function studies.

5. Inadequate support was provided for the improvement of environmental transport models, including development and validation of transfer coefficients and concentration ratios for many radionuclides.

TABLE 19

SUMMARY OF FY85 FUNDING BY RESEARCH CATEGORY
(In Thousands of Dollars)

	CDC	CDRH	DOD	DOE	DOI	NASA	NBS	NIH	NRC	NSF	VA
<u>Physics, Chem., & Related Areas</u>											
Radiation Physics (2.1-2.5)	0	0	1451	2855	0	80	495	147	0	0	0
Radiation Chemistry (2.6-2.13)	0	0	524	937	0	0	258	1022	0	0	0
Radiation Measurement (2.14-2.20)	0	240	1871	6934	205	143	1906	371	150	0	25
<u>Biological Sciences</u>											
Molecular & Cell Biology (3.1-3.12)	0	92	1008	11790	0	198	0	12959	0	90	12
Animal Radiobiology (3.13-3.18)	0	373	250	15136	0	404	0	5008	576	0	0
<u>Epidemiology and the Health Sciences</u>											
Genetic Effects (4.1-4.2)	0	33	0	1062	0	95	0	0	0	0	0
Human Epidemiology (4.3-4.12)	223	262	0	7160	0	15	0	5996	0	0	0
Birth Defects (4.13-4.14)	0	0	0	0	0	0	0	87	0	0	0
Other Somatic Effects (4.15-4.20)	30	83	0	10609	0	0	0	688	150	0	0
<u>Sources of Exposure to Ionizing Radiation</u>											
Environmental Sources (5.1-5.3)	0	0	0	14207	0	0	0	794	0	0	0
Occupational Exposures (5.4-5.5)	0	5	193	1322	0	80	0	0	0	0	0
<u>Support Services</u>	0	0	0	910	0	0	0	574	0	0	0
Total	253	1088	5297	72922	205	1015	2659	27646	876	90	37

TABLE 20

SUMMARY OF FY85 PROJECT NUMBERS AND FUNDING

Category	CDC	CDRH	DOD	DOE	DOI	NASA	NBS	NIH	NRC	NSF	VA	TOTAL
Physics, Chem. & Measurements (2.1-2.20)	0 1/	1	9	58	1	3	11	11	1	0	1	96 2/
	0 2/	240	3846	10726	205	223	2659	1540	150	0	25	19614 5/
Biological Sciences (3.1-3.18)	0 1/	4	4	100	0	5	0	123	4	1	1	242 2/
	0 2/	465	1258	26926	0	602	0	17967	576	90	12	47896 5/
Epidem. & Health Science (4.1-4.20)	10 1/	6	0	21	0	2	0	21	1	0	0	61 5/
	253 2/	378	0	18831	0	110	0	6771	150	0	0	26493 5/
Sources of Exposure (5.1-5.5)	0 1/	1	1	66	0	1	0	1	0	0	0	70 2/
	0 2/	5	193	15529	0	80	0	794	0	0	0	16601 5/
Support Services	0 1/	0	0	6	0	0	0	3	0	0	0	9 2/
	0 2/	0	0	910	0	0	0	574	0	0	0	1484 5/
Total	10 3/	12	14	251	1	11	11	159	6	1	2	478 2/
	253 4/	1088	5297	72922	205	1015	2659	27646	876	90	37	112088 8/

- 1/ Number of projects.
- 2/ Funding in thousands of dollars
- 3/ Total number of projects in agency
- 4/ Total funding in thousands of dollars in agency
- 5/ Total number of projects in needs.
- 6/ Total funding in thousands of dollars in needs
- 7/ Total number of projects in all agencies for all needs
- 8/ Total funding in thousands of dollars for all agencies for all needs

SECTION C

COMPARISON OF FY81 AND FY85 FEDERAL RADIATION RESEARCH AGENDAS

The purpose of this section is to compare the Federal radiation research agendas for FY81 and FY85 in order to identify overall trends in Federal support of radiation research. The FY81 data used in this comparison study were extracted from the Implementation Report (Appendix B); and the FY85 data were extracted from Section B in this report. While only a general comparison of the two reports is provided and specific differences among individual needs are not addressed, Table 21 provides a listing of the tables in the FY81 and FY85 reports to facilitate comparison of specific data. It is noted that one of the inherent difficulties in contrasting research efforts separated by several years is obtaining comparable data bases. Some of the apparent increases in effort and support reported in this section for FY85 over FY81 may be due to a more concerted response by agencies in FY85 to more thoroughly identify relevant research.

This section is divided into three chapters: Chapter I is a comparison of the two Federal radiation research agendas with regard to research categories and needs; Chapter II is a comparison of the two radiation research agendas with regard to contributions by the various Federal agencies; and Chapter III is a summary of the comparisons.

TABLE 21

LOCATION OF INFORMATION IN FY85 REPORT AND FY81 REPORT

	<u>FY85 Data</u>	<u>FY81 Data</u>
	Table Number in Current Report	Table Number in FY81 Report (Appendix B)
<u>Research Needs in Physics and Related Areas</u>	2	II-1
Number of projects for each agency	3	II-2
Funding for each agency	4	II-3
Summary for all agencies combined	5	II-4
<u>Research Needs in the Biological Sciences</u>	6	III-1
Number of projects for each agency	7	III-2
Funding for each agency	8	III-3
Summary for all agencies combined	9	III-4
<u>Research Needs in Epidemiology and the Health Sciences</u>	10	IV-1
Number of projects for each agency	11	IV-2
Funding for each agency	12	IV-3
Summary for all agencies combined	13	not provided
<u>Research Needs to Characterize Sources of Exposure to Ionizing Radiation</u>	14	V-1
Number of projects for each agency	15	V-2
Funding for each agency	16	V-3
Summary for all agencies combined	17	V-4
<u>Research Support</u>	18	not provided
<u>Summary of Funding by Research Category</u>	19	VI-3, VI-4

Chapter I: Research Needs--Comparison of FY81 and FY85 Federal Radiation Research Agendas

In this chapter, a comparison of how the FY81 and FY85 Federal radiation research agendas addressed the needs described in the Strategy Report (1) are provided. Table 22 is a comparison of the total number of projects and total funding in the research categories in FY81 versus FY85. Figure 1 is a pie chart, based on the data in Table 22, showing the percentage of total funds used to support research in the various categories. Table 23 is a more complete comparison of Federal radiation research budgets for FY81-85. It is noted that the values taken from the Implementation Report for FY81-83 were actual dollars for FY81 and projected dollars for FY82 and FY83. To more accurately portray trends in the annual budgets, corrections have been made for inflation between FY81 and FY85. Thus, the numbers in parentheses in Table 23 represent real FY81 dollars. When corrected for inflation, there was only an 8 percent increase in funding from FY81 to FY85. However, in FY82 and FY83 there was a net decrease in real 1981 dollars.

From review of Table 22 and Figure 1, in which a comparison of the distribution of research support in FY81 and 85 are shown, it is apparent that the distributions of funds in FY81 and 85 were roughly equal with biological sciences and human health research accounting for approximately two-thirds of the total budgets in each fiscal year. Support services, which were not separately identified in the assessment report, but were separately identified in the present report, accounted for only 1 percent of the total budget in FY85.

Below are brief comparisons of individual research categories for FY81 and FY85.

Physics, Chemistry and Related Areas

In terms of FY81 dollars, there was a 44 percent increase in research in this area in FY85 compared to FY81. Research in radiation physics accounted for 25 percent of the funding in this research category in both FY81 and FY85. The emphasis in radiation physics continued to be related to studies on the primary transfer of energy from radiation to matter (Need 2.1). In radiation chemistry, there was an increased level of support in FY85. Only 5 percent of the funding in physics, chemistry and measurement went to chemistry research in FY81, whereas 14 percent of the total funding in this research category was available for radiation chemistry studies in FY85. Funds were equally distributed among Needs 2.1 to 2.6 although, in FY85, no

funding was identified for pulse radiolysis studies (Need 2.8), which were supported in FY81. The largest portion of funding in this research category went to radiation measurement studies. Seventy percent of the funds in FY81 and 61 percent of the funds in FY85 supported measurements and related areas.

Biological Sciences

There was an 18 percent increase, in terms of FY81 dollars, in research in the biological sciences in FY85 compared to FY81. Whereas in FY81 24 percent of research funding supported molecular and cell biology studies, 55 percent of the FY85 support went to molecular and cell biology studies, reflecting a dramatic shift in the biological sciences emphasis. No doubt the dramatic decrease in support for whole animal research resulted from the sizeable costs of performing these studies. With regard to the molecular and cell biology studies, emphasis in FY81 was placed on Needs 3.2, 3.4, 3.8, and 3.9. In FY85, emphasis was placed on Needs 3.2, 3.5, 3.6, and 3.9. No funding in Need 3.3 was identified in FY81, but there was funding for this category in FY85. Although there was a substantial decrease in support for animal studies in FY85, the emphasis in animal radiobiology remained the same as in FY81 with primary focus on Needs 3.13 and 3.16.

Epidemiology and the Health Sciences

In terms of FY81 dollars, there was a 9% decrease in the level of support for epidemiology and the health sciences in FY81 and FY85. In FY81, 9 percent of funding in this category went to genetic studies, 49 percent to human cancer epidemiology, 11 percent to birth defects, and 31 percent to other somatic effects. In FY85, 4 percent of the funding provided for this category went to genetic studies, 51 percent to human cancer epidemiology, 1 percent to birth defects, and 44 percent to other somatic effects. Thus, a shift in emphasis occurred in FY85: away from genetic effect studies and birth defect studies; and in favor of additional studies to determine the prevalence of somatic diseases other than cancer.

Characterization of Sources of Exposure to Ionizing Radiation

In terms of 1981 dollars, there was a decrease of 21 percent in funding in FY85 compared to FY81 for studies to characterize sources of exposure to ionizing radiation. In FY85, 90 percent of support was for environmental studies, particularly to evaluate transport of radionuclides in the environment, and 10 percent of funds supported evaluation of occupational sources. In FY81, 72 percent of support was for environmental studies, particularly internal dosimetry from ingestion or inhalation of radionuclides. The total reduction in support for studies in this category primarily resulted from a de-emphasis in occupational exposure studies.

Support Services

Support for radiation research related activities accounted for 1 percent of the FY85 research agenda. Although not identified as such, agency funding for support services was incorporated within the various research categories in the assessment report for FY81 so a comparison between the two agendas can not be made.

TABLE 22

FY81-FY85 COMPARISON OF FEDERAL RADIATION RESEARCH AGENDAS

Category	FY81 ^{1/}		FY85	
	Number of Projects	Total Funding (In Thousands of Dollars)	Number of Projects	Total Funding (In Thousands of Dollars)
Physics, Chemistry, and Radiation Measurements	128	11,535	96	19,614
Biological Sciences	196	34,305	242	47,896
Epidemiology and the Health Sciences	---- ^{2/}	24,625	61	26,493
Characterization of Sources of Exposure to Ionizing Radiation	88	17,923	70	16,601
Research Support Services	---- ^{3/}	---- ^{3/}	9	1,484

^{1/} Source: Implementation Report (Appendix B).

^{2/} Data not available.

^{3/} Not considered as a separate category in Implementation Report (Appendix B).

FIGURE 1
 DISTRIBUTION OF RESEARCH SUPPORT AMONG RESEARCH CATEGORIES

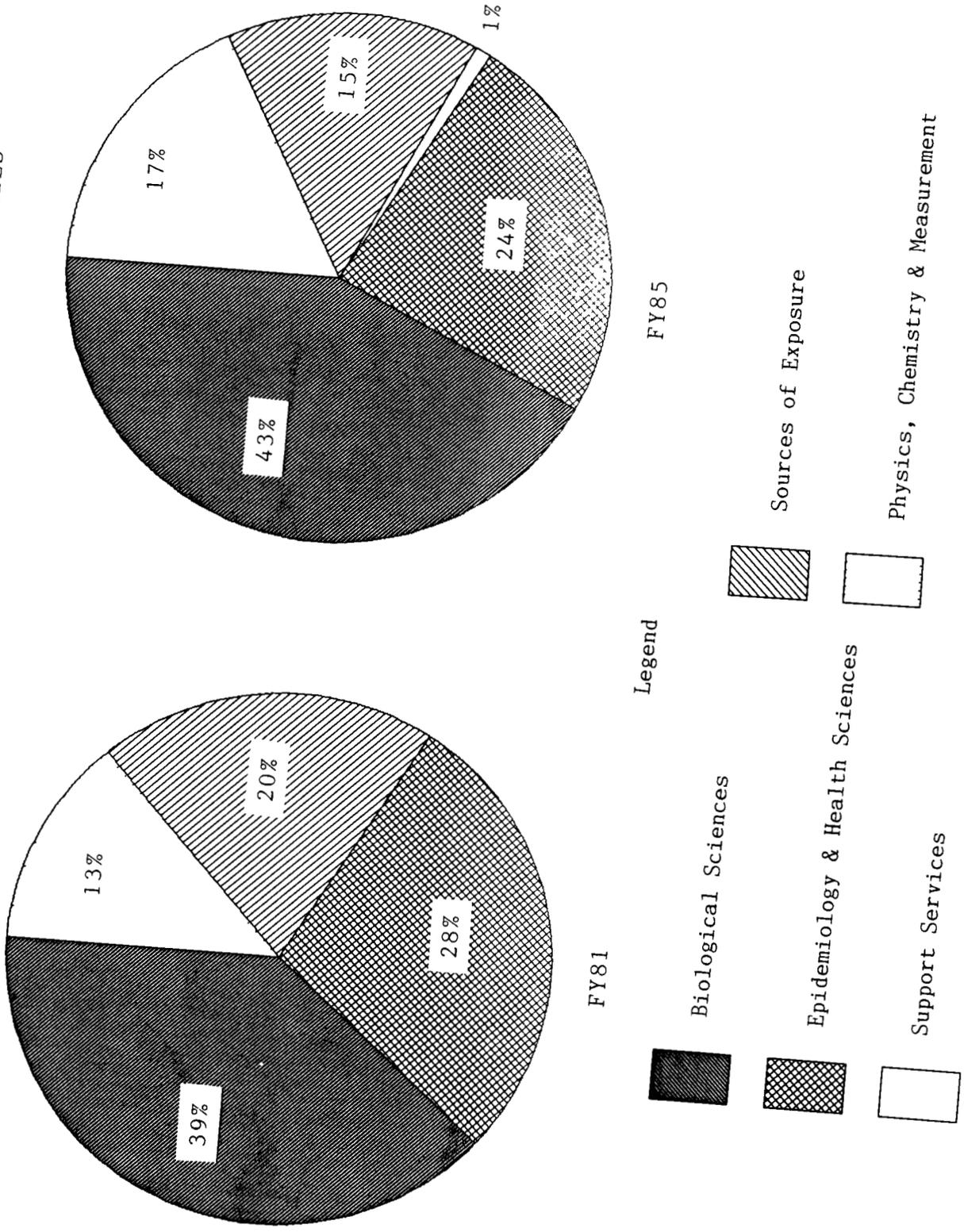


TABLE 23

FY81-FY85 COMPARISON OF FEDERAL RADIATION RESEARCH BUDGETS

Category	FY81 ^{1/}	FY82 ^{1/2/}	FY83 ^{1/2/}	FY85 ^{2/}
Physics, Chemistry, and Radiation Measurements	11,535	12,545 (11,835)	11,850 (10,773)	19,614 (16,622)
Biological Sciences	34,305	34,433 (32,484)	31,326 (28,478)	47,896 (40,590)
Epidemiology and the Health Sciences	24,625	25,939 (24,471)	24,327 (22,115)	26,493 (22,452)
Characterization of Sources of Exposure to Ionizing Radiation	17,923	18,482 (17,436)	15,865 (14,423)	16,601 (14,069)
Research Support Services ^{3/} ^{3/} ^{3/}	1,484 (1,257)
Total	88,388	91,399 (86,226)	83,368 (75,789)	112,088 (94,989)

^{1/} Source: Implementation Report (Appendix B). It is noted that the Implementation Report contained actual dollars for FY81 and projected dollars for FY82 and FY83.

^{2/} Numbers in parentheses are equivalent to FY81 dollars using the following Federally accepted levels of inflation: 1982-6.2%, 1983-3.8%, 1984-3.9%, and 1985-3.3%

^{3/} Projects providing research support services were not identified as such in FY81, 82, and 83, but rather were incorporated in one or more of the other categories.

Chapter II: Federal Agency Support--Comparison of FY81 and FY85 Federal Radiation Research Agendas

In this chapter, a comparison is made of the distribution of funding sources for the FY81 and FY85 Federal radiation research agendas. This distribution is illustrated in Figure 2, which shows that DOE and NIH were the major sources of support, providing 85 percent of the funding in FY81 and 90 percent of the funding in FY85.

As discussed earlier, the present report does not consider all radiation related research, especially with regard to the NIH and DOD research efforts. For instance, NIH conducts a large comprehensive program in radiotherapy development. In FY85, this program was funded to a level of approximately \$60 million dollars. When this radiotherapy program funding is added to the NIH total, NIH support for all radiation research was approximately the same as DOE's. Similarly, support for radiation research was greatly increased (by approximately \$20 million) for DOD when other radiation programs, not addressed in this report, are considered.

Below is a breakdown of the distribution of Federal agency support by research category for FY81 and FY85. Percentages for the FY81 agenda were calculated from the data in Table VI-3 of the Implementation Report (Appendix B); and percentages for the FY85 agenda were calculated from Table 20 of the present report.

In physics, chemistry, and related areas, 57 percent of the funding came from DOE, 14 percent from NBS, 11 percent from NIH, and 18 percent from all other agencies combined for FY81. In FY85, 55 percent of the funding came from DOE, 20 percent from DOD, 14 percent from NBS, 8 percent from NIH, and 3 percent from all other agencies combined. Of note was the major shift, mainly in the area of dosimetry, in support of this research category by DOD; 4 percent in FY81 compared to 20 percent in FY85.

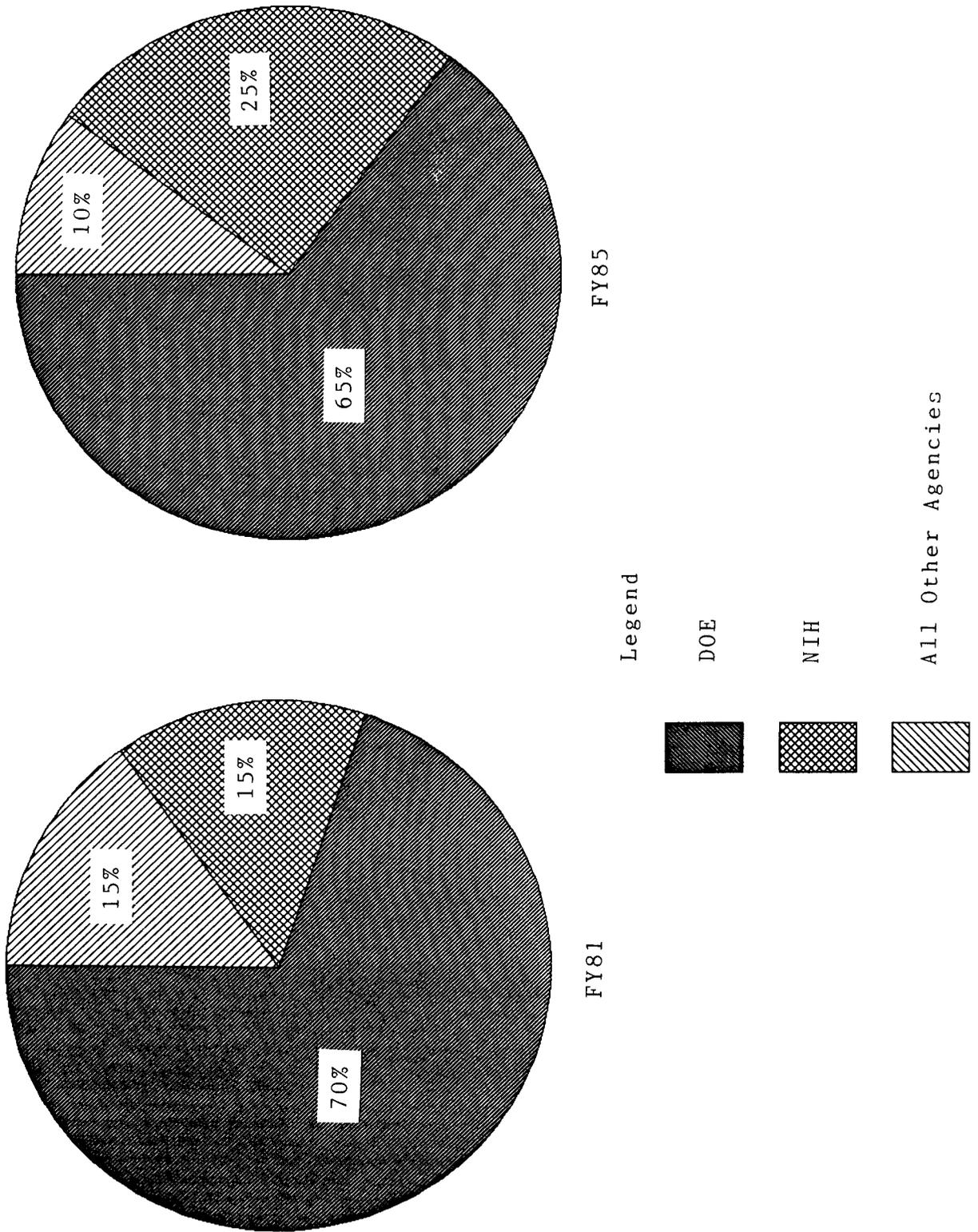
In the biological sciences, 66 percent of the funding was provided by DOE, 19 percent from NIH, 5 percent from NRC, and 10 percent from all other agencies combined in FY81. In FY85, 56 percent of the funding came from DOE, 38 percent from NIH, and 6 percent from all other agencies combined. The drop in support by DOE was primarily a result of a reduced level of funding for animal radiobiology studies. The increased percentage of support by NIH was a result of a significant commitment to molecular and cell biology studies in FY85. NRC had a significant decrease in level of support in FY85 for biological sciences, particularly for animal radiobiology studies.

In epidemiology and the health sciences, 71 percent of the funding came from DOE, 25 percent from NIH, and 4 percent from

all other agencies combined in FY81; in FY85, 71 percent of the funding came from DOE, 26 percent from NIH, and 3 percent from all other agencies combined. In FY81, NRC and EPA together contributed 4 percent of the total; in FY85, only NRC supported research in epidemiology and health sciences at a level of 0.5 percent of the total. EPA did not identify any support in this area.

In characterization of sources of exposure, DOE contributed 94 percent of the total funding in FY85, NIH 5 percent and all other agencies 1 percent. In FY81, DOE contributed 88 percent of the total funding, NRC 7 percent, NIH 2 percent and EPA 3 percent. NRC and EPA did not support research in this area in FY85.

FIGURE 2
DISTRIBUTION OF RESEARCH SUPPORT AMONG FEDERAL AGENCIES



Chapter III: Summary

As discussed in this section, major shifts occurred in the Federal radiation research agenda in FY85, both with regard to emphasis in research categories and in the level of agency support. The following points summarize the major findings in the comparison of the FY81 and FY85 Federal radiation research agendas.

1. There was an increased emphasis on radiation chemistry studies in FY85, although chemistry was still a small portion of the total funds in the physics, chemistry and related areas research category.

2. In FY85, there was a shift toward greater support of molecular and cell biology studies. Support for animal radiobiology studies decreased dramatically.

3. In epidemiology and health sciences studies there was a substantial de-emphasis of human genetics and birth defects studies in FY85.

4. There was a substantial decrease in FY85 in the total support of studies to characterize sources of exposure to ionizing radiation, primarily due to decreased support of occupational exposure studies.

5. DOE and NIH were the principal funding agencies in both the FY81 and FY85 radiation research agendas. NSF, NRC and EPA had noticeable decreases in support or were totally absent as supporting agencies in FY85.

6. In terms of 1981 dollars, between FY81 and FY85 there was:

a. A 44 percent increase in support for radiation physics, chemistry, and related areas.

b. An 18 percent increase in support for biological sciences studies.

c. A 9 percent decrease in the level of support for epidemiology and the health sciences.

d. An overall 21 percent decrease in support of characterization of radiation sources.

7. Two-thirds of the total budgets in the FY81 and FY85 radiation research programs supported biological sciences and epidemiology and health sciences research.

SECTION D

RECOMMENDATIONS

The following recommendations are offered in planning future reports on the Federal radiation research agenda. Comments on current scientific programs and recommendations pertaining to future research directions are not enclosed since they are not within the charge under which this report was developed.

1. It is recommended that, within the next 3 years, a follow-up review be made of the Federal radiation research agenda related to low level effects, including comparisons with the FY81 and FY85 Federal radiation research agendas. Such comparisons, as shown in this report, can identify trends in Federal radiation research and identify areas of strength and weakness in the overall Federal program. A complimentary effort by Federal agencies to identify specific agency priority research needs would better focus this comparison and assist in matching priorities with programs.

2. It is recommended that, to the extent that it is practical, a compatible information retrieval system exist in each Federal agency. Such a retrieval system will facilitate exchange of budget and project information among Federal agencies to coordinate and minimize overlap of radiation programs among agencies. The information retrieval system will also facilitate future summary reports of the Federal radiation research agendas. It is recommended that the information retrieval systems contain as a minimum, project titles, information abstracts, and current total budget information.

3. Substantial Federal funding is used to support high level radiation research. In FY85, DOD funded high dose radiation research to a level of approximately \$19.5 million; NIH also supported a comprehensive radiotherapy program to a level of approximately \$60 million in FY85. A report of the Federal radiation research effort in high dose effects should also be carried out. Many studies, particularly in physics, chemistry, dosimetry, biological sciences and epidemiology, are applicable to low dose and high dose research agendas.

REFERENCES

1. Federal Strategy for Research into the Biological Effects of Ionizing Radiation, Interagency Radiation Research Committee, National Institutes of Health, NIH Publication No. 81-2402, June 1981. ("Strategy Report")
2. Federal Research on the Biological and Health Effects of Ionizing Radiation, Committee on Federal Research on the Biological and Health Effects of Ionizing Radiation, National Research Council, National Academy Press, Washington, D. C., 1981. ("FREIR Report")

APPENDIX A

FY85 DATA BASE

AGENCY PROJECT TITLES
AND FUNDING INFORMATION

APPENDIX A

FY85 DATA BASE

AGENCY PROJECT TITLES
AND FUNDING INFORMATION

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INTRODUCTION

Appendix A is a listing of titles of 478 research projects comprising the FY85 Federal research agenda related to low level radiation effects. The data base is organized by individual agency. Within each agency, the project titles are grouped according to the research needs identified in the Interagency Radiation Research Committee's 1981 report on Federal Strategy for Research into the Biological Effects of Ionizing Radiation. A number of project titles have asterisks, which denote that the project fulfilled more than one need and that the project title is repeated elsewhere. In cases where a project fulfilled multiple needs, the total funds for the project were divided equally among all needs addressed, unless specific apportionments were provided by the agency.

DEPARTMENT OF COMMERCE
NATIONAL BUREAU OF STANDARDS (NBS)

Physics, Chemistry, and Related Areas

<u>Need**</u>	<u>NBS FY85 Project Title</u>	<u>FY85 \$(K)</u>
2.1	Ionizing Radiation Technical Support	107
	*Neutron Measurements and Research	87
	*Radiation Physics Theory	101
2.3	*Radiation Physics Theory	100
2.4	*Radiation Physics Theory	100
2.6	*Biochemical Effects	129
2.11	*Biochemical Effects	129
2.14	*Neutron Field Standards	128
2.15	*Dosimetry Standards and Measurements	227
	Development of Radioactivity Standards	331
	High-Dose Dosimetry	131
	*Neutron Measurements and Research	87
	Neutron Source Standards	81
	Radiology	221
2.18	*Dosimetry Standards and Measurements	227
	*Neutron Field Standards	127
	Office of Radiation Measurement	346

* The project addresses more than one need and, therefore, the title is repeated elsewhere.

** The research needs referenced in this appendix are those specified in Federal Strategy for Research into the Biological Effects of Ionizing Radiation, Interagency Radiation Research Committee, National Institutes of Health, NIH Publication No. 81-2402, June 1981.

DEPARTMENT of DEFENSE (DOD)

Physics, Chemistry, and Related Areas

<u>Need</u>	<u>DOD FY85 Project Title</u>	<u>FY85 \$(K)</u>
2.1	*High Energy Astrophysics (Navy)	192
	Radiation Beams and Sources (Navy)	300
	*Radiation Transport (Navy)	35
	*Dosimetry Technology Base (AFRRI)	178
	*Photochemical and Radiobiological Studies of DNA (AFRRI)	54
2.2	*Photochemical and Radiobiological Studies of DNA (AFRRI)	54
2.3	*High Energy Astrophysics (Navy)	193
	*Radiation Transport (Navy)	35
	*Dosimetry Technology Base (AFRRI)	178
2.4	*Photochemical and Radiobiological Studies of DNA (AFRRI)	54
2.5	*Dosimetry Technology Base (AFRRI)	178
2.6	*Photochemical and Radiobiological Studies of DNA (AFRRI)	54
2.7	*Photochemical and Radiobiological Studies of DNA (AFRRI)	54
2.10	*DNA Damage and Repair, Radioprotective Compounds and Chemical Agents (Military Effects), (AFRRI)	121
2.11	*DNA Damage and Repair, Radioprotective Compounds and Chemical Agents (Military Effects), (AFRRI)	121
2.12	*Photochemical and Radiobiological Studies of DNA (AFRRI)	53

2.13	*DNA Damage and Repair, Radioprotective Compounds and Chemical Agents (Military Effects), (AFRRI)	121
2.14	*Dosimetry Technology Base (AFRRI)	178
	*Operational Radiation Dosimetry (AFRRI)	4
2.15	Laser Heated TLD (Navy)	123
	*High Energy Astrophysics (Navy)	193
	Development of Integrating Dosimeter System (Air Force)	75
	*Dosimetry Technology Base (AFRRI)	177
2.16	*Photochemical and Radiobiological Studies of DNA (AFRRI)	53
	*Dosimetry Technology Base (AFRRI)	177
2.18	Radiation Analysis (Navy)	887
	*Operational Radiation Dosimetry (AFRRI)	4

Biological Sciences

<u>Need</u>	<u>DOD FY85 Project Title</u>	<u>FY85 \$(K)</u>
3.1	*Photochemical and Radiobiological Studies of DNA (AFRRI)	53
	*DNA Damage and Repair, Radioprotective Compounds and Chemical Agents (Military Effects), (AFRRI)	121
3.2	*DNA Damage and Repair, Radioprotective Compounds and Chemical Agents (Military Effects), (AFRRI)	121
3.3	*Effect of Radioprotective Compounds WR-1065 and WR-2721 on DNA and Membrane Systems (Navy)	14
3.4	*Effect of Radioprotective Compounds WR-1065 and WR-2721 on DNA and Membrane Systems (Navy)	13

	*DNA Damage and Repair, Radioprotective Compounds and Chemical Agents (Military Effects), AFRI)	121
	Spectroscopic Analysis of Calcium and pH in Single Epithelial and Endothelial Cells (AFRI)	183
3.5	Role of the Nuclear Envelope in Radiation Damage (AFRI)	155
	*Photochemical and Radiobiological Studies of DNA (AFRI)	53
3.12	*DNA Damage and Repair, Radioprotective Compounds and Chemical Agents (Military Effects) (AFRI)	121
	*Photochemical and Radiobiological Studies of DNA (AFRI)	53
3.13	Follow-up of Proton Irradiated Monkeys (Air Force)	250

Sources of Exposure to Radiation

<u>Need</u>	<u>DOD FY85 Project Title</u>	<u>FY85 \$(K)</u>
5.4	*High Energy Astrophysics (Navy)	193

DEPARTMENT OF ENERGY (DOE)

Physics, Chemistry, and Related Areas

<u>Need</u>	<u>DOE FY85 Project Title</u>	<u>FY85 \$(K)</u>
2.1	Ion Chemistry and Molecular Clustering Phenomena	390
	Molecular Radiation Physics	445
	Atomic and Molecular Physics	125
	Interactions of Slow Electrons with High-Pressure Gases	64
	Electronic Properties of Liquids	40
	Energy Pathways in Irradiated Gases	170
	Chemical Physics Studies	190
	Liquid and Submicron Physics	170
	Transport and Surface Physics	190
	Surface Interactions and Ion Particulate Accretion	190
2.3	Radiation Physics	495
	Electron Transport Calculations with Biomedical and Environmental Applications	45
2.4	Neutron Interactions with Biological Tissue	50
2.5	Microdosimetry, Biological Modeling, and Theoretical Biophysics	190
	Biophysical Studies Related to Energy Generation	35
	Theory of Relative Biological Effectiveness	66
2.7	Mechanism for Radiation Damage in DNA	30

	Oxidative and Free Radical Mechanisms in the Toxicity and Carcinogenicity of Radiation and Pollutants	250
2.9	Electron Reactions in Liquids, Reversed Micelles, and Biological Systems	75
2.10	The Nature of Oxygen-Containing Radicals in Radiation Chemistry and Photochemistry of Aqueous Solutions	29
2.11	The Role of the Local Environment on the Radiation Chemistry of Biological Molecules: Proline in Single Crystals	38
	Solid State Radiation Chemistry of the DNA Backbone	160
2.12	Energy Transformation in Molecular Electronic Systems	75
	Selective Excitation, Relaxation, and Energy Channeling in Molecular Systems	40
	A Physico-Chemical Study of Some Areas of Fundamental Significance to Biophysics	110
2.13	Calculations and Experiments for Study of Radiation Effects on Biological Systems	130
2.14	Pulse-Characterization Neutron Dosimetry	100
	Radiological Physics and Microdosimetric Concepts in Radiation Protection	200
	Extremity Dose Measurements Evaluation and Upgrade	70
2.15	Real-Time Monitor for Airborne Tritium	50
	Radiation Transport and Dosimetry	385
	Fast Neutron Dosimetry	120
	Neutron Detection with Superheated Drops	80
	Semiconductor Radiation Detector Technology	360
	Symposium on Low Energy X-and Gamma-Rays, Sources and Applications	11
	Instrumentation for Nuclear Applications	46

2.16	Internal Microdosimetry	85
	*Radiation Physics, Biophysics, and Radiation Biology	290
	Nonequilibrium Effects of Dose to the Basal Layer of the Skin from Gamma Emitting Contamination	75
2.17	In Vivo Measurements of Bone-Seeking Radionuclides	78
	Radiation Detection Systems for Trace Radionuclide Measurements	85
	Effective Dose from Inhaled Nuclear Energy Materials	1100
	Radiopharmaceutical Internal Dosimetry Information Center	110
	Evaluation and Upgrade of Internal Dosimetry Practices	260
2.18	Fast-Neutron Personnel Dosimeters Using Proportional Counters	100
	Health Physics Research Reactor	375
	Advanced Laser Heating Technology for Fast Neutron Dosimetry	50
	Personnel Neutron Dosimeter Evaluation and Upgrade	870
	Beta Measurement Evaluation and Upgrade	400
2.19	Atom Counting Standards and Doppler-Free RIMS	45
	Evaluate High Sensitivity Laser Isotopic Analysis	275
2.20	Hiroshima/Nagasaki Reevaluation Studies	150
	Thermoluminescence Studies in Hiroshima and Nagasaki	190
	Thermoluminescence Studies of NTS-Related Fallout Exposures	90

Radiation Emergency Assistance Center/Training Site (REAC/TS)	500
Dosimetry for Human Exposures	240
Skeletal Microdosimetry of Inhaled Radionuclides	100
*TL Measurement of Fallout Doses in Ducheene County, Utah	44

Biological Sciences

<u>Need</u>	<u>DOE FY85 Project Title</u>	<u>FY85 \$(K)</u>
3.1	Studies on Human Germinal Mutations by DNA Hybridizations	150
	Radiogenic Neoplasia in Thyroid Clonogens	250
	Mammalian Genetics	650
3.2	Molecular Mechanisms of Cell Effects	125
	Studies of the Repair of Radiation-Induced Genetic Damage in Drosophila	77
	Cellular and Molecular Mechanisms of Radiation and Chemical Mutagenesis	180
	Radiation and Chemical Damage to DNA and Its Repair	300
	Repair of DNA Treated with Gamma-Irradiation and Chemical Carcinogens	52
	DNA Repair Processes in Mutagenesis and Carcinogenesis in Mammalian Cells	40
3.3	Direct Assays of Radiation-Induced DNA Base Lesions in Mammalian Cells	134
	Immunochemical Approach to the Study of DNA Repair	118
3.4	Biological and Environmental Research: Radiological Physics and Chemistry	300
	Modeling Cellular Response to Genetic Damage	167

	Mechanisms of Genotoxicity In Vitro	140
	Environmental Insults to DNA	170
	Molecular Cytogenetics	135
	Correlation of Chromosome Patterns in Human Leukemic Cells with Exposure to Chemicals and/or Radiation	230
	Endocrine Receptor Studies	250
3.5	Genetic Effects of High LET Radiation	180
	Long-Term Biological Effects	155
	Radiation Biophysics	165
	Radiation Dosimetry	325
	The Oncogenic Action of Proton and Electron Radiation on Rat Skin	148
	Papovavirus Probes for DNA Repair in Human Cells	205
3.6	Effects of Energy-Related Wastes on Aquatic Ecosystems	150
	Use of Radiation-Free Organisms to Determine Threshold Level for Radioactivity	85
	Mutagenic Effect of Radionuclides Incorporated into DNA of <i>Drosophila melanogaster</i>	80
	Molecular Mechanisms of Misrepair Mutagenesis	127
	Nucleic Acid Replication	190
	Nucleic Acid Structure	245
	Basic Cellular Hematology: Detection, Characterization and Purification of Hemopoietic Regulatory Feedback Loops	200
	Microbial Mutagenesis and Cell Division	150
	Enzyme Regulation	180
	Mechanisms of Mammalian Mutagenesis	130

	Biological Effects of DNA Repair, Including Mutagenesis	65
3.7	Analysis of Mammalian Genetic Lesions	300
	Chromosome Structure and Function	276
	Mammalian Biochemical Genetics	320
	Mammalian Cytogenetics	420
	Elucidation of Cytogenetic Damage	420
3.8	Tumour Models and Mechanisms	110
	Late Somatic Effects of Energy Pollutants	20
	*Radiation Physics, Biophysics, and Radiation Biology	290
3.9	Studies of Oncogenesis in Cells from Radium Patients	205
	Carcinogenesis In Vitro	350
	Mechanisms and Secondary Factors Involved in the Induction of Radiation Transformation In Vitro	160
	Radiation Carcinogenesis and DNA Alterations	9
	Mechanism of Delayed Radiation Pathology	100
	Chemical and Radiation Carcinogenicity and Dose Effect Relationship-Benzene; Neutrons	105
	Thymus-Marrow Interrelationships	138
	Genotoxicity of Inhaled Energy Effluents	425
	Identification of Human Proteins with Two-Dimensional Electrophoresis	640
	Genome Organization and Function	180
	Carcinogen-Cell Genome Interaction	225
3.10	Radiation-Induced Changes in Mammalian Cells	120
	Mechanisms in Radiation Carcinogens	150

	Control of Gene Expression in Normal and Neoplastic Liver	400
3.12	Synergisms and Interactions in Aquatic Systems	119
	Physicochemical Studies of Radiation Effects in Cells	60
3.13	Radiation Toxicity Studies in Dogs for Interspecies Comparisons	875
	Life Shortening and Tumour Induction by Low Dose Neutron and Gamma Irradiation	1100
	Interpretation of Cancer Tests	125
	Neutron Dose Curves at Low Doses	370
	Dosimetry of Internal Emitters Relative to Carcinogenesis	95
	Fission Neutrons and Gamma Rays	575
	Radiation Carcinogenic Time-Dose Relation	140
3.14	Mammalian Cell Culture Systems for Molecular Studies of DNA	185
	DNA Replication and Repair	490
3.15	Cigarette Smoke and Plutonium	210
3.16	Gastrointestinal Absorption of Actinides	90
	Hazards of Radioactive Environmental Pollutants	120
	Tumorigenesis in the Lung	325
	Dose-Response Relationships for Inhaled Low LET Radionuclides	1200
	Relative Radiosensitivity of Respiratory Tissues	330
	Dose-Response Relationships for Inhaled High L.E.T. Radionuclides	800
	Inhalation Hazards to U-Miners	535
	Inhaled Plutonium Oxide in Dogs	965

	Low Level 239 PuO ₂ Lifespan Studies	495
	Comparative Toxicity of Sr-90 and Ra-226	645
	Effect of Prolonged Low-Dose Rate Co-60 Gamma Ray Exposure of Beagles: Mechanisms of Leukemogenesis	500
	Fundamental Studies of Bone: Interlaboratory Collaboration of Mechanisms of Radiation Effects	140
	Metabolic Evaluation in Nonhuman Primates of Bone and Liver Risks from Internally Deposited Actinides	160
	The Localization, Distribution, and Dosimetry of Pu-239 in the Gonads	70
	Toxicity of Pu-239 and Ra-226 in Young Adult Beagles-Risk Estimation in Man	285
	The Deposition, Retention, and Toxicity of Selected Actinide Elements in Beagles	135
	Radionuclides in Rodents	70
	Studies of Actinide Metabolism	103
	Physiological Systems and Their Response to Energy-Related Toxic Agents	924
	A New Technique for the Rapid Production of Somatic Cell Hybrids	50
	Effects of Heavy Particle Radiation	400
	Studies on Isolation and Characterization of Vanadium Binding Components in Rat Tissue and Blood	24
	Inhaled Pu-239 Nitrate in Dogs	415
	Toxicity of Pu-239 and Ra-226 in Juvenile and Mature Beagles-Risk Estimation in Man	350
3.17	Radiosensitivity of Oocytes and Other Cells During Mammalian Development	210
	Genetic Effects of Plutonium in Mice	450
	Fetal and Juvenile Radiotoxicity	215

	Embryo Cultures and Environmental Toxicity	270
3.18	Hematopoiesis in Chronic Toxicity Studies	180
	Radiation Immunology	160
	Mechanism of Radiation Carcinogenesis	160
	Mechanisms of Internal Emitter Skeletal Toxicity	195

Epidemiology and the Health Sciences

<u>Need</u>	<u>DOE FY85 Project Title</u>	<u>FY85 \$(K)</u>
4.1	*Follow-Up of Japanese Atomic Bomb Survivors to Evaluate Long-Term Effects of Ionizing Radiation Upon Health	910
	Development of New Technologies for Human Health Effects Studies	100
	Screening Human Populations for Chromosome Damage	52
4.3	*Human Health Studies and Evaluations	40
	*Follow-Up of Japanese Atomic Bomb Survivors to Evaluate Long-Term Effects of Ionizing Radiation Upon Health	550
4.4	*DOE Hanford Health and Mortality Study	178
	*Human Health Effects of Plutonium	300
	*Health and Mortality Study	564
4.5	Caloric Intake, Ionizing Radiation, and Aging: An Approach to the Hormetic Effect of Radiation	45
4.6	*Follow-Up of Japanese Atomic Bomb Survivors to Evaluate Long-Term Effects of Ionizing Radiation Upon Health	218
4.9	*Follow-up of Japanese Atomic Bomb Survivors to Evaluate Long-Term Effects of Ionizing Radiation Upon Health	852

4.10	*Human Health Studies and Evaluations	41
	*Follow-Up of Japanese Atomic Bomb Survivors to Evaluate Long-Term Effects of Ionizing Radiation Upon Health	2405
4.11	DOE/Death Certificate Retrieval Office(DCRO)	290
	DOE/SSA Data Searches for Health and Mortality Studies	65
	Human Health Studies: DOE/Data Processing and Storage Facility	440
4.12	*Health and Mortality Study	563
	Lung Cancer Epidemiology in New Mexico Uranium Miners	380
	DNA Repair, Cytogenetics, and Epidemiology	230
4.15	Mammalian Gametogenesis	160
4.17	*Follow-Up of Japanese Atomic Bomb Survivors to Evaluate Long-Term Effects of Ionizing Radiation Upon Health	725
4.18	Statistical Health Effects Studies	300
	Health Effects of Low-Level Radiation in Shipyard Workers	1600
	Health and Mortality Study of Nuclear Workers	55
	*Follow-Up of Japanese Atomic Bomb Survivors to Evaluate Long-Term Effects of Ionizing Radiation Upon Health	4100
4.19	Effects of Internally Deposited Alpha Emitters	1700
	*United States Transuranium Registry	178
	*Determination of Plutonium and Metals in Man	275
	Ra-224 Toxicity in Humans, Beagles, and Mice	235
	*Follow-Up of Japanese Atomic Bomb Survivors to Evaluate Long-Term Effects of Ionizing Radiation Upon Health	240

4.20	*DOE Hanford Health and Mortality Study	177
	*Human Health Effects of Plutonium	300
	*Health and Mortality Study	563

Sources of Exposure to Radiation

<u>Need</u>	<u>DOE FY85 Project Title</u>	<u>FY85 \$(K)</u>
5.1	Radioactivity and Other Energy-Related Pollutants on the Earth's Surface	945
	Radioactivity and Other Energy-Related Pollutants in Surface Air	615
	Radioactivity and Other Energy-Related Pollutants in the Biosphere	522
	Radioactivity and Other Energy-Related Pollutants in Stratospheric Air	742
	Analytical Development Studies	795
	Documentation of Natural Activity in the Biosphere	265
	Physical Processes Affecting Levels of Radon, Thoron, and Their Decay Products in an Indoor Environment	60
	Study of the Atmospheric Chemistry of ²¹⁸ Po	59
	Assessment of Radioactive and Chemically Active Air Contaminants	310
	Environmental Radiological Research	595
	Radiological Impact of Alternate Energy Sources	120
	Project Airstream-Measurements and Field Support	90
	Air Transport of Pollutants	335
	Behavior of Transuranic Elements in Natural Waters	422

Anaerobic Microbial Transformation in Subsurface Environments	200
Biogeochemical Cycling of Transuranics and Other Radionuclides in the Marshall Islands	457
Environmental Behavior of Radionuclides in the Marine Environment	50
Radionuclides in the Coastal Zone	55
Radioecology of Nuclear Fuel Cycles	450
Identification, Transport and Conversion of Energy-Related Pollutants in the Environment	420
Air/Earth Cycling of Pollutants	150
Plutonium, Cesium, and Uranium Series Radionuclides in the Hudson River Estuary and Other Environments	60
An Integrated Study of the Behavior of Transuranic Elements in the Marine Environment	134
Studies of Transport Pathways of Th, U, Rare Earth Elements, Ra-228, and Ra-226 from Soil to Farm Animals	100
Cycling of Transuranic Radionuclides in the Columbia River	160
Geochemical Behavior of Uranium and Thorium Series Nuclides and of Plutonium in the Gulf of Mexico	80
International Congress on the Hydrology of Rocks of Low Permeability	15
The Oceanic Geochemistry of Natural and Artificial Radionuclides: The SEEP Project	100
Distribution of Some Chemical Elements Between Dissolved and Particulate Phases in the Ocean	154
Fate of Nuclides in Natural Water Systems	83
Dynamics of Wild Populations	138
INEL Radioecology Program	145

	Response of a Forest Ecotone to Ionizing Radiation	2
	Studies in Iodine Metabolism: Monitoring of Animal Thyroids	35
	Measurement Resuspension in a Desert Environment	100
	Measure Radionuclide Inventory and Distribution at NTS	200
	Transport/Cycling of Tritium in the Environment	350
	Aquatic Transport-Begin Experiments to Obtain Creek Transport and Diffusion as a Function of Water Stage	150
	Radiometrics-Conduct Isotopic Transuranic Environmental Analysis	100
	Transport of Heavy Metals and Radionuclides	120
	Mobilization of Trace Contaminants from L-Lake Sediments as Affected by Oxidation-Reduction Status (Pre-L-Lake Study)	26
	Inventory and Fractionation of Metals and Radionuclides in Sediments of L-Lake Basin	69
5.2	*TL Measurement of Fallout Doses in Ducheeene County, Utah	45
	Assessment of Radon and Radon Daughters in U.S. Single-Family Housing	90
	Characterization of Airborne Radon Concentrations	125
	Direct Determination of Environmental Levels of Radon-222 Using the Electret to Remove Daughters at Formation	86
	Studies of Radon in Buildings	60
	Radioecological Investigations of Uranium Mill Tailings Systems	120
	Radon Transport from Uranium Mill Tailings Via Plant Transpiration: Growth Chamber Experiments and Computer Simulation	72

	Indoor Air Pollution	300
	Reconstruct Radiation Doses to Population Downwind of NTS	353
	Develop Model to Predict the Dose to Man from Living in a Pu-Contaminated Environment	109
	Technical Advice and Equipment to the Junta de Energia Nuclear in Spain for Measuring Radionuclides in People and in Environmental Samples Such as Food Products, Soil and Air	130
5.3	Radionuclides in the Environment	656
	Environmental Behavior of Tc-99, I-129	170
	Radionuclide Behavior in Soils and Plants	265
	Identification, Transport and Conversion of Energy-Related Pollutants in the Environment: Cycling of Radioisotopes	125
	Cycling of Long-Lived Radionuclides	250
	Determination of the Fraction of the Radionuclides Consumed by Cows and Hens that is Found in Milk, Eggs, and Meat	98
	Measure Food Uptake Parameters for the Marshall Islands	950
	Food Chain Transport	225
5.5	Aerosol Technology Development	115
	Medical Physics and Internal Dosimetry	350
	*United States Transuranium Registry	177
	*Determination of Plutonium and Metals in Man	275
	Binding of Actinides and Lanthanides by Serum Proteins: In Vitro Kinetic and Thermodynamic Evaluation	90
	Comparative Metabolism of the Actinides	140
	Delayed Immunologic Effects of Low Dose Radiation in Japanese A-Bomb Survivors	100

Toxicology of Thorium Cycle Nuclides
 DEPARTMENT OF HEALTH AND HUMAN SERVICES

75

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)
Support Services

	<u>DOE FY85 Project Title</u>	<u>FY85 \$(K)</u>
	Physical, Chemical, and Related Areas	
	<u>CETO Logistical Support</u>	475
240	<u>NBS Natural Matrix Standards Program</u>	150
	Support for Radiological Research Accelerator Facility	400
	Biological Sciences Synchrotron Radiation Facility for the Analysis of Biological Structures	150
	Biostatistics and Mathematics	150
46	*Low-level or Chronic Exposure to Toxic Agents Set Up and Maintain Data Bank for Marshall Islands	120
40	*Low-level or Chronic Exposure to Toxic Agents	
110	*Health Effects of Ionizing Radiation in the Beagle Dog	
5	*Collaborative Radiologic Health Laboratory Support (CRHL)	
44	*Health Effects of Ionizing Radiation in the Beagle Dog	
46	*Low-level or Chronic Exposure to Toxic Agents	
45	*Low-level or Chronic Exposure to Toxic Agents	
8	Radiologic Effects of X Rays in Mice	
110	*Health Effects of Ionizing Radiation in the Beagle Dog	
5	*Collaborative Radiologic Health Laboratory Support (CRHL)	

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTER for DEVICES and RADIOLOGICAL HEALTH (CDRH)

Physics, Chemistry, and Related Areas

<u>Need</u>	<u>CDRH FY85 Project Title</u>	<u>FY85 \$(K)</u>
2.20	National Evaluation of X-Ray Trends (NEXT)	240

Biological Sciences

<u>Need</u>	<u>CDRH FY85 Project Title</u>	
3.6	*Low-Level or Chronic Exposure to Toxic Agents	46
3.12	*Low-Level or Chronic Exposure to Toxic Agents	46
3.13	*Health Effects of Ionizing Radiation in the Beagle Dog	110
	*Collaborative Radiologic Health Laboratory Support (CRHL)	5
3.14	*Health Effects of Ionizing Radiation in the Beagle Dog	44
	*Low-Level or Chronic Exposure to Toxic Agents	46
3.15	*Low-Level or Chronic Exposure to Toxic Agents	45
3.17	Teratologic Effects of X-Rays in Mice	8
	*Health Effects of Ionizing Radiation in the Beagle Dog	110
	*Collaborative Radiologic Health Laboratory Support (CRHL)	5

Epidemiology and the Health Sciences

<u>Need</u>	<u>CDRH FY85 Project Title</u>	<u>FY85 \$(K)</u>
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Epidemiology and the Health Sciences

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Biological Sciences

<u>Need</u>	<u>NIH FY85 Project Title</u>	<u>FY85 \$(K)</u>
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Epidemiology and the Health Sciences

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Sources of Exposure to Radiation

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DEPARTMENT of INTERIOR (DOI)

Physics, Chemistry, and Related Areas

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NATIONAL AERONAUTICS and SPACE ADMINISTRATION (NASA)

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Biological Sciences

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Epidemiology and the Health Sciences

<u>Need</u>	<u>NASA FY85 Project Title</u>	<u>FY85 \$(K)</u>
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Sources of Exposure to Radiation

<u>Need</u>	<u>NASA FY85 Project Title</u>	<u>FY85 \$(K)</u>
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NATIONAL SCIENCE FOUNDATION (NSF)

Biological Sciences

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Biological Sciences

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APPENDIX B

ASSESSMENT OF RADIATION RESEARCH

STRATEGY IMPLEMENTATION

ASSESSMENT OF
RADIATION RESEARCH STRATEGY IMPLEMENTATION
RESPONDING TO THE CONGRESSIONAL MANDATE
UNDER THE BIOLOGICAL RESEARCH EXTENSION ACT
OF 1978 (P.L. 95-622)

Submitted to the
INTERAGENCY RADIATION RESEARCH COMMITTEE

By the
SUBCOMMITTEE ON RADIATION RESEARCH STRATEGY IMPLEMENTATION

NOVEMBER 1982

Incorporated in this Report with
the Permission of the
National Institutes of Health

Previously Unpublished

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service National Institutes of Health



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

September 17, 1982

James B. Wyngaarden, M.D.
Director
National Institutes of Health
Bethesda, Maryland 20205

Dear Doctor Wyngaarden:

As Chairman of the Interagency Radiation Research Committee's Subcommittee on Radiation Research Strategy Implementation, I am pleased to submit to you our draft report entitled "Assessment of Radiation Research Strategy Implementation." This draft report is in response to the Committee's charge to the Subcommittee, "to review agency radiation research programs and budgets and to report on the adequacy of support of such research and the appropriateness of the allocation of research funds among the Federal agencies." This charge was given to the Subcommittee by letter dated February 9, 1982, from Edward Brandt, Jr., then Chairman of the Interagency Radiation Research Committee.

In accord with Dr. Brandt's letter, the Subcommittee has used as its primary references the Interagency Radiation Research Committee's Strategy Report and the National Research Council's FRIER Report to perform its task. The Subcommittee evaluated the Federal Research Program on the Biological Effects of Ionizing Radiation in light of the needs and recommendations provided in the above two mentioned reports. Its review of agency programs and budgets is limited to fiscal years 1981, 1982, and 1983, and as expected in such reviews, we recognized the uncertainties inherent in a projection of the plans.

The Subcommittee is concerned that the level of funding for radiation research is decreasing and that this may adversely effect the implementation of the strategy. It notes that this decrease has taken place during a period of increased public concern and controversy.

In the event that the Interagency Radiation Research Committee accepts this draft report without major revision, I take this opportunity to express my sincere thanks to my dedicated colleagues on the Subcommittee and especially to Dr. Victor H. Zeve of NIH for his most able assistance as Executive Secretary.

Sincerely,

A handwritten signature in cursive script that reads "William Mills".

William Mills, Chairman
Chief of Health Effects Branch
Division of Health, Siting,
and Waste Management
Nuclear Regulatory Commission

cc: Dr. David A. Pistenmaa
Dr. Victor H. Zeve

ASSESSMENT OF RADIATION RESEARCH STRATEGY IMPLEMENTATION

EXECUTIVE SUMMARY

The Subcommittee on Radiation Research Strategy Implementation was established by the Chairman of the Interagency Radiation Research Committee (IRRC) on August 6, 1981, and charged to review the radiation research programs and budgets of the various Federal agencies and to report on the adequacy of support and appropriateness of allocations of research funds among the agencies. The present report, entitled "Assessment of Radiation Research Strategy Implementation", is the result of the Subcommittee's efforts to meet this charge and was approved by the IRRC at its meeting on October 8, 1982. The principal references used by the Subcommittee were the "Federal Strategy on Research into the Biological Effects of Ionizing Radiation" ("Strategy Report", IRRC, 1981) and "Federal Research on the Biological and Health Effects of Ionizing Radiation" ("FREIR Report", NAS/NRC, 1981).

The present report is divided into six chapters. The prefatory material includes a list of the Interagency Radiation Research Committee, a list of the Subcommittee members, a Table of Contents, and an Introduction outlining the charge to the Subcommittee and the contents of the report. In Chapter I, a brief description is provided of each Federal agency's mandate and involvement in radiation research. Chapters II through V contain the substance of the report. These chapters provide assessments of how well the Federal radiation research program meets the research needs described in the Strategy Report and the recommendations contained in the FREIR Report. These assessments are made by reviewing each agency's research program and budget with regard to these needs and recommendations. These chapters are identified according to the research categories outlined in the Strategy Report as (II) physics, chemistry, and related areas; (III) biological sciences; (IV) epidemiology and health sciences; and (V) characterization of sources of exposure.

Chapter VI contains a summary and conclusions as to the degree to which the Federal research effort adequately addresses research needs. Finally, several recommendations to the IRRC are offered to better implement a program that enhances our knowledge of the biological effects produced in humans by exposure to ionizing radiation.

The general conclusions of the report are as follows:

- The Federal radiation research program is generally, if not always, adequately addressing the scope of research needs as outlined in the Strategy and FREIR Reports.
- Agency programs and funding have been decreasing dramatically at a time of increasing public concern about possible health effects of ionizing radiation.
- As a result, although the distribution of Federal funding among the various categories is generally consistent with the identified needs, some needs of high priority, such as detailed dosimetry coupled with mechanistic studies of radiation effects at molecular and cellular levels, are inadequately addressed.
- On the other hand, support to initiate a number of epidemiologic studies appears to have grown during the past few years, in some instances for studies that may, at best, be able only to refine estimates of the upper limits of health effects from low doses. Although carefully designed and controlled epidemiologic studies of human populations are the cornerstone of our current estimates of health risk, it is also considered important to gain additional information on the basic mechanisms of disease induction by expanding current studies of biochemical, chromosomal, cellular, and metabolic effects of radiation exposure. In addition, more emphasis should be placed on studying interactions of radiation and exposure to other toxic substances.
- The Federal agencies are supporting research within their mandated responsibilities and no unnecessary duplication of effort is evident from this review.

While not specifically charged to offer recommendations, the Subcommittee concluded its report by formulating the following views that it believes warrant consideration.

- The IRRC should establish a storage and retrieval system for exchanging budget and project information on all Federal research investigating the biological effects of ionizing radiation.
- The IRRC should consider publicizing the research needs identified in the Strategy Report with the goal of encouraging young scientists to enter the field of radiobiology or other radiation-related disciplines, possibly by direct financial aid to students.
- The IRRC members should use the Committee as a forum for communicating their agency's specific research needs for scientific information on the biological and

health effects of ionizing radiation and other related needs.

- The IRRRC should conduct, in the next three years, a follow-up review of the Federal programs of research into the biological effects of ionizing radiation.

**ASSESSMENT OF RADIATION RESEARCH
STRATEGY IMPLEMENTATION**

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INTERAGENCY RADIATION RESEARCH COMMITTEE

CHAIRMAN

Dr. James B. Wyngaarden
Director
National Institutes of Health
Building 1, Room 132
Bethesda, MD 20205

VICE CHAIRMAN

Dr. Charles Edington
Associate Director
Office of Health and
Environmental Research
Department of Energy
Mail Station ER-70
Washington, DC 20545

EXECUTIVE SECRETARY

Dr. David A. Pistenmaa
Associate Director
Radiation Research Program
National Cancer Institute
Landow Bldg., Room 8C03
Bethesda, MD 20205

CONSUMER PRODUCT SAFETY
COMMISSION

Dr. Peter Pruess
Associate Executive Director
for Health Sciences
Consumer Product Safety
Commission
5401 Westbard Avenue, Room 700
Bethesda, MD 20207

Dr. Miriam Bloom (Alternate)
Geneticist
Directorate for Health
Sciences
Division of Hazard Assessment
Consumer Product Safety
Commission
5401 Westbard Avenue, Room 132
Bethesda, MD 20207

DEPARTMENT OF AGRICULTURE

Dr. Mary E. Carter
Associate Administrator
Agriculture Research Service
Department of Agriculture
Administration Building
Room 302-A
Washington, DC 20250

Mr. Robert D. Jarret
(Alternate)
USDA Radiological Safety
Officer
Agriculture Research Service
Department of Agriculture
Bldg. 001, Room 226
BARC-West
Beltsville, MD 20705

DEPARTMENT OF COMMERCE

Dr. Chris E. Kuyatt
Director
Center for Radiation Research
National Bureau of Standards
Bldg. 245, Room C-229
Washington, DC 20234

DEPARTMENT OF DEFENSE

LTG. Harry A. Griffith, USA
Director, Defense Nuclear
Agency
Department of Defense
Washington, DC 20234

Lt. Col. Carl Stroud
(Alternate)
Assistant to the Director
(Biomedical Effects)
Defense Nuclear Agency
6801 Telegraph Road
Alexandria, VA 22310

DEPARTMENT OF ENERGY

Mr. Hal L. Hollister
Scientific Advisor to the
Assistant Secretary for
Environment
Department of Energy
Forrestal Building
Room 4G-039
Washington, DC 20585

Dr. J.W. Thiessen
(Alternate)
Acting Deputy Associate
Director
Office of Health and
Environmental Research
Mail Station ER-71
Department of Energy
Washington, DC 20545

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Office of General Counsel

Ms. Maureen Corcoran
Legal Counsel
Office of General Counsel, HHS
Hubert Humphrey Bldg.
Room 707F
200 Independence Avenue
Washington, DC 20201

Centers for Disease Control

Dr. Clark W. Heath, Jr.
Director, Chronic Diseases
Division
Center for Environmental
Health
Centers for Disease Control
1600 Clifton Road
Atlanta, GA 30333

Dr. Glyn G. Caldwell
(Alternate)
Chief, Cancer Branch
Chronic Diseases Division
Center for Environmental
Health
Centers for Disease Control
1600 Clifton Road
Atlanta, GA 30333

National Institute for
Occupational Safety and Health

Dr. Paul Strudler
Senior Scientist, Radiation
National Institute for
Occupational Safety and
Health, CDC
Parklawn Building
Room 8A05
Rockville, MD 20857

Food and Drug Administration

Mr. John C. Villforth
Director
Bureau of Radiological Health
FDA
12720 Twinbrook Pkwy., Rm. 501
Rockville, MD 20857

Dr. Charlotte Silverman
(Alternate)
Deputy Director
Division of Biological Effects
Bureau of Radiological Health,
FDA
Room 101
12709 Twinbrook Parkway
Rockville, MD 20857

National Institutes of Health

Dr. Vincent T. DeVita
Director
National Cancer Institute
Bldg. 31, Room 11A52
Bethesda, MD 20205

DEPARTMENT OF LABOR

Dr. Sheldon R. Weiner
Director
Office of Physical Agents
Standards
Occupational Safety and Health
Administration
Room N3718
200 Constitution Ave., NW
Washington, DC 20210

DEPARTMENT OF TRANSPORTATION

Dr. H.L. Reighard
Federal Air Surgeon
Federal Aviation
Administration
800 Independence Ave., SW
Washington, DC 20591

ENVIRONMENTAL PROTECTION
AGENCY

Mr. Paul Magno
Health Physicist
U.S. Environmental Protection
Agency (ANR 460)
401 M Street, SW
Washington, DC 20460

FEDERAL EMERGENCY MANAGEMENT
AGENCY

Dr. David W. Bensen
Program Manager for Nuclear
Hazards
National Preparedness Programs
Research Office, Rm. 601
Federal Emergency Management
Agency
500 C Street, SW
Washington, DC 20472

Mr. Carl R. Siebentritt
(Alternate)
Chief, Radiological Defense
and Technologies Hazards
Branch
State and Local Program
Support
Emergency Management Program
Office
Federal Emergency Management
Agency
500 C Street, SW, Room 607
Washington, DC 20472

NATIONAL AERONAUTICS AND SPACE
ADMINISTRATION

Dr. Gerald A. Soffen
Director, Division of Life
Sciences (SB-3)
National Aeronautics and Space
Administration Headquarters
Washington, DC 20546

Dr. Paul C. Rambaut
Manager, Biomedical Research
Programs (SBR-3)
National Aeronautics and Space
Administration Headquarters
Washington, DC 20546

NATIONAL SCIENCE FOUNDATION

Dr. Kin-Ping Wong
Program Director for
Biophysics
Division of Physiology,
Cellular, and
Molecular Biology
National Science Foundation
1800 G Street, NW, Rm. 329
Washington, DC 20550

NUCLEAR REGULATORY COMMISSION

Mr. Robert Minogue
Director, Office of
Nuclear Regulatory Research
Nuclear Regulatory Commission
Washington, DC 20555

Mr. Frank Arsenault
(Alternate)
Director, Division of
Safeguards, Fuel Cycle,
and Environmental Research
Nuclear Regulatory Commission
Washington, DC 20555

VETERANS ADMINISTRATION

Dr. Lawrence B. Hobson
Clinical Assistant for
Environmental Medicine
(102A)
Veterans Administration
810 Vermont Ave., NW
Room 848
Washington, DC 20420

NIH STAFF CONSULTANTS

Dr. Charles U. Lowe
Associate Director for
Medical Applications of
Research (Acting)
National Institutes of
Health
Bldg. 1, Room 216
Bethesda, MD 20205

Dr. Oddvar Nygaard
Special Assistant to
the Director
National Cancer Institute
Bldg. 31, Room 4B29
Bethesda, MD 20205

Dr. Gilbert Beebe
Expert, Clinical Epidemiology
Branch
National Cancer Institute
Landow Bldg., Rm. 5A21
Bethesda, MD 20205

Dr. Victor Zeve
Special Assistant for
Intra and Interagency
Affairs
Radiation Research Program
Division of Cancer Treatment
National Cancer Institute
7910 Woodmont Ave., Rm. 4A22
Bethesda, MD 20814

RADIATION RESEARCH STRATEGY IMPLEMENTATION SUBCOMMITTEE

CHAIRMAN

Dr. William Mills
Chief of Health Effects Branch
(1130SS)
Division of Health, Siting,
and Waste Management
Nuclear Regulatory Commission
Washington, DC 20555

EXECUTIVE SECRETARY

Dr. Victor H. Zeve
Special Assistant for Intra
and Interagency Affairs
Radiation Research Program
National Cancer Institute
National Institutes of Health
7910 Woodmont Avenue
Room 4A22
Bethesda, MD 20814

DEPARTMENT OF AGRICULTURE

Dr. Reginald Handwerk
U.S. Department of Agriculture
Agriculture Research Service
BARC-West
Building 005, Room 133
Beltsville, MD 20705

Dr. Roy McDonald (Alternate)
U.S. Department of Agriculture
Agriculture Research Service
BARC-West
Building 005, Room 138
Beltsville, MD 20705

DEPARTMENT OF COMMERCE

Dr. Charles Eisenhauer
Center for Radiation Research
National Bureau of Standards
Building 245, Room C310
Washington, DC 20234

DEPARTMENT OF ENERGY

Dr. Charles Edington
Associate Director
Office of Health
and Environmental Research
Department of Energy
Mail Station ER-70
Washington, DC 20545

Dr. Murray Schulman
(Alternate)
R & D Coordinator
Office of Health and
Environmental Research
Department of Energy
Mail Station ER-70
Washington, DC 20545

**CONSUMER PRODUCT SAFETY
COMMISSION**

Dr. Miriam Bloom
Geneticist
Directorate for Health
Sciences
Division of Hazard Assessment
Consumer Product Safety
Commission
5401 Westbard Avenue, Room 132
Bethesda, MD 20207

DEPARTMENT OF DEFENSE

Lt. Col. Carl Stroud
Assistant to the Director
(Biomedical Effects)
Defense Nuclear Agency
6801 Telegraph Road
Alexandria, VA 22310

Dr. Lawrence S. Myers
(Alternate)
Scientific Director
Armed Forces Radiobiology
Research Institute
Bethesda, MD 20814

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Office of General Counsel

Ms. Maureen Corcoran
Legal Counsel
Office of General Counsel, HHS
Hubert H. Humphrey Building
Room 707F
200 Independence Avenue
Washington, DC 20201

Ms. Shelley Steuer (Alternate)
National Institutes of Health
Office of General Counsel
Building 31, Room 2B-50
Bethesda, MD 20205

National Institute for
Occupational Safety and Health

Dr. Paul Strudler
Senior Scientist, Radiation
National Institute for
Occupational Safety and
Health
Parklawn Building, Room 8A07
Rockville, MD 20857

Centers for Disease Control

Dr. Glyn Caldwell
Chief, Cancer Branch
Chronic Diseases Division
Center for Environmental
Health
Centers for Disease Control
1600 Clifton Road
Atlanta, GA 30333

Mr. Larry Posey (Alternate)
Chronic Diseases Division
Center for Environmental
Health
Centers for Disease Control
1600 Clifton Road
Atlanta, GA 30333

Food and Drug Administration

Dr. Marvin Rosenstein
Bureau of Radiological Health
(HFX-7)
12720 Twinbrook Parkway
Room 501
Rockville, MD 20857

National Institutes of Health

Dr. David Pistenmaa
Program Director
Radiation Research Program
Division of Cancer Treatment
National Cancer Institute
Landow Building, Room 8C03
7910 Woodmont Avenue
Bethesda, MD 20814

Dr. Kenneth L. Mossman
(Alternate)
Dr. Oddvar Nygaard (Alternate)
Low-level Radiation Effects
Branch
Radiation Research Program
Division of Cancer Treatment
National Cancer Institute
Building 31, Room 4B29
Bethesda, MD 20205

DEPARTMENT OF LABOR

Dr. Sheldon Weiner
Director, Office of
Physical Agents Standards
Occupational Safety and Health
Administration
200 Constitution Avenue, NW
Room N3718
Washington, DC 20210

Mr. Arthur Gass (Alternate)
Occupational Safety and Health
Administration
200 Constitution Avenue, NW
Washington, DC 20210

NUCLEAR REGULATORY COMMISSION

Dr. Judith Foulke (Alternate)
Radiobiologist
Health Effects Branch
Division of Health, Siting,
and Waste Management
Nuclear Regulatory Commission
Washington, DC 20555

**NATIONAL AERONAUTICS AND SPACE
ADMINISTRATION**

Dr. Paul Rambaut
Manager, Biomedical Research
Programs (SBR-3)
National Aeronautics and Space
Administration Headquarters
Washington, DC 20546

NATIONAL SCIENCE FOUNDATION

Dr. Michael Cusanovich
Program Director for
Biochemistry
National Science Foundation
1800 G Street, NW, Room 329
Washington, DC 20550

VETERANS ADMINISTRATION

Dr. John Sullivan
Deputy Director for Medical
Research Service
VA Central Office
Washington, DC 20420

**FEDERAL EMERGENCY MANAGEMENT
AGENCY**

Dr. David Bensen
Program Management for Nuclear
Hazards
National Preparedness Programs
Research Office
Federal Emergency Management
Agency
Washington, DC 20472

**ENVIRONMENTAL PROTECTION
AGENCY**

Dr. Neal Nelson
Office of Radiation Programs
(ANR-460)
401 M Street, SW
Washington, DC 20460

INTRODUCTION

The Interagency Radiation Research Committee (IRRC) was established by the Secretary of Health, Education, and Welfare¹ (HEW) upon instruction of President Carter by memorandum, dated February 21, 1980. The IRRC is composed of representatives of all Federal agencies with significant research, operational, or protective functions in the area of radiation. The mandate of the Committee, as stated in its charter, is to:

...assure that the Federal program of research to characterize the risks to humans and the ecosystem from exposure to ionizing radiation is comprehensive and carried out efficiently, objectively, openly, and in accord with the highest scientific standards. The Committee must assure that Federal research programs are also directed to provide the regulatory agencies with the knowledge required to set appropriate standards for protecting the public and environment.

On August 6, 1981, the Chairman of the IRRC established the Subcommittee on Radiation Research Strategy Implementation. The Subcommittee was charged with reviewing agency radiation research programs and budgets, reporting on the adequacy of support for such radiation research, and the appropriateness of the allocation of research funds among the Federal agencies. As its principal sources of reference on program content, the Subcommittee was asked to rely on the "Federal Strategy on Research into the Biological Effects of Ionizing Radiation" ("Strategy Report," IRRC 1981) and "Federal Research on the Biological and Health Effects of Ionizing Radiation" ("FREIR Report," NAS/NRC 1981). In its deliberations, the Subcommittee has also taken cognizance of the relevant conclusions and recommendations of the Comptroller General of the General Accounting Office in his Report to the Congress entitled "Problems in Assessing the Cancer Risks of Low-Level Ionizing Radiation Exposure" ("GAO Report," January 1981).

The present report, entitled "Assessment of Radiation Research Strategy Implementation," hereafter to be referred to as the "Implementation Report," is the result of the Subcommittee's

¹ The HEW became the Department of Health and Human Services (HHS) on May 7, 1980.

efforts to fulfill this charge. In Chapter I, a brief description of each Federal agency's mandate and interest in radiation research related to the biological effects of ionizing radiation is provided.

Presented in Chapters II through V are assessments of how well the Federal radiation research program meets the research needs specified in the Strategy Report and satisfies the recommendations contained in the Strategy and FREIR Reports. These chapters are identified according to the research categories outlined in the Strategy Report as (II) physics, chemistry and related areas; (III) biological sciences; (IV) epidemiology and health sciences; and (V) characterization of sources of exposure.

Finally, Chapter VI contains a summary and conclusions as to the degree to which the Federal research effort adequately addresses research needs. Also included are improvements that are warranted in the Federal effort to better implement a program that enhances our knowledge of the biological effects in humans exposed to ionizing radiation.

In making this assessment, it was necessary that each Federal agency supporting or having substantive interest in radiation research related to biological effects provide budget information for fiscal years 1981, 1982, and 1983, and descriptions of FY81 projects funded. These project descriptions were required to be of sufficient detail that the research could be judged as to its contribution to the specific needs listed in the Strategy Report. On the basis of this information, a determination has been made of the number of FY81 projects and the dollar amounts in FY81, 82, and 83 budgets that are directed to a given research need. To facilitate analysis and discussion, each need has been identified by a number that relates it to the corresponding chapter in the Federal Strategy Report.

I. FEDERAL AGENCIES CONDUCTING RESEARCH ON THE BIOLOGICAL AND HEALTH EFFECTS OF IONIZING RADIATION

At least 18 Federal agencies have authority to perform or fund others to perform research related to the biological and health effects of ionizing radiation, and, therefore, authority to implement the Federal radiation research program. Some of these agencies, such as the National Institutes of Health (NIH), are expressly mandated to conduct and/or support radiation research; others, such as the Department of Labor (DOL), do no research but are authorized to fund research as deemed appropriate to the agency's mission.

Some Federal agencies, such as the Department of Energy (DOE), the NIH, the National Bureau of Standards (NBS), and the National Science Foundation (NSF) provide basic information on the biological effects of ionizing radiation or contribute through their support of the basic sciences or the study of specific diseases. Other agencies must rely on these basic data and supplement them with specific research that is required to meet their missions, e.g., promulgating regulatory or other radiation protection actions. Among these agencies are the Nuclear Regulatory Commission (NRC), the DOL, the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). Still other Federal agencies have research interests that are quite specific to their needs, such as the Department of Agriculture (USDA), the Veterans Administration (VA), the Federal Emergency Management Agency (FEMA), the National Aeronautics and Space Administration (NASA), and the Department of Defense (DOD).

In this chapter, each agency's basic mandate and authority is described, as well as a brief description of the agency's program or specific interests in ionizing radiation matters. This provides a perspective from which to view each agency's role in implementing the strategy and in evaluating the total Federal effort.

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

This Department was organized on April 11, 1953, to advise the President on health, welfare, and income security programs and to carry out related Federal programs. The HHS health program is supported by the Public Health Service (PHS), which was established on July 16, 1798 (ch. 77, 1 stat. 605), to care for merchant seamen. Subsequent legislation has broadened the scope

of PHS activities to include both clinical and scientific research including studies of the biological effects of ionizing radiation. These research studies are now divided among three separate PHS agencies according to mission, goals, or objectives as defined by the following legislative mandates for the NIH, the Centers for Disease Control (CDC), and the FDA.

National Institutes of Health (NIH)

National Cancer Institute (NCI)

Under Section 301 of the PHS Act (42 U.S.C. 241) and related sections of that Act, HHS has general authority to conduct and support research relating to the causes, diagnosis, treatment, control, and prevention of human diseases and impairments. Sections 401 through 404 of the PHS Act authorize the NCI to conduct, assist, and foster research relating to prevention, methods of diagnosis, and treatment of cancer (42 U.S.C. 282-285). The National Cancer Act of 1971 made the conquest of cancer a national goal for the NCI and led to increased support of a wide spectrum of research studies encompassing diagnostic imaging; radiation oncology, biology, chemistry, and physics; and radiation epidemiology.

In 1978, an amendment to Section 301 (P.L. 95-622) required the HHS to conduct a comprehensive program of research into the biological effects of low-level ionizing radiation. In response to this mandate, a Low-Level Radiation Effects Branch was established at the NCI to provide a focus for planning, developing, administering, and evaluating research into the biological and health effects of ionizing radiation.

Some ionizing radiation research is supported by the National Institute of Environmental Health Sciences.

Centers for Disease Control (CDC)

Center for Environmental Health (CEH)

National Institute for Occupational Safety and Health (NIOSH)

Established on July 1, 1973, the CDC is charged with protecting the public health of the Nation by providing leadership and direction in the prevention and control of diseases and other preventable conditions. Under Section 301 of the Public Health Service Act (58 Stat. 682; 42 U.S.C. 241), CDC supports and conducts epidemiological studies designed to develop information for the prevention and control of diseases and other conditions such as exposure to ionizing radiation. The Center for Environmental Health (CEH) has primary responsibility for

of the CDC is the National Institute for Occupational Safety and Health (NIOSH), established in 1970 by the Occupational Safety and Health Act (29 U.S.C. 669, 671). The NIOSH mission is to assure safe and healthful conditions for workers by providing for research in the field of occupational safety and health. These efforts are coordinated with the missions and goals of the Occupational Safety and Health Administration (OSHA) and with the Mine Safety and Health Administration (MSHA) in the Department of Labor. Under enabling legislation (30 U.S.C. 801), MSHA is directed to consider NIOSH's recommendations and criteria, in addition to any other information obtained, for setting safety or health standards for mining. In filling some research needs, MSHA can utilize a Memorandum of Understanding with the NIOSH, dated May 4, 1978, that specifies that NIOSH can conduct long-term field epidemiology studies and laboratory studies for the toxic or physiological effects of physical agents in mines, including radioactive materials.

Food and Drug Administration (FDA)

Bureau of Radiological Health (BRH)

The FDA was established under the Agriculture Appropriation Act of 1931 (46 Stat. 392) to administer the Food and Drug Act of 1906 (21 U.S.C. 1-15) and to protect the health of the Nation against impure and unsafe foods, drugs, cosmetics, and other potential hazards. The Bureau of Radiological Health (BRH) and its antecedent organizations have had an active program in ionizing radiation bioeffects research since 1958 under Section 301 of the Public Health Service Act (42 U.S.C. 241). Its mission is to carry out programs to control unnecessary radiation exposures from electronic products and medical devices, to develop performance standards for electronic products, and to conduct research on related health effects. The BRH derives its ionizing radiation bioeffects research authorities from the Public Health Service Act, Reorganization Plan No. 3 of 1970 (42 U.S.C. 4321 note), and the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263(b)-263(N)).

Research into the biological effects of ionizing radiation in the BRH and its predecessor organizations has included epidemiologic, animal, and cellular studies. This research has been designed to deal principally with concerns related to lower levels of exposure to ionizing radiation, in support of its regulatory and other radiation protection programs. With reduced funding in 1983, the BRH program will focus on health risk assessments and depend more on research supported by other institutions to meet its basic data needs.

DEPARTMENT OF ENERGY (DOE)

The Atomic Energy Act of 1946 (P.L. 79-585) provided the initial charter for a comprehensive program of applied and basic radiobiological research. This Act authorizes the Department to conduct research and development related to the utilization of fissionable and radioactive materials for medical, biological, and health purposes. It also provided for the protection of health during the same research and development activities. The Atomic Energy Act of 1954 (P.L. 83-703), as amended, authorized the Atomic Energy Commission "...to conduct and support research and development activities, including authority to conduct research on the biologic effects of ionizing radiation..." for "...the protection of health and the promotion of safety during research and production activities..." and for "...the preservation and enhancement of a viable environment..."

The Energy Reorganization Act of 1974 (P.L. 93-438) specifically provided that the responsibilities of the Administrator of the Energy Research and Development Administration (ERDA) shall include "...engaging in and supporting environmental, biomedical, physical, and safety research related to the development of energy sources and utilization technologies..."

The Department of Energy Organization Act of 1977 (P.L. 95-91) mandated the DOE "...to assure incorporation of national environmental protection goals in the formulation and implementation of energy programs, and to advance the goal of restoring, protecting and enhancing environmental quality and assuring public health and safety...", and to conduct "...a comprehensive program of research and development on the environmental effects of energy technology and programs..."

The Office of Health and Environmental Research (OHER) is the health and environmental research arm of the DOE. The OHER goal is to conduct an authoritative and comprehensive Federal program of research and assessment to identify, analyze, and reduce those health and environmental uncertainties which would unnecessarily impede the safe and economical implementation of U.S. energy policy. In the area of radiation research, the program addresses the occupational and public health concerns associated with the nuclear fuel cycle as well as the production, testing, and use of nuclear devices. The knowledge gained is also applied to radiological issues in other energy technologies including fission, conservation, and coal combustion. This research is carried out in the areas of human health, health effects in biological systems, radionuclide transport and behavior in the environment, physical and chemical processes, measurement and instrumentation, and health and environmental effects risk and analysis. The research is designed to identify, measure, and characterize biologically important radiation and radionuclides and understand their transport, conversion, and fate in the environment; determine their ecological impact and pathways to man; define their potential effects on human health through both

direct observation and via studies with experimental biological systems; and provide realistic analysis of the interactions between nuclear energy activities and human health and the environment.

NUCLEAR REGULATORY COMMISSION (NRC)

The NRC licenses and regulates the uses of nuclear energy to protect the public health and safety and the environment. This agency was established as an independent regulatory agency under the provisions of the Energy Reorganization Act of 1974 (42 U.S.C. 5801) from a component of the former Atomic Energy Commission (42 U.S.C. 2011).

The NRC's authority to contract for or conduct research is provided by Sections 31(a) and 32 of the Atomic Energy Act of 1954 and Sections 201(f) and 205 of the Energy Reorganization Act of 1974 (42 U.S.C. 2051, 2052, 5841(f), 5845). The Atomic Energy Act authorized the Atomic Energy Commission (AEC) to contract for and conduct research for the protection of health and promotion of safety during research and production activities. Section 201(f) of the Energy Reorganization Act transferred the AEC's licensing and regulatory functions to the NRC, including, by implication, AEC research authorities necessary to the support of these functions. Section 205 directs the head of every Federal agency to: (1) cooperate with respect to setting priorities for furnishing the NRC with requested research services, (2) furnish to the NRC, on a reimbursable basis, research services that the NRC deems necessary for the performance of its functions, (3) consult with the NRC on matters of mutual interest, and (4) provide the NRC access to facilities and information which will assist it in performing its functions. Therefore, other agencies are encouraged to conduct biological research under this mandate if the NRC needs the data.

The primary responsibility of the NRC is to ensure that civilian nuclear energy activities are conducted in a manner which will adequately protect the health and safety of nuclear industry workers and the public. These activities include the operation of nuclear power plants, the related fuel cycle facilities, and users of material made radioactive in nuclear reactors. Fuel cycle facilities range from uranium mills which process uranium ore to waste disposal sites for storing the unusable products. By far the largest number of licensees include users of radioactive materials for such activities as medical diagnosis and therapy or nondestructive testing of metal welds.

The NRC relies heavily on the research supported by the DOE, the NIH, and others for basic knowledge of the biological effects of radiation. In certain cases, however, it is necessary for the NRC to support its own research programs to obtain results more relevant to its regulatory mission. A number of such projects

provide metabolic data necessary for development of bioassay programs for various classes of licensees.

DEPARTMENT OF DEFENSE (DOD)

Title 10, U.S.C., Section 2358 authorizes the Secretary of Defense or his designee to engage in research projects necessary to the DOD and related to weapons systems and other military needs. Within the DOD, this operational mandate was implemented in part by DOD Directive No. 5105.31 dated November 3, 1971, which established the Defense Nuclear Agency (DNA). The DNA has the mission to plan, coordinate, and supervise the conduct of DOD nuclear weapons effects research. DNA accomplishes its research into the biological effects of ionizing radiation mainly through the Armed Forces Radiobiology Research Institute (AFRRI), as outlined in the DOD Directive No. 5105.33, dated November 17, 1981. This laboratory was established to serve as the principal ionizing radiation research laboratory for the DOD and to support requirements identified by DOD components. Its program is an integral part of the DOD medical and life sciences research, development, and evaluation program. It conducts research in the fields of radiobiology and related matters essential to the operational and medical support of the DOD and the Military Services, and may provide services and perform research for other Federal and civilian agencies and institutions with the approval of the Director, DNA. The DNA also sponsors supplementary extramural research in radiobiology, and other DOD units conduct or sponsor radiobiological research specifically related to their missions.

ENVIRONMENTAL PROTECTION AGENCY (EPA)

The goal of the EPA is to protect and enhance the environment. The agency's mission extends to the control and abatement of radiation pollution in air, water, and waste. It is also responsible for developing radiation protection guidance for Federal agencies with authority transferred under Reorganization Plan No. 3 of 1970. The EPA's research authority exists under the following laws: (1) Uranium Mill Tailings Radiation Control Act of 1978 (42 U.S.C. 7901 et seq.); (2) Clean Air Act, as amended (42 U.S.C. 7401 et seq.); (3) Resource Conservation and Recovery Act (42 U.S.C. 6901 et seq.); (4) Toxic Substances Control Act (15 U.S.C. 2601 et seq.); general authority under Section 301 of the PHS Act (42 U.S.C. 214) has been granted to the EPA pursuant to Reorganization Plan No. 3 of 1970 (42 U.S.C. 4321 note) to conduct and support health research related to control of (radiation) pollution in the environment; (5) Safe Drinking Water Act (42 U.S.C. 300(f) et seq.); (6) Federal Water Pollution Control Act, as amended (33 U.S.C. 1251 et seq.); and (7) Marine Protection, Research, and Sanctuaries Act of 1972 (42 U.S.C. 1401 et seq.).

The EPA must rely on other agencies to support the basic research that provides information for the transport and health risk analyses that it must make in supporting its mission.

DEPARTMENT OF COMMERCE (DOC)

The DOC serves to promote the Nation's economic development and technological advancement. Two principal agencies, the National Oceanic and Atmospheric Administration and the National Bureau of Standards, are authorized to investigate radiation effects in commerce and the environment.

National Bureau of Standards (NBS)

The NBS has the responsibility to strengthen and advance the Nation's science and technology and to facilitate their effective application for public benefit. It derives its goals and objectives from the Organic Act (15 U.S.C. 271 et seq., as amended). These goals include, but are not limited to, providing infrastructure services for the physical and engineering sciences; establishing and maintaining reference bases for measurements, data, and materials; and providing technical support to other Government agencies. Since the agency was established in 1901, the NBS has had the authority to provide advisory services to Government agencies and to investigate radiation, radioactive substances, X-ray use, and the means of protection of persons from their harmful effects (15 U.S.C. 272(9)). Under the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263(d)), the BRH receives assistance from NBS in the development of performance criteria to control machine-produced radiation.

National Oceanic and Atmospheric Administration (NOAA)

The NOAA has broad authority to promote the increased use of science and technology to improve understanding of Earth's physical environment and oceanic life, to predict impending destructive natural events, and to monitor environmental modifications. Statutory authorities contained in 16 U.S.C. 742(f), 758-760(g), and 1854 support the mission of developing, advancing, managing, conserving, and protecting fish and wildlife resources. The development of coastal management programs is authorized by 16 U.S.C. 1456(c). Other potential areas of research include: (1) geophysical sciences (33 U.S.C. 883(d)), (2) ocean and coastal resources (33 U.S.C. 1121-1131), (3) effects of ocean pollution (33 U.S.C. 1441-1444), and (4) meteorology (49 U.S.C. 1463).

FEDERAL EMERGENCY MANAGEMENT AGENCY (FEMA)

The FEMA's authority to conduct radiation research is provided by Executive Order 12148 of July 20, 1979, which transferred all functions delegated under Public Law 81-920, the Federal Civil Defense Act of 1950, as amended (50 U.S.C. 2251 et seq.) to the Federal Emergency Management Agency. Public Law 81-920 states that "...It is the policy and intent of Congress to provide a system of civil defense for the protection of life and property in the United States from attack." In support of this mission, authority is specifically provided (under Title II, Sect. 201, para. d) "...to study and develop civil defense measures designed to afford adequate protection of life and property, including, but not limited to, research and studies as to the best methods of treating the effects of attack..."

The objectives of the FEMA's radiation research program are to provide scientific and technical support for the agency's delegated responsibilities and activities that require radiation exposure criteria and the means to mitigate and control radiation exposure of the population. This is accomplished by developing concepts to contain, control, or otherwise mitigate radiation hazards. Events of concern include transient and residual radiation from nuclear attack and other large-scale radiation exposure incidents.

DEPARTMENT OF AGRICULTURE (USDA)

The USDA is empowered under its general research authority (7 U.S.C. 2201, 2204) to carry out experiments related to its missions, including experiments into the biological effects of ionizing radiation. Consequently, most of this effort is incidental to studies in the production and protection of agricultural products and the conservation of national resources.

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION (NASA)

The authority for the NASA to engage in human research, including that concerning the biological effects of ionizing radiation relevant to space and flight crews, is implicit in Section 102(c) (1), (3), and (4) of the National Aeronautics and Space Act of 1958, P.L. 85-568, as amended, which states that "...the aeronautical and space activities of the United States shall be conducted so as to contribute materially to one or more of the following objectives: (1) the expansion of human knowledge of phenomena in the atmosphere and space...; (3) the development and operation of vehicles capable of carrying instruments, equipment, supplies and living organisms through space; (4) the establishment of long-range studies of the potential benefits to be gained from the opportunities for, and the problems involved in the utilization of aeronautical and space activities for peaceful and scientific purposes..."

DEPARTMENT OF LABOR (DOL)

Occupational Safety and Health Administration (OSHA)

The OSHA has two primary means of obtaining the research data that the agency needs to regulate industrial hazards in the workplace. Under provisions of Sections 20 and 22 of the Occupational Health and Safety Act, the OSHA relies on the NIOSH to carry out basic and applied research necessary to support its regulatory mission. Under Section 20(c), the OSHA is also authorized to enter into contracts, agreements, or other arrangements for the purpose of conducting studies relating to the OSHA's responsibilities as needed.

Mine Safety and Health Administration (MSHA)

The Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951) requires the Secretaries of Labor, HHS, and Interior to coordinate research to promote occupational safety and health in the mining industry. Pursuant to this mandate, the MSHA and the Bureau of Mines, the Department of Interior, entered into a Memorandum of Understanding on May 1, 1978, in order to better utilize the resources and capabilities of both agencies in managing and conducting mine safety research. In addition, the MSHA and the NIOSH entered into a Memorandum of Understanding on May 4, 1978, to enable both agencies to effectively and efficiently share data and coordinate research in these areas.

NATIONAL SCIENCE FOUNDATION (NSF)

Section 3 of the National Science Foundation Act of 1950 (42 U.S.C. 1862) gives the NSF broad authority to support basic and applied scientific research in all fields of science except the clinical sciences. Its support is provided through grants, cooperative agreements, and contracts.

VETERANS ADMINISTRATION (VA)

The VA is authorized to carry out medical research for the purpose of improving the delivery of medical care to veterans and to contribute to the Nation's knowledge about disease and disability (38 U.S.C. 4101), including the effects of ionizing radiation. This authorization is broad in scope but has rarely been used.

DEPARTMENT OF THE INTERIOR (DOI)

The DOI's Bureau of Mines (BOM), under the provisions of the Organic Act of 1910, was commissioned as a research and fact-finding agency (36 Stat. 369; 30 U.S.C. 1, 3, 5-7) with typical areas of research in safety and health. Provisions of the Federal Mine Safety and Health Act of 1977 and a current Memorandum of Understanding dated May 1, 1978, provide a formal mechanism for the transfer of research data developed by the BOM to the MSHA.

II. PHYSICS, CHEMISTRY, AND RELATED AREAS

In Chapter II of the Strategy Report, research needs in physics, chemistry, and related areas are addressed. The "related areas" refer mainly to the measurement and monitoring activities that support studies on the biological effects of ionizing radiation. Table II-1 lists the needs identified in the Strategy Report.

Implementation of the research needs by the various Federal agencies is shown in Tables II-2 and II-3. Table II-2 lists the number of FY81 funded projects by agency and need. Table II-3 shows FY81, 82, and 83 budgets allocated to the various needs by agency. Projects and FY81, 82, and 83 budgets for each need are combined for all agencies and presented in Table II-4.

Table II-3 indicates that the Department of Energy is the major funding agency for research needs in these areas. The NBS, the NIH, and the NSF also contribute significantly to these efforts. The total annual effort planned for FY81 through FY83 is approximately level, with slightly higher funding in FY82.

Following is a brief description of the research efforts. Research needs have been grouped together according to the main categories of physics, chemistry, and measurement.

Radiation Physics (Needs 2.1-2.5)

Studies in radiation physics are supported mainly by the DOE, with the NIH and the NSF providing lesser amounts of support, and the DOD, the NASA, and the NBS supporting small amounts of research in this area. The DOE program funding, which covers mainly research Needs 2.1, 2.4, and 2.5, includes studies of the initial products formed by the interaction of ionizing radiation with matter, low-energy electron-molecule processes, energy conversion processes, and interaction of protons and electrons with molecular targets. Projects at the NIH and the NSF include application of heavy-ion beams to therapy, effects of low doses of ionizing radiation, and collisions of ions with atoms and molecules. Much of the work categorized under Needs 2.14 and 2.16 is also relevant to Needs 2.1 and 2.5, and could properly be included under "Radiation Physics."

Table II-2 shows that most research projects in this group are being devoted to Need 2.1. This is reasonable since such studies, representing the initial step in the energy transfer

process, provide the basic data and understanding necessary for other studies. Needs 2.3, 2.4, and 2.5 are all covered by at least one project. While Need 2.2 (the mapping of activation spectra for molecules of chemical and biological importance) has no identifiable project covering it, work supported by the DOE includes closely related projects in studying ionization of complex molecules by electron impact. No significant changes in direction of research for FY82 and FY83 are noted.

Radiation Chemistry (Needs 2.6-2.13)

Tables II-2 and II-3 indicate that the NIH and the NBS are the largest sources of funding with lesser funding being supplied by the DOD and the DOE. These agencies are funding studies in energy transport processes, electron paramagnetic resonance, relationship of chemical radiosensitization to dose rate, and models for describing this relationship.

The appearance given by Tables II-2 and II-3 that the funding for radiation chemistry is inadequate and that only the DOE, the NBS, and the NIH are funding more than one project is somewhat misleading. Chemical research is involved throughout the field of radiation research. Needs 2.7 and 2.10 are addressed in some of the projects more appropriately included in Chapter III of this report. For example, the application of electron spin resonance methods to studies of DNA damage are included in Chapter III (see discussion of Needs 3.1-3.4). Several studies in chemical desensitization to radiation effects are also covered in Chapter III (see discussion of Need 3.12).

Radiation Measurement (Needs 2.14-2.20)

Projects to improve current dosimetry techniques and equipment and to develop new techniques and equipment are supported primarily by the DOE. Most of the research projects in this area not only address multiple research needs, but encompass two or more of the areas of instrumentation, personnel monitoring, measurement of radionuclides in the human body, and reconstruction of past exposures. The relative biological effectiveness (RBE) of the different types and energies of radiation is being studied as well as absorbed dose and energy deposition. RBE is related to radiation quality or the linear energy transfer (LET) of the radiation.

Efforts to reconstruct past exposures are concentrating on the Nevada Test Site, Hiroshima, and Nagasaki. They include determining the accuracy of environmental indicators of past radiation exposure using thermoluminescence from quartz in housing bricks and Cs-137 and Pu-239 and 240 in soil.

Additional support for development of instrumentation and for research related to standards for radiation measurement is being

provided by the NBS. Research into particular applications of radiation measurement techniques is receiving considerable multi-agency support. For example, research into techniques of neutron dosimetry at nuclear power plants is supported by the NRC and the DOE. Research into capabilities for measuring low and high doses and methods for determining uptake of fallout are also being supported by the DOD. Studies of the effects of cosmic rays on life shortening and cell systems are being supported by the NASA, and research into low-cost approaches to measuring emergency exposures to fallout radiation is being supported by the FEMA.

COMMENTS ON STRATEGY REPORT AND FREIR REPORT RECOMMENDATIONS

Radiation Physics

STRATEGY RECOMMENDATION. Research in radiation physics must be adequately supported if we are to improve our knowledge of radiation and of the interactions that occur in biological systems, and if we are to decrease the physical uncertainties in radiation dosimetry. Of special interest is the improvement in dosimetry of high-LET radiation, dosimetry of internally deposited radionuclides, and microdosimetry.

Funding for the latter two areas is covered by projects described in this chapter and in Chapter III. The NIH is supporting development of heavy-ion (high-LET) beams for therapy. However, support for improvements in dosimetry of high-LET radiation, such as neutrons, has not reflected the high priority placed on this area of research.

Radiation Chemistry

STRATEGY RECOMMENDATION. Support should be expanded for radiation research to address the types and rates of chemical reactions that affect the biological function of cells, including studies which explore the use of chemical compounds to enhance or protect against radiation effects.

Although research in this area is covered by projects described in this and other chapters, there has been no notable expansion of support to meet this recommendation.

Radiation Measurements

STRATEGY RECOMMENDATION. High priority support is warranted for the development and application of new technologies and analytical techniques for improving the measurements of ionizing radiation. Such

improvements are needed particularly for personnel dosimetry of high-LET radiation.

FREIR RECOMMENDATION (2). The committee recommends that emphasis be placed upon dosimetric research for neutrons and mixed radiations. Added emphasis should also be placed on the development of dosimetric instrumentation to be used in measurements of nonuniform field distributions of radionuclides. Particular attention should be directed toward measurements of doses to organs and tissues and to specific cells within these organs and tissues.

FREIR RECOMMENDATION (9). The committee, therefore, finds that practical methods to improve occupational dosimetry and to reduce radiation exposure require greater emphasis, and urges attention to vulnerable occupational groups, especially in the mining industries.

All three recommendations point to the need for improved occupational radiation dosimetry, particularly in mixed neutron-gamma and beta-gamma fields. Improvements in miniaturization of electronic components has encouraged the development of small portable area monitors for neutron and gamma radiation. A short-term program to upgrade existing systems for area and personnel monitoring for mixed radiation fields (neutron-gamma and beta-gamma) and some longer-term research into new detector systems is sponsored by the DOE, but a more substantial effort is required for developing the next generation of dosimeters.

The three areas of emphasis in Recommendation 2 of the FREIR Report generally overlap with Research Needs 2.15, 2.16, and 2.17, respectively, and are addressed by DOE programs. Recommendation 9 of the FREIR Report is concerned with occupational groups, especially in the mining industries. Of particular concern in uranium mines is the evaluation of inhalation exposure from the decay products of the radioactive gas radon. The DOE has cooperated with the Bureau of Mines on the development, testing, and evaluation of radon dosimeters for miners and in measurements of particulates and radon daughters in mines and mills. Although the problem of radon dosimetry is not solved, research is underway that addresses this part of Recommendation 9.

Table II-1

RESEARCH NEEDS IN PHYSICS, CHEMISTRY, AND RELATED AREAS,
INCLUDING DOSIMETRY

(Chapter II of the Strategy Report)

- 2.1 Continued studies on the primary transfer of energy from radiation to matter, especially condensed matter
- 2.2 Mapping of activation spectra for molecules of chemical and biological importance
- 2.3 Determination of the energy distribution spectrum for single collisions between specific charged particles and molecules
- 2.4 Research into the details of multiple collision processes
- 2.5 Research into the structure of radiation tracks--the time sequence and spectral distribution of secondary radiation-induced events
- 2.6 The application of steady-state radiolysis techniques to complex systems, with product analysis
- 2.7 The application of electron spin resonance methods to the study of radicals in irradiated complex systems, including living organisms
- 2.8 Pulse radiolysis studies for the investigation of events at very short times following irradiation of complex systems in both polar and nonpolar media
- 2.9 An expansion of studies of micellar systems and other synthetic models of biological structures
- 2.10 Studies of the mechanisms of radiation sensitization and desensitization, including the role of molecular oxygen
- 2.11 Studies on the chemistry of free radicals and excited states in irradiated biological systems
- 2.12 Investigations of energy transfer processes between molecules following irradiation
- 2.13 Detailed radiation chemical studies relevant to specific biological effects (mutation, cell death, or cell transformation)

- 2.14 Improvement of the dosimetry system in current use, which is based primarily upon absorbed dose (usually in rads), by including the determination of additional physical parameters (e.g., differences in radiation quality) in order to provide the basis for estimating the biological effectiveness of a given dose
- 2.15 The development of improved instrumentation for accurate dosimetry for mixed radiation fields, which can yield some information on the type and energy spectrum of radiation
- 2.16 Studies to improve dose-distribution information in living tissue, particularly over dimensions less than one micrometer
- 2.17 Research to improve the dosimetry of radionuclides in the human body, including the precise location and quantity of each
- 2.18 The development of improved personnel monitors capable of giving all biologically relevant information quickly and accurately, especially for the measurement of low-energy neutrons, beta particles, low-energy photons, and mixtures of different types of radiation
- 2.19 The development of improved environmental monitors, which (1) are accurate at both ambient low doses and emergency doses, (2) respond to all radiations present (photons and beta rays), and (3) are highly reliable
- 2.20 Research into dosimetry methods for the dose reconstruction of past exposures to aid epidemiological studies

Table II-2

NUMBER OF FY81 PROJECTS RELATED TO RESEARCH NEEDS
IN PHYSICS, CHEMISTRY, AND MEASUREMENTS

RESEARCH NEED	DOD	DOE	EPA	FEMA	NASA	NBS	NIH	NRC	NSF	DOI
<u>Radiation Physics</u>										
2.1		6			1	2	3		6	
2.2										
2.3		2							2	
2.4	1	4			1	1				
2.5		4					1			
<u>Radiation Chemistry</u>										
2.6						1				
2.7	1						1			
2.8						1				
2.9						1				
2.10						1	1			
2.11							1		1	
2.12		2				1				
2.13						1	1			
<u>Radiation Measurement</u>										
2.14	2	4				6	6	4		
2.15		9		1		1				2
2.16		7								
2.17		5	1			1		1		
2.18	1	5			1	4		1		1
2.19		9				1		1		1
2.20	2	3								

Table II-4

NUMBER OF PROJECTS AND BUDGETS FOR RESEARCH NEEDS
IN PHYSICS, CHEMISTRY, AND MEASUREMENTS

RESEARCH NEED	NUMBER OF PROJECTS	BUDGET (In Thousands of Dollars)		
		FY 1981	FY 1982	FY 1983
<u>Radiation Physics</u>				
2.1	18	\$1,315	\$1,700	\$1,215
2.2	0	0	0	0
2.3	4	360	360	225
2.4	7	445	595	665
2.5	<u>5</u>	<u>780</u>	<u>800</u>	<u>750</u>
Subtotal	34	\$2,900	\$3,455	\$2,855
<u>Radiation Chemistry</u>				
2.6	1	\$ 15	\$ 40	\$ 40
2.7	2	78	80	85
2.8	1	15	40	40
2.9	1	10	40	40
2.10	2	125	150	150
2.11	2	40	110	110
2.12	3	125	150	130
2.13	<u>2</u>	<u>150</u>	<u>180</u>	<u>180</u>
Subtotal	14	\$ 558	\$ 790	\$ 775
<u>Radiation Measurement</u>				
2.14	22	\$2,115	\$1,810	\$1,790
2.15	13	1,350	1,685	1,870
2.16	7	810	1,000	780
2.17	8	465	270	400
2.18	13	845	1,090	1,225
2.19	12	1,605	1,315	855
2.20	<u>5</u>	<u>885</u>	<u>1,130</u>	<u>1,300</u>
Subtotal	80	\$8,075	\$8,300	\$8,220
Total	128	\$11,533	\$12,545	\$11,850

III. BIOLOGICAL SCIENCES

In Chapter III of the Strategy Report, research needs in the biological sciences are addressed. Physicochemical and biologic studies offer the most probable means of obtaining information on the biologic effects of radiation at low levels of exposure, the principal effects being cancer induction several years after exposure and genetic effects in future generations. Since direct observations of radiation effects in humans are necessarily limited, and the more so for low doses, it is important to use animal models, animal and human cell lines in culture, and lower life forms such as bacteria to gain the necessary information.

Table III-1 summarizes the needs identified in the various areas of molecular and cell biology and animal radiobiology research described in Chapter III of the Federal Strategy. Implementation of the research needs by the various Federal agencies is shown in Tables III-2 and III-3. Table III-2 lists the number of funded projects by agency and need. Table III-3 considers FY81, 82, and 83 budgets allocated to the various needs by agency. Table III-4, in which the number of projects and FY81, 82, and 83 budgets are combined for all agencies for each need, summarizes the information in Tables III-2 and III-3. Following is a brief description of the research efforts related to the Federal Strategy needs: Needs 3.1 through 3.12 address molecular and cell biology, and Needs 3.13 through 3.18 address animal radiobiology. It should be emphasized that some projects address more than one need. In those cases, the total budget was divided equally among the needs. This was done for many of the NIH projects. No attempt has been made to completely describe all of the research; only brief descriptions of representative research areas have been provided.

It is important to note that a large effort directed toward the study of immediate effects of high doses and radioprotective agents for those effects sponsored by the DOD has not been included in this assessment. This effort is supported at a level of approximately \$16 million per year, of which about \$3 million is devoted to molecular and cellular studies and \$6 million to animal studies. In addition, 80 percent of the NIH radiation effort pertains to high-dose effects, particularly preclinical and clinical radiotherapy studies. For the purpose of this report, the NIH and DOD high-dose-effect studies were excluded. This exclusion was made to be consistent with the Strategy Report, which recognized the need for research on high-dose effects but did not include this type of research in its

recommendations. However, like the IRRC, the Subcommittee recognizes that: "Such research has utility in the development of concepts and theories that may be used to extrapolate high-dose data to the effects which occur at low-dose radiation exposure."

MOLECULAR AND CELL BIOLOGY

Damage to Biologically Important Molecules (Especially DNA) and Repair (Needs 3.1-3.4)

A number of studies, supported principally by the DOE (12 projects for \$1.3 million in FY81) and the NIH (20 projects for \$1.3 million in FY81), are concerned with radiation damage and repair. DNA damage is investigated by immunochemical, electron spin resonance, and double resonance techniques. Damage-specific DNA-binding proteins have been identified. DNA repair in normal and repair-deficient cells is under study in several laboratories. The role of chromatin function and structure in determining radiosensitivity and the importance of the cell cycle in DNA repair are also being evaluated. Though effects on DNA are attracting most of the interest, several projects are concerned with radiation effects on amino acids, proteins, chromatin, etc. A wide variety of biological systems are used to carry out these studies including protozoa, bacteria, mammalian cells, and human cells. The effects of X and gamma rays, protons, and heavy ions are being investigated.

Of particular interest is the fact that Need 3.3 is not addressed by any of the Federal agency projects that were reviewed. This need is concerned with research to identify those radiation-induced lesions in DNA and other structures which are repairable, and the extent to which each is repaired in human cells in vivo. The lack of activity in Need 3.3 may be attributable to the continuous lack of quantitative assays for specific types of damage in DNA and other biomolecules.

Mutagenesis (Needs 3.5-3.7)

Work on radiation mutagenesis is primarily being conducted by the DOE and the NIH. In FY81, the DOE funded 8 projects for \$825,000; the NIH spent \$1.1 million on 20 projects. The effects of radiation doses down to 1 rad on mutation induction are being studied. Factors that may influence mutation frequency, including temperature, oxygen concentration, dose fractionation, stage of the cell cycle, repair capacity, and radiation quality or linear energy transfer (LET), are being investigated. The role of DNA damage and repair in mutagenesis is also of interest as it pertains to the dose-response relationship. These studies are being carried out in vivo and in vitro, utilizing human cells, including cells with known DNA repair deficiencies, various rodent cell lines, bacterial systems, and Drosophila.

Cell Killing, Mutations, and Transformation (Need 3.8)

In several projects, funded primarily by the NIH (12 projects funded in FY81 for \$700,000), the relationships between cell lethality, mutation induction, and transformation following radiation exposure are being studied. Included in these investigations are interaction of ionizing and non-ionizing radiations in the induction of mutations and transformation, the importance of repair processes in mutagenesis and transformation, cell cycle dependence in radiation-induced mutagenesis and transformation, characterization of DNA damage important in mutation and transformation induction, and DNA repair in some human cancer-prone genetic diseases. Various human and rodent cell lines are used in these studies, in addition to specialized strains of certain bacterial species.

Cell Transformation and Carcinogenesis (Needs 3.9-3.11)

In studies funded primarily by the DOE (5 projects in FY81 for \$740,000) and the NIH (13 projects in FY81 for \$540,000), mechanisms of cell transformation and carcinogenesis following radiation exposure are being investigated. Several laboratories are interested in transformation of cells in culture at doses near 1 rad. In other studies, the importance of dose fractionation, LET, cell age, and other factors which may modify transformation frequency is of interest. Various techniques are being used to study mechanisms of radiation-induced transformation and carcinogenesis including studies of cell surface membranes, repair of DNA damage in human cancer-prone diseases, expression of viral genes in transformed cells, and studies of fixation and expression of cellular damage related to transformation. These studies utilize primarily human and rodent cells in culture.

Modification of Radiation Effects (Need 3.12)

Methods to modify radiation-induced cell transformation, mutagenesis, and carcinogenesis are being studied. Included in these investigations are comparisons of high- and low-LET radiations in producing cell transformation; effects of various environmental factors, such as oxygen concentration, temperature, and non-ionizing radiations; and various chemical and pharmacologic agents on X-ray-induced mutation and transformation. These studies are conducted primarily on cells in culture. The NIH is the primary funding agency; in FY81, 7 projects were funded at a level of \$260,000.

ANIMAL RADIOBIOLOGY

Animal Radiobiology--Radiation Carcinogenesis, Mutagenesis, and Teratogenesis (Needs 3.13-3.15, 3.17, 3.18)

Studies in animal radiobiology, as described in Table III-1, comprise the greatest funding effort by the various Federal agencies, particularly the DOE and the NIH. Since animal experiments are inherently more expensive than cell research, more money was allocated to these needs.

Studies on radiation mutagenesis in laboratory animals are identified in Need 3.13. Projects include assessment of dominant lethal mutations in spermatogenic cells after photon or particulate radiation exposure; genetic effects of Pu-239; determination of genetic risks in first generation offspring by skeletal analysis; characterization of the nature of specific-locus mutations by genetic, cytological, and biochemical means for the purpose of relating these treatments to mutational spectra; and tritium toxicity in germ cells.

Studies on radiation carcinogenesis are identified in Needs 3.13 through 3.15. Experiments are being carried out to investigate the effects of different total doses and dose delivery schedules on the incidence of various cancers in laboratory animals, including mice, rats, and dogs, in order to develop dose-response curves to predict cancer risks at low doses of radiation. Studies on the interaction of various host and environmental factors on radiation carcinogenesis are also being carried out. These studies will help clarify mechanisms of radiation carcinogenesis, including the roles these factors play in initiation and promotion. Included in these studies are the role of hormones in mammary cancer, the role of immunodepression in the development of cancer, the effect of neonatal and adult thymectomy on the prevalence of cancer, and the interaction of various chemicals, such as chemotherapeutic agents and DMBA (7, 12 dimethylbenz(a)anthracene), with radiation to produce cancers. To conduct all the studies in 3.13 (mutagenesis and carcinogenesis), the DOE allocated \$4.2 million to 8 projects; the BRH spent \$688,000 on part of one project; and, the NIH spent \$1.7 million on 20 projects (FY81 figures). For Needs 3.14 and 3.15 (interaction of various host and environmental factors on radiation carcinogenesis), the DOE spent \$1 million on 4 projects; the DOD spent \$440,000 on 4 projects; and the NIH spent \$297,000 on 10 projects (FY81 figures).

Studies on radiation teratogenesis (Need 3.17) include determination of the incidence of neoplasia and malformations in rats and mice irradiated in utero, analysis of behavioral and functional changes occurring in rodents irradiated during development, and effects of radiation exposure on the developing central nervous system in rats. The NIH and the DOE are conducting these studies, with the NIH sponsoring 5 projects for

\$210,000 and the DOE 1 project for \$125,000 in FY81. The BRH study, identified in Need 3.13 above, also addresses health effects in the beagle dog after radiation exposure in utero (part of one project, \$685,000).

Several projects are concerned with the modification of radiation effects, particularly carcinogenesis (Need 3.18). For example, in beagles injected with Pu-239 or Am-241, chelation therapy with Zn-DTPA or Ca-DTPA (diethylenetriaminepentaacetic acid) is being investigated as a means of reducing the cancer risk; in other studies, hormone treatments are being used to modify radiation carcinogenesis, especially in breast neoplasia. The DOE sponsored 5 projects for \$1.3 million in FY81; the NASA spent \$480,000.

Fate of Inhaled or Ingested Radionuclides (Need 3.16)

Research in this area is almost totally sponsored by the DOE. The radionuclides of concern in this category are fission products such as Sr-90, I-131, Ce-144, and tritium (H-3), and actinides such as Pu-239, Am-241, and Cf-252. Research on the metabolism and fate of these radionuclides in animals has been ongoing for several decades so that current projects have well-defined objectives and fall into one of several groups. The largest group of projects is providing dose-response data (such as dose versus cancer incidence or life span shortening) for actinides (20 projects funded at an FY81 level of \$7.1 million). Within this group, the actinide being studied most extensively is Pu-239, and the most common mode of administration of the actinides is by inhalation of well-characterized particles, both soluble and insoluble, by beagles and rodents. Also included in this group of projects are several studies on injected actinides and isotopes of radium in beagles and rodents in order to establish a relationship between the known dose-response data for radium in humans (watch dial painters) and the dose response data for actinides in humans.

The second largest group of projects (18 projects at an FY81 funding level of \$2.8 million) involves studies on the metabolism and tissue localization (fate) of actinides. Again, the actinide most frequently studied is plutonium, and the means of entry are principally via inhalation, with a few projects utilizing ingestion or injection. Besides plutonium, other actinides studied include Np-237, various isotopes of U, Am-241, and Cm-244.

The next largest group of projects (8 projects funded at an FY81 level of \$864,000) focuses on dosimetry of internal emitters, modeling dose-response relationships, biological factors which may alter the metabolism of, and response to, internal emitters, and physicochemical characterization of aerosols of actinides and fission products. The smallest group of projects (7 projects at an FY81 level of \$2 million) involves studies on tritium and

fission products such as I-131, Kr-85, Sr-90, and Ce-144. These studies are quite evenly divided, in terms of the objectives, between determining metabolism and fate of the radionuclides versus dose-response relationships. The small size of the group reflects the relatively well-understood behavior of fission products in biological systems.

COMMENTS ON STRATEGY REPORT AND FREIR REPORT RECOMMENDATIONS

Molecular and Cell Biology

The Federal Strategy and FREIR Reports have made the following recommendations concerning research needs in molecular and cell biology.

STRATEGY RECOMMENDATION. Physicochemical and biological studies at cellular and molecular levels are of high priority. Such studies offer the most likely means of obtaining information on the biological effects of ionizing radiation at levels of exposure at which the probability of observing such effects in animals (including humans) is very small. Of particular significance to establishing better dose-effect relationships for cancer induction and genetic effects are additional studies on repair of DNA damage.

Physicochemical and biochemical studies are of high priority. Such studies offer the most likely means of obtaining information on the biological effects of ionizing radiation at levels of exposures at which the probability of observing such effects in animals (including humans) is very small. Of particular significance to establishing better dose-effect relationships for cancer induction and genetic effects are additional studies on repair of DNA damage.

FREIR RECOMMENDATION (4). The committee recommends that future studies in the field of radiation biology place increased emphasis on an understanding of the mechanisms of radiation carcinogenesis. This is particularly important with respect to carcinogenesis following low doses of low linear energy transfer (LET) radiation. This research should involve cellular and molecular experiments combined with selected studies on irradiated animals and appropriate observations of irradiated human populations. The committee encourages the design and conduct of experiments that test the current concepts in models of carcinogenesis in general and radiation carcinogenesis in particular.

FREIR RECOMMENDATION (5). The committee recommends that future research on radiation genetics place increasing emphasis on resolving the uncertainties surrounding the nature of genetic damage and its biological consequences whether or not radiation is used as a probe of the system. Such research should be directed toward observations not only on single cells from animals and plants but also of whole organisms.

These recommendations reflect the importance of molecular and cellular research, not only in improving the understanding of mechanisms of damage and repair, but also as the potential key to better quantitative understanding of effects having very low incidence (e.g., carcinogenesis following low doses of low-LET radiation). Based on the review of projects supported by the various Federal agencies, it is clear that much effort is directed toward understanding DNA damage and repair, radiation mutagenesis, and carcinogenesis. However, a major problem in the progress of these studies is the difficulty in identifying particular biologically-relevant lesions in DNA and other cellular structures. Without this knowledge, studies on repair of radiation damage will be necessarily limited. Studies related to radiation mutagenesis and carcinogenesis in *in vitro* systems have provided valuable information concerning the nature of these effects at very low doses of radiation. Though many questions remain unanswered, the key unresolved question is the molecular basis of radiation cell killing, mutagenesis, and carcinogenesis, i.e., what is the nature of the molecular lesions in the cell, and of the associated repair processes responsible for cell killing, mutation, and transformation?

Animal Radiobiology

The Federal Strategy and FREIR Reports have made the following recommendations concerning research needs in animal radiobiology.

STRATEGY RECOMMENDATION. Animal studies designed to derive risk estimates for cancer and genetic effects and to better define metabolic pathways and organ distributions of radionuclides require continued support. In order to obtain useful information from life span studies, long-term commitments of resources are necessary.

FREIR RECOMMENDATION (5). The committee recommends that future research on radiation genetics place increasing emphasis on resolving the uncertainties surrounding the nature of genetic damage and its biological consequences whether or not radiation is used as a probe of the system. Such research should be directed toward observations not only on single cells from animals and plants but also of whole organisms.

FREIR RECOMMENDATION (6). The committee recommends the continuance of research on radiation effects on whole organisms, especially studies evaluating these effects in appropriate subpopulations and the physiological and metabolic processes that determine dose distributions in both time and space from internal and external radiation sources.

These recommendations indicate the importance of continued support of animal radiobiology research. The response of a complex organism cannot be fully predicted on the basis of molecular and cellular research. Because there is a deficiency of data on human responses to radiation exposure, animal studies are important to an understanding of the metabolic processes which determine dose distribution of internally incorporated radionuclides and of the response of complex biological systems, including repair mechanisms, to both internal and external radiation exposure.

Ionizing radiation is probably the most extensively studied carcinogen in man. Yet, little information is available about cancer risks at low radiation doses. Other questions which remain incompletely answered include: are there tissues and organs yet to be identified which are particularly sensitive to radiation carcinogenesis? and, why do tissues and organs vary in their sensitivity to cancer induction? Numerous studies sponsored by the various Federal agencies are actively seeking answers to these and other questions about radiation carcinogenesis.

Cancer induction is the chief somatic effect of radiation at low doses. However, genetic damage to the germ cells is also important since mutations in germ cells can be passed on to future generations. To date, no significant genetic damage has been reported in the Japanese atomic bomb survivors, the largest source of data on human radiation exposure. However, more sensitive detection methods of mutational damage are needed. Thus, it is important to continue to develop and evaluate mutational assay systems in laboratory animal systems to assess the genetic effects of low levels of radiation exposure.

The developing embryo and fetus are relatively radiosensitive. In medical radiodiagnosis, irradiation of patients during unsuspected pregnancies occurs occasionally. There are not enough data to accurately evaluate the risks of developmental abnormalities, postnatal neoplasia, and other effects that may be produced by low doses of radiation. Compared to other animal radiobiology studies (e.g., radiation carcinogenesis and mutagenesis), relatively little effort is directed toward understanding the teratogenic effects of radiation. Increased support of radiation teratogenesis studies should be encouraged.

Inhalation and ingestion of radionuclides is a major source of radiation exposure in the nuclear fuel cycle. In order to pro-

protect nuclear workers and the general population, it is important to evaluate environmental and metabolic pathways of all radionuclides in the nuclear fuel cycle. Small and large animal research is valuable in developing models of internal dosimetry that may be applicable to man in assessing radiation risks. Much information has already been collected on a number of important radionuclides, especially fission products and transuranics. However, continued support is still necessary to evaluate other radionuclides such as those listed in Need 3.16.

Table III-1

RESEARCH NEEDS IN THE BIOLOGICAL SCIENCES

(Chapter III of the Strategy Report)

- 3.1 Studies to characterize and measure quantitatively the full spectrum of lesions produced in DNA, particularly when irradiated in vivo
- 3.2 Continued efforts to elucidate the basic mechanisms of DNA replication and repair
- 3.3 Research to identify those radiation-induced lesions in DNA and other structures which are repairable, and the extent to which each is repaired in human cells in vivo
- 3.4 Studies to correlate certain biological end-points with specific lesions in DNA or other structures
- 3.5 Studies of "single-hit" or linear dose effects, their possible dependence on dose rate, and how they are influenced by the rates of molecular and cellular repair processes
- 3.6 Studies on the underlying mechanisms of mutagenesis in microorganisms and cultured animal cells
- 3.7 Investigations on radiation-induced chromosome anomalies to determine the functional significance of such lesions
- 3.8 Studies of the relationship(s) between cell killing, mutation, and transformation
- 3.9 Increased efforts to elucidate the mechanisms of cell transformation, both by radiation and other agents, and its relationship to carcinogenesis
- 3.10 Research to clarify the role of "initiators," "promoters," and other agents which may influence the process of carcinogenesis
- 3.11 The development of new cellular systems for in vitro investigations of transformation, including diploid cells rather than polyploid cell "lines," from appropriate individuals with identifiable genetic diseases, cancer, etc.
- 3.12 Studies to determine which agents are additive to, synergistic with, or antagonistic to the different effects of ionizing radiation, and how these act

- 3.13 Population studies to determine the dose-response characteristics of different types of radiation and for different time patterns of dose delivery for carcinogenesis, mutagenesis, and teratogenesis
- 3.14 Studies of the influence of host factors on radiation effects utilizing model animal systems, including radiation-sensitive, repair-deficient, and other specialized animal strains
- 3.15 Studies to characterize the interaction between radiation and toxic or carcinogenic chemical agents
- 3.16 Research on the fate of inhaled and/or ingested radionuclides and the biological effects which may be produced in specific tissues and organs
- 3.17 Studies on the long-term effects of fetal irradiation leading to cancer, birth defects, or other abnormalities
- 3.18 Studies of the mechanisms of the induction of radiation effects (cancer, birth defects, etc.), including the promoting and modifying conditions and the underlying bases for variations in susceptibility

Table III-2

NUMBER OF FY81 PROJECTS RELATED TO RESEARCH NEEDS
IN THE BIOLOGICAL SCIENCES

RESEARCH NEED	BRH	DOD	DOE	FEMA	NASA	NIH	NRC	NSF	USDA
<u>Molecular and Cell Biology</u>									
3.1		1	2		1	2			
3.2			4			5		4	
3.3									
3.4		1	5			13			
3.5	2		1			8			
3.6			5	1		8		3	
3.7			2			4			
3.8			2			12			
3.9			3		1	8		1	
3.10						3			
3.11			2			2			
3.12		1				7			
<u>Animal Radiobiology</u>									
3.13	1	1	8			20	3		2
3.14		4	2			6	1		
3.15			1			4			
3.16		1	48			4	7		
3.17	1		1			5			
3.18		3	5			6			

Table III-3

FY 1981, 1982, AND 1983 FUNDING RELATED TO RESEARCH NEEDS
IN THE BIOLOGICAL SCIENCES
(In Thousands of Dollars)

RESEARCH NEED	BRH			DOD			DOE			FEMA			NASA			NIH**			NRC			NSF			USDA*					
	81	82	83	81	82	83	81	82	83	81	82	83	81	82	83	81	82	83	81	82	83	81	82	83	81	82	83			
Molecular and Cell Biology																														
3.1				40	40	40	99	223	101																					
3.2										105	215					174														
3.3							710	712	637							274			140	150	180									
3.4				50	50	50	483	522	406																					
3.5	19	30	28				120	80	80																					
3.6							219	311	125	50	50	80				881														
3.7							486	480	367							481												125	160	190
3.8							477	482	430							291														
3.9							936	783	677							703														
3.10							25	70	70							363									50	90	100			
3.11							150	150	185							125														
3.12							40	40	40							52														
Subtotal	19	30	28	130	130	130	3682	3743	3018	50	50	80	25	175	285	3922												315	400	470

Table III-3 (Continued)
 FY 1981, 1982, AND 1983 FUNDING RELATED TO RESEARCH NEEDS
 IN THE BIOLOGICAL SCIENCES
 (In Thousands of Dollars)

	BRH			DOD			DOE			FEMA			NASA			NIH**	NRC			NSF			USDA*			
	81	82	83	81	82	83	81	82	83	81	82	83	81	82	83		81	82	83	81	82	83				
RESEARCH NEED																										
<i>Animal Radiobiology</i>																										
3.13	688	378	3	200	225	250	4237	4735	4184																	
3.14				439	400	450	244	315	285																	
3.15							780	750	650																	
3.16							215	300	12107	12016	10500															
3.17							125	120	120																	
3.18																										
Subtotal	1373	753	3	759	1050	1225	18796	19221	16860																	
Total	1392	783	31	889	1180	1355	22478	22964	19878	50	50	80	508	834	987											

* Other agencies (NBS, DOL, EPA, CDC) did not identify research in areas related to Chapter III.
 ** FY81 only. It may be assumed that FY82 and FY83 budgets are similar to FY81.
 + FY81, FY82 only.

IV. EPIDEMIOLOGY AND THE HEALTH SCIENCES

The principal focus of Chapter IV of the Strategy Report is to define research needs designed to directly study the biological effects of ionizing radiation exposures on humans. Although limited to a few unique populations, such studies do not require extrapolations from animal studies, which complement and supplement the human data. The primary purpose of epidemiologic research is to assess the human health risk at radiation doses too low to cause immediate health effects. However, large populations and accurate exposure measurements are required in order to draw conclusions, conditions lacking in most populations studied thus far. In this section, a review is made of the extent to which Federal research efforts are attempting to fulfill the needs in epidemiology and clinical research. Table IV-1 is a listing of research needs, Table IV-2 shows the number of FY81 projects by Federal agency, and Table IV-3 is a summary of funding for research related to needs listed in Chapter IV of the Federal Strategy. It was not productive to construct a table showing funding by agencies classified according to need because almost every project addressed multiple needs.

Human Population Genetics (Needs 4.1-4.2)

The DOE supports several epidemiologic and genetic studies of Japanese populations exposed to the atomic bomb explosions in Hiroshima and Nagasaki. These studies include long-term epidemiologic follow-up of two generations of children born to exposed parents, and are designed to detect increases in the number of mutations, genetic diseases, and cancers. Other studies on both the parents and subsequent children are designed to detect subtle differences, major abnormalities, or absence of any of 35 different proteins. This work has required determination of the feasibility of using two-dimensional electrophoresis for detecting changes in several hundred proteins per sample.

Another DOE project is attempting to link the demographic data of Icelanders born since 1840 into pedigrees, and make various medical health and performance data available to provide a baseline for epidemiologic, genetic, and radiation effects studies.

Human Epidemiology (Needs 4.3-4.12)

Research needs in the area of human epidemiology are being funded principally by the NIH and the DOE; however, all agencies shown in Table IV-2 support projects addressing one or more of these needs.

The NIH supports studies on induction of cancer by medical radiation exposure, including diagnostic and therapeutic procedures. Several of these studies are designed to determine the incidence of cancer in patients previously given radiotherapy, particularly for benign disease. Included are children with tinea capitis, children previously treated with radiation and chemotherapy or irradiated for lymphoid hyperplasia, cervical cancer patients, and patients treated for Graves' disease. In another study, the primary objective is to evaluate radiation-induced chromosome damage in humans following radiotherapy for lymphoid hyperplasia and following diagnostic X-ray exposures in cervical cancer patients. Epidemiologic studies are also in progress to determine the incidence of cancer following other selected radiodiagnostic procedures. These studies include follow-up of fluoroscopically-examined tuberculosis patients, and evaluation of the risk of leukemia and lymphoma following diagnostic X-ray exposures. Follow-up studies are also conducted among patients who had I-131 and other radiodiagnostic procedures during childhood and adolescence as well as studies to examine the relationship between incidence of parotid gland tumors and previous exposure to diagnostic dental X-rays. In addition, the NIH supports radiation-related epidemiologic studies as well as basic science studies of radiation cataractogenesis.

The DOE projects emphasize epidemiologic studies of cancer induction, genetic diseases, and other health effects in atomic bomb survivors and persons with either occupational or environmental radiation exposure. Two major DOE studies are defining the risk of cancer induction in Japanese atomic bomb survivors. These studies are designed to characterize radiation-induced cancer in terms of tissues at risk; dose-response relationships; and the effects of radiation quality, age at exposure, and potentially modifying environmental and host factors, particularly for breast and lung cancer.

The induction of cancer following occupational and environmental exposure to radiation is the subject of seven studies. In one study, the major objective is to determine any delayed health effects in workers who have been exposed to low levels of ionizing radiation for many years in DOE facilities; another evaluates lung cancer incidence in uranium miners. Others evaluate the risk of cancer in X-ray technologists and of multiple myeloma and brain tumors in physicians exposed to repeated low-dose radiation. The effects of exposure to small concentrations of plutonium and other transuranics on a general

population living in a contaminated area are also being investigated.

The DOE Health and Mortality Study attempts to establish dose-response relationships for low-level exposures. Included are specific substudies on Hanford employees and workers exposed to plutonium. In several studies, the effects of demographic and lifestyle factors on sensitivity to radiogenic cancer as well as the interaction of radiation with other toxic agents in producing neoplastic disease are investigated. The conduct of epidemiologic studies requires refinement of analytical methods and the development of more sensitive biometric methods and procedures to facilitate the acquisition of exposure and outcome data, so a substantial portion of the resources for the larger studies has been devoted to these needs. Comparatively less effort has been devoted to investigations of the effects of radiation quality, dose rate, and differential tissue sensitivity.

Other agencies perform and/or support epidemiologic studies on a somewhat smaller scale. The FDA/BRH supports studies related to diagnostic medical radiation exposure. The NRC, the EPA, the CDC/NIOSH, and the CDC/CEH provide other occupational and environmentally-related radiation studies.

Human Birth Defects (Needs 4.13-4.14)

A number of Federal agencies support projects which address one or both of these needs. Studies of Japanese atomic bomb survivors, supported primarily by the DOE with some additional support by the NIH, represent the major source of human data on teratogenic effects of ionizing radiation. Further analyses of these data include recalibration of dose-response characteristics based on the expected new dose data. In FY83, a project will be initiated to study reproductive outcomes among Hanford employees. The EPA is funding a retrospective study at the Mayo Clinic to evaluate prenatal radiation exposures and the incidence of birth defects. The CDC/CEH occasionally carries out field investigations of birth defects related to radiation exposure or utilizes data from the Birth Defects Monitoring Program for such analyses.

Other Somatic Effects (Needs 4.15-4.20)

Three NIH projects involve basic science studies related to radiogenic cataracts; biochemical and cytopathologic mechanisms of radiogenic cataracts are being investigated. A major focus of DOE-supported studies is the determination of dose-response relationships for a variety of biological end points. This effort spans a wide range of doses and includes several unique populations, in particular Japanese atomic bomb survivors, radium dial painters, nuclear shipyard workers, and the DOE center

employees. Complementary studies on samples of these populations emphasize elucidating the fate of internally-deposited radionuclides by radiochemical, autoradiographic, and histopathological analyses, and evaluation of the clinical consequences of such internal exposure.

COMMENTS ON STRATEGY REPORT AND FREIR REPORT RECOMMENDATIONS

STRATEGY RECOMMENDATION. Current epidemiologic studies of atomic bomb survivors, uranium miners, radium-dial painters, and many of the various groups of people exposed to ionizing radiation for medical reasons warrant continued high-priority support. Other groups, such as workers in nuclear research and defense installations, in facilities for nuclear power generation, and medical patients, also warrant study if the exposures are sufficiently high and the populations large enough that the studies are scientifically sound and technically and economically feasible. These studies should be designed to provide the most information possible on the effects of age, sex, and confounding factors, such as smoking and exposure to nonradioactive toxic materials. To increase the value of all studies, it is important to develop standardized methods of obtaining radiation exposure and medical data. The support of further development of methods and techniques in biostatistics for use in human and laboratory studies is strongly recommended.

FREIR RECOMMENDATION (3). The committee recommends that currently-supported, large-scale epidemiologic studies on the health effects of ionizing radiation be continued with periodic peer review until they have reached their logical conclusions. Meanwhile, Federal agencies supporting epidemiologic research in this field should reexamine their priorities and confine future scientific research to areas that are likely to yield statistically reliable data. The committee recognizes that social and political processes may require responses in the form of surveys and epidemiologic studies even when such efforts are predictably unrewarding scientifically. In such cases, a clear distinction should be made between these studies and those that are scientifically justifiable.

Both the FREIR Recommendation 3 and the Federal Strategy Report recognized the importance of direct human study and urged continuation of large-scale epidemiologic studies, but cautioned that future studies should be carefully considered and designed.

Exposed populations with adequate exposure data are limited. Most populations were exposed for purposes other than scientific research, resulting in relatively poor documentation of demography and exposure. In fact, planned animal experimental studies are often the only reasonable way to acquire data through deliberate exposure. Therefore, the only available populations for such study are atomic bomb survivors, persons exposed through the weapons program to low levels of mixed radiation, and persons with occupational or medical exposure.

From this review of epidemiologic studies supported by the Federal agencies, it appears that the majority of the needs in this category of research are being met to the extent that they can be, that is, that available radiation-exposed populations that have been identified as useful for scientific study are being followed. As new study opportunities are identified and examined for scientific merit, and as many of the current projects reach additional conclusions, the described research needs will be further met. Regarding current projects, continued funding of the projects studying the atomic bomb survivors is critical to the overall Federal program and must be supported adequately until its scientific objectives are met, which probably means the remaining lifetime of the present study population.

It is also important to recognize that meeting the scientific objectives of epidemiologic studies is highly dependent on the development of procedures to acquire medical, occupational, and exposure records. Such a recordkeeping system requires the evaluation and establishment of a means to link multiple data, including exposures to other carcinogenic and mutagenic agents from a variety of sources. A universal identifier, such as Social Security number, is needed to overcome constraints due to preservation of confidentiality and privacy.

Table IV-1

RESEARCH NEEDS IN EPIDEMIOLOGY AND THE HEALTH SCIENCES

(Chapter IV of the Strategy Report)

- 4.1 The development of rapid screening techniques to detect missing or abnormal proteins
- 4.2 A study to determine the feasibility of the development of a program to obtain complete medical and family histories on patients with clinical genetic disorders, in order to facilitate the analysis of such data for correlations with parental exposure to radiation or mutagenic agents
- 4.3 The integration of animal data, cytogenetic data, and the knowledge of basic radiation mechanisms with epidemiological data in order to establish dose-response relationships for low levels of exposure, as a function of the type of radiation and site of tumor
- 4.4 Studies on human populations exposed to agents in addition to radiation, in order to assess possible synergistic or antagonistic effects
- 4.5 Investigation of the effects of age, diet, general health, genetic factors, etc., on sensitivity to radiogenic cancer
- 4.6 Studies to characterize the differential sensitivity of tissues and organs to radiogenic cancer
- 4.7 Research on the role of radiation quality in the carcinogenic response to ionizing radiation
- 4.8 Studies of the effect of dose-rate on the risk of cancer
- 4.9 Investigation of the patterns of appearance of radiogenic cancer with time and their relationship to the temporal patterns of spontaneous cancer
- 4.10 The refinement and development of epidemiological designs and biostatistical methods to improve the sensitivity of epidemiological studies by accurately correcting for extraneous variables
- 4.11 The development of procedures to facilitate the acquisition of medical, occupational, and exposure records for radiation and other toxic agents, possibly utilizing the Social Security record system
- 4.12 The preliminary screening of populations exposed to ionizing radiation to select those which may be suitable subjects for epidemiological studies

- 4.13 Efforts to construct dose-response relationships for teratogenic effects of fetal exposure at different developmental stages for different types of radiation and LETs, from both animal experiments and existing human data
- 4.14 Studies to assess the placental transfer of radionuclides
- 4.15 Further investigations of the mechanisms of impaired organ functions, such as radiation-induced eye cataracts in animals
- 4.16 Studies to improve quantitative estimates of the effect of radiation exposures on human fertility from existing human exposure data
- 4.17 Studies on human populations, animals, and cellular systems to determine the significance, if any, of radiation-induced chromosome anomalies
- 4.18 Studies to determine the dose-response relationships for the effects of radiation exposure on the increased susceptibility to disease, impaired organ function, reduced capacity of physiological systems, and a general lowering of health status
- 4.19 Studies on the clinical consequences of radionuclide deposition at specific internal sites (e.g., liver, lungs, and bone), including post-mortem pathology
- 4.20 The development of complete and easily accessible medical records which include radiation exposure data as well as exposure information on other toxic agents

Table IV-2

NUMBER OF FY81 PROJECTS RELATED TO RESEARCH NEEDS
IN EPIDEMIOLOGY AND THE HEALTH SCIENCES

RESEARCH NEED	CDC	BRH	NIH	DOD	DOE	EPA	FEMA	NRC
4.1			1	1	3			
4.2				1	1			
4.3	3		17		6		2	2
4.4	6	1	5		2			5
4.5	3	1	11		1			5
4.6	4	2	13		1			
4.7	2	1	2		1			
4.8	2		1					
4.9	5	1	7					
4.10	4	1			6			
4.11	6		1		4			
4.12	3	1						
4.13	3	1			1	1		1
4.14	3					1		
4.15			3					
4.16			1		2			
4.17			1		1			
4.18					10			
4.19					6			
4.20					2			

Table IV-3

FY 1981, 1982, AND 1983 FUNDING RELATED TO RESEARCH NEEDS
IN EPIDEMIOLOGY AND THE HEALTH SCIENCES
(In Thousands of Dollars)

RESEARCH NEED	CDC		BRH		NIH		DOD		DOE		EPA		FEMA		NRC													
	81	82	83	81	82	83	81	82	83	81	82	83	81	82	83	81	82	83										
Genetic Effects																												
Human Epidemiology	490	459	245	87	550	550	550	30	50	50	1,741	1,908	1,703															
Birth Defects					4,429	5,023	4,084				6,516	7,209	6,602															
Chromosomal Effects					90	47	2				1,879	1,950	1,950	613														
Totals	490	459	245	177	47	2	4,979	5,573	4,634	30	50	50	17,681	18,255	18,516	613												
																180	205	130	475	350	650							
																						100						
																							180	205	130	475	350	750

V. SOURCES OF EXPOSURE TO RADIATION

Chapter V of the Strategy Report focuses on the transport of radionuclides in the environment; their movement through air, land, and water; the possibility of their concentration in components of the food chain; and the extent of their return to man. Although care has always been taken to dispose of toxic radionuclides in parts of the environment away from contact with man, nevertheless, the ability of plants and animals to incorporate materials from their surroundings provides an inadvertent but major pathway to man. On the other hand, the ability of the environment to absorb, dilute, and render harmless some pollutants can be used to help us solve our disposal problems, which grow each year. Learning the strengths and weaknesses of the natural environment is needed if we are to make maximum use of the assimilative capacity of our surroundings, with minimum impact on human and environmental health.

Sources of radiation exposure are given in Table V-1, while the division of effort in this research, in terms of numbers of projects in each area, appears in Table V-2. In Table V-3 is a breakdown in funding levels for FY81, 82, and 83 in each category, by agency, to compare with the projects in Table V-2. Finally, Table V-4 summarizes information given in more detail in Tables V-2 and V-3 so that the total program can be more easily visualized. These research efforts are described below.

Transport of Radionuclides in the Environment (Need 5.1)

The largest portion of environmental research on radionuclides is directed towards characterizing the environmental transport of man-made isotopes. Such information helps to map environmental distribution and permits calculations of radiation dose to the human population. This area is represented by 54 projects targeted mostly on transuranic elements and long-lived fission products. This information is important to the assessment of impacts of radioactive waste disposal.

Studies of radionuclides in the terrestrial environment receive approximately \$3.4 million. About \$1 million is devoted to studies of natural radioisotopes, the rest to reactor products and fallout. Some research is performed on the natural oxidation of tritium in ecosystems and its subsequent distribution. Two projects focus on the movement of radionuclides from mill tailings.

Studies of the marine environment received about \$2.7 million, the majority of the work being for study of transuranic and selected reactor products in the oceans, including coastal and

estuarial areas. Studies of rivers and watersheds comprised about 25 percent of the total marine-oriented funding.

Of the \$2 million for atmospheric studies, approximately \$1.3 million is devoted to a stratospheric study of selected radionuclides and trace gases, with the data interpreted in terms of worldwide distribution patterns. Other studies in this category include the definition of meteorological factors influencing mechanisms of particle resuspension for radioactive waste sites, and the development of atmospheric dispersion models for tritium and krypton. This support is expected to decline to \$400,000 in FY83.

About \$1.5 million is presently directed to the development of improved models of transport and fate of radionuclides.

Approximately \$2.6 million is directed towards site-specific projects, including radioecological studies at the Nevada Test Site and in the Marshall Islands.

Human Exposure to Radionuclides in the Environment (Need 5.2)

Studies of radon, highlighted in the FREIR Report as a high-priority study area, received \$428,000 in FY81. The DOE (\$290,000) sponsors studies to characterize levels of radon concentration in homes, and the environmental factors influencing the observed levels. Additionally, transport processes for radon in and near the Earth's surface are detailed. An EPA study focuses on technology assessments relating to the control of radon in underground uranium mines (\$138,000) and mill tailings.

Approximately \$1.6 million was allocated in 1981 for studies related to this need, which focuses on the assessment of environmental sources directly exposing humans, such as radon from building materials.

Food Chain Pathways of Radionuclides (Need 5.3)

In quantifying human intake of radioactivity, it is important to detail food chain pathways. Present research includes uptake and movement of radionuclides from soil to plants to humans, and organ uptake of radionuclides from foods. The activities supported in this category received about \$3.4 million in FY81. Of this, \$60,000 is applied to studies of naturally-occurring isotopes.

Occupational Sources of Radiation Exposure (Need 5.4)

The Strategy Report specifies three needs in the area of occupational exposure: (1) the characterization of aerosols and particulates produced in various phases of the nuclear fuel cycle, (2) the development of techniques for accurately measuring cosmic radiation, and (3) the development of personnel monitors for other specific occupational applications (such as uranium miners). Most of the above is summarized under other headings in this document, particularly in Chapter II. Research that uniquely relates to the characterization of sources and pathways for occupational exposure accounts for some \$700,000 per year. By way of comparison, epidemiological studies that are directed towards determining the effects on workers of occupational exposure to radiation account for \$7 million per year, a fraction of which is directed towards characterizing the source and pathway to workers.

While Chapters III and IV of the Strategy Report list the needs for investigation of interactive effects (i.e., synergistic or antagonistic combinations of radiation and chemicals--Needs 3.15 and 4.4) and for studies of potential biological indicators of internal dose effects (Needs 3.7 and 4.17), there is very little activity underway with regard to occupational populations. The need for further research on biological indicators is echoed by the Strategy Report which states: "Human clinical studies of...those accidentally ingesting or inhaling radioactive substances are desirable and include scanning methods, where possible, and direct measurements of body fluids."

Organ Dosimetry (Need 5.5)

Efforts here are funded primarily by the DOE and the NRC. Biological half-life determinations of yellowcake in the lungs of uranium millers are being performed. Excreta from millers is being evaluated for Th-230. Thorium and uranium burdens are being determined in deceased miners and millers by autopsy. Animal studies and mathematical modeling studies are being conducted to improve internal dosimetry estimates from inhalation and other routes of exposure to meet Need 3.16. Studies addressed in Chapter IV also provide information on organ dosimetry.

COMMENTS ON STRATEGY REPORT AND FREIR REPORT RECOMMENDATIONS

Environmental Sources

STRATEGY RECOMMENDATION. Research on transport of radionuclides in the environment and the refinement of pathway models describing this transport is necessary.

Environmental transport of radioactive wastes is of major interest, and research addressing this interest should receive high priority.

FREIR RECOMMENDATION (8). The committee recommends that long-term, broadly focused research programs be undertaken to increase understanding of the complex transport systems used by radionuclides in a contaminated environment. Supportive research on dietary pathways is especially important. Adequate support should also be given to the continuing development and validation of models by which radionuclide levels within the ecological system may be predicted following radionuclide contamination of the environment.

The recommendations focus on support for environmental transport modeling, improved characterization of food chain pathways, and attention to the environmental transport of radioactive waste. To that end, further information on the transfer coefficients and concentration ratios for some additional radionuclides, including naturally occurring radionuclides and those specific to waste disposal, are in need of improvements in dose predictions from ingestion. These should be determined for various expected chemical species, environmental media, food plants, and food animals including fish. Biological availability of elements at different points in the food chain should be considered.

While many radionuclides produced in fission and some transuranics are well-studied and understood, other nuclides expected to be produced by advanced power-generating systems require additional information on their environmental behavior.

Occupational Sources

STRATEGY RECOMMENDATION. Efforts to characterize major sources of radiation exposure warrant continued support. Any gaps of information, necessary for assessing health risks from these sources, should be considered for study in the other areas described in this strategy. Research addressing the health risks from exposure to radon is of high priority in this context.

FREIR RECOMMENDATION (9). The committee, therefore, finds that practical methods to improve occupational dosimetry and to reduce radiation exposure require greater emphasis, and urges attention to vulnerable occupational groups, especially in the mining industries.

The Strategy Report recommendation urges continued support for efforts to characterize major sources, including addressing gaps in information necessary for assessing health risks. The study of interactive effects and that of biological indicators of internal exposure to occupational population address such gaps.

Additionally, both the Strategy Report and the FREIR Report urge special attention to the mining industry, focused on the health risks from exposure to radon. Given the uncertainties in dosimetry; characterization of confounding variables (smoking, diesel fumes, heavy metals); and characterization of radiation sources (radon, external gamma rays, ore dust inhalation), additional support in this area may be warranted.

Table V-1

RESEARCH NEEDS CONCERNING THE CHARACTERIZATION OF SOURCES OF
EXPOSURE TO IONIZING RADIATION

(Chapter V of the Strategy Report)

- 5.1 Empirical and theoretical studies of the transport of radionuclides in the atmosphere, and in the terrestrial and aquatic environments
- 5.2 The assessment of human exposures to radiation from radionuclides in the surrounding environment, including water supplies, building materials, etc.
- 5.3 The uptake of radionuclides in the environment by living organisms, and the passage to human populations through the food chain
- 5.4 Studies to determine specific sources and routes of exposure in occupational settings
- 5.5 Research to elucidate the fate of radionuclides inhaled or ingested by humans and to assess the radiation doses received by specific organs and tissues

Table V-2

NUMBER OF RESEARCH PROJECTS RELATED TO RESEARCH NEEDS
TO CHARACTERIZE SOURCES OF EXPOSURE

RESEARCH NEED	DOE	EPA	NIH	NRC
<u>Environmental Sources</u>				
5.1	47	2		6
5.2	11	1	3	2
5.3	21		3	
<u>Occupational Sources</u>				
5.4	7	2		2
5.5	18	2	1	6

Table V-3

FY81, 82 AND 83 FUNDING FOR RESEARCH RELATED TO NEEDS
TO CHARACTERIZE SOURCES OF EXPOSURE
(In Thousands of Dollars)

RESEARCH NEED	DOE			EPA			NIH*	NRC		
	81	82	83	81	82	83	81	81	82	83
<u>Environmental Sources</u>										
5.1	6,618	7,077	5,735	220	100	0		237	430	0
5.2	2,058	2,342	2,301	7	0	0	240	110	0	0
5.3	3,230	3,543	3,556					255	265	0
<u>Occupational Sources</u>										
5.4	476	732	342	158	150	0	131	0	10	100
5.5	<u>3,348</u>	<u>3,198</u>	<u>3,111</u>	<u>138</u>	<u>0</u>	<u>0</u>	<u>69</u>	<u>628</u>	<u>195</u>	<u>280</u>
Total	15,730	16,892	15,045	523	250	0	440	1,230	900	380

*FY81 only.

VI. SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

In Chapters II-V, the Federal research programs are analyzed according to research needs. This chapter examines and summarizes these findings in the context of the comprehensive program supported by the Federal government. Based on this summary, conclusions are drawn and presented that express the judgments of the IRRC subcommittee concerning the adequacy of the Federal program to meet the research requirements recommended by the IRRC in its 1981 Strategy Report and by the NAS in its 1981 FREIR Report. The appropriateness of the research conducted by a given Federal agency in meeting its responsibilities is reviewed, and recommendations are offered to improve the Federal program.

SUMMARY

In compiling the Federal projects, underway or planned, relevant to the research needs and recommendations stated in the Strategy and FREIR Reports, a substantial amount of radiation research conducted by Federal agencies for other purposes was not included. This includes over \$30 million by the NIH for preclinical and clinical radiotherapy investigations; over \$16 million by the DOD for the Nuclear Test Personnel Review and for evaluating human performance degradation shortly after exposure to acute high doses of mixed-field radiation; all high energy physics research sponsored by the NSF and the DOE; over \$6 million by the DOE for support services relevant to the medical surveys of the Marshallese; for environmental support related to the remedial action program at former uranium mill tailing sites; and for evaluating high-level waste disposal options in subseabeds and various geological formations.

Table VI-1 provides a comparison of total annual budgets for the period FY79 through FY83 for comparable scopes of research projects covered in Chapters II-V of this report. The funding has remained approximately constant at a level of approximately \$90 million through FY82 and falls to its lowest level in FY83.

In Table VI-2, the total annual budgets for FY81, 82, and 83 are shown for the four major categories of research identified in the Strategy Report: approximately 10 percent for physics, chemistry and instrumentation; 40 percent for the biological sciences; 30 percent for epidemiology and health studies; and 20 percent for studies that characterize radiation sources in terms of

environmental and workplace conditions involving human exposure. Thus, about 70 percent of Federal support is in research that directly investigates radiation effects in biological systems and humans.

In Tables VI-3, VI-4, and VI-5, budgets for FY81, 82, and 83 are shown. In these tables, information is listed by specific research areas within a designated Strategy Report category and the supporting Federal agency. While the budgets shown for FY81 and FY82 are believed to be accurate, budgets for FY83 can only be estimated at this time for several reasons, primarily because the actual FY83 budgets are not yet known.

The DOE supports a research effort that addresses nearly every area of need expressed in the Strategy Report. In FY81, it provided about \$63 million or 70 percent of the total Federal funding. The NIH program places major emphasis on research in molecular and cell biology and animal radiobiology (approximately \$6.6 million) and in cancer epidemiology studies (approximately \$4.4 million). Together, the DOE and the NIH support about 85 percent of the total radiation research effort at a level of approximately \$75 million. Except for the NRC's program, which is funded at a level of about \$4 million, the research programs in other agencies are each less than \$2 million. These programs and the DOD program are entirely related to specific research objectives of the sponsoring agencies.

CONCLUSIONS

Federal resources are being used in research projects that seek answers to the research needs given in the Strategy Report. This effort addresses broad research categories and the scope of research supported by the Federal agencies is consistent with that outlined in the Strategy Report. Within any category, some research is supported, but in some instances perhaps not to the degree warranted.

As shown in Table VI-1, Federal funding over the period 1979 through 1983 amounts to about \$90 million per year. When inflation is taken into account, the FY83 projection is some 40 percent less than the funding five years ago. Although the Subcommittee has not traced the historical funding for research in the biological effects of ionizing radiation, it is known that a decade ago the DOE (then the AEC) effort alone in medicine and biology was about \$100 million per year. This constancy in available annual funding over the period 1979 through 1983 does, in fact, represent a decrease in the level of effort that can be undertaken. Ironically, this decrease in available funds has taken place during a period of increased public concern and controversies arising in spite of our extensive knowledge of the biological effects of radiation.

Although it may be concluded that the distribution of Federal funding for radiation research among the various categories is generally consistent with the identified needs, some needs are not being adequately addressed. Reductions in "real" dollars not only reduce the continuing programs, but also inhibit new research initiatives. The net result is that recommendations suggesting a high priority be given to specific research areas have, in some cases, not yet been implemented.

Perhaps the key example is the inadequacy of funding for new initiatives or expanded programs to materialize on studies of mechanisms of radiation interactions and the consequent manifestations of chemical and biological transformations, despite the high-priority recommendations in both the Strategy and FREIR Reports. Clearly, there is still a need for an interdisciplinary approach that closely couples detailed dosimetry with chemical and biological studies. These studies, which are needed mainly at the molecular and cell culture level and which can make use of the latest advanced techniques and technologies in biological research, hold the greatest promise of resolving the nature of macromolecular lesions and allowing a better quantitative definition to be made of dose-response relationships at low radiation doses and dose rates.

Other examples of research where the identified priority is not reflected by sufficiently expanded programs include (1) development of a new generation of mixed-field personnel and area monitors for more reliable occupational dosimetry, (2) further development of personal air samplers for radon decay products in underground mines, and (3) development of improved models of environmental transport of radionuclides important in high-level waste disposal.

On the other hand, support to initiate a number of epidemiologic studies appears to have grown during the past few years, in some instances for studies that may, at best, be able only to refine estimates of the upper limits of health effects from low doses. However, carefully designed and controlled epidemiologic studies of human populations are the cornerstone for our current estimates of health risk, and those having scientific merit are irreplaceable in this regard.

Ongoing studies of populations exposed to low levels of radiation appear adequate for investigating classical epidemiologic outcomes such as morbidity and mortality, given continued long-term support. However, much important information on the basic mechanisms of disease induction could be gained by expanding current studies to examine cellular, biochemical, metabolic, and chromosomal endpoints. Furthermore, additional emphasis should be placed on studying the interactions between exposure to radiation and exposure to other toxic substances.

A continued effort is needed to determine more accurate and precise environmental transport and food chain variables for long- and intermediate-lived radionuclides not as extensively studied as, for example, plutonium. Many of the present estimates are derived from collateral data and in some cases, such as technetium, by comparison with analog elements. Some of these values are uncertain by as much as two orders of magnitude. Field validation experiments of food chains to humans are needed, in particular, in order to appraise the reliability and accuracy of the dose assessment models.

The Subcommittee concludes, also, that Federal agencies are supporting research within their mandates and responsibilities, and no unnecessary duplication is evident from this review. Although knowledge by staff of each interested Federal agency of the total Federal program can be improved, such general knowledge appears to exist and has been enhanced by this review. This sharing of information on research programs is vital because, from the analysis, it is evident that many Federal agencies are highly dependent on the broad science supported by the DOE and the NIH to meet their responsibilities of regulating radiation sources and responding to public concerns. Any reduction in research by these agencies will result in a net loss of information needed by other agencies.

Uncertainties regarding health impacts of low levels of radiation exposure, though not large compared to other toxicants, can be a major impediment to the application of technologies that may involve increased exposures to radiation and radioactivity. Further reduction in this uncertainty promises substantial societal benefit and should continue to be the major objective of Federally-funded radiation research.

RECOMMENDATIONS

The Subcommittee, in its deliberations, has formulated several views that it believes warrant further consideration by the Interagency Radiation Research Committee.

Considerable information on research projects about "who is doing what" has been assembled by the Subcommittee. While the Subcommittee has not collected this information in a standard format, it does believe that an effort should be made to computerize such information for future reference. Information collected and stored in retrievable form would be useful in judging whether or not future Federal efforts are adequately addressing scientific questions in a manner that conserves limited resources.

RECOMMENDATION. The IRRC should establish a storage and retrieval system for exchanging budget and project

information on all Federal research investigating the biological effects of ionizing radiation.

More complete implementation of the Strategy Report depends on the availability of scientists to bring creativity, scientific curiosity, and dedication for understanding the public health implications of radiation exposure. A viable research program attracts such scientists, particularly young scientists searching for areas of intellectual stimulation.

RECOMMENDATION. The IRRC should consider publicizing the research needs identified in the Strategy Report with the goal of encouraging young scientists to enter the field of radiobiology and other radiation-related disciplines, possibly by direct financial aid to students.

As noted in the conclusions, the majority of Federal agencies are dependent on the research programs of the DOE and the NIH to provide information on the biological effects of ionizing radiation needed to adequately meet their responsibilities to protect public health and the environment. It is, therefore, necessary that all agencies have an opportunity to communicate their particular research needs to the DOE and the NIH.

RECOMMENDATION. The IRRC members should use the committee as a forum for communicating their agency's specific research needs for scientific information on the biological and health effects of ionizing radiation and other related needs.

Implementation of a Federal research program that meets fully the research needs described in the Strategy Report and the recommendations in that report and the FREIR Report is not foreseen in the near future. Therefore, it is important that Federal agencies reexamine their programs and make changes to reflect the research needs within the limitations of their missions. Consequently, the IRRC should consider a follow-up review that would not only determine the state of implementation but also identify areas of research needing greater or less emphasis. This assessment could use the storage and retrieval system indicated above.

RECOMMENDATION. The IRRC should conduct, in the next 3 years, a follow-up review of the Federal program of research into the biological effects of ionizing radiation.

Table VI-1
COMPARISON OF TOTAL RESEARCH BUDGETS

FISCAL YEAR	BUDGET (In Millions)
1979	\$87.5*
1980	91.7*
1981	88.4
1982	91.4**
1983	83.4**

* Assumes expenditure for DOD and NIH at FY81 level.

** Assumes NIH expenditure at FY81 level.

Table VI-2

TOTAL RADIATION RESEARCH BUDGETS
BY STRATEGY CATEGORIES

CATEGORY	FY81	FY82	FY83
Physics, Chemistry, and Radiation Measurements	\$11,535	\$12,545	\$11,850
Biological Sciences	34,305	34,433	31,326
Epidemiology and the Health Sciences	24,625	25,939	24,327
Characterization of Sources of Exposure to Ionizing Radiation	<u>17,923</u>	<u>18,482</u>	<u>15,865</u>
Total	\$88,388	\$91,399	\$83,368

Table VI-3
 FY81 RADIATION RESEARCH FUNDING
 (In Thousands of Dollars)

RESEARCH	NH	DOC	BH	DOE	NRC	DOD	EPA	NES	FEMA	USDA	NSA	NSF	DOI	TOTAL
RESEARCH NEEDS IN PHYSICS, CHEMISTRY, AND RELATED ITEMS														
Radiation Physics	\$520	\$ 0	\$ 0	\$1,840	\$ 0	\$ 0	\$ 0	\$ 125	\$ 0	\$ 0	\$ 80	\$ 335	\$ 0	\$ 2,900
Radiation Chemistry	330	0	0	110	0	40	0	80	0	0	0	0	0	560
Radiation Measurement	390	0	0	4,615	500	405	55	1,410	100	0	180	0	420	8,075
RESEARCH NEEDS IN THE BIOLOGICAL SCIENCES														
Molecular and Cell Biology	3,922	0	19	3,682	0	130	0	0	50	0	25	315	0	8,143
Animal Radiobiology	2,723	0	1,373	18,796	1,817	759	0	0	0	211	483	0	0	26,162
RESEARCH NEEDS IN EPIDEMIOLOGY AND THE HEALTH SCIENCES														
Genetic Effects	550	0	0	1,741	0	30	0	0	0	0	0	0	0	2,321
Human Epidemiology	4,429	490	87	6,516	475	0	0	0	180	0	0	0	0	12,177
Birth Defects	0	0	90	1,879	0	0	613	0	0	0	0	0	0	2,582
Other Somatic Effects	0	0	0	7,545	0	0	0	0	0	0	0	0	0	7,545
RESEARCH NEEDS CONCERNING THE CHARACTERIZATION OF SOURCES OF EXPOSURE TO IONIZING RADIATION														
Environmental Sources	240	0	0	11,906	602	0	227	0	0	0	0	0	0	12,975
Occupational Exposures	131	0	0	476	0	0	158	0	0	0	0	0	0	765
The Rate of Radionuclides in the Human Body	69	0	0	3,348	628	0	138	0	0	0	0	0	0	4,183
TOTAL	\$13,304	\$490	\$1,569	\$62,454	\$4,022	\$1,364	\$1,191	\$1,615	\$330	\$211	\$768	\$650	\$420	\$88,388

FY82 RADIATION RESEARCH FUNDING
 (In Thousands of Dollars)

RESEARCH NEED	NIH	CDC	BRH	DOE	NRC	DOD	EPA	NBS	FEMA	USDA	NASA	NSF	DOI	TOTAL
RESEARCH NEEDS IN PHYSICS, CHEMISTRY, AND RELATED ITEMS														
Radiation Physics	\$ 520	\$ 0	\$ 0	\$ 1,850	\$ 0	\$ 150	\$ 0	\$ 125	\$ 0	\$ 0	\$ 80	\$ 730	\$ 0	\$ 3,455
Radiation Chemistry	330	0	0	110	0	40	0	240	0	0	0	70	0	790
Radiation Measurement	390	0	0	4,740	200	730	0	1,390	200	0	270	0	380	8,300
RESEARCH NEEDS IN THE BIOLOGICAL SCIENCES														
Molecular and Cell Biology	3,922	0	30	3,743	0	130	0	0	50	0	175	400	0	8,450
Animal Radiobiology	2,723	0	753	19,221	1,420	1,050	0	0	0	157	659	0	0	25,983
RESEARCH NEEDS IN EPIDEMIOLOGY AND THE HEALTH SCIENCES														
Genetic Effects	550	0	0	1,908	0	50	0	0	0	0	0	0	0	2,508
Human Epidemiology	5,023	459	0	7,209	350	0	0	0	205	0	0	0	0	13,246
Birth Defects	0	0	47	1,950	0	0	0	0	0	0	0	0	0	1,997
Other Somatic Effects	0	0	0	8,188	0	0	0	0	0	0	0	0	0	8,188
RESEARCH NEEDS CONCERNING THE CHARACTERIZATION OF SOURCES OF EXPOSURE TO IONIZING RADIATION														
Environmental Sources	240	0	0	12,962	695	0	100	0	0	0	0	0	0	13,997
Occupational Exposures	131	0	0	732	10	0	150	0	0	0	0	0	0	1,023
The Fate of Radio-nuclides in the Human Body	69	0	0	3,198	195	0	0	0	0	0	0	0	0	3,462
TOTAL	\$13,898	\$459	\$830	\$65,811	\$2,870	\$2,150	\$250	\$1,755	\$455	\$157	\$1,184	\$1,200	\$380	\$91,399

Table VI-5

FY83 RADIATION RESEARCH FUNDING
(In Thousands of Dollars)

RESEARCH NEED	NIH	OCC	ERH	DOE	NRC	DOD	EPA	NBS	FEWA	USDA	NASA	NSF	DOI	TOTAL
RESEARCH NEEDS IN PHYSICS, CHEMISTRY, AND RELATED ITEMS														
Radiation Physics	\$ 520	\$ 0	\$ 0	\$1,730	\$ 0	\$250	\$ 0	\$ 125	\$ 0	\$ 0	\$ 80	\$150	\$ 0	\$2,855
Radiation Chemistry	330	0	0	90	0	45	0	240	0	0	0	70	0	755
Radiation Measurement	390	0	0	3,950	430	960	0	1,390	400	0	370	0	330	8,220
RESEARCH NEEDS IN THE BIOLOGICAL SCIENCES														
Molecular and Cell Biology	3,922	0	28	3,018	0	130	0	0	80	0	285	470	0	7,933
Animal Radiobiology	2,723	0	3	16,860	1,870	1,225	0	0	0	0	712	0	0	23,393
RESEARCH NEEDS IN EPIDEMIOLOGY AND THE HEALTH SCIENCES														
Genetic Effects	550	0	0	1,703	0	50	0	0	0	0	0	0	0	2,303
Human Epidemiology	4,084	245	0	6,602	650	0	0	0	130	0	0	0	0	11,711
Birth Defects	0	0	2	1,950	100	0	0	0	0	0	0	0	0	2,052
Other Somatic Effects	0	0	0	8,261	0	0	0	0	0	0	0	0	0	8,261
RESEARCH NEEDS CONCERNING THE CHARACTERIZATION OF SOURCES OF EXPOSURE TO IONIZING RADIATION														
Environmental Sources	240	0	0	11,592	0	0	0	0	0	0	0	0	0	11,832
Occupational Exposure	131	0	0	342	100	0	0	0	0	0	0	0	0	573
The Fate of Radionuclides in the Human Body	69	0	0	3,111	280	0	0	0	0	0	0	0	0	3,460
TOTAL	\$12,959	\$245	\$33	\$59,209	\$3,430	\$2,660	\$ 0	\$1,755	\$610	\$ 0	\$1,447	\$690	\$330	\$83,368

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ORAU 88/C-68

THE FEDERAL IONIZING RADIATION RESEARCH AGENDA
DELATED TO LOW LEVEL BIOLOGICAL EFFECTS: FY 1985

MARCH