DOCUMENT RESUME

04796 - [B0245103]

The Environmental Protection Agency Needs Congressional Guidance and Support To Guard the Public in a Period of Radiation Proliferation. CED-78-27; B-166506. January 20, 1978. 37 pp. + 7 appendices (44 pp.).

Report to the Congress; by Elmer B. Staats, Comptroller General.

Issue Area: Consumer and Worker Protection: Standards and Regulations Adequacy and Timeliness (902); Environmental Protection Programs: Environmental Protection Standards (2201).
Contact: Community and Economic Development Div.
Budget Function: Natural Resources, Environment, and Energy: Pollution Control and Abatement (304).
Organization Concerned: Environmental Protection Agency.
Congressional Relevance: House Committee on Public Works and Transportation; Senate Committee on Environment and Public Works; Congress.
Authority: Atomic Energy Act of 1954, as amended (42 U.S.C. 2011). Clean Air Act Amendments of 1977. Reorganization Plan Number 3 of 1970.

In 1970, the Environmental Protection Agency, (EPA) was given unclear authority to protect the American people and their environment from radiation hazards. EPA officials agree that the agency currently is unable to provide complete protection under its ambiguous authorities and that clarification by the Congress is needed. Recommendations: To overcome the apparent controversies regarding EPA's role in developing standards and Federal guidance for environmental exposure to radiation, the Congress should: define more clearly the agency's role as the Federal overseer of environmental radiation; outline the scope of radiation dangers to be determined by EPA; and require timely development of necessary standards and guidance and periodic advisement of EPA's progress in meeting its radiation protection goals. The Administrator of EPA should provide the EPA radiation protection program with sufficient support to do its job. Specifically, the Administrator should: assign additional staff and resources as available to the program, reexamine the environmental monitoring network and develop the capability to provide accurate and complete information on radiation dangers, coordinate EPA research with that performed by others, require that reports on radiation levels in the environment be continued and issued at least annually, and develop a comprehensive assessment of the need for standards and guidance such as those required for radioactive air pollutants. (Author/SC)

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REPORT TO THE CONGRESS

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

The Environmental Protection Agency Needs Congressional Guidance And Support To Guard The Public In A Period Of Radiation Proliferation

A clearer understanding of the Environmental Protection Agency's responsibilites for providing guidance in radiation matters could lead to more efficient protection of the American people and their environment from the hazards of radiation.

This report discusses a need to better define radiation authorities assigned by law to the Agency so that jurisdictional confrontations may be eliminated and staffing and funding limitations may be corrected.

CED-78-27

JANUARY 20, 1978

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-166506

To the President of the Senate and the
Speaker of the House of Representatives

This report discusses a need to define the radiation authorities of the Environmental Protection Agency to eliminate jurisdictional confrontations and correct existing staffing and funding limitations. A clearer understanding of the Environmental Protection Agency's role could lead to a more efficient program to protect the American people and their environment from the hazards of radiation.

We made our review pursuant to the Budget and Accounting Act, 1921 (31 U.S.C. 53), and the Accounting and Auditing Act of 1950 (31 U.S.C. 67).

Copies of this report are being sent to the Acting Director, Office of Management and Budget; the Administrator, Environmental Protection Agency; the Chairman, Nuclear Regulatory Commission; the Secretaries of the Departments of Energy; Health, Education, and Welfare; and Labor; and to interested congressional committees, various Members of Congress, and other interested parties.

Comptroller General
of the United States

COMPTROLLER GENERAL'S
REPORT TO THE CONGRESS

THE ENVIRONMENTAL PROTECTION AGENCY NEEDS CONGRESSIONAL GUIDANCE AND SUPPORT TO GUARD THE PUBLIC IN A PERIOD OF RADIATION PROLIFERATION

D I G E S T

Everyone in American society is exposed to some form of radiation daily. Sources include natural environment, dental and medical X-rays, nuclear powerplants, homes built on radioactive landfill, clocks and watches with luminous dials (to a much smaller degree), and some food products. (See pp. 1 to 5.)

The Environmental Protection Agency in 1970 was given unclear authority to protect the American people and their environment from radiation hazards. Its officials agree with GAO that the Agency currently is unable to provide complete protection under its ambiguous authorities and that clarification by the Congress is needed. (See pp. 7 and 36.)

The Agency's radiation programs have been plagued by

--jurisdictional challenges to the Agency's authority,

--staffing and funding reductions,

--an inability to retain competent professionals,

--limited cooperation with other agencies and research groups, and

--low priority placed on radiation protection.

Of all Environmental Protection Agency programs, radiation protection is the least funded. Continual reductions in radiation protection staff and budget, transfers of professionals to other Agency programs, and discussions with Agency officials currently working at the Office of Radiation Programs lead GAO to the conclusion that

the Environmental Protection Agency has not been given enough support in its radiation protection efforts. (See pp. 15 to 19 and 21 to 26.)

This means that (1) the Agency's program for monitoring radiation levels to which the American people currently are exposed is limited and (2) without extensive changes, the Environmental Protection Agency will continue to be limited in its ability to protect public health and the environment from radiation dangers.

The Agency does not know the scope of dangers caused by all current radiation sources and is unable to anticipate future problems adequately. Some data is incomplete and inadequate. It does not have sufficient staff or money to perform necessary research and so it has not fully secured available data or developed new data. It has been unable to issue timely standards and guidance and has been consistently unable to meet its own deadlines for issuing significant reports, standards, and guidelines. (See pp. 29 to 33.)

The Agency received two authorities for providing radiation protection when it was created in 1970. It can

--issue standards for radioactivity in the environment, including general environmental guidelines for particular industries and for radiation doses to the public, and

--provide guidance to Federal agencies affecting all forms of radiation protection in Federal activities. (See pp. 7 to 9.)

To date from these authorities the Agency has issued one standard--currently not enforced--and has issued no new formal guidance to other Federal agencies. (See pp. 11 to 15.)

Much of man's exposure to radiation is from unavoidable natural background sources as compared to manmade sources. It is recognized that improvements in radiation techniques and control could reduce exposure.

As the sources of radiation increase, the health of the general population may be adversely affected. Because genetic effects are involved, radiation exposure affects the lives of future generations.

Many of the materials that emit radiation have the potential to contaminate the environment for years, some for hundreds of thousands of years. After they've been used in the production of weapons, in the manufacture of electricity, etc., these materials become waste which must be disposed of safely without contaminating drinking water, future home sites, food supplies, or the natural environment.

There have been problems in disposing of nuclear waste materials safely. In some instances accidents have occurred, and in others the dangers were not understood until after contamination had already taken place. (See p. 1.)

RADIATION PROTECTION PHILOSOPHY AND STANDARD

Federal policy is based on the axiom that nuclear energy and the medical, agricultural, scientific, and industrial uses of radiation are essential for human advancement. The proliferation of existing applications and the development of new technology mean that the total sources of radiation are increasing and will continue to increase. The Environmental Protection Agency currently sees its radiation responsibility as balancing potential damage to health and the environment against the benefits of radiation use.

When the Agency issued its first standard on January 13, 1977, after 6 years of development and delays, it established a new criteria for exposure to individual members of the public and limited the quantities of long-lived radioactive materials entering the general environment. (See pp. 10 to 11.)

A HISTORY OF PROGRAM REDUCTIONS

Over the years the Environmental Protection Agency has reduced its emphasis on radiation control. In

1972 funding and overall staffing levels were at a high of $8.8 million and 335 positions. The Agency's request for fiscal year 1978 is $4.8 million and 184 positions for radiation abatement and control. As a result, morale in the Agency's radiation program is low and most people interviewed said that there is not adequate staff, data, laboratory support, or research to do an effective job.

In the beginning of the program, all of the Agency's radiation efforts were centralized in its Office of Radiation Programs. This office had the task of developing guidance and standards and monitoring the environment. Agency officials said that funding and staffing for the office has been cut drastically over the years to the point that further reduction will directly affect its mission capabilities. They explained that because the Congress has not mandated specifically that the Agency provide radiation protection, this protection has not received the same priority as other authorized Agency programs. (See pp. 21 to 22.)

AN INADEQUATE MONITORING NETWORK

The Environmental Protection Agency operates the only nationwide network for monitoring levels of radiation in the environment. Officials responsible for development of criteria, guidance, and standards repeatedly emphasized to GAO that the network and individual field measurement studies are limited and do not support the Agency's full informational needs in all areas. Network monitoring officials said that because of program curtailments, periodic population exposure readings result in an estimated 40 percent of American people not being monitored. (See pp. 22 to 23.)

INABILITY TO SET PRIORITIES

In October 1976 the Agency outlined a draft of the Agency's radiation protection strategy. This called for placing priority on radiation problems that pose the greatest threat to public health and the environment. However, officials told

GAO that staff shortages have prevented the Agency from projecting all needed standards and guidance for the future.

In May 1976 the Environmental Protection Agency acknowledged in a published report that " * * * there are radiation sources for which data are either incomplete or not available * * *" and that much of the existing information is of questionable value. For example, medical X-rays contribute to a large, significant dose of radiation, but the Agency does not know how large and significant the dose actually is. Nor does the Agency sufficiently understand the relationships between exposure to some forms of radiation and their consequences in order to issue reliable predictions. More must be learned about the effects of amount and duration of exposure. The Agency admits that it does not know all the radiation sources that may provide a danger to health and the environment nor do measurements exist for many of the sources that have been identified as a potential threat. (See pp. 29 to 30.)

RECOMMENDATIONS TO THE CONGRESS

To overcome the apparent controversies regarding the role of the Environmental Protection Agency in developing standards and Federal guidance for environmental exposure to radiation, the Congress should:

--Define more clearly the Agency's role as the Federal overseer of environmental radiation.

--Outline the scope of radiation dangers to be determined by the Agency.

--Require timely development of necessary standards and guidance and periodic advisement of the Agency's progress in meeting its radiation protection goals.

RECOMMENDATIONS TO THE ADMINISTRATOR

The Administrator of the Environmental Protection Agency should provide his radiation protection program with sufficient support to do its job. Specifically the Administrator should:

--Assign additional staff and resources as available to the Office of Radiation Programs and to the radiation research program.

--Reexamine the environmental monitoring network and develop the capability to provide accurate and complete information on radiation dangers.

--Coordinate Agency research with that performed by others so that appropriate data can be compiled and developed in a timely manner.

--Require that reports on radiation levels in the environment be continued and issued at least annually.

--Develop a comprehensive assessment of the need for standards and guidance such as those required for radioactive air pollutants.

--Develop standards and guidance based on an explicit time and priority determination of the greatest or potential risks.

--Issue Federal guidance and standards based on that timetable. (See p. 35.)

AGENCY COMMENTS

In a December 1977 letter (see app. II) commenting on GAO's proposed report, the Environmental Protection Agency advised that it has planned or started actions on all GAO recommendations. The Agency recognized the problems in operating a national radiation protection program under its authorities and agreed that congressional clarification of its authorities would be valuable. (See p. 36.)

Comments on the proposed report from other Federal agencies are contained in appendixes III to VI. These agencies cite their own radiation protection activities as active, aggressive, and comprehensive efforts even in the absence of Environmental Protection Agency actions. They generally agreed, however, that a need exists for the Congress to mandate a clearer understanding of responsibilities for environmental and public health protection. (See pp. 37.)

Contents

ABBREVIATIONS

AEC	Atomic Energy Commission
DOE	Department of Energy
DOL	Department of Labor
EPA	Environmental Protection Agency
ERDA	Energy Research and Development Administration
GAO	General Accounting Office
HEW	Department of Health, Education, and Welfare
HUD	Department of Housing and Urban Development
NRC	Nuclear Regulatory Commission

CHAPTER 1

INTRODUCTION

The Environmental Protection Agency (EPA) estimates that each year thousands may contract cancer or genetic diseases as a result of exposure to radiation. Each American citizen is exposed to many sources of radiation in his or her daily life. Much of man's radiation exposure is from unavoidable natural background sources as compared to manmade sources. It is recognized, however, that further improvements in radiation techniques and control could reduce exposures.

The sources of radiation are increasing, and as they do, the health of the general population may be adversely affected. Because genetic effects are involved, radiation exposure affects the lives of future generations.

Many of the materials that emit radiation have the potential to contaminate our environment for years, some for hundreds of thousands of years. After these materials have been used in the production of weapons, in the manufacture of electricity, etc., they become waste which must be disposed of safely without contaminating our drinking water, future homes sites, the food supply, or the natural environment. However, there have been problems in disposing of nuclear waste materials safely. In some instances, accidents have occurred; in others the dangers were not understood until after contamination had already taken place. Until technology is completely developed and applied, the potential for radiation leakage exists.

RADIATION DANGER

Radiation dose is measured in units called rads. The extent of biological damage to humans depends on the type of radiation, the amount absorbed, where it is absorbed, and the time period of exposure. When the dose has been adjusted for such factors, the dose equivalent has units called rems.

There are two types of radiation: ionizing, which is produced by radioactive materials and radiation-producing machines such as X-ray equipment; and nonionizing, which is produced by radio and television transmitters, radars, microwave devices, ultraviolet light, lasers, and high-voltage transmission lines. The primary health effects associated with these two types of radiation are different; ionizing

radiation causes somatic and genetic effects; nonionizing radiation causes heat stress and neurophysiological and teratogenic effects.

Forms of ionizing radiation affects living tissue by depositing energy in the cells which can cause cell damage or destruction. High radiation doses can cause immediate death, acute radiation sickness, cataracts, sterility, cancer, and genetic damages. It has been well documented that large or prolonged radiation exposures, such as that experienced by radiologists and by the survivors of the atomic bomb explosions in Japan, result in higher incidences of leukemia and other cancers. At low radiation levels, health effects are not immediately observable and may not occur at all. Health effects such as cancer may take from 10 to 20 years or more after exposure to develop assuming they were caused by the radiation source. Therefore, the consequences of exposure to small doses of radiation, which are the most common, may not be completely known. Although massive amounts of research have been done, much of the data is not directly applicable to humans because of difficulties of relating health effects in animals to those in humans.

In 1972 the National Academy of Sciences published a report entitled "The Effects on Populations of Exposure to Low Levels of Ionizing Radiation." On the basis of this report, EPA estimated the following health risk for each million man-rems 1/ of radiation:

Estimated Health Risk From Radiation

Effect	Cases per million man-rems
Lethal cancer	200
Other cancer	200
Serious genetic damage	200

1/Rem is a unit of radiation dose equivalent applicable to all types of ionizing radiation. Man-rem is the product of the dose, measured in rems, times the number of persons exposed. For example, natural background radiation has an average exposure level of one-tenth of a rem per year.

EPA estimated that in 1970 the annual dose equivalent from both natural background and manmade radiation to the U.S. population was 43 million man-rems. In addition, EPA estimates that by the year 2000 this average radiation dose will be 72 million man-rems considering the estimated population increase. Therefore, simply because of exposure to radiation in the general environment, EPA estimates many Americans each year may contract cancer or may have serious genetic disorders.

The other form of radiation is nonionizing radiation. This is produced by such sources as television broadcast and radio transmitters, radars, microwave ovens, high-voltage electrical lines, and laser devices. Little is known about all levels of nonionizing radiation, and research programs are still attempting to assess their health effects. Exposure can cause heat stress, cataracts, disorders of the nervous system, and teratogenic effects. The thermal effects result from temperature increases in tissue caused by the radiation.

In addition to potential adverse health effects from exposure to radiation, there is a continuing risk of contamination of our land, air, water, and natural resources. For example, there are the environmental problems associated with commercial nuclear plants that manufacture electricity. One of the more serious potential accidents in such plants is a reactor core meltdown, where the loss of coolant allows a rise in temperature, overheating the core and causing a rapid melting of the fuel and rupture of the reactor structure. The occurrence of a core melt accident is extremely small. However, other accidents of lesser consequences, such as a plant fire, have already occurred. As more plants are built over the next 10 to 20 years, EPA believes that more accidents are a definite possibility.

Part of the threat to the environment comes from the lack of a facility for the permanent disposal of high-level radioactive wastes. Until technology is completely developed and applied, such wastes and other materials in the form of spent fuel elements are stored in temporary recepticles, and the potential for leakage continually exists. Contamination problems have already occurred. In 1973, for example, 115,000 gallons of highly radioactive waste products leaked into the soil at Richland, Washington. Richland also is the site of one of five low-level radioactive waste repositories. At two other sites--one at Maxey Flats, Kentucky, and the

other at West Valley, New York--environmental studies by EPA also indicate leakage.

Powerplants are not the only source of environmental problems. For example, mining operations in Colorado 1/ have resulted in a waste material called "tailings" that was used by developers as free landfill. Residents of buildings erected on the landfill were exposed to significant concentrations of radiation. In Grand Junction, Colorado, concern about the contamination caused State and Federal Government officials to recover the waste in, under, and around some houses and to relocate some schools. In Florida, residents of buildings erected on reclaimed phosphate mines were exposed to "undesirable" concentrations of radiation.

Landowners in the vicinity of a Rocky Flats, Colorado, nuclear weapons plant filed lawsuits because of contamination from leaking radioactive materials. Local county officials claimed that the area has increased levels of radiation, and there is public health concern for residents living on land that has been contaminated.

THE NEED FOR PROTECTION

EPA has grouped ionizing radiation into three general categories:

1. Natural radiation. The radiation naturally present in the environment (includes both terrestrial and cosmic background radiation) accounts for about 60 percent of man's exposure. Airline passengers are exposed to higher levels because the atmosphere screens off some cosmic rays. On the same principle, miners and others involved in the discovery of fuel products are exposed to higher levels as the earth's crust is broken and radiation enters the atmosphere. Construction materials, phosphate fertilizers, and energy production further release natural radiation sources into the environment. As fertilizers are used, radiation enters the products grown and becomes part of the food cycle.

1/This environmental problem was the subject of a GAO report "Controlling the Radiation Hazards from Uranium Mill Tailings" (RED-75-365, May 21, 1975).

2. Nuclear energy applications. These sources come from producing energy by nuclear processes and include nuclear weapons and the waste products associated with their production.

3. Healing arts, commercial products, and industrial applications. These include the use of machine sources such as x-rays for medical and dental purposes and for such industrial uses as locating leaks in pipelines. Other sources include nuclear medicine and such consumer items as watches and clocks with luminous dials and smoke detectors with radioactive devices.

The exposure to ionizing radiation principally results from naturally occurring sources, some of which have been increased through man's intervention in mining and manufacturing processes, from medical and industrial applications of X-rays and radioactive materials, and from various aspects of the nuclear power industry. EPA has estimated the annual health effects from these major radiation sources as shown in the following table.

Annual Health Effects From Major Radiation Sources (note a)

Naturally occurring radioactive materials and radiation.....	
Natural background.....	12,000
Construction materials.....	1,000
Air travel.....	100
Radiation in healing arts..... (Preventable 3,000)	8,000
Nuclear activities	
Power generation b/.....	24
Weapons.....	800
Occupational.....	100
Consumer products.....	200
	22,224

a/These estimates of potential health effects are limited to cancers (including leukemia), serious genetic effects, and increases in diseases that are specifically genetic, such as certain forms of mental defects, dwarfism, diabetes, schizophrenia, epilepsy, and anemia.

b/Effects committed for releases in year 1975 which will occur over the next 100 years.

A basic EPA conclusion is that any radiation exposure may involve some risk and the biological risk (particularly cancer induction) associated with low levels of exposure can for the purpose of deriving risk estimates be assumed to be proportional to risks observed at higher levels of exposure (the linear, non-threshold concept). Risk estimates reflect the most likely estimates in the judgement of the scientists involved and their assumptions are used in calculations. The EPA estimate shows some insight into the impact of radiation sources and does not represent absolute numbers. Additional factors of man's extent of avoidability may also cause the actual effects to be higher or lower.

EPA states that most of the potential health effects from natural exposure result from uncontrollable background levels. However, an estimated 100 to 500 annual health effects resulting from increased exposure above usual background levels due to industrial processes can be avoided through various control measures.

Previous efforts to reduce unnecessary exposure to X-rays have included performance standards for equipment and improved medical practices in the use of X-rays.

Although the potential health impact from the existing nuclear energy sector is low, EPA in 1976 estimated that projected nuclear energy growth could greatly increase this problem. The estimates indicate that as many as 13,500 serious health effects could result by a combination of krypton-85, tritium, iodine-129, and Carbon-14 releases from nuclear industry activities by the year 2000, given no additional controls beyond those currently in effect.

For nonionizing radiation sources there exists a potential threat to personnel and equipment from such sources as radar, radiofrequency communication devices, microwave ovens, and high-voltage transmission lines. Until about 1945 there was little concern about the environmental levels of nonionizing radiation. Since then, the electronics, navigation, and communications industries have increased. Thousands of sources currently operate and the number of radiofrequency and microwave sources alone is estimated to be increasing at fifteen percent annually. Therefore, until fully studied, there could be significant exposures in environmental levels of nonionizing radiation at these frequencies.

LEGISLATIVE RESPONSIBILITIES

The President created EPA by Reorganization Plan Number 3 of 1970. It was thought that an independent agency would give greater attention to the importance of setting environmental radiation standards and guidance for protecting health and the environment.

The Reorganization Plan transferred to EPA from the Atomic Energy Act 1/ certain radiation authorities. One authority was that of providing overview guidance to all Federal agencies. Before EPA was created, the President had a Cabinet-level Federal Radiation Council, which was to "consult qualified scientists and experts in radiation matters * * * and qualified experts in the field of biology and medicine and in the field of health physics * * *" to "* * * advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in formulation of radiation standards * * *." In creating EPA, the President dissolved the Federal Radiation Council and transferred its authority to the new agency. This gave EPA the power to make recommendations to the President which, if approved, would be published as guidance to the appropriate Federal regulatory agencies. The Departments of Health, Education, and Welfare (HEW); Energy (DOE); Housing and Urban Development (HUD); and Labor (DOL); and the Nuclear Regulatory Commission, etc., all have jurisdiction over various programs relating to radiation hazards and currently are enforcing existing radiation standards. Thus, any new EPA guidance would assure uniformity and would eliminate diversity in Federal radiation standards. Although recommendations made by EPA in the exercise of this statutory authority are only advisory, according to NRC officials once the President approves such recommendations as guidance, Federal agencies may not issue standards and regulations under their existing statutory authority which are inconsistent with EPA guidance.

The Atomic Energy Act governs the development, use, and control of nuclear power. A second radiation authority given to EPA was to establish generally applicable environmental standards for the protection of the general environment from radiation and radioactive materials. It was not deemed necessary to give EPA authority to set standards on radiation

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1/The Atomic Energy Act of 1954, as amended, (42 U.S.C. 2011 et seq.)

inside nuclear facilities; such internal standards are currently established and implemented by NRC and DOE. NRC regulates nuclear facilities used in the manufacture of commercial electricity, while DOE has radiation jurisdiction over weapons plants and for energy research and development.

Through these authorities EPA has had a unique responsibility for protecting the general population and the environment from the dangers of radiation. Although these authorities do not provide for direct enforcement, EPA's guidelines and environmental standards are to be enforced by the appropriate Federal regulatory agencies.

Since 1970, EPA's radiation protection authority has been supplemented by other important legislation. Following are some of the most important:

1. Federal Water Pollution Control Act of 1972.

2. Toxic Substances Control Act of 1976.

3. Resource Conservation and Recovery Act of 1976.

4. Safe Drinking Water Act of 1974.

5. Clean Air Act Amendments of 1977.

6. Marine Protection, Research, and Sanctuaries Act of 1972.

In 1973 the President issued an Executive order which requires that EPA provide "leadership" for prevention, control, and abatement of environmental pollution at Federal facilities in a nationwide effort to protect the general environment from the hazards of radiation. While this leadership role and the other assigned radiation authorities were not specifically included in the scope of our review, the difficulties EPA has experienced in carrying out these two specific authorities reflect on the Agency's ability to provide leadership.

The Deputy Assistant Administrator for Radiation Programs said that EPA's approach is to respond to current problems, cooperate with other Federal agencies, and prevent or reduce avoidable adverse health effects from radiation exposures. In its first year of operation, the Office of Radiation Programs spent over $7.5 million to carry out its responsibilities. In 1978 it requested only $4.8 million. Radiation protection is the least funded program in EPA.

In the future, the Clean Air Act Amendments of 1977, enacted on August 7, 1977, will give the EPA Administrator new authority to establish standards to control emissions of radioactive pollutants into the ambient air. The amendments will require within 2 years a determination if such pollutants will cause or contribute to air pollution that may endanger public health. This will allow EPA to regulate radioactive pollutants under several options of the Clean Air Act Amendments. EPA will also be required to study the effect on the public health and welfare of radioactive pollutants in the ambient air.

SCOPE OF REVIEW

We reviewed the effectiveness of EPA's environmental program for developing radiation guidance and standards on the basis of its Reorganization Plan Number 3 authorities. We reviewed relevant documents and interviewed responsible officials at EPA. Since these authorities require the cooperation of the appropriate agencies, we also reviewed materials and spoke to officials in those Federal agencies. In addition, we reviewed pertinent reports and interviewed representatives of various State, industry, and public interest organizations involved in radiation activities. The review was performed at EPA headquarters in Washington, D.C., at the Agency's Eastern Environmental Radiation Facility in Montgomery, Alabama, and at its Las Vegas, Nevada, facility.

CHAPTER 2

DELAYS IN ISSUING ENVIRONMENTAL RADIATION PROTECTION STANDARDS

EPA's radiation program has not effectively and completely accomplished its goals of preventing radiation contamination to the environment and protecting public health. After 6 years of operation, it has failed to (1) issue under the authorities discussed a single standard which is being enforced or (2) provide new formal guidance to Federal agencies. It has been engaged in a series of jurisdictional conflicts with the Federal agencies whose cooperation is needed to implement EPA's radiation authority. Not only is EPA's authority questioned, but there have been challenges to the Agency's technical ability to perform its duties.

RADIATION PROTECTION PHILOSOPHY

Federal policy is based on the axiom that nuclear energy and the medical, agricultural, scientific, and industrial uses of radiation are essential for human advancement. As a result, the proliferation of existing applications and the development of new technology mean that total sources of radiation are increasing and will continue to increase. EPA currently sees its radiation responsibility as balancing potential damage to health and the environment against the benefits of radiation use.

The Agency's policy statement 1/ assumes that no matter how low the level of radiation exposure, some potential for damage to health and the environment will exist. The assumption is based on a "linear hypothesis" that the adverse health effects are in proportion to the amount of the radiation dose.

Known health effects from high-dosage exposures, such as the atomic bombings in Japan, are extrapolated in a straight line to predict the effect of low doses. In the absence of conclusive experiments on exposure to low levels of radiation, this use of a mathematical formula provides a numerical figure on the numbers of persons who may be affected. EPA assumes that for the purposes of setting

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1/A complete text of this statement is found on p. 38.

radiation standards and making environmental analysis, these mathematical projections are a prudent method of determining risk. Before EPA was created, Federal agencies with jurisdiction in radiation matters relied on broad guidelines established by the Federal Radiation Council. One guideline established in 1960 set a limit of 500 millirems a year for exposure to individuals in the general population. With the exception of natural background radiation or purposeful exposure of patients by medical doctors, the radiation dose should not exceed that 500 millirem limit from any manmade radiation exposure, including nuclear powerplants.

EPA's RADIATION PROTECTION STANDARD

When EPA issued its first standard on January 13, 1977, after 6 years of development and delays, it established--at 25 millirems--a new criteria for exposure to any individual members of the public and limited quantities of long-lived radioactive materials.

EPA did not rely on its guidancemaking authority, inherited from the now defunct Federal Radiation Council. (That authority will be discussed in ch. 3.) Rather, it exercised the powers transferred from the Atomic Energy Act which related to protection of the general environment from radioactive material.

Today, uranium is the primary ingredient used in the commercial manufacture of nuclear energy, and in order for electrical energy to be produced, uranium goes through what is called a fuel cycle. Each step in the cycle is a potential source of radiation exposure. The EPA standard applies to the following steps of the cycle:

1. Milling the uranium ore.
2. Chemically converting the uranium ore to a purer form.
3. Enriching the uranium in its percentage of uranium 235.
4. Fabricating the fuel.
5. Generating electricity by the light-water-cooled nuclear powerplant.
6. Reprocessing the spent fuel.

Other steps in the cycle that are not covered by the standard are:

1. Mining the uranium ore.

2. Transporting the radioactive materials.

3. Disposing of the waste.

EPA is currently studying these steps to determine whether additional standards are needed.

The EPA standard requires that applicable steps of the uranium fuel cycle will not release so much pollution into the environment that any member of the public will be exposed to more than 25 millirems of radiation. The 25-millirem limitation is in addition to all other sources of exposure. This will affect relatively small populations near mills and conversion and fabrication plants because most fuel cycle operations are now conducted well within these guidelines. This portion of the standard is scheduled to go into effect on December 1, 1979, except for milling operations, which will be implemented by December 1, 1980.

NRC has regulatory authority over the country's commercial nuclear plants and must use the EPA standard as the basis for regulations which it will publish and enforce. EPA, to assure that its standard is being met, plans to (1) oversee and monitor NRC implementation actions, (2) evaluate NRC's regulations, (3) keep current with what the nuclear industry is doing, and (4) study reactors and fuel cycle processes. EPA officials admit that this work needs to be done but say that resource limitations on monitoring and field studies may prevent them from doing as much as they would like. EPA envisions taking actual field measurements on one or two facilities a year, with primary reliance on the NRC and on reports from individual operators to find out whether its standard is being met. (See ch. 4 for problems EPA has been having with monitoring radiation hazards.)

Another section of the published standard would limit the quantity of radioactive materials entering the general environment from the applicable steps in the uranium fuel cycle. The standard limits irreversible contamination of the local, national, and global environment due to releases of radioactive krypton-85 (half-life 10.7 years), iodine-129 (half-life 17 million years), and transuranics

(half-life 18 years to 2 million years). EPA estimates the total reduction in potential health effects through the year 2000 to be in excess of 1,000 cases of cancer, leukemia, and serious genetic effects, on the basis of the assumed level of annual nuclear production of electrical power by that year. In some instances, technology has not been developed or is not yet in place for controlling the release of these substances. Therefore, for scientific and other jurisdictional reasons, all parts of EPA's nuclear power operations standard will not be effective until January 1, 1983.

DEVELOPMENT DELAYS

EPA interpreted its authorities as a mandate to (1) define the scope of the environmental problems and (2) establish standards on the basis of the problems it had discovered. In 1971, it began examining the uranium fuel cycle. EPA decided that separate standards were needed to deal with the health problems that might be caused by each specific step in the cycle. On August 16, 1973, EPA proposed for interagency review standards for the fuel supply, reactors, and reprocessing. It decided that these processes provided the most significant potential danger; reducing potential hazards in the fuel cycle was EPA's first priority.

In 1973 the now defunct Atomic Energy Commission (AEC) had regulatory responsibility for all nuclear facilities. In commenting on the proposals, AEC opposed the EPA standards. EPA's authority to issue such standards stemmed from that portion of the Atomic Energy Act which related to protecting the general environment from hazards caused by nuclear facilities. The authority did not include those hazards that remained within the boundaries of those plants. AEC, which then had that responsibility, argued that the EPA standards were a wasteful, unnecessary, and conflicting duplication of AEC's authority and were not technically supportable. EPA disagreed and argued that its environmental credibility would be jeopardized if the standards were not issued.

On December 7, 1973, the Office of Management and Budget adjudicated the dispute in favor of AEC. It ordered EPA to discontinue its plan to issue the standards, stating that EPA had exceeded its authority. The Office of Management and Budget ruled that rather than establish standards for specific steps in the nuclear fuel cycle, EPA should set limits on the pollutants released into the general environment and leave it up to AEC to regulate how the

individual steps in the cycle would conform to the total limitations. The Office of Management and Budget also called for mutual cooperation between the two agencies.

EPA and AEC officials met to discuss strategy, and on May 10, 1974, EPA published in the Federal Register an advance notice of intent to propose ambient environmental radiation protection standards for the uranium fuel cycle. On January 19, 1975, AEC was dissolved when its authority was transferred to ERDA and NRC. On May 29, 1975, EPA circulated its standards for written comments and public review. Public hearings were held in March of 1976, at which time representatives of the general public, the industry, professional groups, the States, and other Federal agencies questioned whether EPA had jurisdiction and whether its standard was necessary, reasonable, or capable of being implemented.

On the basis of the hearings and comments, changes were made in the standard which deleted the transportation area in the uranium fuel cycle, extended the time period for implementation, and allowed the regulatory agencies discretion in granting temporary or unusual variances from the standard. EPA officials explained that it took them 6 years to develop a nuclear power operations standard which has yet to take effect during a period of unresolved conflicts with other Federal agencies and low staff morale at EPA.

CHAPTER 3

FAILURE TO ISSUE ENVIRONMENTAL RADIATION PROTECTION GUIDANCE

The previous chapter discussed some of the problems EPA has been having in issuing standards for the general environment and public health from avoidable radiation hazards. Part of EPA's radiation protection authority stems from the responsibilities transferred to it from the Federal Radiation Council, which will be discussed in this chapter, and from the relevant sections of the Atomic Energy Act, which was discussed in the previous chapter. EPA's attempt to implement its responsibilities from both sources has resulted in challenges to its authority and technical competence and considerable disagreements in getting cooperation with the relevant regulatory agencies.

STAFF DEFICIENCIES

The Federal Radiation Council provided advice on radiation matters. The advice took the form of guidance, signed by the President, which the appropriate Federal agency would be required to implement in its specific regulations. In order for EPA to effectively carry out its Federal Radiation Council-inherited responsibilities, it must know how present guidance is working, what effect various changes would make, and what additional guidance is necessary. The Federal Radiation Council was comprised of the heads of many Government agencies and was able to draw on the many staff and financial resources of these agencies. EPA officials said that EPA currently does not have this type of support or authority to direct other agencies to do specific types of investigations. EPA receives support at the technical level through participation of certain agencies on working groups. A former Federal Radiation Council member told us that EPA has neither the scientific leadership nor the expertise to adequately perform its guidance role. In fact, many of EPA's program staff believe that EPA has largely ignored its Federal Radiation Council-transferred authority in terms of resources assigned or requested to fully implement this authority. Although EPA has offered interpretations and reaffirmation of existing guidance in areas involving exposures to uranium miners, fallout incidents, and aircraft contamination and exposures to people traveling on aircraft carrying radioactive shipments, no formal new guidance has been issued through the White House.

During 1976 EPA allocated approximately 30 staff-years to its radiation guidance role. Current EPA programs in developing guidance include efforts in medical X-ray, occupational radiation exposure, plutonium contamination, radiation exposure in structures built on reclaimed phosphate land, radioactive waste disposal, nonionizing radiation exposure in the general environment, and Protection Action Guides related to nuclear incidents.

EPA officials said that limited resources have prevented them from addressing all problems and that many more staff would be required to do all the necessary background work. 1/ To overcome these limitations, EPA has formed four interagency working groups--occupational safety, medical radiation, naturally occurring radiation, and waste disposal--to develop new guidance and obtain the needed expertise.

The working group on occupational safety has only one full-time EPA professional. Guidance on occupational safety is being further delayed because EPA's Office of Radiation Programs has given staff priority to developing waste disposal standards and guidance. During 1976, two professionals working on medical radiation and naturally occurring radiation were reassigned to waste disposal. Currently, medical radiation is assigned only one EPA staff-year, and the coordinator for the working group said the process of collecting data, holding meetings, and timely review by other Federal agencies add additional delays to developing guidelines. He said that EPA has little control over the speed at which other agencies do the necessary backup work.

The working group on naturally occurring radiation is also assigned only one EPA staff-year. The division director for EPA's Criteria and Standards Division of the Office of Radiation Programs explained that staff for Federal guidance must be rotated frequently to meet other Office of Radiation Programs demands. EPA's timetables for issuing guidance on occupational safety, waste disposal, medical radiation, and naturally occurring radiation have all slipped. Guidelines scheduled for 1976 and early 1977 have been delayed.

1/ Ch. 4 discusses resource limitations in greater detail.

JURISDICTIONAL DISPUTES AND X-RAY SAFETY

In 1972 the National Academy of Sciences report entitled "The Effects on Populations of Exposure to Low Levels of Ionizing Radiation" stated that medical diagnostic radiology accounts for at least 90 percent of the total manmade radiation dose to which the U.S. population is exposed. The report cited estimates that improved technical and educational methods could result in a 50-percent reduction of the "genetically significant dose."

Of the over 22,000 yearly potential health effects of leukemia, other forms of cancer, and serious genetic disorders and diseases which EPA estimated could be caused by radiation, approximately 8,000 were attributed to radiation in the healing arts. EPA believes that as many as 3,000 cases per year could be prevented by eliminating excessive or unnecessary exposure to medical X-rays. EPA singled this out as a radiation source in which a major further reduction in existing levels of exposure was possible.

For several years, EPA experienced considerable difficulties in getting complete cooperation from DOL and HEW. Cooperation with these two agencies is essential because they have a responsibility and have issued regulations protecting workers and the general public against the hazards of medical X-rays. DOL and HEW must incorporate any new EPA-developed guidance in their existing regulations. DOL's Occupational Safety and Health Administration has the authority to protect workers including technicians and others working with medical X-ray machines.

In September 1973 EPA attempted to establish a working agreement with HEW for developing guidance. In October 1973 HEW stated

> "We believe that Public Law 90-602 (Radiation Control for Health and Safety Act of 1968), the medical device provisions of Chapter V of the Federal Food, Drug, and Cosmetic Act, and Section 301 of the Public Health Service Act require HEW to maintain its present leadership role in the promulgation of standards and guidelines in the use of medical equipment."

EPA disagreed with HEW's conclusions about exposure in the healing arts and continued to work on guidance. In July 1974 EPA sent an invitation to the appropriate Federal

agencies requesting representatives to participate in an interagency working group chaired by EPA. The purpose of the working group was to assist EPA in initiating a comprehensive Federal effort to reduce unnecessary radiation exposure. Both HEW and DOL declined to participate formally, stating that EPA's proposed working group was a duplication of their X-ray protection authority and that EPA did not have a role in Federal guidance for medical or occupational radiation.

In July of 1974, the Secretary of HEW stated that medical radiation is the "top priority" of the Food and Drug Administration's Bureau of Radiological Health and that over half of its 397-person staff and over $8 million of its budget are used in this effort. He said that the Bureau has already issued performance standards for medical and dental X-ray machines and is working on standards for the use of those machines. The Secretary suggested

> "Since our review process in the development of such guidelines considers all facets of their impact and will include an environmental assessment analysis and impact statement, if required, we feel they could readily be adopted without considerable expense or staff on your part. We feel that this would also negate the need for an EPA-chaired ad hoc interagency work group."

In January 1977 EPA published in the Federal Register 12 medical radiation recommendations and noted that the report of the interagency working group--on which the recommendations were based--was also available for comment. In February 1977 formal comments, HEW said

> "No research results or validation of the recommendations * * * were contained in the report. No detailed analysis of medical contradictions to these recommendations was included and no adequate consideration has been given to their likely consequences * * *."

An EPA official stated that the Agency has not yet formally responded to HEW comments.

Over the years, numerous letters from DOL and HEW have questioned EPA's legal authority over medical radiation. In March 1977 HEW stated that EPA's radiation protection authority

applies only to nuclear materials. HEW stated that the Presidential Reorganization Plan, which created EPA, only transferred to EPA radiation authority under the relevant sections of the Atomic Energy Act of 1954. Therefore, HEW concluded that EPA cannot legally issue guidance or advice on X-rays or any nonionizing radiation.

EPA disagrees. It states that

> "The Federal Radiation Council function transferred to EPA gives EPA full authority to advise the President with respect to radiation matters directly or indirectly affecting health * * * without limitation being placed on the authority * * *."

As of December 1977 the issue had not been fully resolved.

JURISDICTIONAL DISPUTES AND OCCUPATIONAL SAFETY

EPA currently plans to propose guidance on occupational safety. It states that approximately one million American workers may be potentially exposed to ionizing radiation. EPA believes that the adequacy of existing guidelines, which were written in 1960, should be reassessed.

In September 1974 EPA invited various Federal agencies to participate in an EPA-led interagency committee. Seven agencies were represented, but DOL and HEW both declined to formally participate in developing new guidance. HEW, in December 1974, stated that the National Institute for Occupational Safety and Health and Bureau of Radiological Health has the statutory authority for preparing occupational and health standards. In 1975 DOL stated that its Occupational Safety and Health Administration has primary responsibility in this area. DOL's authority is based on the Occupational Safety and Health Act of 1970, and DOL informed EPA that it, in addition to regulatory authority, also has the responsibility for providing guidance on matters of occupational safety and health to workers throughout the Federal Government. As of July 1977 neither HEW nor DOL had formally participated in EPA's proposal of new guidance.

COORDINATION PROBLEMS AND WASTE DISPOSAL

One of the problems involved in the safe disposal of radioactive waste was brought to the attention of EPA when

it was learned that some homeowners in Florida were exposed to higher levels of radiation than usual. The source of exposure was found to be the reclaimed phosphate mines on which the housing was constructed. On June 24, 1976, EPA published in the Federal Register interim recommendations for adiation levels on reclaimed phosphate lands.

Although the recommendations were directed to the State of Florida, HUD was concerned that its policy of loaning Federal housing funds would be affected. HUD would, for example, be protecting future homeowners against radiation hazards by refusing to loan money to developers who planned to build on land with recorded radiation levels higher than a stipulated level. Commenting on the recommendations in an August 1976 letter, HUD stated: "We in HUD were unaware of these interim recommendations until we learned of them in a roundabout manner."

After discussions the two agencies agreed to keep each other fully informed. However, our discussions with officials in other Federal agencies and representatives of the private National Council on Radiation Protection and Measurements indicate that the coordination problems with HUD are not unique and that EPA has continually had difficulty informing other agencies and groups of its activities and drawing on their resources. Their concern was that by publishing recommended radiation exposure levels without adequate coordination, it would be difficult to establish higher radiation exposure levels even if they were warranted. In the public mind, a less restrictive level would be seen to be a compromise with the figure EPA had originally published even if EPA had agreed to it. In addition, ERDA officials raised serious questions regarding the technical adequacy and scientific justification for the recommendations and suggested guidance which EPA is presenting on environmental limits of plutonium contamination in soils. The two agencies are currently working together toward establishing the necessary protection guidance.

CHAPTER 4

LIMITED STAFF AND INADEQUATE INFORMATION

Over the years EPA has reduced its emphasis on radiation control. In 1972 funding and overall staff levels were at a high of $8.8 million and 335 positions. The Agency's request for fiscal year 1978 is $4.8 million and 184 positions for radiation abatement and control. As a result of these reductions, morale in EPA's radiation program is low and most people we interviewed said that EPA does not have adequate staff, data, laboratory support, or research to do an effective job.

A HISTORY OF PROGRAM REDUCTIONS

In fiscal years 1971 and 1972 the staff of EPA's radiation program was 335 persons. These had been transferred to EPA from the Federal Radiation Council (which was dissolved when EPA was created), from AEC, from HEW's Bureau of Radiological Health, and from HEW's Bureau of Environmental Health Services. Those 335 persons formed the staff of EPA's radiation program, and in fiscal year 1972 its operating budget was $8.8 million. Since then, EPA's Office of Radiation Programs has suffered from a continual reduction in resources, as the following chart illustrates.

Resources for EPA's Office of Radiation Programs

Fiscal year	Number of positions	Funding
1973	216	$5,352,400
1974	226	$5,659,000
1975	216	$5,263,000
1976	198	$5,008,100
1977	188	$4,543,900
1978 (estimated)	184	$4,815,000

Initially, all of EPA's radiation efforts were centralized in the Office of Radiation Programs. During 1972 research resources were transferred to EPA's Office of Research and Development. However, since fiscal year 1975, EPA's research efforts have been continually reduced both in appropriations and in staff. In 1975 EPA had 73 persons and spent $[illegible]32,000 working on radiation research. On the basis that EPA's research efforts were inadequate and duplicative of

other agencies, its radiation research staff for fiscal year 1978 had been cut to 30 staff members and a budget of $830,000.

EPA's Office of Radiation Programs has the task of developing guidance and standards and monitoring the environment. EPA officials said that the Office of Radiation Programs has been cut over the years to the point that any further reductions will directly affect mission capabilities. Several officials said that further reductions of personnel will require that certain lower priority radiation control efforts be discontinued. The officials said that the program has been drastically reduced because the Office of Radiation Programs could not compete for EPA's limited resources with other major pollution control programs. They explained that because the Congress has not specifically mandated that EPA provide radiation protection, radiation protection has not received the same priority in EPA as other congressionally authorized programs. In fiscal year 1975, for example, EPA transferred 10 staff positions from the Office of Radiation Programs to the Noise Abatement and Control Program.

EPA personnel said that resource reductions and EPA's failure to provide any radiation guidance has demoralized the Office of Radiation Programs and has caused it to lose quality staff. EPA officials said that the Office of Radiation Programs staff is spread so thin that "It's one man deep in some cases * * *." Sometimes personnel must be continually shifted among projects to meet changing priorities. This sometimes makes it difficult to attract and keep the caliber of personnel required. Office of Radiation Programs officials told us that EPA has not provided adequate support to implement an effective radiation protection program in all areas. One problem that officials pointed out was that the size of the larger regulatory agencies made it possible to overwhelm EPA during jurisdictional disputes. They pointed to some of the early confrontations with NRC and ERDA in EPA's 6-year effort to establish its nuclear regulation standard.

EPA staff members also said that their work could be accomplished much faster and more comprehensively but that the environmental monitoring and technical funding cuts over the years have frustrated their efforts by reducing the information available to support standards and guidance.

AN INADEQUATE MONITORING NETWORK

EPA operates the only nationwide network for monitoring levels of radiation in the environment. Officials responsible

for development of criteria, guidance, and standards repeatedly emphasized to us that the network and individual field measurement studies are limited and do not fully support EPA's informational needs in all areas. Network monitoring officials said that because of program curtailments over the years, EPA's periodic population exposure readings at selected locations result in an estimated 40 percent of the American people not being monitored.

EPA established its Environmental Radiation Ambient Monitoring System on July 1, 1973. It did so by adapting existing networks that had been set up originally to monitor radioactive fallout from atmospheric nuclear detonations. By rearranging the locations of the old sampling stations, EPA reoriented its monitoring more toward determining the levels of radiation to which the population is exposed. It also began monitoring the environmental levels of radioactivity more representative of materials released by various radiation sources. EPA's lack of resources has reduced the present system to a minimally operating level. This has limited EPA's objectives to estimate the public's exposure to significant radioactive pollutants, and to use such estimates in its standard-setting activities.

As of July 1977 the nationwide network included 21 continuously operating air stations, 51 stand-by air stations, 77 drinking water stations, 55 surface water stations, 64 milk sampling stations, and 19 precipitation (snow, rain, etc.) sampling stations for the entire United States. The samples are collected voluntarily by members of State and local health agencies and are mailed to EPA's Eastern Environmental Radiation Facility in Montgomery, Alabama, for analysis. Because the samples are collected by volunteers, EPA has no way of guaranteeing that they are collected regularly. The samples are analyzed--monthly, quarterly, annually, or at other intervals. The analyses provide some information on general exposure to radiation--such information, for example, comes from concentration measurements of gross alpha and beta atomic particles found in the samples. The analyses also provide information on ambient levels and trends in the environment from nuclear facilities.

Before December 1974 monitoring data was published monthly. However, due to resource constraints this data is now compiled only on a quarterly basis. Data from State monitoring programs and from other organizations is not included in the quarterly compilations. Annually, all available environmental data is published in an EPA report entitled

"Radiological Quality of the Environment." Data is analyzed and summarized with special emphasis on trends in population radiation exposure.

During 1976, 14 EPA employees were assigned to the entire monitoring network, which cost $350,000. In 1978 this program will continue to be operated with the same limited staff and budget. An EPA official told us the program curtailments over the years--funding, personnel, and organizational changes--have reduced the mission to the "bare bone," with the existing network providing only periodic population exposure readings at selected locations.

In the fall of 1976, EPA was involved in detecting, monitoring, and reporting on radioactive fallout from two nuclear detonations by the People's Republic of China. In October 1976 we reported to the Administrators of EPA, ERDA, National Oceanic and Atmospheric Administration, and NRC on the confusion and public concern that was generated because of a misunderstanding about the source and potential hazard of the resulting radioactive fallout to the American people.

We recommended that the EPA Administrator take the lead in the future collection and release of environmental information and that the other Federal agencies involved cooperate fully. Interagency memorandums of understanding outlining respective responsibilities have been drafted but are still not completed. Such action may improve public awareness of the nature and extent of danger in future cases of fallout from nuclear weapons testing.

EPA's total radiation monitoring program also includes special field studies and a computational model, which, by using meteorological data and data on airborne emissions, can provide estimates on doses that individuals and the general population may receive. The total budget for this effort, which includes the monitoring network, was $1.2 million in 1976. In fiscal years 1977 and 1978, EPA made budget submissions for only $1.3 and $1.4 million per year.

Agency officials responsible for managing the monitoring program recognize that the existing information is minimal and admit that EPA does not currently have quantitative understanding of all the radiological dangers to our health and environment. Officials said that there is no way that the EPA network can adequately monitor radiation emission from all nuclear facilities currently in existence. EPA has performed special field studies, such

as analyses of pollutants from a specific reactor site, which are useful. However, because of resource constraints, such studies are limited. Since 1971 EPA has performed complete field studies at only 4 of the 63 nuclear power facilities. Seven additional studies have been conducted on a more limited basis. EPA uses its limited information to make general assumptions. For example, it conducted a study in South Carolina to determine the radionuclide accumulation in a small cooling lake at the H. B. Robinson Nuclear Power Station. On the basis of that study, EPA assumes that other facilities operate similarly. EPA also relies on the operators of nuclear powerplants to monitor data on their facilities. This means that EPA and the regulatory agencies often depend on the facilities themselves for the information needed to regulate them.

EPA, in attempting to develop guidance on levels of plutonium contamination in the soil, for example, needs a soil-sampling data program on specific sites which it was unable to operate because of limited staff and budget. Consequently, EPA had to rely on reports from operators of ERDA's nuclear facilities for information. EPA personnel developing the guidance said they have no way of validating the data and that most of the data is not in a form that can be applied to EPA's needs.

Carbon 14 provides another example of the problems of inadequate information. Carbon 14 occurs naturally and also is released into the environment by nuclear fuel plants. Information is needed on the technology for controlling its emissions. EPA must learn what happens to Carbon 14 in the environment, how to trace it, what it does, and how to extract it from the environment for sampling purposes. Right now EPA's nuclear standard does not require that Carbon 14 be controlled.

EPA officials said that the existing network can be improved with more elaborate sampling techniques, more stations, samples, and monitoring devices. The network also can be improved by establishing a greater concentration of stations near operating nuclear facilities, by adding fixed sampling stations and by developing scientifically designed sampling techniques to replace the current improvised network. EPA officials said that such improvements would increase the quantity of reliable data needed for developing effective standards and guidance.

LIMITED ENVIRONMENTAL RESEARCH PROGRAM

An effective radiation control program requires a strong scientific research effort to eliminate many of the uncertainties associated with health effects and environmental processes. However, EPA is currently performing no scientific research at all on the effects of ionizing radiation. A 1976 decision by the Office of Management and Budget required that EPA concentrate on nonionizing radiation while research on ionizing radiation be conducted primarily by ERDA. The Office of Management and Budget required a 1-year trial period to determine if funding ERDA for ionizing research would provide EPA with the data it needs. As a result, EPA has been working during the past year to make known its research needs both to ERDA and NRC. ERDA and NRC have accepted EPA's overview of its needs, and they have pledged to cooperate with EPA. A formal agreement is being developed.

An EPA official stated that there are reservations about this arrangement because the technical personnel within each organization appear to be somewhat reluctant to participate vigorously, probably because of past differences in priorities. The funding process for EPA's research needs remains extremely slow due to the lag time between EPA's recognized need and its success in convincing the other agencies to conduct the research. On those occasions when EPA has had some money to contribute to the research, the project has been accepted with more enthusiasm. When EPA has been able to conduct the research itself or pay for most or all of it, the projects have been considered more valuable. Officials explain that this is partially due to the minimal delay between the recognized need and the action. One official said that as EPA becomes more dependent on other Federal agencies for research support, its ability to develop timely radiation standards and guidance may be jeopardized. The fear is that in addition to delays, the data developed may not be applicable to the Agency's needs.

In July of 1976, EPA published a statement of research needs. Discussing its activities in developing guidance for radon from construction materials, for example, EPA said:

> "The specific need for obtaining data on actual structures will not be met for a considerable time period because of resource restrictions * * *. EPA must rely on very limited information from the literature to estimate population

impact and determine the need for standards. As a result, promulgation of necessary standards will be delayed and may suffer from the lack of a significant data base."

In the past, EPA has been criticized for failing to make use of outside resources. ERDA officials, for example, said that many of the confrontations with EPA resulted from EPA's proposing standards and guidance without the necessary expertise and resources needed to do so. The ERDA officials said that EPA could have made use of the extensive technical capabilities that exist in ERDA, but that requests for assistance have usually come only after EPA has made its proposals. In commenting on a draft guidance for plutonium soil contamination, the ERDA Administrator wrote in October 1976:

"Based on the results of our review, we have concluded that the proposed guidelines are seriously lacking in technical adequacy and scientific justification. Lacking such a sound technical basis, the major assumptions and relationships used in the derivation of the guidance appear unsupportable. Furthermore, there is considerable uncertainty in understanding which criteria are intended to be enforceable and what manner of implementation is expected * * *. I am aware that the ERDA (and the AEC before it) has repeatedly offered the EPA access to and assistance from those ERDA laboratory scientific and technical personnel who have expertise with regard to the matter at hand but that these resources have not been utilized by the EPA. I am seriously concerned over the apparent lack of communications on this matter, and I urge that the EPA avail itself of ERDA's resources in preparing these important guidelines."

The private National Council on Radiation Protection and Measurements, which is able to provide considerable experience on radiation issues, said that EPA's attitude is one of not needing outside assistance. Rather, EPA is willing to proceed on its own regardless of its limitations. In 1973 the National Council on Radiation Protection and Measurements expressed concern about "the prospects of future regulatory actions being taken before additional careful consideration of the available radiobiological information

is completed." It expressed willingness to assist and said that it is uniquely suited to offer objective recommendations on radiation protection matters. The Director of the National Council on Radiation Protection and Measurements said, however, that the Council has not been involved in EPA's recent drinking water standards and had not seen EPA's proposal for diagnostic X-ray guidance. National Council on Radiation Protection and Measurements officials said that EPA's radiation guidance role has been a disaster because of its limited staff and money. In past discussions with EPA, the National Council on Radiation Protection and Measurements was unable to communicate effectively with EPA or provide EPA with the useful data which it had. EPA's own monitoring network is limited, and consequently EPA must rely heavily on non-EPA sources. Program officials also admit that research capabilities are limited and that gaps and uncertainties exist in some of the data bases which EPA currently uses.

In an internal assessment in mid-1976 for developing standards for radon in construction materials, EPA concluded that the continued deficiencies in staff, technical expertise, and research will significantly delay these necessary standards and guidance, while existing employees and limited resources are working on higher priority problems.

CHAPTER 5

INABILITY TO SET PRIORITIES AND UNCERTAINTIES FOR THE FUTURE

In October 1976, EPA outlined a draft of its radiation protection strategy. This called for placing priority on radiation problems which pose the greatest threat to public health and the environment. However, EPA officials told us that staff shortages have prevented EPA from looking into the future and projecting all needed standards and guidance. The officials said that in the past, radiation protection has often been crisis oriented. Rather than working toward establishing public confidence in EPA by identifying and working on radiation problems that may present the greatest dangers, EPA has shifted its limited resources as each crisis has developed. In addition, by taking 6 years to develop a standard on nuclear power operations, EPA's limited resources have been further strained. EPA's radiation protection authority is still being subjected to jurisdictional disputes by other Federal agencies. Many scientific problems dealing with the health and ecological effects of radiation remain to be solved.

SCOPE OF THE DANGER

In May 1976 EPA published a report entitled "Radiological Quality of the Environment." EPA acknowledged that "* * * there are radiation sources for which data are either incomplete or not available * * *" and that much of the existing information is of questionable value. In the Agency's words:

> "It is important to note that the population dose values mentioned here are based upon the data available to us at this time. It is quite possible that these values * * * could change in the future as more information on this subject becomes available."

As an example of one of the "many gaps that appear in the data," the medical use of X-rays was cited. While conceding that medical X-rays contribute to a large and significant dose of radiation, EPA does not know how large and significant the population dose actually is. The stated purpose of the report was to pull together existing information and to establish the first in a series of future "annual" reports on the scope and quantity of radiation to which the environment is exposed. However, EPA's 1977 report is currently being delayed due to staff limitations.

EPA still does not sufficiently understand the relationships between exposure to some forms of radiation and their consequences to issue reliable predictions. More must be learned about the effects of amount and duration of exposure. EPA admits that it does not currently know all the radiation sources that may provide a danger to health and the environment and measurements do not exist for many of the sources that have been identified as a potential threat.

EPA is currently working on major areas where guidance is needed such as:

1. Medical X-ray.

2. Occupational radiation exposures.

3. Plutonium contamination.

4. Radioactive waste disposal.

5. Nonionizing radiation exposure in the general environment.

6. Protection guides related to nuclear incidents.

7. Natural radioactivity from mining operations.

In addition--other areas although not areas where significant health effects or potential health effects are likely to occur, according to EPA--may require future environmental guidance involving such sources as:

1. Nuclear medicine.

2. Radiation equipment used by students in educational institutions (not covered by occupational exposures).

3. Consumer products such as clocks with luminous dials and smoke detectors with radioactive devices.

4. Radioactivity in food products, such as oranges receiving uptake of radiation from the use of phosphate fertilizer.

5. Radioactivity released from increased burning of coal.

EPA admits that the effects of nonionizing radiation are especially unknown. It is still trying to determine what effects nonionizing radiation has, the amount of radiation these sources emit, their patterns of growth, and criteria for deciding what environmental levels are acceptable. EPA plans to conduct and analyze field measurements and laboratory studies on nonionizing radiation. In fiscal year 1978, EPA plans to decide whether guidance is needed. If it so decides, developing the guidance will not be completed until fiscal year 1979 or later.

NATURALLY OCCURRING MATERIALS

EPA's 1976 draft strategy singled out for special attention naturally occurring radioactive materials and the control of nuclear energy applications. Although 60 percent of the U.S. population's total exposure is from naturally occurring sources, EPA admits that this form of ionizing radiation is the least studied. EPA says that as mining and energy-based industries continue, radioactive materials which naturally are confined beneath the Earth's crust can adversely affect health and the environment in four basic ways. First, as radioactive particles and gasses are released in the air, people may inhale them. Second, radioactive materials from ores or associated by-products can enter the environment from effluent discharges, land runoff, and leaching from waste piles. Third, workers can have close contact with the materials. Fourth, the food chain can become contaminated when people eat radioactive products--like oranges grown with phosphate fertilizer.

Initial investigations have found that people are unnecessarily exposed to radiation from increased use of materials such as phosphate, coal, and construction materials--all of which contain radioactive elements. Current EPA studies indicate that while much exposure to natural radiation is unavoidable, such exposure can be better controlled and the concomitant health effects reduced. EPA plans to issue guidance on buildings constructed from radioactive materials or built on radioactive landfill.

NUCLEAR ENERGY USE

Nuclear reactors operating in the United States will increase by the year 2000. In order for the facilities to operate, uranium must be mined, radioactive materials

must be transported, and waste must be deposited in permanent or semipermanent sites. The new EPA standard, which is not yet in effect, will not cover any of these sources of exposure. 1/

It is not technically possible to produce nuclear energy without discharging small quantities of liquid and gaseous radioactive material. One such release is Carbon 14. EPA is studying the release, distribution, and potential uptake in humans, as well as means and costs of control at reactors and fuel reprocessing facilities.

While such small quantities are released at the nuclear facility, additional radioactive waste is created by chemically reprocessing reactor fuel which contains many potentially harmful long-lived materials, such as strontium-90, cesium-137, and plutonium-239. Strontium-90 and cesium-137 require about 600 years to decay, while plutonium takes about 500,000 years. No satisfactory method has yet been developed and applied for containing these materials which remain toxic for so long. Until such a method is developed, the wastes are stored at temporary sites.

There are 7 million cubic feet of radioactive wastes from spent reactor fuels and defense related activities. By the year 2000, these wastes are projected to be 11 million cubic feet. Leaks have already occurred in the underground tanks at the Government's Hanford storage reservation, at Richland, Washington. The President, in an October 1976 policy statement, specifically required EPA to set standards on high-level wastes. He mandated that such standards provide acceptable numerical levels for contamination to the environment. EPA made a commitment to develop final standards by June 1978. These standards and future environmental guidance developed by EPA will be used by NRC and ERDA, which have the responsibility for regulating such waste deposits.

Before the President's message, EPA had devoted a moderate amount of effort to the issue and had planned to provide criteria and standards by the early 1980s. Now, EPA regards high-level waste disposal as an urgent priority. Even so, delays in meeting the Presidential commitment have already occurred. As of May 1977, EPA had extended the majority of the developmental target dates. It had failed

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1/See ch. 2 for more information on the standard.

to receive a crucial report on implementation methodology which was already overdue. EPA staff was not always available because of other program responsibilities. While EPA says that it will meet the final deadline, these events make it doubtful that there will be adequate data for developing the necessary standards. EPA officials told us that the Presidential mandate enabled EPA to refocus its program so it could address this major area of concern. EPA believes the potential for release of radioactivity from waste disposal is one of the major problem areas.

Another nuclear-related issue is plutonium. It is a product which in small quantities can be used not only to produce power but to manufacture atomic bombs. The substance is also extremely toxic. Sabotage or accidents increase the dangers of environmental contamination. Accidents have already taken place at plutonium-handling facilities, and area and worldwide contamination from nuclear atmospheric weapons testing has occurred. EPA is currently developing standards for cleaning up and restoring areas which have already been contaminated with plutonium. It also is developing plans to protect the environment from future uses of the substance. In its February 1975 program plan, EPA had estimated that cleanup guidelines and a plutonium standard would both be developed by October 1976. The plan has been delayed until 1978.

There are no other Federal agencies which claim overseer authority to coordinate and develop comprehensive measures to protect the public and the environment from radiation hazards. Yet, EPA admits that it does not know the entire scope of the radiation danger, that it does not have the resources to find out, and that its limited staff is unable to develop all the needed standards and guidance simultaneously. Some EPA officials admit that what it has done may not be the result of scientifically identified public need but rather may reflect a crisis-oriented approach led by a public perception that the problem is serious. The future ability of EPA's radiation protection program to do its job remains in question.

CHAPTER 6

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The Environmental Protection Agency was provided unclear overview authority necessary for protecting the American people and their environment from the hazards of radiation. EPA officials admit that EPA is currently unable to provide complete protection under its ambigious authorities.

EPA's Office of Radiation Programs and its radiation research programs have been plagued by jurisdictional challenges to EPA's authority, by staff and funding reductions, by an inability to retain competent professionals, by limited cooperation with other agencies and research groups, and by the low priority placed on radiation protection.

Radiation protection is the least funded of all EPA programs, and continual reductions in radiation protection staff and resources, transfers of professionals to other Agency programs, and discussions with EPA officials currently working at the Office of Radiation Programs indicate that sufficient support has not been given to EPA's radiation protection efforts.

EPA received two authorities for providing radiation protection when it was created in 1970. First, it can issue standards for radioactivity in the environment, including general environmental guidelines for particular industries and for radiation doses to the general public. Second, it can issue guidance to the appropriate Federal agencies affecting all forms of radiation protection in Federal activities. To date, EPA, under the authorities discussed, has issued one standard--which has not yet taken effect--and has issued no new formal guidance.

EPA's program for monitoring the levels of radiation to which the American people are currently exposed is limited. It does not know the scope of the dangers caused by all current radiation sources and so is unable to adequately anticipate all future problems. Much more information is needed. Some data which it currently uses is incomplete and inadequate, and it does not have all the resources to perform necessary research nor has it functioned efficiently in securing data which exists or can be developed outside EPA. EPA has been unable to issue timely standards and guidance.

It has been consistently unable to meet deadlines which it has established for issuing significant reports, standards, and guidelines. Without extensive changes, we believe that EPA will continue to be unable to protect public health and the enviroment from the dangers of radiation.

We believe that an early review and resolution of these ambiguities is required and we would be glad to assist the appropriate congressional committees in the development of such legislative initiatives.

The Congress in the enactment of the Clean Air Act Amendments of 1977 has provided a step in the right direction toward more clarification of environmental and public health protection from radiation exposures. A December 28, 1977, report by the Senate Committee on Governmental Affairs citing its study on Federal regulation states that Americans are being exposed to increased amounts of radiation while some hazards are not subject to any Federal controls. The Committee report supports our findings, citing radiation jurisdictional disputes and regulatory confusion among the Federal regulatory agencies. It recommends that more Government regulation to control radiation levels should be assigned to EPA.

RECOMMENDATIONS TO THE CONGRESS

To overcome the apparent controversies regarding the EPA role in developing standards and Federal guidance for environmental exposure to radiation, we recommend that the Congress:

--Define EPA's role as the Federal overseer of environmental radiation protection so as to clearly delineate its authorities and responsibilities with regard to the various Federal agencies.

--Define the scope of radiation dangers to be addressed by EPA.

--Require the timely development of necessary standards, guidance, and periodic advisement of EPA's progress in meeting its radiation protection goals.

RECOMMENDATIONS TO THE ADMINISTRATOR OF EPA

We recommend that the Administrator of EPA in consideration with the other program priorities provide the radiation

protection program with sufficient support to do its job. Specifically, the Administrator should:

--Assign additional staff and resources as they become available to the Office of Radiation Programs and to the radiation research program.

--Reexamine the environmental monitoring network and take appropriate measures for insuring that it will have the capability to provide accurate and complete information on radiation dangers.

--Coordinate in-house research with that performed by other agencies and research groups and provide the administrative direction necessary for working relationships with other groups and agencies so that appropriate research can be compiled and developed in a timely manner.

--Require that reports on radiation levels in the environment be continued and be issued, as had been promised, at least annually so that the magnitude of radiation hazards can be documented.

--Develop a comprehensive assessment of the need for standards and guidance such as required for radioactive air pollutants.

--Issue a program strategy with a timetable for developing standards and guidance based on an explicit priority determination of the greatest actual or potential risks.

--Issue Federal guidance and standards based on that timetable.

AGENCY COMMENTS AND OUR EVALUATION

In a December 1977 letter (see app. II) commenting on our report, EPA advised that it has planned or started actions on all our recommendations. EPA recognized the problems in operating a national radiation protection program under EPA's authorities and agrees that congressional clarification of its authorities would be valuable. EPA states, however, that although establishing standards and regulations is an important aspect of EPA's role, there are other authorities and functions it performs in modifying Federal agency programs such as through its environmental impact

statement reviews. EPA stated that although the impacts of resource constraints will be considered in future EPA decisions, its limited resources and the multiplicity of environmental program areas competing for those resources precludes commitment of a given level of funding to any specific program area, including radiation protection.

We believe the difficulties EPA has experienced in carrying out the specific authorities addressed in the report and its staffing and funding limitations will continue to impact on its ability to insure radiation protection.

Comments on the report from NRC, ERDA, HEW, and DOL are contained in appendixes III to VI. These agencies generally agreed with the recommendation that a need exists for the Congress to mandate a clearer understanding of responsibilities for environmental and public health protection. They cite their own protection activities as active, aggressive, and comprehensive efforts to protect the American people from radiation hazards even in the absence of EPA actions. They state that the finding of shortcomings in EPA's overall efforts should not alone be evidence of the ineffectiveness of all Federal radiation protection activities, without comprehensive evaluation of all Federal activities programs and accomplishments.

The NRC agreed that legislation might be considered to clarify and rationalize the authorities and responsibilities of the various agencies that have important and ongoing roles to play in the regulation of radiation activities. NRC disagreed with our assessment that the recent Clean Air Act Amendments represent a desirable step in clarifying responsibilities citing uncertainty and duplication of effort which a comprehensive and cooperative approach could avoid. It supports actions which might enhance the Federal guidance role of EPA and legislation for agencies other than EPA which would give them clear responsibility and authority to implement the radiation guidance provided by EPA.

We believe that EPA's activities relating to the environmental aspects of radiation clearly shows confusion concerning the various roles of Federal programs. A clearly defined and mandated EPA role necessitating possible realignment of agency jurisdictional roles and allocation of resources would reduce the confusion and confrontations which currently exist. We agree that further studies of possible realignment of Federal agency jurisdictions could promote more efficient radiation protection programs, and agency officials expressed willingness to participate in such studies.

EPA Policy Statement on

Relationship Between Radiation Dose and Effect

March 1975

The actions taken by the Environmental Protection Agency to protect public health and the environment require that the impacts of contaminants in the environment or released into the environment be prudently examined. When these contaminants are radioactive materials and ionizing radiation, the most important impacts are those ultimately affecting human health. Therefore, the Agency believes that the public interest is best served by the Agency providing its best scientific estimates of such impacts in terms of potential ill health.

To provide such estimates, it is necessary that judgments be made which relate the presence of ionizing radiation or radioactive materials in the environment; i.e., potential exposure, to the intake of radioactive materials in the body, to the absorption of energy from the ionizing radiation of different qualities, and finally to the potential effects on human health. In many situations the levels of ionizing radiation or radioactive materials in the environment may be measured directly, but the determination of resultant radiation doses to humans and their susceptible tissues is generally derived from pathway and metabolic models and calculations of energy absorbed. It is also necessary to formulate the relationships between radiation dose and effects; relationships derived primarily from human epidemiological studies but also reflective of extensive research utilizing animals and other biological systems.

Although much is known about radiation dose-effect relationships at high levels of dose, a great deal of uncertainty exists when high level dose-effect relationships are extrapolated to lower levels of dose, particularly when given at low dose rates. These uncertainties in the relationships between dose received and effect produced are recognized to relate, among many factors, to differences in quality and type of radiation, total dose, dose distribution, dose rate, and radiosensitivity, including repair mechanisms, sex, variations in age, organ, and state of health. These factors involve complex mechanisms of interaction among biological, chemical, and physical systems, the study of which is part of the continuing endeavor to acquire new scientific knowledge.

APPENDIX I

Because of these many uncertainties, it is necessary to rely upon the considered judgments of experts on the biological effects of ionizing radiation. These findings are well-documented in publications by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the National Academy of Sciences (NAS), the International Commission on Radiological Protection (ICRP), and the National Council on Radiation Protection and Measurements (NCRP), and have been used by the Agency in formulating a policy on relationship between radiation dose and effect.

It is the present policy of the Environmental Protection Agency to assume a linear, nonthreshold relationship between the magnitude of the radiation dose received at environmental levels of exposure and ill health produced as a means to estimate the potential health impact of actions it takes in developing radiation protection as expressed in criteria, guides, or standards. This policy is adopted in conformity with the generally accepted assumption that there is some potential ill health attributable to any exposure to ionizing radiation and that the magnitude of this potential ill health is directly proportional to the magnitude of the dose received.

In adopting this general policy, the Agency recognizes the inherent uncertainties that exist in estimating health impact at the low levels of exposure and exposure rates expected to be present in the environment due to human activities, and that at these levels the actual health impact will not be distinguishable from natural occurrences of ill health, either statistically or in the forms of ill health present. Also, at these very low levels, meaningful epidemiological studies to prove or disprove this relationship are difficult, if not practically impossible, to conduct. However, whenever new information is forthcoming, this policy will be reviewed and updated as necessary.

It is to be emphasized that this policy has been established for the purpose of estimating the potential human health impact of Agency actions regarding radiation protection, and that such estimates do not necessarily constitute identifiable health consequences. Further, the Agency implementation of this policy to estimate potential human health effects presupposes the premise that, for the same dose, potential radiation effects in other constituents of the biosphere will be no greater. It is generally accepted that such constituents are no

more radiosensitive than humans. The Agency believes the policy to be a prudent one.

In estimating potential health effects it is important to recognize that the exposures to be usually experienced by the public will be annual doses that are small fractions of natural background radiation to at most a few times this level. Within the U.S. the natural background radiation dose equivalent varies geographically between 40 to 300 mrem per year. Over such a relatively small range of dose, any deviations from dose-effect linearity would not be expected to significantly affect actions taken by the Agency, unless a dose-effect threshold exists.

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

The linear hypothesis by itself precludes the development of acceptable levels of risk based solely on health considerations. Therefore, in establishing radiation protection positions, the Agency will weigh not only the health impact, but also social, economic, and other considerations associated with the activities addressed.

APPENDIX II

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

DEC 20 1977

OFFICE OF
PLANNING AND MANAGEMENT

Mr. Henry Eschwege
Director, Community and Economic
Developments Division
U. S. General Accounting Office
Washington, D. C. 20548

Dear Mr. Eschwege:

In general, we appreciate the depth in which the General Accounting Office staff reviewed the EPA Radiation Program and their recognition of the problems in operating a national radiation protection program under EPA's current authorities.

However, the report only examines in depth a few of the activities of the Office of Radiation Programs, namely, standards and guides set under authorities transferred to EPA under the Atomic Energy Act and monitoring of the environment. The report fails to address or even acknowledge other activities of significant impact. These include final radiation standards promulgated under the Safe Drinking Water Act of 1974 and the Ocean Disposal Act of 1972, as well as proposed effluent guidelines for natural radioactive pollutants established under the Federal Water Quality Act of 1972. The detailed review of environmental impact statements under the National Environmental Policy Act of 1969 has resulted in major modification of programs leading to increased protection of health and the environment. These include nuclear power plants, fuel cycle facilities, and generic statements in such areas as mixed oxide fuel (GESMO), the liquid metal fast breeder reactors (LMFBR), and waste disposal to name a few. It is important to realize that establishing standards and regulations is only one aspect of radiation protection and that EPA's role in modifying other Federal Agency programs through environmental impact statement review has been very effective. Since discussion of these other activities is not included, we feel that the report does not provide a balanced view of EPA's radiation protection efforts.

On the recommendations of the report to the EPA Administrator, our comments are as follows:

The report does provide guidance to the Administrator on how resource constraints may have impacted Agency performance in the areas reviewed.

These impacts will be considered in future Agency decisions on resource allocations. However, given the multiplicity of program areas in which the Congress has given EPA environmental protection responsibilities and that all of these major program areas must compete for what are always limited resources, this Agency cannot commit itself to a position which assures a given level of funding to any specific program.

We believe that some of the Reports' concerns have not been put in proper perspective. The Report states that a large portion of the population is not monitored, that there are gaps in our knowledge that affect our decision-making, that we often depend upon the nuclear facilities to monitor themselves, and so forth. All of these are true and represent legitimate concerns. However, these are concerns that apply to control of other pollutants as well. Billions of dollars have been spent on radiation research; monitoring is as detailed and sophisticated as for other pollutants; coal power plants, for example, also monitor their own emissions. We therefore recommend that the Report be revised to indicate that, in perspective, the concerns we have regarding our lack of information in the radiation area are no more severe, and possibly less severe, than those in other areas.

A review will be undertaken to assure that the environmental radiation monitoring program provides adequate information for program decisions. However, "complete information" is not a realistic objective of any environmental monitoring program.

The Office of Radiation Programs has established a Research Committee to develop research needs and coordinate their implementation within EPA and other agencies and groups. A formal methodology for defining research needs, identifying areas where work is being done by others, and coordinating such efforts has been implemented.

Reports on radiation levels in the environment will continue to be issued on an annual basis.

We have undertaken a two-year study pursuant to the Clean Air Act Amendments to make a comprehensive assessment of the need for standards and guidance. This information and other ongoing studies will allow us to extend this assessment to all natural radioactive pollutants which we feel may be controlled under a variety of authorities already established within EPA. A workshop in this area, involving international cooperation with the Nuclear Energy Agency of OECD, is scheduled for May 1978. We have already undertaken a comprehensive study of non-ionizing radiation and expect to determine whether there is a need for standards and guides in this area in early 1978.

APPENDIX II

We have developed a program strategy with timetables for developing standards and guidelines based upon priority determinations, including the magnitude of actual and potential risks. Such strategy needs periodic updating. The next update will reflect such priority reconsiderations as may be necessary based on new information.

The first recommendation to Congress (p. 47 of the Report) is that Congress "define EPA's role as the Federal overseer of environmental radiation so as to clearly delineate its authorities and responsibilites with regard to the various Federal agencies." Our role in developing environmental standards and guidance has not been challenged. The conflicts over authority have stemmed from transference of the Federal Radiation Council authorities in non-environmental radiation (e.g. medical and occupational radiation). We have followed Reorganization Plan No. 3 of 1970, creating EPA, that states in Sec. 2(a), "There are hereby transferred to the Administrator: (7) All functions of the Federal Radiation Council (42 U.S.C. 2021 (h))." We have interpreted this transfer to EPA as conferring authority for all types of radiation. Because this interpretation has been challenged, Congressional clarification would be valuable.

[See GAO note below.]

Sincerely yours,

William Drayton, Jr.
Assistant Administrator
for Planning and Management

Enclosure

GAO note: Page references in this letter refer to draft report and do not necessarily agree with the page numbers in the final report.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

OCT 13 1977

Mr. Gregory J. Ahart
Director, Human Resources
Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your request for our comments on your draft report entitled, "Failure to Adequately Protect the American People From the Hazards of Radiation," directed to the Environmental Protection Agency. The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

Thomas D. Morris
Inspector General

Enclosure

DEPARTMENT COMMENTS TO GAO DRAFT REPORT ENTITLED
FAILURE TO ADEQUATELY PROTECT THE AMERICAN
PEOPLE FROM THE HAZARDS OF RADIATION

The Department of Health, Education and Welfare recognizes that this draft report focuses almost exclusively on radiation protection activities of the Environmental Protection Agency. Although the report mentions related radiation programs in the Food and Drug Administration, the Department of Housing and Urban Development and the Department of Labor, it does not explain or assess these programs. After discussions with the responsible GAO auditors, we understand that the report is not intended to be a comprehensive evaluation of all federal radiation activities, and that the scope of the report is limited to examining EPA's activities relating to the environmental aspects of radiation.

Having understood the restrictions on the scope of this study, we do not believe that a comprehensive discussion of FDA authorities, programs and accomplishments absolutely essential but we are concerned that readers of this report will interpret the finding of shortcomings in EPA's overall coordination efforts as evidence of the ineffectuality of all federal radiation protection activities.

[See GAO note p. 46.]

There is also a recurring notion in the report that EPA's failure to provide guidance to all Federal agencies has hamstrung the operation of other programs. In the case of FDA this is not true. We believe that the past performance of FDA's Bureau of Radiological Health demonstrates an active, aggressive and comprehensive effort to protect the public from medical radiation hazards. The linkage between EPA guidelines and the success or effectiveness of programs in other agencies is not examined by the report, although it is clearly presumed. It may be a valid assumption for some programs, but if EPA had issued more guidelines, they would not have necessarily benefited FDA's program or saved FDA effort since past EPA guidelines have not included environmental impact assessments, opportunity for public comment and other essential requirements of FDA's regulatory process.

The report also mentions problems regarding HEW cooperation and jurisdictional disagreements with EPA. We believe the brief discussion of these matters does not present a sufficient record of the correspondence and negotiations between EPA and this Department and thereby limits the reader's understanding of the scope and complexities of the issues involved. We also believe that this section should make clear that the jurisdictional matters have resulted in neither a significant redundancy of FDA/EPA effort nor conversely, an absence of significant regulatory action in areas where FDA is responsible.

Specific comments on several of the recommendations are appropriate. The report urges the Congress to mandate a clearer understanding of responsibilities for environmental and public health protection from radiation. It may be appropriate to propose this recommendation, but to take action we believe the Congress will need a more comprehensive analysis of the various legislative authorities and program interfaces than the scope of this report permits. The report also recommends that the Administration of EPA coordinate in-house research with that performed by other agencies. In this regard, the Commissioner of Food and Drugs is committed to cooperation and coordination among regulatory agencies on problems of mutual interest. Radiation research is clearly an area where maximum inter-agency coordination is desirable, and FDA will do its part to ensure such coordination.

GAO note: The deleted material pertained to a matter contained in the draft report which has been changed or is not included in this report.

APPENDIX IV

UNITED STATES
ENERGY RESEARCH AND DEVELOPMENT ADMINISTRATION
WASHINGTON, D.C. 20545

SEP 30 1977

Mr. Monte Canfield, Jr., Director
Energy and Minerals Division
U.S. General Accounting Office
Washington, DC 20548

Dear Mr. Canfield:

We appreciate the opportunity to review your proposed report to the Congress entitled "Failure to Adequately Protect the American People From the Hazards of Radiation," Environmental Protection Agency. While we believe that it is not appropriate for us to discuss the responsiveness of other Federal agencies, we offer our comments for the purposes of clarification and to put the problem of establishing new standards in proper perspective. We feel that the report, as presently written, could be misleading to the general public and have harmful effects far beyond the concerns of EPA as well as have an adverse effect on our programs and on nuclear energy programs generally.

In general, the report appears to exhibit a lack of appreciation of the enormous effort by researchers over the past 30 years in characterizing our radiation environment and studying the biological effects of radiation. This research has been used to develop a basis for standards established to protect the public from radiation. This body of information has been and continues to be used by the NCRP, ICRP, and other private and governmental agencies to review, evaluate, and establish standards. ERDA's responsibilities and experience, while extensive, do not encompass all aspects of radiation and radiation protection. In areas of ERDA responsibility and experience to imply that the American people are not adequately protected from the hazard of radiation is a misstatement of technical fact and judgmental conclusion not supportable by established scientific information.

GENERAL COMMENTS

1. Protection of the Public from Radiation

The report states that additional radiation controls are necessary but does not clearly identify which sources of radiation need additional controls. While it is true that the redistribution of natural radiation has resulted in increased exposure to a few individuals, it can generally be concluded that the 56 percent of the total population dose equivalent attributed to natural background is fixed.

The report refers to natural radiation as though it were a constant source of exposure. In fact, natural radiation background in the U.S. varies from about one-tenth of a rem per year to about

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Mr. Monte Canfield, Jr.

one-quarter of a rem per year. For example, a person changing his residence from Texas to Colorado will increase his annual radiation exposure by about one-sixth of a rem; from Maine to Colorado, by about one-tenth of a rem (state-by-state data are in EPA document No. CSD-ORP 72-1). It is essential to recognize that these increments are large relative to the increments incurred by moving close to a modern, well-designed and well-operated large nuclear facility.

Approximately 2 percent of the total population dose equivalent arises from global fallout from previous nuclear tests. Data indicate that this population dose equivalent has been declining and will continue to decline in the absence of atmospheric testing.

Nuclear power, which contributes only 0.0002 percent of the population dose equivalent, might be expected to increase somewhat, depending upon the usage as well as the possible improvements of environmental control technology. The Nuclear Regulatory Commission's Occupational Radiation Exposure Reports indicate that occupational exposures are increasing somewhat as the age of plants increases. However, the general trend for ERDA's contractors shows occupational exposures declining. The total occupational dose equivalents for those reporting to NRC and for those reporting to ERDA are comparable. The total occupational dose equivalent accounts for less than 2 percent of the total population dose equivalent.

Approximately 40 percent of the total dose equivalent arises from medical uses. HEW has clearly established regulatory authority applicable to manufacturers of radiation producing devices.

From the above, it is evident that the guidance which EPA may be responsible for would apply to sources responsible for less than 3 percent of the total population dose equivalent. Therefore, additional regulatory structure with more stringent controls would have a small impact on population dose equivalent.

2. Existing Knowledge of the Radiation Environment

For more than 30 years, scientists and governments throughout the world have been concerned about the biological effects of ionizing radiation. Massive amounts of money and time have been expended studying these effects, most of which are published in the open scientific literature. Research continues today primarily to determine the health effects from exposure to low levels of radiation and at low dose rates. Although there is much to be

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learned in this area, the biological effects from exposure to radiation are better understood than the biological effects from any other carcinogen. Short-term funding in this area of research will not be fruitful and cannot compete with the established programs throughout the world.

The environmental radiation monitoring efforts in the U.S. have provided a sound basis for assessing the population dose equivalent near all nuclear facilities. The results of the national laboratories and other ERDA contractors' extensive monitoring programs are published annually. The nuclear industries in the private sector are required by the NRC to monitor the environment. The ERDA and the NRC are required to independently assure the validity of these data. These monitoring efforts, along with the extensive information in the literature on natural background levels and EPA's monitoring network, provide a good basis for characterizing the radiation environment. In addition, the NCRP has recently published a review of the radiation exposure from consumer products.

3. Radiation Standards

In the development of radiation protection guides, the FRC reviewed available knowledge, consulted with scientists, and solicited views of the public. They also drew heavily upon the advice of the organizations recognized to be best able to provide guidance such as the National Council on Radiation Protection and Measurements (NCRP), the National Academy of Sciences (NAS), and the International Commission on Radiation Protection (ICRP). This knowledge, along with considering the benefits from using radiation, was used to establish recommendations for Federal agencies.

The NCRP and ICRP continue to reassess the information available and issue new guidance when needed. The primary issue in establishing standards at this time is defining an acceptable risk and then assessing this risk.

At the present time, it is not evident how increased funding to EPA for research or data collection could provide a better understanding of the health effects from the exposure to low levels of radiation, nor would it permit the development of technically sound regulatory guidelines.

The report makes such limited reference to any standards other than those of EPA that the reader is likely to believe he is dangerously unprotected in those areas where EPA is cited for not yet generating

Mr. Monte Canfield, Jr.

standards. This is not the case. ERDA sites, for example, are subject to a comprehensive internal set of radiation protection standards which closely follow the guidance of NCRP, ICRP, and the model regulatory code of the United Nations. The U.S. Government, incidentally, has joined in a unanimous recommendation (by the Board of Governors of the International Atomic Energy Agency) that all member nations adopt the UN model regulatory code, or revise their existing codes to conform. NRC also has certain standards which follow the NCRP-ICRP-UN pattern.

Specific Comments on Main Text of Report [See GAO note 1., p.53.]

[See GAO note 2., p. 53.]

3. Page 3, sentence concluded on line 2: it is correct to say that low radiation exposures have not been studied clinically or experimentally to the same extent as high exposures; however, keeping the subject in perspective requires two additional statements. First, in spite of the uncertanties about low-level radiation, "few, if any, other environmental hazards have been studied to a comparable extent" (NCRP Report No. 39, page 7). Second, large populations have been exposed to differing radiation levels for many generations with no results which, by the ordinary layman's standards of common-sense observation, seem significant (see preceding General Comment #1).

[See GAO note 2., p. 53.]

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5. Pages 4-5: the discussion of a possible nuclear accident is inadequate. No mention is made of the Reactor Safety Study by the Nuclear Regulatory Commission (WASH-1400), which analyzed in depth the likelihood of occurrence, and the consequences, of different types of reactor accidents. One fact which was reaffirmed by this study is that it is physically impossible for a nuclear reactor to explode like a nuclear bomb. The most severe accident which might occur - termed a "core melt" - would release limited amounts of radioactive material to the surrounding environment, but its harmful consequences would be far less than those of a nuclear explosion. Also, and most importantly, the study predicted that the likelihood of occurrence of a core melt accident is extremely small.

6. Page 5, first complete paragraph: technology for permanent disposal of radioactive waste is available (see ERDA 76-43); the need is to apply that technology to the siting and construction of specific repositories. The danger of "leakage" (which from the context means high-level liquid waste leakage) is not continuous. All of the leaks of high-level liquid waste from tanks into the ground at ERDA sites have come from single-walled tanks of a design which has not been used for new construction since the late 1960's. There have been no leaks of high-level liquid waste into the ground from tanks of the newer design. Also, no radiation exposure to any persons in the environment resulted from the leaks, contrary to the implication from the use of the term "threat" in the text. Richland is one of the five major ERDA sites in terms of volume of waste in burial grounds, which is quite a different subject than the high-level waste storage in the preceding sentence. At the Maxey Flats and West Valley burial grounds, the position of the two State regulatory agencies having jurisdiction is, in each case, that the levels of radioactivity detected outside the burial ground boundaries represent a condition to be watched closely, but not a present threat to public health and safety. Even if all of the errors and misconceptions in this

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paragraph were corrected, its relevance to the subject of the audit would be questionable. EPA's role is to set "generally applicable environmental standards," and standards on such specific problems as waste tank construction or burial ground management would seem to be the role of NRC or the agreement states.

[See GAO note 2., 53.]

The cited decay periods of about 600 years for strontium-90 and cesium-137 and about 500,000 years for plutonium are meaningless unless an original concentration is specified. It would be more pertinent to state that typical high-level solid waste emplaced in a deep geologic formation would be reduced by decay to a point of comparable potential hazard with natural radioactive ore deposits in a thousand to several tens of thousands of years, depending on what assumptions are made about pathways of exposure.

9. Page 41, paragraph continued to page 42: the first three sentences mixed "low-level" solid waste and high-level liquid waste, without properly identifying either. The point on waste tank leaks should not be what publicity resulted, but whether there was any actual radiation exposure to the public (there was not). See also comment #5, above. [See GAO note 2., p. 53.]

10. Page 42, last paragraph: the second sentence could help perpetuate the fallacy that nuclear power is a prerequisite to the production of nuclear weapons. The statement that "accidents have already taken place at plutonium-handling facilities" is meaningless without an evaluation of the consequences. A number of ERDA environmental statements or reports (for example, ERDA 76-104) could have been cited to show how nominal the public exposures are in the vicinity of the ERDA plutonium facilities, with or without accidents. The reference to accidents "during transportation of nuclear devices" presumably refers to Palomares and Thule, which

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hardly seem applicable to any transportation accidents in the commercial nuclear fuel cycle. The concern for standards for clean-up of areas already contaminated with plutonium should be qualified as including concern for areas involved in nuclear weapons testing, especially atmospheric weapons testing. It is highly misleading to permit the reader to think that such concerns are relevant to the nuclear power industry.

[See GAO note below.]

Fred L. Hiser
Assistant to the Controller

GAO note:

1. Page reference in this Appendix refer to draft report and do not necessarily agree with the page numbers in the final report.

2. The deleted material pertained to a matter contained in the draft report which has been changed or is not included in this report.

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

DEC 2 1977

Mr. Monte Canfield, Director
Energy and Materials Division
United States General Accounting Office
Washington, D. C. 20548

Dear Mr. Canfield:

Thank you for the opportunity to comment on the GAO draft report entitled, "Need to Clarify Environmental Protection Agency Radiation Authorities to Ensure Protection from the Hazards of Radiation."

We appreciate GAO's revision of the report to satisfy some of our technical concerns. In general the GAO identifies a number of issues which we believe are internal problems at EPA and upon which we offer no comment. Our comments identify important omissions as well as topics which are presented in a technically inaccurate manner. The conclusions and recommendations of the GAO report do not appear to be based on information or rationale developed or presented in the draft report and there are alternative conclusions and recommendations, in addition to those presented by GAO, which should be investigated. We agree with GAO that legislation might be considered to clarify and rationalize the authorities and responsibilities of the various agencies that have important and on-going roles to play in the regulation of radiation activities. However, we do not agree with GAO's assessment that the recent Clean Air Act Amendments represent a desirable step in clarifying Federal radiation protection responsibilities. Amendments of that type create uncertainty and duplication of effort which a comprehensive and cooperative approach could avoid.

Sincerely,

for Lee V. Gossick
Executive Director
for Operations

Enclosure:
NRC's Detailed Comments

APPENDIX V

AUTHORITIES AND RESPONSIBILITIES

The GAO report fails to relate clearly EPA's guidance and standard-setting authority roles to those of the other Federal agencies having radiation protection missions, and to other EPA authorities and responsibilities. GAO's tacit thesis seems to be that EPA has been designated as the Federal guardian or "watchdog" of radiation protection covering all sources including naturally occurring and accelerator produced radioactive material (NARM), nuclear energy and weapons, and the healing arts. This seems to be the result of an overly simplistic interpretation of the scope of EPA's radiation protection jurisdiction under Reorganization Plan No. 3 of 1970, which is more complex and less clear than the GAO report reflects. As a result, the reader is given the impression that EPA provides the only protection of the public against radiation sources where actually there are very few ionizing radiation sources which are not regulated by one or more federal and/or state agencies. Appended is a paper, "Exercise of NRC Jurisdiction," which GAO might find instructive and helpful in gaining a better understanding of the fragmented authorities and the complex roles of the several Federal agencies which have responsibilities for programs which provide protection against radiation.

JURISDICTIONAL DISPUTES

After appearing to be critical of EPA for numerous shortcomings, GAO concludes that assigning additional authorities and responsibilities for EPA such as the Clean Air Act Amendments of 1977 is a "step in the right direction" and recommends that "additional such legislative authorities" are needed. We find these conclusions and recommendations to be inconsistent with the information contained in the GAO report.

A more complete study of the exercise of jurisdictions of the several agencies with responsibilities for providing protection against radiation would lead to alternative recommendations that would improve the existing situation. Some of the evolutionary changes also should be identified and factored into the recommendations. For example, one major source of confusion concerning the roles of EPA and the NRC has been the fragmentation of authorities of the Atomic Energy Act, some of which were transferred to the EPA from the Atomic Energy Commission to avoid what in 1970 was perceived to be a possible conflict between the promotion and regulatory interests of the AEC. Such potential conflicts were removed in 1975 when the AEC was replaced by the Energy Research and Development Administration and the independent Nuclear Regulatory Commission under the Energy Reorganization Act of 1974. Thus, one important reason for separating the authority for setting ambient environmental radiation standards from the authority for implementing the standards no longer exists. Indeed, the role of Federal agencies other than the EPA could be expanded rather than eroded as has occurred in recent years by the transfer to EPA of additional authorities through certain provisions of the Clean Air Act and other legislative actions.

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There are good reasons why agencies other than EPA should have authority to regulate radiation in their areas of expertise. Radiation cannot be considered in a vacuum, e.g., in the case of NRC, radiation control must be considered in the context of other factors such as nuclear safety (criticality), safeguards, nuclear proliferation, and other facets of the regulated activities. In the case of the healing arts, control must be balanced with adequate health care delivery and patient alternatives to radiation diagnosis or therapy and could be considered part of a cost/benefit analyses. Thus, a substantial gain might be realized if the EPA could concentrate on the important role of providing guidance for radiation protection programs of Federal agencies (FRC authority) and the other regulatory agencies could carry out more effectively their role of ensuring implementation of and compliance with the EPA guidance while taking into account the many other variables within their jurisdictions rather than being involved in jurisdictional confrontations. A realignment of agency jurisdictional roles would reduce the confusion and confrontations which currently exists and promote more efficient regulation and more evenhanded radiation protection programs. Therefore we support actions which might be taken to enhance the FRC role of EPA and legislation for agencies other than EPA which would give them clear responsbility and authority to implement the radiation guidance provided by EPA. The NRC has expressed a willingness to participate in studies of possible realignment of Federal agency jurisdictions.

EDITORIAL AND TECHNICAL COMMENTS

A number of specific areas in drafts of the GAO report have been identified by the task force as requiring revisions and we believe that the final report will be improved substantially. We believe that the report still suffers because GAO attempts to address too broad a spectrum of topics in the subject report: e.g., ionizing and non-ionizing radiation; routine operations and accident occurrences; hypothetical situations and actual experience; high level and low level radioactive wastes; naturally occurring and "man made" radiation sources; civilian and weapons programs; nation-wide monitoring programs; national research efforts; and legal and political aspects of regulatory programs. Consequently, the GAO report is somewhat confusing and ambiguous, particularly when complex issues are simplified for a lay reader or when topics are mixed almost at random.

[See GAO note p. 58.]

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[See GAO note p. 58.]

GAO cites a leak of 115,000 gallons of liquid waste at Richland and "public fear" when the occurrence was announced but does not cite the basis for the statement. GAO does not attempt to place the incident in perspective by providing the additional "follow-up" information on corrective actions which have been taken and the perspective that to date there has been no one injured, no known health effects, and no substantial environmental impact which resulted from the release. It also should be noted that environmental radiation protection regulations, as such, would not have prevented this incident.

CONCLUSIONS AND RECOMMENDATIONS

We believe that the GAO report should be revised to:

[See GAO note p. 58.]

-- Identify the other Federal agencies and their specific missions and activities to indicate unambiguously that they have radiation protection responsibilities even in the absence of the new EPA standards.

-- Identify areas where the poorly defined boundaries of standards setting authority have created problems in the past and may lead to problems in the future, and make these findings known.

Revised in this way, the report would go further towards placing EPA's role in better perspective, as well as presenting a more balanced picture of how the Federal government carries out its radiation protection mission, how effective that mission has been, and where the residual problem areas lie.

We do find that there are facets of the radiation protection programs which can and should be improved. Such improvements have been made in the past and continue to be made as part of an evolutionary process. For

example, naturally occurring and accelerator produced radioactive materials are sources of radiation exposure which currently are not adequately regulated owing to fragmented regulatory authority. In addition to identifying areas needing improvements, the GAO report should cite the studies* which characterize the importance of the problem, suggest solutions and present alternatives for ensuring the adequate control of these radiation sources. Such information would provide insight into the causes of confusion and confrontation among regulatory agencies.

*For example, see "Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials," NRC, NUREG-0301, July 1977 and other reports on this subject.

GAO note: The deleted material pertained to a matter contained in the draft report which has been changed or is not included in this report.

Exercise of NRC Jurisdiction

I. Environmental Protection

A. NEPA-related Statutory Authorities

Pursuant to the provisions of the National Environmental Policy Act of 1969 (NEPA), the Nuclear Regulatory Commission is required to carry out its licensing and related regulatory responsibilities in a manner which will protect and enhance the environment. Specifically, the Commission is required, in accordance with the environmental impact statement procedures prescribed by section 102(2)(C) of NEPA (42 U.S.C. 4332), to evaluate the environmental impacts of each proposed major action and the available alternative actions and, to determine, on the basis of an analysis which considers and balances the environmental effects of the facility, the alternatives available for reducing or avoiding adverse environmental effects, and economic, technical and other costs and benefits, whether a license or permit for a nuclear power plant or other facility or activity should be issued, denied or issued with conditions designed to mitigate undesirable environmental effects.

In carrying out its responsibilities under NEPA, the Commission has become aware of certain areas in which its responsibilities impinge on those of other Federal agencies. In these areas of common concern, the broad environmental review responsibilities vested in NRC by NEPA overlap with other more specific environmental review responsibilities related to nuclear activities vested in other Federal agencies - e.g., The Federal Water Pollution Control Act, as amended, Coastal Zone Management Act of 1972, Wild and Scenic Rivers Act, National Historic Preservation Act, Endangered Species Conservation Act, Fish and Wildlife Coordination Act. At present, these overlaps are most substantial in connection with implementation of the Federal Water Pollution Control Act Amendments of 1972. These overlaps could be substantial in connection with the implementation of the Coastal Zone Management Act.

1. The Federal Water Pollution Control Act Amendments of 1972 (hereafter referred to as FWPCA), Public Law 92-500, October 18 1972, 86 Stat. 816 et seq.

Background. Prior to the enactment of the National Environmental Policy Act of 1969 (NEPA), Federal and State agencies other than the Atomic Energy Commission (NRC's predecessor) exercised control over the discharge of non-radiological pollutants, such as heat, from nuclear power plants. Following the enactment of NEPA and the Water Quality Improvement Act of 1970, but prior to the enactment of the 1972 amendments to the Federal Water

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Pollution Control Act, AEC was precluded from issuing construction permits for nuclear power plants until a water quality certificate from the state in which the proposed facility was to be located was furnished (33 U.S.C. 1171(b)). This certificate, known as a "21(b) certificate" after the section of the Federal Water Pollution Control Act which established the need for it, had to indicate that there was "reasonable assurance" that the discharges from the facility would not violate the State's water quality standards. In addition to insuring that such a certificate was obtained, AEC understood its obligations under NEPA to require that it make an independent appraisal of the impact of the discharge on water quality, implement any cooling system alternatives that could, at a favorable cost-benefit balance, reduce the impact of the discharge, and consider any residual adverse environmental impact in the overall cost-benefit balance.

The Federal Water Pollution Control Act Amendments of 1972 expanded the role of the Environmental Protection Agency with respect to the protection of water quality. At the same time, in furtherance of a policy of reducing "needless duplication and unnecessary delays at all levels of government" 1/ it significantly reduced the scope of the obligations otherwise assigned to the Commission under NEPA (sec. 511(c)(2), FWPCA, 33 U.S.C. 1371(c)(2)).

Pursuant to section 402 of the FWPCA (33 U.S.C. 1342), EPA is authorized to issue a permit allowing the discharge of a pollutant if the discharge complies with certain standards established by the provisions of the FWPCA. (See e.g., secs. 301, 302, 306, 307, 308, 316, 403, 33 U.S.C. 1311, 1312, 1316, 1317, 1318, 1326, 1343.) Heat and chemical wastes are discharged from nuclear power plants and are considered pollutants within the meaning of the FWPCA (33 U.S.C. 1362(b)). However, pursuant to the opinion of the U.S. Supreme Court in Train v. Colorado Public Interest Research Group, Inc., 426 U.S. 1, June 1, 1976, source, byproduct and special nuclear materials regulated by NRC are not pollutants within the meaning of the FWPCA.

The Federal Water Pollution Control Act Amendments of 1972 changed the role of the former Atomic Energy Commission (now exercised by the Nuclear Regulatory Commission) in this regulatory scheme. Instead of the prior requirement that NRC obtain a state certification of reasonable assurance that state water quality standards will be met, NRC is now required to obtain a state certification (sec. 401, FWPCA, 33 U.S.C. 1341) that the proposed discharge will comply with Federal standards, i.e., with certain applicable provisions, such as section 301, of FWPCA. Certain requirements and limita-

1/ Sec. 101(f), FWPCA, 33 U.S.C. 1251(f).

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tions contained in this certificate must be included as conditions in the NRC permit or license. If the requisite certificate is denied, NRC is prohibited by section 401, as it was also prohibited by sec. 21(b), from issuing a permit or license. Section 511 of the FWPCA (33 U.S.C. 1371) explicitly provides that nothing under NEPA shall be deemed to authorize any Federal agency to review any effluent limitation or other requirement established pursuant to the FWPCA, or to impose, as a condition of any license or permit, any effluent limitation other than any such limitation established pursuant to the FWPCA.

These statutory changes have altered the nature of NRC's NEPA review. Instead of specifying requirements for inclusion in permits and licenses to minimize aquatic environmental impacts from nuclear power reactors, NRC's role is confined to evaluating, as one factor in the overall cost-benefit balance prescribed by NEPA, the environmental impacts of nuclear facilities on water quality assuming EPA standards and requirements have been met. Thus, both NRC and EPA (or permitting States under sec. 402 of the FWPCA, 33 U.S.C. 1342) must evaluate water pollution impacts, but EPA and the States have the preeminent role in setting and enforcing water pollution standards and limitations.

For the system to work to maximum advantage, it is necessary for EPA to have made its determination relative to a nuclear power plant's cooling system in advance of NRC's consideration of the matter. The close interface between the respective statutory authorities of EPA and NRC in the area of water quality and the resultant problems of implementation led NRC and EPA on December 17, 1975 to enter into a Second Memorandum of Understanding to clarify their respective roles in the decision-making processes concerning nuclear power plants and other facilities requiring an NRC license or permit. A copy of this Second Memorandum of Understanding, which became effective January 30, 1976, is attached.

The purpose of the Second Memorandum of Understanding is to reduce demands for water quality data placed on applicants for nuclear facilities by assuring that applicants' environmental reports contain sufficient information to meet both NRC's needs under NEPA and EPA's needs under the FWPCA, and to minimize any duplication of effort between NRC and EPA in meeting their respective responsibilities under NEPA and the FWPCA.

The Second Memorandum of Understanding provides, among other things, that:

NRC is to serve as the lead agency for preparation of environmental impact statements for nuclear facilities;

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NRC and EPA will cooperate in identifying and consolidating their respective requirements under NEPA and FWPCA for water quality data;

EPA will participate with NRC in the evaluation of water quality impacts;

In those states which do not have NPDES permitting authority, EPA will issue NPDES section 402 permits, section 316(a) exemptions and section 316(b) analyses of intake structures "as far as possible in advance" of the date of issuance by NRC of its final environmental impact statement; (Emphasis supplied.)

NRC and EPA will consider the feasibility of holding joint or concurrent hearings.

Circumstances in which EPA's FWPCA responsibilities and NRC's NEPA responsibilities are most likely to cause difficulties are those in which EPA's FWPCA requirements with respect to a particular nuclear facility (the need for cooling towers or the location of water intake structures, for example) have not been finally determined. In those instances in which a proposed applicant is seeking a section 316(a) exemption from EPA, any uncertainty as to the final disposition of the applicant's request before EPA can have a significant impact on both the scope and outcome of NRC's NEPA review, since it is possible that in some cases NRC may be unable to complete its NEPA review without knowledge of the requirements to be imposed under FWPCA. In at least one case, uncertainty as to final action on a section 402 discharge permit has had a substantial impact on the Commission's licensing process.

2. Coastal Zone Management Act of 1972, as amended, Pub. Law 92-583, October 27, 1972, 86 Stat. 1280, 16 U S.C.A. §§ 1451, et seq.

The Coastal Zone Management Act of 1972, as amended, establishes a statutory scheme under which states are encouraged, with Federal assistance, to develop and implement coastal zone management programs which will achieve wise use of the land and water resources of the coastal zone giving full consideration to ecological, cultural, historic, and esthetic values as well as the need for economic development. State coastal zone management programs are required to include a "planning process for energy facilities likely to be located in, or which may significantly affect, the coastal zone, including but not limited to, a process for anticipating and managing the impacts from such

facilities." The term "energy facilities", as defined in the Act, includes electric generating plants (nuclear power reactors fall in this category) and uranium enrichment and nuclear fuel processing facilities. These facilities are subject to regulation by NRC.

In passing the Coastal Zone Management Act, Congress included a provision (usually referred to as the "FEDERAL CONSISTENCY" provision, Section 307, as amended, 16 U.S.C.A. § 1456) to encourage states to enter into the program and to promote comprehensive Federal-State cooperative coastal zone land and water use management. Generally, the provision requires Federal agencies to administer their direct activities, regulatory functions, and assistance programs in a manner consistent with approved state coastal management programs. Pursuant to subsection (c)(3)(A) of section 307 (16 U.S.C.A. 1456(c)(3)(A)),

> any applicant for a required Federal license or permit to conduct an activity affecting land or water uses in the coastal zone of a state with an approved coastal zone management program shall provide in his application for a federal permit or license "... a certification that the proposed activity complies with the state's approved program and that such activity will be conducted in a manner consistent with the program...."

This subsection also provides that:

> "No license or permit shall be granted by the Federal agency until the state or its designated agency has concurred with the applicant's certification or until, by the state's failure to act, the concurrence is conclusively presumed, unless the Secretary, on his own initiative or upon appeal by the applicant, finds, after providing a reasonable opportunity for detailed comments from the Federal agency involved and from the state, that the activity is consistent with the objectives of this chapter or is otherwise necessary in the interest of national security."

The national coastal zone management program has now reached the stage where a number of states are completing development of their management programs and will be seeking the requisite approval of those programs which must be obtained in order to trigger the requirements of the Federal Consistency

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provision. The Department of Commerce is currently engaged in developing proposed regulations to be issued for public comment to implement that provision.

Although it is still too early to evaluate the workability of the Federal Consistency provision and its impact on NRC's regulatory program, indications are that the certification and state concurrence requirements of section 307 (c)(3)(A) could become an important factor in NRC's grant of construction permits and licenses for facilities which are either located in coastal zones or are located in areas outside of but affecting coastal zones. Under NEPA, NRC would be required to independently evaluate coastal zone impacts, notwithstanding the approval of the proposed license by the State and/or Secretary.

B. Radiological-related Statutory Authorities

1. Authority transferred to EPA by Reorganization Plan No. 3 of 1970 to carry out

(a) Certain functions of the former Atomic Energy Commission respecting the establishment of "generally applicable environmental standards for the protection of the general environment from radioactive material."

(b) All functions of the Federal Radiation Council.

(a) Transferred functions relating to generally applicable environmental radiation standards.

The functions transferred from the former AEC respecting the establishment of generally applicable environmental standards were those administered by the AEC's Division of Radiation Protection Standards. These standard-setting functions involved the establishment of ambient standards, i.e., limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

In the message to Congress transmitting Reorganization Plan No. 3 of 1970, the President stated that "AEC would retain responsibility for the implementation and enforcement of radiation standards through its licensing authority."

Recognizing their complementary responsibilities in the areas of environmental protection and the control of radiation effects occasioned by

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this transfer of functions, EPA and the former AEC executed a Memorandum of Understanding with respect to AEC-Licensed Facilities in August 1973. The purpose of this Memorandum of Understanding (copy attached) was "to fix an appropriate interface of the respective functions of the two agencies, to further facilitate their useful cooperation, and to avoid unnecessary duplication of regulatory effort, ..."

On January 13, 1977, pursuant to its transferred authority to set generally applicable environmental standards, EPA published a new Part 190 to its regulations (40 CFR Part 190 - Environmental Radiation Protection Standards for Nuclear Power Operations; 42 FR 2858-2861) establishing environmental radiation protection standards for the uranium fuel cycle. These standards specify levels below which normal operations of the uranium fuel cycle are determined to be environmentally acceptable.

In the statement of considerations which accompanied the rule, EPA stated that "[t]he authority to regulate fuel cycle facilities under these standards resides in the Nuclear Regulatory Commission. . ." EPA also pointed out that "[i]n situations where members of the public are actually exposed, these standards, [40 CFR Part 190] in effect, preempt those regulations which are based upon the Federal Radiation Protection Guides (25 FR 4402) insofar as exposure of the public is due to operations defined to be included in the uranium fuel cycle. For example, the dose limits in 10 CFR Part 20 [NRC regulations establishing standards for protection against radiation hazards arising out of activities under licenses issued by NRC] would not be the limiting consideration regarding exposure of members of the public as a result of uranium fuel cycle operations. . . ."

As contemplated by the provisions of the 1973 Memorandum of Understanding, NRC staff has recently established a task group to prepare recommendations for Commission consideration on the regulatory changes which will be needed to implement EPA's Uranium Fuel Cycle Standard. In theory, there can be no conflict between NRC's and EPA's responsibilities under the Atomic Energy Act since NRC is obligated to enforce the EPA general standards. However, the precise limits of EPA's general standard-setting authority are uncertain. In this "gray area" there is a potential for confusion and overlap. In the uranium fuel cycle area, the limits of authority are now defined. In the nuclear waste management area, the precise limits are as yet to be defined.

On December 6, 1976, EPA published an Advance Notice of Proposed Rulemaking (41 FR 53363) in which it announced its intent to develop environmental radiation protection standards for high-level radioactive wastes to assure protection of the public health and the general environment from these wastes. In its notice, EPA stated that it intended to develop applicable

environmental criteria for all radioactive wastes and that in the development of these criteria and standards it would consider all currently available information on long-term implications of radioactive wastes and the risks associated with such wastes. The EPA notice announced that the subject would be discussed in depth at a series of workshops and requested pertinent information respecting the following matters:

> The capability of various types of source encapsulation to retain high activity wastes or long-lived alpha wastes for long periods.
>
> The geologic media that may be used to contain high activity wastes, long-lived alpha wastes, or combined wastes and the retention capabilities of those media over long periods of time.
>
> Predictions of the most likely transfer co-efficients of radioactive material for selected combinations of source encapsulation, engineering containerization, geologic media, and predicted environmental levels for long periods of time.
>
> The probability and risks associated with accidental disturbances, either occurring naturally or as a result of institutional failures, and the impact of these risks on the predictions mentioned above.
>
> Factors important to providing reasonable assurance that environmental protection standards can be satisifed and that methods are available to implement environmental protection standards.

In the exercise of its statutory responsibilities for licensing and regulating nuclear power plants as well as other production and utilization facilities, for licensing and regulating certain ERDA facilities and for licensing and regulating special nuclear material, byproduct material and source material, NRC is actively engaged in developing criteria for use in licensing radioactive waste repositories which will assure that those repositories are constructed and operated in a manner which will preserve the common defense and security and protect the health and safety of the public. In connection with this regulatory program, NRC has underway a series of in-depth studies in many of the same areas in which EPA has announced its intent to conduct

studies and investigations. In consequence, duplicative investigations which have a potential for yielding conflicting conclusions are currently in progress in the same substantive areas.

(b) Transferred FRC functions

The functions of the Federal Radiation Council as specified in its organic act 2/ and transferred to the Environmental Protection Agency are to ". . . consult qualified scientists and experts in radiation matters, . . . and qualified experts in the field of biology and medicine and in the field of health physics...." to ". . . advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States. . . ." and to ". . . perform such other functions as the President may assign to it by Executive order. . . ." This statutory authority was designed to furnish a mechanism which would enable the President, on the basis of objective, independent advice reflecting the best scientific knowledge as well as policy considerations, to issue guidance to all Federal agencies which would assure uniformity and eliminate diversity in federal radiation standards. Although recommendations made by EPA in the exercise of this statutory authority are only advisory, once the President has approved these recommendations as guidance, it has generally been understood that federal agencies may not promulgate standards and regulations under their existing statutory authority which are inconsistent with that guidance.

Pursuant to its transferred FRC authority, EPA is engaged in reviewing Federal Radiation Protection Guides (25 FR 4402-4403, May 18, 1960) with a view to preparing revised recommendations for submission to the President for his approval and subsequent issuance as guidance to Federal agencies. In conducting these reviews, EPA has sought the counsel and advice of other federal agencies, including NRC. At the present time, for example, a representative from NRC is serving on the Interagency Committee on Federal Guidance for Occupational Exposures to Ionizing Radiation established by EPA to develop recommendations on occupational radiation exposures. A representative from NRC is also serving on an Interagency Liaison Committee which is working with EPA to develop guidelines for the cleanup of plutonium and other transuranium elements and the restoration of contaminated areas. The objective of these guidelines is to set a level or levels of soil contamination above which cleanup is recommended. NRC, as well as other members of the Federal Interagency Central Coordinating Committee for Radiological

2/ Public Law 86-373, 73 Stat. 688, 1959, Sec. 274h. of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2021(h).

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Emergency Preparedness, has provided comments to EPA on proposed nuclear accident protective action guides for airborne release of radioactive gases and particulates. These Protective Action Guides are being prepared for use of Federal agencies and States in emergency planning for accidents at fixed nuclear facilities and during transportation of nuclear materials. These interagency committees provide forums for the resolution of differences regarding the appropriate radiation standards. Following issuance of EPA recommendations as Presidential guidance, it is incumbent on NRC to review and amend its regulations as appropriate to bring them into conformity with this guidance. In this way, any potential conflict between NRC's regulatory authority and EPA's FRC authority to make recommendations regarding radiation standards is effectively resolved. However, in many cases both NRC and EPA would be authorized to conduct the same activities--NRC in the course of developing its own regulations (e.g., emergency preparedness requirements) and EPA in the course of developing guidance on radiation protection standards.

2. Safe Drinking Water Act, Public Law 93-523, December 16, 1974, 88 Stat. 1661, as amended. 42 U.S.C.A. §§ 300f - 300j-9.

Part C of the Safe Drinking Water Act establishes a system of Federal-State controls to prevent underground injection which endangers drinking water sources. Under the provisions of the Act, State underground injection control programs must meet certain minimum requirements to secure federal approval, including the requirement that they prohibit any underground injection not authorized by State permit or State rule. The Act defines "underground injection" as the "subsurface emplacement of fluids by well injection." The Act further provides that underground injection shall be considered to endanger drinking water sources ". . . if such injection may result in the presence in underground water which supplies or can reasonably be expected to supply any public water system of any contaminant, and if the presence of such contaminant may result in such system's not complying with any national primary drinking water regulation or may otherwise adversely affect the health of persons." The term "contaminant" as used in the Act means "any physical, chemical, biological, or radiological substance or matter in water. . . ." Under this definition, special nuclear material, byproduct material and source material regulated by NRC would be considered contaminants. Whether there is a potential conflict between the provisions of the Atomic Energy Act of 1954, as amended, and the provisions of Part C of the Safe Drinking Water Act which authorize States to conduct underground injection permit programs depends on the manner in which the statutory definition of "underground injection" is interpreted. The potential scope of this definition is rather broad and could conceivably include the emplacement below the surface of high-level or other radioactive wastes.

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On August 31, 1976, EPA published proposed regulations for State underground injection control programs (40 CFR Part 146; 41 FR 36730 - 36745, August 31, 1976). Although the statutory concepts of "underground injection" and "subsurface emplacement of fluids by well injection" were discussed at some length in the Federal Register notice, the issue of whether these concepts include emplacement below the surface of high level or other radioactive wastes was not addressed.

3. Occupational Health and Safety

In 1970, Congress enacted the Occupational Safety and Health Act of 1970 (Pub. L. 91-596, December 29, 1970, 84 Stat. 1590, 29 U.S.C. §§ 651 et seq.) to assure safe and healthful working conditions for working men and women. Section 4(b)(1) (29 U.S.C.A. § 653(b)(1)) of that Act states:

> "Nothing in this Act shall apply to working conditions of employees with respect to which other Federal agencies, and State agencies acting under section 274 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2021), exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health."

OSHA regulations specifically provide that employers who possess or use source material, byproduct material or special nuclear material under NRC or Agreement State licenses shall be deemed to be in compliance with OSHA regulations with respect to such possession and use (29 CFR § 1910.96(p).) Each year, NRC routinely makes a redetermination of continuing compatibility and adequacy of Agreement State regulatory programs. The U.S. Department of Labor has agreed to accept NRC's determination in lieu of their making independent investigations and determinations on safe working conditions for radiation workers in Agreement State licensee establishments under the Occupational Safety and Health Act of 1970.

Despite these procedures, uncertainty as to whether an overexposure in the workplace was occasioned by agreement materials (i.e., source material, byproduct material and special nuclear material in quantities not sufficient to form a critical mass) non-agreement sources of radiation or some combination of the two has resulted in the past in some overlapping in enforcement actions taken under State Agreements with the Nuclear Regulatory Commission and under OSHA-approved State plans. Following a meeting between NRC and OSHA staff members, an understanding was reached that violations arising from noncompliance with Agreement State radiation control regulations for agreement materials would be cited against the Agreement State radiation

control regulations and violations of occupational safety and health standards for nonagreement sources of radiation would be cited under appropriate OSHA standards and procedures in those States which have OSHA approved State plans. A further understanding was reached that citations would be predicated upon a determination of whether agreement materials or nonagreement sources of radiation were the major contributor to the violation.

II. Floating Nuclear Power Plants and Nuclear Power Electric Generating Stations Located on Coastal and Inland Navigable Waters

A. U.S. Coast Guard - NRC

On January 4, 1974, the former Atomic Energy Commission and the United States Coast Guard entered into a Memorandum of Understanding for the Regulation of Floating Nuclear Power Plants (39 FR 2124, January 17, 1974, copy attached). (As defined in the Memorandum of Understanding a "floating nuclear power plant" is "a nuclear power plant, mounted on and thereby integrally with a barge, fabricated at a central shipyard facility, then towed to a fixed position where it is installed and moored, nuclear fuel is loaded, and where it is operated as a floating facility to supply electrical energy into an onshore electrical load network.") The Memorandum of Understanding, which remains in effect and is adhered to by NRC specifies detailed procedures under which the respective statutory responsibilities of both agencies for the regulation of safety and protection of the environment from effects of construction and operation of floating nuclear power plants are to be exercised. (These statutory authorities are described in detail in section 2 of the Memorandum.) The Memorandum also identifies with particularity those aspects of floating nuclear power plants of primary concern to each agency and of joint concern to both agencies.

The purpose of the Memorandum, as stated therein, is to coordinate and implement consistent and comprehensive requirements to maximize safety with respect to the design, fabrication, construction and operation of floating nuclear power plants, to minimize the possible adverse environmental impact of such plants, and to minimize duplication and avoid possible inconsistency in safety requirements applied to such plants.

When the AEC and the U.S. Coast Guard began the negotiations which led to the preparation and execution of the Memorandum of Understanding, it was readily apparent that there were extensive areas of overlap and potential conflict with respect to their respective responsibilities for floating nuclear power plants. To date, NRC has found the Memorandum effective in achieving its objective of providing an orderly framework within which the regulatory responsibilities of the NRC and the U.S. Coast Guard with respect

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to floating nuclear power plants can be carried out in an efficient and consistent manner.

We would expect similar problems to arise in connection with the regulation of the construction and use of nuclear-powered merchant ships. NRC and the U.S. Coast Guard are presently engaged in discussions concerning memoranda of understanding to clarify their respective responsibilities in this area, including responsibilities relating to the presentation of U.S. views regarding the safety of nuclear-powered merchant ships in such international forums as the Intergovernmental Maritime Consultative Organization (IMCO) and the Nuclear Energy Agency of the Organization for Economic Cooperation and Development (NEA/OECD).

B. U.S. Army Corps of Engineers - NRC

Similar concerns regarding the impact of the regulatory authority of the U.S. Army Corps of Engineers over the construction of structures in navigable waters of the United States upon nuclear power electric generating stations, including floating nuclear power plants, located on coastal and inland navigable waters and at offshore sites led the Nuclear Regulatory Commission and The Corps of Engineers to enter into a Memorandum of Understanding on July 2, 1975. (40 FR 37110, August 25, 1975, copy attached.) The purpose of this Memorandum of Understanding is to provide for the coordination and implementation of consistent and comprehensive requirements to assure effective, efficient and thorough regulation of nuclear power plants and to avoid conflicting and unnecessary duplication of effort and of standards related to overall public health and safety and environmental protection. The Memorandum details the relevant statutory authorities of each agency (sec. 2) 3/ and describes the manner in which their respective responsibilities for issuing permits and licenses (sec. 4), taking enforcement actions (sec. 3), preparing environmental impact statements (sec. 3), conducting inspections (secs. 3b, 5d, e), reviews (sec. 5c, e), and public hearings (sec. 3c) will be carried out. Based on experience to date, NRC has found the procedures specified in the Memorandum effective in eliminating or minimizing areas of potential conflict between The Corps of Engineers and NRC and in enhancing the efficiency and effectiveness of their respective regulatory activities.

3/ In the case of the U.S. Army Corps of Engineers, these statutory authorities include, among others, Section 404 of the Federal Water Pollution Control Act Amendments of 1972 and the Marine Protection, Research and Sanctuaries Act of 1972 which relates to ocean dumping.

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III. Transportation

Despite enactment of the Hazardous Materials Transportation Act in 1975, there has been little change since 1968 in the respective responsibilities of the U.S. Department of Transportation and the former Atomic Energy Commission (now the Nuclear Regulatory Commission) with respect to safety in the transportation of byproduct, source and special nuclear material on land in interstate and foreign commerce. As explained more fully herein, the continuing need to develop and implement consistent, comprehensive and effective regulations and to avoid duplication of effort led these agencies, on March 22, 1973, to enter into a revised Memoranda of Understanding which is presently in effect.

The licensing and related regulatory authority assumed by the U.S. Nuclear Regulatory Commission upon its establishment January 19, 1975 pursuant to section 201 of the Energy Reorganization Act as amended 4/, included authority to license and regulate 5/, in a manner which will protect the environment 6/, promote the common defense and security and protect the public from the standpoint of radiological health and safety, the receipt, possession, use and transfer, including packaging, shipment and transportation, of byproduct material, source material and special nuclear material as defined in sections 11e, z and aa of the Atomic Energy Act of 1954, as amended. (42 U.S.C. 2014(e), (z), (aa)).

Since most shipments of radioactive materials move in routine commerce on conventional transportation equipment and are subject to the same transportation environment, including accidents, as non-radioactive cargo, the NRC, in exercising its regulatory responsibilities under the Atomic Energy Act of 1954, as amended, has placed primary reliance on packaging to assure safety in

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4/ Pub. Law 93-423, 88 Stat. 1233 at 1242, as amended by Pub. Law 94-79, 89 Stat. 413-414 (42 U.S.C. 5841).

5/ See, for example, secs. 53, 57, 62, 63, 69 and 81 (42 U.S.C. 2073, 2077, 2092, 2093, 2099 and 2111) which authorize the issuance of licenses to, among other things, receive, possess and transfer special nuclear material, source material and byproduct material and sec. 161(b) (42 U.S.C. 2201(b)) which authorizes the establishment "by rule, regulation or order, [of] such standards and instructions to govern the possession and use of ... [these materials] as the Commission may deem necessary or desirable to promote the common defense and security or to protect health or to minimize danger to life or property."

6/ Pursuant to the National Environmental Policy Act of 1969, Pub. Law 91-190, 83 Stat. 852-856, 42 U.S.C. Ch. 55.

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transport. To make certain that only those shipments of radioactive materials which are safe enough to withstand transportation hazards without detriment to the health and safety of the public are delivered to a carrier for transport, the NRC has promulgated and continuously monitors compliance with detailed regulations pertaining to procedures and standards for packaging, labeling, and shipment of radioactive material (10 CFR Part 20, Standards for Protection Against Radiation, and Part 71, Packaging of Radioactive Material for Transport and Transportation of Radioactive Material under Certain Conditions). The NRC has also promulgated and monitors compliance with detailed regulations for the physical protection, including physical protection during transportation, of certain quantities of strategic special nuclear material (see generally 10 CFR Part 73, Physical Protection of Plants and Materials).

NRC safety standards for packages used in the transportation of radioactive materials (10 CFR Part 71) are applicable to packages used in all modes of transport. These standards and regulations are directed primarily towards assuring that packaging for radioactive materials is designed and constructed to maintain, under both normal and accident conditions over its useful lifetime, the necessary design integrity, considering the type, form and quantity of radioactive contents, to prevent a significant loss of radioactive material from a package or a significant increase in radiation levels from a package, to assure nuclear criticality safety, and to provide adequate heat removal. These standards reflect two basic considerations: (1) protection of the public from external radiation, and (2) assurance that either the radioactive contents of the package are unlikely to be released during normal or accident conditions of transport or, if the container is not designed to withstand accidents, the contents are so limited in quantity as to preclude a significant safety problem if released.

In addition to safety standards for packages, NRC regulations also include procedural controls applicable to the use of shipping containers. In particular, NRC regulations provide that NRC licensed materials may not be transported or delivered to a carrier for transport unless the licensee complies with applicable Department of Transportation (DOT) regulations and the shipment is authorized by a general or specific NRC license or is exempted from this license requirement by NRC regulations (10 CFR §§ 71.3, 71.5). Under the provisions of the general license contained in § 71.12 of NRC's regulations (10 CFR § 71.12) NRC licensed materials may be delivered to a carrier for transport in previously approved containers. NRC regulations also contain detailed procedures for opening and closing packages and for inspection of packages both before and after the first and each subsequent use (see generally 10 CFR § 20.205 and §§ 71.51 - 71.63).

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Since its establishment in 1966, the U.S. Department of Transportation has had broad responsibility for transportation safety, including continuing and increasing authority to regulate the transportation of explosives, and other hazardous materials, including radioactive materials. This authority, which overlaps that of the Nuclear Regulatory Commission with respect to safety in the transportation of byproduct, source and special nuclear material on land in interstate and foreign commerce, is exercised pursuant to the Transportation of Explosives Act (18 U.S.C. 831-835), the Dangerous Cargo Act (R.S. 4472, as amended, 46 U.S.C. 170), Title VI and section 902(h) of the Federal Aviation Act of 1958 (49 U.S.C. 1421-1430 and 1472(h)) and most recently pursuant to the Transportation Safety Act of 1974, particularly Title I of that Act entitled the Hazardous Materials Transportation Act (49 U.S.C. 1801-1812). DOT authority includes authority formerly vested in the Interstate Commerce Commission under the provisions of the Transportation of Explosives Act which was expressly transferred to the Secretary of Transportation by Congress in 1966 (49 U.S.C. 1655(e)(4)).

Under the provisions of the Transportation of Explosives Act, which extend the authority of the Department of Transportation to land shipments and carriers in interstate commerce, the Secretary of Transportation is authorized to formulate regulations for the safe transportation of radioactive materials "which shall be binding upon all carriers engaged in interstate or foreign commerce" (18 U.S.C. 834(a)) and which "shall be in accord with the best-known practicable means for securing safety in transit, covering the packing, marking, loading, handling while in transit, and the precautions necessary to determine whether the material when offered is in proper condition to transport." (18 U.S.C. 834(c)). The Transportation of Explosives Act (18 U.S.C. 843(b)) also contains an express requirement that the Department of Transportation advise and consult with the Nuclear Regulatory Commission before adopting any regulations relating to radioactive materials. (As noted earlier, the responsibilities of the Interstate Commerce Commission under this Act have been transferred to the Department of Transportation.)

The authority of the Secretary of Transportation under the Transportation of Explosives Act has been strengthened by the provisions of the Hazardous Materials Transportation Act (49 U.S.C. 1801-1812) which empower the Secretary to promulgate and enforce uniform hazardous materials regulations for all modes of transportation. Pursuant to this authority, the Secretary is authorized to promulgate "regulations for the safe transportation in commerce of hazardous materials ... [which] shall be applicable to any person who transports, or causes to be transported or shipped, a hazardous material, or who manufactures, ... repairs, or tests a package or container ... certified, or sold ... for use in the transportation ... of certain hazardous materials." These regulations "may govern any safety aspect of the transportation of hazardous materials which the Secretary deems necessary or appropriate,

including ... [among other things,] packing, ... handling, labeling, ... placarding, and routing ..." (49 U.S.C. 1804(a)). Before issuing any regulations with respect to the routing of hazardous materials, the Secretary of Transportation is required by section 105(b) of the Hazardous Materials Transportation Act (49 U.S.C. 1804(b)) to consult with representatives of the Interstate Commerce Commission. Once those regulations have been adopted, the Interstate Commerce Commission is obligated to implement them to the extent of its lawful authority.

In the exercise of this broad authority, the Department of Transportation has promulgated extensive regulations, codified in 49 CFR Parts 170-189, pertaining to certain types of packaging, labeling and conditions of carriage. These regulations provide controls over the handling, stowage and storage of radioactive materials by carrier personnel and other cargo handlers. The regulations also set forth basic package performance, design and use requirements, and specify standards for marking and labeling radioactive material packages and for the preparation of standardized shipping papers which identify the basic characteristics of the radioactive material packages.

In 1966, in order to develop and implement consistent comprehensive and effective regulations for the safe transport of radioactive material and to avoid duplication of effort, the Department of Transportation and the former Atomic Energy Commission (now the Nuclear Regulatory Commission) entered into a Memorandum of Understanding. 1/ On March 22, 1973, a revised Memorandum of Understanding was signed which is presently in effect. (38 FR 8466, April 2, 1973, copy attached.) Under the provisions of this Memorandum of Understanding, the NRC develops safety standards for packaging design and performance for packages of fissile material and for Type B and large quantities of radioactive material and evaluates designs for containers for these materials. DOT is responsible for developing safety standards for packaging design and performance for all other types of radioactive material packages used in transportation and for evaluating designs for those packages.

DOT is also responsible for developing safety standards governing mechanical conditions of carrier equipment and qualifications of carrier personnel, carrier loading, unloading, handling and storage of radioactive material, and any special transport controls to be provided during carriage.

1/ The Memorandum of Understanding was initially entered into between the Interstate Commerce Commission and the Atomic Energy Commission on March 21, 1966. On April 1, 1967, the Department of Transportation assumed the functions and responsibilities of the Interstate Commerce Commission under the Memorandum of Understanding.

including construction standards for transport vehicles. The Memorandum of Understanding also contains mutual undertakings whereby NRC will adopt regulations requiring NRC licensees not otherwise subject to DOT regulations to comply with the applicable requirements of those regulations when transporting or shipping radioactive material, and DOT will adopt regulations imposing on shippers and carriers subject to its jurisdiction and not otherwise subject to NRC regulations requirements comparable to those contained in NRC regulations. The Memorandum of Understanding also provides that each agency shall conduct an inspection and enforcement program within its jurisdiction, that DOT will be the lead agency in investigating accidents and suspected leakage from radioactive material packages occurring during transit and that NRC will be the lead agency in conducting such investigations when the accidents or suspected leakage occur prior to or after transit.

To date NRC has found the Memorandum of Understanding effective in providing an orderly framework in which the regulatory responsibilities of the NRC and the U.S. Department of Transportation can be carried out in an efficient and consistent manner.

IV. Nuclear Medicine

In the field of nuclear medicine, there are several areas in which the regulatory authority of the Nuclear Regulatory Commission is affected by the statutory responsibilities of other federal agencies. 8/ While some of the areas of concern are of long standing, the announcement in 1974 by the Food and Drug Administration of its intention to terminate the exemption for AEC controlled drugs and the subsequent enactment of the Medical Device Amendments of 1976 have made the need to develop consistent regulations and avoid duplicative regulatory controls acute. The Commission is currently engaged in a comprehensive review of its regulatory policies and practices in an effort to determine how these concerns may best be resolved and to clarify NRC's role in the regulation of nuclear medicine.

Under the provisions of the Atomic Energy Act of 1954, as amended, the NRC is empowered to regulate the manufacture, distribution and clinical use of byproduct, source and special nuclear material by means of a licensing program in which the Commission licenses the possession and use of such materials by manufacturers, distributors, pharmacies, researchers, medical institutions and private physicians. The objective of this regulatory scheme

8/ The Social Security Administration, for example, controls medical services, including the medical use of radioisotopes, by controlling the reimbursement process for Medicare and Medicaid.

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is to protect the health and safety of the worker, the patient and the general public in the medical uses of byproduct, source and special nuclear material. In accordance with this authority, NRC now regulates virtually all aspects of the radiation safety of the workers and the general public and certain aspects of the safety and efficacy of radioactive drugs and devices containing these materials with respect to the patients.

For many years, the former AEC, in consultation with its Advisory Committee on the Medical Uses of Radioisotopes, regulated the safety and efficacy of radioactive drugs and devices with respect to the patient. During this period, the Food and Drug Administration, which is recognized as the lead agency in regulating nuclear medicine, was not empowered to regulate radioactive devices and expressly exempted radioactive drugs controlled by the AEC from its regulatory authority. In 1974, the FDA announced its intention to terminate the exemption for AEC-controlled drugs and the AEC withdrew from regulating the safety and efficacy of radioactive drugs. However, the AEC, now NRC, continued to evaluate the safety and efficacy with respect to the patient of certain radioactive devices, for example, bone mineral analyzers, Pu-238 pacemakers and brachytherapy sources.

The Federal Food, Drug and Cosmetic Act of 1938 (42 U.S.C.A. §§ 301 et seq.) authorized the Food and Drug Administration to regulate the safety of drugs offered for interstate commerce through control of product labeling. Legislative amendments in 1962 gave the FDA tighter controls over drug safety and introduced controls over the efficacy of drugs to foreclose the marketing of safe, adequately labeled drugs that do not work. The Federal Food, Drug and Cosmetic Act of 1938, as amended, also authorized the FDA to control the manufacture of drugs, including radioactive drugs. In 1976, Congress enacted the Medical Device Amendments of 1976, (Public Law 94-295, May 28, 1976, 90 Stat. 539-583) which gave the Food and Drug Administration authority to regulate medical devices similar to its authority to regulate the safety and efficacy of drugs.

In carrying out its statutory responsibilities, FDA employs a system of pre-market approval for drugs and pre-market approval, performance standards or general controls for medical devices. Under this regulatory scheme, FDA requires drug manufacturers to carry out extensive investigational programs to establish the safety and efficacy of new drugs or of new uses of drugs previously approved for other uses before these new drugs or new uses are approved for routine use. During this investigational stage, FDA exercises regulatory control over the use of radioactive drugs and devices.

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Although Congress clearly required the FDA to control the availability of drugs for prescribing physicians, it did not intend FDA to regulate or interfere with the practice of medicine. Accordingly, Congress did not give FDA statutory authority to regulate the use of drugs after their approval for routine use. Instead, Congress limited FDA's responsibilities to determining the safety and effectiveness of drugs and the truthfulness of their labeling. Final judgment as to which, if any, of the available drugs a patient should receive, remained the responsibility of the physician to be exercised by the physician in the light of the information contained on the drug label and other data available to him.

APPENDIX VI

U.S. DEPARTMENT OF LABOR
OFFICE OF THE ASSISTANT SECRETARY
WASHINGTON, D.C. 20210

DEC 8 1977

Mr. Gregory J. Ahart
Director, Human Resources Division
United States General Accounting Office
Washington, D. C. 20548

Dear Mr. Ahart:

Enclosed, as requested, is the Occupational Safety and Health Administration's response to the draft General Accounting Office Report entitled "Failure to Adequately Protect the American People from the Hazards of Radiation."

Sincerely,

for ALFRED M. ZUCK
Assistant Secretary for
Administration and Management

Enclosure

OSHA RESPONSE TO DRAFT GENERAL ACCOUNTING OFFICE REPORT "FAILURE TO ADEQUATELY PROTECT THE AMERICAN PEOPLE FROM THE HAZARDS OF RADIATION"

On page 23 of the draft General Accounting Office report entitled "Failure to Adequately Protect the American People from the Hazards of Radiation," it was stated that the Department of Labor, specifically the Occupational Safety and Health Administration (OSHA), had not fully cooperated with the Environmental Protection Agency (EPA) Interagency Committee on Radiation. In response to this statement, OSHA submits the following information:

The Environmental Protection Agency has a broad mandate to protect the general public and the environment from radiation exposures. OSHA, on the other hand, has jurisdiction over occupational radiation exposures from sources such as x-ray machines and accelerator-produced and naturally occurring radioactive materials. To the extent permitted by its statutory authority and resources, OSHA cooperated with the EPA Interagency Committee to protect workers from radiation hazards.

Early this spring, OSHA, EPA, the Consumer Product Safety Commission (CPSC), and the Food and Drug Administration (FDA) agreed that improvement in the overall coordination by regulatory agencies responsible for safeguarding worker and public health was needed. As a result, on September 26, 1977, OSHA, EPA, CPSC and FDA entered into an interagency agreement relating to the regulation of toxic and hazardous substances which includes radiation control. The objectives of this agreement are threefold: 1) to make the most efficient use of resources, 2) to achieve consistent regulatory policy, and 3) to improve the protection of the environment and of worker and public health. To meet these objectives, the agencies will coordinate: regulations where a hazard can most effectively be controlled by joint participation; compliance and enforcement procedures and policies; research and development policies; methods of obtaining, analyzing, storing, and exchanging information which could be of mutual interest; and public communication and education programs. Furthermore, the four agencies have established interagency communications channels to facilitate the exchange of information and to explore options for increasing cooperation and coordination.

Under this interagency agreement, a Regulatory Development Workgroup has been formed to study and make recommendations about regulatory problems common to two or more of the agencies. One of the topics to be studied by the workgroup is ionizing radiation, and a specific subgroup has been formed for this purpose with the Food and Drug Administration as the lead agency.

APPENDIX VII

PRINCIPAL ENVIRONMENTAL PROTECTION AGENCY OFFICIALS RESPONSIBLE FOR ADMINISTERING ACTIVITIES DISCUSSED IN THIS REPORT

	Tenure of office	
	From	To
ADMINISTRATOR:		
Douglas M. Costle	Mar. 1977	Present
John R. Quarles, Jr. (acting)	Jan. 1977	Mar. 1977
Russell E. Train	Sept. 1973	Jan. 1977
John R. Quarles, Jr. (acting)	Aug. 1973	Sept. 1973
Robert W. Fri (acting)	Apr. 1973	Aug. 1973
William D. Ruckelshaus	Dec. 1970	Apr. 1973
ASSISTANT ADMINISTRATOR FOR AIR AND WASTE MANAGEMENT:		
Edward F. Tuerk (acting)	Jan. 1977	Present
Roger Strelow	Apr. 1974	Jan. 1977
Charles Elkins (note a)	Oct. 1973	Apr. 1974
David Dominick (note a)	June 1971	Oct. 1973
DEPUTY ASSISTANT ADMINISTRATOR FOR RADIATION PROGRAMS		
William D. Rowe	May 1972	Present
William A. Mills (acting)	Nov. 1971	May 1972
Joseph Lieberman	Jan. 1971	Nov. 1971

a/ Before Jan. 1974, the title of this position was Assistant Administrator for Categorical Programs.

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