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

AUG 2 1979

MEMORANDUM FOR THE PRESIDENT

FROM : The Secretary of Health, Education, and Welfare

SUBJECT: Radiation Exposure Inquiry

In a memorandum that you initialed, Messrs. Eizenstat and Brzezinski asked me in May 1978 to work with the Secretary of Defense, the Secretary of Energy, and the Administrator of Veterans' Affairs to coordinate formulation of a program on the health effects of ionizing radiation. Subsequently, the Nuclear Regulatory Commission, the Environmental Protection Agency, and the Department of Labor were added to the addressees of the White House request.

This memorandum responds to your assignment. It is the last memorandum I will send to you as Secretary of Health, Education, and Welfare. These recommendations and the attached report represent more than 15 months of hard work by people in this Department and throughout the Government.

I make the recommendations contained in this memorandum on the basis of my profound concern that the Government protect the public health in the area of low level radiation as effectively as possible. I make these recommendations without any bureaucratic stake in the outcome.

You asked that the program include:

- o A research program to determine the effects of radiation on human populations exposed to it;
- o A public information program to inform people who might have been affected and the general public about Federal agency activities;
- o A plan for ensuring that persons adversely affected by radiation exposure receive the care and benefits to which they may be or should be entitled;
- o Recommendations on steps to be taken to reduce radiation exposure in the future.

To carry out this directive, I established an Interagency Task Force on the Health Effects of Ionizing Radiation, chaired by the General Counsel of HEW. The Task Force included a high level official from each of seven agencies: HEW, the Department of Defense (DoD), the Department of Energy (DoE), the Department of Labor (DoL), the Environmental Protection Agency (EPA), the Nuclear Regulatory Commission (NRC), and the Veterans Administration (VA).

The Task Force conducted its proceedings openly, consulting with interested members of Congress and their staffs, scientists representing different viewpoints on radiation, public interest and environmental groups, representatives of the nuclear power industry and of the medical professions, State agencies, labor unions, and veterans' organizations.

The Task Force addressed only ionizing ra on for a variety of reasons: The agencies involved with non-ionizing radiation are quite different; and a task force established by the Office of Science and Technology Policy is addressing non-ionizing radiation.

The Task Force issued its final report in June and made several major findings:

- o <u>There is inadequate coordination among Federal agencies</u>.

  The Task Force found that coordination of radiation protection and research activities among the fifteen Federal agencies engaged in radiation use, study, and control has been <u>ad hoc</u> and inadequate. In addition, there are both overlaps and gaps in statutory authorities. These problems contribute to the public perception that the government has failed to address radiation issues in an effective and credible way.

- o <u>DoE currently dominates research into the health effects of radiation</u>.

  Research into the health effects of ionizing radiation is dominated by DoE, an agency which is responsible for developing nuclear weapons and promoting and developing energy sources that can involve some exposure to

radiation. Although numerous agencies have research needs in this area, DoE conducts or supports more than 60 percent of research on the biological effects of ionizing radiation and more than 75 percent of the portion dealing with the effects on humans.

- o Additional research is needed.

  While more is known about the effects of ionizing radiation than is known about the effects of most other environmental and occupational hazards, there remain serious gaps in our knowledge about low-dose effects of radiation. In addition, improved access to records is necessary to facilitate epidemiologic research.

- o Great difficulties exist in resolving radiation-related claims.

  A number of persons are seeking care and benefits for injuries that may have resulted from radiation exposures, yet most programs do not have criteria for deciding radiation-related claims. The major barrier to resolving claims is the difficulty in distinguishing cancer and other injuries that may be radiation-related from those that are not.

- o The greatest opportunity at present to reduce exposure to radiation lies in controlling unnecessary medical and dental exposures.

  The Food and Drug Administration (FDA) estimates that a substantial number of exposures of medical and dental patients to radiation are unnecessary and can be eliminated. This is significant, since more than 90 percent of all exposure to man-made radiation comes from medical and dental sources.

- o There is a lack of reliable public information.

  Many people are concerned about radiation but do not have ready sources of information to answer questions.

These findings led the Task Force to recommend the establishment of a comprehensive and coordinated program on the health effects of ionizing radiation. It recommended changes in the institutional framework for handling both of the government's two major activities: the setting of radiation protection standards and the carrying out of research. In addition, the Task Force recommended many specific changes to improve Federal oversight

of the public's health and safety with respect to ionizing radiation. Members of the Task Force unanimously approved the final report and its recommendations and submitted it to me and to the heads of other Task Force agencies.

With two exceptions, described below, I am recommending that you adopt the Task Force's recommendations.

Following are the broad-based institutional changes that I recommend in the Federal government's program on the health effects of ionizing radiation:

- o Establish a radiation policy council which would be responsible for advising on broad radiation protection policy, chaired by EPA. (This differs from the Task Force recommendation that the chair be appointed by you from among the agencies represented on the committee.)

- o Establish an interagency research committee to coordinate research activities with respect to the health effects of ionizing radiation, chaired by the National Institutes of Health (NIH).

- o Shift the balance of funding and management of research in this area from DoE to NIH and other agencies that have health-related missions. (This differs from the Task Force's recommendation, as described on p. 7.)

- o Improve the capacity of Federal compensation programs to resolve claims of persons who believe their injuries to be the result of radiation exposure. You have established an interagency task force to study the compensation issue, which should consider this Task Force's recommendations.

The following sections describe in more detail and seek your approval of these recommendations affecting institutional arrangements and others concerning programmatic improvements.

I. INSTITUTIONAL ARRANGEMENTS

In one of its most important and difficult tasks, the Task Force examined ways to improve the coordination and credibility of the Federal government's handling of issues relating to the use, study, and control of ionizing radiation. The Task Force recommended changes in the organization and coordination of Federal radiation protection and research activities.

A. Radiation Policy Council

The Federal Government is both a major user (e.g., medical x-rays, radiation therapy, weapons production) and a regulator (e.g., power generation) of sources of radiation. One of the most important issues considered by the Task Force was how to coordinate the activities of the Federal agencies involved to ensure that workers and the general public are adequately protected from unnecessary exposure to radiation.

EPA, the agency charged with providing guidance to Federal agencies on basic exposure limits, has over the years given a low priority to its responsibilities to provide radiation guidance. Recently, EPA has moved to increase significantly its commitment to these activities. The scope of EPA's authority is ambiguous in some areas, however, leading some other agencies to dispute its authority to provide guidance to them in their areas of responsibility. The Task Force considered two methods for coordinating radiation activities -- a lead agency approach and an interagency radiation council.

I support -- and I urge you to adopt -- the Task Force's recommendations to coordinate overall Federal radiation policy:

- That a radiation policy council be established to be comprised of high level officials from all Federal agencies with major regulatory, operational, and research responsibilities in the field of radiation. It should be terminated automatically after four years unless the President decides otherwise.

- The council should:

  -- Advise on the formulation of broad radiation protection policy;

  -- Coordinate Federal activities related to radiation use and control;

  -- Resolve problems of jurisdiction among the agencies and recommend legislation to fill gaps in authority;

-- Ensure effective liaison with the States and the Congress;

-- Provide a forum for public participation and comment.

o One of the council's first tasks should be to conduct a review of the guidance authority now exercised by EPA and the statutory authorities of other agencies to determine the appropriate scope of guidance, how the setting of guidance can be improved, and how its implementation can be reviewed to assure appropriate modifications in the future.

o The council should be responsible for ensuring that the major recommendations of the Task Force on reduction of exposure and public information are implemented as soon as possible.

The council would centralize responsibility to review policy development on radiation-related issues and encourage coordination among the many agencies with relevant authorities. Since the sources and uses of radiation are varied, it is difficult for a single agenc to provide leadership in all areas. The establishment of such a council is supported by most groups and individuals concerned with radiation protection.

I believe that EPA should remain as lead agency in establishing guidance authority bearing on radiation protection and recommend that you appoint EPA to chair the policy council. The policy council should have a small budget and immediate staff of 3-4 persons. EPA is probably the appropriate agency to provide the staff and budget support as needed.

Decision

o Establish council as overall advisory and coordinating body as described.

yes _____ no _____

o Appoint EPA to chair the council.

yes _____ no _____

B. Interagency Research Committee

While research on the health effects of ionizing radiation has been concentrated largely in DoE, numerous agencies have research needs in this area. The Congress has recognized the need to broaden the research effort in this area by directir several different agencies to expand their research activities:

- o HEW has been directed to establish a comprehensive program of research into the biological effects of low-level ionizing radiation and to review existing Federal agency research programs;

- o NRC and EPA, in consultation with HEW, have been directed to conduct preliminary studies of epidemiologic research into the health effects of low level ionizing radiation and to report to the Congress on the feasibility of options for study.

The Task Force recommended that steps be taken to improve coordination of the research effort on the health effects of low-level radiation and to ensure that different agencies' research needs were met. I support the following Task Force recommendations to accomplish these goals:

- o An interagency radiation research committee should be established, chaired by the National Institutes of Health and including representatives from all major research and regulatory agencies.

- o The interagency committee would be directed to perform the following functions:

  - -- Assure that the Federal government conducts a comprehensive research program on the biological effects of ionizing radiation;

  - -- Establish appropriate research priorities and coordinate agency research programs;

  - -- Ensure that the research needs of regulatory agencies will be addressed, by research agencies as well as by the regulatory agencies themselves;

-- Identify appropriate agencies to fund research, according to guidelines developed by the committee;

-- Review agency budgets and report to the Office of Management and Budget and to the President on the adequacy of support for radiation research;

-- Develop criteria for research management, following a review by the National Academy of Sciences of Federal research management practices in this area;

-- Review the status of on-going research projects;

-- Ensure prompt dissemination of research results and promote the exchange of substantive ideas among scientists employed by Federal agencies.

-- Provide a point of contact to groups and individuals outside government who are concerned with radiation research issues and seek their advice, consultation, and participation in the work of the committee.

In addition, the chair of the committee would be directed to consult regularly with the chair of the policy council.

Finally, I recommend that you require that the Director of NIH/Chair of the committee provide a separate report which describes whether sufficient research is being undertaken with respect to the health effects of ionizing radiation and, if not, what additional research is needed.

Decision

o Establish an interagency research committee, as described.

yes _____ no _____

o Appoint NIH to chair the committee.

yes _____ no _____

o Require that the Director of NIH/Chair of the committee provide a separate report to OMB and the President.

yes_____ no_____

C. Agency Research Roles

The Task Force members agreed that the research roles of health and regulatory agencies should be increased in relation to the role of DoE. It considered recommending either increasing the future radiation research budgets of NIH and other research agencies, without increasing DoE's or transferring a portion of DoE's budget to those agencies.

However, it was not able to agree on either approach. As a compromise, it recommended that:

o NIH assume a lead role in funding research.

o Other health-oriented agencies like EPA, FDA, the Center for Disease Control, and the National Science Foundation expand their research roles in this area.

o The research committee review existing programs and proposed research agenda, determine whether it is appropriate to transfer portions of DoE's research budget to other agencies, and, if transfer is appropriate, recommend which projects to transfer.

My recommendation goes beyond the Task Force's on this issue. I feel strongly that the major responsibility for research into the health effects of low-level radiation should be placed on an agency which has health-related research as its primary responsibility. The credibility of government-supported research in this area will be compromised if the major source of funding continues to be the agency responsible for developing nuclear weapons and developing and promoting energy sources that result in radiation exposure.

The inherently schizophrenic nature of this dual mission has already damaged the credibility of the government's effort to protect the public health; indeed there are responsible scientists who believe it has damaged the public health itself.

I believe that the balance of resources should be shifted from DoE to NIH and other health-related agencies over the next 2-3 fiscal years. A gradual building up of other agencies' research budgets, without shifting resources from DoE, would take too long and, in view of the other research priorities these agencies have, there is some question about whether a large increase primarily in this one area of research would be justified.

Other agencies disagree with this position. DoD opposes any shift in funding. DoE and EPA believe that the research committee should consider this issue, without prejudgment of whether or not any transfer should occur. The view of these agencies is that management of scientific studies in this field requires considerable specialized expertise as well as rapport with scientists and institutions that have performed this type of research in the past. They believe that DoE now possesses this expertise and these connections, whereas it will take NIH and others considerable time to develop them.

I believe that research funding could be shifted without losing valuable scientific expertise. The National Labs, for example, would continue undoubtedly to perform much of the radiation research regardless of where the funding and supervision were housed.

HEW has a strong interest in radiation research, particularly since it is responsible for helping ensure public safety in the area of medical x-rays. It is true that HEW has not played as strong a role in the past as it could have with respect to research in this area, but that is changing. The Director of NIH has established an Interagency Committee on Research into the Health Effects

of Ionizing Radiation, which includes representatives from all of the radiation-related agencies. That Committee is conducting a comprehensive review of radiation research and has already begun coordinating research efforts in some areas, including followup studies of the accident at Three Mile Island and a study of residents downwind from the Nevada atomic bomb test site. In addition, NIH is assuming greater responsibility in this area by enlarging significantly its own research effort on ionizing radiation.

Decision

- o Shift a significant portion of research funding and management from DoE to NIH and other health and regulatory agencies over the course of the next 2-3 fiscal years.

yes_____ no_____

If yes, how should it be accomplished?

_____ Shift a significant portion of research funding and management from DoE to NIH and other health and regulatory agencies over the course of the next 2-3 fiscal years. (Recommended)

_____ Increase research budgets of health and regulatory agencies, leaving DoE's as it is.

_____ NIH assume a lead role; other health oriented agencies like EPA, FDA, CDC, and NSF expand research roles; research committee reviews existing programs and the research agenda and determines which, if any, portions of DoE's budget should be transferred to other agencies.

_____ Other

D. Care and Benefits

You have recently established a task force to study compensation of persons who may have developed radiation-related illnesses as a result of exposure to nuclear weapons tests, particularly civilians residing

downwind from test sites. In addition, the task force will look at questions concerning compensation of workers and veterans that were raised by this Task Force. I recommend that the compensation task force also consider carefully the recommendations of this Task Force on care and benefits as it formulates its own recommendations.

Decision

- o Direct the compensation task force to consider the care and benefits recommendations of the Interagency Task Force on the Health Effects of Ionizing Radiation.

yes _____ no _____

II. PROGRAMMATIC IMPROVEMENTS

In addition to these important institutional changes, the Task Force made, and I support, a number of other significant recommendations to improve the Federal government's programs in the health effects of ionizing radiation.

While the following is not a comprehensive list of Task Force recommendations, I believe these are the recommendations that call for Presidential direction. Many of these, and others that are not included on this list, can be considered and implemented by the policy council once you have made decisions on the basic policy issues.*

A. Records and Privacy

The Administration's "Privacy of Researchers Records Act," if enacted, will significantly improve access to necessary Federal records, with safeguards to protect the privacy of individuals. In addition, the Task Force recommended certain other steps that can be taken within HEW to improve such access and I have directed the appropriate HEW components to implement them.

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*The Task Force report, containing its recommendations is attached.

However, one important obstacle remains in this area. The Internal Revenue Code, with one limited exception, prohibits IRS or SSA from disclosing return information for research purposes. In some cases, researchers' access to this information could be crucial to the success of a research project because of the time, expense, and risk of failure in relying exclusively on decentralized local resources for the identification and location of study subjects.

The Task Force recommended the following action, which I support:

- o The Department of the Treasury and the Secretary of Health, Education, and Welfare should prepare a legislative proposal to amend the Internal Revenue Code to authorize the Internal Revenue Service and the Social Security Administration to disclose return information that is necessary for epidemiologic research with appropriate safeguards to protect the privacy of individuals whose records are disclosed.

Decision

- o Direct the Departments of Treasury and HEW to consider the need for a legislative proposal to amend the Internal Revenue Code as described and to develop a proposal, if needed.

yes_____ no_____

B. Reduction of Exposure

Half of radiation exposure is from man-made sources. The most significant exposure from man-made sources occurs during purposeful exposure of medical and dental patients to radiation for diagnosis of disease. The Task Force recommended that the following measures be taken to reduce exposure primarily from these sources:

- o Each potential opportunity for radiation exposure reduction should be reviewed in terms of its feasibility, cost, and the risks and benefits it would provide to society.

- o A program should be undertaken to reduce radiation exposure from medical sources.
- o Federal agencies should undertake on full and open review of existing exposure standards.
- o Human exposure and environmental monitoring should be expanded and better measurement technology developed.
- o State radiation control programs should be strengthened to help them to take on more responsibility for exposure reduction.

I recommend that the policy council consider these, and other recommendations of the Task Force on exposure reduction and where appropriate, develop recommendations for implementing them.

Decision

- o Refer Task force recommendations on exposure reduction to the policy council.

yes_____ no_____

C. Public Information

Information programs should be developed for the following target audiences, adapted to their needs and using appropriate channels of communication.

- o Health care personnel and patients
- o Workers exposed to radiation on the job
- o Persons exposed as a result of atmospheric nuclear tests
- o Those who live near facilities using radioactive materials
- o The general public

I recommend that the policy council consider what type of public information programs should be developed for each of these groups and to recommend steps to implement such programs.

Decision

o Refer Task Force recommendations on public information to the policy council.

yes _____ no _____

Joseph A. Califano, Jr.