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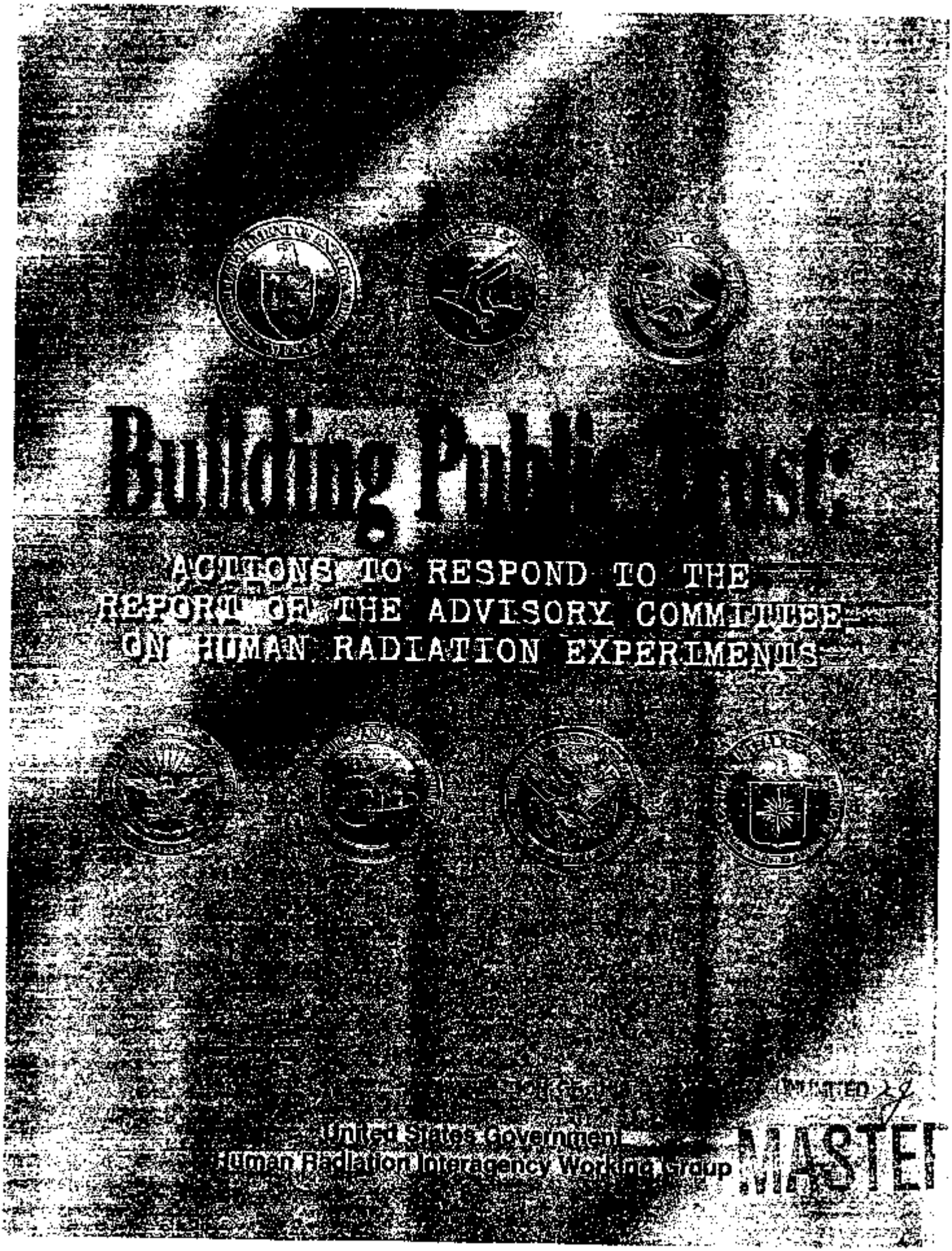
ACTIONS TO RESPOND TO THE REPORT OF THE ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS



Building Public Trust

ACTIONS TO RESPOND TO THE REPORT OF THE ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

United States Government
Human Radiation Interagency Working Group

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WASHINGTON

In January 1994, after accounts of Cold War-era experiments involving the effects of radiation on humans came to light, I established an independent Advisory Committee on Human Radiation Experiments to investigate these reports. I asked the Committee to determine the truth about this dark chapter in our nation's history.

After taking extensive testimony and conducting numerous public hearings, the Advisory Committee issued its report in October, 1995. The Committee's report included recommendations to make the record of these experiments open to the public, improve ethics in human research today, and right the wrongs of the past inflicted on unknowing citizens. In my remarks when I accepted the report, I promised that it would not be left on the shelf to gather dust. I made a commitment that we would learn from the lessons that the Committee's report offered and use it as a road map to lead us to better choices in the future.

This document -- my Administration's response to the Advisory Committee's report -- is a milestone in meeting that commitment. We have actively worked to respond to the important recommendations made by the Advisory Committee through a special interagency working group. This group includes representatives from the Executive Office of the President, the Departments of Energy, Defense, Health and Human Services, Justice, Veterans Affairs, the National Aeronautics and Space Administration, and the Central Intelligence Agency. The Environmental Protection Agency has also joined the effort. This report reflects the joint progress of these agencies to address the Advisory Committee's recommendations.

My Administration has made significant achievements in opening government and making information more easily available to the citizens to whom it belongs. Agencies have also improved the protections in place for subjects of future human research. Finally, the Federal government is providing redress to those who have suffered from radiation experiments, as recommended by the Advisory Committee.

I emphasize that this document is by no means the end of the journey. Much work remains to be done. I am confident that all of us -- the eminent committee that produced the original report, the Federal officials who worked so hard to support the Committee's efforts and now are implementing its recommendations, and most importantly, the citizens of this great country from whose experiences we have learned so much -- can together help ensure a better world for our children.

My thanks to all of you for a job well done. I pledge my strong support for your continued efforts.

Bill Clinton

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Executive Summary

"Our greatness is measured not only in how we . . . do right but also [in] how we act when we know we've done the wrong thing; how we confront our mistakes, make our apologies, and take action."

—President Clinton
October 3, 1995

In January 1994, President Clinton established the Advisory Committee on Human Radiation Experiments (ACHRE) to examine reports that the government had funded and conducted unethical human radiation experiments and releases of radiation during the Cold War. The President directed ACHRE to uncover the truth, recommend steps to right past wrongs, and propose ways to prevent unethical human subjects research from occurring in the future. The Committee published its findings and recommendations in October 1995.

The Administration has adopted most of ACHRE's recommendations and has acted throughout the government to implement them.

This report presents the Administration's actions to respond to ACHRE's findings and recommendations. The Committee found that the government had conducted several thousand human radiation experiments from 1944 to 1975. Although the majority of the experiments advanced biomedical science and were unlikely to have caused harm, some were conducted unethically. ACHRE made 18 recommendations to improve openness in government, protect human subjects in the future, and redress past wrongs. The Administration has adopted most of ACHRE's recommendations and has acted throughout the government to implement them.

Opening the Record

ACHRE recommended that the government take a number of steps to organize the historical records of human radiation experiments and to give the public access to these records. ACHRE identified the National Archives as the appropriate repository for documents. The Committee also recommended an independent review of the CIA's recordkeeping system and all of its documents related to human radiation experiments.

Key Actions

- The Administration has invested heavily in making documents accessible. ACHRE transferred more than 1 million pages of documents to the National Archives. The Administration has made 300,000 fully searchable pages of documents available on the Internet, and will add an additional 200,000 pages shortly. The Departments of Energy and Defense have published document search guides.

The Administration has invested heavily in making documents accessible.

- The President signed Executive Order 12958 directing Federal agencies to review and declassify thousands of documents, including documents on radiation experiments.

- The National Archives and Records Administration is conducting an independent review of the Central Intelligence Agency's (CIA's) recordkeeping system and the CIA's Inspector General reviewed and reported on the CIA's human experiments.

Protecting Human Subjects in the Future

The Advisory Committee recommended steps to strengthen protections for human subjects and ensure the government does not repeat past mistakes.

Key Actions

- President Clinton is issuing a directive to strengthen protections for subjects of classified (secret) research. Agencies will propose new rules to eliminate waiver of informed consent; disclose the identity of the sponsoring agency; ensure a more independent review process; and require permanent records. Agencies will also report annually on the number of classified human research projects and the number of human subjects involved in each project.

A subcommittee of National Bioethics Advisory Committee will address certain broad questions raised by ACHRE, including how to strengthen Institutional Review Boards—the local ethics panels for federally sponsored research.

- President Clinton established the National Bioethics Advisory Committee (NBAC) to examine bioethical issues, including human research issues. A subcommittee of NBAC will address certain broad questions raised by ACHRE, including how to strengthen Institutional Review Boards (IRBs)—the local ethics panels for federally sponsored research.

- President Clinton directed agencies to develop plans to improve oversight of ethics rules. NBAC will review these plans in the coming months.

- Agencies have undertaken nationwide education efforts to raise the profile of ethical considerations, and are funding research to improve our understanding of ethical issues.

Righting Past Wrongs

The Advisory Committee recommended, among other things, that the government apologize to all subjects, compensate certain subjects, and consider modifying the Radiation Exposure Compensation Act, and its regulations, to compensate additional uranium miners.

Key Actions

- The President apologized to all subjects on behalf of the government; former Energy Secretary Hazel O'Leary made apologies in certain individual cases.

- ACHRE recommended that the government compensate the families of the 18 subjects of the plutonium injection experiments. The government has settled compensation claims with the 16 families who have come forward. ACHRE and the government have not been able to identify participants in additional experiments that ACHRE included in its recommendation for compensation.

The Federal government has settled the compensation claims of the 16 families of plutonium injection subjects who have come forward.

- The Administration will propose legislative and regulatory changes to the Radiation Exposure Compensation Act to incorporate the latest science and better compensate affected uranium miners.

- The Administration will propose legislation to make veterans treated with nasopharyngeal radiation eligible for health screening under the Department of Veterans Affairs' Ionizing Radiation Program.

The actions and policies described in this report will help bring justice to those harmed by the mistakes of the Cold War, and prevent the recurrence of past wrongs. The report presents those actions that are completed or underway. The Administration will continue to take steps to open the government's records, raise ethical standards, and right the wrongs of the past.

Introduction

Democratic government requires trust: people need to know and believe that the government is telling the truth. Without information about what the government is doing and why, citizens cannot exercise democratic control over government institutions.

During his first year in office, President Clinton became concerned about reports that the government had conducted unethical secret human radiation experiments during the Cold War. To address this issue, in January 1994, President Clinton established the Advisory Committee on Human Radiation Experiments (ACHRE), chaired by bioethicist Dr. Ruth Faden of Johns Hopkins University. The President also directed all Federal agencies to search for records related to human subjects radiation research and provide them to the Advisory Committee.

During his first year in office, President Clinton became concerned about reports that the government had conducted unethical secret human radiation experiments during the Cold War.

The Committee's charge was to provide advice regarding scientific and ethical issues related to biomedical experiments that involved ionizing radiation and certain intentional releases of radiation. The President directed the Committee to focus on the period 1944 to 1974 (before regulations on human subject research were adopted by the Department of Health Education and Welfare). The Advisory Committee published an interim report in 1994, and a final report in October of 1995. Two years of work culminated with a final report containing 23 findings and 18 specific recommendations.

After the Advisory Committee made its recommendations, Federal agencies sponsored a 2-day workshop for members of the public concerned about these issues. The workshop gave private citizens with an interest in human radiation experiments an opportunity to provide input into the government response to the recommendations of the Advisory Committee. The Administration has considered the views of the stakeholders in responding to ACHRE's recommendations. The full transcript of this workshop is available on the Internet (www.ohre.doe.gov).

This report presents the Administration's actions to respond to ACHRE's recommendations. The Administration has adopted most of the Committee's recommendations, has done more than the Committee recommended in a few instances, and has not accepted a few of the Committee's recommendations. This report explains these decisions.

This report is divided into three sections. Part 1: Openness in Government, describes steps the Administration has taken to make government records of human radiation experiments readily available to the public. Part 2: Protecting Future Human Subjects, sets forth the Administration's actions to strengthen the protection of human subjects. Part 3: Righting Past Wrongs, summarizes the Administration's efforts to notify the public and individuals about past human radiation experiments and bring justice to those affected by the government's mistakes.

This report presents those actions that are completed or underway. The Administration will continue to take steps to open the government's records, raise ethical standards, and right the wrongs of the past.

Part 1: Openness in Government

Overview

Throughout our nation's history, the government has needed to operate with some secrecy to protect our nation's security. At the same time, Americans have recognized that the government's power to act in secret conflicts with core democratic principles. Misuse of secrecy feeds a sense of mistrust in government that can undermine our cohesion as a nation.

The Administration has changed rules that kept documents secret for many years after it was necessary.

During the Cold War, the government funded human radiation experiments, some of which were secret. It is imperative that the public have access to the record of the government's activities. The Administration has opened the record, as discussed below, and has changed rules that kept documents secret for many years after it was necessary. These changes, along with other safeguards in place already, will help to ensure that the government does not repeat the wrongs of the human radiation experiments.

Actions to Open the Record

When the Advisory Committee on Human Radiation Experiments (ACHRE) began its work, it found that there was no complete and accurate history of the government's actions. Moreover, the records of what had happened were dispersed, difficult to access, and some were classified. The Administration mobilized all key Departments to examine, declassify where necessary, and bring together the documents that ACHRE needed. Only after these documents became available could ACHRE fully examine and evaluate the government's conduct and make recommendations for the future. ACHRE collected and transferred to the National Archives over 1 million pages of documents. Supplementing that material are over 5 million pages of documents from the Department of Energy (DOE), the Department of Defense (DOD), the Central Intelligence Agency (CIA), the Department of Veterans Affairs (VA), the Department of Health and Human Services (HHS), and the National Aeronautics and Space Administration (NASA).

The Administration mobilized all key Departments to examine, declassify where necessary, and bring together the documents that ACHRE needed.

A large and growing body of documents collected by the Federal agencies is available for online searching through the Internet at the Human Radiation Experiments Interagency Web Site (hrex.dis.anl.gov). This site currently allows citizens to examine nearly 300,000 pages of material and will contain approximately

half a million pages when completed later this year. The database provides both document images and sophisticated full-text searching capabilities. Many of these documents were originally unclassified, but approximately 7,000 were specifically declassified for this project.

The general availability of information about human radiation experiments has caused citizens to wonder about their own role in this history. As a result, thousands have sought information about their possible participation in human radiation experiments. To protect individual privacy, personal information is not publicly available. However, individuals can request information related to their possible personal involvement through the Helpline at (202) 586-8439.

The general availability of information about human radiation experiments has alerted citizens to wonder about their own role in this history.

ACHRE Findings and Recommendations on Openness

The Advisory Committee found "that the government did not routinely undertake to create records needed to ensure that secret programs could be understood and accounted for in later years, and that it did not adequately maintain such records where they were created." Further, "many important record collections (including records that were not initially classified) have been maintained in a manner that renders them practically inaccessible to those who need them, thereby limiting the utility of the records to the government itself, as well as the public's rights under the Freedom of Information Act." (Finding 19)

The Advisory Committee recommended that the government take the following steps to organize the historical records of human radiation experiments and to give access to the public, and to the government itself.

- **The most important historical collections should be entrusted to the National Archives.**
- **Agencies should make readily available all existing inventories, indexes, folder listings, and other finding aids to record collections now under agency control.**
- **Classified finding aids should undergo declassification review, and declassified versions of these finding aids should also be made available.**
- **The government should ensure the development of policies to improve public access to records held by agencies or deposited in Federal records centers.**
- **Agencies should maintain complete records, available to the public, of document destruction.**
- **The government should review and develop policies concerning public access to records generated or being held by private contractors and institutions receiving Federal funding.**

The Advisory Committee also recommended that the CIA's recordkeeping system be reviewed to ensure that records are accessible upon legitimate request from the public or governmental sources. The Advisory Committee further recommended that all records of the CIA bearing on programs of secret human research from the late 1940s through the early 1970s be reviewed for declassification. ACHRE expressed the expectation that most, if not all, of these CIA documents would be declassified and made public. (Recommendations 17 and 18)

Response to Recommendations on Openness

ACHRE's recommendations are intended to ensure that the records of the human radiation experiments are organized and accessible, and to promote better access to government records.

ACHRE's recommendations are intended to ensure that the records of human radiation experiments are organized and accessible, and to promote better access to government records. This section responds to those specific recommendations. The next section describes in more detail the actions that individual agencies have taken to make records available for public scrutiny.

ACHRE identified the National Archives as the appropriate repository for many of the documents related to human radiation experiments. The Administration agrees. All of the Advisory Committee's records have been transferred to the Archives. The principal Departments and agencies are transferring large volumes of records there as well.

All of the Advisory Committee's records have been transferred to the Archives. The principal Departments are also transferring large volumes of records there as well.

ACHRE recommended that the Departments make finding aids more readily accessible. The government supports this recommendation and has taken steps to implement it. The Departments involved in radiation experiments have a tremendous volume of records. This volume makes providing tools to find information as critical as allowing access to files. The vast majority of relevant documents are DOE or DOD records. DOE is putting finding aids to historical records still in agency custody in public reading rooms and on the Internet, and has published a guide to its human radiation records. DOD has also taken steps to simplify the research process and to provide staff support for individuals who wish to search for relevant documents, and has also published a guide to its human radiation collection.

ACHRE recommended that the government take steps to improve public access to records that remain in the Departments' custody. Part of ACHRE's concern focuses on those records that needlessly remain classified and that would be of significant interest to the public. President Clinton's Executive Order 12958 of April 17, 1995, addresses this concern. The Order requires that most older records that are determined to be of permanent historical value be automatically declassified 5 years from the date of the Order. The Order

applies to all records, not just those relating to human radiation experiments. Agencies are actively reviewing their records and releasing those that are not exempt to comply with the Order. Although the Executive Order does not include Restricted Data (atomic energy information), DOE is actively reviewing this material as well. DOE is also reviewing and updating its classification authorities and guidelines.

President Clinton's Executive Order requires that most older records that are determined to be of permanent historical value be automatically declassified 5 years from the date of the Order.

ACHRE found references to records that they could neither find nor confirm were destroyed. As a result, the Committee recommended that the Federal government permanently maintain copies of all records destruction notices. The Federal government generates an enormous number of records, many of which are of no long-term interest. These records are routinely destroyed. It would be impractical to retain records destruction notices of all of these records, therefore the Administration does not fully accept this recommendation. However, to meet the Committee's concerns, the President is directing agencies to permanently retain records relating to classified human subject experiments.

ACHRE recommended that a citizen's right to know about the activities undertaken by the government should not depend on whether the work was carried out by government employees or contractors. Thus, ACHRE recommended reviewing policies governing access to records of grantees and contractors. Federal records regulations (36 CFR 1222.48) already specify that data created for Federal government use by contractors are Federal records if they are delivered to, or fall under the legal control of, the government. All Federal records must be managed according to rules that provide for appropriate access. Administration policy requires each agency to use contract provisions or other mechanisms to assert ownership of, or appropriate access to, contractor records.

The President is directing agencies to permanently retain records relating to classified human subject experiments.

ACHRE recommended review and declassification of CIA historical records and a review of CIA's recordkeeping system. The CIA recognizes the special scrutiny that is given information about CIA-sponsored human subjects research. The National Archives and Records Administration (NARA) has undertaken an independent review of the CIA's records management program that will be completed in the spring of 1997. In addition, the CIA is reviewing for declassification a few documents relevant to the MKULTRA program that have not been previously declassified and released. The CIA has already transferred approximately 1,000 pages of declassified documents and a CIA Inspector General report on human subjects research, to the National Archives. This material is also available on the Internet (hrex.dis.anl.gov).

Actions to Date

Below is a more detailed description of some of the steps agencies have taken to achieve the goal of opening the historical record. In addition, Appendix B summarizes information resources related to human radiation experiments, including a list of record sources, Internet sites, and publications.

DOE has posted over 250,000 pages of historical documents on the Internet.

The Department of Energy

Making records available: DOE has posted over 250,000 pages of historical documents on the Internet—making the documents available in libraries, community centers, and schools in this country and around the world. These documents are now available through the Interagency Database (hrex.dis.anl.gov) which will eventually contain more than 500,000 pages of documents from all the agencies involved in this effort. Paper copies of all DOE and DOD documents are at the Coordination and Information Center (CIC) in Nevada. Additional related series of records of historical interest have been transferred to the National Archives.

Making records accessible: DOE has summarized how to find its records in its publication, *Human Radiation Experiments: The Department of Energy Roadmap to the Story and the Records*, published in February 1995. The list of experiments in that volume is updated and expanded in, *Human Radiation Experiments Associated with the U.S. Department of Energy and its Predecessors*. The text of these documents is also available via the Office of Human Radiation Experiments (OHRE) Home Page (www.ohre.doe.gov). DOE also has developed a 1-day course on how and where to locate information about human radiation experiments and related historical records.

DOE's report offers scholars and interested lay persons a vivid glimpse inside one of the most controversial chapters in our nation's postwar history.

Understanding the record: DOE staff interviewed researchers and others possessing first-hand knowledge of the human radiation experimentation and therapy that occurred during World War II and the Cold War. The result is, *Human Radiation Studies: Remembering the Early Years*. This 29-part series comprises some 1,350 pages of transcripts. This series offers scholars and interested lay persons a vivid glimpse inside one of the most controversial chapters in our nation's postwar history.

The Department is currently developing a plan to fund an oral history project, conducted by a non-Federal institution, which will allow the subjects and their families to tell the story from a different perspective. This project will provide a reminder of the importance of protecting individual rights, even in times of national security crisis.

The Department of Defense

The Department of Defense (DOD) is searching records for members of the armed services who may have been experimental subjects.

Identifying subjects: The Department of Defense (DOD) is searching records for members of the armed services who may have been experimental subjects. In particular, DOD is seeking rosters of those who were treated experimentally or therapeutically with nasopharyngeal radiation. This effort is similar to an effort several years ago to identify those service members who were present at above-ground nuclear tests. (The full story of that effort was chronicled by the Defense Special Weapons Agency in DNA 6041F, *For the Record—A History of the Nuclear Test Personnel Review Program, 1978–1993*, March 1996.)

Making records accessible: DOD has prepared a guide, similar to the DOE *Roadmap*, that describes the search process for the records of human radiation experiments, and provides the result of the search. This guide is entitled, *The Department of Defense Report on the Search for Human Radiation Experiments Records, 1944–1994.*

The National Aeronautics and Space Administration

NASA has established a permanent collection of human radiation experiment records and a database at Johnson Space Center.

National database: The National Aeronautics and Space Administration (NASA) has established a permanent collection of human radiation experiment records and a database at Johnson Space Center. For the first time, these records will be organized, accessible, and available by request from the collection and on the Internet (hrex.dis.anl.gov).

Part 2: Protecting Future Human Subjects

Overview

The success of the effort to open the historical record will be measured, in part, by whether we avoid repeating the mistakes of the past. ACHRE's review of human radiation experiments raised questions of whether the current system of protection is adequate for all types of human subjects research. The measures described below will strengthen the protection of human subjects and address ACHRE's findings.

The measures described below will strengthen the protection of human subjects and address ACHRE's findings.

Federal responsibilities for maintaining ethics in human subjects research are dispersed in several agencies and committees in the government. First, each agency is responsible for the ethical administration of its programs, including grants and contracts. Second, the President's Office of Science and Technology Policy has a statutory oversight role, and will continue to monitor and address issues of science and ethics. Third, the Department of Health and Human Services has a convening role among agencies that are bound by the Common Rule—the Federal Policy for the Protection of Human Subjects which, along with Food and Drug Administration (FDA) regulations, governs all federally conducted, funded, or regulated research (56 *Federal Register* 28010, June 18, 1991). Finally, the National Bioethics Advisory Commission (NBAC)—an independent body recently established by the President—is taking up some of the most pressing ethical issues faced by this country. (For a description of NBAC see page 11.)

The National Bioethics Advisory Commission (NBAC) is taking up some of the most pressing ethical issues that we face.

The Human Radiation Interagency Working Group (IAWG) is a temporary collaboration among several Federal agencies. The IAWG has worked to support ACHRE and to respond to its recommendations. The policies in this report seek to ensure appropriate follow-up on ACHRE recommendations by more permanent bodies.

ACHRE Findings and Recommendations on Protecting Human Subjects in the Future

Based on its review of current human subject protections, the Advisory Committee found, among other things, that

> **[H]uman research involving radioisotopes is currently subjected to more safeguards and levels of review than most other areas of research involving human subjects. The Advisory Committee further finds that there are no apparent differences between the treatment of human subjects of radiation research and human subjects of other biomedical research. (Finding 20)**

Responsibility for ethical conduct of research begins with researchers and extends to their institutions, and the Institutional Review Boards (IRBs).

> **[T]oday research involving human subjects sponsored by the government may be classified and conducted in secret, but it must comply with the provisions of the Common Rule. (Finding 21)**

> **[I]n comparison with the practices and policies of the 1940s and 1950s, there have been significant advances in the protection of the rights and interests of human subjects of biomedical research. However, we also find that there is evidence of serious deficiencies in some parts of the current system for the protection of the rights and interests of human subjects. (Finding 22)**

ACHRE Recommendation on the Centrality of Ethics

ACHRE recommended that active efforts on a national scale be made to ensure that human subjects researchers fully understand the ethical implications and responsibilities of their work, and the centrality of ethical decisions. (Recommendation 9)

Response

Responsibility for the ethical conduct of research begins with researchers and extends to their institutions and the Institutional Review Boards (IRBs). The Administration has multiple efforts underway to reach, educate, oversee, and hold accountable each layer of the research system. The Administration is also taking steps to promote understanding of, and consensus about, ethical issues.

National Bioethics Advisory Commission

The National Bioethics Advisory Commission (NBAC), a national deliberative body of private citizens, was established by the President to provide guidance to all Federal agencies on the ethical conduct of human behavioral and clinical research, and the applications of that research. NBAC was established, in part, to respond to ACHRE, and the Administration expects NBAC will choose to address the key issues identified in ACHRE's recommendations. NBAC will not be able to review all issues raised by ACHRE. The Administration has been careful to ensure that issues not taken up by NBAC will be addressed elsewhere.

The Executive Order establishing NBAC, required each agency to review its current human subjects research in light of the Advisory Committee recommendations and report the results to NBAC.

As a first priority, NBAC will seek to improve protection of the rights and welfare of human research subjects. The Executive Order establishing NBAC, required each agency to review its current human subjects research in light of the Advisory Committee recommendations and report the results to NBAC. NBAC is currently reviewing these documents. Appendix C details specific activities currently being carried out by the agencies as a result of their reviews.

NBAC's meetings are public and provide a forum for dialogue on ethics issues. NBAC has heard presentations on issues related to genetic research, including cloning, as well as the broader area of human subjects research. Members of Congress, Congressional staff, and representatives from diverse organizations including the Task Force on Radiation and Human Rights, the College of American Pathologists, the Biotechnology Industry Organization, and Citizens for Responsible Care in Psychiatry and Research testified on ethics issues and on NBAC's mission. Further information can be obtained from the NBAC Web Site (www.nih.gov/nbac/nbac.htm).

Education

ACHRE's report made clear that a key to preventing the repetition of past mistakes is thorough and continuing education about ethics and how they apply to current human subjects research.

ACHRE's report made clear that a key to preventing the repetition of past mistakes is thorough and continuing education about ethics and how they apply to current human subjects research. The Administration is responding to ACHRE's specific recommendations by co-sponsoring educational programs with external groups such as medical schools, universities, and scientific societies. The goals of these educational efforts are to strengthen human subjects protection, to provide a forum for addressing ongoing as well as emerging issues in human subjects research, and to familiarize professionals engaged in non-federally funded human subjects research with relevant ethical considerations.

Part of the ongoing educational process is a reinforcement of the importance of Institutional Review Boards (IRBs) at institutions conducting federally funded research. These IRBs are local groups

whose membership and responsibilities are regulated by the Federal government. They are responsible for reviewing and approving the ethical content of all proposed human subjects research projects. IRBs are a linchpin in the protection of human subjects, and their credibility and effectiveness depend on adequate awareness of basic ethical topics.

Similarly, educational programs are also being targeted at government-regulated research that is not government-funded (e.g., FDA-regulated research sponsored by the pharmaceutical industry). In September of 1996, the FDA sponsored its first nationwide conference on human subjects protection.

Government employees who have responsibility for supporting or overseeing human subjects research are also targeted for educational programs. Thus, Federal agencies are implementing training programs to educate senior level officials on regulations and policies governing this research. For example, NASA is working with international research partners to develop common ethical principles that ensure the protection of human subjects. DOE educational efforts target laboratory staff, field office personnel, and program officials.

Despite the vigor with which all parties embrace the informed consent process, it is not well understood.

Information Gathering

ACHRE's report highlighted the limited state of knowledge regarding some key issues in human subjects research. Most importantly, NBAC will be reviewing and evaluating the IRB process.

In addition, Departments have pooled resources to sponsor research on the informed consent process. The informed consent process is intended to help each potential research subject decide whether to participate in research by providing advance information about the research. Information includes a description of the nature of the research, the subject's role and potential risks, and the subject's rights and responsibilities. Despite the vigor with which all parties embrace the informed consent process, it is not well understood. Much of the Advisory Committee's commentary on current human subjects research was centered on informed consent. The National Institutes of Health (NIH), VA, and DOE are committed to supporting research that will more fully illuminate the informed consent process. A Request for Applications (RFA) to conduct research on this issue was published in the fall of 1996, and Fiscal Year 1997 monies are earmarked to support this RFA.

ACHRE Recommendation on Institutional Review Boards

ACHRE recommended specific changes to IRBs in five critical areas (Recommendation 10):

(1) mechanisms to ensure a stronger focus on studies that pose more than minimal risk to subjects;
(2) better means of explaining to potential subjects the distinction between research and treatment, the realistic likelihood of medical benefit to the subject from participation, and the potential for discomfort and pain;
(3) ensuring that potential subjects fully understand the sponsors and purposes of the research;
(4) ensuring that potential subjects fully understand the financial implications of participation; and
(5) recognition that the IRBs must decide if the quality of the science justifies the risk to the subjects.

The Administration anticipates specific recommendations from NBAC regarding reform of IRBs, including recommendations that address ACHRE's concerns.

Response

The Administration agrees that there are indications that the IRB system is not always adequate to ensure protection of human subjects. NBAC has undertaken to review the current IRB system and intends to finish that project within a year. The Administration anticipates specific recommendations from NBAC regarding reform of IRBs, including recommendations that address ACHRE's concerns.

In the interim, agencies are informing IRBs of ACHRE's recommendations and are working to improve IRBs.

The Office for Protection from Research Risks (OPRR), part of NIH, is undertaking a national effort to educate the research community about ACHRE's recommendations. OPRR and FDA support an annual public meeting for individuals interested in the governance of human subjects research. In addition, OPRR, in cooperation with FDA and local academic institutions, has held discussions of the recommendations at national workshops in Atlanta, Oklahoma City, Honolulu, Peoria, Houston, and San Diego.

OPRR and the FDA make extensive use of public meetings, forums, hearings, and electronic media to address evolving issues on human subject protection. OPRR and FDA also regularly mail information directly to IRBs and other interested parties. FDA seeks public input through the *Federal Register* and by mailing proposals to the IRB and clinical investigator communities. In October 1995, FDA issued

a major revision of its "Information Sheets for Institutional Review Boards and Clinical Investigators," to take into account the latest thinking and to provide guidance to IRBs. This information is available on the Internet (www.fda.gov/oc/oha/toc.html).

As noted above, ACHRE recommended that IRBs focus the bulk of their time on studies that present more than minimal risk to subjects. To educate the research community about the importance of this recommendation, OPRR sent information to 5,500 addressees worldwide. The information highlighted regulatory provisions for (1) exemption from IRB review of 6 categories of low-risk research, and (2) expedited IRB review of 10 other kinds of research when it is judged by IRBs to be of minimal risk. Proper use of these time-saving mechanisms permits IRBs to devote greater effort to the areas of concern to ACHRE.

ACHRE Recommendation on Maintaining an Open Public Forum

The National Bioethics Advisory Commission (NBAC) will provide an opportunity for public participation in the continuing review and interpretation of ethical rules.

ACHRE recommended the creation of a mechanism to provide for continuing public discussion and interpretation of ethical rules and principles that govern human subjects research. (Recommendation 11)

Response

The Administration agrees that continuing discussion of ethical rules is vital to protection of human subjects in government-sponsored and privately sponsored research. Both the government and private institutions have key roles in ensuring that this debate continues. The National Bioethics Advisory Commission (NBAC) will provide an opportunity for public participation in the continuing review and interpretation of ethical rules.

Private organizations and periodicals also serve an important role in the continuing public discussion of ethical rules.

The Administration also agrees that there is a need for a mechanism to interpret the existing rules that apply to government-sponsored research. The Department of Health and Human Services (HHS), particularly OPRR and FDA, provides information and interpretations of the regulations for protection of human subjects. OPRR also maintains an Information-by-FAX service (301-594-0464) and a World Wide Web site (nih.gov:80/grants/oprr/oprr.htm) to distribute information, and responds to inquiries by mail. FDA provides these functions for FDA-regulated research and OPRR provides them for other federally supported research.

Individual agencies are also promoting public discussion of current ethical issues. For example, DOE's Ethical, Legal, and Social Issues (ELSI) program sponsors a wide variety of educational programs, including meetings and seminars. DOE has recently sponsored two highly acclaimed public television programs on the human genome program. DOE has also sponsored a workshop for trial judges to receive information about, and discuss the use of, DNA evidence in the courtroom. The genome program has also sponsored conferences to discuss genetics in light of religion, discrimination, and other ethical issues.

These projects are good examples of public and private entities working together to promote civil discourse over ethical issues. The Administration will seek additional opportunities to support this kind of effort.

The Administration agrees that continuing discussion of ethical rules is vital to protection of human subjects in government-sponsored and privately sponsored research.

ACHRE Finding and Recommendation on the Protection of Military Personnel

ACHRE found that it is often difficult, in a military setting, to distinguish requests for volunteers from orders.

> **The military setting, with its strict hierarchical authority structure and pervasive presence in the lives of its members, poses special problems for ensuring the voluntariness of participation in research activities. Thus, although the DOD has adopted and implemented the consent requirements of the Common Rule, additional procedural safeguards and educational activities for officers may be warranted to counteract the generalized deference to authority inherent in military culture. Also, because the opportunity to serve the nation as subjects in defense-oriented research projects is closely akin to the demands placed on members of the military in their routine duties, it is desirable to emphasize the distinction between research and course-of-duty risks both in consent procedures and in officer training programs.**

ACHRE recommended that the military better ensure the protection of rights and interests of military personnel who are involved in human subjects research by reviewing general policies and procedures, educating officers and investigators, implementing policies and practices that make certain participation is genuinely voluntary, and maintaining a registry of volunteers. (Recommendation 12)

Response

The Administration agrees that extraordinary steps are needed to protect military personnel, and DOD is implementing ACHRE's recommendations. Among other steps, DOD is revising directives and Military Department regulations, and incorporating needed training into courses for commanders, senior leadership, and those involved in human subjects research. In the summer of 1997, DOD will publish a revised human subjects protection directive that includes policy changes recommended by the Advisory Committee. For example, to avoid undue command influence, the new policy will preclude officers and noncommissioned officers from playing a role in selecting volunteers for military tests. (See Appendix C for more details).

In the summer of 1997, DOD will publish a revised human subjects protection directive that includes policy changes recommended by the Advisory Committee.

ACHRE Findings and Recommendation on the Federal Oversight of Research

ACHRE found that oversight of human subjects research is limited and is constrained by practical considerations. ACHRE found that the "current mechanisms for oversight . . . do not provide a sufficient basis for ensuring that the current system is working properly."

ACHRE found that sanctions may be inadequate for violations of human subjects research protections. For example failure to obtain consent from subjects (who are not physically injured) is generally punishable only by the withdrawal of research funding.

ACHRE also found that "there is a need to assess the level of research performed outside [the Common Rule] and to consider action to ensure that all subjects are afforded the protections it offers." ACHRE recommended the improvement of three parts of the current Federal system for human research subject protection: oversight of the research process; sanctions for violations of human subjects protections; and protections for subjects of non-federally funded research. (Recommendation 13)

Response

The Administration agrees that there are important gaps in the current system of human subjects protection, and has identified, in testimony before Congress, examples of research that does not fall within the ambit of Federal protection. Congress has proposed the Human Research Subject Protection Act of 1997 (S. 193) to ensure that all human subjects are adequately protected. The Administra-

tion believes that Congress is also the appropriate place to consider whether additional civil or criminal sanctions for the violation of human subject protections are necessary and desirable. (Sanctions, including criminal liability, apply to investigators conducting FDA-regulated research who violate FDA regulations protecting human subjects.) Any legislation would need to protect research subjects and avoid deterring needed research.

In addition to exploring legislation, Federal agencies are undertaking specific activities to strengthen oversight, some of which are described in Appendix C. The Administration expects that NBAC will recommend additional actions to improve oversight of Federal research, and will identify the highest priority steps.

The Administration expects that NBAC will recommend additional actions to improve oversight of Federal research, and will identify the highest priority steps.

ACHRE Findings and Recommendation on the Compensation of Subjects in the Future

ACHRE found that the Federal government lacks a "policy or guide for a fair system of compensation of research subjects."

ACHRE recommended that the government resolve the longstanding issue of whether and how all persons injured in the future from federally funded human subjects research should be compensated. ACHRE recommended that the Federal government consider a system of compensation for research subjects who suffer physical injury or dignitary harm as a result of federally funded research. (Recommendation 14)

Response

In the absence of a finding that a significant number of modern research subjects are unfairly denied compensation, the Administration is not prepared to propose a system outside the existing network of Federal and state liability and insurance systems.

The Administration does, however, view the debate over the extent and effectiveness of our current human subject protections to encompass this issue. The Administration would be open to considering any recommendations from NBAC or legislation from Congress that seek to address this issue.

The desire to spread the cost of research injury is a reason to consider a compensation scheme. The current tort system, though imperfect, provides one mechanism to seek compensation for injuries that arise from research. In addition, the tort system

provides a powerful incentive to researchers to observe appropriate standards of care in conducting the research. These standards generally include providing for informed consent and exercising care in the conduct of research.

ACHRE Recommendations Regarding Classified Research

Because of its concerns about past use of secret research, ACHRE recommended that (a) the Administration establish a formal policy prohibiting waiver of informed consent for classified research and requiring that potential subjects of classified research must be told the identity of the sponsoring agency. ACHRE also recommended that (b) for classified research, the Administration establish an independent panel to review scientific merit, risk/benefit balance, consent procedures, and whether subjects need a security clearance to assure fully informed consent. The records of this panel would be permanent. (Recommendation 15)

Response

Federal agencies will jointly propose modifications to the Federal Policy for the Protection of Human Subjects (Common Rule) as it applies to classified research.

ACHRE acknowledged that it is in the nation's interest to continue to allow the government to conduct classified research using human subjects where such research serves important national security interests. The Committee found, however, that classified human subjects research should be a "rare event" and that the "subjects of such research, as well as the interests of the public in openness in science and in government, deserve special protections." ACHRE was concerned about "exceptions to informed consent requirements and the absence of any special review and approval process for human research that is to be classified." ACHRE recommended that all classified research meet the following requirements:

- obtain informed consent from all human subjects;
- inform subjects of the identity of the sponsoring agency;
- inform subjects that the project involves classified research;
- establish permanent records; and
- be approved by an "independent panel of nongovernmental experts and citizen representatives, all with the necessary security clearances."

The Administration agrees with the first four recommendations. The President is issuing a memorandum directing Federal agencies to jointly propose modifications to the Federal Policy for the Protection of Human Subjects (Common Rule) as it applies to classified research in order to implement these changes. Further, subjects will be informed of the sponsoring agency, except in limited, minimal-risk cases. In all secret studies, researchers will obtain informed consent, disclose that the project involves classified research, and keep permanent records.

The Administration also agrees with ACHRE's call for a special review process for classified research and permanent recordkeeping. The Federal agencies will jointly propose (1) amending the common rule to require that IRBs for secret projects include a non-governmental member; (2) establishing an appeals process so that any member of a review board who believes a project should not go forward can appeal the board's decision to the head of the agency and, if necessary, the Assistant to the President for Science and Technology; and (3) requiring the sponsoring agency to keep permanent records of the panel's deliberations and the informed consent process, and to declassify such records as soon as appropriate.

The Administration is taking two additional steps to ensure that classified human subjects research remains rare. The President is directing the heads of Federal agencies to disclose annually the number of secret human research projects undertaken by the agency and the number of human subjects participating in each project.

These steps will preserve the government's ability to conduct any necessary classified research involving human subjects while ensuring adequate protection of research participants. (See Appendix E for the directive from the President regarding classified research.)

These steps will preserve the government's ability to conduct any necessary classified research involving human subjects while ensuring adequate protection of research participants.

ACHRE Findings and Recommendations Regarding Secret Environmental Releases

The Advisory Committee found that events that raise the same concerns as the intentional environmental releases of radiation in 1948 to 1952, "could still take place in secret under current environmental laws and regulations."

The Advisory Committee further noted that,

> **Today the law provides that environmental reviews may be conducted in part or even in whole in secret, thereby eliminating provision for public notice and comment. In classified programs, the government must still comply with environmental standards, and the Environmental Protection Agency must oversee and review environmental compliance. However, the EPA has not maintained records of environmental releases where the reviews were conducted in whole or in part in secret. (Finding 23)**

The Advisory Committee recommended that (a) there be review by an independent panel of any planned environmental release where any aspect involves secrecy; and that (b) environmental oversight of classified programs, now done by the Environmental Protection Agency (EPA), should include keeping review records permanently and reporting to Congress. (Recommendation 16)

Response

EPA, in conjunction with Federal agencies conducting classified programs, is taking steps to improve environmental oversight and enforcement capability over all classified activities.

The Administration agrees that the framework for oversight and recordkeeping of reviews of secret environmental releases needs to be improved.

EPA, in conjunction with Federal agencies conducting classified programs, is taking steps to improve environmental oversight and enforcement capability over all classified activities. These steps include formal agreements between EPA and other Federal agencies to streamline the process of providing information about environmental compliance related to classified activities. This effort will give environmental enforcement authorities the information they need to appropriately review secret environmental releases. It would be difficult, if not impossible, to create similar enforcement capabilities in a new regulatory entity, such as an independent review panel, that focuses only on these extremely rare occurrences. In addition, a new entity would add to the bureaucratic complexities of ensuring environmental safety and would not necessarily increase public protection.

EPA will establish and maintain a permanent file to document EPA's classified reviews under the National Environmental Policy Act (NEPA). The EPA policy establishing this permanent file will address transport, storage, review, and permanent recordkeeping of classified NEPA documents and EPA review comments. EPA will notify all Federal agencies of its new classified filing and review procedures and will provide Congress with information on request.

Part 3: Righting Past Wrongs

Overview

The ACHRE report reviewed in detail several case studies of government-supported human radiation research including: the injections of plutonium into 18 hospital patients during and after World War II, research with prisoners, and research on patients who were exposed to total body irradiation in clinical settings.

The Advisory Committee also considered issues related to certain radiation exposures associated with government activities that the Advisory Committee concluded should not be considered "human experiments." These exposures were sustained as a result of government activity undertaken for purposes other than human radiation research. The exposed populations include atomic veterans, uranium miners, and residents of the Marshall Islands exposed to fallout from U.S. weapons testing.

The ACHRE report reviewed in detail several case studies of government-supported human radiation research.

The Committee recommended several steps that the government should take to make amends for the specific wrongs for which the government bears moral responsibility.

This section of the report discusses ACHRE's findings and recommendations in the areas of notification, apology, and compensation and presents the Administration's response. Within the discussion of compensation, the report addresses individual cases, uranium miners, other populations covered under the Radiation Exposure Compensation Act, veterans, and Marshall Islanders.

ACHRE Findings and Recommendations on Notification

The Advisory Committee found "no subjects of biomedical experiments for whom there is a need to provide notification and medical follow-up for the purpose of protecting their health." In addition, the Committee found no evidence that descendants of subjects of human radiation experiments have a greater likelihood of inheriting genetic effects.

The Advisory Committee recommended that (Recommendation 4):

- **For any newly-discovered experiments the government should notify participants and provide medical follow-up for "those subjects for whom there is a significant risk of developing a**

radiation-related disease that has not yet occurred, or has occurred but may still be undetected or untreated, and in whom there might be an opportunity to prevent or minimize potential health risks through detection and treatment."

- **The government need not notify subjects of experiments reviewed by ACHRE for public health reasons because they did not meet the recommended criteria for notification.**

Response

Beyond protecting public health, the government will seek to support as fully as possible an individual's right to know about actions that may have affected him/her.

The Administration's view is that, *in general*, ACHRE's recommendation is correct. For public health reasons, the government will notify any identified subjects who meet the criteria in the ACHRE report; these include any subjects placed at a significant risk for development of a radiation-related disease, where there is a recognized medical benefit from early detection and treatment. (Because medical science is not static, neither is the decision as to whether there is a medical benefit.)

Beyond protecting public health, the government will seek to support as fully as possible an individual's right to know about actions that may have affected him/her. Therefore, the government will also notify an identified experimental subject if the subject requests the information; if the government determines that a subject is likely to fall within the criteria for government compensation; and, on a case-by-case basis, if there is uncertainty about the effects of the experiment and notification is necessary to investigate whether subjects were placed at significant risk and whether there is a potential benefit from treatment. The Administration believes that this approach fulfills the government's grave responsibility to inform subjects while maintaining respect for those people who would not want information that has no tangible benefit.

It is important to be clear that notification is not simply the process of taking existing lists of names, current addresses, and phone numbers and contacting people. For most experiments, names are unavailable. Much of the information about past experiments comes from the published literature which does not generally include names. Even where more detailed records have survived, information about individuals is generally fragmentary and does not include anything about their current whereabouts. Much of the information about individuals is in the records of private hospitals and universities where confidentiality and privacy rules prohibit government access.

For all of these reasons, the process of locating individuals or next of kin many years after the experiments took place is difficult, time consuming, costly to the taxpayer, and likely to have limited success. Where individuals can be found, it is difficult to assess their exposure and risk given the limited data available.

Notwithstanding the difficulties of undertaking individual notification, the government reaffirms its continuing commitment to openness. Where the government does not undertake individual notification, it will continue to make material relating to human radiation experiments available to the public, to respond to individual inquiries relating to these experiments, and to carefully review any newly identified experiments in the light of the Advisory Committee notification criteria.

Discussion

ACHRE was charged to make a recommendation about notification for the purpose of protecting the health of subjects or their descendants. After careful consideration, however, ACHRE recommended that decisions about notification be based on "evaluation of both the level of risk from radiation exposure and the potential medical benefit from medical follow-up in exposed individuals." In discussing this recommendation, ACHRE observed that notification can impose new burdens on subjects that must be weighed against the potential for medical benefit from notification. These burdens include anxiety; medical harm; inconvenience; possible stigmatization by friends, family, employers, or insurance carriers; and cost of seeking medical testing or follow-up. ACHRE recommended notification in the limited circumstances where the criteria for medical benefit were satisfied or where the individual seeks notification. ACHRE endorsed the principle that citizens are entitled to know if they or a relative were a subject in a radiation experiment. To assist individuals in pursuing answers to this important question, ACHRE included a citizen's guide in its *Final Report*.

Even where more detailed records have survived, information about individuals is generally fragmentary and does not include anything about their current whereabouts.

ACHRE's recommendation on notification has generated controversy among stakeholders, including those who participated in the Stakeholders Workshop of February 26–27, 1996, held by the Federal Departments. As the Advisory Committee detailed, many of the wrongs in experimentation involved the failure to obtain consent from subjects or to fully disclose risks and benefits (or lack of benefits) of the experiments, rather than actual adverse health effects from the testing. Some stakeholders believe the government has a responsibility to notify and provide medical follow-up to all who were wronged by the government; not only those who were physically harmed by the government's conduct. Although it is difficult to generalize about the diversity of views presented at the

Workshop, the stakeholders generally advocate that the government pursue some form of notification, and fund medical care by individually chosen physicians. Many subjects and families of subjects do not have confidence that the government can honestly make a judgment about notification, or that the government can, without bias or intimidation of subjects, implement any needed medical follow-up. Others suggested that subjects would want to be notified, whether or not they were harmed.

The Administration agrees that the decision of when and how to notify experimental subjects requires a judgment about whether individuals would want to be notified even if there is no public health reason for notification.

The government has provided widespread opportunities for individuals to seek information about their own involvement as subjects of research.

Where the agencies discover new records containing information that would allow notification, the Administration will notify subjects that meet the ACHRE public health criteria, and will also notify those that meet any one of three additional criteria which are intended to shed light on the non-health benefits that may accrue to those who may be notified. As noted above, notification will take place if the subject requests the information; if the government determines that a subject is likely to fall within the criteria for government compensation; and, on a case-by-case basis, if there is uncertainty about the effects of the experiment and notification is necessary to understand whether subjects were placed at significant risk and whether there is a potential benefit from treatment. The Administration believes that these other benefits—where they are present—would cause most subjects to prefer notification.

Information requests: Where information is available, it will be provided to the possible experimental subject, if they so request. The government will use all reasonable means to let individuals know that they have the opportunity to ask questions about their own history and a choice about whether to pursue that information.

To make the choice meaningful, the government has provided widespread opportunities for individuals to seek information about their own involvement as subjects of research. Publicity about the existence of experiments, and the widespread availability of information about human radiation experiments, has generated thousands of inquiries from those who want to know whether they were experimental subjects. This response suggests that the government's outreach efforts allowed many possible subjects to choose whether to seek more information.

Based on the response so far, the Administration believes that continued publication of general information and follow-up of individual inquiries satisfies much of the government's obligation to notify experimental subjects.

Additional research: In the event that the Departments uncover additional experiments, any newly-discovered subjects will be notified of their participation by the Department that sponsored the research, based on the criteria discussed above.

As experiments are identified, there may be uncertainty about whether initial exposures to radiation significantly increased the risk to subjects. In at least one case, that of members of the armed services exposed to nasopharyngeal radiation, there may be a sufficient number of identifiable subjects to allow for a follow-up study. The follow-up study would be designed to identify any risk to subjects and whether medical follow-up could be beneficial. The Administration's policy does not preclude conducting such a study—even though the government cannot answer with certainty what level of risk is faced by former subjects and whether there is any prospect of medical or other benefit to subjects from a follow-up study. Any follow-up study should move forward only under the following conditions:

In at least one case, that of members of the armed services exposed to nasopharyngeal radiation, there may be a sufficient number of identifiable subjects to allow for a follow-up study.

1) All care has been taken to minimize any harmful effects of participating in a study.

2) Members of the public have been consulted regarding the study and its fairness to individuals who will be notified of their prior participation in an experimental treatment.

Actions to Date

The most important actions the government has taken to notify subjects are the actions described in Part 1 of this report, Openness in Government. This widespread public availability of information has given individuals the opportunity to choose whether they will seek additional information about their own possible involvement in experiments.

Individual inquiries: Those who would like more information about their individual experience can obtain assistance by a phone call; the current number is (202) 586-8439. By calling this number, individuals who think they may have been involved in experiments can have their cases reviewed by the appropriate agency. As of December 1, 1996, DOE has answered over 20,000 information requests, and researched 3,000 cases; DOD has responded to approximately 7,000 case inquiries of which approximately 800 are currently undergoing active research; VA has responded to approximately 1,750 inquiries; and HHS, to approximately 90.

The Departments are continuing their efforts to research cases. There are several factors beyond the government's control that influence the ultimate success in each individual quest for information. For example, some government records are more complete than others and some individuals can provide more kinds of information (e.g., dates, place and researcher names, and other identifying information) upon which to base a search. In cases where the possible experiment took place in a non-governmental facility (e.g., a hospital or university), access to information may be limited.

DOD and VA are reviewing the records of hundreds of Service members who received NP irradiation during and immediately following World War II.

Notification of NASA employees: Consistent with the effort to provide general information to the widest possible group of people, the National Aeronautics and Space Administration (NASA) has notified approximately 110,000 current and former NASA employees, contractors, and grantees about the human radiation research review. This notification included those universities and institutions at which human radiation research was performed through NASA grants.

Notification of veterans: VA convened an expert committee including specialists in nuclear medicine, radiation oncology, health physics, and radiation dosimetry to review information about certain projects, and to determine whether notification of known subjects was warranted. The VA focused its attention on early radiation research projects for which at least some of the names of research subjects were known. These studies were chosen because of the possibility of contacting veterans or family members to encourage medical surveillance or submission of a compensation claim, if warranted. The expert committee did not identify any veterans who required special follow-up actions specifically because of their radiation exposure.

Nasopharyngeal irradiation with radium (NP) during military service: DOD and VA are reviewing the records of hundreds of Service members who received NP irradiation during and immediately following World War II. In April 1996, DOD discovered a Navy medical log book which lists the names of submariners who were given the NP treatment from 1945 to 1946 under an experimental protocol. Using the log book as the focal point, DOD and VA are conducting intensive research at the National Records Center and other repositories to identify other Service members who received NP treatment and, if feasible, to retrieve medical data for possible cohort or epidemiological studies to notify individuals as appropriate. NP treatment was a widely used conventional therapy, particularly for children, during the 1940s and 1950s. Therefore a study could be valuable to many civilians as well as veterans.

The VA, along with the Centers for Disease Control (CDC) and Yale University, co-sponsored a workshop on the public health response to NP irradiation which was held in New Haven, Connecticut, in September 1995. Consensus did not support medical screening of asymptomatic individuals but recommended that individuals treated with NP irradiation inform their health care providers when they are examined or evaluated. VA officials have published information on NP irradiation treatments in medical journals and provided it to veterans' newsletters.

The VA and CDC held a satellite teleconference in September 1996 to provide health professionals with information about this issue. Currently, veterans treated with NP irradiation do not have special eligibility for VA care. The Administration will propose legislation that will extend eligibility for the VA's Ionizing Radiation Program to veterans treated with NP irradiation.

Alaskan natives: A number of Alaskan Natives were involved in the U.S. Air Force Arctic Aeromedical Laboratory Iodine-131 thyroid test, which took place in 1956 and 1957. Although both the Advisory Committee and the Institute of Medicine (IOM) determined that there was no evidence of lifetime risk to the participants in these tests, notification and follow-up of the juvenile participants was recommended by the latter as prudent. The Air Force and the Radiation Experiments Command Center (RECC) are following up on the recommendations of the IOM. Efforts are ongoing with representatives of the Native Alaskans to determine appropriate follow-up remedies.

Identifying additional subjects: DOE notified subjects of the plutonium and uranium injection experiments, or their next of kin, when these could be located. In addition, DOE asked all its facilities at which human radiation experiments were identified, to provide detailed information about the availability of data relating to individual subjects, the feasibility of notification, and whether any notification process had occurred. Where employees or former employees had been involved in experiments, notification generally had taken place. Otherwise, it was determined that the available data did not warrant notification in light of the Advisory Committee criteria. If new information or experiments come to light, the Department will review these according to the Advisory Committee criteria.

DOE notified subjects of the plutonium and uranium injection experiments, or their next of kin, when these could be located.

ACHRE Findings and Recommendations Regarding Remedies

The Advisory Committee found that:

> **[T]he government sponsored . . . several thousand human radiation experiments. In the great majority of cases, the experiments were conducted to advance biomedical science; some experiments were conducted to advance national interests in defense or space exploration; and some experiments served both biomedical and defense or space exploration purposes. (Finding 1)**
>
> **[P]eople who were used as research subjects without their consent were wronged even if they were not harmed." In addition, the Committee was "not persuaded that even where the facts are clear and the identities of subjects known, financial compensation is necessarily a fitting remedy when people have been used as subjects without their knowledge or consent but suffered no material harm as a consequence. (Recommendation 3)**
>
> **[S]ome government agencies required the consent of some research subjects well before 1944 . . . [and] government agencies did not generally take effective measures to implement their requirements and policies on consent to human radiation research. (Findings 4 and 5)**
>
> **[T]he government and government officials are morally responsible in cases in which they did not take effective measures to implement the government's policies and requirements. . . .**
>
> **[G]overnment officials and investigators are blameworthy for not having had policies and practices in place to protect the rights and interests of human subjects who were used in research from which the subjects could not possibly derive medical benefits (nontherapeutic research in the strict sense). By contrast, to the extent that there was reason to believe that research might provide a direct medical benefit to subjects, government officials and biomedical professionals are less blameworthy for not having had such protections and practices. (Findings 11a and 11c)**

> **[S]ince the end of the Manhattan Project in 1946 human radiation experiments (even where expressly conducted for military purposes) have typically not been classified as secret by the government. Nonetheless, important discussions of human experimentation took place in secret, and information was kept secret out of concern for embarrassment to the government, potential legal liability, and concern that public misunderstanding would jeopardize government programs. In some cases, deception was employed. In the case of the plutonium injection experiments, government officials and government-sponsored researchers continued to keep information secret from the subjects of several human radiation experiments and their families, including the fact that they had been used as subjects of such research. Some information about the plutonium injections, including documentation showing that data on these and related human experiments were kept secret out of concern for embarrassment and legal liability, was declassified and made public only during the life of the Advisory Committee. (Finding 17)**

The Administration agrees that the subjects identified by the Committee were owed an apology by the government.

ACHRE Recommendations on Apology

The Advisory Committee recommended

> **[f]or subjects who were used in experiments for which there was no prospect of medical benefit to them and there is evidence specific to the experiment in which the subjects were involved that (1) no consent, or inadequate consent, was obtained, or (2) their selection as subjects constituted an injustice, or both, the government should offer a personal, individualized apology to each subject. (Recommendation 3)**

Response

The Administration agrees that the subjects identified by the Committee were owed an apology by the government. At the ceremony in which Dr. Faden presented him the report, President Clinton formally apologized on behalf of the government to the victims of human radiation experiments. He said,

> So today, on behalf of another generation of American leaders and another generation of American citizens, the United States of America offers a sincere apology to those of our citizens who were subject to these experiments, to their families, and to their communities.

> When the government does wrong, we have a moral responsibility to admit it. The duty we owe to one another to tell the truth and to protect our fellow citizens from excesses like these is one we can never walk away from. Our government failed in that duty, and it offers an apology to the survivors and their families and to all the American people who must be able to rely upon the United States to keep its word, to tell the truth, and to do the right thing.

The Administration will continue to apologize to subjects and their families in appropriate cases as they are considered and settled.

In addition, former Energy Secretary O'Leary has apologized on behalf of the government as part of the settlements of individual cases. The Administration will continue to apologize to subjects and their families in appropriate cases as they are considered and settled.

At the same time, the Administration believes that, for most subjects, the President's apology on behalf of the government to all subjects of human radiation experiments is sufficient, as opposed to pursuing individualized evidentiary investigations, to fulfill the Committee's admonition that "an apology should be offered only where there is evidence specific to an experiment or subject that no consent, or inadequate consent, was obtained, or the subject's selection constituted an injustice, or both." (Recommendation 3)

ACHRE Recommendations on Financial Compensation

The Advisory Committee recommended that the government provide financial compensation to subjects of human radiation experiments in two cases. First, those cases "in which efforts were made by the government to keep information secret from these individuals or their families, or from the public, for the purpose of avoiding embarrassment or potential legal liability, or both, and where this secrecy had the effect of denying individuals the opportunity to pursue potential grievances." Second, those experiments, "that for subjects of human radiation experiments that did not involve a prospect of direct medical benefit to the subjects, or in which interventions considered to be controversial at the time were presented as conventional or standard practice, and physical injury attributable to the experiment resulted."

The Advisory Committee identified three sets of subjects that fit the first class of cases: one set of 18 whose identity is known, and two sets, totaling 52 people, whose identity is not known. The Advisory Committee did not make conclusive findings about which subjects fit the second class of cases. Instead, the committee identified several experiments that might fit the second class of cases, with the expectation that the government would consider the Committee's recommendation in deciding whether to compensate individuals. (Recommendations 1 and 2)

Response

The Administration agrees with the Advisory Committee's recommendation for both classes of cases. The Department of Justice (DOJ) has worked closely with the Departments to resolve the claims that have been made in connection with human radiation experiments, and will, to the extent permitted by law, offer reasonable financial compensation to subjects of human radiation experiments for which a government agency was responsible and which fall within the Advisory Committee criteria. If compensation cannot be offered under existing law in any case which falls under the ACHRE criteria, the Administration will work with Congress to seek appropriate legislative relief.

DOJ is using the Federal Tort Claims Act (FTCA) claims process, or other existing law, to consider compensation as part of the settlement of relevant claims. Thus, individuals can file claims using a well-established process. At the same time, the government's policy is to seek to resolve these claims quickly and fairly, while avoiding unnecessary litigation. To further these aims, the government's policy is to use alternate dispute resolution, such as mediation, where appropriate. In considering the issue of compensation, the critical factors are the extent of physical injury to the subject, the nature of the experiment, and the degree of government involvement. As needed, agencies seek expert advice on scientific and medical issues.

To date, DOE and DOJ have settled compensation claims with the 16 families of plutonium injection subjects who have come forward.

To date, DOE and DOJ have settled compensation claims with the 16 families of plutonium injection subjects who have come forward, representing compensation to the families of all known subjects recommended for compensation by the Advisory Committee.

ACHRE Findings and Recommendations on Compensation of Uranium Miners

The Advisory Committee found that "as a consequence of exposure to radon and its daughter products in underground uranium mines, at least several hundred miners died of lung cancer and surviving miners remain at elevated risk."

> **The miners, who were the subject of government study as they mined uranium for use in weapons manufacturing, were subject to radon exposures well in excess of levels known to be hazardous. The government failed to act to require the reduction of the hazard by ventilating**

the mines, and it failed to adequately warn the miners of the hazard to which they were being exposed, even though such actions would likely have posed no threat to national security. (Finding 16)

The Advisory Committee recommended that the Administration,

together with Congress, give serious consideration to amending the provisions of the Radiation Exposure Compensation Act of 1990 relating to uranium miners in order to provide compensation to *all* miners who develop lung cancer after some minimal duration of employment underground (such as 1 year), without requiring a specific level of exposure. The Act should also be reviewed to determine whether the documentation standards for compensation should be liberalized. (Recommendation 7)

The Administration is proposing a bill that would make significant and substantial modifications to the statutory compensation criteria for lung cancer in uranium miners.

Response

The Administration agrees that the Radiation Exposure Compensation Act of 1990 (RECA) does not presently ensure that all uranium miners who suffered from lung cancer as a result of their mining employment receive compensation, and that RECA should be amended to better achieve this goal. The Administration is proposing a bill that would make significant and substantial modifications to the statutory compensation criteria for lung cancer. The bill will bring the law into line with current science, and will address some of the issues of fairness that have been raised about the Act's coverage. The Administration will strongly urge the 105th Congress to enact this bill.

Proposed legislative changes to RECA: Congress enacted RECA to provide compensation to certain groups of people who developed radiation-related diseases as a result of radiation exposure from the government's Cold War nuclear weapons program, including military and civilian nuclear weapons test participants, and people living "downwind" of the Nevada Test Site. In addition, the Act recognizes the tragedy created by the government's failure to use available resources to ensure that the companies and individuals operating uranium mines in Arizona, Colorado, New Mexico, Utah, and Wyoming between 1947 and 1971 provided adequate ventilation in the mines to reasonably reduce the risk of radon-induced lung cancer. The Act provides for compensation to some affected uranium miners, but ACHRE questioned whether the eligibility requirements for compensation were fair and reflected our present scientific knowledge about the effects of radon.

The Administration's proposed changes to RECA are supported by an analysis undertaken by an ad hoc committee of government scientists and attorneys with experience in radiation exposure and claims. Their analysis is available in a report, *Final Report of the Radiation Exposure Act Committee,* which was submitted to the Human Radiation Interagency Working Group in July of 1996, and is available on the Internet (www.ohre.doe.gov).

The Administration's bill proposes amendments in three key areas. First, current law requires miners to show that they were exposed to a threshold of 200 working level months of radiation (for nonsmokers) and 300 to 500 working level months (for smokers, depending on the miner's age at the date of diagnosis of disease). The Administration's bill would substitute new criteria for compensation based on an updated scientific analysis of risk factors for lung cancer from uranium mining. Specifically, the criteria include: cumulative exposure, age at which the miner developed cancer, and time since last exposure. These criteria would ensure full compensation to miners with lung cancer where the government's best estimate indicates that the miner's exposure to radiation in the uranium mines is the probable cause of his or her lung cancer. The Administration recognizes, however, that there are documented uncertainties inherent in the process by which the criteria were generated, including uncertainties in the radiation measurements used to calculate miners' exposure. Up to now, the eligibility criteria in RECA have not accounted for these uncertainties. The administration proposes to incorporate known and quantifiable uncertainties into the compensation scheme, so that, in effect, miners are given the benefit of the doubt. In those cases where it can be concluded that a miner's exposure to radiation was the cause of his or her lung cancer only by resolving the uncertainties in favor of the miner, the Administration proposes to provide partial compensation to the miner.

The Administration's proposed changes in RECA are supported by an analysis undertaken by an ad hoc committee of government scientists and attorneys with experience in radiation exposure and claims.

The second major change in the Administration's bill responds to ACHRE's concern that conditioning compensation based on specific radiation exposure levels is too burdensome for some miners to prove and the historical exposure data are too uncertain a base for compensation decisions. Under current law, compensation is based in part on cumulative exposure to radon; the Administration's proposal would continue to allow miners to qualify in this manner, albeit under new, fairer exposure criteria. The Administration's bill would also allow the duration of employment in the mines to be used as a surrogate for exposure in determining whether a miner qualifies for compensation. This change reflects the reality that accurate measurements of radon levels do not exist for many mines, and that the measurements that do exist do not necessarily record the miners' actual exposures.

Third, the proposed bill expands the list of compensable diseases for the downwinders and the on-site nuclear test participants to reflect current science. The text of the Administration's proposed bill and an analysis of it are attached to this report in Appendix D.

ACHRE described concerns from many citizens regarding the administration of RECA.

Proposed regulatory changes to RECA: ACHRE described concerns from many citizens regarding the administration of RECA. These concerns focussed on the difficulty of the documentation requirements and other burdens on those who seek compensation under the Act. The Administration has undertaken a thorough review of the regulations with the intention of making them fairer and more straightforward. While these are the paramount goals, the regulations must also effectively implement the limitations and requirements in RECA. The result of these efforts is a set of proposed changes to the rules that are designed to relieve some of the burden of those seeking compensation, without sacrificing the accuracy of the decision as to whether particular claimants qualify for compensation. These regulations will be published shortly.

The Administration expects that, as a result of these legislative and regulatory changes, additional uranium miners and others will qualify for compensation.

ACHRE Finding and Recommendation on Compensation of Other Exposed Populations

The Advisory Committee found "that for both the Green Run (at Hanford) and the RaLa tests (at Los Alamos), where dose reconstructions have been undertaken, it is unlikely that members of the public were directly harmed solely as a consequence of these tests." (Finding 14)

The Advisory Committee recommended that the Administration,

> **together with Congress, give serious consideration to amending the provisions of the Radiation Exposure Compensation Act of 1990 to encompass other populations environmentally exposed to radiation from government operations in support of the nuclear weapons program, should information become available that shows that areas not covered by the legislation were sufficiently exposed that a cancer burden comparable to that found in populations currently covered by the law may have resulted. (Recommendation 5)**

Response

The Administration agrees with the Advisory Committee's concern for fair treatment of exposed populations. DOE has undertaken studies of the communities near the Hanford nuclear facility and at other sites including Fernald, Savannah River, Rocky Flats, and Oak Ridge to determine whether there is any increase in cancer resulting from the operation of DOE facilities. If these studies conclude that there is an increase in cancer, the government will work with Congress to amend existing laws to cover those affected. DOE has provided the General Accounting Office with a list of all studies currently in process, and an estimated schedule for their completion.

ACHRE Findings and Recommendations on Compensation of Veterans

The Advisory Committee found that

> **some service personnel were used in human experiments in connection with tests of atomic bombs. The Committee finds that such personnel were typically exposed to no greater risks than the far greater number of service personnel engaged in similar activities for training or other purposes. The Committee further finds that there is little evidence that the 1953 Secretary of Defense Nuremberg Code memorandum was transmitted to those involved with human experiments conducted in conjunction with atomic testing. However, some of the requirements contained in the memorandum were implemented in the case of a few experiments, apparently independently of the memorandum. The Committee also finds that the government did not create or maintain adequate records for both experimental and nonexperimental participants. (Finding 12)**

The Advisory Committee also concluded that "although there was a real possibility that human subjects research had been conducted in conjunction with the bomb tests, the tests were not themselves experiments involving human subjects." The Advisory Committee further noted that "while the studies all took place in the context of the atomic bomb, and therefore involved some potential exposure to radiation, none of them were designed to measure the biological effects of radiation itself (as opposed to the levels of exposure)." The Advisory Committee recommended that the Administration,

together with Congress, give serious consideration to reviewing and updating epidemiological tables that are relied upon to determine whether relief is appropriate for veterans who participated in atomic testing so that all cancers or other diseases for which there is a reasonable probability of causation by radiation exposure during active military service are clearly and unequivocally covered by the statutes. (The Radiation-Exposed Veterans Compensation Act of 1988 and the Veterans Dioxin and Radiation Exposure Compensation Standards Act) (Recommendation 6)

The Advisory Committee further recommends to the Human Radiation Interagency Working Group that it review whether existing laws governing the compensation of atomic veterans are now administered in ways that best balance allocation of resources between financial compensation to eligible atomic veterans and administrative costs, including the costs and scientific credibility of dose reconstruction.

The President has recognized the special obligation that we owe the men and women who have served their country in the Armed Forces.

Response

The Administration agrees with these recommendations. The VA will update the epidemiological tables and has reviewed the implementation of these programs to seek ways to make them fairer and more efficient.

Hundreds of thousands of veterans were exposed to radiation—those who were present at atomic tests, those who were part of the American occupation of Hiroshima and Nagasaki, and many who were otherwise exposed to radiation in the course of their duties. The President has recognized the special obligation that we owe the men and women who have served their country in the Armed Forces. The President recently said

> . . . [O]ur country can face up to the consequences of our actions . . . we will bear responsibility for the harm we do, even when the harm is unintended . . . we will continue to honor those who served our country and gave so much. Nothing we can do will ever fully repay the . . . veterans for all they gave and all they lost . . . but we must never stop trying.

It is in this spirit that the Administration has considered radiation exposure issues related to veterans.

Current law authorizes comprehensive VA health care for veterans who were either atomic test participants or who served in the postwar occupation of Hiroshima or Nagasaki, and who suffer from radiogenic diseases (diseases caused by radiation). This care is provided, free of charge, regardless of whether these veterans' diseases are determined to have resulted from radiation exposure during service.

Veterans are also eligible for compensation based on their radiation exposure during their service if they have radiogenic diseases and their claims otherwise meet the criteria for benefits. In determining whether certain claimants qualify for compensation, VA uses radioepidemtological tables. The Advisory Committee recommended that these epidemiological tables be updated to reflect the latest scientific information. The government will contract with preeminent scientists to update the tables. The project is expected to take approximately 2½ years. The Departments are considering a proposal from the Institute of Medicine, part of the National Academy of Sciences, to accomplish this update. The updated tables will more accurately identify whether there is a reasonable probability that certain diseases were caused by radiation exposure.

The government will contract with preeminent scientists to update the epidemiological tables used for determining probability of radiation-induced disease.

Implementing existing law: The Advisory Committee also recommended that the Administration examine and respond to the criticisms that have been made of VA's implementation of existing compensation laws. The Advisory Committee noted numerous concerns voiced about the claims process. The Administration takes these concerns seriously, and has taken several steps to respond. At the same time, the Administration has found that in some cases the system strikes a reasonable balance among the legitimate goals of fairness, speed, and accuracy in the decisions made by VA.

First, reported concerns included whether the list of diseases for which compensation is available is fair. VA currently provides benefits for veterans exposed to radiation based on two separate statutory schemes. The Radiation-Exposed Veterans Compensation Act of 1988 provides that if a veteran has a disease listed in the statute, and meets the criteria for exposure, the veteran is entitled to benefits. Thus, for qualified veterans, the list of compensable diseases establishes a presumption of a service connection. This approach has the advantage of simplicity and goes as far as possible toward providing the benefit of doubt to the claimant. It does, however, qualify some people for benefits for whom there is a low

probability of a connection between their in-service exposure to radiation and their disease.

Radiation-exposed veterans may also seek benefits under the Veterans Dioxin and Radiation Exposure Compensation Standards Act. Regulations issued pursuant to this Act require a determination that the disease is both radiogenic and connected to the type and amount of radiation the veteran was exposed to during service. The implementing regulations include a list of diseases that claimants do not have to prove were caused by radiation. HHS' epidemiological tables then provide additional information to help VA adjudicate claims and provide some measure of predictability for claimants. This approach has the potential to be scientifically more accurate in determining service connection. It has, however, been criticized for a variety of reasons, including that the epidemiological tables are out of date, the system creates a difficult burden of proof, and the process is expensive for claimants and the government.

The Administration's view is that we owe veterans both a complete look at the facts and compensation for service-connected disease.

The Administration has taken steps to make this claims process work better. In September of 1996, the Department of Veterans Affairs proposed to include all forms of cancer in the list of diseases recognized as radiogenic. This proposal would mean that each claim will be evaluated based on an individual's estimated dose and all other pertinent information, but will no longer require a showing that the cancer is radiogenic. In addition, the Administration has worked with the Veterans Advisory Committee on Environmental Hazards (VACEH), an independent panel that reviews the scientific literature related to radiation-induced disease, to determine whether other diseases should be added to the list of diseases. Transcripts of VACEH's discussions and citations to the scientific papers they considered are available from VA. As new information becomes available, the VACEH will review it carefully and advise the Secretary if changes in VA's regulations are warranted.

ACHRE noted that many have raised questions about the level of investment in dose reconstruction and scientific investigation compared to the amount spent compensating veterans. The Administration's view is that we owe veterans both a complete look at the facts and compensation for service-connected disease. VA and DOD have invested heavily in making sure that full and fair information is available for every veteran who may have been exposed to radiation during service. The dose reconstructions, including their methodology, have been independently peer-reviewed. Every veteran who seeks compensation needs this information, and it can be enormously frustrating for veterans when the information is incomplete or indeterminate. The principal reason the government has spent more on dose reconstruction than on compensation is that the

dose reconstruction has suggested that most veterans were exposed to levels not expected to cause a significant increase in risk for disease. Unfortunately, there is no shortcut to this information, and it has been expensive to develop.

ACHRE noted that complaints have been raised about the appeals process for radiation-related claims. VA recognizes it must do a better job to meet veterans' needs, and is taking steps to improve compensation claims processing. For example, VA is redesigning the claims process to provide a partnership among the veteran making a claim, the veteran's representative, and the VA employees processing the claim. VA will discuss the claim, issues that arise, and evidence needed. Once a decision is made, VA will discuss it with the veteran and the veteran's representative, and if necessary, will provide help framing the claim for any appellate review. VA believes that this personal interaction will lead to better and faster decisions and will provide a transparent claims process.

VA remains open to other reforms that will make the process of deciding claims fairer and more streamlined.

ACHRE Finding and Recommendations on Compensation of Marshall Islanders

VA recognizes it must do a better job to meet veterans' needs, and is taking steps to improve compensation claims processing.

The Advisory Committee found that

> **[a]s a consequence of a U.S. hydrogen bomb test conducted in 1954, several hundred residents of the Marshall Islands and the crew of a Japanese fishing boat developed acute radiation effects. Some of the Marshall Islanders subsequently developed benign thyroid disorders and thyroid cancer as a result of the radiation exposure. Surviving Marshallese also may remain at elevated risk of thyroid abnormalities. (Finding 16)**

The Advisory Committee recommended that the U.S. Government should continue the current medical monitoring and treatment program for citizens of the Marshall Islands as long as any member of the exposed population remains alive. In addition, ACHRE recommended that the Administration consider adding the populations of other exposed atolls to the south and east; that the Administration involve the Marshall Islanders in the design of any further medical research conducted on them; and that the Administration establish an independent panel to review the adequacy of the current monitoring and treatment program. (Recommendation 8)

Response

DOE has undertaken a reorientation of the Republic of the Marshall Islands (RMI) programs to support more local involvement and control over the resources available as a part of this program.

The Administration recognizes the difficulties and inequities in the current program of medical care for the Marshall Islands and fundamentally agrees with ACHRE's recommendations. The recommendations address the scope and effectiveness of programs designed to provide benefit to citizens of the Marshall Islands because of their exposure to radioactive fallout from atmospheric tests. Before discussing the particular recommendations that ACHRE put forward, it is appropriate to set out the Administration's vision for the implementation of these programs. DOE has undertaken a reorientation of the Republic of the Marshall Islands (RMI) programs to support more local involvement and control over the resources made available as a part of this program. This reorientation means open discussion between the U.S. Government and the Marshallese regarding resources available for, and realistic goals of, this program, along with better coordination of DOE and Department of Interior (DOI) programs. These tasks are underway.

The heads of delegations of the Government of RMI, the DOE, and the U.S. Departments of State and Interior held a meeting in May 1996. A Joint Communiqué was signed that outlined a path forward to address the basic ACHRE issues of concern to the Marshall Islands people.

At a subsequent meeting on June 7, 1996, a 30-day action plan was mutually agreed upon. This action plan establishes objectives for eight working groups and a time table for achieving these defined objectives. These objectives include how best to include RMI in decisionmaking on future direction of programs and in evaluating the DOE Marshall Islands medical program.

The Republic of the Marshall Islands decided to address all eight working group issues by hosting a meeting in Majuro, Marshall Islands, on January 29–31, 1997. The U.S. Government (USG) agreed to fully address four of the working group issues and to discuss issues in the other four working groups, with meetings of these working groups to follow at a later time. The meeting was conducted as bilateral discussions with decisions reached, successes achieved, and forward actions identified to meet the objectives of the four working groups held. The meeting was attended by the leaders of the RMI Government and Local Atoll Government Councils. The U.S. Government was represented by the DOE and their contractors, as well as the Departments of State and Defense.

The major outcome of the January Majuro meeting was the development of a joint USG/RMI committee to deal collectively with the four working groups issues related to the redesign of the current medical delivery process for the Rongelap and Utirik exposed

community. The Marshall Islands called for an open competitive process that would provide a more community-based medical delivery program on a more frequent basis than the current twice-yearly medical missions. The Committee set an accelerated timetable to have an instrument for open competition published in the *Federal Register* by mid-1997 with a new medical delivery process in place by the latter part of calendar year 1998.

An independent review of the DOE Marshall Islands Medical Program is still under discussion. At the request of the Government of RMI, the mechanism for such a review is being reevaluated. RMI has requested a broader historical review that might be done by the National Research Council/National Academy of Sciences. The Department is considering the use of a Blue Ribbon Panel as another possible mechanism for this review.

DOE is also working with the RMI to systematically review and collect historical documents which will help to complete the record of U.S. atmospheric testing in the Marshall Islands and the impact on its people. As part of this effort, DOE is also providing support to facilitate Marshallese access to these and previously collected documents. Documents are being scanned into an electronic retrieval system available via the Internet that makes it possible to search many documents of direct pertinence to the RMI concerns.

DOE is also working with the RMI to systematically review and collect historical documents which will help to complete the record of U.S. atmospheric testing in the Marshall Islands and the impact on its people.

As ACHRE recommended, the Administration plans to continue to support the current monitoring and treatment program. This program is an important element of our nation's commitment to those who were harmed by the atomic testing program.

As ACHRE recommended, the Administration has considered whether additional populations should be included in this program. Extensive analyses to date of radiation exposures in the Marshall Islands have indicated that the exposures to inhabitants of Ailuk and other northern Marshall Island atolls were a factor of 30 to 90 times less than at Rongelap and about 10 to 25 percent of those at Utirik, based upon external dose measurements and on estimates of thyroid doses. Consequently, the Administration does not believe that additional populations should be added to the medical surveillance program. The connection between radiation exposure and thyroid disease is the subject of several ongoing studies sponsored by DOE and managed by CDC. If these or other studies reveal new data to indicate that residents of atolls south and east of Bikini, other than Rongelap and Utirik, are at a significantly increased health risk, DOE will propose any needed expansion of the current medical surveillance program.

APPENDIX A

REMARKS BY PRESIDENT WILLIAM J. CLINTON IN ACCEPTANCE OF HUMAN RADIATION FINAL REPORT

October 3, 1995
Old Executive Office Building

Let me begin with a simple thank you to everyone who participated in this extraordinary project and to everyone who supported them.

I want to thank Secretary O'Leary for her extraordinary devotion to this cause. And you heard in her remarks basically the way that she views this. It's a part of her ongoing commitment to finish the end of the Cold War. And perhaps no Energy Secretary has ever done as much as she has to be an advocate, whether it is for continued reforms within the Energy Department or her outspoken endorsement of the strongest possible commitment on the part of the United States to a Comprehensive Test Ban Treaty, which I believe we will achieve next year in no small measure thanks to the support of the Secretary of Energy.

And, of course, I want to thank Dr. Ruth Faden for her extraordinary commitment of about a year and a half of her life to this unusual but important task.

And all of you who served on the committee—I remember the first time we put this committee together. I do thank you so much for the work you have done.

I saw this committee as an indispensable part of our effort to restore the confidence of the American people in the integrity of their government. All of these political reform issues to me are integrated. When I became the President, I realized we had great new economic challenges, we had profound social problems, that a lot of these things had to be done by an energized American citizenry, but that our national government had a role to play in moving our country through this period of transition. And in order to do it, we needed to increase the capacity of the government to do it through political reform, but we also needed, as much as anything else, to increase the confidence of the American people that, at the very least, they could trust the United States Government to tell the truth and to do the right things.

So you have to understand that, for me, one reason this is so important is that I see it as part of our ongoing effort to give this government back to the American people—Senator Glenn's long effort to get Congress to apply to itself the same laws it imposes on the private sector—the restrictions that I imposed on members of my administration in high positions for lobbying for foreign governments; and when the lobby bill failed in the Congress, I just imposed it by executive order on members of the Executive Branch. All these efforts at political reform, it seems to me, are important.

But none of these efforts can succeed unless people believe that they can rely on their government to tell them the truth and to do the right thing. We have declassified thousands of government documents, files from second world war, the Cold War, President Kennedy's assassination. These actions are not only consistent with our national security, they are essential to advance our values.

So, to me, that's what this is all about. And to all those who represent the families who have been involved in these incidents, let me say to you, I hope you feel that your government has kept its commitment to the American people to tell the truth and to do the right thing.

We discovered soon after I entered office that with the specter of an atomic war looming like Armageddon far nearer than it does today, the United States government actually did carry out on our citizens experiments involving radiation. That's when I ordered the creation of this committee. Dr. Faden and the others did a superb job. They enlisted many of our nation's most significant and important medical and scientific ethicists. They had to determine first whether experiments conducted or sponsored by our government between 1944 and 1974 met the ethical and scientific standards of that time and of our time. And then they had to see to it that our research today lives up to nothing less than our highest values and our most deeply-held beliefs.

From the beginning, it was obvious to me that this energetic committee was prepared to do its part. We declassified thousands of pages of documents. We gave committee members the keys to the government's doors, file cabinets and safes. For the last year and a half, the only thing that stood between them and the truth were all the late nights and hard work they had to put in.

This report I received today is a monumental document—in more ways than one. But it is a very, very important piece of America's history, and it will shape America's future in ways that will make us a more honorable, more successful and more ethical country.

What this committee learned I would like to review today with a little more detail than Dr. Faden said, because I think it must be engraved on our national memory. Thousands of government-sponsored experiments did take place at hospitals, universities, and military bases around our nation. The goal was to understand the effects of radiation exposure on the human body.

While most of the tests were ethical by any standards, some were unethical, not only by today's standards, but by the standards of the time in which they were conducted. They failed both the test of our national values and the test of humanity.

In one experiment, scientists injected plutonium into 18 patients without their knowledge. In another, doctors exposed indigent cancer patients to excessive doses of radiation, a treatment from which it is virtually impossible that they could ever benefit.

The report also demonstrates that these and other experiments were carried out on precisely those citizens who count most on the government for its help—the destitute and the gravely ill. But the dispossessed were not alone. Members of the military—precisely those on whom we and our government count most—they were also test subjects.

Informed consent means your doctor tells you the risk of the treatment you are about to undergo. In too many cases, informed consent was withheld. Americans were kept in the dark about the effects of what was being done to them. The deception extended beyond the test subjects themselves to encompass their families and the American people as a whole, for these experiments were kept secret. And they were shrouded not for a compelling reason of national security, but for the simple fear of embarrassment, and that was wrong.

Those who led the government when these decisions were made are no longer here to take responsibility for what they did. They are not here to apologize to the survivors, the family members or the communities who's lives were darkened by the shadow of the atom and these choices.

So today, on behalf of another generation of American leaders and another generation of American citizens, the United States of America offers a sincere apology to those of our citizens who were subjected to these experiments, to their families, and to their communities.

When the government does wrong, we have a moral responsibility to admit it. The duty we owe to one another to tell the truth and to protect our fellow citizens from excesses like these is one we can never walk away from. Our government failed in that duty, and it offers an apology to the survivors and their families and to all the American people who must—who must be able to rely upon the Untied States to keep its word, to tell the truth, and to do the right thing.

We know there are moments when words alone are not enough. That's why I am instructing my Cabinet to use and build on these recommendations, to devise promptly a system of relief, including compensation, that meets the standards of justice and conscience.

When called for, we will work with Congress to serve the best needs of those who were harmed. Make no mistake, as the committee report says, there are circumstances where compensation is appropriate as a matter of ethics and principle. I am committed to seeing to it that the United States of America lives up to its responsibility.

Our greatness is measured not only in how we so frequently do right, but also how we act when we know we've done the wrong thing; how we confront our mistakes, make our apologies, and take action.

That's why this morning, I signed an executive order instructing every arm and agency of our government that conducts, supports, or regulates research involving human beings to review immediately their procedures, in light of the recommendations of this report, and the best knowledge and standards available today, and to report back to me by Christmas.

I have also created a Bioethics Advisory Commission to supervise the process, to watch over all such research, and to see to it that never again do we stray from the basic values of protecting our people and being straight with them.

The report I received today will not be left on a shelf to gather dust. Every one of its pages offers a lesson, and every lesson will be learned from these good people who put a year and a half of their lives into the effort to set America straight.

Medical and scientific progress depends upon learning about people's responses to new medicines, to new cutting-edge treatments. Without this kind of research, our children would still be

dying from polio and other killers. Without responsible radiation research, we wouldn't be making the progress we are in the war on cancer. We have to continue to research, but there is a right way and a wrong way to do it.

There are local citizens' review boards, there are regulations that establish proper informed consent and ensure that experiments are conducted ethically. But in overseeing this necessary research, we must never relax our vigilance.

The breathtaking advances in science and technology demand that we always keep our ethical watchlight burning. No matter how rapid the pace of change, it can never outrun our core convictions that have stood us so well as a nation for more than 200 years now, through many different scientific revolutions.

I believe we will meet the test of our times—that as science and technology evolve, our ethical conscience will grow, not shrink. Informed consent, community right-to-know, our entire battery of essential human protections—all these grew up in response to the health and humanitarian crises of this 20th century. They are proof that we are equal to our challenges.

Science is not ever simply objective. It emerges from the crucible of historical circumstances and personal experience. Times of crisis and fear can call forth bad science, even science we know in retrospect to be unethical. Let us remember the difficult years chronicled in this report, and think about how good people could have done things that we know were wrong.

Let these pages serve as an internal reminder to hold humility and moral accountability in higher esteem than we do the latest development in technology. Let us remember, too, that cynicism about government has roots in historical circumstances. Because of stonewallings and evasions in the past, times when a family member or a neighbor suffered an injustice and had nowhere to turn and couldn't even get the facts, some Americans lost faith in the promise of our democracy. Government was very powerful, but very far away and not trusted to be ethical.

So today, by making ourselves accountable for the sins of the past, I hope more than anything else, we are laying the foundation stone for a new era. Good people, like these members of Congress who have labored on this issue for a long time, and have devoted their careers to trying to do the right thing, and having people justifiably feel confidence in the work of their representatives. They will continue to work to see that we implement these recommendations.

And under our watch, we will no longer hide the truth from our citizens. We will act as if all that we do will see the light of day. Nothing that happens in Washington will ever be more important in anyone's life affected by these experiments, perhaps, than these reports we issue today. But all of us as Americans will be better off because of the larger lesson we learned in this exercise and because of our continuing effort to demonstrate to our people that we can be faithful to their values.

Thank you very much.

APPENDIX B

ACCESS TO RECORDS AND INFORMATION RELATING TO HUMAN RADIATION EXPERIMENTS

Advisory Committee on Human Radiation Experiments (ACHRE) Collection at the National Archives, College Park

Overview: 665 cubic feet of records from the Advisory Committee on Human Radiation Experiments have been deposited at the National Archives and made part of Record Group 220, Presidential Committees, Commissions, and Boards. The collection can be accessed through the Archive's Textual Reference Branch located at Archives II, 8601 Adelphi Road, College Park, Maryland. The phone number is (301) 713-7250.

The collection consists primarily of documents collected from Federal agencies and other sources during the Committee's research process, but also includes the Committee's administrative files, meeting documentation, notes, and other records generated by the staff.

Organization: The ACHRE collection is divided into 12 major series. The series of primary interest to most researchers is the Research Collection Series, which consists of two major components—the Archives file and the Library file. The Archives file represents the primary documents collected from agencies and other sources; the Library file encompasses secondary sources, such as journal articles and published reports. The Archives file is organized by accession number. Each deposit of records to ACHRE was assigned an accession number which consists of an acronym for the document source, the deposit date, and an alpha designator which represents the sequence of deposits from that source on that date; i.e., DOD-062194-C represents the third Defense Department deposit of June 21, 1994. An accession may consist of one document or several boxes of documents.

Finding Aids at the Archives: Paper copy finding aids are found in five binders at the National Archives. The finding aids provide basic access to the 12 records series. The finding aid for the Archives file identifies the current box number for each accession number. Copies of the ACHRE *Final Report* and supplemental volumes are

also available. Supplemental Volume 2A includes a complete listing of all accessions in the Archives collection, of all publications in the Library collection, of all experiments identified by ACHRE, and of individual documents within each accession which were specifically described, including those cited in the *Final Report*. Volume 2A also includes indexes of this data sorted in several ways, such as by subject. The electronic index to the collection is not available to researchers at NARA.

Other Finding Aids to the ACHRE Collection: The Lotus Notes database created by the Advisory Committee is available to researchers at the National Security Archive, a private nonprofit organization, located in the Gelman Library at George Washington University, (202) 994-7000. However, some familiarity with Lotus Notes may be necessary for a researcher to search the database.

The National Security Archive also maintains a Web site for ACHRE information (www.seas.gwu.edu/nsarchive/radiation/). The site includes information such as transcripts and related materials for Committee meetings, the text of the *Final Report*, and the complete listing of the research document (archives) collection, publications (library) collection, and experiments. Word searches can be performed using the capabilities of an Internet browser (such as Netscape).

Barriers to Access: The ACHRE collection at the National Archives has material protected by the Privacy Act interspersed throughout. As a result, most boxes of records must be screened by Archives staff to remove this material prior to being provided to researchers. The Archives has indicated that it needs at least 1 week of lead time for any requests which involve more than a few folders, to allow time to review the requested material. In some cases, it can take up to several months. Researchers are asked to be as specific as possible in their requests.

Please note that it may be difficult to locate a specific document within an accession because the documents have not been assigned individual document identifiers (i.e., document numbers). It may be necessary to review an entire accession to locate the desired document.

Other Resources

DOE Office of Human Radiation Experiments (OHRE) Home Page (www.ohre.doe.gov): OHRE created a Web site in early 1995 to make its human radiation experiment document collection and other important information readily available to the public. The site provides access to the text of OHRE's publications—the *Roadmap*, the *Experiment List*, and a series of oral histories conducted by

OHRE (*See* List of Publications, below)—as well as other material of interest such as the transcript of a stakeholder's workshop held in February 1996. The text of the Advisory Committee Report is also accessible from this home page. This site also provides links to other relevant sites, including all those referenced in this document.

The major feature of the home page is the Human Radiation Experiments Information Management System (HREX), which was developed by DOE to provide users with the ability to conduct full-text searches of its 250,000 page historical document collection and to retrieve images of those documents. All documents placed on the Web have been screened for Privacy Act material and personal identifiers have been removed (redacted). Each document in the collection has been assigned a unique document number and identified with provenance (source) information. The original copy of the document is maintained by the facility or institution identified in the provenance information. Please note that most, but not all, of the documents provided to the Advisory Committee are in HREX. The exceptions are a small number of documents retrieved by Committee staff directly from DOE sites and not processed through OHRE.

Interagency HREX (hrex.dis.anl.gov): In November 1996, a new version of HREX was made available to the public. This enhanced version of HREX allows access to historical documents collected by other agencies involved in the Interagency Working Group (Department of Defense, Department of Health and Human Services, Department of Veterans' Affairs, Central Intelligence Agency, and the National Aeronautics and Space Administration). As above, all documents placed in the Interagency HREX are screened for material protected by the Privacy Act, and personal identifiers are removed (redacted). This interagency system currently has more than 300,000 pages of documents (including the DOE documents) and when completed will contain approximately 500,000 searchable pages.

The Coordination and Information Center (CIC): Paper copies of all DOE documents found in HREX are stored at the CIC in Las Vegas, NV. Paper copies of all DOD's documents have recently been transferred there as well. In addition to its holdings related to human radiation experiments, the CIC possesses a large collection of documents from the era of atmospheric atomic weapons testing. To request documents, contact the CIC in writing at P.O. Box 98521, Las Vegas, NV 89193-8521 or by phone at (702) 295-0731. Small numbers of documents can be printed off the Internet, but large volume requests for paper documents are better directed to the CIC. Individuals may access unredacted documents about themselves or about their next-of-kin from the CIC if they provide proof of identity.

The complete index of DOE holdings at the CIC (including the human radiation experiments collection) is available on the Internet via OpenNet (apollo.osti.gov/html/osti/opennet/opennet1.html). OpenNet, sponsored by the DOE Office of Declassification, also provides bibliographic information on recently declassified DOE documents and other document collections.

DOE Public Reading Rooms: Redacted paper copies of all documents located by DOE facilities as part of the human radiation experiments search and included in HREX have also been deposited in the public reading room for that facility.

List of Publications

1. *Final Report: Advisory Committee on Human Radiation Experiments* was released in October 1995, and includes the text of the report (over 900 pages) plus three supplemental volumes. Copies can be obtained from the U.S. Government Printing Office, (202) 512-1800. The text of the report is also accessible on the Internet through several sources including the OHRE and ACHRE sites described above.

2. *The Human Radiation Experiments: Final Report of the President's Advisory Committee* was also published in one volume by Oxford University Press in 1996. While this book does not include the supplemental volumes, it does contain President Clinton's remarks on accepting the final report of the Committee and a useful index. Copies can be obtained in bookstores or directly from Oxford University Press.

3. *Human Radiation Experiments: The Department of Energy Roadmap to the Story and the Records*, released in February 1995 by DOE's Office of Human Radiation Experiments (OHRE), includes project background, site histories, records series descriptions, topical essays, and a preliminary list of experiments. Hard copies of this report (DOE-EH-0445) are available from DOE's Office of Public Inquiries at (202) 586-5575. The report is also available on the World Wide Web (www.ohre.doe.gov).

4. *Human Radiation Experiments Associated with the United States Department of Energy and its Predecessors*, released in July 1995 by OHRE, contains a listing, description, and selected references for 435 documented human radiation studies dating back to World War II. Hard copies of this report (DOE-EH-0491) are available from DOE's Office of Public Inquiries at (202) 586-5575. The report is also available on the World Wide Web (www.ohre.doe.gov).

5. *Human Radiation Studies: Remembering the Early Years,* completed November 1995 by OHRE, consists of a 29-part series of oral histories whose purpose is to enrich the documentary record, provide missing information, and allow an opportunity for the researchers to provide their perspective. A descriptive brochure, which lists all of the subjects of the oral histories and provides brief background on each, as well as copies of the individual oral histories, are available from OHRE at (202) 586-8439. The oral histories are also available on the World Wide Web (www.ohre.doe.gov).

6. *Radiation Protection and the Human Radiation Experiments,* Los Alamos Science, Number 23, 1995, is a special issue of this journal which discusses the work and the findings of the Laboratory's Human Studies Project Team. The team was formed to address questions concerning the ethics and conduct of human radiation experiments that were carried out by Los Alamos researchers from the Manhattan Project days through the 1960s. The report is available from Los Alamos Science, Mail Stop M708, Los Alamos National Laboratory, Los Alamos, NM 87545 or on the World Wide Web (lib-www.lani.gov/pubs/number23.htm).

7. *The Department of Defense Report on the Search for Human Radiation Experiment Records, 1944-1994,* March 1997, covers, among other topics, DOD human subjects protection policy, total-body and partial-body irradiation studies, nasopharyngeal irradiation therapy, and radiological warfare. It is published by the Office of the Assistant to the Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs and is available through the National Technical Information Service, Springfield, VA 22161.

8. Central Intelligence Agency Inspector General Report of Investigation, *Agency Human Subject Research,* April 26, 1995. This report can be obtained from the Information and Privacy Coordinator of the CIA, at (703) 613-1287. The report is also available on the World Wide Web (hrex.dis.anl.gov).

9. The Arctic Aeromedical Laboratory's Thyroid Function Study: A Radiological Risk and Ethical Analysis, National Academy Press 1996. This report can be ordered from the National Academy Press, 2101 Constitution Ave., N.W., Box 285, Washington, D.C. 20055 or via telephone at 1-800-624-6242. It can also be found on the National Academy Press Web Site (www.nap.edu/readingroom/).

10. S. Hrg. 104-588, Hearing before the Committee on Governmental Affairs, United States Senate, March 12, 1996. *Human Radiation Experiments.*

APPENDIX C

CURRENT AGENCY ACTIVITIES RELATING TO IMPROVING HUMAN SUBJECTS RESEARCH PROTECTIONS

The following are specific activities that have been undertaken by agencies involved in the human radiation experiments effort in relation to, or as a result of, their review of current human research in light of the Advisory Committee recommendations.

The Department of Energy

- Revised and updated the *DOE Human Subjects Research Handbook (2nd Edition)*. The handbook specifically addresses issues raised by the Advisory Committee on informed consent and classified research as well as all other areas of human subjects protections and provides regulations, resources, and models. The manual has been distributed throughout DOE and to other parts of the government as well.

- Has begun a program of regular site visits to its facilities performing human subjects research, for education and review. Each site will be visited approximately once every 3 years. Five laboratories and three field offices were visited by a team in 1996.

- Requested all DOE laboratories to provide a sample of current informed consent documents. These were reviewed to improve and monitor the quality of these documents and a similar request will be made in late 1997.

- Has begun drafting three model informed consent documents that will be sent to all sites to adapt and use, one for genetic research, one for biomedical research, and one for human factors research.

- Requested all laboratories to provide plans that detail local education activities to improve the human subjects research review system. This request will be updated during FY 1997.

- Put DOE's Fiscal Year 1995 and 1996 Human Subjects Database on the Internet.

- Updated the DOE Human Subjects Research Home Page with access to all DOE information, contacts, and resources. These include information about educational workshops and conferences related to generic human subjects research issues. (www.er.doe.gov/production/oher/humsubj/index.html)

- Continued the twice-yearly meetings of DOE-wide human subjects working group. The DOE human subjects research newsletter, *Protecting Human Subjects*, is widely distributed twice-yearly both inside and outside the agency.

- Sponsored a large, interagency human subjects workshop to highlight the ACHRE report and other bioethical issues. This ongoing series is undertaken every other year. The meeting in June 1997 is on "Human Subjects and Genetics Research: The Changing Landscape."

- Is joining NIH and VA in co-sponsoring a research program on the informed consent process.

The Department of Defense

- Reviewed in detail existing DOD policies and procedures for the protection of human research subjects and has undertaken extensive revision of DOD Directive 3216.2, "Protection of Human Subjects in DOD Supported Research."

- Implemented changes to current policies that:

  - Adopt investigator assurances of familiarity with the Nuremberg Code, the Belmont Report, the Common Rule, and related requirements;

  - Incorporate research ethics into graduate medical education curricula at Military Department teaching hospitals;

  - Include specific language in the revised directive that would emphasize the expedited review process for certain categories of minimal risk research that are detailed in the Common Rule (32 CFR 219);

  - Require education in human subjects regulations at the executive level of training for commanders and senior civilians who may be involved in human subjects research and for individual investigators, IRB members, research administrators, and support personnel; and

- Ensure that officers and senior NCOs (non-commissioned officers) in the chain of command not be present during research recruitment briefings of personnel under their command, and that an ombudsman be present at group recruitment briefings.

The National Aeronautics and Space Administration

- Established an external Bioethics Policy Task Force to review all NASA human use research policies and procedures, chaired by Baruch Brody, Ph.D., Leon Jawarski Professor of Biomedical Ethics and Director of the Center for Ethics, Medicine and Public Issues at Baylor College of Medicine. The final report of the Task Force was provided on February 14, 1996. In collaboration with the Task Force, NASA enhanced the conduct of human subjects research so that it satisfies the requirements both of the Federal Common Rule and of the highest principles of research ethics.

- Updated the NASA Management Instruction (NMI) on the conduct of Human Research, issued on August 8, 1995, to reflect the Federal Common Rule and incorporate the relevant recommendations reflected in the Advisory Committee's *Final Report*. NASA Headquarters has also established a process for oversight and assurance. An Agency Authorizing Official has been named for the authorization of human research and the protection of human subjects. Documentation of assurance of human subjects protection is required every 5 years, from all nine NASA Field Installations and the Jet Propulsion Laboratory, if the Center is conducting human subjects research. Centers not conducting such research must recertify by letter every year.

- Conducted internal reviews at Headquarters, Johnson Space Center, and Ames Research Center to ensure that elements of the Common Rule and Advisory Committee recommendations were incorporated into agency and center instructions.

- Because much of its future space research will be conducted with its partners on the International Space Station, has conducted the first in a series of forums to inform NASA's international biomedical community on issues related to the ethics of human subjects research. These workshops will effect a transnational understanding of the sensitivity to ethical issues in human research and ensure that all international partners support common ethical principles regarding the protection of human subjects. A common consent form for use on the International Space Station was agreed upon and will undergo periodic review.

- Initiated ethics forums on the Common Rule and protection of human subjects for its domestic biomedical research community.

The Central Intelligence Agency

- Obtained the services of a prominent ethicist from the academic community to become a permanent voting member of the Agency's Human Subjects Research Panel (HSRP).

- Revised agency regulations to indicate that all research carried out or sponsored by the Agency that utilizes human subjects shall be brought to the HSRP for approval. The Chairman must certify as exempt or approve a research proposal before it can proceed; final approval rests with the Agency Director.

- Disseminated an agency bulletin to all employees specifying the rationale and function of the panel and necessity of referring human subjects research to it for approval.

- Revised the Agency's Contracting Manual to guarantee that HSRP approval is obtained prior to approval of any contract involving human subjects research.

The Department of Health and Human Services

- Coordinates Interagency Request for Applications from researchers, to develop new knowledge related to the informed consent process.

- Expanded technical assistance to IRBs at institutions receiving DHHS research funds, by means of 12 to 24 site visits per year.

- Increased activities to improve the procedures for protecting human subjects. For example, CDC is developing an online education system in research integrity and ethics that will be mandatory for investigators.

- Provides administrative support for NBAC.

The Food and Drug Administration

- Has the largest IRB oversight program of any Federal agency and the only Federal program for oversight of radioactive drug research committees.

- Performs periodic on-site inspections of all IRBs that are known to review FDA-regulated studies. In cases of serious non-compliance, FDA suspends approval of new studies and accrual of new subjects into ongoing studies. Such sanctions are imposed on over 20 IRBs per year.

- Has recently expanded the cope of its on-site inspection program of radioactive drug research committee (RDRC) to include evaluation of the quality of the drugs and the scientific and medical justification of radiation use.

- Is revising the RDRC regulations to strengthen the safeguards to human subjects.

Other Agencies

- VA has planned IRB site visits to review procedures and their Office of Research and development is reviewing its policy manual to identify any needed revisions.

- The Department of Education anticipates reporting to NBAC on ongoing training activities, and efforts to disseminate information through guidance documents and establish networks within that Department.

- The Environmental Protection Agency (EPA) is updating an internal order on human research subjects to implement the Common Rule.

- The Consumer Product Safety Commission is updating and changing its internal documents and policies.

APPENDIX D

PROPOSED LEGISLATION TO AMEND THE RADIATION EXPOSURE AND COMPENSATION ACT

A BILL

To amend the eligibility criteria of the Radiation Exposure Compensation Act and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "The Radiation Exposure Compensation Act Amendments of 1997."

SEC. 2. The Radiation Exposure Compensation Act, 42 U.S.C. § 2210 note (Supp. 1995), (referred to in this Act as "the Act"), is amended as follows:

(a) CLAIMS RELATING TO ATMOSPHERIC NUCLEAR TESTING.—(1) Section 4(a)(1) of the Act is amended to read as follows:

"(1) Claims relating to childhood leukemia - Any individual who -

"(A) was physically present in an affected area for a period of at least 1 year during the period beginning on January 21, 1951, and ending on October 31, 1958,

"(B) was physically present in the affected area for the period beginning on June 30, 1962, and ending on July 31, 1962, or

"(C) participated onsite in a test involving the atmospheric detonation of a nuclear device,

and who submits written medical documentation that he or she, after such period of physical presence or such onsite participation (as the case may be), and between 2 and 30 years after first exposure to fallout, contracted leukemia (other then chronic lymphocytic leukemia), shall receive $50,000 (in the case of an individual described in subparagraphs (A) or (B)) or $75,000 (in the case of an individual described in subparagraph (C)), if -

"(i) initial exposure occurred prior to age 21,

"(ii) the claim for such payment is filed with the Attorney General by or on behalf of such individual, and

"(iii) the Attorney General determines, in accordance with section 6, that the claim meets the requirements of this Act."

(2) Section 4(b)(2) of the Act is amended—

(i) by inserting "male or" before "female breast"; and

(ii) by striking "and low coffee consumption"; and

(iii) by inserting "salivary gland," after "gall bladder."

(b) CLAIMS RELATING TO URANIUM MINING.— Section 5 of the Act is amended to read as follows:

"SEC. 5. CLAIMS RELATING TO URANIUM MINING.

"(a) Eligibility of Individuals for Full Compensation for Lung Cancer — Any individual who was employed in a uranium mine in a specified State at any time during the designated time period, shall receive $100,000 if the individual submits written medical documentation that he or she contracted lung cancer, and

"(1) if a nonsmoker,

"(a) was exposed to 200 or more working level months of radon progeny; or

"(b) was exposed to at least the amount of radon progeny in working level months specified in Table 1-A, based on the individual's age at disease incidence, and number of years since last exposure to radon progeny in the designated time period; or

"(c) was employed during the designated time period for at least the amount of time specified in Table 2-A, based on the individual's age at disease incidence, year of first exposure to radon progeny during the designated time period, and number of years since last exposure to radon progeny during the designated time period; or

"(2) if a smoker,

"(a) was exposed to 300 or more working level months of radon progeny and cancer was contracted before age 45, or was exposed to 500 or more working level months of radon progeny, regardless of age when cancer was contracted; or

"(b) was exposed to at least the amount of radon progeny in working level months specified in Table 1-B, based on the individual's age at disease incidence, and number of years since last exposure to radon progeny during the designated time period, or

"(c) was employed during the designated time period for at least the amount of time specified in Table 2-B, based on the individual's age at disease incidence, year of first exposure to radon progeny during the designated time period, and number of years since last exposure to radon progeny during the designated time period.

"(b) Eligibility of Individuals for Partial Compensation for Lung Cancer — Any individual who was employed in a uranium mine in a specified State at any time during the designated time period, shall receive $50,000 if

the individual submits written medical documentation that he or she contracted lung cancer, and

"(1) if a nonsmoker, was exposed to at least the amount of radon progeny in working level months specified in Table 3-A, based on the individual's age at disease incidence, and number of years since last exposure to radon progeny in the designated time period; or,

"(2) if a smoker, was exposed to at least the amount of radon progeny in working level months specified in Table 3-B, based on the individual's age at disease incidence, and number of years since last exposure to radon progeny during the designated time period.

"(c) Eligibility for Full Compensation for Nonmalignant Respiratory Disease — Any individual who was employed in a uranium mine in a specified State at any time during the designated time period, shall receive $100,000 if the individual submits written medical documentation that he or she, after such employment, contracted a nonmalignant respiratory disease, and

"(1) if a nonsmoker, was exposed to 200 or more working level months of radon progeny; or

"(2) if a smoker, was exposed to 300 or more working level months of radon progeny and the nonmalignant respiratory disease was contracted before age 45, or was exposed to 500 or more working level months of radon progeny, regardless of age the disease was contracted.

"(d) Any individual eligible for full or partial compensation under subsections (a), (b) or (c) shall receive payment if —

"(1) a claim for payment is filed with the Attorney General by or on behalf of such individual, and,

"(2) the Attorney General determines, in accordance with section 6, that the claim meets the requirements of this Act.

Payments under this section may be made only in accordance with section 6.

"(e) The tables referred to in subsections (a) and (b) are as follows:

TABLE 1-A
Minimum Radiation Exposure Levels
for Full Compensation for Lung Cancer
(in Working Level Months)
Nonsmokers

Age at disease incidence	Years since last radon progeny exposure		
	<10	10-19	≥20
<50	1	2	9
50-59	4	8	33
60-69	16	45	141
≥70	24	50	203

TABLE 1-B
Minimum Radiation Exposure Levels
for Full Compensation for Lung Cancer
(in Working Level Months) Smokers

Age at disease incidence	Years since last radon progeny exposure		
	<10	10-19	≥20
<50	5	11	46
50-59	19	40	163
60-69	81	174	703
≥70	117	250	1,010

TABLE 2-A
Minimum Duration of Employment
for Full Compensation For Lung Cancer
(in Years)
Nonsmokers

Age at disease incidence	Years since last radon progeny exposure <10	10-19	≥20
		First exposed: <1955	
<50	0.0[a]	0.0	0.0
50-59	0.1	0.2	0.3
60-69	0.5	0.7	1.5
≥70	0.7	1.1	2.4
		First exposed: 1955-59	
<50	0.0	0.0	0.0
50-59	0.1	0.2	0.3
60-69	0.6	0.9	1.9
≥70	0.9	1.4	3.0
		First exposed: ≥1960	
<50	0.0	0.0	0.1
50-59	0.3	0.4	0.8
60-69	1.6	2.4	5.0
≥70	2.5	3.8	8.0

[a] A value of 0.0 years denotes employment in an underground uranium mine for at least 1 day but less than 18 days (.05 years or 102 working hours).

TABLE 2-B
Minimum Duration of Employment
For Full Compensation for Lung Cancer
(in Years)
Smokers

Age at disease incidence	Years since last radon progeny exposure <10	10-19	≥20
		First exposed: <1955	
<50	0.0[a]	0.0	0.0
50-59	0.2	0.3	0.6
60-69	1.1	1.6	3.4
≥70	1.7	2.6	5.5
		First exposed: 1955-59	
<50	0.0	0.0	0.1
50-59	0.2	0.4	0.7
60-69	1.4	2.1	4.3
≥70	2.2	3.3	7.0
		First exposed: ≥1960	
<50	0.0	0.1	0.1
50-59	0.6	0.9	1.9
60-69	3.6	5.5	11.5
≥70	5.8	8.8	18.5

[a] A value of 0.0 years denotes employment in an underground uranium mine for at least 1 day but less than 18 days (.05 years or 102 working hours).

TABLE 3-A
Minimum Radiation Exposure Levels
For Partial Compensation For Lung Cancer
(in Working Level Months)
Nonsmokers

Age at disease incidence	Years since last radon progeny exposure <10	10-19	≥20
<50	0.4	0.7	3
50-59	1	3	12
60-69	5	16	50
≥70	9	18	72

TABLE 3-B
Minimum Radiation Exposure Levels
For Partial Compensation For Lung Cancer
(in Working Level Months)
Smokers

Age at disease incidence	Years since last radon progeny exposure <10	10-19	≥20
<50	2	4	16
50-59	7	14	57
60-69	29	61	248
≥70	41	88	356

"(f) Definitions — For purposes of this section —

"(1) the term 'working level month of radon progeny' means exposure to radon progeny at the level of one working level every work day for a month, or an equivalent exposure over a greater or lesser amount of time;

"(2) the term 'working level' means the concentration of the short half-life daughters of radon that will release 1.3 x 10^5 million electron volts of alpha energy per liter of air;

"(3) the term 'nonmalignant respiratory disease' means either pulmonary fibrosis, cor pulmonale related to pulmonary fibrosis, or moderate or severe silicosis, or pneumoconiosis;

"(4) the term 'Indian tribe' means any Indian tribe, band, nation, pueblo, or other organized group or community, that is recognized as eligible for special programs and services provided by the United States to Indian tribes because of their status as Indians.

"(5) the term 'specified State' means Arizona, Colorado, New Mexico, Utah, or Wyoming; and

"(6) the term 'designated time period' means the period beginning January 1, 1947 and ending on December 31, 1971."

(c) DETERMINATION AND PAYMENT OF CLAIMS.

(1) Section 6(c)(2)(A)(ii) of the Act is amended by striking "5(a)" and inserting "5(f)(6)".

(2) Section 6(c)(2)(B) of the Act is amended—

(A) in clause (I) by inserting "(other than a claim for workers compensation)" after "claim"; and

(B) in clause (ii) by striking "Federal Government" and inserting "Department of Veteran Affairs."

(3) Section 6(d) of the Act is amended by inserting at the end the following:

"The Attorney General may request from any claimant, or from any individual or entity on behalf of any claimant, any additional information or documentation necessary to complete the determination on the claim in accordance with the procedures established under subsection (a). The period of time from the Attorney General's request for additional information or documentation until the time such information or documentation is provided or the requested party informs the Attorney General the information or documentation cannot or will not be provided, is not counted toward the 12-month limit established in this subsection."

SECTION-BY-SECTION ANALYSIS

Section (1). This section would state the short title of the bill.

Section (2). This section would amend sections 4, 5, and 6 of the Radiation Exposure Compensation Act of 1990, P.L. 101-426, 42 U.S.C. § 2210 note.

Subsection (a). This section would amend section 4 of the Act by expanding the eligibility criteria for downwinder and onsite participant claimants.

Subsection (1) would amend section 4(a)(1) of the Act by expanding the class of claimants eligible for compensation for childhood leukemia to include certain onsite participants. The amendment would add individuals who were exposed to radiation before the age of 21 while participating onsite in a test involving the atmospheric detonation of a nuclear device.

Subsection (2) would amend the list of compensable diseases in section 4(b) of the Act to account for the latest scientific findings regarding the effects of radiation exposure. The amendment would add two new diseases that have now been associated with exposure to radiation — primary cancers of the male breast and salivary gland — and eliminate the requirement that claimants seeking compensation for pancreatic cancer not have a history of heavy coffee drinking. The bill would limit compensation for salivary gland cancer to claimants who were not heavy smokers.

Subsection (b). This section would amend section 5 of the Act, defining the eligibility criteria for uranium miner claimants. This section would delete the present exposure-based eligibility criteria that apply to all uranium miner claimants — whether they are seeking compensation for lung cancer or a nonmalignant respiratory disease — and substitute in lieu thereof separate, and in the case of lung cancer, new eligibility criteria for each compensable disease. This section would further modify section 5 of the Act by adding provisions stating new eligibility criteria for partial compensation for lung cancer.

This section would amend section 5(a) of the Act by deleting the eligibility criteria for nonmalignant diseases, and adding to the existing exposure-based criteria for lung cancer two additional sets of criteria — one set also based on exposure to radiation, and a second set based on duration of employment — and allow claimants to qualify for full compensation ($100,000) by meeting either the existing criteria or either of the two new alternative sets of criteria. These new sets of standards are the result of an effort by the Administration to generate new compensation criteria that more accurately reflect the risk of lung cancer from uranium mining, and thus better provide compensation to deserving claimants. The new criteria are based on the latest data and an updated analysis of the risk factors for lung cancer from uranium mining; they represent the best estimate of the level of radiation at

which the miner's exposure (measured either directly by working level months or indirectly by duration of employment) is the probable cause of his lung cancer. The set of criteria based on duration of employment are proposed because potential claimants are likely to find them easier to understand and use than exposure-based alternative criteria.

This section would also delete the existing subsection (b), which defines a number of terms used in section 5 of the Act, and substitute in lieu thereof a new set of eligibility criteria that would provide partial compensation ($50,000) to a class of miner-claimants who are not qualified under the present criteria and who will not qualify under the newly proposed criteria for full compensation. The new criteria in section 5(b) are based on the same data and analysis as the newly-proposed criteria for full compensation, but, additionally, give the miner-claimants the benefit of known uncertainties in the underlying data. Thus, section 5(b), as amended, would newly enfranchise those miner-claimants whose exposure to radiation we can confidently say, giving them the benefit of known uncertainties in the underlying data, caused their lung cancers.

This section would, further, add a new subsection (c) that restates separately the present eligibility criteria for full compensation for nonmalignant respiratory diseases.

This section would also add a new subsection (d) that would restate the requirements presently found in section 5(a) of the Act that the compensation can be paid only when a claim is filed with the Attorney General, determined to meet the requirements of the Act, and payment can be made in accordance with the provisions of section 6 of the Act.

This section would add a new subsection (e) that would incorporate into the Act tables containing the new eligibility criteria for lung cancer, for both full and partial compensation. Table 1 contains the new, alternative exposure-based eligibility criteria for full compensation; Table 2 contains the new, alternative employment-based eligibility criteria for full compensation; and Table 3 contains the new exposure-based eligibility criteria for partial compensation.

Finally, this section would add a new subsection (f) that would restate the definitions presently found in section 5(b) of the Act, with some additions and modifications. The definition of the term "nonmalignant respiratory disease" in section 5(b)(3) of the existing Act would be modified by eliminating the redundant reference to pulmonary fibrosis in the list of compensable nonmalignant respiratory disorders, and by eliminating the limitation on compensation for silicosis and pneumoconiosis to uranium mines on Indian Reservations. This latter modification would ensure that miners employed in uranium mines off Indian Reservations (yet within one of the specified mining States) are compensated on the same conditions as miners employed in mines on Indian Reservations; the evidence suggests that the risk of silicosis due

to uranium mining was not restricted to mines on Indian Reservations. The proposed subsection (f) would also include definitions of two new terms — "specified States" and "designated time period" — employed in the proposed amendments to section 5.

Section (c). This section would amend the provisions of section 6(c)(2) of the Act defining the circumstances in which awards to onsite participants must be offset by payments received from other parties.

Subsection (1) would amend section 6(c)(2)(A)(ii) by substituting for the existing reference the new subsection where the designated time period within which a claimant must have been employed in a uranium mine is defined.

Subsection (2) would amend section 6(c)(2)(B)(I) to clarify that awards under the Act to on-site participants should not be offset by payments to the claimant based on a worker's compensation claim for the same injuries. It would also amend section 6(c)(2)(B)(ii) to clarify that an award under the Act should be offset only by payments to the claimant from the Department of Veteran's Affairs, and not by disability payments from other Federal agencies, such as Social Security. These amendments are designed to enhance parity among the eligible populations by ensuring that payments to onsite participants are offset on the same terms as payments to downwinders and uranium miners.

Subsection (3) would amend section 6(d) of the Act by adding explicit authorization for the Attorney General to seek and obtain from claimants, or from any individual or private or public entity on behalf of claimants, any documentation or information necessary to determine eligibility. This section also provides that the time period during which the Attorney General is awaiting the requested information shall not count toward the 12-month statutory limit on processing claims.

APPENDIX E

DIRECTIVE FROM THE PRESIDENT REGARDING CLASSIFIED RESEARCH

(Begins on next page)

THE WHITE HOUSE

WASHINGTON

March 27, 1997

MEMORANDUM FOR THE SECRETARY OF DEFENSE
THE ATTORNEY GENERAL
THE SECRETARY OF AGRICULTURE
THE SECRETARY OF COMMERCE
THE SECRETARY OF LABOR
THE SECRETARY OF HEALTH AND HUMAN SERVICES
THE SECRETARY OF HOUSING AND URBAN DEVELOPMENT
THE SECRETARY OF TRANSPORTATION
THE SECRETARY OF ENERGY
THE SECRETARY OF EDUCATION
THE SECRETARY OF VETERANS AFFAIRS
THE DIRECTOR OF CENTRAL INTELLIGENCE
THE ADMINISTRATOR OF THE ENVIRONMENTAL PROTECTION AGENCY
THE ADMINISTRATOR OF THE AGENCY FOR INTERNATIONAL DEVELOPMENT
THE ADMINISTRATOR OF THE NATIONAL AERONAUTICS AND SPACE ADMINISTRATION
THE DIRECTOR OF THE NATIONAL SCIENCE FOUNDATION
THE CHAIR OF THE NUCLEAR REGULATORY COMMISSION
THE DIRECTOR OF THE OFFICE OF SCIENCE AND TECHNOLOGY POLICY
THE CHAIR OF THE CONSUMER PRODUCT SAFETY COMMISSION

SUBJECT: Strengthened Protections for Human Subjects of Classified Research

I have worked hard to restore trust and ensure openness in government. This memorandum will further our progress toward these goals by strengthening the Federal Government's protections for human subjects of classified research.

In January 1994, I established the Advisory Committee on Human Radiation Experiments (the "Advisory Committee") to examine reports that the government had funded and conducted unethical human radiation experiments during the Cold War. I directed the Advisory Committee to uncover the truth, recommend steps to right past wrongs, and propose ways to prevent unethical human subjects research from occurring in the future. In its October 1995 final report, the Advisory Committee recommended, among other things, that the government modify its policy governing classified research on human subjects ("Recommendations for Balancing National Security Interests and the Rights of the Public," Recommendation 15, Final Report, Advisory Committee on Human Radiation Experiments). This memorandum sets forth policy changes in response to those recommendations.

The Advisory Committee acknowledged that it is in the Nation's interest to continue to allow the government to conduct classified research involving human subjects where such research serves important national security interests. The Advisory Committee found, however, that classified human subjects research should be a "rare event" and that the "subjects of such research, as well as the interests of the public in openness in science and in government, deserve special protections." The Advisory Committee was concerned about "exceptions to informed consent requirements and the absence of any special review and approval process for human research that is to be classified." The Advisory Committee recommended that in all classified research projects the agency conducting or sponsoring the research meet the following requirements:

- obtain informed consent from all human subjects;
- inform subjects of the identity of the sponsoring agency;
- inform subjects that the project involves classified research;
- obtain approval by an "independent panel of nongovernmental experts and citizen representatives, all with the necessary security clearances" that reviews scientific merit, risk-benefit tradeoffs, and ensures subjects have enough information to make informed decisions to give valid consent; and
- maintain permanent records of the panel's deliberations and consent procedures.

This memorandum implements these recommendations with some modifications. For classified research, it prohibits waiver of informed consent and requires researchers to disclose that the project is classified. For all but minimal risk studies, it requires researchers to inform subjects of the sponsoring agency. It also requires permanent recordkeeping.

The memorandum also responds to the Advisory Committee's call for a special review process for classified human subjects research. It requires that institutional review boards for secret projects include a nongovernmental member, and establishes an appeals process so that any member of a review board who believes a project should not go forward can appeal the boards' decision to approve it.

Finally, this memorandum sets forth additional steps to ensure that classified human research is rare. It requires the heads of Federal agencies to disclose annually the number of secret human research projects undertaken by their agency. It also prohibits any agency from conducting secret human research without first promulgating a final rule applying the Federal Policy for the Protection of Human Subjects, as modified in this memorandum, to the agency.

These steps, set forth in detail below, will preserve the government's ability to conduct any necessary classified research involving human subjects while ensuring adequate protection of research participants.

1. Modifications to the Federal Policy for the Protection of Human Subjects as it Affects Classified Research. All agencies that may conduct or support classified research that is subject to the 1991 Federal Policy for the Protection of Human Subjects ("Common Rule")(56 Fed. Reg. 28010-28018) shall promptly jointly publish in the Federal Register the following proposed revisions to the Common Rule as it affects classified research. The Office for Protection from Research Risks in the Department of Health and Human Services shall be the lead agency and, in consultation with the Office of Management and Budget, shall coordinate the joint rulemaking.

(a) The agencies shall jointly propose to prohibit waiver of informed consent for classified research.

(b) The agencies shall jointly propose to prohibit the use of expedited review procedures under the Common Rule for classified research.

(c) The joint proposal should request comment on whether all research exemptions under the Common Rule should be maintained for classified research.

(d) The agencies shall jointly propose to require that in classified research involving human subjects, two additional elements of information be provided to potential subjects when consent is sought from subjects:

(i) the identity of the sponsoring Federal agency. Exceptions are allowed if the head of the sponsoring agency determines that providing this information could compromise intelligence sources or methods and that the research involves no more than minimal risk to subjects. The determination about sources and methods is to be made in consultation with the Director of Central Intelligence and the Assistant to the President for National Security Affairs. The determination about risk is to be made in consultation with the Director of the White House Office of Science and Technology Policy.

(ii) a statement that the project is "classified" and an explanation of what classified means.

(e) The agencies shall jointly propose to modify the institutional review board ("IRB") approval process for classified human subjects research as follows:

(i) The Common Rule currently requires that each IRB "include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution." For classified research, the agencies shall define "not otherwise affiliated with the institution," as a nongovernmental member with the appropriate security clearance.

(ii) Under the Common Rule, research projects are approved by the IRB if a "majority of those (IRB) members present at a meeting" approved the project. For classified research, the agencies shall propose to permit any member of the IRB who does not believe a specific project should be approved by the IRB to appeal a majority decision to approve the project to the head of the sponsoring agency. If the agency head affirms the IRB's decision to approve the project, the dissenting IRB member may appeal the IRB's decisions to the Director of OSTP. The Director of OSTP shall review the IRB's decision and approve or disapprove the project, or, at the Director's discretion, convene an IRB made up of nongovernmental officials, each with the appropriate security clearances, to approve or disapprove the project.

(iii) IRBs for classified research shall determine whether potential subjects need access to classified information to make a valid informed consent decision.

2. Final Rules. Agencies shall, within 1 year, after considering any comments, promulgate final rules on the protection of human subjects of classified research.

3. Agency Head Approval of Classified Research Projects. Agencies may not conduct any classified human research project subject to the Common Rule unless the agency head has personally approved the specific project.

4. Annual Public Disclosure of the Number of Classified Research Projects. Each agency head shall inform the Director of OSTP by September 30 of each year of the number of classified research projects involving human subjects underway on that

date, the number completed in the previous 12-month period, and the number of human subjects in each project. The Director of OSTP shall report the total number of classified research projects and participating subjects to the President and shall then report to the congressional armed services and intelligence committees and further shall publish the numbers in the Federal Register.

5. Definitions. For purposes of this memorandum, the terms "research" and "human subject" shall have the meaning set forth in the Common Rule. "Classified human research" means research involving "classified information" as defined in Executive Order 12958.

6. No Classified Human Research Without Common Rule. Beginning one year after the date of this memorandum, no agency shall conduct or support classified human research without having proposed and promulgated the Common Rule, including the changes set forth in this memorandum and any subsequent amendments.

7. Judicial Review. This memorandum is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, it agencies, its officers, or any other persons.

8. The Secretary of Health and Human Services shall publish this memorandum in the Federal Register.