



Department of Defense

Report on Search  
for  
Human Radiation Experiment  
Records

1944 — 1994

Volume 1

Assistant to the Secretary of Defense for  
Nuclear and Chemical and Biological Defense Programs

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Department of Defense

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Nuclear and Chemical and Biological  
Defense Programs

June 1997



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# F OREWORD

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On behalf of the Department of Defense, I am pleased to present to the American people this report on our search for information on the Department's participation in human radiation experiments, beginning with the dawn of the Atomic Age in 1944. Our effort was in support of an intensive, Government-wide search for all relevant records directed by President Clinton in January 1994, as part of the administration's initiative for openness in government. Within the Department of Defense, the effort involved hundreds of people throughout the Military Services and Defense Agencies. In this regard, I recognize the tremendous effort required in a search of this magnitude and want to thank them for their dedicated work.

Within this report, the reader will find four basic types of information: first, guidance for the search issued by the President and more detailed instructions issued by other officials; second, extensive summaries of several projects which either were "human radiation experiments" or for other reasons have attracted wide public attention; third, brief descriptions of the more than 2,000 projects initially identified in the records search as having some connection between humans and radiation; and finally, references for obtaining additional information.

Of note, although most of the above projects actually involved common and routine medical practices, in the spirit of openness, all are included in this report. Further, in cases where we have not been able to reconstruct full information from the old records, this fact is so noted with an explanation that more data will be provided in a subsequent report.

I believe this report will answer many of the questions which the American people may still have about human radiation experiments, and I invite them to let us know of any more information that we might be able to provide.





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# I NTRODUCTION

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## BACKGROUND INFORMATION

The intent of this publication is to inform the public about the Department of Defense (DoD) involvement in ionizing radiation experiments, studies or projects with human subjects which occurred from 1944 to 1994. This information is part of DoD's extensive effort in support of President William J. Clinton's openness in government initiatives that began in January 1994. In the spirit of openness, this book includes a wide range of records retrieved by the DoD.

Defining human radiation experiments (HRE) is essential if the reader is to understand the "what" and the "why" regarding the contents of this publication. To focus this effort, Executive Order (EO) 12891, signed by President Clinton on 15 January 1994, established the Presidential Advisory Committee on Human Radiation Experiments (ACHRE) and provided the definition used by the DoD and other Federal departments and agencies in identifying HRE.

EO 12891 defined Human Radiation Experiments as:

1. Experiments on individuals involving intentional exposure to ionizing radiation. This category does not include common and routine clinical practices, such as established diagnosis and treatment methods involving incidental exposures to ionizing radiation.
2. Experiments involving intentional environmental releases of radiation that were designed to test human health effects to ionizing radiation, or were designed to test the extent of human exposure to ionizing radiation.

When reading this book, it is essential to remember the three components of an HRE:

1. There had to be "human" participation.

2. There had to be involvement of ionizing "radiation."
3. There had to be an "experimental" element.

In this regard, we are aware that many of the 2,600 studies initially reported by the DoD to the ACHRE did not meet the established criteria. However, to ensure a full accounting, the entire range of experiments/studies/projects was forwarded to the ACHRE for review and analysis. Such reporting was consistent with DoD's guidance which required researchers to err on the side of inclusion during the records search when there was insufficient information to determine whether or not the studies were human radiation experiments within the scope of the definition. Of the 2,600 studies forwarded to the ACHRE, 2,389 are listed in this book and provided without judgment. The difference between the two totals is due to analysis conducted by the DoD after forwarding of the studies to the ACHRE that identified some studies as being duplicate reporting, some that were not implemented, and others which were found not to involve humans. The results of this refined DoD records search for experiments or studies are included in appendix 1.

In some of the 1944 - 1974 projects, the RECC was unable to compile a complete description. In these instances, a notation has been made in the project entry that if this information becomes available, it will be provided in volume 2 to this publication.

In setting the scope, EO 12891 also identified certain events that required specific attention by the ACHRE. They are the "Green Run" release at the Hanford Reservation, the six radiation warfare tests conducted at Dugway Proving Ground in Utah, and four atmospheric radiation tracking tests conducted in 1950 near Los Alamos, New Mexico. These are addressed in this book along with information about both HRE and non-HRE events involving ionizing radiation that have stirred public interest. These are

total body irradiation studies, nasopharyngeal irradiation, cold weather tests involving radioactive iodine-131, human aspects research involving U.S. nuclear weapons tests, and food irradiation studies. Appendices 2 through 4 provide additional reference information.

#### HISTORICAL OVERVIEW OF 1944 - 1974 AND WHAT LED TO HUMAN RADIATION EXPERIMENTS

In the years following World War II, a period of intense confrontation evolved between the communist and democratic governments of the world. Many former allies became fierce opponents in an era that became known as the Cold War. The two principal powers—the United States and the Soviet Union—came to be symbolically identified as superpowers advocating opposing ideologies. The military establishments in each camp heightened their preparations for what many expected to become an eventual state of open warfare.

Into this already highly charged environment came the threat of nuclear warfare. The United States developed the first atomic bombs during World War II and used them against Japan. The war ended soon after the United States dropped the bombs on Hiroshima and Nagasaki. The United States' monopoly of atomic weapons lasted only until 1949 when the Soviet Union detonated its first atomic bomb, thereby starting the nuclear arms race.

When a nuclear weapon explodes near the ground, most of the energy goes into three effects. Two of these are readily apparent and received most of the initial focus of attention: the blast (shock wave) and thermal energy (heat). Pictures of the aftermath of an atomic explosion portray the vast damage caused by these two effects. The vivid pictures of Hiroshima and Nagasaki after the atomic bombing focused on the effects of blast and heat.

The third effect was completely new in the annals of warfare: ionizing radiation. The short-term effects of high-level exposures to ionizing radiation generated by an atomic bomb were self-evident because they led to almost immediate death. What

was least known were the long-term effects of a less-than-immediately lethal exposure. The body of knowledge about these effects was woefully deficient as the United States began preparing for a possible nuclear conflict. The need to expand the body of knowledge about this phenomenon was pressing, and initiatives were undertaken to meet the need. The newly formed DoD, along with other agencies, began research into the effects of ionizing radiation.

Ionizing radiation effects were not completely new to science. Ionizing radiation had been used in both industrial and medical procedures before World War II. As the nuclear age began, the benefits and hazards of exposure to ionizing radiation were just being realized. Although it could be deadly in certain instances, ionizing radiation also showed great promise in treating serious illnesses and analyzing metals and substances.

X-ray machines emitting ionizing radiation enabled doctors to “see” illnesses or injuries in the body whose diagnosis previously required exploratory surgery or educated guesses. In industrial uses, x-ray machines permitted viewing the insides of welds and metals to identify defects. Many lives would be saved by detecting such deficiencies.

However, in many of the early applications of ionizing radiation, it soon became clear that more knowledge about the effects of long-term exposure to ionizing radiation was necessary. It also became apparent to both the military and scientific communities that they shared a common interest in broadening the body of knowledge in this arena. A period of cooperation began between these two communities to develop the critically needed knowledge about ionizing radiation. This document is a record of that cooperation and the research activities that were part of this joint search for additional knowledge.

#### THE BEGINNING OF THE HUMAN RADIATION EXPERIMENT RECORD SEARCH EFFORT

Even before the end of the Cold War in the early 1990s, questions arose concerning U.S. Government

involvement in human subject ionizing radiation research. In November 1986, U.S. Representative Edward J. Markey of Massachusetts reported that the U.S. Government had conducted experiments exposing humans to radioactive material.<sup>1</sup> However, this report received relatively little public attention at the time. Shortly after the end of the Cold War, there was renewed interest about human subject experimentation that occurred during the Cold War era. In the early 1990s, this interest began to accelerate.

In November 1993, the Albuquerque Tribune published a series of articles by reporter Eileen Welsome citing a group of hospital patients who had been injected with plutonium as part of a Government-sponsored research study begun before the end of World War II. In the same month, a congressional report identified a number of cases of planned environmental releases of radiation at nuclear weapons production sites after World War II.<sup>2</sup> In early December 1993, Secretary of Energy Hazel O'Leary publicly stated that, in addition to conducting unannounced nuclear weapons tests, the U.S. Government may have used human subjects in ionizing radiation research.

The Department of Energy (DOE) opened a national help line on 24 December 1993 to provide the public with a means to submit reports of possible or suspected experimental exposures. On 3 January 1994, the Human Radiation Experiments Interagency Working Group was established, chaired by the Secretary to the Cabinet and composed of the Departments of Defense, Energy, Justice, Health and Human Services, and Veterans Affairs, as well as the Central Intelligence Agency, the National Aeronautics and Space Administration, and the Office of Management and Budget. This group focused its effort to identify ionizing radiation experiments involving human subjects, hereafter referred to as HRE.

In support of this initiative, Secretary of Defense Les Aspin, on 7 January 1994, instructed the DoD to compile information on the Department's radiation experiments. Secretary Aspin appointed the Assistant to the Secretary of Defense (Atomic Energy) (ATSD[AE]), Dr. Harold P. Smith, Jr., as the DoD

focal point for this effort. Concurrently, President Clinton responded to growing public interest in this issue by establishing the ACHRE by EO on 15 January 1994.<sup>3</sup>

The ACHRE was charged with the responsibility to:

- Review experiments conducted from 1944 to 1974 (later extended to 1994)
- Evaluate ethical and scientific standards and criteria on human radiation experiments conducted or sponsored by the U.S. Government
- Prepare a final report to the President on its findings.

The year 1974 was originally established as the end period because, on 30 May 1974, the Department of Health, Education, and Welfare (DHEW) (now Health and Human Services [HHS]) issued regulations protecting human subjects in research.

The DoD also established the Radiation Experiments Command Center (RECC) on 31 January 1994 under the direction of the ATSD(AE) to act as the central repository of records for the DoD effort. The RECC was charged with achieving a full accounting of DoD's involvement in any ionizing radiation research and experimentation on human subjects during the past fifty years. The RECC:

- Coordinated the DoD effort in the HRE records search with the services and DoD agencies
- Conducted an extensive examination and review of relevant documents at the National Archives and National Records Centers throughout the United States
- Coordinated the declassification of more than 1,200 documents
- Initially identified approximately 2,600 possible DoD-sponsored projects or experiments (a high number due to the DoD policy to err on the side of inclusion to ensure full disclosure. Subsequently, this number was reduced to 2,389 after

duplicates and erroneous submissions were identified.)

- Collected and forwarded copies of approximately 10,000 records to the ACHRE
- Coordinated the DoD's review of the ACHRE's draft Final Report to ensure completeness and accuracy
- Participated in six congressional hearings as well as several briefings on DoD-sponsored activities.

Additionally, the RECC began an outreach program to respond to public inquiries. Under this process, the RECC received DoD-related inquiries forwarded by the DOE national help line, as well as direct inquiries from the public, members of Congress, and the White House. To date, the RECC has received almost 7,000 inquiries.

After researching these inquiries, the RECC found that very few involved any human radiation experimentation. Approximately 40 percent of the inquiries involved U.S. atmospheric nuclear weapons testing participants. The Defense Special Weapons Agency (DSWA), formerly the Defense Nuclear Agency (DNA), administers a separate program for these participants called the Nuclear Test Personnel Review (NTPR) program. The RECC referred all identified U.S. atmospheric nuclear weapons test participants to the NTPR program.

A significant number of inquiries were related to approved and accepted medical procedures of the day. Other exposures occurred in occupational situations not related to human subjects research. There were also a significant number of inquiries that did not contain enough information from which to draw a conclusion.

With release of the ACHRE Final Report and the conclusion of the committee's work on 3 October 1995, the DoD reaffirmed its commitment to ensuring full and complete disclosure of its involvement in any human radiation experiments. On 30 October 1995, Secretary of Defense William J. Perry reappointed Dr. Harold P. Smith, Jr., ATSD(AE), as the DoD focal point to continue the efforts toward openness.<sup>4</sup>

On 2 November 1995, Dr. Smith further amplified Secretary Perry's reappointment memorandum by stating that "the RECC has begun initial work to publish a book to reflect DoD's commitment to openness by summarizing what DoD found during its human radiation experiments review."<sup>5</sup> This publication is the result of that effort.

#### NOTES

1. U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Energy Conservation and Power, November 1986, "American Nuclear Guinea Pigs: Three Decades of Radiation Experiments on U.S. Citizens."
2. U.S. Senate, Committee on Governmental Affairs, 11 November 1993, "Nuclear Health and Safety: Examples of Post World War II Radiation Releases at U.S. Nuclear Sites," GAO/RCED-94-51-FS.
3. Presidential Documents, "Executive Order 12891 of January 15, 1994," Federal Register, vol. 59, No. 13, 20 January 1994.
4. Memorandum from the Secretary of Defense, Subject: Response by the DoD to the Findings and Recommendations of the ACHRE, dated 30 October 1995.
5. Memorandum from the Assistant to the Secretary of Defense (Atomic Energy), Subject: Response by the DoD to the Findings and Recommendations of the ACHRE, dated 2 November 1995.



## CHAPTER

# 1

# DoD HUMAN SUBJECTS PROTECTION POLICY 1944 TO THE PRESENT

## INTRODUCTION

The possibility of having to conduct combat operations on a battlefield contaminated by the effects of atomic, biological, or chemical weapons prompted the Department of Defense (DoD) to initiate research concerning the biomedical effects of these agents on humans. This concern and that for the safety of human volunteers in potentially dangerous research and the human experimentation atrocities revealed at the end of World War II were driving forces behind the development of the DoD human subjects protection policy. These concerns sparked years of serious debate among DoD and non-DoD medical and scientific authorities regarding the use of human participants in research. The culmination of this debate resulted in a written policy in February 1953 by Secretary of Defense Charles E. Wilson known as the Wilson Memorandum (see figures 1, 2 and 3.)

In the years before the Wilson Memorandum, senior DoD officials and high-level DoD boards participated in developing DoD's human subjects protection policy. For example, the Nuclear Energy for the Propulsion of Aircraft/Medical Advisory Committee on Radiation Tolerance of Military Personnel (NEPA/MAC), the Committee on Medical Sciences (CMS), the Joint Panel on the Medical Aspects of Atomic Warfare (JPMAAW), the Research and Development Board (RDB), the Armed Forces Medical Policy Council

(AFMPC), and the General Counsel's (GC) office of the Office of the Secretary of Defense (OSD) were all substantively involved in formulating a policy for using humans in research studies.<sup>1</sup>

This initial human subjects protection policy debate spanned 1942 to 1953 until the Wilson Memorandum established a formal policy. This directive required each military department to implement the policy as outlined in the memorandum. Thus, the Wilson Memorandum set the standard for each service's development of human subjects protection policy from 1953 through mid-1974. In May 1974, the Department of Health, Education, and Welfare (DHEW) issued its own comprehensive regulations for DHEW human subject research. These regulations were the foundation for today's DoD human subjects protection policy.

## EVOLUTION OF DoD HUMAN SUBJECTS PROTECTION POLICY

As early as 1942, concern regarding the participation of human subjects in medical research

### TERMS USED IN THIS CHAPTER

dosimetry	measurement of the number of roentgens absorbed in a single exposure to radiation
ionizing radiation	(see appendix 4 for discussion)
Radioisotope	a radioactive isotope of a chemical element used in medical therapy, biological research
World War II	WWII, 1939-1945, fought between the Allies (Great Britain, France, the Soviet Union, Canada, and the United States as well as other nations) and the Axis (Germany, Italy, Japan and other countries)

## 2 Chapter 1—DoD Human Subjects Protection Policy 1944 to the Present

### ACRONYMS USED IN THIS CHAPTER

ACHRE	Advisory Committee on Human Radiation Experiments
AEC	Atomic Energy Commission [predecessor of the Department of Energy]
AFMPC	Armed Forces Medical Policy Council
AFR	Air Force Regulation
AFRRI	Armed Forces Radiobiology Research Institute
AFSWP	Armed Forces Special Weapons Project [predecessor to the Defense Special Weapons Agency]
AMA	American Medical Association
AR	Army Regulation
CMS	Committee on Medical Sciences of the Research and Development Board
DBM	Division of Biology and Medicine (of the Atomic Energy Commission)
DHEW	Department of Health, Education, and Welfare
DHHS	Department of Health and Human Services
DNA	Defense Nuclear Agency [now DSWA]
DoD	Department of Defense
DSWA	Defense Special Weapons Agency
GC	General Counsel
HURAD	Human Use and Regulatory Affairs Division
IRB	Institutional Review Board
JAG	Judge Advocate General
JCS	Joint Chiefs of Staff
JPMAAW	Joint Panel on the Medical Aspects of Atomic Warfare
LASL	Los Alamos Scientific Laboratory, now Los Alamos National Laboratory (LANL)
NEPA/MAC	Nuclear Energy for the Propulsion of Aircraft/Medical Advisory Committee
ONR	Office of Naval Research
OSD	Office of the Secretary of Defense
RDB	Research and Development Board
TBI	total-body irradiation
USAF	United States Air Force
USUHS	Uniformed Services University of the Health Sciences

and concern for their safety was raised by the Committee on Medical Research of the Office of Scientific Research and Development. During its forty-second meeting on 29 October 1942, the committee stated:

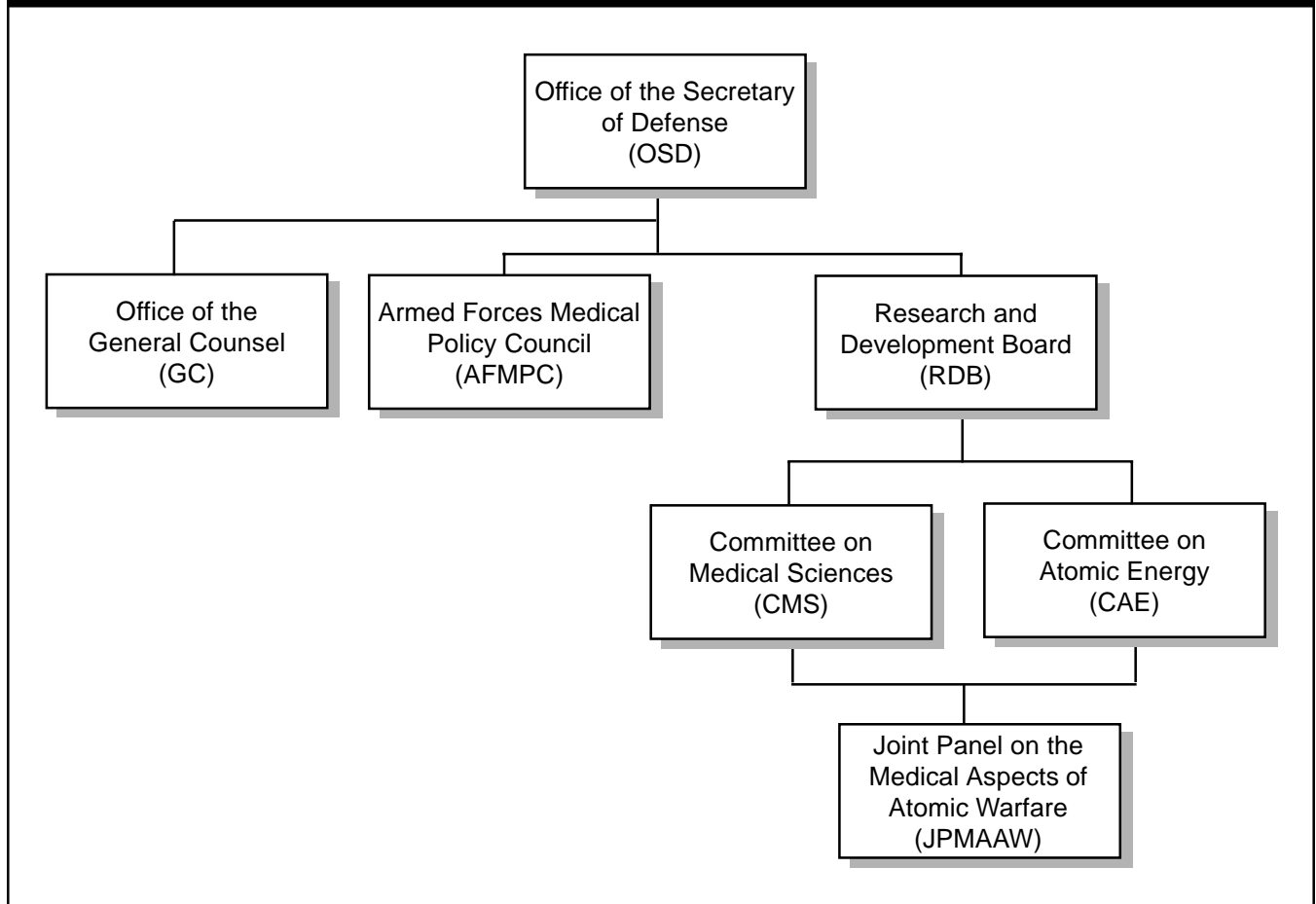
that experiments on human beings were both desirable and necessary in certain types of medical research related to the war effort; that the subjects of such experiments should be volunteers whose attention had been called to the dangers of the experiment; and that no categorical answer could be given to the desirability of experiments on human beings in particular cases until after all the details of the proposed experiments are placed before the Committee.<sup>2</sup>

The issues of informed consent and institutional review were central to the discussion.

During the late 1940s, DoD and the United States Air Force (USAF) investigated the possibility of developing a nuclear-powered aircraft, a program commonly referred to as the Nuclear Energy for the Propulsion of Aircraft (NEPA) project.

In 1949, NEPA officials recommended conducting unclassified research on human volunteers to study the biological effects of radiation on the air crew of a nuclear-powered aircraft.<sup>3</sup> This recommendation highlighted the need for a DoD-wide policy for using humans in research. At a meeting of the NEPA/MAC held on 3 April 1949, the

FIGURE 1 DoD ORGANIZATIONS INVOLVED IN THE DEVELOPMENT OF THE WILSON MEMORANDUM



committee argued that human experimentation was necessary for several reasons. First, animal experiments showed that animals of various species as well as animals of different strains within a given species differed in their response to given amounts of radiation. Therefore, it would be impossible to predict accurately what would happen to humans exposed to moderate doses of radiation. Second, although therapeutic exposures of radiation provided some indications of how sick people responded, patients' responses varied depending on their clinical condition. Often, disease effects were indistinguishable from radiation effects. Finally, accidental exposures and the mass exposures at Hiroshima and Nagasaki in Japan provided some indications of how healthy people responded to radiation, but there were no scientific controls over

these types of exposures and no accurate dosimetry, which made it impossible to draw any definitive conclusions.<sup>4</sup>

In addition to providing these justifications for human experimentation, the committee endorsed three principles laid down by the Judicial Council of the American Medical Association (AMA) in 1946 to govern the use of humans in medical research:

1. The voluntary consent of the person on whom the experiment is to be performed must be obtained.
2. The danger of each experiment must have been previously investigated by animal experimentation.
3. The experiment must be performed under proper medical protection and management.<sup>5</sup>

FIGURE 2 THE WILSON MEMORANDUM

**C O P Y**

**SECRETARY OF DEFENSE**  
Washington

26 Feb 1953

**MEMORANDUM FOR THE SECRETARY OF THE ARMY**  
**SECRETARY OF THE NAVY**  
**SECRETARY OF THE AIR FORCE**

**SUBJECT: Use of Human Volunteers in Experimental Research**

1. Based upon a recommendation of the Armed Forces Medical Policy Council, that human subjects be employed, under recognized safeguards, as the only feasible means for realistic evaluation and/or development of effective preventive measures of defense against atomic, biological or chemical agents, the policy set forth below will govern the use of human volunteers by the Department of Defense in experimental research in the fields of atomic, biological and/or chemical warfare.

2. By reason of the basic medical responsibility in connection with the development of defense of all types against atomic, biological and/or chemical warfare agents, Armed Services personnel and/or civilians on duty at installations engaged in such research shall be permitted to actively participate in all phases of the program, such participation shall be subject to the following conditions:

a. The voluntary consent of the human subject is absolutely essential.

(1) This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by

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per S. Clements  
DDR&E OSD(PA)

FIGURE 2 THE WILSON MEMORANDUM (CONTINUED)

C O R E Y

which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

(2) The concept of the human subject shall be in writing; his signature shall be affixed to a written instrument setting forth substantially the aforementioned requirements and shall be signed in the presence of at least one witness who shall attest to such signature in writing.

(a) In experiments where personnel from more than one Service are involved the Secretary of the Service which is exercising primary responsibility for conducting the experiment is designated to prepare such an instrument and coordinate it for use by all the Services having human volunteers involved in the experiment.

(3) The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

b. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

c. The number of volunteers used shall be kept at a minimum consistent with item b., above.

d. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

e. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

f. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur.

g. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

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FIGURE 2 THE WILSON MEMORANDUM (CONTINUED)

C O P Y

h. Proper preparation should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

i. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

j. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

k. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

l. The established policy, which prohibits the use of prisoners of war in human experimentation, is continued and they will not be used under any circumstances.

3. The Secretaries of the Army, Navy and Air Force are authorized to conduct experiments in connection with the development of defenses of all types against atomic, biological and/or chemical warfare agents involving the use of human subjects within the limits prescribed above.

4. In each instance in which an experiment is proposed pursuant to this memorandum, the nature and purpose of the proposed experiment and the name of the person who will be in charge of such experiment shall be submitted for approval to the Secretary of the military department in which the proposed experiment is to be conducted. No such experiment shall be undertaken until such Secretary has approved in writing the experiment proposed, the person who will be in charge of conducting it, as well as informing the Secretary of Defense.

5. The addresses will be responsible for insuring compliance with the provisions of this memorandum within their respective Services.

/signed/  
C.E. WILSON

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Research and Development Board

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FIGURE 3 WILSON MEMORANDUM TYPESET FROM ORIGINAL FOR LEGIBILITY

SECRETARY OF DEFENSE  
Washington

26 Feb 1953

Memorandum for the SECRETARY OF THE ARMY  
SECRETARY OF THE NAVY  
SECRETARY OF THE AIR FORCE

SUBJECT: Use of Human Volunteers in Experimental Research

1. Based upon a recommendation of the Armed Forces Medical Policy Council, that human subjects be employed, under recognized safeguards, as the only feasible means for realistic evaluation and/or development of effective preventive measures of defense against atomic, biological or chemical agents, the policy set forth below will govern the use of human volunteers by the Department of Defense in experimental research in the fields of atomic, biological and/or chemical warfare.

2. By reason of the basic medical responsibility in connection with the development of defense of all types against atomic, biological and/or chemical warfare agents, Armed Services personnel and/or civilians on duty at installations engaged in such research shall be permitted to actively participate in all phases of the program, such participation shall be subject to the following conditions:

a. The voluntary consent of the human subject is absolutely essential.

(1) This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

(2) The concept [sic: consent] of the human subject shall be in writing, his signature shall be affixed to a written instrument setting forth substantially the aforementioned requirements and shall be signed in the presence of at least one witness who shall attest to such signature in writing.

(a) In experiments where personnel from more than one Service are involved the Secretary of the Service which is exercising primary responsibility for conducting the experiment is designated to prepare such an instrument and coordinate it for use by all the Services having human volunteers involved in the experiment.

(3) The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

b. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

c. The number of volunteers used shall be kept at a minimum consistent with item b., above.

d. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

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### FIGURE 3 TYPESET WILSON MEMORANDUM (CONTINUED)

- e. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
  - f. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur.
  - g. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
  - h. Proper preparation should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
  - i. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
  - j. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
  - k. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.
  - l. The established policy, which prohibits the use of prisoners of war in human experimentation, is continued and they will not be used under any circumstances.
3. The Secretaries of the Army, Navy and Air Force are authorized to conduct experiments in connection with the development of defenses of all types against atomic, biological and/or chemical warfare agents involving the use of human subjects within the limits prescribed above.
4. In each instance in which an experiment is proposed pursuant to this memorandum, the nature and purpose of the proposed experiment and the name of the person who will be in charge of such experiment shall be submitted for approval to the Secretary of the military department in which the proposed experiment is to be conducted. No such experiment shall be undertaken until such Secretary has approved in writing the experiment proposed, the person who will be in charge of conducting it, as well as informing the Secretary of Defense.
5. The addresses [sic] will be responsible for insuring compliance with the provisions of this memorandum within their respective Services.

/signed/  
C. E. WILSON

Copies furnished:  
Joint Chiefs of Staff  
Research and Development Board

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The NEPA recommendation initiated an intra-DoD and inter-agency debate on whether human radiation experimentation was necessary. On 3 June 1949, two months after NEPA/MAC's meeting, the JPMAAW held its first meeting. The panel discussed the problem of human tolerance to radiation and the determination of maximum doses of radiation that the military would find acceptable. The panel stated that it was desirable and necessary for the national defense to pursue human experiments on the effects of total-body irradiation to psychologically and socially acceptable limits. The panel voted to table its decision pending the study of the NEPA report on the same subject. The panel also appointed a working group to study and report on the issue and make recommendations on conducting research involving human subjects.<sup>6</sup>

The JPMAAW met for the second time four months later on 7 October 1949. At that meeting, the working group presented the NEPA/MAC report on human experimentation. The full panel endorsed the NEPA/MAC recommendations, which included the AMA's three principles.<sup>7</sup> The panel then presented its recommendations to the CMS for approval. At its tenth meeting on 8 November 1949, the CMS endorsed the action of the JPMAAW.<sup>8</sup>

During the months following this tenth meeting, some members of the CMS learned that the Atomic Energy Commission's (AEC) Division of Biology and Medicine (DBM) did not favor human experimentation.<sup>9</sup> The AEC's concerns prompted the CMS to reconsider its endorsement. At its eleventh meeting on 1 February 1950, the committee revoked its previous endorsement and voted to refer the issue of human experimentation back to the JPMAAW for further consideration.<sup>10</sup> The panel immediately convened to reconsider its endorsement of the NEPA/MAC recommendations and appointed another working group to reformulate panel opinion on the subject. The next day, the working group submitted its report and the JPMAAW reaffirmed its position endorsing the use of human volunteers to conduct experimentation. The JPMAAW maintained that although the AEC's civilian charter might not indicate a need for human experimentation, DoD needed information on soldiers' capabilities and

limitations on contaminated battlefields. Because other methods of obtaining these data were not useful, human studies were necessary.<sup>11</sup>

The CMS reconvened for its twelfth meeting on 23 May 1950 to review the JPMAAW reaffirmation of its original action. After deliberations, the committee passed the following motion:

The Committee on Medical Sciences endorses the view that it is essential to obtain all necessary scientific information concerning radiation doses and the effect on man by all means of biological experimentation, as promptly as possible, including if necessary human experiments under established principles of such experiments.<sup>12</sup>

In addition, the NEPA/MAC recommendations received a firm endorsement from the Navy and a conditional endorsement from the Army. The Under Secretary of the Navy stated:

(1). Accurate experimental data on the biological effects of known levels of radiation exposure in human subjects is essential for complete knowledge of the problems involved. (2). It is believed that the procedures proposed by the Chairman of the Subcommittee of the NEPA Medical Advisory Committee are sound from a research point of view.<sup>13</sup>

The Army recognized the need to determine radiation tolerances in humans but stated that such experimentation presented significant difficulties and dangers. In light of its reservations, Assistant Secretary of the Army Archibald S. Alexander recommended a more modest beginning than that proposed by the NEPA/MAC. He commented:

Significant progress has been made in protecting animals against radiation injury by use of certain endocrine products or chemicals acting through the endocrine system. It is believed that these studies should be continued. When it appears that reliance can be placed upon these findings, one or two cancer patients, who must have intense radiation treatment for their condition, should be sought on

## 10 Chapter 1—DoD Human Subjects Protection Policy 1944 to the Present

a volunteer basis to undergo what appears to be, from animal experimentation, the probable maximum tolerance level for man. If these acute experiments prove successful, and the treatment methods as good as prior experimental results indicate, then it is recommended that consideration be given to establishing a significant experiment to validate the limits of human tolerance to radiation.<sup>14</sup>

In a 13 April 1950 memorandum, Air Force Surgeon General Harry G. Armstrong did not concur with the recommendations of the NEPA/MAC that the Armed Services arrange for experimentation on humans. He stated that radiation was not solely a military threat but had civilian repercussions as well. Because General Armstrong viewed radiation research as both a civilian and a military problem, he concluded that the AEC, whose interests encompassed civilian and military areas, should be the agency primarily responsible for any research program.<sup>15</sup>

In a memorandum dated 8 August 1950, the Director of Medical Services for the DoD, Richard L. Meiling, M.D., agreed with General Armstrong's assessment and stated the DoD position:

The research program required to develop necessary scientific information concerning radiation doses involves both civilian and military problems. Hence, it is considered to be a problem for the Division of Biology and Medicine of the Atomic Energy Commission.<sup>16</sup>

However, at its sixth meeting held 31 October to 1 November 1950, the JPMAAW approved by a majority vote a motion to continue its efforts to secure approval for human research.<sup>17</sup>

Members of the Advisory Board of the DBM met on 10 November 1950 with representatives from the Surgeon General's offices of each branch of the military. During the meeting, Army Brigadier General James P. Cooney "proposed human experimentation on a group of 200 service volunteers to determine the effects of operational effectiveness to dosages of total body radiation within presumably low safe zones [sic]."<sup>18</sup> The proposal generated

discussion among the board, which concluded "that human experimentation was not justified and that sufficient information could be obtained from animal experimentation and interpolation from clinical data."<sup>19</sup>

By the end of 1950, the DoD and the AEC agreed not to move forward with a human research program or detailed policy. Throughout 1951, the consensus remained that human research was not indicated at that time. M. C. Leverett, Technical Director of the NEPA project, announced the discontinuation of "efforts to obtain governmental approval for experiments on humans along the lines recommended by our [NEPA] Advisory Committee."<sup>20</sup>

The DoD funded some observational studies on patients who were receiving doses of radiation as part of a therapeutic procedure. Beginning in 1951, the Air Force funded post-treatment observational studies at the MD Anderson Hospital and Tumor Clinic of Houston, Texas. The Air Force provided funds for data collection on the physical symptoms of radiation sickness and the effects of radiation on psychomotor capabilities. Air Force funds were not used for radiation treatments or other patient care. In a description of the MD Anderson study before it began, the Air Force explained its involvement in the civilian programs in the following statement:

It is desired to measure certain mental and psychomotor abilities of patients who are undergoing radiation therapy in order to evaluate any differences in performance that may result from radiation effects. This information is urgently required by the U.S. Air Force in connection with the NEPA Project. It is clear that before attempting to operate its proposed nuclear powered aircraft, the U.S. Air Force must evaluate its radiation hazards. There are no scientific data with which to assess these dangers of the NEPA aircraft in terms of their probable effects upon crew performance and well-being. The most direct approach to this information would be by human experimentation in specifically designed radiation studies; however, for several important reasons, this had been forbidden by top military authority. Since the need is pressing, it would appear

mandatory to take advantage of investigation opportunities that exist in certain radiological centers by conducting special examinations and measures of patients who are undergoing radiation treatment for disease. While the flexibility of experimental design in a radiological clinic will necessarily be limited, the information that may be gained from the studies of patients is considered potentially invaluable; furthermore, this is currently the sole source of human data.<sup>21</sup>

(See chapter 2 for more information on the MD Anderson study.)

A belief in the necessity for guiding principles for these types of studies persisted. In a letter to Leslie M. Redman, Los Alamos Scientific Laboratory (LASL,) (now Los Alamos National Laboratory [LANL]), dated 5 March 1951, Shields Warren, M.D., Director of the DBM for the AEC, informed Mr. Redman of the guiding principles the AEC followed regarding human experimentation.

We believe that no substances known to be, or suspected of being, poisonous or harmful should be given to human beings unless all of the following conditions be fully met: (a) that a reasonable hope exists that the administration of such a substance will improve the condition of the patient, (b) that the patient give his complete and informed consent in writing, and (c) that the responsible nearest of kin give in writing a similarly complete and informed consent, revocable at any time during the course of such treatment.<sup>22</sup>

This statement reflects the AEC's human subjects protection policy in 1951. As mentioned before, the DoD's decision in August 1950 to defer to the AEC on this matter made the AEC policy de facto DoD policy.

By early 1952, the JPMAAW and the CMS again reexamined the need for a human subjects protection policy. Although the original debate had been initiated by a perceived need to conduct biomedical research related to ionizing radiation, the major impetus in 1952 for developing the DoD's human subjects protection policy stemmed from the need to

counter suspected Soviet advances in biological and chemical warfare. Intra-agency discussions during 1952 focused on writing a detailed human subjects protection policy. On 8 April 1952, the AFMPC, a DoD organization established in January 1951, requested that any directives or statements of policy issued to the branches of the military as guidelines using humans in studies be forwarded to the AFMPC for information and study.<sup>23</sup> The deliberations throughout 1952 provided the foundations and framework for a definitive DoD human subjects protection policy.

Many circulating internal DoD letters and memoranda referred to changes, additions, or suggestions for the proposed DoD human subjects protection policy. On 13 October 1952, Stephen S. Jackson, Counsel to the AFMPC, submitted a memorandum to the Director of the AFMPC, Melvin A. Casberg, M.D., recommending that the council adopt, as the DoD human subjects protection policy, the principles and conditions set forth in the Nuremberg Code (see box, "The Nuremberg Code," next page).<sup>24</sup> In addition, Mr. Jackson recommended the language, "Whereas prisoners incarcerated in penal institutions may and have been used if the required conditions are met, prisoners of war will not be used in human experimentation."<sup>25</sup> Mr. Jackson later amended this proposed language in a follow-up memorandum dated 4 December 1952, removing the first part of the sentence so it read, "Prisoners of war will not be used in human experimentation."<sup>26</sup>

In a 22 October 1952 memorandum to Dr. Casberg, Mr. Jackson passed along a recommendation from the Assistant Secretary of Defense for Manpower, Anna Rosenberg, "that a provision be added requiring that the consent be expressed in writing before at least one witness."<sup>27</sup> This language was approved by the OSD GC.

At a 30 - 31 October 1952 meeting, the CMS discussed the problem of human experimentation and appointed an ad hoc working group to study the merits of issuing a policy statement.<sup>28</sup> A memorandum dated 24 December 1952 from Dr. Casberg to the Secretary of Defense reported that the AFMPC recommended that a policy be established for using human volunteers in

## THE NUREMBERG CODE

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. The latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiments. The duty and responsibility for ascertaining the quality of the consent rest upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparation should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill, and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

experimental research. In addition, the AFMPC recommended “that the ten rules promulgated at the Nuremberg Trials be adopted as the guiding principles to be followed.”<sup>29</sup> (For explanation of the Nuremberg Trials, see box, “The Nuremberg Trials,” next page.) Dr. Casberg also included the statement regarding prisoners of war suggested by Mr. Jackson as part of the recommendation from AFMPC.<sup>30</sup>

Throughout 1952 and early 1953, the JPMAAW, the AFMPC, the CMS, and members of the GC’s

office drafted what would become the Wilson Memorandum. By the end of 1952, most of the deliberations on the use of humans in research had concluded, and recommendations were ready to be passed on to Secretary of Defense Robert Lovett for approval and distribution. However, 1952 was an election year and a new administration was about to take office in 1953. In light of the change in administration, final approval was delayed. The Director of the Executive Office of the OSD,

Col. G. V. Underwood, asked Dr. Casberg to hold the matter “for safe keeping with the understanding that at an appropriate time, after the installation of the new Administration, the matter will be brought up again.”<sup>31</sup> The reasoning behind the delay was simply that the incoming Secretary of Defense would ultimately have responsibility for administering the policy.

#### THE WILSON MEMORANDUM

The new Secretary of Defense, Charles E. Wilson, signed a memorandum on 26 February 1953 that finally established a DoD human subjects protection policy.<sup>32</sup> This policy, based on the principles defined in the Nuremberg Code, required the written consent of the research subject and prohibited the use of prisoners of war in human experimentation. This policy applied to human volunteers only in the fields of atomic, biological, and chemical warfare research.

The Wilson Memorandum was classified Top Secret, which was consistent with other memoranda conveying information related to weapons of mass destruction. However, that classification limited its distribution. The memorandum was addressed only to the Secretaries of the three branches of the military, and copies were furnished to the Joint Chiefs of Staff (JCS) and the RDB.

#### Dissemination and Implementation of the Wilson Memorandum

Despite the restrictive classification attached to the memorandum, efforts were made to forward the information to other organizations within the DoD. In a memorandum dated 27 February 1953, just one

#### THE NUREMBERG TRIALS

As early as 1943 the United States, Great Britain, and the Soviet Union agreed that at the conclusion of World War II they would prosecute individuals who may have violated international law during the war. Shortly after the end of the war, representatives from the American, British, French, and Soviet governments established the International Military Tribunal in Nuremberg, Germany on 8 August 1945. The tribunal was composed of a panel of international judges; the purpose was to provide a forum for Allied prosecutors to present cases against German government and military officials and Nazi party members charged with wartime atrocities. The subsequent trials came to be known as the Nuremberg trials. A first set of trials ran from October 1945 to October 1946.

A second set of trials began on 9 December 1946. The first of these trials was officially called *United States v. Karl Brandt et al.*, but was commonly referred to as “The Doctors’ Trial,” “The Medical Case,” and the “Nuremberg Medical Trial.” The prosecutors in this case charged that the defendants were responsible for murders, tortures, and other atrocities committed in the name of medical science.

At the conclusion of the case on 19 August 1947, the judges handed down, along with seven death sentences, a ruling that has come to be known as the Nuremberg Code. This code formally set standards, in practice at the time, governing the use of humans in medical experimentation. The Nuremberg Code also served as a starting point for DoD’s human use policy.

day after Secretary Wilson issued the human subjects protection policy, Director of Administration for the RDB, Astrid Kraus, requested permission (which was denied) from the Director, Executive Office, OSD, to reproduce the Wilson Memorandum for five RDB committees directly concerned with the human subjects protection policy.<sup>33</sup> In addition, legal interpretations of the memorandum were requested on at least two occasions. At its eighteenth meeting on 26 - 27 February 1953, the CMS passed a motion requesting “the official legal interpretation of all the clauses of the document and the rationalization of apparent discrepancies.”<sup>34</sup> On 16 April 1953, the Chief of Research and Development of the Army General Staff asked the Judge Advocate General’s (JAG) office to express an opinion on the Wilson Memorandum.<sup>35</sup>

Dissemination and implementation within the branches of the military fell to the individual branch Secretaries and thus varied from service to service. Within the Army, a 30 March 1953 memorandum from Lt. Gen. L. L. Lemnitzer, Deputy Chief of Staff for Plans and Research, to the Secretary of the Army indicated that the Wilson Memorandum had been distributed to the Chief of Research and Development, Office of the Chief of Staff; Deputy Chief of Research and Development, Office of the Chief of Staff; Deputy Assistant Chief of Staff, G-4, for Research and Development; Chief Chemical Officer; The Surgeon General; Assistant Chief, Research and Development Division; and Chairman, Medical Research and Development Board.<sup>36</sup> Furthermore, a memorandum dated 12 May 1953 from a biochemist at the Toxic Chemical Warfare branch of the Army Chemical Corps<sup>37</sup> indicated that the policies contained in the Wilson Memorandum had been disseminated down to the level of researchers.

By 30 March 1953, the Army proposed a draft directive designed to implement the Wilson Memorandum for Army-conducted human experimentation.<sup>38</sup> The draft policy received endorsements from the Army Surgeon General<sup>39</sup> and the Chief Chemical Officer.<sup>40</sup> By late April 1953, the Army JAG was reviewing the draft directive's legal implications.<sup>41</sup> On 20 May 1953, Secretary of the Army Robert Stevens approved the 30 March draft policy on using humans in experimental research in light of Secretary Wilson's 26 February directive. In addition, he "requested that the security classification of this subject be reviewed to determine if it cannot be downgraded" in an attempt to further disseminate Secretary Wilson's directive.<sup>42</sup>

Further clarification of the Army policy resulted from a 30 June 1953 Army Chief of Staff memorandum<sup>43</sup> and a 12 March 1954 Army Surgeon General memorandum.<sup>44</sup> Both documents raised the issue of whether Secretary Wilson's policy as implemented by the Secretary of the Army applied to contract research. Although the Army Surgeon General's memorandum stated that the human subjects protection policy was "to be used as far as applicable as a non-mandatory guide for planning and

conducting contract research,"<sup>45</sup> neither document specifically stated that the policy applied as a mandatory policy to contractors.

As a result of inquiries by several Senate committees, the Secretary of the Army directed eighteen years later that research be conducted to determine the Army's role in hallucinogenic drug research. A portion of this report focused on the Army's implementation of its human use policy. This 1975 Army Inspector General's Report, "Use of Volunteers in Chemical Agent Research," suggested that Army implementation of the Wilson human use policy had been inconsistent.<sup>46</sup>

No documentation was located during the HRE review to verify distribution or implementation of the Wilson Memorandum within the Navy below the level of the Secretary of the Navy. However, by 1953, the Navy already had a long history of requiring Secretarial approval before conducting experiments with human subjects. For example, in 1932, the Secretary of the Navy approved a study using divers with the condition that the participants be informed volunteers, and by 1943, the Secretary of the Navy required that all research involving service personnel be approved by the Secretary.<sup>47</sup> By 1951, the Navy recorded its policy on human experimentation in the "Manual of the Medical Department." This policy required that:

[e]xperimental studies of a medical nature involving persons in the Naval Establishment are forbidden except when the experimental design in each case has received the prior approval of the Secretary of the Navy. . . . Participation by personnel of the Naval Establishment (military and civilian) shall be on a voluntary basis only.<sup>48</sup>

In addition, the policy required the Bureau of Medicine and Surgery to review all studies before submission to the Secretary of the Navy.<sup>49</sup>

Within the Air Force, the policy was forwarded by 10 March 1953 to the Inspector General; Deputy Chief of Staff, Development; Director of Operations; Director of Plans; Deputy Chief of Staff, Personnel; and Deputy Chief of Staff, Materiel.<sup>50</sup> However, no other documentary evidence indicated further

distribution or implementation of the Wilson Memorandum.

Questions remain on whether DoD components directly involved with atomic issues, such as the Armed Forces Special Weapons Project (AFSWP) (predecessor to the Defense Special Weapons Agency [DSWA] and an organization that reported directly to the JCS), were notified of the Wilson Memorandum. AFSWP personnel were aware as early as November 1953 that a DoD human subjects protection policy had been established;<sup>51</sup> however, no indication is available that the policy was formally transmitted from OSD or implemented by AFSWP.

#### EVOLUTION OF POLICIES AND REGULATIONS

Each branch of the military began issuing its own policies and regulations to govern human experimentation as a result of increasing concern for protection of human research subjects.

**Army.** A formal Army Regulation (AR 70-25) was issued in 1962 and incorporated the policies set forth in the Wilson Memorandum. It applied to all types of research, not just research related to atomic, biological, and chemical warfare and specifically excluded clinical research. The following year, the Army issued a regulation for radioisotope use that required local institutions to appoint review committees. These review committees were required to obtain approval from the Secretary of the Army when radioisotopes were to be used with volunteer experimental subjects. Clinical investigations continued to be excluded from AR 70-25 until 1973 when the Army issued AR 40-38 which specifically applied to clinical investigations involving either patients or healthy subjects. The regulation restated the requirement for informed consent and required that clinical research be reviewed by a human use committee.

**Navy.** As noted earlier, the Navy had a history, before the Wilson Memorandum, of requiring informed consent and secretarial review of research projects. These policies were first recorded in the

Navy Manual of the Medical Department in 1951. In 1967, a requirement for written consent, which did not distinguish between research on patients and research on healthy subjects, was added to the manual.<sup>52</sup> In 1969, two years later, the Secretary of the Navy issued a comprehensive policy that covered both groups and included a requirement for written informed consent from research subjects.<sup>53</sup>

In addition to the military departments, the Department of Health, Education and Welfare (DHEW), on 30 May 1974, published a comprehensive human subjects protection policy that provided a framework for subsequent human subjects protection policies for many Government agencies, including the DoD. The regulations required each institution requesting research funds from DHEW to form a committee to approve all research proposals before they were submitted. These committees came to be known as Institutional Review Boards (IRBs) and were responsible for ensuring the overall safety of the proposed projects and the adequacy of the informed consent obtained from each subject before participation in the project. In addition, the regulations defined the criteria for informed consent and detailed the procedures for obtaining informed consent. Although the regulations applied only to research funded by DHEW, the policy was an important step in the development of Federal standards for human subject research and provided the framework for current DoD human subjects protection policies. Following the adoption of this policy, other Government agencies began to develop their own human subjects protection policies using the DHEW policy as a foundation.

**Air Force.** Before the Wilson Memorandum, one of the early Air Force Regulations (AFR 80-22, dated 11 July 1952) required the officer conducting the research to provide justification for the investigation, background references, research design, and lines of authority; however, there was no mention of consent requirements. The regulation was revised in July 1956, September 1960, and January 1963. In April 1963, AFR 80-22 was superseded by AFR 169-6. In addition to the requirements in AFR 80-22, AFR 169-6 required the Surgeon General to approve all

clinical investigation protocols. By April 1968, a revision of AFR 169-6 created the Surgeon General's Clinical Investigation Committee and a review board for investigational drugs. Like AFR 80-22, AFR 169-6 did not mention informed consent. However, approximately two years later, in October 1965, a new regulation, AFR 169-8, stated that informed consent was absolutely essential and required in writing. The regulation further required that participants be informed of the study's nature, duration, purpose, methods, inconveniences, hazards, and effects on health. Moreover, AFR 169-8 directed the commander of the facility conducting the research to appoint a research committee. This research committee was charged with reviewing all human use protocols and recommending approval or disapproval. If the protocol received approval from the local research facility, it was then sent to the Surgeon General for approval before the investigation started. This regulation was revised in May 1968 and August 1974. In September 1976, AFR 169-8 was incorporated into AFR 169-6.

### CURRENT DoD POLICY FOR HUMAN SUBJECTS PROTECTION

The authority for oversight of human subjects protection within the DoD is established within the reporting chain of command. Title 32, Code of Federal Regulations, Part 219 (32 CFR 219), Federal Policy for the Protection of Human Subjects (the DoD version of the Federal "Common Rule," a copy of which is provided in appendix 2, exhibit 1), and Title 10, United States Code, Section 980 (10 U.S.C. 980) establish the fundamental regulatory requirements for human subjects protection. Execution of these regulations and written standards for performance are found in DoD Directive 3216.2, Protection of Human Subjects in DoD Supported Research, in DoD Guidance for the Assurance of Compliance with the Federal Policy for the Protection of Human Subjects,<sup>54</sup> and in the implementing regulations and instructions of the military departments and agencies.<sup>55</sup> Additionally, research involving a new drug or medical device in

human subjects must comply with the regulations of the Food and Drug Administration.

Human subjects protection oversight within the DoD currently resides with the Director, Defense Research and Engineering (DDR&E), who develops policies in coordination with the Assistant Secretary of Defense (Health Affairs). Operational oversight has been delegated to the individual military departments or defense agencies through the Director, Environmental and Life Sciences of the office of DDR&E. Within the various service components or agencies, human subjects protection is implemented at biomedical research and development facilities and at medical treatment facilities conducting clinical investigations. With minor exceptions, both the biomedical research and development programs and clinical investigation efforts of the military departments come under the purview of each service's Surgeon General.

### Clinical Investigations Programs

Primary responsibility for oversight of human medical research resides with each hospital commander whose facility sponsors a clinical investigation program. Oversight is exercised primarily through the Chief of the Department of Clinical Investigations at each major teaching hospital. These chiefs also use the deliberations and contributions of human use protection (IRBs), clinical investigations, radiation protection, pharmacy and therapeutics, and quality assurance committees. Independent medical monitors (health care providers qualified by training, experience, or both) are appointed for most studies that involve more than minimal risk to monitor human subjects during the research and to ensure the ongoing protection of human subjects involved in each project. An annual review of each human subjects research protocol is required. Also, each service conducts headquarters-level reviews of all clinical human subjects protocols involving more than minimal risk. Each service has a central office that provides human subjects protection oversight and



coordination among its hospitals that perform human subjects research. These central offices are as follows:

- Army. The Clinical Investigation Regulatory Office (CIRO), U.S. Army Medical Department Center and School, Fort Sam Houston, Texas
- Navy. The Clinical Investigations Program Office, Naval School of Health Sciences, Bethesda, Maryland
- Air Force. The Headquarters, Air Force Medical Operations Agency, Office of the Surgeon General (HQ AFMOA/SGOT), Bolling Air Force Base, Washington, D.C.

#### Biomedical Research and Development Programs

The commanding officers of the military biomedical laboratories or institutes are ultimately responsible for local institutional oversight. Commanders use several review committees to exercise their responsibilities regarding scientific integrity and protection of human subjects. The principal committees for protocol reviews are the scientific review committees and the human use review committees or IRBs. Independent medical monitors are appointed for each study that involves more than minimal risk:

- Army. The Human Use and Regulatory Affairs Division (HURAD) of the Office of the Deputy Chief of Staff for Regulatory Compliance and Quality, U.S. Army Medical Research and Materiel Command (USAMRMC), Fort Detrick, Maryland, exercises protocol review oversight for all human subjects research conducted by both uniformed and civilian Army personnel, as well as contractors.
- Navy. The Committee for the Protection of Human Subjects within the Naval Medical

Research and Development Command (NMRDC), Bethesda, Maryland, exercises oversight for all human subjects research conducted by both uniformed and civilian Navy personnel, as well as contractors. The Office of Naval Research (ONR) also supports contracted research activities involving human subjects. Under authority of the Chief of Naval Research, the Head, Personnel Optimization and Biomolecular Science and Technology Department, is responsible for human subjects protection oversight.

- Air Force. Headquarters, Air Force Medical Operations Agency, Office of the Surgeon General (HQ AFMOA/SGOT), Bolling Air Force Base, Washington, D.C., is the central office that oversees human subjects protection at Air Force research and development facilities performing human subjects research.
- Uniformed Services University of the Health Sciences (USUHS). Within the USUHS, oversight for human subjects protection is the responsibility of the Dean, School of Medicine, and the Dean, Graduate School of Nursing. The USUHS Research Administration Office coordinates the oversight and review of human subjects research protocols by the USUHS IRB.
- Armed Forces Radiobiology Research Institute (AFRRI). The Director of AFRRI is ultimately responsible for all research activities conducted or sponsored by the Institute. AFRRI reports through the USUHS and therefore uses the USUHS oversight and review committees for research involving human subjects.
- Defense Special Weapons Agency (DSWA). Protocol review and project oversight occur through the appropriate office of the participating military service.

The functions of the various offices are conducted in accordance with requirements delineated in 32 CFR 219. The other offices described by the services or agencies function as the regulatory offices to ensure compliance with the requirements of the Federal Common Rule and other regulations and policy guidance. The headquarters-level oversight offices review, monitor, and inspect the programs under their authority. The various oversight offices ensure that accurate records of all research protocols (including study design), investigator credentials, approved informed consent forms, compliance and assurance documents, progress reports, and minutes of IRB or Human Subject Review Board (HSRB) transactions (including meeting minutes) are maintained. In addition, the oversight offices coordinate the collection and dissemination of information essential in conducting reviews of research protocols involving human subjects and serve as central locations for access to local, State, and Federal regulations and to directives and policies about research involving human subjects. The oversight offices also serve as the central point for information about program management and operations within their respective service or agency.

The services conduct announced and unannounced site visits to facilities to evaluate program management and to monitor compliance with regulations. Since 1993, the services have conducted more than 180 such visits by local or headquarters authorities of facilities conducting human subjects research. This number does not include all of the internal quality assurance committee monitoring programs or periodic administrative and record keeping audits that are conducted.

DoD policy and Federal regulations (32 CFR 219) require institutions, either foreign or domestic, that conduct human subjects research sponsored by the DoD components to hold an assurance of compliance with the human subjects protection regulations of the Department of Health and Human Services (DHHS) (45 CFR 46) or negotiate an equivalent assurance with the DoD component concerned. Accordingly, institutions with assurances

of compliance must have one or more IRBs established and duly constituted under the provisions of the Federal Common Rule. Continuing reviews of research programs involving human subjects are vested in the IRBs and are conducted at intervals appropriate to the level of risk, but at least annually. Department-sponsoring components require that reports of the continuing reviews be filed with headquarters-level review boards for further inspection. Component sponsors also perform on-site reviews of selected grantee or contractor institutions; however, limited personnel and budgets do not allow on-site reviews of all extramural programs. All reviews, inspections, and site visits are documented. Permanent records of such inspections or reviews are maintained by the office conducting or sponsoring the inspection or review.

In its Final Report, the Advisory Committee on Human Radiation Experiments (ACHRE) listed a number of recommendations specifically directed to the protection of the rights and interests of human subjects in the future. The DoD will implement several of these recommendations through revision of its policy directives and the implementing regulations and instructions of the military departments and DoD agencies. Others are beyond the scope of DoD regulations and may require amendment of the Federal Common Rule or legislative action. Some deal with broad, overarching ethical considerations and will fall under the purview of the newly created National Bioethics Advisory Commission (NBAC).

### NOTES

(To obtain copies of the following documents, see appendix 2.)

1. Directive, Committee on Medical Sciences, 11 February 1948. This directive established the Committee on Medical Sciences as an agency of the Research and Development Board; Directive, Joint Panel on Medical Aspects of Atomic Warfare, 23 February 1949. This directive established the Joint Panel on Medical Aspects of Atomic Warfare as a joint agency of the Committee on Medical Sciences and the Committee on Atomic Energy; Directive for the Armed Forces Medical Policy Council, 2 January 1951. This directive established

the Armed Forces Medical Policy Council, which reported directly to the Secretary of Defense.

2. Minutes, Forty-Second Meeting of the Committee on Medical Research of the Office of Scientific Research and Development, 29 October 1942, p. 4.

3. Minutes, Second Meeting of the NEPA/MAC on Radiation Tolerance of Military Personnel, 3 April 1949, pp. 4-5.

4. Ibid, pp. 3-4.

5. Ibid, p. 4.

6. Minutes, First Meeting of the JPMAAW, 3 June 1949, p. 5.

7. Minutes, Second Meeting of the JPMAAW, 7 October 1949, p. 4.

8. Memorandum, from James E. McCormack, M.D., Executive Director, CMS, to Astrid Kraus, Director of Administration, RDB, Subject: "Problem of Experimentation with Human Volunteers," 25 July 1950, p. 2.

9. Letter, from Wallace O. Fenn, to Dr. James E. McCormack, Executive Director, Committee on Medical Sciences, 5 December 1949, and Letter, from Dr. James E. McCormack, Executive Director, Committee on Medical Sciences, to Dr. Joseph C. Aub, 7 December 1949.

10. Memorandum, from James E. McCormack, M.D., Executive Director, CMS, to Astrid Kraus, Director of Administration, RDB, Subject: "Problem of Experimentation with Human Volunteers," 25 July 1950, p. 2.

11. Minutes, Fourth Meeting of the JPMAAW, 16-17 February 1950, p. 5, Appendix C.

12. Memorandum, from James E. McCormack, M.D., "Problem of Experimentation with Human Volunteers," pp. 2-3.

13. Memorandum, from Under Secretary of the Navy, to the Secretary of Defense, 24 April 1950.

14. Memorandum, from Archibald S. Alexander, Assistant Secretary of the Army, to Director of Medical

Services, Office of the Secretary of Defense, Subject: "Recommendation That the Armed Services Conduct Experiments on Human Subjects to Determine Effects of Radiation Exposure," 3 May 1950.

15. Memorandum, from Maj. Gen. Harry G. Armstrong, USAF, the Surgeon General, to General Powell, Subject: "Recommendation That the Armed Services Conduct Experiments on Human Subjects to Determine Effects of Radiation Exposure," 13 April 1950.

16. Memorandum, from Richard L. Meiling, M.D., Director of Medical Services, Office of the Secretary of Defense, to The Honorable Gordon E. Dean, Chairman of the AEC, 8 August 1950.

17. Minutes, Sixth Meeting of the JPMAAW, 31 October to 1 November 1950, p. 6.

18. Meeting summary for the Advisory Board of the AEC DBM, 10 November 1950, p. 2.

19. Ibid.

20. Letter, from M. C. Leverett, Technical Director, NEPA Project, to Shields Warren, M.D., Director of the AEC DBM, 15 February 1951, p. 1.

21. Project Specifications for "A Study of Intellectual, Perceptual, and Psychomotor Abilities of Patients Following Radio-Therapy," p. 1, Attached to Memorandum, from Lt. Lando Haddock, USAF, to Commanding General, Air Materiel Command, Wright-Patterson Air Force Base, Subject: "Negotiation of Cost Reimbursement Contract," 19 October 1950.

22. Letter, from Shields Warren, M.D., Director of the AEC DBM, to Leslie M. Redman, "D" Division, LANL, 5 March 1951, p. 1.

23. Memorandum, from Melvin A. Casberg, M.D., Chairman of the AFMPC, to Secretary of the Army, Secretary of the Navy, Secretary of the Air Force, and Chairman, CMS RDB, Subject: "Policy and Procedures in Connection with the Use of Human Beings as Subjects in Experimentation," 8 April 1952.

24. Memorandum, from Stephen S. Jackson, Counsel to the AFMPC, to Melvin A. Casberg, M.D., Subject: "The Standards and Requirements To Be Followed in Human Experimentation," 13 October 1952.

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25. Ibid.
26. Memorandum, from Stephen S. Jackson, Counsel to the AFMPC, to Melvin A. Casberg, M.D., Chairman of the AFMPC, Subject: "The Standards and Requirements To Be Followed in Human Experimentation," 4 December 1952.
27. Memorandum, from Stephen S. Jackson, Counsel to the AFMPC, to Melvin A. Casberg, M.D., Chairman of the AFMPC, 22 October 1952.
28. Memorandum, from F. Lloyd Mussells, M.D., Executive Director of the CMS, to Dr. Floyd L. Miller, Vice Chairman of the CMS RDB, Subject: "Human Experimentation," 12 November 1952.
29. Memorandum, from Melvin A. Casberg, M.D., Chairman of the AFMPC, to the Secretary of Defense, Subject: "Use of Human Volunteers in Experimental Research," 24 December 1952.
30. Ibid.
31. Memorandum, from Col. G. V. Underwood, U.S. Army, Director, Executive Office of the OSD, to Melvin A. Casberg, M.D., Chairman of the AFMPC, Subject: "Use of Human Volunteers in Experimental Research," 9 January 1953.
32. Memorandum, from Secretary of Defense C. E. Wilson, to Secretary of the Army, Secretary of the Navy, Secretary of the Air Force, Subject: "Use of Human Volunteers in Experimental Research," 26 February 1953.
33. Memorandum, from Astrid Kraus, Director of Administration of the CMS RDB, to Director, Executive Office, OSD, 27 February 1953.
34. Memorandum, from Lowell T. Coggeshall, M.D., Chairman of the CMS, to Chairman, CMS RDB, Subject: "Human Experimentation," 12 March 1953.
35. Memorandum, from Col. R. B. Firehock, General Staff Assistant, to The JAG, U.S. Army, Subject: "Use of Volunteers in Research," 16 April 1953.
36. Memorandum, from Lt. Gen. L. L. Lemnitzer, General Staff, Deputy Chief of Staff for Plans and Research, to Secretary of the Army, Subject: "Use of Human Volunteers in Experimental Research," 30 March 1953, p. 1.
37. Memorandum, from E. S. Josephson, Biochemist, TCW Branch, Army Chemical Corps, to Chief, BW Branch, Army Chemical Corps, Subject: "Status of Use of Human Volunteers in TCW," 12 May 1953.
38. Memorandum, from Col. R. B. Firehock, General Staff Assistant, to Chief Chemical Officer, the Army Surgeon General, Subject: "Use of Volunteers in Experimental Research," 31 March 1953.
39. Memorandum, from Maj. Gen. George E. Armstrong, The Surgeon General, to Chief of Research and Development, Office of the Army Chief of Staff, Subject: "Use of Human Volunteers in Experimental Research," 9 April 1953.
40. Memorandum, from Col. Marshall Stubbs, Chemical Corps, Chief, Research and Development Division, to Chief of Staff, U.S. Army, Subject: "Use of Human Volunteers in Experimental Research," 10 April 1953.
41. Memorandum, from Col. R. B. Firehock, General Staff Assistant, to The JAG, U.S. Army, Subject: "Use of Volunteers in Research," 16 April 1953.
42. Memorandum, from Robert T. Stevens, Secretary of the Army, to Chief of Staff, U.S. Army, 20 May 1953.
43. Memorandum, from Brig. Gen. John C. Oakes, Secretary of the General Staff, to Chief Chemical Officer of the Surgeon General, Subject: "Use of Volunteers in Research," 30 June 1953.
44. Memorandum, from Army Surgeon General, Subject: "Use of Human Volunteers in Medical Research, Principles, Policies, and Rules of the Office of the Surgeon General," 12 March 1954.
45. Ibid, p. 1.
46. Army Inspector General Report, "Use of Volunteers in Chemical Agent Research," 1975.
47. Memorandum, from Frank Knox, Secretary of the Navy, to All Ships and Stations, Subject: "Unauthorized Medical Experimentation on Service Personnel," 7 April 1943.
48. Department of the Navy, Bureau of Medicine and Surgery, "Manual of the Medical Department," Section 4, Research Article 1-17, 26 September 1951, p. 2.

49. Ibid, p. 2.

50. Memorandum, from Col. Perry B. Griffith, USAF, Deputy Assistant for Atomic Energy, USAF, to Lt. Gen. B. L. Boatner, The Inspector General, Subject: "Use of Human Volunteers in Experimental Research," 10 March 1953.

51. Memorandum, For The Record, Attached to Memorandum, from Col. Irving L. Branch, USAF, Acting Chief of Staff, AFSWP, to Assistant Secretary of Defense (Health and Medicine), Subject: "Status of Human Volunteers in Bio-Medical Experimentation," 5 March 1954.

52. Department of the Navy, "Manual of the Medical Department," 20-8, Change 36, 7 March 1967.

53. Department of the Navy, SecNav Instruction 3900.39, 28 April 1969.

54. DoD Policy Memorandum, 10 June 1993.

55. AR 40-7, Use of Investigational Drugs and Devices in Humans and the Use of Schedule I Controlled Drug Substances; AR 40-38, Clinical Investigation Program; AR 70-25, Use of Volunteers as Subjects of Research; Secretary of the Navy Instruction 3900.39B, Protection of Human Subjects; HSETC Instruction 6000.41A, Clinical Investigation Program; AF Instruction 40-402, Using Human Subjects in Research, Development, Testing and Evaluation; AF Instruction 40-403, Clinical Investigation in Medical Research, Guidance and Procedures; AF Policy Directive 40-4, Clinical Investigations and Human Use in Medical Research.



## CHAPTER 2

# TOTAL-BODY & PARTIAL-BODY IRRADIATION STUDIES

### TOTAL-BODY IRRADIATION TREATMENT FOR CANCER

Interest in radiation as a treatment for disease developed within the civilian medical community in the early part of this century. The effects of radiation observed by doctors and researchers provided valuable information on radiation's use as a treatment for different types of cancer. Early radiation research led to the development of two treatment methods known as total-body irradiation (TBI) and partial-body irradiation (PBI). Total-body irradiation, also known as whole-body irradiation, involves the use of external radiation sources to deliver a relatively uniform amount of radiation to the entire body. Partial-body irradiation delivers a relatively uniform amount of radiation to a specific part of the body.

In its initial uses, civilian doctors had more success with TBI in treating radiosensitive cancers (those that generally respond well to radiation treatments) than in treating radioresistant cancers. By the 1940s, therefore, TBI was considered an acceptable treatment for radiosensitive cancers, such as leukemia and lymphoma. The definition of which types of cancers were radioresistant was changing in the 1950s. Technological advances in equipment by the late 1950s caused researchers to reconsider TBI as a treatment to reduce the intensity of radioresistant cancers of the lung, breast, colon, and other organs. These later attempts to treat radioresistant cancers with TBI were reasonable because new sources could produce high-energy radiation. The availability of high-energy radiation sources (cobalt-60, cesium-137, and megavolt x-ray machines) allowed researchers to treat radioresistant cancers with TBI because "[t]hese new teletherapy units allowed high-energy radiation to penetrate deeper into the body without damaging the overlying skin and soft tissues; thus, higher

...doses could be delivered than with previous equipment."<sup>1</sup>

These high-energy treatments were initially unsuccessful. Due to bone marrow depression, patients were unable to tolerate the higher doses of radiation used. Bone marrow, the soft fatty tissue found in bone cavities, is the factory for red and white blood cells and platelets (blood particles that play a major role in blood clotting). Bone marrow depression can lead to potentially fatal complications, such as anemia and infection.

During the 1960s and 1970s, the development of bone marrow transfusions led researchers to try TBI and PBI again on radioresistant cancers. Bone marrow transfusion enabled patients to tolerate the higher doses of radiation needed to combat radioresistant cancers.

### DEPARTMENT OF DEFENSE INTEREST IN TOTAL- BODY IRRADIATION RESEARCH

The relationship of the DoD with the civilian cancer research community began in the early 1950s. The DoD was interested in collecting data on the physical and psychological effects of radiation exposure. The DoD sought to (1) predict the hospitalization requirements and decrease in work capacity of soldiers who were exposed to radiation on a nuclear battlefield, (2) estimate the manifestations of radiation exposure on workers at nuclear weapons production facilities of the Atomic Energy Commission (AEC), (3) estimate the manifestations of radiation exposure on the general population in the event of a nuclear war.

The DoD funded post-treatment data collections and analyses during five clinical TBI projects between 1950 and 1972 that have been of recent

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public interest. The DoD’s interest in these projects was that information could be collected on the biological and psychological effects of TBI. This data collection included observing and recording the physical manifestations of post-irradiation syndrome or radiation sickness. Additionally, the DoD was looking for a biological dosimeter, or marker, to enable military doctors to estimate from a simple test (such as a test of body fluids) the radiation dose an individual received. The studies took place at the University of Texas MD Anderson Hospital and Tumor Clinic of Houston in Texas, Baylor University College of Medicine in Houston, Texas, the Sloan-Kettering Institute for Cancer Research in New York, the University of Cincinnati College of Medicine (UCCM) in Ohio, and the U.S. Naval Hospital in Bethesda, Maryland. This chapter discusses these five projects (see table 1).

“SYSTEMATIC AND CLINICAL EFFECTS OF WHOLE-BODY X-IRRADIATION”

The University of Texas MD Anderson Hospital and Tumor Clinic of Houston

Background of Total Body Irradiation Research at MD Anderson Hospital

Between 1951 and 1956, the University of Texas MD Anderson Hospital and Tumor Clinic of Houston conducted studies involving TBI. The principal investigator was Gilbert Fletcher, M.D.

Shortly before this research began, during the late 1940s, the DoD and the United States Air Force (USAF) began investigating the possibility of developing a nuclear-powered aircraft, a program

TABLE 1 CHRONOLOGICAL LISTING OF TOTAL-BODY IRRADIATION/PARTIAL-BODY IRRADIATION STUDIES DISCUSSED IN THIS CHAPTER

Human Radiation Experiment Title	Location	Dates	Number of Participants
Systematic and Clinical Effects of Whole-Body X-Irradiation	University of Texas, MD Anderson Hospital and Tumor Clinic, Houston, TX	1951-1956	263
The Effects of TBI and PBI on Iron Metabolism and Hematopoiesis	Baylor University College of Medicine, Houston, TX	1952-1964	112
The Study of the Post-Irradiation Syndrome in Humans	Sloan-Kettering Institute for Cancer Research, New York, NY	1954-1964	34
Radiation Effects in Man: Manifestations and Therapeutic Efforts	University of Cincinnati College of Medicine, Cincinnati, OH	1960-1972	88*
Use of Total-Body Radiation in the Treatment of Far-Advanced Malignancies	U.S. Naval Hospital, Bethesda, Bethesda, MD	1960-1961	17

\* “Radiation Effects in Man: Manifestations and Therapeutic Efforts,” DNA 3024F, Report of 1 April 1971 through 31 March 1972, p. 1, states that 88 patients were irradiated in this program; however, the American College of Radiology and the UCCM Ad Hoc Committee Review reported that 106 patients were referred to the program but 24 dropped out, which indicated 6 fewer patients than listed in the Technical Report.



commonly referred to as the Nuclear Energy for the Propulsion of Aircraft (NEPA) project. The Air Force was concerned about the potential adverse health effects on the crew of a nuclear-powered aircraft, and wanted:

to determine the effects of exposures to ionizing radiation upon one's ability to perform simple and complex mental and psychomotor tasks in order to predict the effects upon the crew operating the NEPA aircraft.<sup>2</sup>

Therefore, in 1951, the Air Force School of Aviation Medicine (SAM) issued contract AF-18 (600)-926 to MD Anderson Hospital, which remained in effect until 1956.

This Air Force contract funded post-treatment data collection on (1) the effects of ionizing radiation, including documenting the physical symptoms of radiation sickness, and (2) the effects of radiation on psychomotor capabilities (the relationship between mental processes and muscular activities).

### Research Goals

Observational research on the potential effects of radiation exposure to aircrews operating a nuclear-powered aircraft was performed in conjunction with MD Anderson Hospital's ongoing clinical study comparing the value of radiotherapy and chemotherapy for treating generalized cancer. In addition to investigating TBI as a treatment for

TERMS USED IN THIS CHAPTER	
amino aciduria	excretion of amino acids in the urine
bone marrow	the tissue found in bone cavities, the factory for red and white blood cells and platelets
bone marrow depletion/depression/failure	failure to produce the normal amount of blood cells or overproduction of only certain blood cells
carcinoma	any malignant tumor arising from cells in the lining membrane of a body organ (includes most cancers of the lungs, breast, stomach, skin, and cervix)
cobalt-60	a radioactive isotope used in the treatment of cancer
hematologic	of the blood and its diseases
irradiate/irradiation	to treat by exposing to x-rays, ultraviolet rays, radium, or some other form of radiant energy
palliative	providing relief but not cure
platelet	cells associated with the process of blood clotting
post-irradiation sickness	(radiation sickness) sickness produced by overexposure to radiation, characterized by nausea, diarrhea, bleeding, loss of hair, and increased susceptibility to infection
rad	a unit of absorbed dose of ionizing radiation; acronym for radiation absorbed dose
red blood cells	blood cells that carry oxygen to the body tissues
white blood cells	cells important in the body's defenses against infection
World War II	1939-1945, fought between the Allies (Great Britain, France, the Soviet Union, Canada, and the United States as well as other nations) and the Axis (Germany, Italy, Japan, and other countries)

cancer, the researchers attempted to determine the effects of ionizing radiation exposures on one's ability to perform simple and complex mental and psychomotor tasks and to develop a biological marker that would quantify or reveal the level of radiation exposure an individual had received.<sup>3</sup>

**Patients and Treatments**

A total of 263 patients participated in this research. All of the participants were patients at MD Anderson Hospital. Patients were assigned to TBI treatment levels according to the severity of their disease.<sup>4</sup>

**Exposure to Total-Body Irradiation**

Exposure to TBI as a treatment for cancer was divided into two phases. The first phase comprised 233 patients exposed to doses ranging from 15 to 200 roentgen (R). The radiation source was a 250 kVp General Electric Maxitron.<sup>5</sup> Patients received either single doses or a series of small repeated doses. This segment of the participants was further subdivided into three groups. The second phase involved a series of thirty patients who received single doses of 200 R (see table 2).<sup>6</sup>

**Psychomotor Tests**

Psychomotor tests were initiated in 1951 to chart the effects of low-level ionizing radiation on some of

the psychomotor capabilities needed to operate aircraft.<sup>7</sup> Participants for these tests were selected from the 263 patients receiving TBI treatments for cancer. The psychomotor testing was divided into two studies:

The first study was concerned with the question of whether a given air dose would have a greater effect when delivered in a single exposure than when delivered in a series of fractionated exposures. The second study was organized as a straightforward dose-response study extending to relatively high exposure levels.<sup>8</sup>

In the first study, participants were adult males in advanced stages of cancer not correctable by surgery or localized radiation therapy. Ages for this study ranged between nineteen and seventy-six years. Participants in this study had been treated with either single or small repeated doses of radiation.<sup>9</sup> Participants in the second study were adult males ranging in age from twenty-three to seventy-six and were in advanced stages of cancer. These participants had been treated with single doses of radiation only.<sup>10</sup>

Psychomotor capabilities were tested using three perceptual-motor tasks. These tests evaluated basic skills necessary to operate aircraft and had been used

**TABLE 2 EXPOSURE TO TBI AS A TREATMENT FOR CANCER, MD ANDERSON HOSPITAL**

	Participants (Hospital Patients with Cancer)	Exposure (in Roentgen)
Phase I (233 patients)		
Group I	199	15 R to 75 R
Group II	18	100 R
Group III	17	125 R, 150 R, 175 R, 200 R
Phase II (30 patients)	30	200 R (single doses only)

Source: Lowell S. Miller, M. D., Gilbert H. Fletcher, M. D., and Herbert B. Gerstner, M. D., "Systematic and Clinical Effects Induced in 263 Cancer Patients by Whole-Body X-Irradiation with Nominal Air Doses of 15 to 200 R" (USAF Randolph AFB, Texas: Air University School of Aviation Medicine, May 1957), pp. 16-17. This report provided an unexplained discrepancy regarding the number of participants. The report indicated that Phase I comprised 233 patients. However, the breakdown into three groups for this phase totaled 234 (i.e., Group I 199, Group II 18, Group III 17).

to select aviation cadets during World War II.<sup>11</sup> The tests were administered to participants before and after receiving radiation to measure whether the treatments would cause these skills to deteriorate. The Air Force SAM Complex Coordination Test required participants to coordinate movement of a stick and rudder bar to match the position of three red lights and three green lights. The Air Force SAM Two-Hand Coordination Test required participants to operate two crank handles to keep a cursor positioned on a moving target. The Air Force SAM Rotary Pursuit Test required participants to follow a rotating target with the tip of a stylus.<sup>12</sup>

### Research Results

The use of TBI as a treatment for radioresistant cancer showed some limited successes. For some patients, 200 R of total-body irradiation produced definite, although temporary, symptomatic relief from their cancer. In a number of other cases, the researchers reported additional improvements in patient conditions.<sup>13</sup>

The investigators also reported on the physical effects (typically referred to as radiation sickness) of TBI treatments. Their report stated:

These effects—predominantly nausea, vomiting, and bone-marrow depression—were practically absent below 100 R. They became noticeable between 125 R and 175 R, and developed into complications requiring treatment in 10 percent of the patients at 200 R.<sup>14</sup>

### ACRONYMS USED IN THIS CHAPTER

ACHRE	Advisory Committee on Human Radiation Experiments
ACR	American College of Radiology
AFIP	Armed Forces Institute of Pathology
AFMPC	Armed Forces Medical Policy Council
AFSWP	Armed Forces Special Weapons Project
DASA	Defense Atomic Support Agency
DoD	Department of Defense
GAO	General Accounting Office
kVp	peak kilovolts
JPMAAW	Joint Panel on the Medical Aspects of Atomic Warfare
NEPA	Nuclear Energy for the Propulsion of Aircraft
PBI	partial-body irradiation
R	roentgen; unit of exposure used in measuring ionizing radiation
REM	acronym for roentgen equivalent man; a unit of dose, taking into account the biological effectiveness of the radiation type
SAM	(Air Force) School of Aviation Medicine
TBI	total-body irradiation
UCCM	University of Cincinnati College of Medicine
USAF	United States Air Force

In the first study, the data collected did not provide any evidence that TBI treatments affected psychomotor performance; radiation treatments did not alter performance on any of the psychomotor tests.<sup>15</sup> Results for the second study were slightly different. There was no evidence from the Two-Hand Coordination and Rotary Pursuit tests that exposure to ionizing radiation affected psychomotor skills. However, performance on the Complex Coordination test decreased after radiation treatments. Although this result may have indicated radiation exposure to have an impact on performance, the investigators noted that the decrease in performance could have been an effect of the disease rather than an effect of radiation or a combination of both. Researchers also

noted that the decrease in performance was slight, and because the decrease was so small, the result may have been of little significance.<sup>16</sup>

“THE EFFECTS OF TBI AND PBI ON IRON METABOLISM AND HEMATOPOIESIS”

Baylor University College of Medicine,  
Houston, Texas

### Background of Total Body Irradiation Research at Baylor University College of Medicine

From December 1952 until January 1964, researchers at Baylor University in conjunction with the Texas Medical Center and Jefferson Davis Hospital in Houston conducted TBI research. The DoD’s interest in this project was the information collected on the biological and psychological effects of TBI. The principal investigator for the project was Vincent P. Collins, M.D.

The DoD realized that the use of nuclear weapons could generate a background of continuous radiation in which people would have to live, work, and fight. Because of this possibility, there was a need to know what “a chronic low dosage of ionizing radiation would do to immunity, blood coagulation, wound healing, infection, nutrition . . . in combat or similar casualties.”<sup>17</sup>

In December 1952, a Baylor University project proposal was reviewed and approved by the following organizations: Armed Forces Special Weapons Project (AFSWP), Armed Forces Medical Policy Council (AFMPC), Joint Panel on the Medical Aspects of Atomic Warfare (JPMAAW), and the Armed Forces Institute of Pathology (AFIP). Three contracts were issued over the study’s twelve-year period. The first two contracts (DA-49-007-MD-302 and DA-49-007-MD-428) were issued by AFSWP. As part of a 1959 reorganization, AFSWP was redesignated the Defense Atomic Support Agency (DASA), which issued the contract (DA-49-146-XZ-032).

### Research Goals

The primary purpose of this investigation was to define and quantify the therapeutic effects of TBI as a treatment for cancer. Initially, the therapeutic aspects and biologic effects of TBI in single doses up to 200 R were the principal objectives of the study. As the research progressed, the investigators expanded their attention to include therapeutic effects of lower doses of radiation over time. From 1956 (four years into the project) through the end of the study, the researchers were not only concerned with the effects of single doses that were well within accepted human tolerance limits but also with the cumulative effects of repeated small doses administered over time.<sup>18</sup> The part of the study involving small repeated doses had the potential to answer some of the questions the DoD had regarding backgrounds of continuous radiation in the event of a nuclear war.

In addition to investigating the therapeutic effects of TBI, researchers at Baylor University sought to establish a predictable relation between radiation exposure and biologic response. More specifically, the researchers focused on identifying enzyme systems in circulating red blood cells to establish a biologic marker of radiation exposure.<sup>19</sup> Information obtained from this research also had the potential to benefit the DoD in developing a simple enzyme test that could determine the amount of radiation an individual had received. This would assist DoD personnel in identifying and treating people following exposure to radiation.

### Patients and Treatment

A total of 112 patients participated in this project. All of the participants were adults with widespread or advanced cancer. Follow-up continued for as long as the patient’s condition permitted. From the beginning of the project until February 1956, the majority of patients received TBI from conventional 250 kVp therapy equipment, and following this

period, researchers used a 2 million electron volt (MeV) Van de Graaff x-ray generator.<sup>20</sup>

Participants, who received TBI for the treatment of advanced cancer, were divided into three groups. Group I received single exposures of 25 to 250 R. There were seventy-one individuals, or 63 percent of the patients, in this group. Group II received protracted irradiation (small repeated exposures) ranging from 25 to 545 R total exposure over a period ranging from two to sixty-three days (e.g., one patient received 545 R total exposure spread over eighteen days, or approximately 30 R per day for eighteen days). There were thirty-four individuals, or 31 percent of the patients, in this group. It was expected that studies of this group would result in information that might be useful among military personnel when occupying a radioactive area. Group III received repeated courses of treatment over several months or, in some cases, several years. This group consisted of seven individuals, or 6 percent of the patients, who initially received either single or repeated exposures and, after months or years of remission, developed recurrent symptoms requiring further TBI treatments. Exposures ranged between 170 R and 500 R total exposure spread over four to forty-two months (e.g., one patient initially received 100 R spread over seven days and twenty-five months later returned to receive 100 R spread over six days).<sup>21</sup>

## Research Results

Although many of the cancer patients referred to the project were terminally ill, positive response to TBI therapy for some was reflected by decreased node size and decreased drug requirements for pain control.<sup>22</sup> “In some instances, response was dramatic; a few completely bedridden patients became ambulatory and several experienced long-term remission,” the report stated.<sup>23</sup> In addition, the study of all patients who developed symptoms of radiation sickness following therapeutic TBI indicated that, for levels up to 200 R in single or repeated exposures,

radiation sickness may be avoided by proper health care management.<sup>24</sup> The researchers concluded from these observations that with factual information regarding the effects of radiation exposure, normal, healthy individuals could tolerate even higher exposures without undue incapacitation.<sup>25</sup>

The researchers also reported the results of supplementary bone marrow studies. Developed first in animals, techniques for removal, processing, storage, and reinfusion of bone marrow were quickly adopted for use with humans.<sup>26</sup> However, despite all the successes and data available from hematologic studies, a definite relationship between the amount of radiation and biological response was not established, and a biological marker was not found.<sup>27</sup>

### “THE STUDY OF THE POST-IRRADIATION SYNDROME IN HUMANS”

Sloan-Kettering Institute for Cancer Research

### Background of Total-Body Irradiation Research at Sloan-Kettering Institute for Cancer Research

From June 1954 until January 1964, researchers at the Sloan-Kettering Institute for Cancer Research in New York conducted TBI research. The principal investigator was J. J. Nickson, M.D.

The project used TBI as a treatment method for cancer. Information was also collected on clinical observations, hematologic parameters, plasma protein distribution, urine excretion, and electroencephalograms (electrical activity of the brain).<sup>28</sup> Several contracts were issued throughout the project. The AFSWP funded the results of the program from 1954 to 1959. AFSWP contracts included DA-49-007-MD-533; DA-49-007-MD-669; DA-49-007-MD-910; and DA-49-007-MD-1022. The final contract, DA-49-146-XZ-037, was issued under DASA in July 1959 and lasted until January 1964. The project was monitored by the Office of the Army Surgeon General.

## Patients and Treatment

A total of thirty-four patients participated in this project. The participants were patients at the Sloan-Kettering Institute for Cancer Research and were selected because they had widespread cancer that was resistant to medical procedures at the time. Throughout the ten years of the study, twenty-two patients received TBI, and twelve received radiation to the head for treatment of tumors. The radiation source was a 2 MeV Van de Graaff x-ray generator. Exposures ranged from 50 to 150 R for TBI and up to 4,000 R for localized cancers. Clinical follow-up continued up to approximately seventy-five days after exposure to radiation.<sup>29</sup> Ages ranged from nineteen to sixty-three years, with an average age of forty-seven years. Existing documents identified the participants by initials, types of cancer, and, in some cases, by age and sex.<sup>30</sup>

## Research Results

Several patients experienced regression of their disease and changes in the abnormal growth of new tissue.<sup>31</sup> The investigators found hematologic changes to be the most consistent biological marker of radiation exposure. Investigators noted that these changes showed variable decreases in white blood cell counts and platelet counts after exposure to radiation. In some cases, the investigators compared post-irradiation counts with the patient's own pre-irradiation counts. Those comparisons led the investigators to conclude that multiple exposures (e.g., three treatments at 30 R) produced a more severe depression of white blood cells and platelets than comparable total dose delivered at one exposure. The researchers also conducted urine studies in an attempt to locate other biological indicators of radiation exposure. They reported that urinary excretion of creatine, creatinine, and pentose appeared to increase as the radiation dose increased.<sup>32</sup> The investigators did not report any definitive conclusions on the post-irradiation syndrome in humans.

“RADIATION EFFECTS IN MAN: MANIFESTATIONS AND THERAPEUTIC EFFORTS”

University of Cincinnati College of Medicine

Background of Total-Body Irradiation Research at the University of Cincinnati College of Medicine

The research at the University of Cincinnati College of Medicine (UCCM) examined the effectiveness of using new, deep-penetrating TBI technology to improve the treatment of patients with advanced cancer. During the 1950s and 1960s, the DoD sought information on the biological and clinical features of radiation injury. The DoD funded laboratory studies and psychological tests of cancer patients after they had received TBI and PBI as treatment for their disease. The DoD's initial objective was to obtain a biological marker of radiation exposure. After 1965, the DoD was also interested in obtaining data on the psychological response to radiation exposure.

Eugene L. Saenger, M.D., a physician in the Department of Radiology at UCCM who later became principal investigator for the research, submitted an unsolicited research application in September 1958 to the Research and Development Division of the Office of the Army Surgeon General.<sup>33</sup> Over the next one and a half years, Army Medical Corps officers reviewed the proposal and recommended approval of the contract application.<sup>34</sup> By October 1959, DASA began negotiating a contract with the University of Cincinnati for the study of the metabolic changes in humans following TBI.<sup>35</sup>

On 1 January 1960, DASA awarded contract DA-49-146-XZ-029 to the University of Cincinnati.<sup>36</sup> This contract, with supplements and modifications, remained in effect through February 1964. On 1 June 1964, the second contract (DA-49-146-XZ-315) was awarded and remained active until April 1969.<sup>37</sup> On 15 June 1969, DASA awarded the third and final contract, DASA-01-69-C-0131, which remained in effect until March 1972.<sup>38</sup> The

project was terminated at the completion of the third contract, and the University of Cincinnati declined to initiate a new contract.<sup>39</sup>

### Patients and Treatments

A total of eighty-eight<sup>40</sup> patients from Cincinnati General Hospital participated in this project. Patient selection criteria required that only individuals with proven metastatic or far-advanced cancer be selected for the studies. In addition, subjects had to be in relatively good nutritional status and, in most cases, have normal hematologic values. These criteria remained relatively constant throughout the twelve years of the study. UCCM researchers also sought patients who had not undergone previous radiation or chemotherapy, had normal kidney function and new, abnormal tissue growth that was not radiosensitive, and were without lymphoma or bronchogenic cancer.<sup>41</sup>

According to a 1972 University of Cincinnati review of the project, the majority of the patients treated in this study were African-American. Most of the patients treated were indigent. Some of the patients had relatively low intelligence quotients. The demographic distribution of study participants reflected the patient population of the Cincinnati General Hospital.<sup>42</sup> All patients received either single or multiple exposures of therapeutic radiation from a cobalt-60 teletherapy unit. Doses ranged from as low as 16 rads in the first year of research to as high as 300 rads in the later years.

### Research Results

UCCM researchers determined that TBI and PBI therapies were effective in controlling certain advanced cancers. They reported that the relief effects of radiation treatments compared favorably with results using anticancer drugs or chemotherapy.<sup>43</sup> Delivery of higher radiation doses caused patients to experience blood problems, which included loss of red and white blood cells and platelets. Doctors

infused bone marrow early in the post-irradiation period, hoping to prevent these problems. In May 1963, researchers in this project proposed establishing facilities for the withdrawal, storage, and reinfusion of bone marrow.<sup>44</sup> By April 1966, a filtration system for the reinfusion of human bone marrow was completed,<sup>45</sup> and by April 1969, success in bone marrow reinfusion was achieved.<sup>46</sup> The use of this process immediately after radiation therapy minimized the characteristic bone marrow depression associated with higher doses of radiation. The degree of illness following reinfusion was significantly decreased and hospitalization greatly shortened.<sup>47</sup>

No success was achieved in the search for a biological marker for radiation exposure. By 1963, the researchers concluded that the elevation of amino acids in urine was nonspecific and not solely characteristic of irradiation. The researchers then began to investigate breakdown products of deoxyribonucleic acid (DNA). Deoxycytidine was one such product that showed elevated levels after irradiation.<sup>48</sup> However, researchers discovered that the presence of elevated levels of this product in urine could have been caused either by radiation or from other sources, such as burns.<sup>49</sup> When the study was discontinued in 1972, the researchers were attempting to develop a means to differentiate between elevated levels of deoxycytidine created by irradiation and elevated levels of deoxycytidine created by other sources.

### Psychological Studies

Psychological studies of the patients in the UCCM project began in 1965.<sup>50</sup> The DoD's objective was to determine the effect of radiation exposure on emotional and intellectual functioning. The tests were designed to take into account the many complex variables that may influence the measurement of these functions after radiation treatment. The tests included the Reitan Trials Test, Cattell's 16 Personality Factor Test, Wechsler Depression Rating Scale, Wechsler Adult Intelligence Scale, and the five-minute verbal content test of Gottschalk and Gleser. The researchers found

evidence of a decrease in intellectual functioning immediately after radiation. This effect was temporary, and functioning improved markedly within three days. Those with higher intelligence quotients showed less of a decrease than those with lower intelligence quotients.<sup>51</sup>

**UCCM Review Processes**

During its course, the UCCM project came under intense scrutiny from groups inside the University of Cincinnati and from outside organizations (see table 3).

In November 1971, Senator Mike Gravel of Alaska requested that the American College of Radiology (ACR) evaluate the UCCM project.<sup>52</sup> In January 1972, the ACR responded to Senator Gravel’s request. The ACR reviewed the science, methodology, and design of the project from a medical point of view to determine if the project conformed to then-contemporary standards for clinical investigations. The ACR report concluded that the UCCM project was validly conceived, stated, executed, controlled, and followed up; the process of patient selection conformed with sound medical practice; and procedures for obtaining patient consent were valid, thorough, and consistent with National Institutes of Health recommendations and the practices of most cancer centers.<sup>53</sup>

Also in November 1971, Clifford Grulee, M.D., Dean of the University of Cincinnati College of

Medicine, appointed an Ad Hoc Committee made up of members of the UCCM faculty to review the project. Dr. Grulee asked the committee to review the project’s scientific content, methodology, and data treatment.<sup>54</sup> The committee’s report, released in January 1972, indicated that there were no problems with the project’s scientific content or methodology. In addition, the committee stated that there was no evidence that DASA funding was made contingent on work, ideas, or suggestions proposed by DASA and all information reported to DASA was kept unclassified and publicly available.<sup>55</sup>

Immediately following the release of the Ad Hoc Committee report in January 1972, three members of the UCCM Junior Faculty Association released “A Report to the Campus Community.” This report was highly critical of the research and urged the cancellation of the project.<sup>56</sup>

“USE OF TOTAL-BODY RADIATION IN THE TREATMENT OF FAR-ADVANCED MALIGNANCIES”

U.S. Naval Hospital, National Naval Medical Center, Bethesda, Maryland

Background of Total Body Irradiation Research at the U.S. Naval Hospital, Bethesda, Maryland

Between 1960 and 1961, the United States Navy sponsored and performed a TBI study at the U.S.

**TABLE 3 SCIENTIFIC AND ETHICAL REVIEWS OF THE UCCM PROJECT**

Organization	Dates
1. UCCM and DoD contract officers	1958-1972 (ongoing throughout project)
2. American College of Radiology	November 1971-January 1972
3. University of Cincinnati College of Medicine Ad Hoc Committee	November 1971-January 1972
4. General Accounting Office	December 1971-May 1972
5. University of Cincinnati Junior Faculty Association	January 1972



Naval Hospital, National Naval Medical Center in Bethesda, Maryland. The military purpose was to establish a biological marker for exposure to radiation by tracking the excretion of amino acids following TBI treatments. The primary researcher for this investigation was Chief of Radiology at the U.S. Naval Hospital, CAPT E. Richard King, Medical Corps, USN.

### Patients and Treatment

There were seventeen patients from the U.S. Naval Hospital, Bethesda, Maryland, participating in the project. All were hospitalized due to advanced cancer and “had received conventional radiation therapy or chemotherapy, or both, in addition to some form of surgery.”<sup>57</sup> To administer TBI to the patients, the doctors at the Naval Hospital arranged to use the cobalt-60 source located at the Naval Medical Research Institute, a separate facility located on the same site as the Naval Hospital.

Patients were divided into two groups. Each patient in the first group (eleven patients) was treated with a single dose of TBI. Each patient in the second group (six patients) was treated with several smaller doses of TBI. For those patients who received single doses of TBI, exposures ranged between 225 R and 1,500 R. For those patients who received multiple doses, total exposures ranged between 200 R and 600 R. These multiple exposures were delivered over a period of time ranging between two and sixteen days. Five of the six patients in this group received treatments in increments of 100 R per treatment, while the sixth patient received treatments in increments of 25 R. Patients in both groups consisted of men, women, and children.<sup>58</sup>

### Research Results

The researchers reported that the results of treatments with TBI were encouraging. TBI therapy in a dose range of between 100 and 400 R appeared to offer relatively safe and reasonably effective relief therapy for advanced radiosensitive cancers. If the

patient’s bone marrow did not appear to be affected by the disease, a portion could be removed for reinfusion following treatment. These bone marrow reinfusions enabled researchers to safely expose patients to larger doses of TBI with only temporary marrow depression.<sup>59</sup> All six patients treated with small multiple exposures experienced marked relief of generalized pain and decreases in the size of cancer lesions. The results from the single exposure group were more varied, although four of the eleven experienced some relief from generalized pain and disease. However, the results did not indicate to the researchers that small repeated exposures were more effective in treating cancer than a large single dose because differences in dose delivery were based on each patient’s clinical status.<sup>60</sup>

In addition to examining TBI as a treatment for cancer, patients’ urine was collected and studies were performed on the urinary excretion of amino acids (such as taurine) following TBI treatments in an attempt to establish a biological marker for exposure to radiation. Although the results from these tests suggested that, at exposure levels of 450 R or greater, urinary excretion of taurine increased, the researchers reported, “However, there appears to be no direct correlation between the dose of radiation and the amount of taurine excreted.”<sup>61</sup> The source of the increased taurine was unknown, and the researchers noted the need for further studies to determine that source.

### SUMMARY

TBI continues to be used today. The Advisory Committee on Human Radiation Experiments (ACHRE) Final Report states:

Since the 1980s, TBI has again been used to treat certain widely disseminated, radioresistant carcinomas at doses as high as 1,575 rads in conjunction with effective bone marrow transplantation, which became routinely available in the late 1970s.<sup>62</sup>

The DoD awarded contracts involving five TBI projects between 1950 and 1972 that have been of

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recent public interest. All five TBI projects used TBI as a treatment method for cancer. The DoD's interest in these projects was the information collected on the biological and psychological effects of TBI. This secondary objective included observing and recording the physical manifestations of post-irradiation syndrome or radiation sickness. Additionally, the researchers were looking for a biological dosimeter or marker to enable military doctors to detect, with a simple test (such as a test of body fluids), the radiation dose an individual received.

### NOTES

(To obtain copies of the following documents, see appendix 2.)

1. Advisory Committee on Human Radiation Experiments, Final Report (Washington, D.C.: U.S. Government Printing Office, October 1995), p. 370.
2. Project Specifications for "A Study of Intellectual, Perceptual, and Psychomotor Abilities of Patients Following Radio-Therapy," p. 1, attached to Memorandum, from Lt. Lando Haddock, USAF, to Commanding General, Air Materiel Command, Wright-Patterson Air Force Base, Subject: "Negotiation of Cost Reimbursement Contract," 19 October 1950.
3. Research proposal for contract extension, "A Study of Intellectual, Perceptual, Psychomotor and Biomedical Status of Patients Following Exposures to Moderate Quantities of Ionizing Radiation," 27 January 1954.
4. Technical Report, Col. Robert B. Payne, Medical Service Corps, USAF, "Effects of Acute Radiation Exposure on Human Performance" (Brooks Air Force Base, Tex.: USAF School of Aerospace Medicine Aerospace Medical Division (AFSC), February 1963), p. 3.
5. Technical Report, Lowell S. Miller, M.D., Gilbert H. Fletcher, M.D., and Herbert B. Gerstner, M.D., "Systematic and Clinical Effects Induced in 263 Cancer Patients by Whole-Body X-Irradiation with Nominal Air Doses of 15 to 200 R" (USAF Randolph AFB, Tex.: Air University School of Aviation Medicine, May 1957), p. 2.
6. Ibid, p. 5.
7. Technical Report, Col. Robert B. Payne, "Effects of Acute Radiation Exposure on Human Performance," p. 3.
8. Ibid, p. 4.
9. Ibid.
10. Ibid, pp. 9 - 10.
11. Ibid, pp. 4-5.
12. Ibid, p. 4.
13. Technical Report, Lowell S. Miller, Gilbert Fletcher, and Herbert B. Gerstner, "Systematic and Clinical Effects Induced," p. 7.
14. Ibid, p. 20.
15. Technical Report, Lt. Col. Robert B. Payne, Medical Service Corps, USAF, "Effects of Ionizing Radiation Upon Human Psychomotor Skills" (USAF Randolph AFB, Tex.: Air University School of Aviation Medicine, December 1958), p. 6.
16. Ibid, p. 9.
17. Letter, from Lt. Col. Harold F. Hamit, Medical Corps, Chief, Surgical Research Branch, Research and Development Division to James D. McMurrey, M.D., Assistant Professor of Surgery, Baylor University College of Medicine, 17 January 1958.
18. Progress Report, Vincent P. Collins, M.D., Professor of Radiology, Baylor University College of Medicine, "A Study of the Effects of Total and Partial Body Radiation on Iron Metabolism and Hematopoiesis," Report of 1 February 1956 to 1 September 1956 (Houston, Tex.: Baylor University College of Medicine), p. 1.
19. Progress Report, Vincent P. Collins, M.D., "A Study of the Effects of Total and Partial Body Radiation on Iron Metabolism and Hematopoiesis," Report of 1 September 1955 to 31 January 1956, p. 1.
20. Progress Report, Vincent P. Collins, M.D., "A Study of the Effects of Total and Partial Body Radiation on Iron

Metabolism and Hematopoiesis,” Report of 1 February 1956 to 1 September 1956, p. 1.

21. Final Report, Vincent P. Collins, M.D., Professor of Radiology, Baylor University College of Medicine, “The Effect of Total Body Irradiation on Immunologic Tolerance of Bone Marrow and Homografts of Other Living Tissue,” 1 February 1963 to 31 January 1964, pp. 2–4.

22. Ibid, p. 6.

23. Ibid.

24. Ibid.

25. Ibid.

26. Ibid, p. 17.

27. Ibid, p. 20.

28. Study Profile, Capt. C. B. Galley, USN, Armed Forces Radiological Research Institute, “Post-Irradiation Syndrome in Man,” 1994.

29. Annual Report, James J. Nickson, M.D., and Irvin S. Glikman, M.D., “The Study of the Post-Irradiation Syndrome in Man” (New York, N.Y.: Sloan-Kettering Institute for Cancer Research, 1 January 1960 to 31 January 1961). (Estimate given in the text here is based on charts at the end of the report.)

30. Study Profile, Capt. C. B. Galley, “Post-Irradiation Syndrome in Man.”

31. Progress Report, James J. Nickson, M.D., and Henry J. Kody, Jr., M.D., “Study of the Post-Irradiation Syndrome in Humans,” 1 April 1954 to 31 March 1955, p. 3.

32. Annual Report, James J. Nickson, M.D., and Irvin S. Glikman, M.D., “The Study of Post-Irradiation Syndrome in Man,” p. 2.

33. Application for Research Contract, “Metabolic Changes in Humans Following Total Body Radiation,” 25 September 1958.

34. Memorandum, from Lt. Col. Arthur D. Sullivan, Medical Service Corps, Assistant Chief, Biophysics and

Astronautics Research Branch, to Col. Hullinghorst, Subject: “Application for Research Contract,” 12 November 1958.

35. Disposition Form, from Capt. David Lambert, USN, Deputy Chief of Staff Weapons Effects and Tests, to Director of Logistics, Subject: “Negotiation of Contract,” 29 October 1959.

36. Contract No. DA-49-146-XZ-029, Contract for: Research Relating to Study the Phenomenon of Amino-Aciduria Following Irradiation, signed 1 March 1960, effective 1 January 1960; includes seven modifications.

37. Contract No. DA-49-146-XZ-315, Contract for: Research to Obtain New Information About the Metabolic Effects of Total Body and Partial Body Irradiation, signed 5 January 1965, effective 1 June 1964; includes six modifications.

38. Contract No. DASA 01-69-C-0131, Contract for: Study of Radiation Effects in Man: Manifestations and Therapeutic Efforts, signed 12 November 1969, effective 15 June 1969; includes three modifications and contract completion statement.

39. Letter, from Eugene L. Saenger, M.D., to Director, Defense Nuclear Agency, 26 April 1972.

40. Technical Report, Eugene L. Saenger, M.D. et al., “Radiation Effects in Man: Manifestations and Therapeutic Efforts,” Report of 1 April 1971 to 31 March 1972, p. 1. (Although this report states that 88 patients were irradiated in this program, the American College of Radiology and the UCCM Ad Hoc Committee Review reported that 106 patients were referred to the program but 24 dropped out, which indicates 6 fewer patients than listed in the technical report. Letter from Robert W. McConnell, M.D., President, ACR, to The Honorable Mike Gravel, 3 January 1972, p. 6. Report, The Ad Hoc Review Committee, “The Whole Body Radiation Study,” January 1972, p. 26.)

41. Technical Report, Eugene L. Saenger, M.D., “Metabolic Changes in Humans Following Total Body Irradiation,” Report of 1 November 1961 to 30 April 1963, p. 3.

42. Report, The Ad Hoc Review Committee of the University of Cincinnati, “The Whole Body Radiation

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Study at the University of Cincinnati: A Report to the Dean of the College of Medicine,” January 1972, p. 28.

43. Technical Report, Eugene L. Saenger, M.D. et al., “Radiation Effects in Man: Manifestations and Therapeutic Efforts,” Report of 1 April 1971 to 31 March 1972, p. 27.

44. Technical Report, Eugene L. Saenger, M.D., “Metabolic Changes in Humans Following Total Body Irradiation,” Report of 1 November 1961 to 30 April 1963, p. 17.

45. Technical Report, Eugene L. Saenger, M.D., “Metabolic Changes in Humans Following Total Body Irradiation,” Report of 1 May 1966 to 30 April 1967.

46. Technical Report, Eugene L. Saenger, M.D., et al., “Radiation Effects in Man: Manifestations and Therapeutic Efforts” (Washington, D.C.: Headquarters, Defense Atomic Support Agency), Report of 1 May 1968 to 30 April 1969, p. 4.

47. Technical Report, Eugene L. Saenger, M.D., et al., “Radiation Effects in Man: Manifestations and Therapeutic Efforts,” Report of 1 April 1971 to 31 March 1972, p. 27.

48. Technical Report, Eugene L. Saenger, M.D. et al., “Metabolic Changes in Humans Following Total-Body Irradiation,” Report of February 1960 to 30 April 1966, p. 2.

49. Technical Report, Eugene L. Saenger, M.D., et al., “Radiation Effects in Man: Manifestations and Therapeutic Efforts,” Report of 1 May 1970 to 30 April 1971, p. 50.

50. Report, The Ad Hoc Review Committee, “The Whole Body Radiation Study,” January 1972, p. 34.

51. Ibid, pp. 36–39.

52. Letter, from Otha W. Linton, Director, Washington Office, ACR, to The Honorable Mike Gravel, 24 November 1971. (This document is a secondary source that mentions the date of Senator Gravel’s letter requesting the ACR to evaluate the UCCM project. Senator Gravel’s original letter has not been located.)

53. Letter, from Robert W. McConnell, M.D., President, ACR, to The Honorable Mike Gravel, 3 January 1972, p. 1.

54. Memorandum, from Clifford G. Grulee, Jr., M.D., to Members of the Ad Hoc Committee, 12 November 1971.

55. Report, The Ad Hoc Review Committee, “The Whole Body Radiation Study,” January 1972, pp. 44, 46.

56. “A Report to the Campus Community,” UCCM Junior Faculty Association, 25 January 1972.

57. E. Richard King, “Use of Total-Body Radiation in the Treatment of Far-Advanced Malignancies,” *Journal of the American Medical Association*, 177 (2 September 1961), p. 88.

58. Ibid, pp. 87–88.

59. Ibid, p. 89.

60. Ibid, pp. 88.

61. Ralph R. Cavalier, Milton Van Metre, F.W. Chambers, Jr., and E. Richard King, “Taurine Excretion in Humans Treated by Total-Body Radiation,” *Journal of Nuclear Medicine*, vol. 1 no. 186 (1960), pp. 187, 190.

62. Advisory Committee, Final Report, p. 370.

## CHAPTER 3

# NASOPHARYNGEAL IRRADIATION THERAPY

### BACKGROUND AND OVERVIEW

Radium, a radioactive metallic element discovered in 1898, was introduced into the world of medical therapy soon after its discovery.<sup>1</sup> Over time, radium irradiation was used internally and externally to treat gastrointestinal, genitourinary, and brain cancers; lymphomas and leukemias; nonmalignant tumors; goiters; thymus problems; thyroid disorders; acne; scalp ringworm; and birthmarks. Radium was also effective in shrinking inflamed tissue.

Nasopharyngeal irradiation therapy was a medical technique, initially using radon then later radium, to treat patients for hearing impairment caused by chronic inflammation of the middle ear (termed otitis media). This therapy has also been called radium rod therapy. Nasopharyngeal radium irradiation (NRI) was also used during and after World War II in the military to treat aerotitis media (also called middle ear barotrauma), a form of otitis media resulting from pressure changes in the middle ear.

Nasopharyngeal radium therapy involved routing a radium tipped applicator (see figure 1) through the nasal passage and leaving it in place for a specified time before removal. The civilian use of radium rod treatment set the precedent for its use in treating certain military personnel. Both civilian and military facilities used this procedure from the late 1940s until the 1960s.

### THE DEVELOPMENT OF RADIUM ROD TREATMENT

#### Civilian Research and Implementation

In the 1920s, nasopharyngeal irradiation using radium, radon, and x-rays was reported in medical journals as highly effective for shrinking lymphoid

tissue at the entrance to the eustachian tubes to prevent middle ear obstructions, infections, and deafness. By the mid-1920s, Johns Hopkins University funded the J. H. Otological Laboratory to study deafness in children. Researchers Samuel J. Crowe, M.D., and his colleagues stated that nasopharyngeal irradiation with radium was the most effective treatment for treating certain types of middle ear deafness.<sup>2</sup> By the late 1920s, Dr. Crowe had developed and standardized a radium applicator and a recommended treatment regime, which was subsequently adopted by many medical practitioners.<sup>3</sup>

As the use of this and other applicators became widespread, the most common procedure was to place the applicators into the nasopharyngeal region for periods that ranged from six to twelve minutes. Typically, the treatment involved using two radium applicators, each containing 50 milligrams of radium. A local anesthetic was given to the patient, and the applicators were inserted into each nostril (see figure 2).<sup>4</sup> The goal of the treatment was to reduce the lymphatic tissue at the opening of the eustachian tubes, allowing the ears to drain. Treatments were routinely repeated over a period of months as determined by tissue response to therapy.

Researchers found that excess lymphoid tissue was present in a substantial percentage of children with middle ear hearing loss. The best time to treat this form of hearing deficiency was found to be during childhood, before recurrent ear infections caused irreversible damage to the inner ear. By the late 1930s, it was standard practice to use NRI for treating repeated viral and bacterial infections, asthma that occurred with repeated viral infections, recurrent middle ear infections, sinusitis, and recurrent tonsillitis.<sup>5</sup>

Proponents of radium rod treatment noted several advantages of nasopharyngeal irradiation over

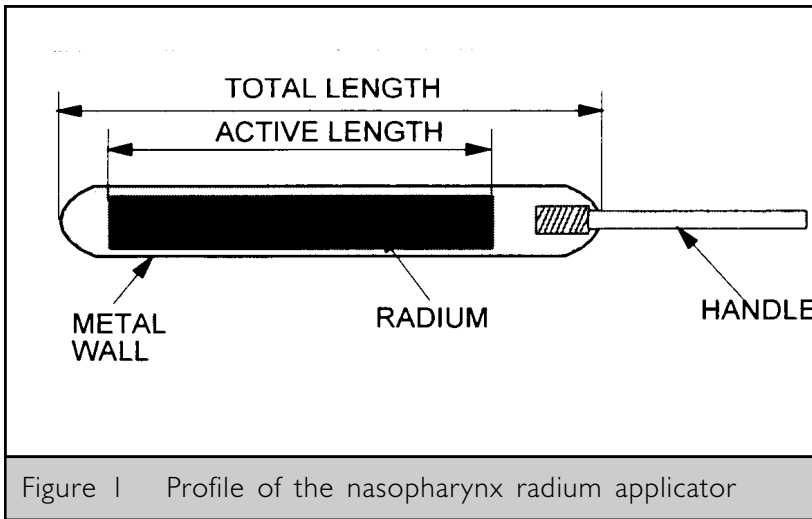


Figure 1 Profile of the nasopharynx radium applicator

study of nasopharyngeal treatment. Funded by the National Institutes of Health (NIH) from 1948 to 1953, this study concluded that nasopharyngeal treatments decreased lymphoid tissue swelling and improved hearing.<sup>6</sup> Radium rod therapy was accepted as the safest treatment to alleviate otitis media in both adults and children.

MILITARY USES OF RADIUM ROD TREATMENT

Aircrew Radium Treatment

conventional x-irradiation and surgery. Radium therapy could shrink lymphoid tissues in areas previously inaccessible to surgeons. Over time, Dr. Crowe became the leader in the area of nasopharyngeal irradiation as a treatment for hearing loss in children and conducted the first extensive

Nasopharyngeal radium treatment was an effective means of alleviating middle ear problems in both Army Air Forces (AAF) and Navy servicemen. The rapid pressurization of the middle ear of aircrews during aircraft descent occurred because pressurized cabins had not yet been developed. When pressure

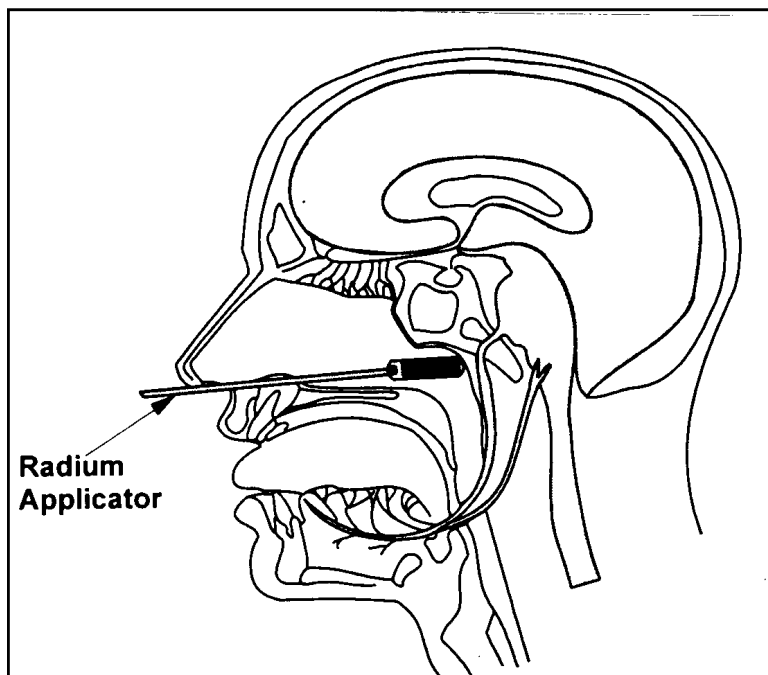


Figure 2 Profile of a human skull depicting the emplacement of a radium applicator for the nasopharyngeal irradiation procedure

equalization in the ear could not occur due to blocked eustachian tubes, aerotitis media could result. Eustachian tube blockage was particularly prevalent during the winter months as a result of upper respiratory tract infections and recurrent colds experienced by servicemen stationed in Europe. Middle ear problems, ranging from pain to ruptured eardrums, would sometimes keep personnel grounded for weeks. In 1944, the AAF Surgeon General officially adopted nasopharyngeal treatments with the radium applicator for AAF servicemen.<sup>7</sup>

A 1944 journal article by E. P. Fowler, Jr., M.D., described how he examined, treated, and collected data on 220 AAF personnel suffering recurrent barotrauma.<sup>8</sup> Dr. Fowler served at an Army hospital in England during the early 1940s. He had obtained radon from British doctors and treated U.S. servicemen from 1942 to 1944 using a radon applicator. His study showed that nasopharyngeal therapy

was 79 percent successful in returning aircrews to duty without further inflammation of the lymphoid tissue.<sup>9</sup>

An AAF report<sup>10</sup> about the Third Air Force Irradiation Unit further documented military use of nasopharyngeal therapy. The report detailed the founding of the unit and its mission, as well as the results and variations in treatment over the one-year program. The program was conducted at Drew Air Field in Tampa, Florida, and the doctors involved in the program traveled to training sites around the continental United States to administer treatment. The locations included Gulfport Army Air Field, Mississippi, Esler Field, Louisiana, Barksdale Field, Louisiana, Will Rogers Field, Oklahoma, Stuttgart Army Air Field, Arkansas, Alexandria Army Air Field, Louisiana, and Dyersburg Army Air Field, Tennessee. By the end of August 1945, 2,289 servicemen had been treated with what were termed “encouraging” results.

Another journal article,<sup>11</sup> published in 1945, detailed the beginning of the AAF nasopharyngeal irradiation treatment program and the events that led to the AAF Surgeon General’s approval of nasopharyngeal radium therapy. Nasopharyngeal irradiation was determined to be easier than using x-rays or performing surgery in the field. To evaluate the results of this one-year program, doctors involved were asked to conduct standard examinations and treatment regimes and to keep records. Servicemen who experienced barotrauma and were stationed in the following units were treated based on medical necessity: 1st Corps at Mitchel Field and Westover Field, 8th Corps in England, 15th Corps in northern Italy, 12th Air Corps in southern Italy, and 3rd Corps at Drew Field, Florida. The results showed this treatment to be highly effective in returning aircrews to the field.

In 1946, the Submarine Medical Research Laboratory published an article on the effectiveness of nasopharyngeal radium therapy for Navy pilots in

#### TERMS/ACRONYMS USED IN THIS CHAPTER

AAF	Army Air Forces
ACHRE	Advisory Committee on Human Radiation Experiments
CDC	Centers for Disease Control and Prevention
DVA	Department of Veterans Affairs
half-life	the time taken for the radioactivity level of a substance to reduce to half its original level
NIH	National Institutes of Health
tympanic tubes/rods	tubes placed in the ear near the tympanic membrane to drain fluids

temperate zones. In the article, CAPT Page Northington, M.C., USN, discussed the problems associated with rapid pressurization and various treatment methods, as well as barotrauma. He described the issue of ear pressure difficulties as the most common ailment experienced by aviators. After treating sixty male naval aviators with the Crowe radium applicator, Dr. Northington concluded, “. . . the effectiveness of radium therapy in relieving lymphoid tissue obstruction to the eustachian tubes recommends it as the treatment of choice.”<sup>12</sup>

#### Submariner Radium Treatment

During World War II, many U.S. Navy submariner trainees experienced barotrauma during submarine escape training. Recognizing barotrauma as an occupational injury for these servicemen, researchers at the Submarine Medical Research Laboratory in New London, Connecticut, sought to perform a “fairly definitive study on the causes, effects, prediction, and treatment of the disorder.”<sup>13</sup> In 1946, they published their findings of a study involving more than 6,000 men.<sup>14</sup> This research was designed to investigate the causes of ear pressure problems, predict who would experience them, and determine ways to prevent and treat this ailment. One research method was to compare different possible treatments after giving subjects a pressure test.

Researchers under the supervision of principal investigators Henry L. Haines, M.D., and J. Donald Harris, Ph.D., collected data on 6,149 young, healthy, male submariner trainees. The patients were divided into six groups: five treatment groups and one control group. The treatments were designed to assist the submarine trainees in accommodating changes during a pressure test without developing barotrauma.

These treatments were:

- Psychological treatment (assurance that the ears would heal without extraordinary intervention; the use of music and chewing gum was also studied)
- Symptomatic treatment with nosedrops (application of a solution of 0.25 percent neosynephrine in saline solution)
- X-ray treatment
- Dental treatment (for those identified with a dental occlusion which may have impacted on the eustachian tube)
- Radium treatment.<sup>15</sup>

The sixth group, the control group, received no treatment.

Of the 6,149 submariner trainees involved in the study, 26.9 percent (approximately 1,600) developed aerotitis media. A total of 732 of the approximately 1,600 were treated with radium therapy,<sup>16</sup> with treatment being effective in more than 90 percent of the cases.<sup>17</sup> Other therapeutic measures used in the study were not as effective as radium. The x-ray treatment was discontinued early in the study. The five test participants showed swelling and discomfort not experienced by those receiving the radium rod treatment, and there were administrative problems arranging the treatments, which had to be performed out of the area.<sup>18</sup>

On 30 April 1996, the Navy found Dr. Haines' original log book, which details the 1944 - 1945 aerotitis media experiment involving submariners at the Submarine Medical Research Laboratory and Submarine Base, New London, Connecticut. The log book contains detailed study data and the names of the approximately 1,600 participants. The

Department of Defense (DoD) and the Department of Veterans Affairs (VA) are reviewing and analyzing these data to determine appropriate actions.

#### DISCONTINUATION OF RADIUM ROD THERAPY

The Centers for Disease Control and Prevention (CDC) estimate that between 8,000 and 20,000 U.S. military servicemen were treated with nasopharyngeal irradiation.<sup>19</sup> As discussed previously, approximately 8,000 AAF aviators, naval aviators, and submariners participated in nasopharyngeal irradiation studies. The CDC also estimates that from 500,000 to 2 million people may have been treated with nasopharyngeal irradiation from 1940 to the mid-1960s.<sup>20</sup>

The emergence of pressurized aircraft cabins and the resulting substantial decrease of barotrauma as well as the advent of effective new medical treatments, such as tympanic tubes and antibiotics, led the Air Force and Navy to discontinue the practice of nasopharyngeal irradiation therapy by the early 1960s. The new treatments were easier to administer and more effective than nasopharyngeal irradiation. In addition, in the 1950s and 1960s, medical literature began to report concern that thyroid cancer might occur from head and neck x-rays and from nasopharyngeal radiation therapy.<sup>21</sup>

#### RETROSPECTIVE STUDIES

In the 1980s, two retrospective studies were conducted regarding the effects of nasopharyngeal irradiation on children. Increased cancer risks in other populations exposed to ionizing radiation and the availability of data on children treated with NRI indicated that this would be an important population to study. However, the two studies were inconclusive regarding the potential excess cancer risks for treated children.

The smaller of the two studies was conducted by Dale P. Sandler, Ph.D., and her colleagues from Johns



Hopkins University in Maryland.<sup>22</sup> Health data were gathered in 1982 in a follow-up survey of 904 people who had received radium rod therapy as children to treat hearing difficulties between 1943 and 1960. Researchers compared this group to a matched control group of 2,021 children with similar medical problems who had not received radium rod therapy. The researchers concluded that the risk for all head and neck cancers combined was higher among persons who had received the treatment than among persons who had not. However, the findings were based on small numbers of cancers and were statistically significant only after all categories of head and neck cancers were combined.

In 1995, Dr. Sandler stated that the results obtained in her study suggest a small excess risk of head and neck cancer in patients receiving NRI but that because of the small numbers of cases involved, interpretation was difficult.<sup>23</sup>

A larger study was conducted in The Netherlands by Peter G. Verduijn, M.D. and his associates. In that study, 2,542 children who had been treated with nasopharyngeal irradiation were compared with 2,381 unexposed children who had also been treated for hearing loss. The researchers reviewed medical records and followed up on patients from five clinics in The Netherlands in a 1989 retrospective study of the excess cancer risk to children treated with nasopharyngeal irradiation.<sup>24</sup> No brain cancers were observed in the treated population; three were observed in the controls. Thus, this study did not find an excess of head and neck cancer.<sup>25</sup> Dr. Verduijn summarized the findings of his study by concluding, "... the present study has found no excess of cancer mortality at any site associated with radium exposure by the Crowe and Baylor therapy. Specifically, the finding of Sandler et al. of an excess of head and neck cancer was not found in this study group."<sup>26</sup>

Due to recent concerns about health risks associated with nasopharyngeal radium therapy, the Johns Hopkins University Department of Epidemiology has continued the follow-up study originally conducted by Dr. Sandler.<sup>27</sup> Dr. Verduijn is also conducting a follow-up study of The Netherlands children.

#### CURRENT FOCUS ON NASOPHARYNGEAL THERAPY

Recent interest in the possible adverse health effects of nasopharyngeal radium therapy led to an examination of the past use of nasopharyngeal radium therapy within the military and civilian medical communities. Civilian and Government officials have conducted several reviews evaluating the treatment and its potential adverse health effects, and members of the public have voiced their concerns.

The Senate Subcommittee on Clean Air and Nuclear Regulation conducted a hearing in August 1994. Chaired by Senator Joseph Lieberman of Connecticut, the hearing participants discussed the past use of nasopharyngeal irradiation in military and civilian practice, possible negative health effects of these treatments on adults and children, and the feasibility of additional studies on the health risks related to radium rod therapy. Testimony at the hearing indicated that military use of nasopharyngeal radium therapy was within the accepted medical practices of the day. However, panel members testified that independent studies investigating long-term health risks associated with this treatment were inconclusive.<sup>28</sup> As a result of the hearing, the VA agreed to conduct a pilot study researching the feasibility of an epidemiological study to determine if service members who received this treatment in the past were now at greater risk for head and neck cancers. The CDC agreed to conduct a workshop on the issue for both medical specialists and the public.

The VA's pilot study in 1995 researched the feasibility of an epidemiologic study on veterans who had received nasopharyngeal irradiation treatments to study the occurrence of disease in this population. This study determined that there was virtually no primary documentation of such treatments for veterans who probably received this treatment. Occasionally, veterans' medical records showed a secondary entry, such as a sick call entry, that mentioned a radium treatment had been received, but no treatment time or delivered dose was recorded. An epidemiologic study of veterans, therefore, would be difficult.<sup>29</sup>

The CDC conducted its workshop, “Nasopharyngeal Radium Irradiation,” on 27 - 28 September 1995. It was hosted by the Yale University School of Medicine and covered such topics as historical medical practices and knowledge, previous and ongoing epidemiologic studies, estimates of the scope and number of people treated, and possible actions for the future. Participants at the workshop were representatives from the U.S. Senate, the Johns Hopkins School of Medicine, the Radiation Epidemiology Branch of the National Cancer Institute, the National Institute of Environmental Health Sciences, the Department of the Navy, the DoD, various university medical centers, and concerned citizens. General comments were that the risk to the treated populations was not substantial and, due to the lack of identifying data and treatment documentation and the relatively small number of military personnel treated, it would probably be difficult to conduct a meaningful epidemiological study.<sup>30</sup>

In addition, President Clinton’s Advisory Committee on Human Radiation Experiments (ACHRE) reviewed studies in the medical community from the 1940s to the present, the evolution of nasopharyngeal irradiation therapy, and current data on the potential health risks concerned with such treatments. The ACHRE Final Report states that although risk estimates to date contain considerable uncertainty, the committee did not recommend notification or medical follow-up of children or adults exposed to this treatment.<sup>31</sup>

In response to recommendations made by panel members of the September 1995 CDC workshop, the CDC, the DoD, and the VA cosponsored a videoconference on current medical issues associated with the past use of NRI. On 5 September 1996, the videoconference was broadcast live via satellite to county extension offices, schools, medical institutions, universities, all VA hospitals, and some local and regional cable television stations. The videoconference was intended as both a public health outreach effort for the CDC and as a continuing education opportunity for physicians to learn the proper means of evaluating and treating individuals who report receiving NRI. Primary discussion points

included the history of the procedure, the doses of radium used, potential dangers associated with the treatment, the possibility of resulting health effects, and physician evaluation and care of patients with a history of NRI. Discussion panel members included representatives from the CDC, Yale University Medical Center, and the VA. To obtain a videotape of the conference from the CDC, call 1-800-418-7246.

#### SUMMARY

Nasopharyngeal irradiation was a common medical practice from the 1940s to the mid-1960s to treat otitis media. Until the 1960, medical texts recommended radium rod therapy as a viable treatment for shrinking lymphoid tissue. Such treatments were used by both civilian and military physicians. During World War II, the AAF and Navy found NRI treatments particularly effective in treating barotrauma caused by rapid pressure changes incurred by servicemen. These treatments allowed thousands of American aircrews and submariners to remain in service and avoid recurrent health problems due to barotrauma.

#### NOTES

(To obtain copies of the following documents, see appendix 2.)

1. Edith H. Quimby, “The Background of Radium Therapy in the United States 1906 - 1956,” *American Journal of Roentgenology*, vol. 75, no. 3 (1956), p. 443.
2. Samuel J. Crowe, M.D., “Irradiation of the Nasopharynx,” *Annals of Otology, Rhinology, and Laryngology*, vol. 55, no. 1 (1946), p. 781.
3. Curtis F. Burnam, M.D., “Irradiation Treatment of Hyperplastic Lymphoid Tissue,” *Laryngoscope*, vol. 50 (1940), pp. 663 - 670.
4. Testimony, James Smith, Ph.D., Chief of the Radiation Studies Branch of the National Center for Environmental Health, Centers for Disease Control and

- Prevention, Before the Senate Subcommittee on Clean Air and Nuclear Regulation, Senate Committee on Environment and Public Works, 29 August 1994, p. 1.
5. Donald F. Proctor, Leroy M. Polvogt, and Samuel J. Crowe, "Irradiation of Lymphoid Tissue in Diseases of the Upper Respiratory Tract," *Bulletin, Johns Hopkins Hospital*, vol. 83 (1948), pp. 383 - 428.
  6. Testimony, James Smith, Before the Senate Subcommittee on Clean Air and Nuclear Regulation, 29 August 1994, pp. 3 - 4; Samuel J. Crowe, "Irradiation of the Nasopharynx," *Annals of Otolaryngology, Rhinology, and Laryngology*, vol. 55 (1946), pp. 779 - 788; W. G. Hardy and J. E. Boardley, "Observations from a Controlled Study on the Effect of Nasopharyngeal Irradiation in a Group of School Age Children," *Annals of Otolaryngology, Rhinology, and Laryngology*, vol. 62, no. 3 (September 1954), p. 825.
  7. "The Use of Radium in the Aerotitis Control Program of the Army Air Forces: A Combined Report by the Officers Participating," *Annals of Otolaryngology, Rhinology, and Laryngology*, vol. 54 (1945), pp. 650, 654.
  8. E. P. Fowler, Jr., "Use of Radon to Prevent Otitis Media Due to Hyperplasia of Lymphoid Tissue and Barotrauma (Aero-Otitis)," *Archives of Otolaryngology*, vol. 40 (1944), pp. 402 - 405.
  9. *Ibid*, p. 405.
  10. Jerome J. Glauber, John N. Smith, and Donald B. Earl, Report of the Third Air Force Irradiation Unit, 31 August 1945.
  11. "The Use of Radium in the Aerotitis Control Program," *Annals of Otolaryngology, Rhinology, and Laryngology*, 1945, pp. 650 - 660.
  12. Capt. Page Northington, M.D., USN, "Radium Therapy in Aerotitis Media," *US Naval Medical Bulletin*, 1946, p. 1567.
  13. H. L. Haines and J. D. Harris, "Aerotitis Media in Submariners, Interval Report No. 1 on Bureau of Medicine and Surgery Research Division Project X-434 (Sub. No. 90): Aerotitis Media Among Submariners—Prevention and Treatment, Section A," Bureau of Medicine and Surgery, 18 February 1946, p. 7.
  14. *Ibid*, p. 1.
  15. Henry L. Haines and J. Donald Harris, "Aerotitis Media in Submariners," *Annals of Otolaryngology, Rhinology, and Laryngology*, vol. 55 (1946), pp. 352 - 353.
  16. H. L. Haines and J. D. Harris, "Aerotitis Media in Submariners, Interval Report No. 1," 18 February 1946, pp. 25, 27.
  17. *Ibid*, p. 2.
  18. *Ibid*, p. 52, and Henry L. Haines and J. Donald Harris, "Aerotitis Media in Submariners," *Annals of Otolaryngology, Rhinology, and Laryngology*, vol. 55 (1946), p. 352.
  19. Summary Report and Executive Summary, "The Public Health Response to Nasopharyngeal Radium Irradiation: A Workshop, Centers for Disease Control and Prevention," 27 - 28 September 1995, p. 6.
  20. CDC, *Morbidity and Mortality Weekly Report*, 29 March 1996, p. 255.
  21. Testimony, Dr. James Smith before the Senate Subcommittee on Clean Air and Nuclear Regulation, 29 August 1994, pp. 4 - 5.
  22. Dale P. Sandler et al., "Neoplasms Following Childhood Radium Irradiation of the Nasopharynx," *Journal of the National Cancer Institute*, vol. 68 (1982), pp. 3 - 8.
  23. Summary Report and Executive Summary, "The Public Health Response to Nasopharyngeal Radium Irradiation: A Workshop, Centers for Disease Control and Prevention," 27 - 28 September 1995, p. 2.
  24. Peter G. Verduijn, M.D., et al., "Mortality After Nasopharyngeal Irradiation," *Annals of Otolaryngology, Rhinology, and Laryngology*, vol. 98 (1989), p. 839 - 844.
  25. *Ibid*, p. 843.
  26. *Ibid*.
  27. Advisory Committee on Human Radiation Experiments, *Final Report* (Washington, D.C.: U.S. Government Printing Office, October 1995), p. 354.
  28. Testimony, Dr. James Smith, Before the Senate Subcommittee on Clean Air and Nuclear Regulation, 29 August 1994, pp. 1, 5.

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29. Summary Report and Executive Summary, “The Public Health Response to Nasopharyngeal Radium Irradiation: A Workshop, Centers for Disease Control and Prevention,” 27 - 28 September 1995, p. 9.

30. Ibid.

31. Advisory Committee, Final Report, p. 843.

## CHAPTER

# 4

# IODINE-131 STUDY CONDUCTED BY THE ARCTIC AEROMEDICAL LABORATORY

## INTRODUCTION

In 1947,<sup>1</sup> the Air Force School of Aviation Medicine established the Arctic Aeromedical Laboratory (AAL) at Ladd Air Force Base near Fairbanks, Alaska. The laboratory was created to study environmentally related hardships affecting military personnel living and working in the Arctic. AAL research and development projects addressed preventive medicine, dietary requirements, emergency survival procedures and equipment, and protective flight clothing.<sup>2</sup> Due to public concerns over Native Alaskan participation, this chapter focuses on one particular study, “Thyroid Activity in Men Exposed to Cold.” This study included the use of a radioisotope tracer to assess the role of the thyroid gland in human acclimatization to cold.

## BACKGROUND

Construction of Ladd Army Airfield began in 1938 near Fairbanks, Alaska. Ladd Field, which became operational in 1940, was intended as a bulwark against growing Japanese ambitions in the Pacific region. During World War II, the airfield also served as the transfer point for aircraft being flown to the Soviet Union under the Lend-Lease Program. Ladd Field was designated the home of the Army Air Corps’ Cold Weather Experimentation Station. It was from this station that the AAL later evolved.

During and after World War II, increasing military operations in severely cold climates necessitated research on protective clothing, survival and emergency techniques, and the effects of cold

weather exposure on human physiology. The importance of this type of research was recognized when, in June 1942, the Japanese attacked Dutch Harbor, Attu, and Kiska in the Aleutian Islands of Alaska—then a U.S. territory.

In the 1950s, increasing tensions between the United States and the Soviet Union escalated the potential for active military operations in Alaska and Canada. The United States increased its military presence in Alaska to offset the threat from the nearby Soviet mainland. Additionally, hostilities in Korea, which also involved U.S. forces, warranted improvements in both equipment and procedures for severe cold weather operations.

The potential for conflict demanded U.S. preparedness for operations in challenging environments, and a better understanding of the effects of the harsh climate on troop activities became more important. Until 1967, the AAL made investigations of such effects easier.

## “THYROID ACTIVITY IN MEN EXPOSED TO COLD”

An important research objective of the AAL was to study the effects of cold stress on human physiology. Researchers collected extensive data on the diet, physiology, and living habits of Native Alaskan men and women living in the Arctic, specifically, the coastal Eskimos of Point Lay and Wainwright, the inland Eskimos of Anaktuvuk Pass, and the Athapascan Indians of Fort Yukon and Arctic Village. Most of these Native Alaskans resided in tents or log-sod or moss dwellings and survived by hunting and gathering. Therefore, they were

TERMS/ACRONYMS USED IN THIS CHAPTER	
AAL	Arctic Aeromedical Laboratory, established by the Air Force School of Aviation Medicine, located at Ladd Air Force Base near Fairbanks, Alaska
AEC	Atomic Energy Commission [predecessor to the Department of Energy]
basal metabolism	the amount of energy needed to maintain essential basic body functions
endemic	a disease or disorder constantly present in a particular region or specific group of people
goiter	enlargement of the thyroid gland, due to lack of sufficient iodine in the diet
half-life	the time for the activity of a substance to decay to half its original level
iodine-131 (I-131)	a radioactive isotope of iodine; used in diagnosis of thyroid disorders and the treatment of toxic goiter and thyroid carcinoma; I-131 has a half-life of eight days
isotope	one of two or more atoms with the same atomic number but with different atomic weights. (The nuclei of isotopes have the same number of protons but different numbers of neutrons. Isotopes usually have very nearly the same chemical properties but somewhat different physical properties.)
microcurie	a unit of radioactivity. One one-millionth curie, or the quantity of radioactive material in which the number of disintegrations is $3.7 \times 10^4$ per second
uptake	the absorption of a nutrient, chemical (including radioactive material), and medicine by an organ or tissue
thyroid (gland)	an organ of the endocrine system; the thyroid secretes hormones that control body metabolism
tracer	a small quantity of radioactive substance introduced into the body so that its distribution, processing, and elimination can be followed by using a radiation detector

any, the thyroid gland served in human acclimatization to cold and to determine if the thyroid activity of Native Alaskans was responsible for their apparent adaptation to Arctic conditions. The thyroid gland was chosen as the focal point of the AAL's research because previous studies had demonstrated: (1) increased thyroid activity in animals correlated with severe exposure to cold, (2) involvement of the thyroid in human acclimatization to cold,<sup>3</sup> and (3) elevated basal metabolism in Native Alaskans.<sup>4</sup> Iodine-131 (I-131) was the tracer of choice for examining the thyroid because of its natural tendency to concentrate there.

Eighty-five<sup>5</sup> Eskimos and seventeen Athapascan Indians participated in this study. A control group of servicemen who were not Native Alaskans was made up of six U.S. Army servicemen, whose regular activities involved exposure to cold, and thirteen Air Force servicemen, who usually worked indoors.<sup>6</sup> Participants were all healthy, "normal" individuals.<sup>7</sup>

During the study, which lasted from August 1955 to February 1957, a total of 200<sup>8</sup> tracer doses of I-131 were

constantly engaged in outdoor activities that involved considerable exposure to cold.

The AAL's study, "Thyroid Activity in Men Exposed to Cold," sought to uncover what role, if

administered to examine the levels of I-131 in blood, thyroid, urine, and saliva samples.<sup>9</sup> For some subjects, fasting blood samples were taken to analyze serum cholesterol and protein-bound I-131.<sup>10</sup> The study also

involved clinical examinations and in some cases, detailed assessments of iodine intake, basal metabolism, and environmental exposure.

The standard administration for radioiodine tracer studies of the time, as authorized by the Atomic Energy Commission (AEC), was fifty microcuries.<sup>11</sup> Although individual administrations were kept as close to fifty microcuries as possible, due to the long transport of the I-131 from Oak Ridge, Tennessee, and the radioisotope's short half-life, administration generally ranged from eighteen to sixty-five microcuries. In one case, nine microcuries were administered.<sup>12</sup> Overall, sixty-eight Native Alaskans from Wainwright, Point Lay, Fort Yukon, and Point Hope received a single tracer dose of I-131 during the study. Twenty-two Native Alaskans and all nineteen servicemen received two doses of I-131; a group of twelve Anaktuvuk Pass Eskimos and Arctic Village Indians participated in three facets of the study and received three doses of I-131 tracer.<sup>13</sup>

Evaluation of thyroid function indicated abnormally high and rapid I-131 uptakes in the Anaktuvuk Pass Eskimos and the Arctic Village Indians. This result was associated with low iodine intake and a high incidence of thyroid enlargement and, therefore, was attributed to endemic goiter rather than an indication of the effect of cold exposure on thyroid function.<sup>14</sup>

Generally, data yielded no results of statistical significance, and researchers concluded that on the basis of the data:

. . . the thyroid does not play any significant role in human acclimatization to the arctic [sic] environment when the cold stress is no greater than what is normally encountered by soldiers engaged in usual arctic [sic] service or by Alaskan Eskimos or Indians in the course of their normal life or activities.<sup>15</sup>

#### SUMMARY

The results of the study, "Thyroid Activity in Men Exposed to Cold," did not support the findings of earlier studies, which indicated that the thyroid

played a significant role in human acclimatization to cold. However, over time, improvements in blood analysis techniques enabled other researchers to demonstrate that there is a relation between the thyroid and acclimatization to cold.<sup>16</sup>

In retrospect, concerns were raised about the possible vulnerability of the Native Alaskan participants in the study, particularly because few of the Native Alaskan subjects spoke English and there were language barriers for interpreting some of the procedures (e.g., Native Alaskan languages do not have a word for "radiation.") The AAL Director of Research at the time of the study, Kaare Rodahl, M.D., maintained that every care was taken to work through village elders, medical services were provided to the Native Alaskans, and they were given the chance to refuse to participate. In addition, Dr. Rodahl stated that the radioactive tracer used in these studies was, in his opinion, "a harmless medical substance that posed no risk to the subjects due to the small amount of radiation involved."<sup>17</sup>

Although I-131 has now been replaced for clinical usage by a shorter lived radioisotope, I-123, the doses used in the study were within the standard doses of the time.<sup>18</sup> I-131 was the only radioactive tracer readily available for use in the 1950s when the AAL thyroid function study was conducted.<sup>19</sup>

To address congressional and Native Alaskan concerns about this study, the Institute of Medicine (IOM) of the National Research Council established a committee to evaluate these studies and determine if any follow-up needs to be provided. In its report, the IOM wrote:

"After examining the records, analyzing the health effects and talking with research subjects as well as researchers, the Committee concludes that the probability of physical harm to the AAL study subjects is negligible, and thus that the subjects were not harmed. From an ethical perspective, the Committee concludes that aspects of the AAL study, especially the informed consent process, were flawed even by 1950s standards and thus the Alaska Natives who participated and, to a lesser extent, the military subjects were wronged."<sup>20</sup>

## 48 Chapter 4—Iodine-131 Study Conducted by the Arctic Aeromedical Laboratory

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### NOTES

(To obtain copies of the following documents, see appendix 2.)

1. This date is based on Air Force historical documents. A date of 1951 is given by the National Research Council, Institute of Medicine, Arctic Aeromedical Laboratory's Thyroid Functions Study: A Radiological Risk and Ethical Analysis (Washington, D.C.: National Academy Press, 1996), p. 2.
2. "History of the Arctic Aeromedical Laboratory," pp. v, 24 (with Air Force Memorandum 22 June 94).
3. As cited in Arctic Aeromedical Laboratory, "Thyroid Activity in Men Exposed to Cold," Technical Report 57-36, p. 1.
4. Statement of Dr. Chester Pierce Before the Advisory Committee on Human Research Experiments, 16 March 1995, p. 4.
5. The text of the AAL Technical Report 57-36 (pp. 3, 81) states "...19 whites, 84 Eskimos and 17 Indians." However, the number of Eskimos who participated in the study was reported as 85 in several of the Technical Report's tables.
6. Arctic Aeromedical Laboratory, "Thyroid Activity in Men," p. 2.
7. Ibid, p. 6.
8. The text of the AAL Technical Report 57-36 (pp. 3, 81) states, "A total of 200 tracer experiments was made in..." The number of doses received per participant indicates only 186 doses of I-131 were used.
9. Arctic Aeromedical Laboratory, "Thyroid Activity in Men," p. 3-5.
10. Ibid, p. 5.
11. National Research Council, Institute of Medicine, The Arctic Aeromedical Laboratory's Thyroid Functions Study: A Radiological Risk and Ethical Analysis (Washington, D.C.: National Academy Press, 1996), p. 12.
12. Arctic Aeromedical Laboratory, "Thyroid Activity in Men," p. 3; National Research Council, The Arctic Aeromedical Laboratory's Thyroid Functions Study, p. 12.
13. National Research Council, The Arctic Aeromedical Laboratory's Thyroid Functions Study, p. 36.
14. Arctic Aeromedical Laboratory, "Thyroid Activity in Men," p. 82.
15. Ibid, pp. 80-81.
16. As cited in National Research Council, The Arctic Aeromedical Laboratory's Thyroid Functions Study, pp. 21, 76.
17. Arctic Aeromedical Laboratory, "Thyroid Activity in Men," p. 85.
18. National Research Council, The Arctic Aeromedical Laboratory's Thyroid Functions Study, pp. 12, 79.
19. Ibid, p. 2.
20. National Research Council, The Arctic Aeromedical Laboratory's Thyroid Functions Study, p. 5



## CHAPTER

# 5

# INTENTIONAL ATMOSPHERIC RELEASES OF RADIOACTIVE MATERIAL

The United States emerged from World War II with a nuclear monopoly—a position it held for only four years. The Soviet Union conducted its first atmospheric nuclear weapons test in August 1949. On 23 September 1949, President Truman announced that the Soviets possessed a nuclear bomb and were undertaking a large nuclear weapon development program. This development highlighted two intelligence and weapons development requirements for the national security infrastructure: (1) the long-range detection of radiological materials to monitor the Soviet Union’s nuclear weapons development program and (2) an increased need for developing the United States’ nuclear arsenal.

Earlier in 1947, General Dwight D. Eisenhower, Army Chief of Staff, assigned the Army Air Forces (AAF) the mission of long-range detection of Soviet nuclear tests. The AAF was responsible for worldwide detection of atomic explosions; the collection, analysis, and evaluation of required scientific data; and the appropriate dissemination of the resulting intelligence.<sup>1</sup> The long-range detection of radioactive releases was an integral component in the development of methods to collect data on foreign countries’ production of radioactive materials and their atmospheric nuclear weapons tests.

One means of developing and testing methods for the long-range detection of radioactive material was to conduct an atmospheric release test. The Department of Defense participated in one such atmospheric release, which was in December 1949 in Washington State. The test was known as “Green Run.” The premise of Green Run was that aerial monitoring and sampling of a radioactive cloud, even at great distances from its release point, could provide evidence of the presence of radioactive materials.

Another intentional atmospheric release of radiation occurred during the Atomic Energy Commission’s (AEC) radioactive lanthanum (RaLa) program conducted at Los Alamos Scientific Laboratory (LASL). The RaLa program was a series of implosion tests critical to the development and improvement of the plutonium bomb.

## GREEN RUN

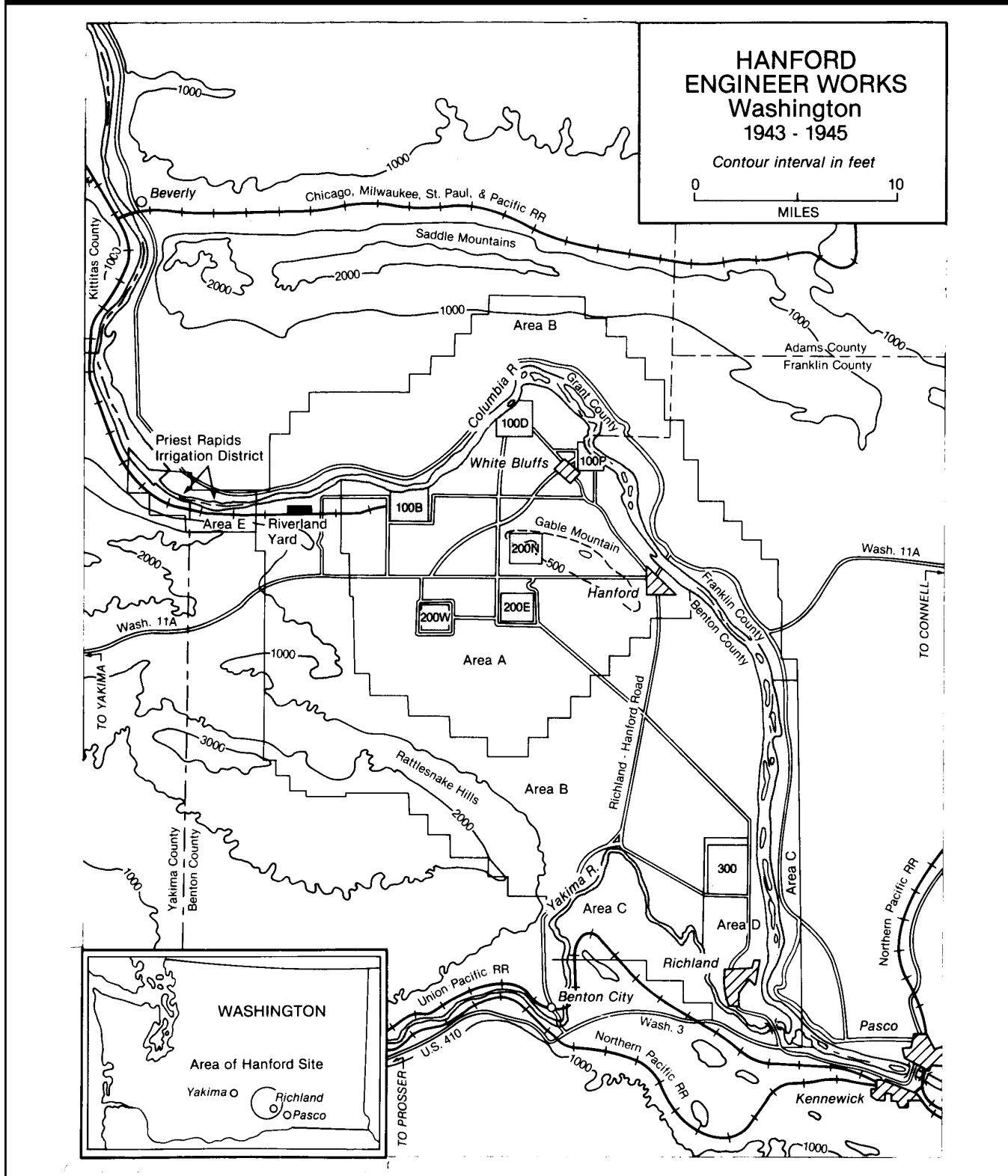
### The Hanford Site

The Manhattan Project was the code name for scientific research that was conducted to build an atomic bomb during World War II. In 1943, Manhattan Project officials selected a site near Richland, Washington, to produce plutonium, an element used in nuclear weapons. This site, known as the Hanford Nuclear Reservation, became the world’s first plutonium factory (see map 1). Hanford production facilities expanded between 1947 and 1953 to meet increased Cold War demands for nuclear weapons materials.<sup>2</sup> Management responsibility for the Hanford Nuclear Reservation transferred from the Manhattan Project to the AEC in 1947.

### What Was Green Run?

After irradiation in one of Hanford’s four nuclear reactors, nuclear fuel was normally stored for 83 to 101 days before it was processed to extract plutonium.<sup>3</sup> This cooling period allowed many radioactive materials with short half-lives to decay.

MAP 1 THE HANFORD ENGINEER WORKS



To release sufficient radioactive material into the environment to conduct the long-range monitoring test, fuel that had been cooled for only sixteen days (i.e., “green” material) was used. The use of the green material resulted in a much greater release of iodine-131 (I-131) and xenon-133 (Xe-133) into the environment than would have occurred under normal production conditions.

Preparations for Green Run

On 25 October 1949, representatives of the Air Force, the AEC, and the General Electric Company (Hanford’s postwar contractor) agreed on a plan for a larger-than-routine release of radioactive material from Hanford for the Green Run long-range detection test.<sup>4</sup> The report “Dissolving of Twenty Day Metal at Hanford” states that Hanford officials planned to release into the environment approximately 4,000 curies of I-131 and 7,900 curies of Xe-133.<sup>5</sup>

The Health Instrument Division (HID) of the General Electric Company, responsible for public health at the Hanford Nuclear Reservation in 1949, required the following weather conditions before initiating Green Run:

- Local inversion of air (a layer of cold air near the ground was required to help prevent released radioactive materials from reaching the ground before they were well diluted)
- No rain or fog, which would prevent the airborne radiological data collection efforts
- Wind speed at less than 15 miles per hour at 200 feet
- West to southwest winds to facilitate airborne radiological data collection effort

ACRONYMS USED IN THIS CHAPTER	
AAF	Army Air Forces
ACHRE	Advisory Committee on Human Radiation Experiments
AEC	Atomic Energy Commission [predecessor of the Department of Energy]
DoD	Department of Defense
HEDR	Hanford Environmental Dose Reconstruction Project
HID	Health Instrument Division of the General Electric Company
LASL	Los Alamos Scientific Laboratory, now called the Los Alamos National Laboratory (LANL)
RaLa	radioactive lanthanum
TSP	Technical Steering Panel
USAF	United States Air Force
Xe-133	xenon, the 54th element on the periodic chart; produced artificially in nuclear reactors and nuclear explosions; has a half-life of 5.7 days

- Conditions allowing the radioactive emissions to stay aloft long enough to be measured.<sup>6</sup>

Because weather conditions were critical to the test, the Air Force’s Air Weather Service expanded existing weather forecasting and observation stations.<sup>7</sup> The Air Force also added a forecaster to the Spokane Air Force Base weather station specifically for the Green Run test.<sup>8</sup>

The Green Run Event

Unusually inclement weather in late November 1949 caused a one-week postponement of the test. Test planners prepared to begin the Green Run release on the night of 2 December. An updated forecast predicted acceptable weather conditions for 2 December, that were expected to continue for the twelve-hour period needed to complete the release.<sup>9</sup>

Originally, the Air Force had recommended beginning the release between 1:00 a.m. and

TERMS USED IN THIS CHAPTER

containment	the policy of attempting to prevent the influence of an opposing nation or political system from spreading
curie	a unit of radioactivity
gamma radiation	electromagnetic, rather than charged particle, radiation; highly penetrating
“green” period	the period before decay, or cooling, of radioactive materials in nuclear fuel
half-life	the time for the activity of a substance to decay to half its original level
iodine-131 (I-131)	a radioactive isotope of iodine; used in diagnosis of thyroid disorders and the treatment of toxic goiter and thyroid carcinoma; I-131 has a half-life of eight days
Los Alamos Human Studies Project Team	A research team that investigated Los Alamos’ involvement in human radiation experiments
Manhattan Project	the top-secret project during WWII to build an atomic bomb; Los Alamos was selected as the bomb laboratory site; Hanford, Wash. and Oak Ridge, Tenn. were selected as the sites for plutonium production
nuclear weapon	a weapon where energy results from the fission of heavy elements or fusion of hydrogen isotopes
point source	radioactive material that is manually placed in a known spot; usually used for calibration or measurement purposes and re-covered after the test
RaLa	radioactive lanthanum
scrubbers	a device designed to prevent the release of radioactive particles
World War II	1939-1945, fought between the Allies (Great Britain, France, the Soviet Union, Canada, and the United States as well as other nations) and the Axis (Germany, Italy, Japan, and other countries)

3:00 a.m. on 3 December so that the bulk of the radioactivity would be released after dawn. This would make the task of tracking the radiation easier. However, a local temperature inversion (one of the weather conditions required by test planners to initiate the test) was predicted to end on the morning of 3 December. The Air Force and HID managers compromised on a start time of 8:00 p.m. on 2 December.<sup>10</sup>

The Green Run release began at 8:00 p.m. on 2 December 1949. The material was released from a spare dissolver in Hanford’s “T” plant (see figure 1). Air scrubbers were intentionally deactivated for Green Run to maximize the radioactive material released into the atmosphere.

The Air Force used air-sampling aircraft mounted with multiple radiological measuring devices to monitor radiation levels in the Hanford area.<sup>11</sup> Air sampling began near dawn on the morning of 3 December and continued until the afternoon of the same day.<sup>12</sup>

Weather conditions during the release were unstable. Several unpredicted changes in the weather occurred during the twelve-hour release. Increased wind speeds decreased the strength of the inversion, and a shift in the wind direction half-way through the release affected the



Figure 1 Hanford's "T" plant, from where the Green Run material was released

distribution of radiation and the amount that was deposited locally.<sup>13</sup>

#### Measuring Contamination

Estimates vary about the actual quantity of radioactive material released into the environment as a result of the Green Run release. The report "Dissolving of Twenty Day Metal at Hanford" estimates that up to 7,780 curies of I-131 (almost twice the original estimated amount) and 20,000 curies of Xe-133 (approximately two and one-half times the original estimated amount) were released.<sup>14</sup> Reasons for the discrepancies in the estimated amounts before and after the test are unknown.

In addition to the Air Force cloud sampling, ground-based static and mobile radiological monitoring devices were used to measure radiation levels. The overall pattern of deposited I-131 on vegetation after the Green Run release "extended in an elongated shape about 40 miles wide and 200 miles long lying northeast and southwest of the" Hanford site.<sup>15</sup>

Approximately 2,500 vegetation samples were taken from October through December 1949, about one-half taken after the Green Run release.<sup>16</sup> According to the Advisory Committee on Human Radiation Experiments (ACHRE) study on the Green Run release, "Measurements of radioactivity on vegetation produced readings that, while temporary, were as much as 400 times the then-

‘permissible permanent concentration’ on vegetation thought to cause injury to livestock.”<sup>17</sup> Animal specimens collected from the Hanford reservation “received thyroid irradiation varying from tolerance to 80 times tolerance daily.”<sup>18</sup>

The HID’s December 1949 activity report stated:

Widespread contamination by I-131 occurred as a result of a specifically requested dissolving at short cooling time. The prediction that this could be accomplished once with negligible risk to personnel was supported by the experimental observations. However, the resultant activity came close enough to significant levels, and its distribution differed enough from simple meteorological predictions that the H.I. Divisions [sic] would resist a proposed repetition of the test.”<sup>19</sup>

#### Access to Further Information on Green Run

The Technical Steering Panel (TSP) of the Hanford Environmental Dose Reconstruction (HEDR) Project was established in 1987 to address public health concerns. The TSP’s main objective was to estimate radiation doses to Hanford residents. Although Green Run was not a major emphasis of the TSP, data related to Green Run were incorporated into this dose reconstruction effort.

Radiological monitoring data routinely collected for the Hanford area were vital tools used by the TSP experts to evaluate the quantity of radioactive material released into the environment as a result of day-to-day plant operations. The HEDR project scientists estimated that 98 percent of the radiation doses received by Hanford area residents were the result of I-131. According to the TSP, “[t]he Green Run release contributed about 2.3 percent of the total I-131 released [from the Hanford Reservation] from 1944 through 1951.”<sup>20</sup>

Measurements of radioactive materials vented to the atmosphere and released to soils and the Columbia River began with the start-up of Hanford facilities in 1944. Environmental studies expanded to include measurements of radioactive materials in the air, ground, vegetation, food, wildlife, Columbia

River water, drinking water, sediment, fish, and other aquatic life.

The TSP disbanded on 31 December 1995. Additional information on the Green Run and other Hanford releases can be obtained from the Hanford Health Information Network (HHIN), 2400 Smith Tower, 506 Second Avenue, Seattle, Washington 98104, Telephone: (206) 223-7660.

#### THE RALA PROGRAM

##### The Los Alamos Scientific Laboratory Site

The RaLa program was developed at LASL in New Mexico. LASL’s main research goal was to study weapon implosion dynamics. The Air Force involvement in the RaLa tests was limited to flying a specially equipped B-17 aircraft to track the location and level of contamination in the atmosphere resulting from three of the 254 RaLa tests. The purpose of these air sampling tests was to examine the military’s capability to track radiological material released into the environment.

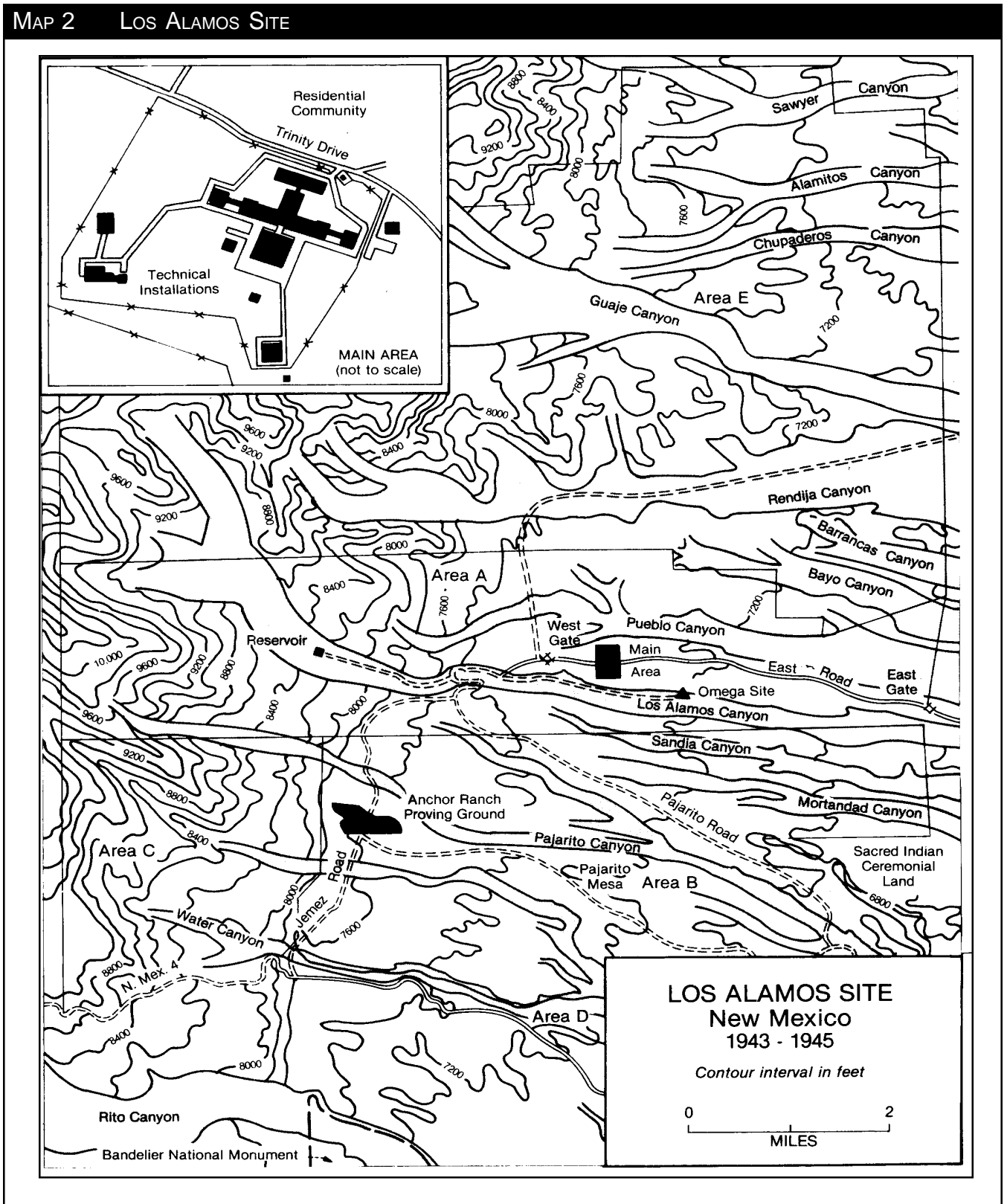
##### The RaLa Studies

From September 1944 to March 1962, 254 implosion experiments involving various amounts of high explosives and radioactive lanthanum were conducted at LASL. The entire RaLa program was conducted in Technical Area 10 in Bayo Canyon (see map 2).

For these implosion tests, a lanthanum-140 (La-140) source was placed inside a high-explosive test assembly. La-140 was used primarily because its short half-life of forty hours ensured short-lived contamination of the test site. Gamma radiation from the La-140 provided information on the progression of the implosion process. No nuclear bombs were detonated during the RaLa program.

According to the Los Alamos Human Studies Project Team, the Atmospheric Physics Laboratory of the Air Force Cambridge Research Laboratory

MAP 2 LOS ALAMOS SITE



took advantage of three of the RaLa events to test radiation detection equipment. A calibration effort was conducted after the last tracking flight.

The three atmospheric tracking tests were conducted in March and April 1950. The purposes of the atmospheric tracking portion of the RaLa tests were:

first to track a radiological gaseous cloud as long as possible, second, to study the rate at which the ionization produced by the radioactive matter decreases and diffuses, and finally to analyze the “fallout” of radioactive substances from the cloud.<sup>21</sup>

The radiological data sampling equipment was mounted in the nose of a B-17 aircraft flown out of Kirtland Air Force Base, New Mexico.<sup>22</sup> The atmospheric sampling tests were divided into three segments: measurement of background conductivity, the tracking of the radioactive cloud, and measurement and mapping of the radioactive “fallout.”<sup>23</sup>

To track the progress of the radiological cloud, the B-17 attempted to fly through the cloud’s center and collect radiological data.<sup>24</sup> The aircraft continued to track the course of the cloud for one and one-half to two hours for each of the three tests. During the 29 March 1950 test, the cloud was tracked as far away as Waltrous, New Mexico, approximately seventy miles from the Bayo Canyon test site.<sup>25</sup> The second tracking test was canceled before completion because the radioactive cloud drifted over restricted airspace at Los Alamos. During the third test on 6 April 1950, the cloud was only visible for a few minutes, making it difficult for the aircraft to fly routes similar to the first test. The tracking lasted two hours.<sup>26</sup> In July 1950, a B-17 flew over an uncovered point source of RaLa to calibrate the onboard instruments. After the flyover, the RaLa container was closed and returned to LASL. No radioactive material was released into the environment during this calibration effort.

Access to Further Information on RaLa

In January 1994, the Human Studies Project Team was established to collect information on Los Alamos National Laboratory participation in human radiation experimentation and the RaLa program. None of the RaLa data collected contained information suggesting that any human experimentation of any kind was planned or performed in conjunction with any RaLa tests. For more information on the RaLa studies, contact the Department of Energy (see appendix 2 for information).

#### NOTES

(To obtain copies of the following documents, see appendix 2.)

1. Memorandum, from General Dwight D. Eisenhower, Army Chief of Staff, to Commanding General, AAF, Subject “Long Range Detection of Atomic Explosions,” 16 September 1947.
2. U.S. Department of Energy, *Human Radiation Experiments: The Department of Energy Roadmap to the Story and the Records* (Oak Ridge, Tenn.: Office of Scientific and Technical Information, 1995), p. 76.
3. H. J. Paas and W. Singlevich, *Radioactive Contamination in the Environs of the Hanford Works for the Period October, November, December 1949* (Hanford Works, Wash.: General Electric Co., 2 March 1950), p. 3.
4. Memorandum, from Chief of Staff, to Commander, Military Air Transport Service, Subject: “Detection of Stack Effluents,” 10 November 1949.
5. Lt. W. E. Harlan, D. E. Jenne, and J. W. Healy, *Dissolving of Twenty Day Metal at Hanford* (Hanford Works, Wash.: General Electric Co. Nucleonics Department, 1 May 1950), p. 7.
6. *Ibid*, pp. 5–6.
7. *Ibid*, p. 8.



8. Ibid.
9. Ibid, p. 18.
10. Ibid, p. 7.
11. Ibid, pp. 12–13.
12. Ibid, p. 46.
13. Ibid, pp. 20–25.
14. Ibid, pp. 26–28.
15. H. J. Paas and W. Singlevich, Radioactive Contamination, p. 3; H. M. Parker, Health Instruments Divisions Report for Month of December 1949 (Hanford Works, Wash.: Health Instruments Division, General Electric Co., 6 January 1950), p. 19.
16. H. J. Paas and W. Singlevich, Radioactive Contamination, p. 13.
17. Advisory Committee on Human Radiation Experiments, Final Report (Washington, D.C.: U. S. Government Printing Office, October 1995), p. 511.
18. Lt. W. E. Harlan, D. E. Jenne, and J. W. Healy, Dissolving Twenty Day Metal, p. 3.
19. H. M. Parker, Health Instruments Divisions Report, p. 3.
20. Technical Steering Panel of the Hanford Dose Reconstruction Project, “The Green Run,” Fact Sheet #12, p. 4.
21. Samuel C. Coroniti, Report on the Atmospheric Electrical Conductivity Tests Conducted in Vicinity of Los Alamos Scientific Laboratories, New Mexico (Cambridge, Mass.: Atmospheric Physics Laboratory, Geophysical Research Directorate, Air Force Cambridge Research Laboratories, 26 May 1950), p. 1.
22. Ibid, pp. 3, 7.
23. Ibid, p. 3.
24. Ibid, p. 4.
25. Ibid, pp. 9, 12.
26. Ibid, pp. 12–14.



# CHAPTER 6

# RADIOLOGICAL WARFARE

## INTRODUCTION

During World War II, scientists explored military uses of radiological materials. The ability to manufacture radioactive materials had already been developed. Scientists began to explore the feasibility of dispersing radioactive material over a land area to deny its use to the enemy. Discussions included using such radiological weapons to destroy crops, poison water supplies, or force the enemy to abandon a critical facility.

Radiological warfare involves:

the use of radioactive substances to produce personnel casualties or to deny the enemy full use of terrain or installations due to the physiological damage which will result from continued occupation of the area.<sup>1</sup>

The dispersal of radiological agents does not involve an atomic bomb but rather uses conventional explosives to disperse radioactive material over a given area.

The Allies knew that Germany had a fledgling atomic weapons development program and that it might also be considering a radiological warfare program. Therefore, the United States developed contingency plans for a response to German use of such weapons. However, allied efforts quickly crippled the German atomic bomb effort, and the threat of their use of any radiological warfare program ceased. As the U.S. atomic bomb program progressed from theory to fact, the United States' interest in radiological weapons decreased.

## RECONSIDERATION OF RADIOLOGICAL WARFARE

After World War II, the United States began an atomic bomb testing program. One test involved an atomic weapon detonated underwater at Bikini Atoll, Pacific Proving Ground, Marshall Islands. This test, known as Shot BAKER, was conducted in July 1946 as part of Operation CROSSROADS. An atomic weapon was suspended ninety feet beneath a ship anchored in the midst of a target fleet.<sup>2</sup> The test weapon had the same power as the bomb dropped at Nagasaki (yield equal to 21 kilotons of TNT). "The detonation caused the fleet to be bathed in radioactive water spray and radioactive debris from the lagoon bottom."<sup>3</sup> Shot BAKER resulted in widespread contamination of the target fleet and consequently renewed interest in the idea of radiological warfare.

Joseph G. Hamilton, M.D., one of the leading civilian scientists studying radiological warfare, wrote a memorandum to the Army in December 1946 discussing not only how much damage radiological warfare could do but also the need for a greater understanding of how the United States could combat the effects of radiological weapons. Dr. Hamilton wrote:

I strongly feel that the best protection that this nation can secure against the possibilities of

### ACRONYMS USED IN THIS CHAPTER

ACHRE	Advisory Committee on Human Radiation Experiments
AEC	Atomic Energy Commission
DoD	Department of Defense
TNT	trinitrotoluene (a high explosive, used for blasting)

**TERMS USED IN THIS CHAPTER**

attenuation	lessen in severity, value, amount, intensity, etc.; weaken
atoll	a ring-shaped coral island nearly or completely surrounding a lagoon
curie	a unit of radioactivity
Dugway Proving Ground	Army Chemical Corps facility in the Utah desert
half-life	the time for the activity of a substance to decay to half its original level
isotope	atoms of an element with the same number of protons but different numbers of neutrons
kilotons	a thousand tons; the energy of a nuclear explosion that is equivalent to the explosive power of 1,000 tons of TNT
Manhattan Project	the top-secret project during WWII to build an atomic bomb; Los Alamos was selected as the bomb laboratory site; Hanford, Wash. and Oak Ridge, Tenn. were selected as the sites for plutonium production
nuclear fission	the splitting of the nuclei of atoms into two fragments of approximately equal mass accompanied by conversion of part of the mass into energy: the principle of the atomic bomb
point source	radioactive material that is manually placed in a known spot; usually used for calibration or measurement purposes and re-covered after the test
tantalum	a rare corrosion-resistant, metallic chemical element used to make nuclear reactors, aircraft, and missile parts, etc.
shot	test
weathering	the effects of weather (wind, rain, etc.) on the residual radioactive material after its initial dispersal
World War II	1939-1945, fought between the Allies (Great Britain, France, the Soviet Union, Canada, and the United States as well as other nations) and the Axis (Germany, Italy, Japan and other countries)

radioactive agents being employed as a military tool by some foreign power is a thorough evaluation and understanding of the full potentiality of such an agent.<sup>4</sup>

There were those who argued that radiological warfare could be a more humane form of warfare. It could effectively contaminate an area without necessarily causing immediate death. The radioactivity level of the weapon and the amount of time spent in the contaminated area would determine the possibility of injury or death. The idea of using radiological warfare weapons to deny an enemy use of an area by contamination was discussed within the military community in the later months of 1946 and into 1947. The interest in radiological warfare became a starting point for the establishment of programs and panels.<sup>5</sup>

THE JOINT RADIOLOGICAL WARFARE STUDY PANEL

In May 1948, the Atomic Energy Commission (AEC) and the Department of Defense (DoD) created a joint study panel chaired by W.A. Noyes, a chemist from the University of Rochester. The panel, called the Noyes Panel, included DoD and AEC officials as well as

non-Government experts. The panel's purposes were to evaluate the feasibility of an offensive radiological warfare program and to establish an understanding of how to defend against a radiological attack. The panel met six times between May 1948 and November 1950.

At the panel's first meeting on 23 May 1948, panel members recommended that the study be broken down into three categories: medical and biological research on the effects of radiation and radioactive materials conducted by the Army Chemical Corps Toxicity Laboratory at The University of Chicago, chemistry studies on the production of radioactive materials for use in radiological warfare carried out mainly by the AEC, and military uses and dissemination of possible radiological warfare munitions conducted mainly by the Chemical Corps.<sup>6</sup>

#### THE ARMY CHEMICAL CORPS TEST SAFETY PANEL

Concurrent with the Noyes Panel, the Army Chemical Corps established a Test Safety Panel in May 1949 to review the test designs of radiological warfare tests and their impact on the safety of the local civilian population.<sup>7</sup> The panel, chaired by Joseph Hamilton, M.D., consisted of prominent Government and civilian physicians and physicists.

The panel reviewed Chemical Corps proposals for radiological warfare tests at Dugway Proving Ground. During the review of the Dugway testing program, the Test Safety Panel investigated possible dangers, such as contamination to water supply, food, crops, and animal population.<sup>8</sup> The Chemical Corps was responsible for the safety of civilian and military personnel working at Dugway Proving Ground.<sup>9</sup> Under Dr. Hamilton's leadership, the panel examined and discussed safety concerns, eventually accepting the test program with the understanding that the first two tests would be subject to review for radiological safety before any further tests were allowed.<sup>10</sup>

On 15 September 1949, a Test Safety Panel report stated, "The Panel was favorably impressed by the careful consideration given to the manifold problems of

protection and undue dissipation of radioactive materials where serious problems might arise."<sup>11</sup>

#### RADIOLOGICAL AGENT SELECTION

During the radiological warfare testing, scientists were researching a variety of radioactive elements for toxicity levels to determine their feasibility as radiological warfare agents. One 1947 memorandum discussed the criteria for radiological agent selection:

- Toxicity by inhalation
- Toxicity by application to the body or to clothing
- Rapidity of action [how fast it affects area or personnel]
- Persistency [how long it remains a danger]
- Stability of the radioactive element [half-life]
- Penetrability of protective devices
- Availability in required quantities.<sup>12</sup>

The elements that met the above criteria included radiological agents with half-lives that ranged from seconds to centuries. It was generally thought that the military operations would benefit most from a radioactive element that had a half-life between several weeks and one year. If the element had too short a half-life, it would no longer be sufficiently active by the time it reached the test site or the battlefield. An excessively long half-life would cause long-term area denial, which would keep U.S. troops from entering a battlefield they might need to use or cross later. The selection processes would enable scientists and researchers to locate the best elements to use for radiological warfare munitions.

#### THE TEST PROGRAMS

##### Oak Ridge Tests

While the majority of the radiological warfare field testing was conducted at Dugway Proving Ground in Utah, the first three field tests were conducted at Oak Ridge, Tennessee. In 1948, Oak Ridge Scientific Laboratory (ORSL) scientists tested

radioactive lanthanum and radioactive tantalum. They also researched the feasibility of zirconium and columbium as radiological warfare agents.

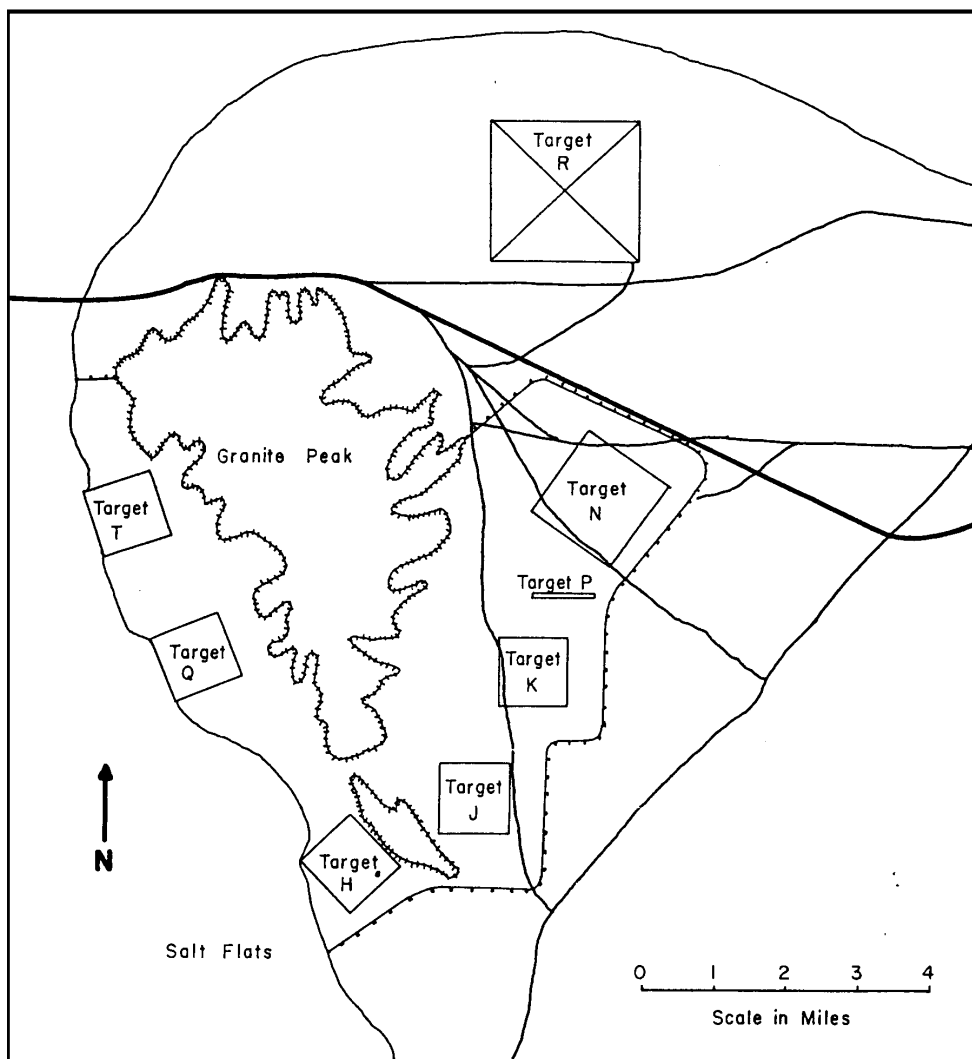
Radioactive lanthanum was placed at designated locations in a field. Measurements were taken at varying distances from the source and then the sources were removed from the field; the sources left no residual radiation in the environment.<sup>13</sup> The first test involved three radioactive sources of approximately 1,280, 100, and 20 curies of lanthanum. The second test involved only the 1,280-curie source. In a third test involving radioactive

tantalum, a grid pattern of more than 250 tantalum wires was placed over a rectangular plot of land. Measurements of radioactive intensity were taken at certain points in the grid, and the wires were removed. These tests left no residual contamination in the environment.<sup>14</sup>

### Dugway Tests

A radiological munition field testing program began at Dugway Proving Ground in Utah in October 1949 and continued until 1952. Field tests used only small amounts of radioactive material so that radiation detection devices could map the dispersal pattern. There was no human experimentation associated with the radiological warfare munition testing program.

Design efforts originally focused on using an explosive force to distribute the radiological agent. Later in the program's development, the designs focused on a munition that would release grooved spheres capable of more efficiently scattering the material. Radioactive tantalum was used because of its availability. In total, approximately 13,690 curies of radioactive tantalum were released onto the ground in the form of dust, small particles, and pellets during the Dugway testing. In contrast, radiological warfare would have required millions of curies per square



Radiological warfare weapons test target area at Dugway Proving Ground, Utah

mile to achieve its military purpose.<sup>15</sup> Toward the end of the program in 1952, there were plans to test a 100,000-curie device, but the program was severely curtailed, and the test of this prototype weapon did not take place.

### Munition Tests

Eighteen field tests were conducted at Dugway Proving Ground by the Army Chemical Corps. Two of these examined the ability to decontaminate an area that had already been contaminated by previous field tests, and another field test examined the attenuation effects of various building materials (such as cinder block and plywood) on radiation levels. This test used a transient point source, leaving no residual radioactivity in the environment. A total of sixty-four munitions were used for all the tests.

The following is a list of field tests beginning in October 1949 and ending in September 1952 (also see table 1).

- The first radiological warfare munition test was conducted on 22 October 1949. The objective was to study how a radiological contaminant spreads when dispersed by a bomb. A 2,000-pound radiological bomb containing 260 curies of tantalum-182 was detonated.<sup>16</sup>
- A second munition test (Field Test 276) was conducted on 30 November 1949. Its objective was the same as the first, but this time the 2,000-pound radiological bomb contained 1,506 curies of tantalum-182.<sup>17</sup>
- Field Test 287 was an airburst test of a single 2,000-pound radiological bomb, E59R1, filled with radioactive tantalum particles. It was conducted on 4 August 1950. The objective of this test was to determine the effect of the type of explosive used on the dispersion of radioactive tantalum particles over large areas and to assess the radiation field produced, the airborne cloud generated, and the effect of weathering on the radioactive tantalum. The radiological material, tantalum-182, was activated to a level of 480 curies.<sup>18</sup>
- Field Test 288 occurred on 6 August 1950. It was a drop test of a single 2,000-pound radiological bomb, E59R2, filled with radioactive tantalum particles. The objective was to determine the effect of the type of explosive used in the 2,000-pound radiological bomb, E59R1, on the dispersion of radioactive tantalum particles over large areas and to assess the radiation field produced, the airborne cloud generated, and the effect of weathering on the contamination. The radioactive tantalum was activated to a level of 480 curies. The test was intended to be an airburst; however, due to mechanical malfunction, the bomb exploded on impact.<sup>19</sup>
- On 11 August 1950, Field Test 293 was conducted. It was a static test of four shaped-charge sections of radiological bomb, E59, filled with radioactive tantalum particles. The objective was to determine the effect of shaping the explosive charge used in the bomb on the dispersion of radioactive tantalum particles and to assess the radiation field produced. Each of the four bomb sections was loaded with 26 curies of radioactive tantalum, for a total of 104 curies.<sup>20</sup>
- Field Test 289 was conducted on 5 September 1950. It was an airburst test of a single radiological bomb, E65, filled with radioactive tantalum particles. The test objective was to determine the effect of the type of explosive used in the bomb on the dispersion of radioactive tantalum particles and to assess the field of radiation produced by the dispersal. The 2,000-pound bomb contained approximately 930 curies.<sup>21</sup>
- Field Test 290, conducted on 7 September 1950, involved an airburst test of a single

**TABLE 1 RADIOLICAL WARFARE MUNITION TESTS CONDUCTED AT DUGWAY PROVING GROUND, UTAH, 1949 - 1952**

Field Test Date(s)	Test Designation	Type of Test	# of Munitions	Radiological Agent Used	Approx. Curie Total
22 October 1949	None given	airburst	1	tantalum-182	260
30 November 1949	Field Test 276	airburst	1	tantalum-182 (90% wire, 10% particles)	1,506
4 August 1950	Field Test 287	airburst	1	tantalum-182	480
6 August 1950	Field Test 288	groundburst	1	tantalum-182	480
11 August 1950	Field Test 293	static	4	tantalum particles	104
5 September 1950	Field Test 289	airburst	1	tantalum particles	930
7 September 1950	Field Test 290	airburst	1	tantalum particles	3,900
13 September 1950	Field Test 292	static	15	tantalum oxide particles, tantalum chloride dust, agent RA	14
29 May 1951	Field Test 619	static	4	tantalum dust pellets	308
3-4 November 1951	Field Test 620	airburst	9	tantalum dust pellets	131
7 November 1951	Field Test 623	airburst	1	tantalum dust pellets	612
8 November 1951	Field Test 624	airburst	1	tantalum dust pellets	756
20 May 1952	Field Test RW 1-52	static	4	tantalum dust pellets (compressed)	1,405
23-27 May 1952	Field Test RW 2-52	airburst	16	99% tantalum dust, 1% molybdenum sulfide	640
23 September 1952	Field Test RW 1-53	static	4	tantalum pellets	2,164

2,000-pound radiological bomb, E65R2, with a water-cooled jacket, filled with radioactive tantalum particles. The test objective was to determine the effect of the explosive type on the dispersion of the radioactive tantalum particles over large areas and to assess the radiation field produced, the airborne cloud

generated, the effect of weathering on contamination, and the effect of a water-cooled jacket for the bomb in relation to the above factors. The curie level was 3,900.<sup>22</sup>

- Field Test 292, conducted on 13 September 1950, involved static tests of experimental



radiological dust generators, E66R2 and E66R3, filled with radioactive tantalum oxide, radioactive tantalum chloride, and radioactive agent RA (an agent not specified in the report). The objective was to determine the feasibility of dispersing, as ground contamination over a small area, radioactive tantalum oxide particles, radioactive tantalum chloride dust, and radioactive agent RA by thermal generation. The objective was also to assess the radiation field produced and the airborne cloud generated. During this test, fifteen munitions were used and approximately 14 curies were emitted into the environment.<sup>23</sup>

- Field Test 619 was conducted on 29 May 1951. It was a static test of four full-diameter sectional munitions, E65 type, filled with compressed radioactive tantalum dust pellets. The test's objective was to determine the effect of shaping the explosive charge of the radiological bomb on the dispersion of the pellets. Each munition contained 77 curies, for a total of 308 curies.<sup>24</sup>
- Field Test 620 took place on 3 - 4 November 1951. It was an airburst test of nine spherical radiological munitions, E78R2 and E78R3. These munitions were filled with aerial pellet disseminators filled with radioactive tantalum dust, which burst at varying altitudes. In addition, three inert munitions containing no radiological material were dropped for practice. The objective was to establish the "area of responsibility" of these two types of individual munitions and to assess the radiation field produced. The nine munitions were filled with radiological material activated to a level between 8.5 and 17.3 curies each, for a total of 131 curies for the test.<sup>25</sup>
- Field Test 623 occurred on 7 November 1951. It was an airburst test of a 1,000-pound radiological bomb, E-83, filled with compressed radioactive tantalum dust pellets. The objective of the test was to determine the effect of varying the explosive and shaping the charge on the range and uniformity of dispersion of the pellets of compressed radioactive tantalum dust. The bomb contained 612 curies.<sup>26</sup>
- Field Test 624 was held on 8 November 1951. It was an airburst test of a 1,000-pound radiological bomb, E-83, filled with compressed radioactive tantalum dust pellets. The objective was the same as Field Test 623. The bomb contained 756 curies.<sup>27</sup>
- Field Test RW 1-52, on 20 May 1952, involved the static test of four segments of full-diameter sectional munitions. The objectives were to determine the effect of shaping the explosive charge of the modified radiological bomb on the dispersion of compressed pellets of radioactive tantalum dust and to assess the radiation fields produced. The activity of the radioactive tantalum in the munitions ranged from 275 to 404 curies, for a total of 1,405 curies.<sup>28</sup>
- Field Test RW 2-52 took place 23 - 27 May 1952. It was an airburst test of spherical radiological munitions containing radioactive tantalum. The objectives were to assess the radiation fields produced by individual spherical munitions filled with a radioactive agent when airburst at various altitudes and to determine the effect of weathering on the ground contamination. Sixteen active munitions were used in this field test. Before this test, six inert simulate munitions were dropped on 21 May 1952 to test the altitude at which they opened. The total activities of the radioactive tantalum in the spheres were calculated to be 38.9 to 40 curies, for a total of 640 curies.<sup>29</sup>
- Field Test RW 1-53 was conducted on 23 September 1952. It was a static test of full-

diameter sections of a radiological munition. The objectives were to determine the effect of shaping the explosive charge of one 1,000-pound radiological bomb, E83 type, on the dispersion and breakup of the agent and to determine the extent and intensity of the field radiation produced. The four functioning munitions contained a level of between 359 and 626 curies, for a total of 2,164 curies.<sup>30</sup>

### Decontamination and Construction Studies

In addition to the munition studies, two decontamination studies and one building construction study were conducted during the years of the Dugway radiological warfare testing (see table 2). This latter test examined the attenuation effects of various building materials, such as cinder block and plywood, on radiation levels.

- Field Test 291, in August 1950, was designed to study gross decontamination of radioactive tantalum dispersed by a single radiological bomb. The radiological agent used in this test was the residue from the 30 November 1949 test (Field Test 276). No new contaminant was used. The objective was to determine the practicality of several proposed methods for gross decontamination of areas (either area wide or paths wide enough for the passage of

troops) that were radiologically contaminated and to test the feasibility of decontamination of construction equipment used in contaminated areas.<sup>31</sup>

- Field Test 311 was conducted to test the effect of various types of construction on the intensity field produced by a radioactive tantalum source. A point source of radiological material was used; no residual radiological material was released into the environment. There were three tests, on 26 July, 31 August, and 1 September 1950, to determine the effectiveness of several types of common construction techniques as a shield to radiation exposure from a point source of radioactive tantalum-182.<sup>32</sup>
- Field Test RW 5-52 was conducted on 4 - 10 June 1952. It dealt with radiological warfare decontamination and land reclamation studies. No radiological material was released into the environment as a result of this field test. The objectives were to investigate the range of depths to which the pellets penetrate the soil, to determine the feasibility of locating individual radiological warfare pellets by means of gamma survey meter or by means of beta probe, to determine the feasibility of removing individual pellets and the time required for

<u>Date of Field Test</u>	<u>Test Designation</u>	<u>Type of Field Test</u>	<u>Source of Contaminants</u>
August 1950	Field Test 291	gross decontamination study	residue from 30 November 1949 field test
26 July 1950 31 August 1950 1 September 1950	Field Test 311	construction test	point source of tantalum-182
4-10 June 1952	Field Test DPG RW 5-52	decontamination and land reclamation studies	residue from previous field test

this operation, to obtain data on the performance of proposed land reclamation measures, and to evaluate waste collection and disposal procedures.<sup>33</sup>

#### THE JOINT RADIOLOGICAL WARFARE STUDY PANEL REEVALUATION

The Noyes Panel, which presented its final report on 20 November 1950, reconvened for a short time in April 1952 to discuss the status of the radiological warfare program. The group evaluated the technical advances that had been made in the field of radiological warfare since the Joint Study Panel's last meeting in 1950. The group found there had been advancements in several categories: production of radiological warfare agents, dissemination of radiological warfare agents, and decontamination and defensive measures. There were no significant changes in the areas of new radiological warfare agent discovery, delivery, or biological effects. The panel decided that "no controversial technical problems have developed since the last Noyes Panel report."<sup>34</sup>

#### THE CANCELLATION OF THE OFFENSIVE RADIOLOGICAL WARFARE PROGRAM

The radiological warfare test program at Dugway Proving Ground continued until 1952, when the Chemical Corps expressed a wish to substantially expand the radiological warfare program. Increasingly larger tests, planned for 1953 and following years, would have needed vastly expanded facilities to maintain radioactive munitions.<sup>35</sup>

However, in 1953, the radiological warfare test program was canceled. Several reasons contributed to the program's discontinuation. There were questions relating to the actual need for a continuing radiological warfare program, and the expansion of the nuclear weapons arsenal made radiological warfare less necessary as an offensive measure. There were also budget cuts in military spending, which were necessary at the conclusion of the Korean War. As of 10 June 1953, the

funding for the 1954 fiscal year had been extremely reduced. The planned budget of \$4.33 million was reduced to \$222,000.<sup>36</sup> This substantial loss of funds resulted in the Chemical Corps not going ahead with the expansion it was proposing.

#### SUMMARY

The development of offensive weapons during World War II was critical, and in the beginning stages of the Manhattan Project the ability to construct an atomic weapon was not a certainty. Radiological warfare provided the U.S. military forces with another possible option. The capability of delivering a radiological contaminant into the environment to deny an enemy control over specific terrain would have been a potentially potent addition to the U.S. weapons arsenal.

The need to explore adequately the potentialities of radiological warfare and the fear that other nations might use this type of warfare motivated the research and development of the radiological warfare program. The tests conducted at ORSL and Dugway Proving Ground were intended to determine the best methods of radiological agent dispersal and damage capability. According to the Advisory Committee on Human Radiation Experiments:

"Whatever public health hazard the [radiological warfare] tests at Dugway may have posed at the time, the radioactive decay of the tantalum caused the risks to dissipate over time. By 1960, no more than a few millicuries of tantalum remained, dispersed so widely that by this time it posed no conceivable human or environmental hazard."<sup>37</sup>

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## CHAPTER 7

# HUMAN ASPECTS RESEARCH & U.S. ATMOSPHERIC NUCLEAR WEAPONS TESTING

### INTRODUCTION

Since 1994, the Department of Defense (DoD) has conducted an extensive search for records involving human use in ionizing radiation research and testing. As of the date of this publication, no documentation has been identified to indicate that human radiation experiments were part of the U.S. atmospheric nuclear weapons testing program. The Advisory Committee on Human Radiation Experiments (ACHRE) concluded in 1995 that, “although there was a real possibility that human subject research had been conducted in conjunction with the bomb tests, the tests were not themselves experiments involving human subjects.”<sup>1</sup>

Human aspects research conducted in conjunction with atomic weapons tests was designed to study the effects atomic weapons would have on combat operations. For example, flashblindness studies, troop training and maneuvers, psychological testing, and decontamination studies were designed with the goal of increasing the capabilities and preparedness of military forces to conduct effective military operations on a nuclear battlefield. Cloud sampling and penetration were conducted to collect radiological samples from nuclear mushroom clouds, to gather radiochemical data, and to identify the potential risk to aircrews. This chapter describes this research.

### BACKGROUND

When the Soviet Union detonated an atomic bomb in 1949, the monopoly of the United States as

the sole nuclear power came to an end. In view of this, the DoD realized it would be necessary to create countermeasures for both personnel and equipment to conduct operations on a contaminated battlefield. First, the effects of atomic warfare on military operations had to be identified.<sup>2</sup> Effects included contaminated fallout from the “mushroom cloud,” flashblindness or dazzle created by the fireball, and the psychological stress on personnel from a nuclear detonation. Second, after the effects were identified, defensive or avoidance techniques had to be developed to minimize or eliminate the threat.

The primary objective of the U.S. atmospheric nuclear weapons test program was to develop and improve nuclear weapons.<sup>3</sup> However, some of the tests were conducted to evaluate nuclear weapons effects. Such weapons tests offered an opportunity to determine the effects on military operations and to develop and test equipment, operational doctrine, and the tactics to be used by U.S. forces in a nuclear environment. Personnel participated in field exercises which were conducted in conjunction with the weapons tests.

### HUMAN INVOLVEMENT

#### Development of Military Operations on a Nuclear Battlefield

Approximately 210,000 personnel participated in U.S. atmospheric nuclear weapons tests.<sup>4</sup> Their participation included observing the explosion, test operations, and tactical maneuvers on a simulated battlefield following a nuclear detonation. Personnel

TERMS/ACRONYMS USED IN THIS CHAPTER	
AEC	Atomic Energy Commission [predecessor of the Department of Energy]
afterimage	temporary image formation remaining on the retina from over stimulation
dazzle	to overpower the vision with very bright light
DoD	Department of Defense
fallout	the descent to earth of radioactive particles, as after a nuclear explosion; the particles themselves
flashblindness	describes both dazzle (a condition where extremely bright light temporarily impairs vision) and afterimage (temporary image formation remaining on the retina from over stimulation)
gamma ray	an electromagnetic radiation of great penetrating power, emitted by the nucleus of a radioactive substance
ground zero	place of detonation
ionizing radiation	(see appendix 4)
mushroom cloud	the cloud produced by an atomic explosion, forming a unique mushroom shape
night vision	vision that has adapted to low light levels
NTPR	Nuclear Test Personnel Review
rad	(radiation absorbed dose) a dosage of absorbed radiation equal to the absorption of 100 ergs of energy per gram of material

after detonation to test air mobile operations around and through a contaminated and cluttered battlefield. The results of these exercises were used to refine and improve military operations on a nuclear battlefield. Decontamination procedures also were used and tested.

Some service members were administered psychological tests to determine the effectiveness of briefings about the atomic bomb. The purpose of such testing was to determine if troops had been given adequate information that they could understand and use in performing safely on a nuclear battlefield.<sup>5</sup>

**Visual Effects**

The Armed Services were confronted with the problem of temporary loss of vision as a result of exposure to visible light emitted by a nuclear detonation. The term “flashblindness” was used to

from all the services, primarily the Army, participated in a series of field maneuvers called “Desert Rock.” The purposes of these exercises included conducting field maneuvers, evaluating the effects of a nuclear detonation on field fortifications and equipment, measuring the ability to estimate target damage, observing psychological responses to nuclear detonations, and radiological safety training. During these exercises, service members first received training on nuclear weapons and their effects and how to survive and operate on a nuclear battlefield. After the blast, some troops executed maneuvers toward ground zero from trenches. Others were airlifted by helicopter to the vicinity of ground zero

describe both dazzle (a condition in which extremely bright light temporarily impairs vision) and afterimage formation from retinal stimulation.<sup>6</sup>The danger to the eye from an atomic detonation lies in the increased light the eye receives, which can be as much as 50 times the light a pupil constricted by daylight admits. There is an even greater effect on pupils that are already dilated, such as when adapted to night vision. There was also concern that the elimination of night-adapted vision caused by intense illumination from a nuclear detonation at night could severely distort peripheral vision in critical situations.

The flashblindness project was conducted during Operations BUSTER-JANGLE,





Intensity of the flash of the detonation of an atomic bomb at night. The intensity of the flash could cause temporary blindness to those unprotected.

TUMBLER-SNAPPER, UPSHOT-KNOTHOLE, PLUMBBOB, HARDTACK II, and DOMINIC I. The flashblindness project examined the ability of filters to decrease the effects of flashblindness on ground troops and aircrews.

Three types of visual tasks were considered for the flashblindness program: (1) reading red-lighted instruments in ships, aircraft, and vehicles; (2) acuity of central vision; and (3) peripheral vision at low light levels. Aircrews increasingly relied on central vision in performing operational tasks, whereas ground soldiers relied on peripheral vision to detect form and movement in night combat tasks.<sup>7</sup>

Researchers designed studies to estimate the usefulness of a specific filter combination for dazzle protection. Typically, service members whose eyes had been adapted to the dark looked at the initial

flash of an atomic bomb for a period of time equal to the blink reflex. Red filters were found to curb the high short-wave content of the early part of detonation flash and thus aid recognition of red-lighted instruments. It was concluded that aircrews would benefit from using red filters in the event of atomic flashes within a few miles at night.<sup>8</sup>

Flashblindness researchers concluded that the temporary loss of vision from dazzle did not cause permanent damage to the eyes.<sup>9</sup> With proper training, coping with temporary vision loss was found to be a surmountable obstacle. Tests showed that permanent eye damage was possible when the detonation was viewed directly; when the detonation was viewed indirectly, the possibility of permanent damage was minimized.<sup>10</sup> In viewing a detonation either directly or indirectly, vision was temporarily impaired. Field



“Box” filter being removed from a B-17 “drone” cloud sampling aircraft

and laboratory flashblindness experiments with human subjects continued into the 1960s and 1970s and led to the development of equipment for improved eye protection.

### Nuclear Cloud Penetration Studies

The Air Force conducted mushroom cloud sampling flights after nuclear weapons tests for several reasons. One was to obtain samples that could be used by the weapons designers to analyze the performance and efficiency of the weapon’s design. Obtaining samples provided diagnostic information to the weapons design laboratories. A second reason was to collect samples from mushroom clouds of nuclear detonations performed by other nations. The purpose of this information was of intelligence value in determining the nature of other countries’ nuclear weapons development programs.<sup>11</sup> A third reason, which is discussed here, was to fly through a mushroom cloud to measure the radiation dose and

dose rates. The Air Force needed the ability to estimate the impact of contamination within a cloud layer to judge the hazards of flying into a mushroom cloud.<sup>12</sup> This information was critical to the Air Force for two reasons: (1) to determine the hazards to pilots who may have to fly through mushroom clouds either during a cloud sampling mission or during a nuclear war and (2) to determine what decontamination procedures would be required if the aircraft became radioactive after passing through these clouds. These studies would also help in identifying requirements for additional protective equipment for personnel and machinery.

The Air Force initially conducted unmanned experimental mushroom cloud penetration missions. However, manned aircraft soon replaced the cumbersome and unreliable remote-controlled aircraft, known as drones, which did not provide the quality of mushroom cloud samples required. In these cloud penetration studies, some air crew flew through mushroom clouds to determine if there was a radiation threat; others flew in or around the clouds



Cloud sampling filter being placed on a cart after being removed from a F-84 sampling aircraft

to gather additional data from the radioactive clouds. The radiation doses that aircrews received during passage through and around the cloud and conditions of the flight inside the cloud and on the return flight were pertinent in the safety planning for aircrews and aircraft.<sup>13</sup>

One objective of the studies involved measuring the radiation dose either from inhaling or swallowing radioactive particles while flying through a mushroom cloud. External radiation dose rates experienced in mushroom clouds were often dangerously high, sometimes 1,800 rads per hour. However, because aircraft did not linger in the cloud, the total dose was much less, but there was concern whether internal doses paralleled these external readings. These cloud penetration tests were able to provide distinction between internal and external doses received during a mushroom cloud penetration flight. Test data showed that the radiation dose

within the body was nearly the same as the dose on the skin surface and indicated that aircraft did not have to be specially modified to filter out airborne particles that could be inhaled by aircrews.<sup>14</sup>

The second objective of the studies was to determine the radiological contamination the aircraft might acquire from flying through or around the mushroom cloud and the extent of the radiation exposure from this contamination to the ground crews who serviced these aircraft. The studies demonstrated that the major risk to ground crews came from residual radiation deposited on both external aircraft surfaces and internal aircraft parts. The major deposition point for such residual radiation was in the engines, which drew in the radioactive fallout as the aircraft traveled through the mushroom cloud.<sup>15</sup> As a result of this and other studies, decontaminating aircraft after passage through a mushroom cloud was deemed necessary to



Air Force F-84 being directed to a holding area to await decontamination. The aircraft had been on a cloud sampling mission. Upon landing, the aircraft was surveyed for radioactivity and found to exceed acceptable levels.

remove residual radiation. Aircraft returning from missions involving mushroom cloud penetration were required to be checked for radioactivity to determine if decontamination was necessary.

The historical narrative “History of Air Force Atomic Cloud Sampling” provides an in-depth overview of the complete cloud sampling operation.<sup>16</sup>

#### EPILOGUE

The ACHRE Final Report stated that ACHRE: “reviewed the historical record to determine if human experiments had taken place in connection with these tests. We found that somewhere in the range of 2,000 to 3,000 military personnel at the tests did serve as the subjects of research in connection with the tests. In most cases, these research subjects were engaged in activities similar to those engaged in by many other service personnel who were not research subjects. For example, some air crew flew through atomic clouds in experiments to measure radiation

absorbed by their bodies, but many others flew in or around atomic clouds to gather data on radiation in the clouds. The Department of Defense generally did not distinguish such research from otherwise similar activities, treating both as part of the duties of military personnel. The experience of atomic veterans illustrates well the difficulty in locating the boundary between research involving human subjects and other activities conducted in occupational settings that routinely involve exposure to hazards.”<sup>17</sup>

#### FOR MORE INFORMATION

In 1978, the DoD established the Nuclear Test Personnel Review (NTPR) program to serve as a source of public information for personnel participating in these tests. The NTPR program is responsible for identifying DoD personnel who participated in U.S. atmospheric nuclear tests and for determining their radiation doses. This program provides participants with confirmation of their



Air Force F-84 undergoing decontamination after flying through an atomic mushroom cloud

participation, their associated radiation dose, and the availability of health care and compensation programs. Contact the NTPR program at the Defense Special Weapons Agency, Attn: ESN/NTPR, 6801 Telegraph Road, Alexandria, VA 22310-3398, or by calling 1-800-462-3683.

#### NOTES

(To obtain copies of the following documents, see appendix 2.)

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17. Advisory Committee on Human Radiation Experiments, Final Report, pp. 455-456.

## CHAPTER 8

# FOOD IRRADIATION

### INTRODUCTION TO IRRADIATED FOOD STUDIES

Food irradiation studies, sponsored by the Army Quartermaster General, were part of the “Atoms-for-Peace” initiative of the mid-1950s and continued until 1980. The Atoms-for-Peace program was initiated by President Eisenhower in 1956 to generate research and development on constructive, peaceful uses of atomic energy.<sup>1</sup> This program, along with the War-on-Hunger program, was strongly supported by Congress and the Department of Defense (DoD).

The purposes of irradiating food were to sterilize foods intended for use as field rations, extend shelf life under nonrefrigerated conditions, and make food preparation easier in combat situations while keeping the Army well nourished. Human testing of irradiated food began in 1956 after several years of animal testing revealed no health risks. These tests were not considered human-use tests; no food used in these studies became radioactive as a result of the irradiation.<sup>2</sup> These food irradiation studies were conducted only to gauge the soldiers’ reactions to the sensory characteristics of the irradiated foods. Today, the use of food irradiation to eliminate microorganisms and to extend shelf life is a common practice in several fields of food processing and packaging in commercial and military food preparation.

### BACKGROUND

The concept of food irradiation was initially developed by the Atomic Energy Commission (AEC) immediately following World War II. In 1952, the DoD expressed interest in a food irradiation program.

In February 1954, the National Research Council’s Subcommittee on Radiological Sterilization

assigned the Quartermaster Corps, Department of the Army, the task of investigating the technical aspects of the radiological sterilization and preservation of foods.<sup>3</sup> This task was conducted in close coordination with the AEC, which supplied the sterilization testing reactor and radiation source used for irradiating foods. Many other governmental organizations became involved in food irradiation studies during the following years. The Army also sponsored laboratory studies of irradiated foods at approximately eighty universities and industrial organizations throughout the country during the 1950s.<sup>4</sup>

The logistical requirements to keep an Army in combat situations well fed for prolonged periods necessitated more efficient food storage and preparation procedures. At the time, field rations required refrigeration, spoiled quickly, were cumbersome to transport, and sometimes required a lot of water or cooking time for preparation. Food irradiation was seen as a means to address these concerns. The sterilization of grain and grain products with heat and the control of parasites in grain, although possible, were limited in their applicability due to how the foods were stored. The DoD sponsored research in food irradiation to determine the feasibility of using ionizing radiation (such as gamma rays and electrons) instead of heat to kill or inactivate micro-organisms that cause food spoilage. Ultimately, the benefits of the irradiation process would include, “a reduction in refrigeration requirements, reduced food losses, improved control of certain food-borne diseases, and a wider availability of fresh foods under field conditions.”<sup>5</sup>

Laboratory tests of irradiated foods were conducted on rats, dogs, and monkeys at various universities and industrial organizations. After extensive animal tests did not reveal any harmful

**TERMS/ACRONYMS USED IN THIS CHAPTER**

AEC	Atomic Energy Commission [predecessor to the Department of Energy]
cobalt-60	a radioactive isotope used in the treatment of cancer
DoD	Department of Defense
FDA	Food and Drug Administration
gamma radiation	electromagnetic, rather than charged particle, radiation; highly penetrating
ionizing radiation	see appendix 4
irradiate	to expose to or treat by exposing to x-rays, ultraviolet rays, radium, or some other form of radiant energy
pasteurization	a method of destroying disease-producing bacteria by heating the liquid to a prescribed temperature for a specified period of time
sterilization	to free from living microorganisms, as by subjecting to great heat or chemical action
TECOM	Army Test and Evaluation Command
World War II	1939-1945, fought between the Allies (Great Britain, France, the Soviet Union, Canada, and the United States as well as other nations) and the Axis (Germany, Italy, Japan and other countries)

The first Army-sponsored human subject study of irradiated food took place in 1956 at the Army Medical Research and Nutrition Laboratory, Fitzsimons Army Hospital, in Denver, Colorado. The participants were Mennonite volunteers: eighteen conscientious objectors, between eighteen and twenty-two years old, who were fulfilling their obligation to the Government by serving in the Armed Forces as test volunteers for an eighteen-month period. Before their participation, the men were given a thorough briefing that provided a history of the program and an explanation that the food was not radioactive and that previous animal toxicity testing had been negative. Before participating, they filled out informed consent forms that

effects, the protocol for human taste testing was established in 1954. By 1956, more than 100 foods had been laboratory tested and were approved for further human subject testing using both civilian and military volunteer personnel.<sup>6</sup>

**HUMAN TESTING OF IRRADIATED FOODS**

Human volunteer tests were conducted to determine the sensory characteristics—taste, texture, and appeal—of the irradiated meats, fruits, and vegetables. The Army Test and Evaluation Command (TECOM) administered the tests through the Quartermaster Corps at the U.S. Army Natick Research, Development, and Engineering Center in Natick, Massachusetts. Much of the human taste testing was also done for psychological reasons to calm public fears of irradiated foods.<sup>7</sup>

included participation in two-year liability insurance policies from the University of Colorado. Complete physical examinations were administered just before, during, and at three, six, and twelve months after the studies were completed.<sup>8</sup>

Seven separate studies were conducted at Fitzsimons Army Hospital, each lasting approximately thirty days. During each test period, the participants were divided into two groups of equal size. One group received meals that included irradiated food, while the other group ate meals with no irradiated food. After approximately fifteen days, the test administrators switched the group that was fed untreated meals with the group that ate irradiated food, so each group ate equal amounts of irradiated food. To maintain the control population and get a more accurate indication of the acceptance of the irradiated foods, the men were not told which foods they were eating.<sup>9</sup> A period of several months elapsed



between the studies to prevent accumulation of possible toxic effects. This testing procedure was used in most of the subsequent irradiated food studies.

The first four studies tested foods that had been kept in a frozen state until they were prepared and consisted of 35 percent, 60 percent, 80 percent, and 100 percent irradiated foods, progressively.<sup>10</sup> Eighteen men participated in these tests, which began in summer 1956 and consisted of taste-testing forty-two food items. The fifth study, conducted in spring 1957, specifically tested the acceptability of irradiated pork that had been stored at room temperature for one year. The sixth and seventh studies, completed in November 1957 and March 1958, investigated eighteen foods that had been stored at room temperature for three months. Thirteen men participated in these two tests.

#### FOLLOW-UP STUDIES

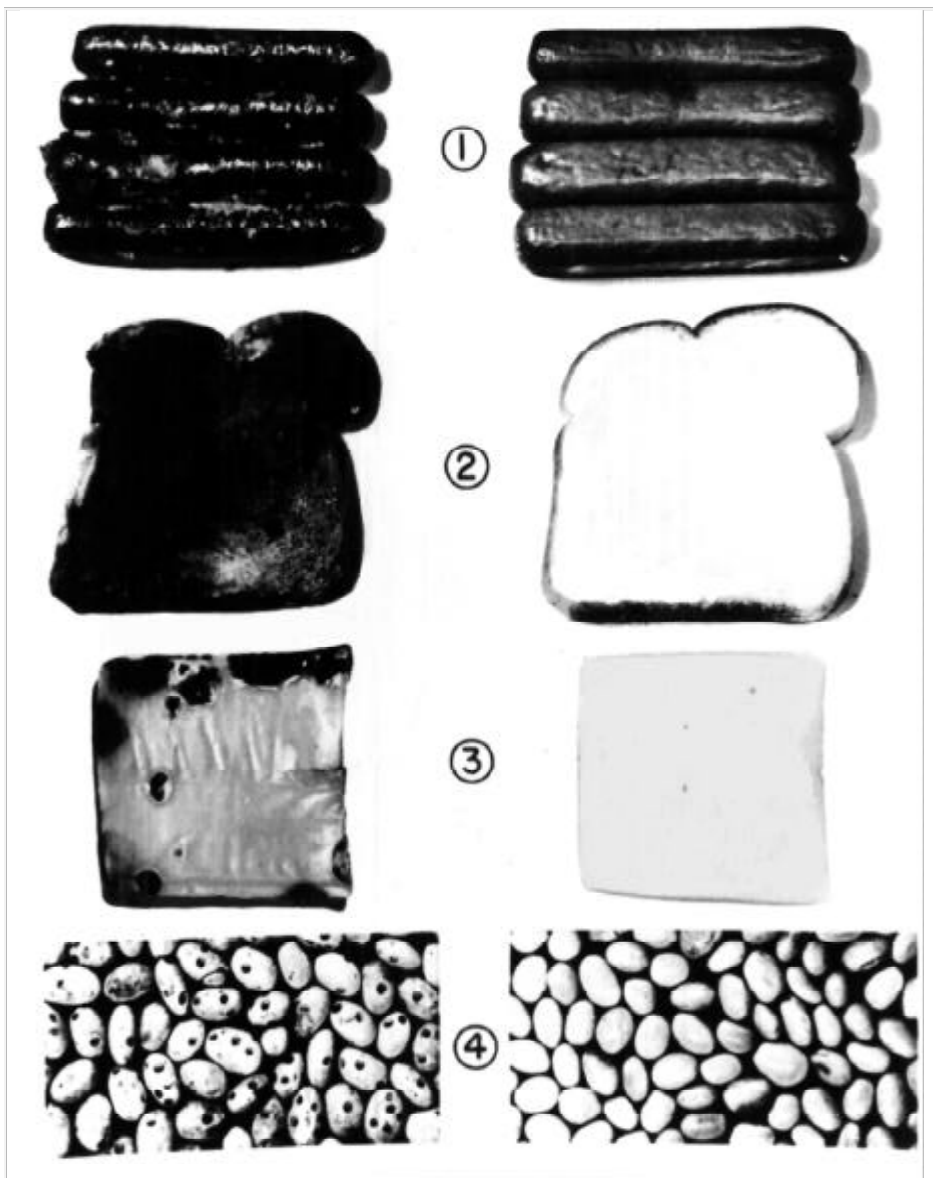
Several follow-up studies were conducted at Fitzsimons Army Hospital. A four-month duration test based on a diet of 100 percent irradiated food was planned to begin on 1 March 1959. The volunteers for these tests were Mennonite conscientious objectors.<sup>11</sup> These follow-up

tests were designed as new techniques of irradiation were developed to be conducted on foods that had not been acceptable to the test subjects in previous studies. However, these further studies were not well documented, and the current data on them are limited.

Letterman Army Medical Center at the Presidio Army Base in San Francisco, California, was the site of several initial and follow-up food irradiation taste tests. The testing techniques and procedures used at Fitzsimons Army Medical Nutrition Laboratory were also used at Letterman. The currently available information on the testing conducted at Letterman Army Medical Center does not contain data on the



Potatoes being irradiated during a food preservation study. This process did not cause the food itself to become radioactive. Rather, it destroyed organisms which would have caused spoilage of the food. This process lengthened the storage life of these foods.



Food test samples depicting effectiveness of irradiation as a preservation process. Food on the right had been irradiated, whereas the food on the left had not. Both samples had been left unprotected for the same period of time. Food on the left shows signs of spoilage, whereas the food on the right does not. Food items are sausage, bread, cheese, and beans.

large-scale food irradiation studies were conducted at Fort Lee, Virginia, Fort Lewis, Washington, and Marine Corps installations on the island of Okinawa from 1958 through the mid-1970s. Personnel involved in these studies were volunteer enlisted men at each site.

The irradiated food taste tests conducted at Fort Lee began in February 1958. Approximately two weeks before these tests began, a series of lectures on the subject of radiation preservation was presented to approximately 2,000 enlisted men, representing most of the 543rd Quartermaster Group, the 9111th Detachment 2, and the Quartermaster School. These lectures were designed to acquaint as many people as possible with the general historical background and progress in the use of radiation to preserve food. The men were told that the irradiated food program was not classified and that all who participated would not only be allowed but encouraged to tell their friends and relatives that they participated in the test. Following each lecture,

foods that were tested, the testing methods used, or the number of participants.

After the initial success of these small-scale human subject irradiated food studies, the Army increased the size and scope of the program. Many

personnel were surveyed to determine whether they would be willing to participate in the program on a volunteer basis.<sup>12</sup>

The Army's Office of the Surgeon General handled the medical supervision of the participants

and laboratory preparation of the irradiated food. All study volunteers at Fort Lee were given physical examinations two weeks before ingesting irradiated food. From the personnel who volunteered for the first study and successfully passed the physical examinations, a group of 240 men was selected to participate. Only 139 volunteers from this group actually ate irradiated food; the remaining men served as the control population. Records indicate that these volunteers were served a meal that included irradiated bacon and pork along with non-irradiated foods on 25 April 1958.<sup>13</sup>

The second series of tests, consisting of two three-day studies, tested the sensory reactions to six irradiated foods. The first of these studies took place on 3, 6, and 10 November 1958 and had 139 volunteers; the second study on 1, 4, and 8 December 1958 had 87 volunteers. As with the first study, after consuming each meal, the participants were asked to fill out nine-point scaled questionnaires on the sensory characteristics of the food, including the texture, taste, and palatability.<sup>14</sup>

Test procedures called for follow-up physical examinations to be given to participants immediately, after six weeks, and three months after eating the irradiated food. However, the three month post-irradiation tests were deemed unnecessary because no ill effects from the irradiated food ingestion were discovered during the previous physicals. In January 1959, after the second phase of testing at Fort Lee was complete, a report on the medical aspects of the program noted, “[t]o date, of the 598 volunteers examined, there has been no evidence from our examinations to suggest any effects attributable to consumed irradiated food.”<sup>15</sup>

Similar testing procedures were used for all the follow-up taste tests of irradiated foods that were administered at Fort Lee, Fort Lewis, and the Marine installations on Okinawa through the mid-1970s. Several other food irradiation taste tests were conducted at many other DoD facilities around the country, but these generally involved fewer troops and were shorter in duration. In 1960, the Food and Drug Administration (FDA) granted approval for the use of a broad class of irradiated foods for general consumption by Army troops.<sup>16</sup> The administration of

## STERILIZATION VERSUS PASTEURIZATION

### Sterilization

Sterilization is primarily used for long-term preservation of meats and meat by-products in an uncooked or unfrozen state. These foods require a high dose of radiation to kill, or inactivate, the microorganisms that cause spoilage. The preservation of foods by sterilization and the foods irradiated by this method are currently being researched for approval by the Food and Drug Administration.

### Pasteurization

Pasteurization is used for highly perishable food, primarily fruits and vegetables, that require a low dose of radiation to extend shelf-life and kill, or inactivate, the microorganisms that cause spoilage. The pasteurization method leaves the food nearly indistinguishable from non-irradiated food. The irradiation pasteurization procedure is commonly used on fruits and vegetables commercially available today.

the continuation of the food irradiation program was directed by the U.S. Army Natick Research, Development, and Engineering Center, in Natick, Massachusetts, where several follow-up taste tests were conducted.

Most of the additional testing was done to get a more accurate indication of the potential broad acceptance and use of irradiated foods. It was eventually determined that the radiation pasteurization process, which used doses that would delay spoilage, when used in conjunction with refrigeration<sup>17</sup> did not affect the sensory qualities of foods as much as the radiation sterilization procedure. This was found to be the case first with fruits and vegetables and was eventually applied to all irradiated foods. However, because the DoD’s intention with the food irradiation program was to prolong the shelf life of meats and high-protein foods, the DoD continued to research and improve on the radiation sterilization process. The development of new and more efficient irradiation techniques (e.g., replacing gamma with electron radiation) also warranted additional testing of irradiated foods. The development of portable radiation sources was

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important because the foods could be irradiated close to their source. Before this, most of the food was frozen, thawed just before irradiation, and then refrozen for shipping, which added to the development of undesirable textures and tastes.<sup>18</sup> The study administrators at Natick eventually discovered that if the foods were kept very cold (at -40° C) during the sterilization process, the undesirable effects of the radiation treatment were virtually eliminated. The Army also attempted to keep up with the dietary guideline changes. As these needs changed over the years, food irradiation studies were continued for sterilization and pasteurization purposes and to extend shelf life.

### SUMMARY

The food irradiation program started by the Army in the 1950s was administered with no reported health effects to the participants. Many people and ideas were involved in the effort to increase the efficiency of the Army in the 1950s and 1960s. The food irradiation program was an integral part of this effort. Taste-test studies similar to those of the past have continued into the present on foods produced with new packaging and preservation techniques. To a large extent, the food irradiation programs conducted at Fitzsimons Army Hospital, Letterman Army Medical Center, Fort Lee, Fort Lewis, and the Marine Corps installations on Okinawa were in the forefront of the effort to improve quality and shelf life of food and, in turn, the quality of food available for military personnel.

### NOTES

(To obtain copies of these documents, see appendix 2.)

1. Ad Hoc Working Group of the Interdepartmental Committee on Radiation Preservation of Foods, A National Civilian Radiation Processed Foods Program, January 1960, pp. 16, 17; Budget message of President Dwight D. Eisenhower to the Congress of the United States, January 1956.

2. Ibid, p. 11

3. Draft Letter, to Lewis L. Strauss, Chairman, Atomic Energy Commission, from Robert LeBaron, Chairman, Military Liaison Committee, 10 February 1954, p. 1.

4. Interdepartmental Committee on Radiation Preservation of Food, Draft Second Report, p. 11 A.

5. Draft Press Release, "Army Troops to Test Palatability of Foods Preserved by Irradiation," 7 April 1958, p. 3.

6. Interdepartmental Committee on Radiation Preservation of Food, Draft Second Report, pp. 16–18.

7. Ad Hoc Working Group, A National Civilian Radiation Processed Foods Program, p. 15.

8. Memorandum, to The Quartermaster General of the Army, from Brig. Gen. Joseph McNinch, Special Assistant for Research & Development Affairs, Office of the Army Surgeon General, 2 October 1959, pp. 2–3.

9. Capt. Virginia E. McGary et al., Acceptability of Irradiated Food Consumed by Humans (Fitzsimons Army Hospital, Colorado: U.S. Army Medical Nutrition Laboratory, 15 March 1957), p. 1.

10. Research Division, Office of the Chief of Research & Development, Office of the Army Chief of Staff, "Status of the U.S. Army Radiation Preservation of Food Program," July 1957, p. 2.

11. Interdepartmental Committee on Radiation Preservation of Food, Draft Second Report, p. 18.

12. Summary of Irradiated Food Studies conducted by the Office of the Quartermaster General, 1958, p. 1, and Enclosure 1, Troop Orientation, p. 2.

13. Capt. C. D. Moore, USA, Human Consumption of Irradiated Food—Medical Aspects (Fort Lee, Va.: Quartermaster Research and Engineering Command, 22 January 1959), p. 1.

14. Interdepartmental Committee on Radiation Preservation of Food, Draft Second Report, p. 19.

15. Capt. C. D. Moore, Human Consumption of Irradiated Food, p. 2.

16. Ad Hoc Working Group, A National Civilian Radiation Processed Foods Program, p. 15.

17. Interdepartmental Committee on Radiation Preservation of Food, Draft Second Report, p. 13.

18. Ad Hoc Working Group, A National Civilian Radiation Processed Foods Program, p. 21.