THE WHITE HOUSE

WASHINGTON

March 11, 1998

MEMORANDUM FOR RECORDS MANAGEMENT

FROM: PHIL CAPLAN

The attached three boxes contain the following material relating to the Human Radiation investigation:

Box 1: Agendas, Search Group Meetings, Summary; ACHRE: First Meeting and Startup; Indemnification of Contractors; Marshall Islanders; GAO Letter; University of Rochester; Presidential Memo- Establishment of Advisory Committee; Working Groups/ Committees; Committee Vacancy; Committee Vacancy Letters; Atomic Vets; Presidential Memorandum: Human Subject Review; Resumes; Patient Interview Study; Compensation; FOIA Requests; Phone Numbers and Sign-ins; Conference Call Summaries; Nasopharyngeal Radiation; Green Run- DOD; Early Talking Points; ACHRE Minutes; Anything Congressional; Markey Report/ CIA Report; Records Retrieval/ Hotline/ Directives to Agencies

Box 2: Clips; Interim Reports- ACHRE; Stakeholder Workshop Parts I and II; Report on Human Radiation Experiments Associated with the Department of Energy; Final Report of the Radiation Exposure Compensation Act Committee; Interim Report of the ACHRE; Final Report of the ACHRE

Box 3: Working Documents: Compensation Subcommittee of Legal Issues Working Group (1/10/94); Victims Task Force; Research; October 3, 1995 Event; Administration's Response to ACHRE Report; Claud Bailey; Governor Leavitt (UT)/ Dugway Proving Ground; NBAC; Journal Issues Contributed by Dr. Faden to ACHRE; Clips; Dr. Saenger/ Cincinnati; Performance of Staff Committee Members; Miscellaneous; Briefing Book Number 2; Briefing Book Volume 15

Box 1 11097 NARA 8531

Box 2 11098 NARA 8532

Box 3 11099 NARA 8533

ENCLOSURES FILED OVERSIZE ATTACHMENTS

3 folders filed 3/13/98 PT

# WORKING DOCUMENTS

# OF THE

# COMPENSATION SUBCOMMITTEE

# OF THE

# LEGAL ISSUES WORKING GROUP

## INTERAGENCY WORK GROUP ON RADIATION EXPERIMENTS

JANUARY 10, 1994

Radiation Subcommittee on Compensation Precedent
Friday, 1/7/94 11:00a.m. Meeting

List of Attendees

| | |
|---|---|
| OMB--NRES | |
| T.J. Glauthier | 395-4561 |
| John Pfeiffer | 395-3876 |
| OMB General Counsel | |
| Robert Damus | 395-5044 |
| DOE | |
| Mark Johnston | 586-5281 |
| Lisa Schiavo | |
| DOJ | |
| Nancy McFadden | 514-3309 |
| Rosemary Hart | 514-9700 |
| Patrick Glean | |
| VA | |
| Jack Thompson | 523-3425 |
| NEC | |
| Heather Ross | 456-2802 |

RADIATION EXPERIMENTS - LEGAL ISSUES WORKING GROUP

| Name | Agency | Phone | Fax |
|---|---|---|---|
| Joel Klein (Chair) | WH Counsel | 202-456-6611 | 202-456-6279 |
| Stephen Neuwirth | WH Counsel | 202-456-7903 | 202-456-1647 |
| T. J. Glauthier | OMB | 202-395-4561 | 202-395-4639 |
| Bob Damus | OMB | 202-395-5044 | 202-395-7289 |
| Holly Gwin | OSTP | 202-456-2735 | 202-395-3261 |
| Harriet Rabb | HHS | 202-690-7741 | 202-690-7998 |
| Beverly Dennis | HHS | 202-690-7721 | 202-690-7998 |
| Andres Hyman | HHS | 202-690-6318 | 202-690-7998 |
| Jamie Gorelick | DOD | 703-695-3341 | 703-693-7278 |
| Amy Jeffress | DOD | 703-697-7228 | 703-693-7278 |
| John Casciotti | DOD | 703-697-9657 | 703-693-7278 |
| Marc Johnston | DOE | 202-586-2909 | 202-586-3437 |
| Bob Nordhaus | DOE | 202-586-5966 | 202-586-5226 |
| Edward Frankle | NASA | 202-358-2450 | 202-358-2741 |
| Lois Schiffer | DOJ | 202-514-2701 | 202-514-0557 |
| Eva Plaza | DOJ | 202-514-3309 | 202-514-8071 |
| Nancy McFadden | DOJ | 202-514-9700 | 202-514-0238 |
| Heather Ross | NEC | 202-456-2802 | 202-456-2223 |
| Jack Thompson | VA | 202-523-3425 | 202-523-3464 |

**WORKING DOCUMENTS OF THE COMPENSATION SUBCOMMITTEE**

**OF THE**

**LEGAL ISSUES WORKING GROUP**

**INTERAGENCY WORK GROUP ON RADIATION EXPERIMENTS**

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# Clinton Presidential Records
# Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

## A

Divider Title: _____

# POTENTIAL ELEMENTS OF A FEDERAL RESPONSE

I. Compensation Options and Financing

A. "Compensation" Options

1. Individual monetary compensation

a. Lump sum

-- Amount(s)

-- Variation by claimant circumstances

b. Periodic

-- Amount(s)

-- Variation by claimant circumstances

c. Duration

-- Survivors' benefits

2. In-kind Services

a. Medical monitoring

b. Health care services (physical, mental)

-- Eligibility for select programs (e.g., VA)

-- Special program

c. Other social services (e.g., housing, transportation, education, life insurance)

d. Follow up study(s) of individuals and groups to determine health and other effects

e. Administering agency(s)

f. Duration

-- Survivors' benefits

3. Disclosure of personal information

   a. For subjects and their families

   b. Full disclosure of government's information on circumstances of each individual case

4. Recognition

   a. Formal Apology

      -- By whom (responsible agency(s), President, Congress, Government, Nation?)

      -- To whom (individual participants, families, groups?)

      -- Form (letter, public announcement, legislation)

   b. Appreciation for contribution to the National interest

   c. Memorial

      -- Plaque/Monument/Memorial building

5. "Living" program to help others

      -- Research program/endowment

      -- Information archives and periodic reports to the Nation

      -- Education programs

B. Financing

1. Program(s) under which benefits administered

      -- Existing program(s)

      -- New program

2. Authorization level

3. Special fund

4. Source of funding for administration

a. Regular appropriation

b. Mandatory spending

c. Emergency appropriation

5. Limitations

a. Payments and contracts subject to the availability of appropriations

b. Duration of funding availability

c. Limitations on overall amount of funding provided

C. Other provisions

1. Limitation on fees for claimants' intermediaries

2. Consequence for other claims against the United States

3. Offsets for other compensation to claimants

a. Waiver for insurance and other benefits

4. Advisory committees

5. Effective date(s)

II. Issues of Eligibility

A. Eligibility (precipitating event)

1. Specific experiments/events by which claimants must have been affected:

a. Substance(s) to which claimants were exposed:

1. Radioactive

2. Nonradioactive

b. Extent of exposure

1. Dosage

2. Method of exposure (injection, oral, other)

3. Length of exposure

c. Dates and places at which exposure occurred.

d. Testing and other post-exposure actions by the government.

e. Nature of Federal government responsibility

1. Direct administrator

2. Direct sponsor

3. Indirect sponsor (e.g., provider of funding for program administered by a nonFederal entity)

4. Regulator

2. Nature of claimants' participation:

a. Experimental subject

b. Worker

c. By-stander

3. Informed consent

a. Claimants' knowledge of exposure (kind/degree/extent of advance information provided)

b. Claimants' volition -- voluntary/involuntary

B. Eligibility (consequences)

1. Diseases/adverse reactions that must occur before compensation may be claimed (if any):

a. Specific diseases/adverse reactions covered

b. Date of onset required

c. Mitigating/disqualifying conditions, e.g., heavy smoker, heavy alcohol/caffeine consumption, etc.

2. Persons eligible for compensation in addition to participant in precipitating event, e.g., spouses, children, other relations

C. Determination of Claims

1. Responsible agency(s)

2. Consultation with other agencies required

3. Documentation required on claimants' participation/exposure

4. Medical documentation required re claimants' reactions/condition

5. Procedures for filing, review and disposition of claims

a. Timing requirements for claimants and decision makers

b. Appeals procedures

c. Notification requirements during the course of disposition

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ISSUES THAT NEED TO BE RESOLVED IN CRAFTING A COMPENSATION SCHEME

- Defining the class of persons to be compensated - -
  - Should compensation be limited to individuals who participated in medical/scientific experiments?
  - Should compensation be offered to other groups who were intentionally exposed to ionizing radiation?
    - Can a distinction be drawn between intentional exposure and exposure that was inadvertent but known to be a likely consequence of a program?
  - Should compensation be offered to everyone who was likely to have been exposed to ionizing radiation in excess of levels to which the general public was exposed?
    - What would be the relationship between such a compensation program and other, preexisting compensation programs (e.g., the compensation schemes for downwinders and uranium miners)?
  - To what extent should compensation be offered to person/groups who were exposed through programs that were aided, but not owned, by the Federal Government?
  - To what extent should compensation be offered to survivors/next of kin?
- What should be the Criteria for compensation?
  - Should compensation be offered to everyone within the targeted class?
  - Does the purpose for which persons were exposed matter?
  - Is it relevant whether the persons exposed gave informed consent?
    - If informed consent is relevant, should its adequacy be determined by current or then-existing standards?
  - Should compensation be limited to persons who may have/probably did suffer some physical injury?

- Determining what constitutes appropriate compensation --
  - Should some system/program for providing medical follow-up be created?
  - Should there be a cash payment?
    - How much?
    - Should payments vary depending on the context in which exposure occurred, whether injury seems likely, or other criteria?
- How would a compensation program be administered?
  - Who administers the program?
  - What evidence must be produced to qualify for compensation? Can that evidence be rebutted?
  - What is the relationship of a compensation program to other remedial procedures?
    - Workers Compensation
    - Civil Liability
    - Other Programs

Veteran Compensation Issues. VA has statutory authority to compensate veterans, or their survivors, for injuries or deaths due to the veterans' exposure to ionizing radation either during military service or during medical treatment at VA facilities.

- Veterans disabled as a result of radiation exposure in service are eligible for disability compensation, a tax-free benefit payable at differing rates (from $87 to over $3,000 per month) depending on the degree of disability suffered. Elgibility is on a no-fault basis.

- Since 1989, veterans exposed to radiation as a result of participating in atomic-weapons tests or during the post-W.W.II occupation of Hiroshima and Nagasaki have benefitted from certain presumptions in law. If they suffer from any of 13 forms of cancer at any time after their exposure, there is a legal presumption of service connection.

- Surviving spouses or children of veterans whose deaths are caused by their service-connected injuries or diseases qualify for "dependency and indemnity compensation" (DIC). Death benefits for surviving spouses would vary from $9,228 to $19,632 per year, depending upon when death occured and the service rank attained by the veteran. Additional amounts of these tax-free benefits are available if there were minor children, and the children qualify in their own right if there is no eligible surviving spouse.

- Compensation may also be paid for disabilities or deaths resulting from either VA hospitalization or other VA treatment, to the same extent as if service connected. Traditionally, VA has interpreted this authority as applying only when there has

been fault on the part of the VA-care providers, but this is currently being litigated. Under either a fault or no-fault interpretation, benefits would be payable for injuries resulting from treatment to which the injured veteran had not given informed consent.

Two other means of compensation may be available to veterans injured as a result of radiation exposure either during service or as a result of VA treatment.

- Under the Radiation Exposure Compensation Act, administered by the Department of Justice, lump-sum awards of $75,000 are payable to veterans who 1) participated onsite during the atmospheric detonation of a nuclear device, and 2) later contracted one of 13 forms of cancer. The same is payable to a surviving spouse in the event of the veteran's death. These payments are in lieu of any other remedy, i.e. a veteran or surviving spouse opting to receive the lump-sum payment forfeits future VA eligibility, and the sum is reduced by the value of VA benefits previously received.

- Treatment-related injuries due to VA neglience may lead to damage awards under the Federal Tort Claims Act.

## THURSDAY, JANUARY 11, 1990

The Presidential Commission on Catastrophic Nuclear Accidents met at 1:00 p.m., Steve C. Griffith, Jr., Chairman, presiding.

Members present: Gerald G. Fain, Kenneth R. Feinberg, S. Robert Foley, Theodore J. Garrish, John J. Kearney, William F. Kennedy, Norman C. Rasmussen, Raymond W. Stahl.

Staff present: Jerome Saltzman, Susan Beach.

- - - - - - - - - -

The CHAIRMAN: Will the Commission come to order.

We are very fortunate to have gentlemen from the Department of Veterans' Affairs who have been handling the claims of radiation exposed veterans.

Mr. Jack Thompson is here along with a colleague of his. We are delighted to have you, gentlemen, and we will be glad to hear whatever you have to say.

Mr. THOMPSON: Thank you very much, Mr. Chairman.

I am pleased to be here this morning to discuss with you the Department of Veterans Affairs' handling of claims for radiation based disability and death benefits.

I will, of course, let you decide whether or to what extent the VA's programs are worth emulating as you proceed with your responsibilities.

First, let me describe the compensation program for disabled veterans and for their survivors.

Each year the VA pays about $11 billion in disability and death benefits under our compensation programs.

That means that every month about 2,200,000 veterans and the survivors of about a third of a million more received checks based upon service-related -- we call them service-connected disabilities or deaths.

Eligibility is based upon disabilities or deaths stemming from injuries or diseases incurred in or aggravated during the course of military service.

It is a no-fault system, if you will. There is no need for showing of governmental negligence for awards to be made. In fact, there need only be shown a temporal relationship between the injury or the disease and military service. There needn't even be showing that the unique demands of military duty were in themselves causative of the injury or disease.

The rate of compensation payable to disabled veterans varies with the degree of disability. We have a rating schedule which assigns disability ratings from 10 to 100 percent for various ailments, with the rates of payment ranging from about $76 a month for 10 percent disability up to over $1,500 a month for total disability with additional amounts payable for certain combinations of catastrophic disablements.

The benefits payable to surviving spouses are dependent upon the pay grade achieved by the veteran during his military service. Current statutory rates range from $564 a month to the widow of an enlisted man, an E-1, to over $1,500 to the widow or surviving spouse of an admiral or general.

Most of our claims are relatively easy to process. Usually we need not look much beyond the service medical records to determine whether current disability or death can be traced to a disease or injury that began in the service.

Claims are initially decided at our 54 regional offices around the country. There is at least one in every state. The process is by rating boards which are three member panels which include one physician as a voting member.

Administrative appeals are permitted to our appeals board, which is here in Washington, D.C. Again, it is these three member panels that decide these cases. All of our disability cases include a physician member.

Until recently it was an administrative-only claims process. Last year Congress for the first time authorized judicial review over the VA's benefit determinations. They established a Court of Veterans' Appeals which commenced operations this past October and really is just now getting off the ground. It is too early to tell what effect, if any, the court's review will have on VA's processing of cases.

Well, by and large, our compensation program enjoys wide popular support. You have never seen legislation move so fast as when cost of living adjustments are introduced in Congress. Our veterans do very well as popular demand for the program and popular support for the program really attest.

The primary controversy is with claims that exposure to toxic substances in service results in disablement and disease primarily arising years and even decades after service.

That leads us into the topic at hand which is: Radiation-related veterans' disability and death cases.

As you might expect, veterans have filed claims with us asserting that all manners of exposures to radiation from both man-made and natural sources have caused some injury. We have had claims from former medical X-ray corpsmen, technicians, nuclear vessel crew members, nuclear armament handlers, the whole gamut.

The balance of our claims have been filed by a group that has come to call themselves, the Atomic Veterans. These are the individuals who, while serving in the military, participated in the United States atmospheric test program between 1945 and 1962. There are approximately 200,000 of these veterans and there are also approximately 40,000 veterans who participated in the American occupation of Hiroshima and Nagasaki after World War II.

We get claims from some of this latter occupation group on the theory that there was residual radiation from the bombings there which later resulted in their disease.

Fortunately the Department of Defense and more specifically the Defense Nuclear Agency contemplated the need for detailed information concerning these events and the exposure of the troops who participated. In 1977 it initiated something called the Nuclear Test Personnel Review. That was an effort to compile a comprehensive roster of the nuclear test participants to ascertain exposure levels as determined from film badges, from monitoring devices that were used and by performing a dose reconstruction based upon mathematical models of the various tests. They also prepared "worst case" estimates for the Japanese occupation forces.

These data which are available to VA as it processes its claims, indicate that, with a few exceptions, these Atomic Veterans were not heavily exposed.

For example, the film badge data indicate that the nuclear test participants received only an average of about 1/2 a rem of whole body gamma radiation. That's the group of 200,00 or so who were actually on-site during the course of the atmospheric nuclear detonation. Eighty-eight percent received whole body gamma doses of 1 rem or less and 99 percent received doses of 5 rems or less.

These film badge readings were pretty much corroborated by the Department of Defense's dose reconstructions, the reconstruction of events from the historical data.

They also did a fairly exhaustive review of the Hiroshima/Nagasaki data. They concluded that based upon the timing of the introduction of troops in Japan after World War II that no individual could have been exposed to more than 1 rem as a residual of the bombings of those two cities.

What we have experienced is a fairly large number, probably around 10,000 claims to date, of various physical ailments that are said to be attributable to what are usually fairly low dose exposures.

I suppose VA's sophistication in handling these claims has grown at roughly the same pace as mankind's knowledge about the effects of low level exposure.

Essentially, early on, back in the 1960's and 1970's, VA had a fundamental, straightforward case-by-case approach to the individual cases. Their rating board members would ascertain effects of a dose to an individual. They would get medical guidance on occasion from outside medical experts as to the likelihood of any cause and effect relationship and rule accordingly.

By about 1981 it was becoming obvious that VA's approach resulted in allowances of benefits at a politically unacceptable rate. For example, for the first 820 claims involving atmospheric nuclear test participants who had later contracted cancer, VA allowed benefits in only 17 cases.

That was the year Congress enacted Public Law 97-72 which created a high priority of health care eligibility for any of the so-called Atomic Veterans regardless of whether a relationship to service could be shown between their particular illness and their exposure to radiation in-service.

Thus, these veterans are assured today, that regardless of the establishment of a cause and effect relationship between their illness and service, free VA health care is available to them.

By 1984, after further congressional hearings, Congress expressed some additional frustration with the pace at which claims were being allowed and enacted legislation that required VA to specifically spell out in its regulations the diseases it would recognize as radiogenic and the circumstances under which benefits would be granted.

Congress enacted Public Law 98-542 -- incidentally, I am going to be handing some copies of these

public laws -- which required VA to adopt specialized rules.

These rules, as well as the public laws essentially list the factors that VA will take into account in determining the radiation relationship to the disease suffered by the individual claimant. It lists a series of evidentiary development steps that VA is to take and lists the sources of expertise to which VA will go in an individual claim to shed further light on the merits of the claim. Basically, it just lays out the procedure in some detail to which VA will adhere in deciding the claims.

The law also created an advisory committee for the Veterans' Administration, called the Veterans' Advisory Committee On Environmental Hazards.

It is quite an interesting body. The panel includes radiation experts and epidemiologists who advise VA on compensation policy matters. My colleague from my office, Fred Conway, will discuss that committee and its operation in a few moments.

Despite all these efforts Congress again acted in 1988 in response to criticism that VA was not allowing enough claims. Of over 9,000 claims, fewer than half of which involved radiogenic diseases, VA had by that time allowed 43 claims.

The veterans' lobby prevailed in securing the enactment of Public Law 100-321, which I have also included in the materials that were handed out. This new law, in effect, requires that VA presume to be service-connected and hence compensable any of 13 different cancers if suffered by these Atomic Veterans. These are the weapons test participants and the occupation forces. It does not address the other veteran claimants that VA deals with, including those exposed from nuclear vessels and so forth.

This enactment, as you might expect, came over the objection of the Administration which argued that it just flew in the face of good science. All the available information was, that is, all the Government's information anyway, indicated that the doses experienced were on the whole very, very small.

Since the enactment of this in 1988, over 300 claims have been allowed by VA purely on the basis of the new public law which in effect presumes service-connected circumstances.

I guess, in summation I would say that what I would portray as a fairly good faith effort on VA 's part to do a careful case-by-case review of these claims, was overrun by the political atmosphere in which we were operating, which was a creation of the veterans' lobby.

The veterans service organizations succeeded in convincing the Congress that there were enough unknowns about the circumstances under which they served and about the doses to which they were exposed to put doubt in the mind of Congress that all meritorious cases weren't being recognized.

Congress reacted and arguably overreacted to that by saying, look, we will not even quibble about these cases. We will presume in every case that if you get cancer, any of the 13 listed cancers, which include many common forms of cancer, we will presume that there is a relationship to your exposure in-service. With that, although I am pleased to answer questions, I think at this point I will turn it over to Mr. Conway to explain a little more about the Veterans' Advisory Committee.

Mr. CONWAY: Thank you. My name is Frederic Conway and I serve as the Executive Secretary to the Veterans' Advisory Committee On Environmental Hazards. By way of a brief background, the committee had its origin in the radiation controversy and concurrent with that radiation controversy, which was being waged by the veterans' community, was also the Agent Orange controversy.

The Congress felt that VA had a lack of credibility and objectivity in assessing the scientific literature relating both to the Agent Orange issue and the radiation issue. To try to address that perception of lack of objectivity and credibility it mandated the establishment of a 15 member advisory committee.

The committee has on it individuals who have areas of expertise in the radiation health effects area and in the area of exposure to dioxin, if you will. They also include members who have particular areas of expertise in epidemiology and biostatistics and genetics. The committee meets on a semiannual basis. The meetings are open to public and notice is given in the Federal Register of the date and the location of the meeting.

The meetings tend primarily to focus on the review of the scientific literature that relates to health effects of exposure to either ionizing radiation or the components of Agent Orange. The studies that are selected for review are obtained by a computer search of the literature. And sometimes studies are suggested by service organizations or by members of Congress or by members of the advisory

committee itself.

The committee will review this literature on a paper by paper basis and critique each paper as to its relative strengths and weaknesses. They will then do an overall cumulative assessment and will provide guidance to the Secretary of Veterans' Affairs as to whether there is a significant statistical association between an exposure and an adverse health effect. A "significant statistical association" is a phrase that came about as a result of the challenge to VA's interpretation of Public Law 98-542.

The advisory committee was using a standard of cause and effect. The court felt that that was too strict a standard, that we must use a more liberal standard of "significant statistical association." The department has interpreted that to mean that when the relative weights of valid positive and valid negative studies are in approximate balance, the department will find an association between exposure and a subsequent adverse health effect.

I will be glad to answer any questions you may have about the operations of this committee or any other issue that you wish to address to Mr. Thompson or myself.

Mr. KENNEDY: Who, within the Veterans' Administration, makes the specific determination in a specific case as to whether there is a significant statistical association?

John Jones is a veteran and says, I have been exposed and there is some record of his exposure. He says, I have this particular illness, and the illness is, he claims, statistically associated with his exposure; who makes the determination as to whether John Jones recovers? What is your decision process?

Mr. THOMPSON: Let me just clarify something that we may not have stated as clearly as we could. The advisory committee that Mr. Conway was describing makes recommendations to VA as to which diseases categorically may be associated with either radiation exposure or dioxin exposure without regard to individual claims. The advisory committee's recommendations get translated into our overall regulations which then list the diseases we will recognize in appropriate cases.

The individual cases are then decided by, in the first instance, what are called rating boards at our regional office level. These are three-member panels which include one physician member.

Now, the way the process works, the rating board after first ascertaining, in the radiation context, that an individual was exposed to radiation, after getting the documentation from the Department of Defense, after ascertaining that the person does in fact have a disease which VA would recognize as radiogenic, forwards that information to our central office which has available to it the expertise of our medical administration which runs VA hospital system.

Within that administration are individuals who have expertise in the area of dose responses and so forth. An opinion is gotten then from this medical administration which in turn is used in ascertaining the validity of the claim.

That decision then, at the regional office level, can be further appealed to an appeals board here in Washington, D.C., which includes a physician member. This board also has available to it outside consultants. They contract with individual medical schools, for example, to get expert advice on individual claims. Many of them draw upon the probability-of-causation tables developed, as you know, not too long ago and the underlying assumptions which have changed in recent weeks with the nuclear data and so forth. The ultimate decision is made by VA personnel with as much input as VA can get from available sources.

Dr. RASMUSSEN: Well, with the new law you don't do that.

Mr. THOMPSON: That's right. If it is one of these cancers, one of the 13 cancers that is now in the statute, all we need determine is that that person was a test participant or one of the occupation troops.

Dr. RASMUSSEN: That assumes the reading is never off?

Mr. THOMPSON: That's right, it can be zero.

Mr. GARRISH: And some of those are not radiogenic, is that correct, or a large fraction of them?

Mr. THOMPSON: Well, I think the diseases Congress listed have all been implicated as being potentially radiogenic diseases.

Mr. GARRISH: Oh. Listed.

Dr. RASMUSSEN: They can be caused.

Mr. THOMPSON: They can be caused, that's right. You know, the merits of the individual claims are in some cases very, very questionable.

Mr. FEINBERG: As was pointed out by both you and Professor Rasmussen there is a presumption of compensation for certain diseases; how do you then determine the level of that compensation?

Mr. THOMPSON: Once an award is made the amount of the monthly check is tied directly to the degree of disability. If a person is laid up as a result of cancer and cannot work, that person will be compensated at the total disability rate, which is, as I indicated, on the order of $1,500 or so a month.

Mr. FEINBERG: And in cases of death, as a result, there is also an additional award?

Mr. THOMPSON: Yes, there is an award to a surviving spouse if there is one and if not, to any surviving children.

The CHAIRMAN: I would like to go back to this phrase, "radiogenic." What does VA mean or what do you mean when you use that phrase?

Mr. THOMPSON: All we mean is that it is one which VA recognizes as a disease which may be caused by ionizing radiation.

Mr. KENNEDY: Is there a scientific body of information that says, take the list of 13, these may be caused by radiation and others may not?

Mr. THOMPSON: Well, obviously there is -- the BEIR reports are what VA draws on heavily.

Mr. KENNEDY: Do you go through the advisory committee?

Mr. THOMPSON: Yes.

Mr. KENNEDY: Does the advisory committee look at the BEIR report and do anything with it, to it, or for it?

Mr. THOMPSON: They have advised us that there are diseases in addition to those listed by BEIR, where there is credible science indicating that at sufficient doses there maybe a relationship. For example, skin cancer is not listed in the BEIR report as one likely to be caused by radiation and yet at a high enough dose it is one which can be caused by ionizing radiation. That is on our list. Other noncarcinogenic diseases, certain forms of cataracts, at a high enough dose can be generated by ionizing radiation. That is on our list. We do rely on our advisory committee heavily with respect to the composition of our list.

Mr. KENNEDY: Your list is in your regulations?

Mr. THOMPSON: Yes. I apologize for not handing those out beforehand. I have them for you.

Mr. KENNEDY: Is that the same list that Congress adopted?

Mr. THOMPSON: No. Actually, Congress' is a little more restrictive than our list. Congress, for example, does not list colon cancer, I think on the basis that typically there is not -- radiation is not typically a cause. There are some other deletions from our list that Congress did not adopt on the basis that while they may be caused by radiation, enough radiation to the organ, typically exposures of these Atomic Veterans were not such that you would expect that the origin of their cancer was that exposure.

Mr. FAIN: Would you characterize the way this works for VA in radiation as similar to Black Lung? As I understand it a miner -- you mentioned a temporal relationship -- a miner shows that he worked in the mines for so many years, he has medical testimony to the effect that he has symptoms and those two factors are sufficient to award compensation?

Mr. THOMPSON: That certainly is the way it works under the new statute.

Mr. CONWAY: But for a certain class of veterans. That benefit only applies to individuals who served in the occupation forces or participated in atomic weapons testing programs. That presumption would not apply to individuals who had other forms of exposure. For example, an X-ray technician who never served in the occupation forces.

Mr. KENNEDY: Well, that is the framework of the legislation.

Mr. CONWAY: Right, that's right.

Mr. KENNEDY: As it is the framework of the Black Lung legislation.

Mr. CONWAY: Right.

Mr. KENNEDY: Thank you.

Mr. FEINBERG: I am interested by some of the tough lessons that VA has learned from all of this that might be of precedential utility to this Commission. The politics of compensation are intriguing. What I hear you folks saying is that despite efforts by VA to develop objective scientific epidemiologically-based criteria for recovery, that in Veterans' organizations and with individual veterans, the emotions run extremely high and you found yourself confronting Congress and these Veterans' groups who didn't --

Maybe I am putting words in your mouth but let me make the argument.

Mr. THOMPSON: You haven't so far.

Mr. FEINBERG: -- who didn't want to accept the available scientific data and instead insisted, in good faith, I will assume in good faith, that compensation of a perceived causal connection is justified.

Is that the dilemma you confront?

Mr. THOMPSON: I think that is a very good characterization. I wouldn't for a minute question the good faith of the veterans' groups or of the individual veterans.

Mr. FEINBERG: Why didn't VA or why doesn't the
Veterans' Administration, in light of this perceived political reaction to VA's policy, become more flexible? Why didn't VA become more flexible without congressional interference in trying to compensate the people for these perceived causal-connected maladies?

Mr. THOMPSON: We, you know, obviously are creatures of authorizing legislation and are limited by authorizing legislation in what we can do. The basic compensation law under which we operated was one which said the
VA had to find that the current disability is traceable to a disease or injury that had its inception in the service. Absent evidence that that was the case, we had no authority to act.

If your question is: Why didn't the Veterans' Administration, for political reasons, go to the Hill and say, give us authority to compensate all of these Atomic Veterans, as attractive as that was, and assuredly it was discussed within the department, we realized we couldn't draw the line where Congress drew it and make a good presentation to Congress. We couldn't say that only Atomic Veterans, based upon the limited scientific justification that we had, should benefit.

Certainly, other radiation exposed veterans and as well veterans exposed to other toxic substances in-service could have made as good case as the Atomic Veterans could for drawing the parameters larger. We had no place to stop and that's one reason that we didn't go forward.

Mr. FEINBERG: See, I am very dubious, this is just a personal view, but I am very dubious that any effort by this Commission to rely on available scientific or epidemiological evidence as the basis of criteria as to who should
recover for personal injury and who should not in the event of a catastrophic nuclear accident, I am dubious that that would get us very far.

If such a catastrophe takes place I envision a situation similar to the one that you confront, namely, absolute argument that any injury, however attenuated, is in the mind of the victim, the result of such an accident. Even though in good faith one relies on the best evidence available, emotions run so high and are so deeply felt that I am not sure that it gets you very far in the bottom line to rely on available scientific and medical evidence, as objective as it may be.

Mr. CONWAY: If I may respond a little bit on that one.

In a sense I share that concern. Taking Agent Orange as an example, as you well know, Judge Weinstein crafted a scheme that divorced itself from the specific causation issue. Even there you have individual veterans expressing extreme displeasure with the way their cases are being handled and how their particular circumstances are not being compensated. Again, I don't know that if one divorces oneself from a causation approach one is getting closer to a better resolution. Mr. FEINBERG: I think that's right. I think the problem with Agent Orange is less divorcing oneself from causation and more the limited amount of payment --

Mr. CONWAY: Right.

Mr. FEINBERG: -- which gives rise and inflames --

Mr. CONWAY: Right.

Mr. FEINBERG: -- of disgruntledness on the part of claimants. But I do agree with you that that is a serious problem.

Mr. KENNEDY: Could you give us some estimate as to how many dollars are involved in this compensation structure?

What is your appropriation for this on an annual basis?

Mr. THOMPSON: The annual appropriation is about $11 billion.

Mr. KENNEDY: Billion dollars?

Mr. THOMPSON: Billion dollars.

Mr. KENNEDY: Billion with a B?

Mr. THOMPSON: Yes.

Mr. FEINBERG: That's not just for radiation. Is it?

Mr. THOMPSON: No, that is for all veterans being compensated for disabilities of all kinds.

The CHAIRMAN: How much of this goes for the radiation-related injuries?

Mr. THOMPSON: Oh, a very small amount.

The CHAIRMAN: A very small amount.

Mr. THOMPSON: We are talking about 300 to 400 claims.

The CHAIRMAN: Let me follow-up on Mr. Feinberg's question, if I might. As I understand it, what you do is you appoint a committee that says certain cancer related diseases can be caused by radiation and that committee makes that determination. Then VA finds that a veteran was exposed to radiation during his service of duty and has one of these diseases and then payment is automatic?

Mr. THOMPSON: Yes. We are operating under this particular law since 1988. With respect to these certain classes of Atomic Veterans, if they have one of the 13 forms of cancer that Congress has specified, that's all that need be shown.

Dr. RASMUSSEN: Now, they either had to be occupying troops or in the bomb tests; is that correct?

Mr. THOMPSON: That's correct, for this special presumption in law to apply.

The CHAIRMAN: And that's the only test that you apply?

Mr. CONWAY: If a veteran has a condition, not on the congressionally-established presumption list, but has a condition which VA has determined can be associated with the exposure to radiation, a separate process is gone through, to which Mr. Thompson alluded to earlier, to ascertain medical opinion as to what is the likelihood that this exposure that this individual had can be associated to a subsequent development of a disease on that list.

Mr. THOMPSON: So we have to still make case-by-case determinations.

The CHAIRMAN: Let me carry that one step further with regard to occupying troops following World War II; do they have to be within the boundaries of Nagasaki or Hiroshima?

Mr. THOMPSON: Yes. We had to devise a boundary and we came within that ambit.

The CHAIRMAN: What if you were within 10 miles of either city?

Mr. THOMPSON: That is approximately the test we came up with. We realized where Congress is coming from on this one and we drew the line very broadly.

The CHAIRMAN: But the way you draw that line if, for example, the line is this table and I am stationed here --

Mr. THOMPSON: You will always miss somebody.

The CHAIRMAN: -- then I don't get it.

Mr. FEINBERG: When you say, "You don't get it," do you automatically bar that claim or on a case-by-case determination you'll say, well, Steve is beyond the table but the wind is blowing that way on that day; are there arguments
made that will be sympathetically received?

Mr. THOMPSON: We had claims, for example, that American prisoners of war had been held within Japan in areas outside of the city but within the path of the fallout, we handle those on a individual basis.

Mr. FAIN: But I take it the congressional presumption covers diseases which in the absence of that presumption VA would have denied the causal connection?

Mr. THOMPSON: Certainly in many cases, if not in the majority of cases.

Mr. GARRISH: In terms of comparison in some of the Agent Orange litigation that was done in court, do you have any feeling as to which one works better in terms of compensation?

Mr. THOMPSON: I don't.

Mr. FEINBERG: I want to hear that.

Mr. CONWAY: I don't think it has been established yet. It is an interesting approach that Judge Weinstein had fashioned out with Mr. Feinberg's assistance. Whether that will satisfy any demand for more compensation or additional forms of compensation, other than direct monetary benefits, I don't know, that remains to be seen.

Mr. GARRISH: Could you talk about the advantages and disadvantages of each from your

standpoint?

Mr. CONWAY: My personal opinion is that the obvious advantage is it eliminates the debate, which is a rather difficult one to engage in, on causation. You get that whole issue behind you. If you assume or if you accept a rather broad based compensation scheme, that is, we will pay for any condition that could remotely be associated with exposure, then you tend to diminish somewhat, but not totally, the emotional atmosphere in which you operate.

The problem is those individuals who always will have this -- the individual who does not meet the criteria of 100 percent disability as determined by Social Security criteria.

Some argument is always going to be made, well, that criteria is too strict, given the unique circumstances of the particular exposure and it should be more liberal than this strict Social Security standard. You are always going to have that argument. So, there is no one answer that will satisfy everybody concerned.

The other problem we have is that we cannot compartmentalize too much. We have to recognize that what we do in one area can spill over into other areas some of which we cannot foresee right now. How we are going to address some unusual circumstances in the future is of concern to us because you may be addressing a short-term, immediate political problem but at a long-term expense that the Congress or the public may not be quite so willing to support.

Mr. FEINBERG: I think that's a very important point. In the Agent Orange case a formula fashioned on the notion of objective physical impairment, regardless of the causal evidence, could work because it was, relatively speaking, a narrow type of case, where you had a finite amount of money and that's all there was. The case involved a class of claimants all alleging Agent Orange illness.

I am just reaffirming what has been said, that the one problem that confronts the United States Government, I think, which is of precedential impact of that type, of a formula that goes well beyond Agent Orange, encompassing all sorts of other perceived diseases and maladies that might break the bank in terms of payment.

On what basis are you going to pay, other than if someone is ill. If you want to send them a check in the Agent Orange case you can do that, it is a small check. When you go beyond Agent Orange and start talking about any related malady or illness or what have you, you run into this problem of where does the line gets drawn, I guess.

Mr. STAHL: First, my apology for not being on time. I wish I had heard all of your remarks. I will read the transcript very carefully.

I will follow Mr. Feinberg's comments. If I understood you correctly, you said there are three or four hundred pending claims?

Mr. THOMPSON: No. Since the enactment of this statute last summer, which created the presumption of service connection for certain diseases, we have allowed that many claims.

Mr. STAHL: You have allowed?

Mr. THOMPSON: There are many more claims in the works and I don't have a handle on that.

Mr. STAHL: That takes me where I want to go. I know you draw on the Three Mile Island guidelines with respect to extensions for reasons that have been mentioned.

How many potential claimants do you believe exist?

Mr. THOMPSON: The class of people we are talking about are approximately 200,000 atomic test participants and some 30 to 40,000 occupation troops.

Mr. STAHL: Next question would be --

Dr. RASMUSSEN: Well, but a fifth or a quarter of them will get cancer.

Mr. THOMPSON: Yes.

Dr. RASMUSSEN: You expect some number like 50,000 potential cancer patients/claimants who might put in a case?

Mr. THOMPSON: That's right.

Mr. STAHL: That leads to this question: Are all of these 230 or 240 thousand people advised to identify themselves, where they are hurt? Do they have people coming in with concerns about future illnesses where there is a cutoff date, if there is one? How do you cope with issues like that?

Mr. THOMPSON: Fortunately, there is no cutoff date for presentation of claims. They can be filed at any point. VA has done a pretty good job, I think, of getting the word out about this presumption, both in press releases and in getting the organized veterans' groups to get the word out in their monthly

magazines of the availability of this new law -- which does generate claims. I think the word has pretty much gotten out.

Mr. CONWAY: The outreach program maintains an 800 number for any radiation veteran or anybody can dial that number. They will be furnished the information regarding the various aspects of the Nuclear Test Personnel Group Program and VA benefits and so forth.

Mr. STAHL: So any veteran who may have been within these parameters can notify you, I was there, please put me on your list for the future?

If they are not hurt today, what do you do in such a situation or don't you get such claims?

Mr. THOMPSON: No, I think in that case VA would write back and say, should you ever develop a disability, we will determine the merits of your individual claim.

Mr. STAHL: Is there any medical monitoring of those people?

Mr. THOMPSON: They are invited -- in fact, the same public law that granted them health care at no cost, authorizes VA to do thorough, physical examinations of them to determine whether they might have any pre-cancerous indicia.

Mr. FAIN: But you do not need medical monitoring if you have a guaranteed medical program.

Mr. THOMPSON: That's right.

Mr. FAIN: There is no basis on which you are accumulating statistical data on these people through a monitoring practice?

Mr. THOMPSON: I think we are not and one reason being that it would have very limited validity and all being sort of self-reported, self-initiated, we would get a self-selected sense.

Mr. KENNEDY: Could you help us on one point? Suppose at the time of the activity, at the time of these atmospheric tests, people had had 20/20 foresight and had taken blood samples and physicians performed analyses to determine chromosomal damage, to what extent would that have helped you in the resolution of these claims? Presumably this could be done post-accident?

Mr. THOMPSON: Yes.

Dr. RASMUSSEN: In the 10 to 20 rem range almost none of these people had doses like that, none of them were in the range which showed chromosomal range --

Mr. THOMPSON: I think of the whole 200 and some thousand test participants 39 were identified as having doses of 20 rem or higher. They were identified and examined, by the way, and were not found to be suffering from any problem.

Mr. STAHL: How many claims have you, in fact, received? Are they coming in and at what rate?

Mr. THOMPSON: I think we've received something on the order of 10,000 claims, less than half of which are cancers or other radiogenic diseases. I am frankly not sure of the rate at which we are getting them now.

Mr. STAHL: But you are getting calls?

Mr. THOMPSON: Certainly. We know we have only compensated 300 and some veterans since this new law was enacted and given the cancer incident rate, we are going to have many, many more potential claims before the program ends.

Mr. CONWAY: And some of those 10,000 claims are for conditions, for example, such as a cancer phobia. I am afraid I might get cancer, therefore, I deserve compensation which we at VA are not authorized to compensate for. Or you might get a claimant saying, I was exposed to radiation, will I have birth-defected children for which we are not allowed to compensate. There is nothing wrong with some of these claimants. They heard about this program and they think, what the heck, I will submit an application. So, the 10,000 does not necessarily mean that there are 10,000 sick veterans out there. It means that there are 10,000 claimants some of whom are sick.

The CHAIRMAN: Our time is about up on this. My executive director has a question.

Mr. SALTZMAN: With respect to the administration's view of the 1988 legislation that the President signed; is there anything in the President's message that would be useful to this Commission?

Mr. THOMPSON: We will be glad to provide that for the record.

Dr. RASMUSSEN: What is the size of a typical death benefit in these cases?

Mr. THOMPSON: Again, that is tied to the service grade attained by the individual while in the military. The death benefits for surviving spouse range from $564 for the widow for a month, for the widow of an E-1 enlisted man, to over $1,500.

Dr. RASMUSSEN: Same rate that they were getting before? That was the range of benefits you gave for the ill person?

Mr. THOMPSON: That's right. The range we gave for individuals, though, for sick veterans is not tied to their service rate. It is tied to their level of disability. That's the difference.

The CHAIRMAN: Okay. Thank you very much, Mr. Thompson, Mr. Conway. We have been very enlightened.

Mr. THOMPSON: Thank you.

The CHAIRMAN: We are very fortunate to have Mr. Berger who had been active in the Three Mile litigation following the accident.

Mr. Berger, we want to thank you very much for coming.

Mr. BERGER: I want to thank you for inviting me. It is a pleasure to be here. I would want to help you in every way I can. I guess the best way to do that would be to share some of our experiences in administering the Three Mile Island settlement.

I know you have a very difficult job not the least reason of which is I spent the last few days trying to parse the amendments to the Price-Anderson Act without much success, to be perfectly candid.

As I said, I would like to share with you some of our experiences. I couldn't help but think of some comments to the last speakers' statements and although I am a layman, I would be happy to share those with you at the conclusion of my remarks if they would be of interest to this Panel.

It is outside my expertise, but I must say that I was a little disappointed about some of the remarks that were made about the administration of the Atomic Veterans Program by the Veterans' Administration but that perhaps is a different issue. But I will return to that and maybe I can work them somehow into my remarks.

I think the best thing for me to do would be to give you some background on the Three Mile Island litigation and the settlement administration which consist in important respect in claims administration of the type that might come up in the course of some other so-called nuclear incident or even an extraordinary occurrence.

As you may recall the accident took place in March of 1979 and the case was settled in February of 1981. There were two settlement funds that were established. There was an Economic Loss Fund to pay, as the name indicates, the economic losses associated with the accident consisting of property damage losses, business losses, wage and evacuation loss claims and other economic losses.

Then there was a separate fund established called the Public Health Fund, the purpose of which was to do basically scientific studies into the health effects of the Three Mile Island accident and also to make recommendations as to how to improve radiation monitoring at the facility and emergency planning at the facility.

The reason -- let me backup by saying, the settlement and litigation did not involve any personal injury claims. Perhaps in retrospect that was a defect of the litigation, as plaintiff's counsel urged the court to certify a personal injury class but the court in its discretion declined to do so.

So that the class action litigation involved economic loss claims, a novel claim which was litigated in the context of that litigation for medical detection and surveillance services and, in fact, those two claims were eventually settled. They led to the formation of the two funds that I've just described: The Economic Loss Fund and the Public Health Fund.

Since that time we have tremendous amount of experience. My firm was chief counsel for the plaintiffs in that litigation and we have a tremendous amount of experience administering both funds.

It turns out that the fund that was most novel and most interesting and challenging was the Public Health Fund because there had never been a claim for medical detection in surveillance services, certainly, in a nuclear incident, in the form of a class action. And also it pushed us into uncharted scientific waters involving questions of radiation exposure and health effects of radiation exposure, things of that nature.

I am going to try to make my remarks so that they may be relevant to some of the concerns that I perceived in the mandate that you have from Congress, which is a difficult one, and that is, to attempt to make recommendations as to

how to improve the adjudication of claims and any recommendations as to changes in legal standards or standards of Rules of Civil Procedure in adjudicating these claims and to deal with the very thorny problem of latent injury that may

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## B

Divider Title: _____

## Preliminary List of Legislation Pertaining to Compensation for Radiation Exposure

| Public Law/Bill Number | TITLE |
|---|---|
| 5 USC 8102 | Compensation for Disability or death of a Government Employee |
| PL 98-542* | Veterans'Dioxin and Radiation Exposure Compensation Standards Act (1984) |
| 38 USC 1112C* | Radiation Exposed Veterans Compensation Act of 1988 |
| 38 USC 1154 | Compensation for Service-Connected Disability or Death: General Compensation Provisions |
| 42 USC 2210/PL 101-426* | Radiation Exposure Compensation Act (1990) |
| 42 USC 2021 | Cooperation Between Federal Government and States concerning Development and Control of Atomic Energy |
| 102-4 | Agent Orange Act of 1991 |
| 42 USC 7274 (i)* | Part of DOD Authorization Act: (requires ongoing DOE health monitoring of people occupationally exposed to radiation) |
| 48 USC 1681/PL 99-239* | "Compact of Free Association" (Marshall Islanders compact). Covers DOE Radiological Health Care Program in Section 103(H) |

* Copies of U.S. Code/bill attached

## SUMMARY OF PRESENT COMPENSATION PROGRAMS

| Compensation Program/Statute | Award Amount Range | Terms/Conditions |
|---|---|---|
| "Compact of Free Association" (Marshall Islands citizens exposed to nuclear testing 1946 - 1958) | $75,000 - $130,000 | Total funding authorization = $183 million; funds distributed for individual islands and dispersed by government. Approximately 450 people granted compensation. |
| Japanese Internment Camp Compensation Provisions | $20,000 | Victims and families eligible. Approximately 125,000 people were interned. |
| Radiation Exposure Compensation Act | $50,000 - $100,000 | $50,000 for claims related to open air nuclear testing;<br>$100,000 for claims related to uranium mining.<br>(Total funding authorization = $100 million) |

"Compact of Free Association"



Section 175

Law enforcement.

A separate agreement, which shall come into effect simultaneously with this Compact, shall be concluded between the Government of the United States and the Governments of the Marshall Islands and the Federated States of Micronesia regarding mutual assistance and cooperation in law enforcement matters including the pursuit, capture, imprisonment and extradition of fugitives from justice and the transfer of prisoners. The separate agreement shall have the force of law. In the United States, the laws of the United States governing international extradition, including 18 U.S.C. §§184, 3186 and 3188-3195, shall be applicable to the extradition of fugitives under the separate agreement, and the laws of the United States governing the transfer of prisoners, including 18 U.S.C. 4100-4115, shall be applicable to the transfer of prisoners under the separate agreement.

Section 176

The Governments of the Marshall Islands and the Federated States of Micronesia confirm that final judgments in civil cases rendered by any court of the Trust Territory of the Pacific Islands shall continue in full force and effect, subject to the constitutional power of the courts of the Marshall Islands and the Federated States of Micronesia to grant relief from judgments in appropriate cases.

Section 177

(a) The Government of the United States accepts the responsibility for compensation owing to citizens of the Marshall Islands, or the Federated States of Micronesia (or Palau) for loss or damage to property and person of the citizens of the Marshall Islands, or the Federated States of Micronesia, resulting from the nuclear testing program which the Government of the United States conducted in the Northern Marshall Islands between June 30, 1946, and August 18, 1958.

Claims.

(b) The Government of the United States and the Government of the Marshall Islands shall set forth in a separate agreement provisions for the just and adequate settlement of all such claims which have arisen in regard to the Marshall Islands and its citizens and which have not as yet been compensated or which in the future may arise, for the continued administration by the Government of the United States of direct radiation related medical surveillance and treatment programs and radiological monitoring activities and for such additional programs and activities as may be mutually agreed, and for the assumption by the Government of the Marshall Islands of responsibility for enforcement of limitations on the utilization of affected areas developed in cooperation with the Government of the United States and for the assistance by the Government of the United States in the exercise of such responsibility as may be mutually agreed. This separate agreement shall come into effect simultaneously with this Compact and shall remain in effect in accordance with its own terms.

Grants.

(c) The Government of the United States shall provide to the Government of the Marshall Islands, on a grant basis, the amount of $150 million to be paid and distributed in accordance with the separate agreement referred to in this Section, and shall provide the services and programs set forth in this separate agreement, the language of which is incorporated into this Compact.

adequate and whether such conclusions are fully supported by the data. If the party reviewing the data concludes that such conclusions as to habitability are fully supported by adequate data, the report to the President of the United States and the Congress shall so state. If the party reviewing the data concludes that the data are inadequate to support such conclusions as to habitability or that such conclusions as to habitability are not fully supported by the data, the Government of the Marshall Islands shall contract with an appropriate scientist or group of scientists to undertake a complete survey of radiation and other effects of the nuclear testing program relating to the habitability of Rongelap Island. Such sums as are necessary for such survey and report concerning the results thereof and as to steps needed to restore the habitability of Rongelap Island are authorized to be made available to the Government of the Marshall Islands.

(3) It is the intent of Congress that such steps (if any) as are necessary to restore the habitability of Rongelap Island and return the Rongelap people to their homeland will be taken by the United States in consultation with the Government of the Marshall Islands and, in accordance with its authority under the Constitution of the Marshall Islands, the Rongelap local government council.

Hazardous materials.

(j) FOUR ATOLL HEALTH CARE PROGRAM.—(1) Services provided by the United States Public Health Service or any other United States agency pursuant to section 1(a) of Article II of the Agreement for the Implementation of Section 177 of the Compact (hereafter in this subsection referred to as the "Section 177 Agreement") shall be only for services to the people of the Atolls of Bikini, Enewetak, Rongelap, and Utrik who were affected by the consequences of the United States nuclear testing program, pursuant to the program described in Public Law 95-134 and Public Law 96-205 and their descendants (and any other persons identified as having been so affected if such identification occurs in the manner described in such public laws). Nothing in this subsection shall be construed as prejudicial to the views or policies of the Government of the Marshall Islands as to the persons affected by the consequences of the United States nuclear testing program.

*Ante*, p. 1761.

91 Stat. 1159.
94 Stat. 84.

(2) At the end of the first year after the effective date of the Compact and at the end of each year thereafter, the providing agency or agencies shall return to the Government of the Marshall Islands any unexpended funds to be returned to the Fund Manager (as described in Article I of the Section 177 Agreement) to be covered into the Fund to be available for future use.

(3) The Fund Manager shall retain the funds returned by the Government of the Marshall Islands pursuant to paragraph (2) of this subsection, shall invest and manage such funds, and at the end of 15 years after the effective date of the Compact, shall make from the total amount so retained and the proceeds thereof annual disbursements sufficient to continue to make payments for the provision of health services as specified in paragraph (1) of this subsection to such extent as may be provided in contracts between the Government of the Marshall Islands and appropriate United States providers of such health services.

Hazardous materials.

(k) ENJEBI COMMUNITY TRUST FUND.—Notwithstanding any other provision of law, the Secretary of the Treasury shall establish on the books of the Treasury of the United States a fund having the status specified in Article V of the subsidiary agreement for the implementation of Section 177 of the Compact, to be known as the

*Post*, p. 1812.

(3) If the Government of the Marshall Islands determines that some other investment firm should act as Fund Manager in place of the firm first (or subsequently) selected by such Government, the Government of the Marshall Islands shall so notify the President of the United States, identifying the firm selected by such Government to become Fund Manager, and the President shall proceed to evaluate the qualifications of such identified firm.

(4) At the end of 15 years after the effective date of the Compact, the firm then acting as Fund Manager shall transfer to the Government of the Marshall Islands, or to such account as such Government shall so notify the Fund Manager, all remaining funds and assets being managed by the Fund Manager under the Section 177 Agreement.

48 USC note prec. 1681. Report. Public availability.

(5) An annual report concerning all actions of the Fund Manager pursuant to the Section 177 Agreement and this joint resolution, including information prepared by the Fund Manager, shall be transmitted by the Government of the Marshall Islands to the Congress. Such report shall include such information (whether received from the Fund Manager or any other source) as relates to the disbursements provided for in Article II of the Section 177 Agreement. Such report shall be made public.

Hazardous materials.

(f) NUCLEAR TEST EFFECTS.—In approving the Compact, the Congress understands and intends that the peoples of Bikini, Enewetak, Rongelap, and Utrik, who were affected by the United States nuclear weapons testing program in the Marshall Islands, will receive the amounts of $75,000,000 (Bikini); $48,750,000 (Enewetak), $37,500,000 (Rongelap); and $22,500,000 (Utrik), respectively, which amounts shall be paid out of proceeds from the fund established under Article I, section 1 of the subsidiary agreement for the implementation of section 177 of the Compact. The amounts specified in this subsection shall be in addition to any amounts which may be awarded to claimants pursuant to Article IV of the subsidiary agreement for the implementation of Section 177 of the Compact.

Post, p. 1812.

(g) ESPOUSAL PROVISIONS.—(1) It is the intention of the Congress of the United States that the provisions of section 177 of the Compact of Free Association and the Agreement between the Government of the United States and the Government of the Marshall Islands for the Implementation of Section 177 of the Compact (hereafter in this subsection referred to as the "Section 177 Agreement") constitute a full and final settlement of all claims described in Articles X and XI of the Section 177 Agreement, and that any such claims be terminated and barred except insofar as provided for in the Section 177 Agreement.

(2) In furtherance of the intention of Congress as stated in paragraph (1) of this subsection, the Section 177 Agreement is hereby ratified and approved. It is the explicit understanding and intent of Congress that the jurisdictional limitations set forth in Article XII of such Agreement are enacted solely and exclusively to accomplish the objective of Article X of such Agreement and only as a clarification of the effect of Article X, and are not to be construed or implemented separately from Article X.

# Clinton Presidential Records
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## C

Divider Title: _____

## RADIATION EXPOSURE COMPENSATION ACT (PL 101-426, OCTOBER 15, 1990)

Rationale for legislation

1. Fallout from above-ground nuclear tests in Nevada exposed individuals who lived downwind in Nevada, Utah and Arizona to radiation.

2. Radiation released in underground uranium mines for the nuclear weapons program exposed miners to large doses of radiation and other airborne hazards.

Purpose

To make partial restitution for the burdens these individuals [and their survivors] have borne for the Nation.

Eligibility for compensation

Claimants must present evidence of presence in the defined geographic area for specified periods and acceptable written medical documentation of the following:

A. Claims related to OPEN AIR NUCLEAR TESTING:

1. Childhood leukemia (other than chronic lymphocytic leukemia): contracted between 2 and 20 years of first exposure to the fallout.

2. Other specified diseases:

- Leukemia (other than chronic lymphocytic leukemia), provided that initial exposure occurred after age 20 and the onset was between 2-30 years of first exposure; and

- Provided onset was at least 5 years after first exposure: multiple myeloma, lymphomas (other than Hodgkin's disease), and primary cancer of : the thyroid (provided initial exposure occurred by the age of 20), female breast (provided initial exposure occurred prior to age 40), esophagus (provided low alcohol consumption and not a heavy smoker), stomach (provided initial exposure occurred before age 30), pharynx (provided not a heavy smoker), small intestine, pancreas (provided not a heavy smoker and low coffee consumption), bile ducts, gall bladder, or liver (except if cirrhosis or hepatitis B is indicated).

B. Claims related to URANIUM MINING:

[Had to have been employed in a uranium mine in Colorado, New Mexico, Arizona, Wyoming, or Utah during January 1, 1947 - December 31, 1971]

1. Lung cancer:

   - Nonsmoker, after exposed to 200 or more working level months of radiation,

   - Smoker, after exposed to 300 or more working level months of radiation and cancer incidence occurred before age 45 or was exposed to 500 or more working level months of radiation, regardless of age of cancer incidence; or

2. Nonmalignant respiratory disease:

   - Nonsmoker, after exposed to 200 or more working level months of radiation,

   - Smoker, after exposed to 300 or more working level months of radiation.

Definitions:

- Working level: the concentration of the short half-life daughters of radon that will release ($1.3 \times 10^5$) million electron volts of alpha energy per liter of air;

- Nonmalignant respiratory disease: fibrosis of the lung, pulmonary fibrosis, and corpulmonale related to fibrosis of the lung; and if the claimant worked in an uranium mine on or within an Indian Reservation, moderate or severe silicosis or pneumoconiosis.

Determination of Claims

Attorney General, in consultation with Surgeon General, sets guidelines for determining what constitutes written medical documentation

Attorney General, in consultation with the Director of the National Institute of Occupational Health and Safety (NIOSH) sets guidelines for determining what constitutes documentation that an individual was exposed to the working level months of radiation.

Payment of Claims

Attorney General pays claims which he determines meet the requirements of the Act, offset by related awards or settlements other than insurance payments.

Levels of Compensation

1. Claims related to Open Air Nuclear Testing: $50,000.

2. Claims related to Uranium Mining: $100,000.

Financing Mechanism

Radiation Exposure Compensation Trust Fund administered by the Treasury, with amounts disbursed by the Attorney General. Fund terminates 22 years after date of enactment of the Act. (Oct. 15, 1990).

The Attorney General's administrative costs may not be paid from the Fund.

Funding Authorization

$100,000,000, to remain available until expended.

Payments and contracts under the Act are subject to the availability of appropriations.

Other Provisions

Congress apologizes on behalf of the Nation to the individuals and their families.

Eligible survivors of a diseased claimant include spouses, children, grandchildren and grandparents.

Acceptance of payment under this Act constitutes payment in full of any related claims against the United States.

Claimant's attorneys may not receive more than 10 percent of any payment made on the claim.

Public Law 101-426
101st Congress

# An Act

Oct. 15, 1990
[H.R. 2372]

To provide jurisdiction and procedures for claims for compassionate payments for injuries due to exposure to radiation from nuclear testing.

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

Radiation exposure compensation.

SECTION 1. SHORT TITLE.

This Act may be cited as the "Radiation Exposure Compensation Act".

42 USC 2210 note.

SEC. 2. FINDINGS, PURPOSE, AND APOLOGY.

(a) FINDINGS.—The Congress finds that—

(1) fallout emitted during the Government's above-ground nuclear tests in Nevada exposed individuals who lived in the downwind affected area in Nevada, Utah, and Arizona to radiation that is presumed to have generated an excess of cancers among these individuals;

(2) the health of the individuals who were unwitting participants in these tests was put at risk to serve the national security interests of the United States;

(3) radiation released in underground uranium mines that were providing uranium for the primary use and benefit of the nuclear weapons program of the United States Government exposed miners to large doses of radiation and other airborne hazards in the mine environment that together are presumed to have produced an increased incidence of lung cancer and respiratory diseases among these miners;

(4) the United States should recognize and assume responsibility for the harm done to these individuals; and

(5) the Congress recognizes that the lives and health of uranium miners and of innocent individuals who lived downwind from the Nevada tests were involuntarily subjected to increased risk of injury and disease to serve the national security interests of the United States.

(b) PURPOSE.—It is the purpose of this Act to establish a procedure to make partial restitution to the individuals described in subsection (a) for the burdens they have borne for the Nation as a whole.

(c) APOLOGY.—The Congress apologizes on behalf of the Nation to the individuals described in subsection (a) and their families for the hardships they have endured.

42 USC 2210 note.

SEC. 3. TRUST FUND.

(a) ESTABLISHMENT.—There is established in the Treasury of the United States, a trust fund to be known as the "Radiation Exposure Compensation Trust Fund" (hereinafter in this Act referred to as the "Fund"), which shall be administered by the Secretary of the Treasury.

(b) INVESTMENT OF AMOUNTS IN THE FUND.—Amounts in the Fund shall be invested in accordance with section 9702 of title 31, United States Code, and any interest on, and proceeds from any such investment shall be credited to and become a part of the Fund.

(c) AVAILABILITY OF THE FUND.—Amounts in the Fund shall be available only for disbursement by the Attorney General under section 6.

(d) TERMINATION.—The Fund shall terminate not later than the earlier of the date on which an amount has been expended from the Fund which is equal to the amount authorized to be appropriated to the Fund by subsection (e), and any income earned on such amount, or 22 years after the date of the enactment of this Act. If all of the amounts in the Fund have not been expended by the end of that 22-year period, investments of amounts in the Fund shall be liquidated and receipts thereof deposited in the Fund and all funds remaining in the Fund shall be deposited in the miscellaneous receipts account in the Treasury.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Fund $100,000,000. Any amounts appropriated pursuant to this section are authorized to remain available until expended.



SEC. 4. CLAIMS RELATING TO OPEN AIR NUCLEAR TESTING.

42 USC 2210 note.

(a)(1) CLAIMS RELATING TO CHILDHOOD LEUKEMIA.—Any individual who was physically present in the affected area for a period of at least 1 year during the period beginning on January 21, 1951, and ending on October 31, 1958, or was physically present in the affected area for the period beginning on June 30, 1962, and ending on July 31, 1962, and who submits written medical documentation that he or she, after such period of physical presence and between 2 and 30 years of first exposure to the fallout, contracted leukemia (other than chronic lymphocytic leukemia), shall receive $50,000 if—

(A) initial exposure occurred prior to age 21,

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

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

(2) CLAIMS RELATING TO SPECIFIED DISEASES.—Any individual who was physically present in the affected area for a period of at least 2 years during the period beginning on January 21, 1951, and ending on October 31, 1958, or was physically present in the affected area for the period beginning on June 30, 1962, and ending on July 31, 1962, and who submits written medical documentation that he or she, after such period of physical presence, contracted a specified disease, shall receive $50,000 if—

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

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

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

(b) DEFINITIONS.—For purposes of this section, the term—

(1) "affected area" means—

(A) in the State of Utah, the counties of Washington, Iron, Kane, Garfield, Sevier, Beaver, Millard, and Piute;

(B) in the State of Nevada, the counties of White Pine, Nye, Lander, Lincoln, Eureka, and that portion of Clark County that consists of townships 13 through 16 at ranges 63 through 71; and

(C) that part of Arizona that is north of the Grand Canyon and west of the Colorado River; and

(2) "specified disease" means leukemia (other than chronic lymphocytic leukemia), provided that initial exposure occurred after the age of 20 and the onset of the disease was between 2 and 30 years of first exposure, and the following diseases, provided onset was at least 5 years after first exposure: multiple myeloma, lymphomas (other than Hodgkin's disease), and primary cancer of: the thyroid (provided initial exposure occurred by the age of 20), female breast (provided initial exposure occurred prior to age 40), esophagus (provided low alcohol consumption and not a heavy smoker), stomach (provided initial exposure occurred before age 30), pharynx (provided not a heavy smoker), small intestine, pancreas (provided not a heavy smoker and low coffee consumption), bile ducts, gall bladder, or liver (except if cirrhosis or hepatitis B is indicated).

e listing. /SC 2210

SEC. 5. CLAIMS RELATING TO URANIUM MINING.

(a) ELIGIBILITY OF INDIVIDUALS.—Any individual who was employed in a uranium mine located in Colorado, New Mexico, Arizona, Wyoming, or Utah at any time during the period beginning on January 1, 1947, and ending on December 31, 1971, and who, in the course of such employment—

(1)(A) if a nonsmoker, was exposed to 200 or more working level months of radiation and submits written medical documentation that he or she, after such exposure, developed lung cancer, or

(B) if a smoker, was exposed to 800 or more working level months of radiation and cancer incidence occurred before age 45 or was exposed to 500 or more working level months of radiation, regardless of age of cancer incidence, and submits written medical documentation that he or she, after such exposure, developed lung cancer; or

(2)(A) if a nonsmoker, was exposed to 200 or more working level months of radiation and submits written medical documentation that he or she, after such exposure, developed a nonmalignant respiratory disease, or

(B) if a smoker, was exposed to 800 or more working level months of radiation and the nonmalignant respiratory disease developed before age 45 or was exposed to 500 or more working level months of radiation, regardless of age of disease incidence, and submits written medical documentation that he or she, after such exposure, developed a nonmalignant respiratory disease,

shall receive $100,000, if—

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

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

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

(b) DEFINITIONS.—For purposes of this section—

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



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

(3) the term "nonmalignant respiratory disease" means fibrosis of the lung, pulmonary fibrosis, and corpulmonale related to fibrosis of the lung; and if the claimant, whether Indian or non-Indian, worked in an uranium mine located on or within an Indian Reservation, the term shall also include moderate or severe silicosis or pneumoconiosis; and

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

SEC. 6. DETERMINATION AND PAYMENT OF CLAIMS.

42 USC 2210 note.

(a) ESTABLISHMENT OF FILING PROCEDURES.—The Attorney General shall establish procedures whereby individuals may submit claims for payments under this Act.

(b) DETERMINATION OF CLAIMS.—

(1) IN GENERAL.—The Attorney General shall, in accordance with this subsection, determine whether each claim filed under this Act meets the requirements of this Act.

(2) CONSULTATION.—The Attorney General shall—

(A) in consultation with the Surgeon General, establish guidelines for determining what constitutes written medical documentation that an individual contracted a specified disease under section 4 or other disease specified in section 5; and

(B) in consultation with the Director of the National Institute for Occupational Safety and Health, establish guidelines for determining what constitutes documentation that an individual was exposed to the working level months of radiation under section 5.

The Attorney General may consult with the Surgeon General with respect to making determinations pursuant to the guidelines issued under subparagraph (A), and with the Director of the National Institute for Occupational Safety and Health with respect to making determinations pursuant to the guidelines issued under subparagraph (B).

(c) PAYMENT OF CLAIMS.—

(1) IN GENERAL.—The Attorney General shall pay, from amounts available in the Fund, claims filed under this Act which the Attorney General determines meet the requirements of this Act.

(2) OFFSET FOR CERTAIN PAYMENTS.—A payment to an individual, or to a survivor of that individual, under this section on a claim under section 4 or 5 shall be offset by the amount of any payment made pursuant to a final award or settlement on a claim (other than a claim for worker's compensation), against any person, that is based on injuries incurred by that individual on account of—

(A) exposure to radiation, from open air nuclear testing, in the affected area (as defined in section 4(b)(1)) at any time during any period specified in section 4(a), or

(B) exposure to radiation in a uranium mine at any time during the period described in section 5(a).

Uranium. ...e safety and ...h.

(3) RIGHT OF SUBROGATION.—Upon payment of a claim under this section, the United States Government is subrogated for the amount of the payment to a right or claim that the individual to whom the payment was made may have against any person on account of injuries referred to in paragraph (2).

(4) PAYMENTS IN THE CASE OF DECEASED PERSONS.—

(A) IN GENERAL.—In the case of an individual who is deceased at the time of payment under this section, such payment may be made only as follows:

(i) If the individual is survived by a spouse who is living at the time of payment, such payment shall be made to such surviving spouse.

(ii) If there is no surviving spouse described in clause (i), such payment shall be made in equal shares to all children of the individual who are living at the time of payment.

(iii) If there is no surviving spouse described in clause (i) and if there are no children described in clause (ii), such payment shall be made in equal shares to the parents of the individual who are living at the time of payment.

(iv) If there is no surviving spouse described in clause (i), and if there are no children described in clause (ii) or parents described in clause (iii), such payment shall be made in equal shares to all grandchildren of the individual who are living at the time of payment.

(v) If there is no surviving spouse described in clause (i), and if there are no children described in clause (ii), parents described in clause (iii), or grandchildren described in clause (iv), then such payment shall be made in equal shares to the grandparents of the individual who are living at the time of payment.

(B) INDIVIDUALS WHO ARE SURVIVORS.—If an individual eligible for payment under section 4 or 5 dies before filing a claim under this Act, a survivor of that individual who may receive payment under subparagraph (A) may file a claim for such payment under this Act.

(C) DEFINITIONS.—For purposes of this paragraph—

(i) the "spouse" of an individual means a wife or husband of that individual who was married to that individual for at least one year immediately before the death of that individual;

(ii) a "child" includes a recognized natural child, a stepchild who lived with an individual in a regular parent-child relationship, and an adopted child;

(iii) a "parent" includes fathers and mothers through adoption;

(iv) a "grandchild" of an individual is a child of a child of that individual; and

(v) a "grandparent" of an individual is a parent of a parent of that individual.

(d) ACTION ON CLAIMS.—The Attorney General shall complete the determination on each claim filed in accordance with the procedures established under subsection (a) not later than twelve months after the claim is so filed.

(e) PAYMENT IN FULL SETTLEMENT OF CLAIMS AGAINST THE UNITED STATES.—The acceptance of payment by an individual under this section shall be in full satisfaction of all claims of or on behalf of that individual against the United States, or against any person with respect to that person's performance of a contract with the United States, that arise out of exposure to radiation, from open air nuclear testing, in the affected area (as defined in section 4(b)(1)) at any time during any period described in section 4(a), or exposure to radiation in a uranium mine at any time during the period described in section 5(a).

(f) ADMINISTRATIVE COSTS NOT PAID FROM THE FUND.—No costs incurred by the Attorney General in carrying out this section shall be paid from the Fund or set off against, or otherwise deducted from, any payment under this section to any individual.

(g) TERMINATION OF DUTIES OF ATTORNEY GENERAL.—The duties of the Attorney General under this section shall cease when the Fund terminates.

(h) CERTIFICATION OF TREATMENT OF PAYMENTS UNDER OTHER LAWS.—Amounts paid to an individual under this section—

(1) shall be treated for purposes of the internal revenue laws of the United States as damages for human suffering; and

(2) shall not be included as income or resources for purposes of determining eligibility to receive benefits described in section 3803(c)(2)(C) of title 31, United States Code, or the amount of such benefits.

(i) USE OF EXISTING RESOURCES.—The Attorney General should use funds and resources available to the Attorney General to carry out his or her functions under this Act.

(j) REGULATORY AUTHORITY.—The Attorney General may issue such regulations as are necessary to carry out this Act.

(k) ISSUANCE OF REGULATIONS, GUIDELINES, AND PROCEDURES.—Regulations, guidelines, and procedures to carry out this Act shall be issued not later than 180 days after the date of the enactment of this Act.

SEC. 7. CLAIMS NOT ASSIGNABLE OR TRANSFERABLE; CHOICE OF REMEDIES. 42 USC 2210 note.

(a) CLAIMS NOT ASSIGNABLE OR TRANSFERABLE.—No claim cognizable under this Act shall be assignable or transferable.

(b) CHOICE OF REMEDIES.—No individual may receive payment under both sections 4 and 5 of this Act.

SEC. 8. LIMITATIONS ON CLAIMS. 42 USC 2210 note.

A claim to which this Act applies shall be barred unless the claim is filed within 20 years after the date of the enactment of this Act.

SEC. 9. ATTORNEY FEES. 42 USC 2210 note.

Notwithstanding any contract, the representative of an individual may not receive, for services rendered in connection with the claim of an individual under this Act, more than 10 per centum of a payment made under this Act on such claim. Any such representative who violates this section shall be fined not more than $5,000.

SEC. 10. CERTAIN CLAIMS NOT AFFECTED BY AWARDS OF DAMAGES. 42 USC 2210 note.

A payment made under this Act shall not be considered as any form of compensation or reimbursement for a loss for purposes of imposing liability on any individual receiving such payment, on the basis of such receipt, to repay any insurance carrier for insurance payments, or to repay any person on account of worker's compensa-

tion payments; and a payment under this Act shall not affect any claim against an insurance carrier with respect to insurance or against any person with respect to worker's compensation.

42 USC 2210 note.

SEC. 11. BUDGET ACT.

No authority under this Act to enter into contracts or to make payments shall be effective in any fiscal year except to such extent or in such amounts as are provided in advance in appropriations Acts.

42 USC 2210 note.

SEC. 12. REPORT.

(a) The Secretary of Health and Human Services shall submit a report on the incidence of radiation related moderate or severe silicosis and pneumoconiosis in uranium miners employed in the uranium mines that are defined in section 5 and are located off of Indian reservations.

(b) Such report shall be completed not later than September 30, 1992.

Approved October 15, 1990.

LEGISLATIVE HISTORY—H.R. 2872:

HOUSE REPORTS: No. 101-463 (Comm. on the Judiciary).
CONGRESSIONAL RECORD, Vol. 136 (1990):
June 5, considered and passed House.
Aug. 1, considered and passed Senate, amended.
Sept. 27, House concurred in Senate amendment.
WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 26 (1990):
Oct. 15, Presidential statement.

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# Department of Justice

## Summary Description of Procedures for

## Administration of Radiation Exposure Compensation Act of 1990

Radiation Exposure Compensation Act of 1990

Background: On October 15, 1990, Congress passed the Radiation Exposure Compensation Act, 42 U.S.C. § 2210 note (Supp. 1992), which provides for compassionate payments to individuals who contracted certain cancers and other serious diseases as a result of their exposure to radiation released during above-ground nuclear weapons tests or as a result of their exposure to radiation during employment in uranium mines. The Attorney General was given wide discretion in administering the program, including drafting regulations, reviewing and processing claims, authorizing payments, and assisting in representation of the Government in any associated litigation. In developing the regulations, the Civil Division contacted numerous experts, agencies and other interested persons. On September 9, 1991, the proposed rules were published. During the 45 day comment period, we received in excess of 125 comments on the regulations. Sections of the regulations were revised in light of these comments. On March 28, 1992, final regulations were signed. These regulations were published in the Federal Register on April 10, 1992. (A copy is attached at Tab A). The procedures established in the regulations are designed to utilize existing records so that claims can be resolved in a reliable, objective, and nonadversarial manner, quickly and with little administrative cost to the United States or to the person filing the claim.

Categories and Criteria: There are 3 categories of claimants: uranium miners, downwinders, and onsite participants. Each

category includes 2 eligibility criteria: exposure to radiation and existence of a compensable disease.[1]

I. Uranium Miners. The Act specifies a payment of $100,000 to eligible uranium miners who worked during the years 1947 and 1971 in Arizona, Colorado, New Mexico, Wyoming or Utah. §5(a), 42 U.S.C. § 2210, 28 CFR 79.32.

A. Exposure criterion. The claimant must have been exposed to certain threshold levels of radiation while mining uranium. The required level of exposure depends on whether the miner smoked cigarettes and the age at which he was diagnosed with the disease. §5(a), 42 U.S.C. § 2210, 28 CFR 79.32.

B. Disease criterion. The claimant must have later developed primary lung cancer or certain specified non-malignant respiratory diseases. §5(b)(3), 42 U.S.C. § 2210, 28 CFR 79.31(h), (i)

II. Downwinders. The Act specifies a payment of $50,000 to individuals satisfying the eligibility criteria.

A. Exposure criterion. The claimant must have lived or worked downwind of atmospheric nuclear tests in certain counties in Utah, Nevada and Arizona for at least 24 months during the time period of January 21, 1951, and ending on October 31, 1958, or the entire period of June 30, 1962, to July 31, 1962. §4(a)(2)(A),(B), 42 U.S.C. § 2210, 28 CFR 79.22(a).

B. Disease criterion. The claimant must have developed one of 13 specified cancers. §4(b)(2), 42 U.S.C. § 2210, 28 CFR 79.21(d). Each disease has its own additional requirements such as age at first exposure, latency period, and absence of heavy smoking and drinking. 28 CFR 79.22(b).

III. Onsite Participants. The Act specifies a payment of $75,000 to individuals satisfying the following eligibility criteria.

A. Exposure Criterion. The claimant must have been present "onsite" (primarily the Nevada or the Pacific Test Sites) at any time during a period of atmospheric

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[1]A 4th category is childhood leukemia. Although included in the downwinder category, the criteria are basically the same except that the child must have been physically present in the area for only 12 months, first exposed to fallout prior to age 21 and includes only the disease of leukemia. §4(a)(1), 42 U.S.C. 2210, 28 CFR 79.12.

nuclear testing and must have participated during that time in the atmospheric detonation of a nuclear device. §4(a)(2)(C), 42 U.S.C. § 2210, 28 CFR 79.42(a), (b).

B. Disease criterion. The claimant must have developed one of 13 specified cancers. §4(b)(2), 42 U.S.C. § 2210, 28 CFR 79.22(b).

Claim Procedures.

I. Submission of the Claim. The claimant, either acting on his or her own behalf or represented by counsel, submits a form provided by this office. A copy of each form and guidebook is attached at Tab B. The claim is then logged in and assigned a database identification number.

II. Verification of Eligibility. This is the most difficult and time-consuming step in the processing of claims. To expedite this process of verification, we have established agreements with numerous information sources enabling us to quickly and easily obtain necessary information directly, without any expense to the claimant. We simply send the entity maintaining the database a form, accompanied by a release signed by the claimant, which the entity returns to us with either the information we need or a statement that it has no records pertaining to the claimant.

A. Information sources for verification of medical condition.

1. Medical information for all categories of claimants is available through state tumor/cancer registries. 28 CFR 79.26(b), 79.35(c).

2. Medical information for claimants in the uranium miner category is also available from records of the Public Health Service and the National Institute of Occupational Safety and Health and from databases maintained at St. Mary's Hospital in Grand Junction, Colorado, and the University of New Mexico School of Medicine in Albuquerque, New Mexico. 28 CFR 79.35(b),(d), 79.36(b),(c). The government conducted extensive studies of uranium miners through the Public Health Service and the National Institute of Occupational Safety and Health. Both St. Mary's Hospital and the University of New Mexico School of Medicine supervise ongoing federally assisted studies that collect information related to miners.

3. The specific records required for uranium miners who are currently alive may be obtained via medical testing at Miners Colfax Medical Center

(MCMC). This evaluation process is used primarily by Navajos. Upon notice that a miner was evaluated by MCMC, we send a release and request for the information directly to MCMC which, in turn, forwards the B reader reports and pulmonary function tests or arterial blood gas studies to our office. In order to alleviate the time and expense involved in providing the actual chest X-ray, we have agreed with MCMC that they will make the X-ray available to us upon request. This system has worked very well for Navajo miners and allowed many Navajo claims to be quickly approved with no expense and little effort by the miner.

4. Most compensable diseases may be established with only 1 medical record, such as a death certificate, pathology report, physician summary, hospital admission or discharge summary.

B. Information sources for verification of exposure to radiation.

1. Downwinders.

a. Church of Jesus Christ of Latter-Day Saints.

b. Contemporaneous documentation submitted by the claimant, such as employment records, property tax rolls, and school transcripts which indicates that the individual was physically present in the area. 28 CFR 79.13.

2. Uranium Miners.

a. Copies of the published results of the Public Health Service Study of Uranium Miners are in our office. The Study contains information on 4126 miners, and it includes data related to dates of employment, particular mines worked in, smoking history, and medical diagnoses. 28 CFR 79.33(a)(1) and 79.34(a).

b. Data obtained but not published by the Public Health Service is held at the National Institute of Occupational Safety and Health (NIOSH) and is available at our request. These NIOSH records provide the same type of information as in the published PHS study, but not calculated totals of radiation exposure. 28 CFR 79.33(a)(2) and 34(a).

c. The databases at the University of New Mexico School of Medicine and St. Mary's Hospital,

in addition to containing information related to the medical condition of miners, also contain information about the miners' exposure to radiation and smoking habits. 28 CFR 79.33(a)(4) and 79.34(a).

d. Social Security Administration. We have established an inter-agency agreement with the Social Security Administration and are now able to obtain a person's Social Security records. 28 CFR 79.33(b)(1)(iii).

e. If these databases fail to provide sufficient information to verify a claimant's exposure, we can recreate his mining history using various other records, including employment records from the mining companies (which we can sometimes directly obtain via our contacts with the mining companies) and federal or state tax records. Our claims examiners have become very skilled at using the records and known radiation levels in mines to calculate (with some certainty) the amount of radiation to which the miner was exposed. We frequently consult with William Chenoweth, a former Atomic Energy Commission contractor, for detailed information regarding specific mines and mining companies. 28 CFR 79.33(b) and 34(b).

3. Onsite Participants.

Few onsite participant claims have been submitted; however, obtaining their exposure information is quite easy. Over the past 15 years, extensive records have been maintained by the Department of Defense and the Department of Energy. Their records include when and exactly where the claimant was present, the duties at the test site, and the claimant's employer. 28 CFR 79.43(a)(3) and (b)(3).

4. Navajo Claimants.

In general, all persons filing a claim must submit routinely created identification records such as a birth certificate, death certificate and marriage certificate. However, other than death certificates, such records are not routinely created in the Navajo culture. Accordingly, the regulations establish a procedure whereby we contact the Navajo Office of Vital Statistics for verification of a claimant's birth, marriage, and death. 28 CFR 79.51(e)(5) and (f)(5). Initially,

we submitted only a form letter requesting the necessary information and a statement that the claimant had applied for compensation and therein authorized the release of this information. However, after 18 months, the Navajo Nation Department of Justice asked that we provide signed releases authorizing the release of the records to the Department of Justice. We now include this written release with all requests.

III. Decision. If these sources supply sufficient information to verify a claimant's eligibility, the claimant is not required to furnish any additional documentation and the claim is then approved. If there is insufficient information in the databases to verify the claim, the claimant must provide original or certified copies of other records which we then use to verify the claimant's eligibility. Each decision is personally reviewed by a staff attorney and the Assistant Director.

Data Processing

The Office of Management Information has developed a sophisticated system for tracking claims from the time they are received in the office until the case is closed. The system includes the following:

A. Notes section. Each claim is entered into the system and has a section for dates on which actions were taken and all dates on which some action is due to be taken.

B. Pending actions. Each staff member has a "pending actions list" that notifies them when they need to take action on the claim.

C. Automated letters. Many "standard" or "form" letters are generated by a single computer command.

Approved Claims

I. Notification. Once a claim is approved by the Assistant Director, an automated letter is generated notifying the person of the approval.

II. Acceptance of Payment letter. All persons eligible to receive payment must sign an "acceptance of payment" letter stating that they wish to receive the money, identifying the method by which they wish to receive it (via check or electronic funds transfer), and providing the information necessary to pay them in the manner requested.

III. Authorization of payment. Upon receipt of a completed acceptance of payment letter, the payment is authorized by the Director and Assistant Director.

IV. Office of Planning, Budget and Evaluation and the Justice Management Division. Upon receipt of the authorization memorandum, these offices assign the appropriate coding, database numbers, the date on which payment was made and verify when and where payment was made.

V. Treasury. The Treasury Department issues the funds to the person(s). The entire payment process generally takes 4 weeks or less. 28 CFR 79.55.

Denied Claims:

I. Deficiency Notice. If a claim does not meet any eligibility criterion, the claimant is notified of the deficiency in writing and allowed 60 days in which to provide documentation correcting the deficiency. More than 60 days may be allowed if requested by the claimant. 28 CFR 79.52(b) and (c).

II. Final Denial. At the expiration of the 60 day period, if the claim remains deficient, a final denial decision is issued by the Assistant Director. The written decision fully explains the reasons for the denial, and a copy is sent to the claimant. 28 CFR 79.52(d).

III. Appeal. The denial decision also explains that the decision of the Assistant Director may be appealed to the Appeals Officer. The Appeals Officer may affirm, reverse or remand to the Assistant Director for further action. 28 CFR 79.53.

IV. Refiling a Claim. If other documentation that corrects the deficiency is subsequently obtained, the claimant may refile the claim up to 2 times. 28 CFR 79.51(j).

III. Staff. Currently, there are 17 staff members, including the Assistant Director, 2 staff attorneys, 2 appellate attorneys, 7 paralegals/claims examiners, 1 nurse consultant, 1 legal assistant, 2 legal technicians, and 1 staffer who works on fiscal and budget matters.

RCZRRA2

RADIATION EXPOSURE COMPENSATION SYSTEM
CLAIMS TO DATE SUMMARY

9:45:55 1/06/94
Page 1

SUMMARY OF CLAIMS RECEIVED BY 1/06/94

COUNT OF CLAIMS

| | Pending | Approved | Denied | Total |
|---|---|---|---|---|
| Childhood Leukemia: | 2 | 18 | 15 | 35 |
| Other Downwinders: | 177 | 800 | 627 | 1,604 |
| Onsite Participants: | 72 | 72 | 288 | 432 |
| Uranium Miners: | 276 | 459 | 938 | 1,473 |
| TOTAL: | 527 | 1,349 | 1,468 | 3,544 |

→ $111,053,294.00

# Clinton Presidential Records
# Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

## D

Divider Title: _____

(Radiation Exposed Veterans Compensation Act of 1988)



**§ 1112. Presumptions relating to certain diseases and disabilities**

(a) For the purposes of section 1110 of this title, and subject to the provisions of section 1113 of this title, in the case of any veteran who served for ninety days or more during a period of war—

(1) a chronic disease becoming manifest to a degree of 10 percent or more within one year from the date of separation from such service;

(2) a tropical disease, and the resultant disorders or disease originating because of therapy, administered in connection with such diseases, or as a preventative thereof, becoming manifest to a degree of 10 percent or more within one year from the date of separation from such service, or at a time when standard or accepted treatises indicate that the incubation period thereof commenced during such service;

(3) active tuberculous disease developing a 10 percent degree of disability or more within three years from the date of separation from such service;

(4) multiple sclerosis developing a 10 percent degree of disability or more within seven years from the date of separation from such service;

(5) Hansen's disease developing a 10 percent degree of disability or more within three years from the date of separation from such service;

shall be considered to have been incurred in or aggravated by such service, notwithstanding there is no record of evidence of such disease during the period of service.

(b) For the purposes of section 1110 of this title and subject to the provisions of section 1113 of this title, in the case of a veteran who is a former prisoner of war and who was detained or interned for not less than thirty days, the disease of—

(1) avitaminosis,

(2) beriberi (including beriberi heart disease),

(3) chronic dysentery,

(4) helminthiasis,

(5) malnutrition (including optic atrophy associated with malnutrition),

(6) pellagra,

(7) any other nutritional deficiency,

(8) psychosis,

(9) any of the anxiety states,

(10) dysthymic disorder (or depressive neurosis),

(11) organic residuals of frostbite, if the Secretary determines that the veteran was interned in climatic conditions consistent with the occurrence of frostbite,

(12) post-traumatic osteoarthritis,

(13) peripheral neuropathy except where directly related to infectious causes,

(14) irritable bowel syndrome, or

(15) peptic ulcer disease,

which became manifest to a degree of 10 percent or more after active

ary, naval, or air service shall be considered to have been incurred in or aggravated by such service, notwithstanding that there is no record of disease during the period of service.

(c)(1) For the purposes of section 1110 of this title, and subject to the provisions of section 1113 of this title, a disease specified in paragraph (2) of this subsection becoming manifest in a radiation-exposed veteran to a degree of 10 percent or more within the presumption period (as specified in paragraph (3) of this subsection) shall be considered to have been incurred in or aggravated during active military, naval, or air service, notwithstanding that there is no record of evidence of such disease during a period of such service.

(2) The diseases referred to in paragraph (1) of this subsection are the following:

(A) Leukemia (other than chronic lymphocytic leukemia).
(B) Cancer of the thyroid.
(C) Cancer of the breast.
(D) Cancer of the pharynx.
(E) Cancer of the esophagus.
(F) Cancer of the stomach.
(G) Cancer of the small intestine.
(H) Cancer of the pancreas.
(I) Multiple myeloma.
(J) Lymphomas (except Hodgkin's disease).
(K) Cancer of the bile ducts.
(L) Cancer of the gall bladder.
(M) Primary liver cancer (except if cirrhosis or hepatitis B is indicated).

(3) The presumption period for purposes of paragraph (1) of this subsection is the 40-year period beginning on the last date on which the veteran participated in a radiation-risk activity.

(4) For the purposes of this subsection:

(A) The term "radiation-exposed veteran" means (i) a veteran who, while serving on active duty, participated in a radiation-risk activity, or (ii) an individual who, while a member of a reserve component of the Armed Forces, participated in a radiation-risk activity during a period of active duty for training or inactive duty training.

(B) The term "radiation-risk activity" means any of the following:

(i) Onsite participation in a test involving the atmospheric detonation of a nuclear device.

(ii) The occupation of Hiroshima or Nagasaki, Japan, by United States forces during the period beginning on August 6, 1945, and ending on July 1, 1946.

(iii) Internment as prisoner of war in Japan (or service on active duty in Japan immediately following such internment) during World War II which (as determined by the Secretary) resulted in an opportunity for exposure to ionizing radiation comparable to that of veterans described in clause (ii) of this subparagraph.

(Sept. 2, 1958, P. L. 85-857, § 1, 72 Stat. 1120; Aug. 25, 1959, P. L. 86-187, 73 Stat. 418; Aug. 25, 1959, P. L. 86-188, 73 Stat. 418; Sept. 7, 1962, P. L. 87-645, § 3, 76 Stat. 442; Aug. 12, 1970, P. L. 91-376, § 3(a), (b), 84 Stat. 788; Aug. 14, 1981, P. L. 97-37, § 4(a), 95 Stat. 936; March 2, 1984, P. L. 98-223, Title I, Part A, § 101(c) in part, Part B, § 111, 98 Stat. 38, 40; Oct. 28, 1986, P. L. 99-576, Title I, § 108(a), 100 Stat. 3252; May 20, 1988, P. L. 100-321, § 2(a), 102 Stat. 485; May 20, 1988, P. L. 100-322, Title III, Part B, § 312, 102 Stat. 534; Aug. 6, 1991, P. L. 102-83, §§ 4(b)(1), 5(a), (c)(1), 105 Stat. 404, 406; Aug. 14, 1991, P. L. 102-86, Title I, §§ 104(a), 105, 105 Stat. 415.)

## HISTORY; ANCILLARY LAWS AND DIRECTIVES

**Prior law and revision:**

This section is based on 38 USC § 2313 (Act June 17, 1957, P. L. 85-56, Title III, Part B, § 313, 71 Stat. 97).

This section is also based on the following provisions, which were repealed by Act June 17, 1957, P. L. 85-56, Title XXII, § 2202, 71 Stat. 162:

Veterans' Regulation No. 1(a), Part I, para. I(c) (as amended Acts June 24, 1948, ch 612, § 1, 62 Stat. 581; June 23, 1950, ch 352, 64 Stat. 255; Oct. 12, 1951, ch 499, 65 Stat. 421; Aug. 8, 1953, ch 395, 67 Stat. 506).

**Amendments:**

**1959.** Act Aug. 25, 1959, P. L. 86-187, in para. (4), substituted "three years" for "two years".

Act Aug. 25, 1959, P. L. 86-188, added para. (5).

**1962.** Act Sept. 7, 1962, in para. (4), substituted "seven years" for "three years". For effective date of this amendment, see Other provisions note to this section.

**1970.** Act Aug. 12, 1970, in the section catchline, inserted "and disabilities"; redesignated existing matter as subsec. (a); added subsecs. (b) and (c).

**1981.** Act Aug. 14, 1981 (effective 10/1/81, as provided by § 4(b) of such Act), deleted subsec. (b) which read: "For the purposes of subsection (c) of this section, any veteran who, while serving in the active military, naval, or air service, was held as a prisoner of war for not less than six months by the Imperial Japanese Government or the German Government during World War II, by the Government of North Korea during the Korean conflict, or by the Government of North Korea, the Government of North Vietnam or the Viet Cong forces during the Vietnam era, or by their respective agents, shall be deemed to have suffered from dietary deficiencies, forced labor, or inhumane treatment in violation of the terms of the Geneva Conventions of July 27, 1929, and August 12, 1949."; and redesignated former subsec. (c) as subsec. (b), and as so designated, substituted such subsec. for one which read: "For the purposes of section 310 of this title and subject to the provisions of section 313 of this title, in the case of any veteran who, while serving in the active military, naval, or air service and while held as a prisoner of war by an enemy government, or its agents during World War II, the Korean conflict, or the Vietnam era, suffered from dietary deficiencies,

forced labor, or inhumane treatment (in violation of the terms of the Geneva Conventions of July 27, 1929, and August 12, 1949), the disease of—

"(1) Avitaminosis, Beriberi (including beriberi heart disease), Chronic dysentery, Helminthiasis, Malnutrition (including optic atrophy associated with malnutrition), Pellagra, or Any other nutritional deficiency, which became manifest to a degree of 10 per centum or more after such service; or

"(2) Psychosis which became manifest to a degree of 10 per centum or more within two years from the date of separation from such service;

shall be considered to have been incurred in or aggravated by such service, notwithstanding that there is no record of such disease during the period of service.".

1984. Act March 2, 1984 (effective 10/1/83, as provided by § 114 of such Act, which appears as a note to this section), in subsec. (b), in para. (8), deleted a concluding "or", in para. (9), added the concluding "or", and added para. (10).

Such Act further (effective 4/1/84, as provided by § 107 of such Act, which appears as 38 USCS § 1114 note) substituted "percent" for "per centum" wherever appearing.

1986. Act Oct. 28, 1986, (effective 10/1/86, as provided by § 108(b) if such Act), in subsec. (b), in para. (9), deleted "or" following "states,", and added paras. (11) and (12).

1988. Act May 20, 1988, P. L. 100-321 (effective 5/1/88, as provided by § 2(b) of such Act, which appears as a note to this section) added subsec. (c).

Act May 20, 1988, P. L. 100-322, in subsec. (b), in para. (11), deleted "or" following "frostbite,", and added paras. (13)-(15).

1991. Act Aug. 6, 1991, redesignated this section, formerly 38 USCS § 312, as 38 USCS § 1112, amended the references in this section to reflect the redesignations made by § 5(a) of such Act (see Table III preceding 38 USCS § 101), and substituted "Secretary" for "Administrator".

Act Aug. 14, 1991, in subsec. (c), in para. (1), substituted "active military, naval, or air service" for "the veteran's service on active duty", and substituted "during a period" for "during the period".

Such Act further, in subsec. (c), in para. (4)(A), added "(i)", ", or" and cl. (ii).

Such Act further (applicable as provided by § 104(b) of such Act, which appears as a note to this section), in subsec. (c), in para. (3), deleted ", except that such period shall be the 30 year period beginning on that date in the case of leukemia (other than chronic lymphocytic leukemia)" following "radiation-risk activity".

Other provisions:

Effective date of amendments made by Act Sept. 7, 1962. Act Sept. 7, 1962, P. L. 87-645, § 4, 76 Stat. 442, provides: "This Act [amending this section and 38 USCS §§ 1114, 5503, and adding note to 38 USCS § 1114] shall take effect on the first day of the first calendar month which begins after the date of enactment of this Act but no payments shall be made

by reason of this Act for any period before such effective date. The increased rate of compensation payable to any veteran entitled thereto on such first day shall be further increased, for such month only, in an amount equal to three times the monthly increase provided for such veteran by the amendments made by this Act.".

**Effective date of amendments made by Title I, Part B, Act March 2, 1984.** Act March 2, 1984, P. L. 98-223, Title I, Part B, § 114, 98 Stat. 40, provides: "The amendments made by this part [amending this section, among other things; for full classification, consult USCS Tables volumes] shall take effect as of October 1, 1983.".

**Effective date of Act May 20, 1986 amendment.** Act May 20, 1986, P. L. 100-321, § 2(b), 102 Stat. 486, provides: "Subsection (c) of section 312 [now section 1112] of title 38, United States Code, as added by subsection (a), shall take effect on May 1, 1988.".

**Applicability of Act Aug. 14, 1991 amendment.** Aug. 14, 1991, P. L. 102-86, Title I, § 104(b), 105 Stat. 415, provides: "No benefit may be paid by reason of the amendment made by subsection (a) [amending subsec. (c)(3) of this section] for any period before the date of the enactment of this Act.".

## CODE OF FEDERAL REGULATIONS

Adjudication, 38 CFR Part 3.

## CROSS REFERENCES

This section is referred to in 38 USCS §§ 1113, 1137.

## RESEARCH GUIDE

**Federal Procedure L Ed:**

33 Fed Proc L Ed, Veterans and Veterans' Affairs §§ 79:70, 71, 74.

**Am Jur:**

60A Am Jur 2d, Pensions and Retirement Funds § 1739.

**Forms:**

16 Fed Procedural Forms L Ed, Veterans and Veterans' Laws § 68:12.

**Law Review Articles:**

Wellen, Armed Forces Disability Benefits—a Lawyer's View. 27 Judge Advocate General Journal 485, Spring, 1974.

## INTERPRETIVE NOTES AND DECISIONS

1. Time of service
2. Degree of disability
3. Time of manifestation of disease or disability
4. Collateral estoppel

**1. Time of service**

Veteran in service on April 6, 1917 and discharged thereafter without serving 90 days during World War is not thereby barred from benefits if he had 90 days continuous service. 1934 ADVA 247.

**2. Degree of disability**

Showing that chronic disease became manifest to degree of 10 percent or more within one year from date of discharge from enlistment entered into prior to November 11, 1918, is necessary to entitle claimant to disability benefits. 1934 ADVA 236.

Physician's statement that veteran was his patient 40 years earlier and suffered from occasional attacks of hypertensive and cardiovascular disease for which he treated veteran was insufficient to establish service connection. Oris v Derwinski (1992) 2 Vet App 95.

Board's conclusion that veteran's low back disorder did not warrant more than 10 percent disabling rating was not clearly erroneous in light of

# PART II. GENERAL BENEFITS

## CHAPTER 11. COMPENSATION FOR SERVICE-CONNECTED DISABILITY OR DEATH

### SUBCHAPTER VI. GENERAL COMPENSATION PROVISIONS



#### HISTORY; ANCILLARY LAWS AND DIRECTIVES

**Amendments:**

1992. Act Oct. 29, 1992, P. L. 102-568, Title IV, § 401(d)(2), 106 Stat. 4336, amended the analysis of this chapter by substituting item 1163 for one which read: "1163. Temporary program for trial work periods and vocational rehabilitation for certain veterans with total disability ratings.".

### SUBCHAPTER II. WARTIME DISABILITY COMPENSATION

**§ 1110. Basic entitlement**

#### INTERPRETIVE NOTES AND DECISIONS

**8. Miscellaneous**

Vietnam veteran who sought increased rating for panic disorder provided medical evidence of some significance that would support disability rating in excess of 10 percent, yet BVA's decision lacked any meaningful discussion of such evidence and there was no indication that Board gave any consideration to veteran's post-hearing letter concerning nature and frequency of his panic attacks. Fisher v Derwinski (1992) 2 Vet App 406, vacated, in part, on reconsideration, remanded South v Derwinski (1992, Vet App) 1992 US Vet App LEXIS 258.

**§ 1112. Presumptions relating to certain diseases and disabilities**

(a), (b) [Unchanged]

(c)(1) For the purposes of section 1110 of this title, and subject to the provisions of section 1113 of this title, a disease specified in paragraph (2) of this subsection becoming manifest in a radiation-exposed veteran shall be considered to have been incurred in or aggravated during active military, naval, or air service, notwithstanding that there is no record of evidence of such disease during a period of such service.

(2) The diseases referred to in paragraph (1) of this subsection are the following:

(A)–(M) [Unchanged]

(N) Cancer of the salivary gland.

(O) Cancer of the urinary tract.

(3) For the purposes of this subsection:

(A) The term "radiation-exposed veteran" means (i) a veteran who, while serving on active duty, participated in a radiation-risk activity, or (ii) an individual who, while a member of a reserve component of the Armed Forces, participated in a radiation-risk activity during a period of active duty for training or inactive duty training.

(B) The term "radiation-risk activity" means any of the following:

(i) Onsite participation in a test involving the atmospheric detonation of a nuclear device.

(ii) The occupation of Hiroshima or Nagasaki, Japan, by United States forces during the period beginning on August 6, 1945, and ending on July 1, 1946.

(iii) Internment as prisoner of war in Japan (or service on active duty in Japan immediately following such internment) during World War II which (as determined by the Secretary) resulted in an opportunity for exposure to ionizing radiation comparable to that of veterans described in clause (ii) of this subparagraph.

(4) [Redesignated]

(Oct. 30, 1992, P. L. 102-578, § 2(a), 106 Stat. 4774.)

#### HISTORY; ANCILLARY LAWS AND DIRECTIVES

**Amendments:**

1992. Act Oct. 30, 1992 (effective Oct. 1, 1992, as provided by § 2(b) of such Act), in subsec. (c), in para. (1), deleted "to a degree of 10 percent or more within the presumption period (as specified in paragraph (3) of this subsection)" following "veteran", in para. (2), added subparas. (N) and (O), deleted para. (3), which read: "The presumption period for purposes

of paragraph (1) of this subsection is the 40-year period beginning on the last date on which the veteran participated in a radiation-risk activity.", and redesignated para. (4) as new para. (3).

INTERPRETIVE NOTES AND DECISIONS

5. Radiation claims

5. Radiation claims

Proper standard for BVA's adjudication of claims for entitlement to service-connected disability compensation based on exposure to ionizing radiation is not "no reasonable possibility" standard, but one under generally applicable regulations giving due consideration to all evidence of record. Douglas v Derwinski (1992) 2 Vet App 435.

## § 1114. Rates of wartime disability compensation

HISTORY; ANCILLARY LAWS AND DIRECTIVES

Other provisions:

Disability compensation and dependency and indemnity compensation rate increases. Act Oct. 24, 1992, P. L. 102-510, § 2, 106 Stat. 3318, provides:

"(a) In general. (1) The Secretary of Veterans Affairs shall, as provided in paragraph (2), increase, effective December 1, 1992, the rates of and limitations on Department of Veterans Affairs disability compensation and dependency and indemnity compensation.

"(2) (A) The Secretary shall increase each of the rates and limitations in sections 1114, 1115(1), 1162, 1311, 1313, and 1314 of title 38, United States Code, that were increased by the amendments made by the Veterans' Compensation Rate Amendments of 1991 (Public Law 102-152; 105 Stat. 985 [for full classification, consult USCS Tables volumes]). The increase shall be made in such rates and limitations as in effect on November 30, 1992, and shall be by the same percentage that benefit amounts payable under title II of the Social Security Act (42 U.S.C. 401 et seq.) are increased effective December 1, 1992, as a result of a determination under section 215(i) of such Act (42 U.S.C. 415(i)).

"(B) In the computation of increased rates and limitations pursuant to subparagraph (A), amounts of $0.50 or more shall be rounded to the next higher dollar amount and amounts of less than $0.50 shall be rounded to the next lower dollar amount.

"(b) Special rule. The Secretary may adjust administratively, consistent with the increases made under subsection (a), the rates of disability compensation payable to persons within the purview of section 10 of Public Law 85-857 (72 Stat. 1263) [38 USCS prec. § 101 note] who are not in receipt of compensation payable pursuant to chapter 11 of title 38, United States Code [38 USCS §§ 1101 et seq.].

"(c) Publication requirement. At the same time as the matters specified in section 214(i)(2)(D) [215(i)(2)(D)] of the Social Security Act (42 U.S.C. 415(i)(2)(D)) are required to be published by reason of a determination made under section 215(i) of such Act [42 USCS § 415(i)] during fiscal year 1992, the Secretary shall publish in the Federal Register the rates and limitations referred to in subsection (a)(2)(A) as increased under this section.".

## § 1115. Additional compensation for dependents

HISTORY; ANCILLARY LAWS AND DIRECTIVES

Other provisions:

Disability compensation and dependency and indemnity compensation rate increases. For increases in disability compensation and dependency and indemnity compensation rates, effective Dec. 1, 1992, see Act Oct. 24, 1992, P. L. 102-510, § 2, 106 Stat. 3318, which appears as 38 USCS § 1114 note.

# SUBCHAPTER VI. GENERAL COMPENSATION PROVISIONS

## § 1151. Benefits for persons disabled by treatment or vocational rehabilitation

INTERPRETIVE NOTES AND DECISIONS

III. PRACTICE AND PROCEDURE

11. Filing of claims

Veteran who is awarded both benefits under 38 USCS § 1151 and damages under FTCA for same VA hospital injuries must have his § 1151 benefits set off against entire amount of FTCA damages, not just against lost earnings portion of award. Morgan v United States (1992, CA2 NY) 968 F2d 200.

Needed Action

**The draft study has violated its mandate in two ways, which should disturb Administration officials:**

(1) Argonne, which has the greatest expertise on high-density LEU, was supposed to be an equal partner in the study's preparation, but instead has been presented with a fait accompli; and

(2) The study was supposed to examine the feasibility of LEU, but has not done so in good faith, instead making unjustified assumptions that preordain a negative conclusion.

**The draft study should be reopened and its deadline extended by a year, to permit further research in two areas:**

(1) A full examination by Argonne and ORNL of the conductivity of irradiated high-density LEU, to resolve any potential safety questions and to ascertain a reliable estimate of the performance penalty from using such fuel in the ANS; and

(2) Independent confirmation by Argonne of ORNL's calculations of predicted performance for both LEU and MEU.

ORNL is demonstrating an urgency to conclude the study that appears to be motivated by a desire for a large funding request in this year's budget. However, postponing the study need not severely hamper their funding request. After all, "concrete is concrete." No party in or outside of the government has advocated changing the size or power of the reactor, or even its general design. This is a multi-billion dollar, ten-year project, with major ramifications for U.S. nonproliferation policy. It is well worth taking a little extra time now for a thorough examination of the feasibility of using LEU, in order to fulfill the mandate contained in the Administration's own budget request last year.

# # #

John:

As discussed at our compensation subcommittee meeting on Friday, I am forwarding 4 documents:

1. A copy of 38 U.S.C. § 1151, our authority for compensating veterans (or their survivors) if injury or death occurs as a result of treatment at a VA medical facility.

2. A copy of the regulation, at 38 C.F.R. § 3.358, implementing this authority.

3. A writeup concerning a recent court decision ruling a portion of VA's regulation invalid. Specifically, the court determined that, contrary to VA's longstanding interpretation, compensation is payable under the statute regardless of whether there has been fault on the part of VA in providng care. Note: It was decided on Friday, January 7, that the Government will seek review of this ruling by the U.S. Supreme Court.

4. The most recent version of 38 U.S.C. § 1112(c). Note that due to recent amendments there are now 15 forms of cancer which may be presumed service connected, and the statute no longer requires that the cancers arise within 40 years after exposure in order that the presumptions arise. (This should replace your current tab G.)

A couple of other things. While your current tab B correctly describes the procedure VA uses in making case-by-

case determinations under 38 C.F.R. § 3.311b, because of the act at tab G those sorts of individualized determinations are now unnecessary for claims involving the diseases for which there are now statutory presumptions of service connection. In other words, in ruling on claims received today VA would first look to see if one of the statutory presumptions applies. Only if not would it have to enage in the factual adjudications described in your tab B. I suggest you replace the heading for your tab B with something like "Summary of Criteria Employed by VA in Deciding Radiation-Related Compensation Claims Not Controlled by Statutory Presumptions (See Tab G)."

Let me know if I may clarify any of the above.

Sincerely

John H. Thompson

FROM:GENERAL COUNSEL PSG IV TO:93953165 JAN 10, 1994 11:57AM P.04



## [§ 1143. Repealed. Pub.L. 93–295, Title II, § 206(b), May 31, 1974, 88 Stat. 183]

### HISTORICAL AND STATUTORY NOTES

Section, Pub.L. 85–857, Sept. 2, 1958, 72 Stat. 1124, § 343; renumbered Pub.L. 102–83, § 5(a), Aug. 6, 1991, 105 Stat. 406, prescribed conditions under which wartime rates of compensation were payable.

**Effective Date of Repeal**

Repeal effective May 1, 1974, see section 401 of Pub.L. 93–295, set out as a note under section 1114 of this title.

## SUBCHAPTER VI—GENERAL COMPENSATION PROVISIONS

### CROSS REFERENCES

Amounts payable under this subchapter exempt from tax levy, see 26 USCA § 6334.

## § 1151. Benefits for persons disabled by treatment or vocational rehabilitation

Where any veteran shall have suffered an injury, or an aggravation of an injury, as the result of hospitalization, medical or surgical treatment, or the pursuit of a course of vocational rehabilitation under chapter 31 of this title, awarded under any of the laws administered by the Secretary, or as a result of having submitted to an examination under any such law, and not the result of such veteran's own willful misconduct, and such injury or aggravation results in additional disability to or the death of such veteran, disability or death compensation under this chapter and dependency and indemnity compensation under chapter 13 of this title shall be awarded in the same manner as if such disability, aggravation, or death were service-connected. Where an individual is, on or after December 1, 1962, awarded a judgment against the United States in a civil action brought pursuant to section 1346(b) of title 28 or, on or after December 1, 1962, enters into a settlement or compromise under section 2672 or 2677 of title 28 by reason of a disability, aggravation, or death treated pursuant to this section as if it were service-connected, then no benefits shall be paid to such individual for any month beginning after the date such judgment, settlement, or compromise on account of such disability, aggravation, or death becomes final until the aggregate amount of benefits which would be paid but for this sentence equals the total amount included in such judgment, settlement, or compromise.

(Pub.L. 85–857, Sept. 2, 1958, 72 Stat. 1124, § 351; Pub.L. 87–825, § 3, Oct. 15, 1962, 76 Stat. 950; Pub.L. 91–24, § 3, June 11, 1969, 83 Stat. 33; Pub.L. 94–[illegible], Title IV, § 404(19) Sept. 30, 1976, 90 Stat. 1379; Pub.L. 98–223, [illegible], § 213(1), Mar. 2, 1984, 98 Stat. 46; renumbered and amend[illegible] Pub.L. 102–83, §§ 4(a)(1), 5(a), Aug. 6, 1991, 105 Stat. 403, 406.)



### HISTORICAL AND STATUTORY NOTES

**Revision Notes and Legislative Reports**

**1958 Act.** Senate Report No. 2259 and House Report No. 1298, see 1958 U.S. Code Cong. and Adm.News, p. 4352.

**1962 Act.** Senate Report No. 2042, see 1962 U.S.Code Cong. and Adm.News, p. 3260.

**1969 Act.** Senate Report No. 91–217, see 1969 U.S.Code Cong. and Adm.News, p. 1022.

**1976 Act.** Senate Report No. 94–1226, see 1976 U.S.Code Cong. and Adm.News, p. 2537.

**1984 Act.** Senate Report No. 98–249, see 1984 U.S.Code Cong. and Adm.News, p. 58.

**Amendments**

**1991 Amendment.** Pub.L. 102–83, § 4(a)(1), substituted "administered by the Secretary" for "administered by the Veterans' Administration".

**1984 Amendment.** Pub.L. 98–223 substituted "title 28" for "title 28, United States Code," in two places.

**1976 Amendment.** Pub.L. 94–433 deleted "him" preceding "under any of the laws" and substituted "such veteran's" for "his" in the first sentence.

**1969 Amendment.** Pub.L. 91–24 substituted ", on or after December 1, 1962," for "hereafter" wherever appearing therein.

**1962 Amendment.** Pub.L. 87–825 provided that where an individual is awarded a judgment under section 1346(b) of Title 28, enters a settlement or compromise under section 2672 or 2677 of such title by reason of a disability, aggravation, or death treated pursuant to this section as if service-connected, then no benefits shall be paid such individual for any month beginning after such judgment, settlement or compromise becomes final until the aggregate amount of benefits equals the total amount included in such judgment, settlement, or compromise, and eliminated provisions which required that no benefits were to be awarded unless application was made therefor within two years after an injury or aggravation was suffered, or a death occurred.

**Effective Dates**

**1976 Act.** Amendment by Pub.L. 94–433 effective Oct. 1, 1976, see section 406 of Pub.L. 94–433, set out as a note under section 1101 of this title.

**1962 Act.** Amendment by Pub.L. 87–825 effective the first day of the second calendar month which begins after Oct. 15, 1962, see section 7 of Pub.L. 87–825, set out as a note under section 110 of this title.

### CROSS REFERENCES

Dependency and indemnity compensation as meaning death compensation and dependency and indemnity compensation under this section for purposes of limiting compensation to incarcerated felons, see 38 USCA § 5313.
Effective dates of awards, see 38 USCA § 5110.
Eligibility for outpatient services, see 38 USCA § 1712.
Injury as result of misconduct, see 38 USCA § 105.
Service-connected defined, see 38 USCA § 101.

### LIBRARY REFERENCES

**American Digest System**

Veterans' benefits; hospitalization and medical care, see Armed Services ⇐107.
Veterans' benefits; rights and benefits in general, see Armed Services ⇐101.

**Encyclopedias**

Veterans' benefits; administration and payment of benefits; payment of benefits, see C.J.S. Armed Services § 265.
Veterans' benefits; general considerations, see C.J.S. Armed Services § 251.
Veterans' benefits; hospitalization and medical care, see C.J.S. Armed Services § 257.

FROM:GENERAL COUNSEL PSG IV TO:93953165 JAN 10, 1994 11:59AM P.05



**§ 3.358 Determinations for disability or death from hospitalization, medical or surgical treatment, examinations or vocational rehabilitation training (§ 3.800).**

(a) *General.* Where it is determined that there is additional disability resulting from a disease or injury or an aggravation of an existing disease or injury suffered as a result of training, hospitalization, medical or surgical treatment, or examination, compensation will be payable for such additional disability.

(Authority: 38 U.S.C. 1151)

(b) *Additional disability.* In determining that additional disability exists, the following considerations will govern:

(1) The beneficiary's physical condition immediately prior to the disease or injury on which the claim for compensation is based will be compared with the subsequent physical condition resulting from the disease or injury, each body part involved being considered separately.

(i) As applied to examinations, the physical condition prior to the disease or injury will be the condition at time of beginning the physical examination as a result of which the disease or injury was sustained.

(ii) As applied to medical or surgical treatment, the physical condition prior to the disease or injury will be the condition which the specific medical or surgical treatment was designed to relieve.

(2) Compensation will not be payable under 38 U.S.C. 1151 for the continuance or natural progress of disease or injuries for which the training, or hospitalization, etc., was authorized.

(c) *Cause.* In determining whether such additional disability resulted from a disease or an injury or an aggravation of an existing disease or injury suffered as a result of training, hospitalization, medical or surgical treatment, or examination, the following considerations will govern:

(1) It will be necessary to show that the additional disability is actually the result of such disease or injury or an aggravation of an existing disease or injury and not merely coincidental

(2) The mere fact that aggravation occurred will not suffice to make the additional disability compensable in the absence of proof that it resulted from disease or injury or an aggravation of an existing disease or injury suffered as the result of training, hospitalization, medical or surgical treatment, or examination.

(3) Compensation is not payable for either the contemplated or foreseeable after results of approved medical or surgical care properly administered, no matter how remote, in the absence of a showing that additional disability or death proximately resulted through carelessness, negligence, lack of proper skill, error in judgment, or similar instances of indicated fault on the part of the Department of Veterans Affairs. However, compensation is payable in the event of the occurrence of an "accident" (an unforeseen, untoward event), causing additional disability or death proximately resulting from Department of Veterans Affairs hospitalization or medical or surgical care.

(4) If the disability resulted from transportation while in a hospitalized status, compensation will be payable only where the injury or death proximately resulted from the carelessness, negligence, lack of proper skill, error in judgement, or similar instances of indicated fault on the part of the Department of Veterans Affairs, or an employee of the Department of Veterans Affairs.

(5) When the proximate cause of the injury suffered was the claimant's willful misconduct or failure to follow instructions, it will bar him (or her) from receipt of compensation hereunder except in the case of incompetent claimants.

(6) Compensation for disability resulting from the pursuit of vocational rehabilitation is not payable unless there is established a direct (proximate) causal connection between the injury or aggravation of an existing injury and some essential activity or function which is within the scope of the vocational rehabilitation course, not necessarily limited to activities or functions specifically designated by the Department of Veterans Affairs in



is not to be expected that each and every different function and act of a veteran pursuant to his or her course of training will be particularly specified in the outline of the course or training program. For example, a disability resulting from the use of an item of mechanical or other equipment is within the purview of the statute if training in its use is implicit within the prescribed program or course outlined or if its use is implicit in the performance of some task or operation the trainee must learn to perform, although such use may not be especially mentioned in the training program. In determining whether the element of direct or proximate causation is present, it remains necessary for a distinction to be made between an injury arising out of an act performed in pursuance of the course of training, that is, a required "learning activity", and one arising out of an activity which is incident to, related to, or coexistent with the pursuit of the program of training. For a case to fall within the statute there must have been sustained an injury which, but for the performance of a "learning activity" in the prescribed course of training, would not have been sustained. A meticulous examination into all the circumstances is required, including a consideration of the time and place of the incident producing the injury.

(7) Nursing home care furnished under section 1720 of title 38, United States Code is not hospitalization within the meaning of this section. Such a nursing home is an independent contractor and, accordingly, its agents and employees are not to be deemed agents and employees of the Department of Veterans Affairs. If additional disability results from medical or surgical treatment or examination through negligence or other wrongful act or omission on the part of such a nursing home, its employees or agents, entitlement does not exist under this section unless there was concurring negligence or wrongful act or omission on the part of the Department of Veterans Affairs and such acts on the part of both were the proximate cause of the additional disability

Federal Circuit Affirms the CVA Decision Invalidating VA Regulation Used to Adjudicate Claims Under 38 U.S.C. § 1151

On September 13, 1993, the United States Court of Appeals for the Federal Circuit affirmed the decision of the Court of Veterans Appeals in Gardner v. Derwinski, 1 Vet. App. 584 (1991). The Federal Circuit held that 38 U.S.C. § 1151, which provides that a veteran injured "as a result of" medical or surgical treatment, hospitalization, or pursuit of a course of vocational rehabilitation may be compensated for that injury, imposes no requirement that a veteran prove that an element of fault or accident in order to obtain compensation. The Federal Circuit held that 38 C.F.R. § 3.358(c)(3), the regulation which includes the requirement that the veteran show fault on the part of VA or accident in order to obtain compensation, is invalid.

The Federal Circuit stated, in regard to this requirement, "[t]he statute does not expressly require the veteran to prove the poor nature or lack of quality of the treatment received, or the occurrence of some mishap during treatment." Rather, the Court said, "compensation must be paid where the veteran proves only that he suffered an injury as the result of a specified treatment." The Federal Circuit noted that VA has had the regulation at 38 C.F.R. § 3.358(c)(3) or a precursor regulation in place for "nearly 60 years" but indicated that no deference was due to the agency's interpretation during that period because the regulation was not expressly made judicially reviewable until 1988. The Court further stated that, "Congress's lengthy deliberation and carefully crafted scheme for judicial review of VA regulations counsels for vigorous review."

The Court also noted that the cost of a no-fault interpretation of the statute would be significant, stating, "That however would be Congress's concern." VA has estimated that benefits under section 1151, if provided without regard to whether the injury following treatment was expected or preventable, could cost more than $2 billion over five years.

We are currently evaluating whether to seek further review of the Federal Circuit's decision.

FROM:GENERAL COUNSEL PSG IV TO:93953165 JAN 10, 1994 12:02PM P.07

§ 1112 Presumptions relating to certain diseases and disabilities

(a) For the purposes of section 1110 of this title, and subject to the provisions of section 1113 of this title, in the case of any veteran who served for ninety days or more during a period of war—

(1) a chronic disease becoming manifest to a degree of 10 percent or more within one year from the date of separation from such service;

(2) a tropical disease, and the resultant disorders or disease originating because of therapy, administered in connection with such diseases, or as a preventative thereof, becoming manifest to a degree of 10 percent or more within one year from the date of separation from such service, or at a time when standard or accepted treatises indicate that the incubation period thereof commenced during such service;

(3) active tuberculous disease developing a 10 percent degree of disability or more within three years from the date of separation from such service;

(4) multiple sclerosis developing a 10 percent degree of disability or more within seven years from the date of separation from such service;

(5) Hansen's disease developing a 10 percent degree of disability or more within three years from the date of separation from such service;

shall be considered to have been incurred in or aggravated by such service, notwithstanding there is no record of evidence of such disease during the period of service.

(Amended P.L. 86–187; P.L. 86–188; P.L. 87–645, § 3; P.L. 98–223, § 101(c); P.L. 102–83, § 5(a), (c)(1).)

(b) For the purposes of section 1110 of this title and subject to the provisions of section 1113 of this title, in the case of a veteran who is a former prisoner of war and who was detained or interned for not less than thirty days, the disease of—

(1) avitaminosis,
(2) beriberi (including beriberi heart disease),
(3) chronic dysentery,
(4) helminthiasis,
(5) malnutrition (including optic atrophy associated with malnutrition),
(6) pellagra,
(7) any other nutritional deficiency,
(8) psychosis,
(9) any of the anxiety states,
(10) dysthymic disorder (or depressive neurosis),
(11) organic residuals of frostbite, if the Secretary determines that the veteran was interned in climatic conditions consistent with the occurrence of frostbite,
(12) post-traumatic osteoarthritis,
(13) peripheral neuropathy except where directly related to infectious causes,
(14) irritable bowel syndrome, or
(15) peptic ulcer disease,

which became manifest to a degree of 10 percent or more after active military, naval, or air service shall be considered to have been incurred in or aggravated by such service, notwithstanding that

(Added P.L. 91–376, § 3(a); amended P.L. 97–37, § 4(a); P.L. 98–223, §§ 101(c), 111; P.L. 99–576, § 108(a); P.L. 100–322, § 312; P.L. 102–83, §§ 4(b), 5(a), (c)(1).)

(c)(1) For the purposes of section 1110 of this title, and subject to the provisions of section 1113 of this title, a disease specified in paragraph (2) of this subsection becoming manifest in a radiation-exposed veteran shall be considered to have been incurred in or aggravated during active military, naval, or air service, notwithstanding that there is no record of evidence of such disease during a period of such service.

(2) The diseases referred to in paragraph (1) of this subsection are the following:

(A) Leukemia (other than chronic lymphocytic leukemia).
(B) Cancer of the thyroid.
(C) Cancer of the breast.
(D) Cancer of the pharynx.
(E) Cancer of the esophagus.
(F) Cancer of the stomach.
(G) Cancer of the small intestine.
(H) Cancer of the pancreas.
(I) Multiple myeloma.
(J) Lymphomas (except Hodgkin's disease).
(K) Cancer of the bile ducts.
(L) Cancer of the gall bladder.
(M) Primary liver cancer (except if cirrhosis or hepatitis B is indicated).
(N) Cancer of the salivary gland.
(O) Cancer of the urinary tract.

(3) For the purposes of this subsection:

(A) The term "radiation-exposed veteran" means (i) a veteran who, while serving on active duty, participated in a radiation-risk activity, or (ii) an individual who, while a member of a reserve component of the Armed Forces, participated in a radiation-risk activity during a period of active duty for training or inactive duty training.

(B) The term "radiation-risk activity" means any of the following:

(i) Onsite participation in a test involving the atmospheric detonation of a nuclear device.

(ii) The occupation of Hiroshima or Nagasaki, Japan, by United States forces during the period beginning on August 6, 1945, and ending on July 1, 1946.

(iii) Internment as prisoner of war in Japan (or service on active duty in Japan immediately following such internment) during World War II which (as determined by the Secretary) resulted in an opportunity for exposure to ionizing radiation comparable to that of veterans described in clause (ii) of this subparagraph.

(Added P.L. 100–321, § 2(a); amended P.L. 102–83, §§ 4(b), 5(a), (c)(1); P.L. 102–86, §§ 104(a), 105; P.L. 102–578, § 2(a).)

R9-4/91.2



Public Law 102-4
102d Congress

# An Act

To provide for the Secretary of Veterans Affairs to obtain independent scientific review of the available scientific evidence regarding associations between diseases and exposure to dioxin and other chemical compounds in herbicides, and for other purposes.

Feb. 6, 1991
[H.R. 556]

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

SECTION 1. SHORT TITLE.

Agent Orange Act of 1991.
38 USC 101 note.

This Act may be cited as the "Agent Orange Act of 1991".

SEC. 2. PRESUMPTION OF SERVICE CONNECTION FOR DISEASES ASSOCIATED WITH EXPOSURE TO CERTAIN HERBICIDE AGENTS.

(a) IN GENERAL.—(1) Chapter 11 of title 38, United States Code, is amended by adding at the end of subchapter II the following new section:

"§ 316. Presumptions of service connection for diseases associated with exposure to certain herbicide agents

"(a)(1) For the purposes of section 310 of this title, and subject to section 313 of this title—

"(A) a disease specified in paragraph (2) of this subsection becoming manifest as specified in that paragraph in a veteran who, during active military, naval, or air service, served in the Republic of Vietnam during the Vietnam era; and

"(B) each additional disease (if any) that (1) the Secretary determines in regulations prescribed under this section warrants a presumption of service-connection by reason of having positive association with exposure to an herbicide agent, and (2) becomes manifest within the period (if any) prescribed in such regulations in a veteran who, during active military, naval, or air service, served in the Republic of Vietnam during the Vietnam era and while so serving was exposed to that herbicide agent,

shall be considered to have been incurred in or aggravated by such service, notwithstanding that there is no record of evidence of such disease during the period of such service.

"(2) The diseases referred to in paragraph (1)(A) of this subsection are the following:

"(A) Non-Hodgkin's lymphoma becoming manifest to a degree of disability of 10 percent or more.

"(B) Each soft-tissue sarcoma becoming manifest to a degree of disability of 10 percent or more other than osteosarcoma, chondrosarcoma, Kaposi's sarcoma, or mesothelioma.

"(C) Chloracne or another acneform disease consistent with chloracne becoming manifest to a degree of disability of 10 percent or more within one year after the last date on which the veteran performed active military, naval, or air service in the Republic of Vietnam during the Vietnam era.

"(3) For the purposes of this subsection, a veteran who, during active military, naval, or air service, served in the Republic of Vietnam during the Vietnam era and has a disease referred to in paragraph (1)(B) of this subsection shall be presumed to have been exposed during such service to an herbicide agent containing dioxin or 2,4-dichlorophenoxyacetic acid, and may be presumed to have been exposed during such service to any other chemical compound in an herbicide agent, unless there is affirmative evidence to establish that the veteran was not exposed to any such agent during that service.

"(4) For purposes of this section, the term 'herbicide agent' means a chemical in an herbicide used in support of the United States and allied military operations in the Republic of Vietnam during the Vietnam era.

Regulations.

"(b)(1) Whenever the Secretary determines, on the basis of sound medical and scientific evidence, that a positive association exists between (A) the exposure of humans to an herbicide agent, and (B) the occurrence of a disease in humans, the Secretary shall prescribe regulations providing that a presumption of service connection is warranted for that disease for the purposes of this section.

"(2) In making determinations for the purpose of this subsection, the Secretary shall take into account (A) reports received by the Secretary from the National Academy of Sciences under section 3 of the Agent Orange Act of 1991, and (B) all other sound medical and scientific information and analyses available to the Secretary. In evaluating any study for the purpose of making such determinations, the Secretary shall take into consideration whether the results are statistically significant, are capable of replication, and withstand peer review.

"(3) An association between the occurrence of a disease in humans and exposure to an herbicide agent shall be considered to be positive for the purposes of this section if the credible evidence for the association is equal to or outweighs the credible evidence against the association.

"(c)(1)(A) Not later than 60 days after the date on which the Secretary receives a report from the National Academy of Sciences under section 3 of the Agent Orange Act of 1991, the Secretary shall determine whether a presumption of service connection is warranted for each disease covered by the report. If the Secretary determines that such a presumption is warranted, the Secretary, not later than 60 days after making the determination, shall issue proposed regulations setting forth the Secretary's determination.

Regulations.

Federal Register, publication.

"(B) If the Secretary determines that a presumption of service connection is not warranted, the Secretary, not later than 60 days after making the determination, shall publish in the Federal Register a notice of that determination. The notice shall include an explanation of the scientific basis for that determination. If the disease already is included in regulations providing for a presumption of service connection, the Secretary, not later than 60 days after publication of the notice of a determination that the presumption is not warranted, shall issue proposed regulations removing the presumption for the disease.

Regulations.

"(2) Not later than 90 days after the date on which the Secretary issues any proposed regulations under this subsection, the Secretary shall issue final regulations. Such regulations shall be effective on the date of issuance.

Effective



"(d) Whenever a disease is removed from regulations prescribed under this section—

"(1) a veteran who was awarded compensation for such disease on the basis of the presumption provided in subsection (a) before the effective date of the removal shall continue to be entitled to receive compensation on that basis; and

"(2) a survivor of a veteran who was awarded dependency and indemnity compensation for the death of a veteran resulting from such disease on the basis of such presumption shall continue to be entitled to receive dependency and indemnity compensation on such basis.

"(e) Subsections (b) through (d) shall cease to be effective 10 years after the first day of the fiscal year in which the National Academy of Sciences transmits to the Secretary the first report under section 3 of the Agent Orange Act of 1991.".

Termination date.

(2) The table of sections at the beginning of such chapter is amended by inserting after the item relating to section 315 the following new item:

"316. Presumptions of service connection for diseases associated with exposure to certain herbicide agents.".

(b) CONFORMING AMENDMENT.—Section 313 of title 38, United States Code, is amended by inserting "or 316" after "section 312" each place it appears.

SEC. 3. AGREEMENT WITH NATIONAL ACADEMY OF SCIENCES.

38 USC 316 note.

(a) PURPOSE.—The purpose of this section is to provide for the National Academy of Sciences, an independent nonprofit scientific organization with appropriate expertise which is not part of the Federal Government, to review and evaluate the available scientific evidence regarding associations between diseases and exposure to dioxin and other chemical compounds in herbicides.

(b) AGREEMENT.—The Secretary shall seek to enter into an agreement with the National Academy of Sciences for the Academy to perform the services covered by this section. The Secretary shall seek to enter into such agreement not later than two months after the date of the enactment of this Act.

(c) REVIEW OF SCIENTIFIC EVIDENCE.—Under an agreement between the Secretary and the National Academy of Sciences under this section, the Academy shall review and summarize the scientific evidence, and assess the strength thereof, concerning the association between exposure to an herbicide used in support of the United States and allied military operations in the Republic of Vietnam during the Vietnam era and each disease suspected to be associated with such exposure.

(d) SCIENTIFIC DETERMINATIONS CONCERNING DISEASES.—(1) For each disease reviewed, the Academy shall determine (to the extent that available scientific data permit meaningful determinations)—

(A) whether a statistical association with herbicide exposure exists, taking into account the strength of the scientific evidence and the appropriateness of the statistical and epidemiological methods used to detect the association;

(B) the increased risk of the disease among those exposed to herbicides during service in the Republic of Vietnam during the Vietnam era; and

(C) whether there exists a plausible biological mechanism or other evidence of a causal relationship between herbicide exposure and the disease.

(2) The Academy shall include in its reports under subsection (g) a full discussion of the scientific evidence and reasoning that led to its conclusions under this subsection.

(e) RECOMMENDATIONS FOR ADDITIONAL SCIENTIFIC STUDIES.—The Academy shall make any recommendations it has for additional scientific studies to resolve areas of continuing scientific uncertainty relating to herbicide exposure. In making recommendations for further study, the Academy shall consider the scientific information that is currently available, the value and relevance of the information that could result from additional studies, and the cost and feasibility of carrying out such additional studies.

(f) SUBSEQUENT REVIEWS.—An agreement under subsection (b) shall require the National Academy of Sciences—

(1) to conduct as comprehensive a review as is practicable of the evidence referred to in subsection (c) that became available since the last review of such evidence under this section; and

(2) to make its determinations and estimates on the basis of the results of such review and all other reviews conducted for the purposes of this section.

(g) REPORTS.—(1) The agreement between the Secretary and the National Academy of Sciences shall require the Academy to transmit to the Secretary and the Committees on Veterans' Affairs of the Senate and House of Representatives periodic written reports regarding the Academy's activities under the agreement. Such reports shall be submitted at least once every two years (as measured from the date of the first report).

(2) The first report under this subsection shall be transmitted not later than the end of the 18-month period beginning on the date of the enactment of this Act. That report shall include (A) the determinations and discussion referred to in subsection (d), (B) any recommendations of the Academy under subsection (e), and (C) the recommendation of the Academy as to whether the provisions of each of sections 6 through 9 should be implemented by the Secretary. In making its recommendation with respect to each such section, the Academy shall consider the scientific information that is currently available, the value and relevance of the information that could result from implementing that section, and the cost and feasibility of implementing that section. If the Academy recommends that the provisions of section 6 should be implemented, the Academy shall also recommend the means by which clinical data referred to in that section could be maintained in the most scientifically useful way.

(h) LIMITATION ON AUTHORITY.—The authority to enter into agreements under this section shall be effective for a fiscal year to the extent that appropriations are available.

(i) SUNSET.—This section shall cease to be effective 10 years after the last day of the fiscal year in which the National Academy of Sciences transmits to the Secretary the first report under subsection (g).

(j) ALTERNATIVE CONTRACT SCIENTIFIC ORGANIZATION.—If the Secretary is unable within the time period prescribed in subsection (b) to enter into an agreement with the National Academy of Sciences for the purposes of this section on terms acceptable to the Secretary, the Secretary shall seek to enter into an agreement for the purposes of this section with another appropriate scientific organization that is not part of the Government and operates as a not-for-profit entity and that has expertise and objectivity comparable to that of the National Academy of Sciences. If the Secretary enters into such an agreement with another organization, then any reference in this section and in section 316 of title 38, United States Code (as added by section 2), to the National Academy of Sciences shall be treated as a reference to the other organization.



SEC. 4. OUTREACH SERVICES.

Section 1204(a) of the Veterans' Benefits Improvement Act of 1988 (division B of Public Law 100-687; 102 Stat. 4125) is amended— 38 USC 241 note.

(1) in clause (1), by striking out ", as such information on health risks becomes known";

(2) by redesignating clauses (1) and (2) as clauses (A) and (B), respectively;

(3) by inserting "(1)" after "PROGRAM.—"; and

(4) by adding at the end the following new paragraph:

"(2) The Secretary of Veterans Affairs shall annually furnish updated information on health risks described in paragraph (1)(A) to veterans referred to in paragraph (1).".

SEC. 5. EXTENSION OF HEALTH-CARE ELIGIBILITY BASED ON EXPOSURE TO AGENT ORANGE OR IONIZING RADIATION.

Section 610(e)(3) of title 38, United States Code, is amended by striking out "December 31, 1990" and inserting in lieu thereof "December 31, 1993".

SEC. 6. RESULTS OF EXAMINATIONS AND TREATMENT OF VETERANS FOR DISABILITIES RELATED TO EXPOSURE TO CERTAIN HERBICIDES OR TO SERVICE IN VIETNAM. 38 USC 316 note.

(a) IN GENERAL.—Subject to subsections (d) and (e), the Secretary of Veterans Affairs shall compile and analyze, on a continuing basis, all clinical data that (1) is obtained by the Department of Veterans Affairs in connection with examinations and treatment furnished to veterans by the Department after November 3, 1981, by reason of eligibility provided in section 610(e)(1)(A) of title 38, United States Code, and (2) is likely to be scientifically useful in determining the association, if any, between the disabilities of veterans referred to in such section and exposure to dioxin or any other toxic substance referred to in such section or between such disabilities and active military, naval, or air service in the Republic of Vietnam during the Vietnam era.

(b) ANNUAL REPORT.—The Secretary shall submit to the Committees on Veterans' Affairs of the Senate and the House of Representatives an annual report containing—

(1) the information compiled in accordance with subsection (a);

(2) the Secretary's analysis of such information;

(3) a discussion of the types and incidences of disabilities identified by the Department of Veterans Affairs in the case of veterans referred to in subsection (a);

(4) the Secretary's explanation for the incidence of such disabilities;

(5) other explanations for the incidence of such disabilities considered reasonable by the Secretary; and

(6) the Secretary's views on the scientific validity of drawing conclusions from the incidence of such disabilities, as evidenced by the data compiled under subsection (a), about any association between such disabilities and exposure to dioxin or any other

toxic substance referred to in section 610(e)(1)(A) of title 38, United States Code, or between such disabilities and active military, naval, or air service, in the Republic of Vietnam during the Vietnam era.

(c) FIRST REPORT.—The first report under subsection (b) shall be submitted not later than one year after the effective date of this section.

(d) FUNDING.—The authority of the Secretary to carry out this section is effective in any fiscal year only to the extent or in the amount specifically provided in statutory language in appropriations Acts.

(e) EFFECTIVE DATE.—(1) This section shall take effect at the end of the 90-day period beginning on the date on which the first report of the National Academy of Sciences under section 3(g) is received by the Secretary, except that this section shall not take effect if the Secretary, after receiving that report and before the end of that 90-day period—

(A) determines that it is not feasible or cost-effective to carry out this section or that carrying out this section would not make a material contribution to the body of scientific knowledge concerning the health effects in humans of herbicide exposure; and

(B) notifies the Committees on Veterans' Affairs of the Senate and House of Representatives of the Secretary's determination and the reasons therefor.

(2) In making a determination under this subsection, the Secretary shall give great weight to the views and recommendations of the Academy expressed in that report with respect to the implementation of this section.

38 USC 216 note.

SEC. 7. TISSUE ARCHIVING SYSTEM.

(a) ESTABLISHMENT OF SYSTEM.—Subject to subsections (e) and (f), for the purpose of facilitating future scientific research on the effects of exposure of veterans to dioxin and other toxic agents in herbicides used in support of United States and allied military operations in the Republic of Vietnam during the Vietnam era, the Secretary of Veterans Affairs shall establish and maintain a system for the collection and storage of voluntarily contributed samples of blood and tissue of veterans who performed active military, naval, or air service in the Republic of Vietnam during the Vietnam era.

(b) SECURITY OF SPECIMENS.—The Secretary shall ensure that the tissue is collected and stored under physically secure conditions and that the tissue is maintained in a condition that is useful for research referred to in subsection (a).

(c) AUTHORIZED USE OF SPECIMENS.—The Secretary may make blood and tissue available from the system for research referred to in subsection (a). The Secretary shall carry out this section in a manner consistent with the privacy rights and interests of the blood and tissue donors.

Privacy.

(d) LIMITATIONS ON ACCEPTANCE OF SAMPLES.—The Secretary may prescribe such limitations on the acceptance and storage of blood and tissue samples as the Secretary considers appropriate consistent with the purpose specified in subsection (a).

(e) FUNDING.—The authority of the Secretary to carry out this section is effective in any fiscal year only to the extent or in the amount specifically provided in statutory language in appropriations Acts.



(f) EFFECTIVE DATE.—(1) This section shall take effect at the end of the 90-day period beginning on the date on which the first report of the National Academy of Sciences under section 3(g) is received by the Secretary, except that this section shall not take effect if the Secretary, after receiving that report and before the end of that 90-day period—

(A) determines that it is not feasible or cost-effective to carry out this section or that carrying out this section would not make a material contribution to the body of scientific knowledge concerning the health effects in humans of herbicide exposure; and

(B) notifies the Committees on Veterans' Affairs of the Senate and House of Representatives of the Secretary's determination and the reasons therefor.

(2) In making a determination under this subsection, the Secretary shall give great weight to the views and recommendations of the Academy expressed in that report with respect to the implementation of this section.

SEC. 8. SCIENTIFIC RESEARCH FEASIBILITY STUDIES PROGRAM.

38 USC 216 note.

(a) ESTABLISHMENT OF PROGRAM.—Subject to subsections (e) and (f), the Secretary of Veterans Affairs shall establish a program to provide for the conduct of studies of the feasibility of conducting additional scientific research on—

(1) health hazards resulting from exposure to dioxin;

(2) health hazards resulting from exposure to other toxic agents in herbicides used in support of United States and allied military operations in the Republic of Vietnam during the Vietnam era; and

(3) health hazards resulting from active military, naval, or air service in the Republic of Vietnam during the Vietnam era.

(b) PROGRAM REQUIREMENTS.—(1) Under the program established pursuant to subsection (a), the Secretary shall, pursuant to criteria prescribed pursuant to paragraph (2), award contracts or furnish financial assistance to non-Government entities for the conduct of studies referred to in subsection (a).

Government contracts. Grants.

(2) The Secretary shall prescribe criteria for (A) the selection of entities to be awarded contracts or to receive financial assistance under the program, and (B) the approval of studies to be conducted under such contracts or with such financial assistance.

(c) REPORT.—The Secretary shall promptly report the results of studies conducted under the program to the Committees on Veterans' Affairs of the Senate and the House of Representatives.

(d) CONSULTATION WITH THE NATIONAL ACADEMY OF SCIENCES.—(1) To the extent provided under any agreement entered into by the Secretary and the National Academy of Sciences under this Act—

(A) the Secretary shall consult with the Academy regarding the establishment and administration of the program under subsection (a); and

(B) the Academy shall review the studies conducted under contracts awarded pursuant to the program and the studies conducted with financial assistance furnished pursuant to the program.

(2) The agreement shall require the Academy to submit to the Secretary and the Committees on Veterans' Affairs of the Senate and the House of Representatives any recommendations that the

Academy considers appropriate regarding any studies reviewed under the agreement.

(e) FUNDING.—The authority of the Secretary to carry out this section is effective in any fiscal year only to the extent or in the amount specifically provided in statutory language in appropriations Acts.

(f) EFFECTIVE DATE.—(1) This section shall take effect at the end of the 90-day period beginning on the date on which the first report of the National Academy of Sciences under section 3(g) is received by the Secretary, except that this section shall not take effect if the Secretary, after receiving that report and before the end of that 90-day period—

(A) determines that it is not feasible or cost-effective to carry out this section or that carrying out this section would not make a material contribution to the body of scientific knowledge concerning the health effects in humans of herbicide exposure; and

(B) notifies the Committees on Veterans' Affairs of the Senate and House of Representatives of the Secretary's determination and the reasons therefor.

(2) In making a determination under this subsection, the Secretary shall give great weight to the views and recommendations of the Academy expressed in that report with respect to the implementation of this section.

38 USC 316 note.

SEC. 9. BLOOD TESTING OF CERTAIN VIETNAM-ERA VETERANS.

(a) BLOOD TESTING.—Subject to subsections (d) and (e), in the case of a veteran described in section 610(e)(1)(A) of title 38, United States Code, who—

(1) has applied for medical care from the Department of Veterans Affairs; or

(2) has filed a claim for, or is in receipt of disability compensation under chapter 11 of title 38, United States Code,

the Secretary of Veterans Affairs shall, upon the veteran's request, obtain a sufficient amount of blood serum from the veteran to enable the Secretary to conduct a test of the serum to ascertain the level of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) which may be present in the veteran's body.

(b) NOTIFICATION OF TEST RESULTS.—Upon completion of such test, the Secretary shall notify the veteran of the test results and provide the veteran a complete explanation as to what, if anything, the results of the test indicate regarding the likelihood of the veteran's exposure to TCDD while serving in the Republic of Vietnam.

(c) INCORPORATION IN SYSTEM.—The Secretary shall maintain the veteran's blood sample and the results of the test as part of the system required by section 7.

(d) FUNDING.—The authority of the Secretary to carry out this section is effective in any fiscal year only to the extent or in the amount specifically provided in statutory language in appropriations Acts, but such amount shall not exceed $4,000,000 in any fiscal year.

(e) EFFECTIVE DATE.—(1) This section shall take effect at the end of the 90-day period beginning on the date on which the first report of the National Academy of Sciences under section 3(g) is received by the Secretary, except that this section shall not take effect if the Secretary, after receiving that report and before the end of that 90-day period—



(A) determines that it is not feasible or cost-effective to carry out this section or that carrying out this section would not make a material contribution to the body of scientific knowledge concerning the health effects in humans of herbicide exposure; and

(B) notifies the Committees on Veterans' Affairs of the Senate and House of Representatives of the Secretary's determination and the reasons therefor.

(2) In making a determination under this subsection, the Secretary shall give great weight to the views and recommendations of the Academy expressed in that report with respect to the implementation of this section.

SEC. 10. CONFORMING AMENDMENTS TO PUBLIC LAW 98-542.

(a) AMENDMENTS TO SECTION 2.—Section 2 of Public Law 98-542 (38 U.S.C. 354 note) is amended by striking out "that chloracne," in paragraph (5) and all that follows through "herbicides and".

(b) AMENDMENTS TO SECTION 3.—Section 3 of such Public Law is amended by striking out "during service in the Armed Forces in the Republic of Vietnam to a herbicide containing dioxin or". 38 USC 354 note.

(c) AMENDMENTS TO SECTION 5.—Section 5 of such Public Law is amended as follows: 38 USC 354 note.

(1) Subsection (a)(1) is amended by striking out "during service—" and all that follows through "in connection with" and inserting in lieu thereof "during service in connection with".

(2) Subsection (b) is amended—

(A) by striking out "of exposure to herbicides containing dioxin or" in the first sentence of paragraph (1)(A);

(B) by striking out "evidence indicating—" in paragraph (2)(B) and all that follows through "(ii) a connection to" and inserting in lieu thereof "evidence indicating a connection to";

(C) in paragraph (3)—

(i) by striking out "herbicide or" in subparagraph (A); and

(ii) by striking out "to a herbicide containing dioxin or" in subparagraph (B); and

(D) by striking out "of the appropriate panel" in the first sentence of paragraph (1)(B), in the first sentence of paragraph (2)(A)(i), and in paragraph (2)(B).

(d) AMENDMENTS TO SECTION 6.—Section 6 of such Public Law is amended as follows: 38 USC 354 note.

(1) Subsection (a) is amended—

(A) in the matter preceding paragraph (1), by striking out "fifteen members" and inserting in lieu thereof "nine members";

(B) in paragraph (1)—

(i) by striking out "eleven individuals" and inserting in lieu thereof "six individuals";

(ii) by striking out subparagraph (A);

(iii) by redesignating subparagraph (B) as subparagraph (A); and

(iv) by redesignating subparagraph (C) as subparagraph (B) and in that subparagraph—

(I) by striking out "five individuals" and inserting in lieu thereof "three individuals"; and

(II) by striking out "dioxin or"; and

(C) in paragraph (2)—

(i) by striking out "four individuals" and inserting in lieu thereof "three individuals"; and

(ii) by striking out "dioxin or".

(2) Subsection (d) is amended—

(A) by striking out "eleven" in paragraph (1) and inserting in lieu thereof "six"; and

(B) by striking out "be divided into" in paragraph (2) and all that follows through "(B) an eight-member panel with" and inserting in lieu thereof "have".

38 USC 354 note.

(e) EFFECTIVE DATE.—(1) Except as provided in paragraph (2), the amendments made by this section shall take effect at the end of the six-month period beginning on the date of the enactment of this Act.

(2)(A) If the Secretary of Veterans Affairs determines before the end of such six-month period that the Environmental Hazards Advisory Committee established under section 6 of Public Law 98-542 (38 U.S.C. 354 note) has completed its responsibilities under that section and the directives of the Secretary pursuant to the Nehmer case court order, the amendments made by this section shall take effect as of the date of such determination.

(B) For purposes of this paragraph, the term "Nehmer case court order" means the court order dated May 2, 1989, in the case of Nehmer v. Department of Veterans Affairs, in the United States district court for the northern district of California (civil action docket number C-86-6160 TEH).

Federal Register, publication.

(3) If the Secretary makes a determination under paragraph (2), the Secretary shall promptly publish in the Federal Register a notice that such determination has been made and that such amendments have thereby taken effect as of the date of such determination.

Approved February 6, 1991.

LEGISLATIVE HISTORY—H.R. 556 (S. 238):

CONGRESSIONAL RECORD, Vol. 137 (1991):
Jan. 29, considered and passed House.
Jan. 30, S. 238 considered and laid aside in Senate. H.R. 556 considered and passed Senate.

WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 27 (1991):
Feb. 6, Presidential remarks and statement.

# Clinton Presidential Records
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the report; and

(3) contain such other information and provide for such other matters as the Secretary determines to be relevant.

(f) Submittal to Congress. (1) The Secretary shall submit to Congress a plan referred to in subsection (a) with respect to a defense nuclear facility within 90 days after the date on which a notice of changes described in subsection (c)(1)(B) is provided to employees of the facility, or 90 days after the date of the enactment of this Act [enacted Oct. 23, 1992], whichever is later.

(2) The Secretary shall submit to Congress any updates of the plan under subsection (e) immediately upon completion of any such update.

(Oct. 23, 1992, P. L. 102-484, Div C, Title XXXI, Subtitle E, § 3161, 106 Stat. 2644.)

**§ 7274l. Program to monitor Department of Energy workers exposed to hazardous and radioactive substances**

(a) In general. The Secretary shall establish and carry out a program for the identification and on-going medical evaluation of current and former Department of Energy employees who are subject to significant health risks as a result of the exposure of such employees to hazardous or radioactive substances during such employment.

(b) Implementation of program. (1) The Secretary shall, with the concurrence of the Secretary of Health and Human Services, issue regulations under which the Secretary shall implement the program. Such regulations shall, to the extent practicable, provide for a process to—

(A) identify the hazardous substances and radioactive substances to which current and former Department of Energy employees may have been exposed as a result of such employment;

(B) identify employees referred to in subparagraph (A) who received a level of exposure identified under paragraph (2)(B);

(C) determine the appropriate number, scope, and frequency of medical evaluations and laboratory tests to be provided to employees who have received a level of exposure identified under paragraph (2)(B) to permit the Secretary to evaluate fully the extent, nature, and medical consequences of such exposure;

(D) make available the evaluations and tests referred to in subparagraph (C) to the employees referred to in such subparagraph;

(E) ensure that privacy is maintained with respect to medical information that personally identifies any such employee; and

(F) ensure that employee participation in the program is voluntary.

(2)(A) In determining the most appropriate means of carrying out the activities referred to in subparagraphs (A) through (D) of paragraph (1), the Secretary shall consult with the Secretary of Health and Human Services under the agreement referred to in subsection (c).

(B) The Secretary of Health and Human Services, with the assistance of the Director of the Centers for Disease Control and the Director of the National Institute for Occupational Safety and Health, and the Secretary of Labor shall identify the levels of exposure to the substances referred to in subparagraph (A) of paragraph (1) that present employees referred to in such subparagraph with significant health risks under Federal and State occupational, health, and safety standards.

(3) In prescribing the guidelines referred to in paragraph (1), the Secretary shall consult with representatives of the following entities:

(A) The American College of Occupational and Environmental Medicine.

(B) The National Academy of Sciences.

(C) The National Council on Radiation Protection.

(D) Any labor organization or other collective bargaining agent authorized to act on the behalf of employees of a Department of Energy defense nuclear facility.

(4) The Secretary shall provide for each employee identified under paragraph (1)(D) and provided with any medical examination or test under paragraph (1)(E) to be notified by the appropriate medical personnel of the identification and the results of any such examination or test. Each notification under this paragraph shall be provided in a form that is readily understandable by the employee.

(5) The Secretary shall collect and assemble information relating to the examinations and tests carried out under paragraph (1)(E).

(6) The Secretary shall commence carrying out the program described in this subsection not later than 1 year after the date of the enactment of this Act [enacted Oct. 23, 1992].

(c) Agreement with Secretary of Health and Human Services. Not later than 180 days after the date of the enactment of this Act [enacted Oct. 23, 1992], the Secretary shall enter into an agreement with the Secretary of Health and Human Services relating to the establishment and conduct of the program required and regulations issued under this section.

(Oct. 23, 1992, P. L. 102-484, Div C, Title XXXI, Subtitle E, § 3162, 106 Stat. 2646.)

**§ 7274l. Definitions**

For purposes of this subtitle [42 USCS §§ 7274h et seq.]:

99th Congress
2d Session

COMMITTEE PRINT

COMMITTEE PRINT 99-NN

# AMERICAN NUCLEAR GUINEA PIGS: THREE DECADES OF RADIATION EXPERIMENTS ON U.S. CITIZENS

REPORT

PREPARED BY THE

SUBCOMMITTEE ON ENERGY CONSERVATION AND POWER

OF THE

COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES

NOVEMBER 1986

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# LETTER OF TRANSMITTAL

U.S. HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON ENERGY CONSERVATION AND POWER,
COMMITTEE ON ENERGY AND COMMERCE,
*Washington, DC, October 24, 1986.*

Hon. JOHN D. DINGELL,
*Chairman, Committee on Energy and Commerce, Rayburn House Office Building, Washington, DC.*

DEAR MR. CHAIRMAN: I am forwarding to you, for the Committee's use, a report prepared by the staff of the Energy Conservation and Power Subcommittee titled, "American Nuclear Guinea Pigs: Three Decades of Radiation Experiments on U.S. Citizens." This report describes material contained in Department of Energy documents on radiation experiments using human subjects.

A review of these documents reveals the frequent and systematic use of human subjects as guinea pigs for radiation experiments. Some of these experiments were conducted in the 1940's and 1950's, and others were performed during the supposedly more enlightened 1960's and 1970's. The report describes in detail 31 experiments during which about 695 persons were exposed to radiation which provided little or no medical benefit to the subjects. The report notes that it seems appropriate to urge the Department of Energy to make every practicable effort to identify the persons who served as experimental subjects, to examine the long-term histories of subjects for an increased incidence of radiation-associated diseases, and to compensate these unfortunate victims for damages.

This report is the result of an ongoing Subcommittee examination of the health and safety policies of the Department of Energy. The previous Subcommittee Chairman, Mr. Ottinger, requested from the Department documentation on experiments involving human test subjects and radiation, which were funded by DOE or its predecessor agencies. During the 99th Congress, the Subcommittee initiated an intensive review of the documents, and requested further information on specifi d experiments. This report is the result of that intensive review.

It should be noted that this report was prepared by the Subcommittee staff for discussion purposes and may not represent the views of all Committee members. I believe the Committee and others will find this report to be extremely useful in examining issues of radiation health and safety and victims' compensation.

Sincerely,

EDWARD J. MARKEY, *Chairman.*

# AMERICAN NUCLEAR GUINEA PIGS: THREE DECADES OF RADIATION EXPERIMENTS ON U.S. CITIZENS

## Summary and Conclusions

Documents provided by the Department of Energy reveal the frequent and systematic use of human subjects as guinea pigs for radiation experiments. Some experiments were conducted in the 1940s at the dawn of the nuclear age, and might be attributed to an ignorance of the long term effects of radiation exposure, or to the atomic *hubris* that accompanied the making of the first nuclear bombs. But other experiments were conducted during the supposedly more enlightened 1960s and 1970s. In either event, such experiments cannot be excused.

These experiments were conducted under the sponsorship of the Manhattan Project, the Atomic Energy Commission, or the Energy Research and Development Administration, all predecessor agencies of the Department of Energy. These experiments spanned roughly thirty years. This report presents the findings of the Subcommittee staff on this project.[1]

Literally hundreds of individuals were exposed to radiation in experiments which provided little or no medical benefit to the subjects. The chief objectives of these experiments were to directly measure the biological effects of radioactive material; to measure doses from injected, ingested, or inhaled radioactive substances; or to measure the time it took radioactive substances to pass through the human body. American citizens thus became nuclear calibration devices.

In many cases, subjects willingly participated in experiments, but they became willing guinea pigs nonetheless. In some cases, the human subjects were captive audiences or populations that experimenters might frighteningly have considered "expendable": the elderly, prisoners, hospital patients suffering from terminal diseases or who might not have retained their full faculties for informed consent. For some human subjects, informed consent was not obtained or there is no evidence that informed consent was granted. For a number of these same subjects, the government covered up the nature of the experiments and deceived the families of deceased victims as to what had transpired. In many experiments, subjects received doses that approached or even exceeded presently recognized limits for *occupational* radiation exposure. Doses were as great as 98 times the body burden recognized at the time the experiments were conducted.

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[1] This report does not necessarily reflect the views of the Members of the Committee.

A later section of this report, Description of Human Radiation Experiments, provides details on 31 experiments, during which about 695 persons were exposed. Experiments are listed by Category and Number as designated by the Department of Energy. Some of the more repugnant or bizarre of these experiments are summarized below.

During 1945 to 1947, as part of the Manhattan Project, 18 patients who were diagnosed as having diseases which gave them expected survivals of less than 10 years were injected with plutonium, to measure the quantity retained by the human body. These experiments were carried out at the Manhattan District Hospital at Oak Ridge, Tennessee; Strong Memorial Hospital in Rochester, New York; the University of Chicago; and the University of California, San Francisco. Despite the original diagnoses, seven of these patients lived longer than 10 years, and five lived longer than 20 years. Internal investigations by the Atomic Energy Commission found that informed consent was not granted in the initial experiments, since even the word "plutonium" was classified during World War II; and living patients were not informed that they had been injected with plutonium until 1974. (Category 1.001, Number 1).

From 1961 to 1965 at the Massachusetts Institute of Technology, 20 subjects, aged 63 to 83, were injected or fed radium or thorium to estimate internal doses and to measure passage of these substances through their bodies. Many of these subjects came from the nearby Age Center of New England, a research facility established to investigate the process of aging and the needs of the elderly. These experiments thus represent a perversion of the Center's original purpose, since feeding the subjects radium and thorium did not benefit them as individuals or the elderly population as a whole. (Category 1.002, Number 118).

During the 1960s, at the Los Alamos Scientific Laboratory, 57 normal adults were fed microscopic spheres containing radioactive uranium and manganese. These experiments were designed to determine how fast such spheres would pass through the human body after ingestion. It was believed that particles of this size could be produced by the atmospheric reentry and burnup of rockets propelled by nuclear reactors, or of radioactive power supplies. (Category 1.003, Number 106).

During 1946 and 1947, at the University of Rochester, six patients with good kidney function were injected with uranium salts to determine the concentration which would produce renal injury. One patient was diagnosed as being in a "hallucinatory state," another was considered suffering from "emotional maladjustment," and a third, admitted to the hospital for a fifth time, was described as follows: "As he had no home, he agreed willingly to enter the metabolic unit for special studies." (Category 1.003, Number 119).

From 1963 to 1971, 67 inmates at Oregon State Prison and 64 inmates at the Washington State Prison received x-rays to their testes to examine the effects of ionizing radiation on human fertility and testicular function. These experiments were conducted by the Pacific Northwest Research Foundation and the University of Washington. Subjects had to agree to receive vasectomies after completion of the experiments. The Energy Research and Develop-

ment Administration planned to begin medical follow up of the irradiated prisoners, but these plans were dropped in 1976 at the request of the U.S. Attorney in Portland after several irradiated inmates filed suits against state and federal governments. (Category 2.001, Number 2 and Category 2.002, Number 189).

From 1953 to 1957, at Massachusetts General Hospital, Boston, approximately 12 terminal brain tumor patients were injected with uranium to determine the dose at which kidney damage began to occur. Most of the patients were described as comatose or in a "semi-coma." (Category 9.001, Number 166).

From 1963 to 1965, at the Atomic Energy Commission National Reactor Testing Station in Idaho, radioactive iodine was purposely released on seven separate occasions. In one of these experiments, seven human subjects drank milk from cows which had grazed on iodine-contaminated land. This experiment was designed to measure the passage of iodine through the food chain into the thyroids of the human subjects. In a second experiment, three human subjects were placed on the pasture during iodine release, and seven subjects were placed on the pasture in a third experiment. In addition, "several" individuals were contaminated during yet another experiment when vials of radioactive iodine accidentally broke. Cows grazed on contaminated land and their milk was counted in four of the experiments; in the remaining three, radiation measurements were made only on the pasture. (Category 10.001, Number 173).

During May 1945, at the Clinton Laboratory, Oak Ridge, Tennessee, two groups of 10 subjects were exposed to beta rays, to determine the dose that would begin to cause reddening of the skin. (Category 11.001, Number 51).

During 1951 and 1952, at least 14 human subjects were exposed to tritium in air, by immersion of body parts in water, or by drinking. These experiments were designed to measure the retention or excretion of tritium by the human body. The experiments were carried out by the Los Alamos Scientific Laboratory, or the General Electric Company in Richland, Washington. (Category 11.001, Numbers 112, 123, 125, 126, 127).

During 1956, the U.S. Air Force sent manned planes through radiation clouds from atomic bomb tests at Eniwetok and Bikini Atolls in the Pacific to measure radiation doses in the clouds and to the crew. (Category 11.001, Number 133).

During the early 1950s, Foster D. Snell, a consulting firm, carried out experiments for the U.S. Army by placing "synthetic" radioactive soil on the hands of about 118 human subjects, and measuring the ability of different cleaning agents to remove the contamination. (Category 11.001, Number 134).

From 1961 to 1963, at the University of Chicago and Argonne National Laboratory, 102 human subjects were fed real fallout from the Nevada Test Site· simulated fallout particles that contained strontium, barium, or cesium; or solutions of strontium and cesium. This experiment was designed to measure human absorption and retention of these radioactive substances. (Category 11.001, Number 186, Part A).

During the early 1960s, at the Oak Ridge Institute for Nuclear Studies, 54 hospital patients with normal intestinal tracts were fed

lanthanum-140. This experiment was designed to measure the rate at which this radioactive substance passed through the body. (Category 13.001, Number 156, Part B.

During the late 1950s, at Columbia University and Montefiore Hospital, the Bronx, 12 terminal cancer patients were injected with radioactive calcium and strontium. This experiment was designed to compare the distribution of these two substances among body tissues after autopsy. (Category 12.001, Number 15).

In 1967 at the Hanford Environmental Health Foundation and the Battelle Memorial Institute, both at Richland, Washington, radioactive promethium was administered to 14 subjects by injection or drinking. These experiments were designed to measure the passage of this substance through the body and the ability of a drug (chelating agent) to increase the removal of promethium. (Category 12.001, Number 110).

During 1963, at the Battelle Memorial Institute, Richland, Washington, five subjects were injected with radioactive phosphorus. In addition, five subjects were fed fish from the Columbia River which contained radioactive phosphorus, produced and discharged into the river by reactors at the Atomic Energy Commission's Hanford Site. These experiments were designed to estimate the doses to humans eating contaminated fish. (Category 12.001, Number 111).

In many of the reported experiments, radiation was used as treatment for diseases which were resistant to more conventional methods. Most frequently, radiation was used in attempts to treat cancer, leukemia, or other malignant disorders of the blood. The Subcommittee staff does not question these applications, since patients were irradiated in an attempt to treat their diseases, and in some cases the treatment was successful. In these cases, the radiation exposure was meant to carry some medical benefit for patients, and observation of the effects of exposure, which enhanced understanding of radiation effects, was incidental to the treatment. In some cases, however, long term medical follow up of the surviving patients, which might have provided information for useful comparison with other treatments that might seem promising, was not conducted.

The studies provided by the Department of Energy amply demonstrate the need for long term medical follow up. Category 10.001, Number 69, describes a retrospective study on the health of humans exposed to radioactive iodine, and includes as a study population the group of Marshallese Islanders exposed to fallout from early atomic bomb tests. This report notes that thyroid nodules, produced by exposure to radioactive iodine, did not first appear among inhabitants of the atoll with the highest fallout until 9 years after the testing. Nodules began appearing some years later among inhabitants of atolls where the doses were lower; and after 22 years, nodules were still being observed.

If there is one thing the government can do for these experimental victims and their families, even at this late date, it is to conduct long term medical follow up of populations exposed to radioactive material. That practice has been adopted by the Defense Department through its Nuclear Test Personnel Review, a registry for military personnel exposed to fallout from atmospheric nuclear tests. The primary objectives of the Review are to identify the ap-

proximately 200,000 Defense Department personnel involved in such tests, to determine their exposures, to identify incidences of death or illness, and to assist veterans in claims for compensation. If this effort can be carried out for military personnel acting in the line of duty, surely a similar effort should be possible for the far smaller number of peaceful atomic soldiers used as human subjects in radiation experiments.

## Recommendations

1. It seems appropriate to urge the Department of Energy to make every practicable effort to identify the persons who served as subjects for the experiments described below, to examine the long term histories of subjects for an increased incidence of radiation-associated diseases, and to compensate these human guinea pigs for damages they have suffered.

These victims face severe obstacles to compensation under current law, embodied by the Federal Tort Claims Act. The Department of Energy should therefore be encouraged to work with the Subcommittee to develop legislation that provides adequate compensation.

2. Human experiments of this nature must never be repeated. Many of these experiments would not be allowed under current federal guidelines, and it is gratifying that experiments of this nature apparently did not continue after the early 1970s.

Two overriding principles for human experimentation must be followed: The first is that the risks of the experimental treatment must be reasonable in relation to anticipated benefits. The second is that subjects must be fully informed, and capable of understanding the benefits and risks of the treatment. Current federal regulations embody these principles, with exceptions that are clearly spelled out in cases where knowledge from the treatment might benefit society as a whole. The Appendix to this report describes these federal regulations.

The Subcommittee is gratified that the Department of Energy follows current regulations in its own experiments. However, the sad history of human radiation experimentation makes it clear that standards that were acceptable forty years ago appear repugnant today. It therefore seems appropriate to urge that all applicable federal agencies, including the Department of Energy, frequently review their regulations to ensure that human experimentation is conducted under the highest ethical standards.

## Background

The investigation into human radiation experiments began as part of an ongoing Subcommittee examination of the health and safety policies of the Department of Energy. In June 1984, Representative Richard Ottinger, then Subcommittee Chairman, requested from the Department a list of experiments involving human test subjects and radiation, which were funded by the Atomic Energy Commission, the Energy Research and Development Administration, or the Department of Energy. The former two agencies were predecessors of the Department of Energy. DOE responded to this initial request in September 1984, enclosing summaries of many

different experiments. In October 1984, Chairman Ottinger requested further clarification and information on the human experiments provided. DOE responded to this request in January 1985, providing supporting material and fuller descriptions of many of the experiments, and in some cases reporting more experiments.

In January 1985, Representative Edward J. Markey became Subcommittee Chairman, and initiated an intensive review of all the documents released by the DOE. Chairman Markey also requested further information on individual experiments in August, November, and December 1985, and in March 1986.

## Review of Released Documents

The initial information released by the Department of Energy consisted of summary factsheets on each of several human radiation experiments. Each factsheet contained an experiment title, designation of federal agency or agencies funding the experiment, a list of institutions conducting the experiments, description of the experiment objective, a short description of the experiment, and where known, the status of long term medical follow up of experimental subjects.

In response to the Subcommittee's October 1984 request for further information, DOE released additional material including dates when experiments started and ended, names of responsible government officials, and in some cases supporting documents, such as scientific references or project reports. DOE also released some material on experiments not previously reported in the summary factsheets.

DOE placed the experiments reported in 12 different categories:

1. Metabolism and Biological Effects of Plutonium, Polonium, Thorium, Uranium, Radium, and Lead-212.
2. Testicular Irradiation.
3. Whole-body Irradiation for Treatment of Leukemia and Lymphoma.
4. Teletherapy with Particle Beams.
5. Other Teletherapy Studies.
6. Treatment of Polycythemia.
7. Hematological Effects.
8. Neutron Capture Therapy.
9. Other Radiation Therapy.
10. Biological Effects of I-131.
11. Other Biological Effects Studies.
12. Metabolic and Physiological Studies.

In many of the reported cases, radiation was used as treatment for diseases which were resistant to more conventional methods. Most frequently, radiation was used in attempts to treat cancer, leukemia, or other maligant disorders of the blood. The Subcommittee staff does not question these applications, since patients were irradiated in an attempt to treat their diseases, and in some cases the treatment was successful. In these cases, the radiation exposure was meant to carry some medical benefit for patients, and observation of the effects of exposure, which enhanced understanding of radiation effects, was incidental to the treatment. The Subcommittee staff readily acknowledges the scientific advancement

produced by such observations and commends those scientists and physicians who engaged in such research.

In many of the cases where radiation was used for medical treatment, there was little long term medical follow up of the irradiated patients. In part, this may have been due to the fact that the benefits of medical radiation were clear: irradiated patients in some cases showed higher survival rates than patients treated with other methods. But since radiation can also cause cancer, long term follow up on surviving patients may have provided information for a useful comparison with other present treatments or with treatments that might seem promising in the future.

The follow up provisions of one particular experiment, designated Category 4.004, Number 179, should be noted with approval. The objective of this project is to determine the effectiveness of neutron beam irradiation as compared to standard irradiation for the management of certain malignant tumors. This project is funded by the National Cancer Institute and is carried out at the Fermi National Acclerator Laboratory, a facility owned by the Department of Energy.

This project began in 1975 and is continuing today. Approximately 1400 patients have been referred to the program. Prior to treatment, patients must agree to comply with long-term follow up requirements, which include regular physical examinations and laboratory tests. Every effort is made to contact patients who miss scheduled appointments, and fewer than 1 percent of patients treated at this facility are currently considered lost to follow up. The follow up efforts at this Fermilab project should be applauded, and they represent a model that should be duplicated in other DOE investigations of medical therapy.

In many of the other human experiments which DOE reported to the Subcommittee, however, subjects received little or no medical benefit from their exposure. These experiments fall into two general categories: In one group, human subjects were injected with or fed radioactive material, and its passage through the body was monitored. The major objective of these experiments was to compare results with mathematical models predicting radiation doses for occupational or accidental exposure. Although these experiments did provide information on the retention and absorption of radioactive material by the human body, the experiments are nonetheless repugnant because human subjects were essentially used as guinea pigs and calibration devices. In a second group of experiments, the administration of radioactive material was actually intended to *cause* damage to the human body, and the experimenters sought to correlate the amount of damage done with the dose received.

In some of the experiments described, the human subjects were captive populations: the elderly, prisoners, and hospital patients who might not have retained their full faculties for informed consent. In other experiments, the subjects were volunteers, but they were willing guinea pigs nonetheless.

The human radiation experiments are described in detail in the following section.

## Description of Human Radiation Experiments

Category and Number labels below are as designated by the Department of Energy in its responses to the Subcommittee. In many cases, occupational exposure limits are provided for comparison with the doses or amounts of radioactive material received by subjects. Present dose limits are taken from Title 10, Code of Federal Regulations, Part 20. The maximum permissible body burden is an occupational limit for the allowable amount of a given substance that may be internally deposited in an individual. It is generally recognized among the scientific community that doses to the general population should be no more than one tenth the allowable doses to radiation workers. Values presented below for maximum permissible body burdens are taken from NCRP-22, a handbook of the National Committee on Radiation Protection, which is a non-governmental organization that recommends standards for radiation exposure.

In addition to the experiments described in the Summary and Conclusions of this report, many experiments are of special concern because of the circumstances of the persons used as subjects, or because of the doses which some subjects received, relative to present occupational limits. In experiments where the radioactive material administered was greater than the present maximum permissible body burden, doses are classified as potentially greater than present occupational limits, since not all of the material administered might have remained in the body. These experiments of special concern are listed below, and are followed by descriptions of all experiments.

Category 1.001, Number 1. Subjects were diagnosed as terminal within 10 years; one subject was a child; no evidence of informed consent; potential doses much greater than occupational limits.

1.002, Number 118. Subjects were elderly; potential doses greater than occupational limits.

1.003, Number 12. Subjects were terminal patients; potential doses greater than occupational limits.

1.003, Number 119. Subjects were hospital patients; some doses produced kidney damage.

2.001, Number 2. Subjects were prisoners; doses were greater than occupational limits.

2.002, Number 189. Subjects were prisoners; doses were greater than occupational limits.

3.001, Number 49. Doses were greater than occupational limits.

9.001, Number 166. Subjects were terminal brain tumor patients, and most were comatose; some doses produced kidney damage.

10.001, Number 173. Radioactive iodine was intentionally released to the environment.

11.001 Number 51. Doses were greater than occupational limits.

11.001, Number 53. Doses were greater than occupational limits.

11.001, Number 121. Subjects were hospital patients; doses were greater than occupational limits.

11.001, Number 123. Potential doses were greater than occupational limits.

11.001, Number 127. Potential doses were greater than occupational limits.

11.001, Number 133. Doses were greater than occupational limits.
11.001, Number 186, Part B. Subjects were hospital patients; potential doses were greater than occupational limits.
Category 12.001, Number 15. Subjects were terminal cancer patients; potential doses were greater than occupational limits.
12.001, Number 109. Potential doses were greater than occupational limits.
12.001, Number 128. Potential doses were greater than occupational limits.

## *Category 1. Metabolism and Biological Effects of Plutonium, Polonium, Thorium, Uranium, Radium, and Lead-212*

### CATEGORY 1.001, NUMBER 1

*Plutonium injections into humans*

During 1945 to 1947, 18 patients were injected with plutonium. These experiments were carried out by the Manhattan Project. The following hospitals were involved in the experiments, with the number of patients involved for each indicated:
Manhattan District Hospital, Oak Ridge, Tennessee (1).
Strong Memorial Hospital, Rochester, New York (11).
Billings Hospital, University of Chicago (3).
University Hospital, University of California, San Francisco (3).
According to an Energy Research and Development Administration (ERDA) fact sheet of February 1976, the rationale for this experiment was that several thousand Manhattan Project workers had been involved in handling plutonium, accurate information was needed on the retention and excretion of internally deposited plutonium for setting safety criteria, and animal experiments had produced conflicting data which could not be extrapolated to humans.

In choosing subjects, the original criteria specified that subjects should be older, with relatively short life expectancies. All subjects chosen were diagnosed as having existing diseases that gave them an expected survival of less than 10 years. Most were over 45, but one subject was five years old, and another was 18. The oldest patients were 68. The quantities of plutonium injected ranged from 1.6 to 98 times the body burden value recognized at the time of the experiments, where a body burden is the permissible occupational limit for an internally deposited radioisotope. 13 of the patients received between 7 and 10 body burdens. Patients were monitored for their excretion of plutonium. They received no medical benefits from the injections.

In 1967, a Berkeley radiobiologist learned that one of the injected patients had lived for 20 years. She investigated the whereabouts of other patients, and in 1972 published a scientific paper noting that four patients were then alive. In a subsequent follow up investigation, the Department of Energy determined that 9 patients died within 3 years, one in 8 years, one each in 11 and 14 years, and four after 20 years. One was lost to follow up, and one was still living as of October 1983. In one case, the original diagnosis of disease later proved to be inaccurate.

In 1974, following the report that four patients were still alive, the Atomic Energy Commission conducted internal investigations to determine if the experimental patients had granted informed consent for their exposures. A report transmitted in August 1974 found that experimenters had failed to obtain informed consent in several instances. Formalized standards for patient consent to experimental procedures did not exist prior to 1946. In addition, even the word "plutonium" was classified until the end of World War II. The AEC, which succeeded the Manhattan Project, established a policy of formalized patient consent in 1947. One patient, injected in 1947, was the only subject injected after the AEC had been formed. This patient's hospital record contained a statement by attending physicians that the individual had been properly informed of the experimental nature of the injection. The AEC could find no records of consent for any other patient, and determined from oral testimony that at least one patient had not been informed.

On this issue, a June 1983 Department of Energy memo concluded that:

> The issue of informed consent, if raised, will be difficult to deal with in the light of present DOE and Federal policies and procedures regarding human subjects. These are vastly more codified and explicit than any guidance available at the time the injections were given, and the procedures used at that time would not meet standards adopted and currently applied by DOE and other federal organizations. (Memo from Nathaniel F. Barr to Alvin W. Trivelpiece, Director, Office of Energy Research, Department of Energy, June 30, 1983.)

In 1973, the Center for Human Radiobiology (CHR), Argonne National Laboratory, initiated a follow up study of surviving patients and a program to exhume deceased patients for whom permission could be obtained. These studies were designed to examine how much plutonium remained in the bodies of subjects. The 1974 AEC investigations found that even by 1973 standards, informed consent had not been obtained for these studies. A memorandum dated December 21, 1972 from [name deleted], Argonne National Laboratory, to [name deleted], Center for Human Radiobiology, contained the following instructions in regard to studies on the surviving patients:

> Please note that outside of CHR we will *never* use the word *plutonium* in regard to these cases. 'These individuals are of interest to us because they may have received a radioactive material at some time' is the kind of statement to be made, if we need to say anything at all [emphasis in original]. (Quoted in Division of Inspection Report 44-2-326, U.S. Atomic Energy Commission, August 16, 1974, p. 19.)

Consequently, patients alive in 1973 were not informed that they had been injected with plutonium in the 1940s. Relatives of deceased patients were told that exhumation was necessary to determine the composition of an "unknown" mixture of injected radioactive isotopes. Injection was also represented as having been an experimental treatment for the patients' diseases, a statement that is not true. As a second AEC investigation concluded:

> Relative to the study undertaken in 1973, informed consent was not obtained from surviving patients who were the subject of the study.
>
> Consent, following improper disclosure, was obtained from the next of kin of an exhumed patient. Improper disclosure was made to the next of kin of additional deceased patients who have not been exhumed. (Division of Inspection Report 44-2-330, U.S. Atomic Energy Commission, August 12, 1974, pp. 11, 12.)

As a result of the 1974 investigation, the AEC contacted the doctors of the four living patients, and asked the doctors to inform the patients of the nature of the Manhattan Project injections. One doctor did not tell his patient because he felt the information would be detrimental to her health; this patient has since died. The other three patients were informed.

A scientific paper published in 1976 calculated doses to the injected patients, and concluded from these calculations that in spite of the apparent lack of induced tumors among the patients:

> The liver doses do not appear to be high enough to be carcinogenic, but comparison of the bone-surface doses with radium doses that have induced bone tumors indicates that six of these cases have received doses high enough to be considered carcinogenic. (R.E. Rowland and P.W. Durbin, Survival, causes of death, and estimated tissue doses in a group of human beings injected with plutonium, in The Health Effects of Plutonium and Radium, J.W. Press, Salt Lake City, 1976.)

CATEGORY 1.002, NUMBER 118

*Administration of radium and thorium to humans*

During the period 1961–1965, doses of the nuclides Radium-224, and Thorium-234 were given to 20 volunteers, 13 men and 7 women, aged 63 to 83. Six subjects were injected with radium, six were injected with thorium, one ingested radium, one ingested thorium, and six ingested both radium and thorium. These experiments were funded by the AEC and carried out at the Massachusetts Institute of Technology.

The experiments were designed to examine the metabolism from radioactive substances that might be smiliar to those ingested by radium dial painters in the earlier part of the 20th century, many of whom subsequently developed cancer of the jaw or mouth. The specific matter of concern was whether Thorium-228, which may have been present in dial paints, would have contributed a significant dose to painters. After the subjects were fed or injected with the radioactive substances, the substances were monitored by measuring their presence in blood, in the breath, in excreted matter, and by whole-body counting of the subjects. Patients were monitored for up to 120 days.

Doses given to patients were 0.2 to 2.4 microcuries of radium, or 1.2 to 120 microcuries of thorium. For comparison, maximum permissible body burdens are 0.07 microcuries for Radium-224, and 20 microcuries for Thorium-234.

Most of the subjects were obtained from the Age Center of New England, Boston. A few were retired MIT employees. The subjects received no medical benefits from the experiment.

According to material received from the Department of Energy, the Age Center of New England was a non-profit research facility established in 1954 to investigate the process of aging and the needs of the elderly. The Center's pool of subjects consisted of several hundred "apparently healthy men and women" over the age of 50 who had declared their willingness to be studied in a variety of research projects on aging. These subjects lived elsewhere and had to be active enough to come to the Center to participate in research.

In 1957, the first published annual report of the Age Center described the following ongoing reseach projects: "Correlates of Anxi-

ety in Older Persons;" "The Nutrition of Apparently Normal Aging Persons;" "Prejudice and Older People," and "A Thematic Analysis of Later Life," which obtained the attitudes of elderly persons through questionnaires and oral interviews. The AEC experiments with Age Center subjects thus represent a perversion of the Center's original purpose: Feeding the subjects radium and thorium was of no direct benefit to the subjects or to the elderly population as a whole, and was not related to phenomena connected to the aging process.

The study was conducted in two phases. In the first phase, subjects were injected with either radium or thorium, and the passage of the material through the body was measured. The principal reason for these experiments was to calibrate counting equipment that would be used in the second phase, which was the oral ingestion of mixtures of radium and thorium. Excretion and whole body counting was also monitored for the phase two patients. These experiments were reported to the AEC in annual progress reports in 1964 through 1966.

In a January 2, 1985 letter to the Subcommittee Chairman, the Department of Energy reported that no follow up had been conducted on the health of the experimental subjects. The Age Center no longer exists and one professor who conducted the study had "no idea how any records of survival history could be obtained." He stated that finding the patients, if still alive, may be "like doing a missing persons search." The youngest volunteer would be approaching 85 years old today.

CATEGORY 1.003, NUMBER 12

*Polonium administered to humans*

From 1943 to 1947, radioactive polonium was injected into 4 hospital patients, and given orally to a fifth. Rates of excretion were measured. These studies were funded by the Manhattan Project and the AEC, and were conducted at the University of Rochester.

The objective of the experiment was to obtain data on human excretion of polonium to obtain a correlation with more extensive data from rats. Hospital patients were used as subjects because the experimenters wanted persons who had not been exposed to polonium through work or accidents.

The experiments were described in a scientific publication: Studies of polonium metabolism in human subjects, Chapter 3 of Biological Studies with Polonium, Radium, and Plutonium, National Nuclear Energy Series, Volume VI-3, McGraw-Hill, New York, 1950. All subjects had incurable diseases. Patient 1 was suffering from lymph cancer, and was injected with 22 microcuries of polonium. Patient 2 had acute leukemia, was injected with 11 microcuries, and died six days later. Patients 3 and 4 suffered from chronic leukemia, and were injected with 12 and 9 microcuries, respectively. Patient 5 suffered from chronic leukemia, and ingested 18 microcuries of polonium. Excretion of polonium was followed, and an autopsy was conducted on the deceased patient to determine which organs absorbed the polonium. The age of the patients ranged from early thirties to early forties.

The isotope administered is not specified, but the most readily available isotope at the time was Polonium-210. For comparison with the doses, the maximum permissible body burden for Polonium-210 is 0.4 microcuries.

In Janaury 1985, the Department of Energy transmitted to the Subcommittee summary factsheets on this, and many other experiments. The factsheet for this experiment reported no follow up on these experimental subjects.

CATEGORY 1.003, NUMBER 21

*Absorption of lead-212 by the human gastrointestinal tract*

Lead-212 was fed to three human subjects and gastrointestinal absorption and excretion over 24 hours were examined. Similar measurements were made on two human subjects injected with Lead-212, and the results for ingestion and injection were compared. These experiments were conducted to compare experimental results with existing models used by the International Commission on Radiological Protection (ICRP) and the National Council on Radiation Protection (NCRP), organizations which recommend radiation exposure standards. These experiments were carried out at the University of Rochester, were funded by the AEC, and were reported in UCRL-18140, Lawrence Radiation Laboratory, University of California, Berkeley, April 1968, pp. 217-232. The material from the Department of Energy on this experiment reported no information on doses, and no follow-up on the experimental subjects.

CATEGORY 1.003, NUMBER 106

*Some biological aspects of radioactive microspheres in humans*

During the 1960s, 57 normal adults were fed very small spheres containing radioactive Uranium-235 and Manganese-54, to determine how long it would take these spheres to pass through the gastro-intesinal tract. The human subjects received no medical benefit from this experiment.

The experiment was designed to assess the potential hazards from atmospheric reentry and burnup of rockets propelled by nuclear reactors, or of radioactive power supplies. Such burnup could produce particles small enough to be inhaled or ingested. In order to estimate internal radiation doses that humans might receive from such accidents, information was needed on the time that radioactive particles might remain in the body. The human subjects were all workers at Los Alamos Scientific Laboratory, except for one individual who was the wife of the principal investigator.

During the experiment, subjects were given a gelatin capsule containing U-235 and Mn-54, in spheres 100-200 microns in diameter (a micron is one-millionth of a meter). Both U-235 and Mn-54 emit radiation which would penetrate the gelatin. The Mn-54 spheres were coated with ceramic, the U-235 spheres were uncoated. Subjects each swallowed a capsule, and feces were collected and counted to determine how long the capsules remained in the body. One subject repeated ingestion of the sample 10 different times to provide an estimate of variation within the same individual. "Sev-

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eral others" repeated ingestion at different times of the day to provide an estimate of how results might change with time of day.

The experiment was conducted at Los Alamos Laboratory, was funded by the Atomic Energy Commission, and was reported in document LA-3365, Los Alamos Scientific Laboratory, August 1965.

The factsheet which the Department of Energy supplied the Subcommittee reported no follow up on these experimental subjects.

CATEGORY 1.003, NUMBER 119

*Injection of uranium salts*

During 1946 and 1947, six patients with good kidney function were injected in increasing doses with uranium nitrate, enriched in U-234 and U-235. The objectives of the experiment were to: determine the dose of uranium salt which produced renal injury; measure the rate of excretion of uranium salts; and observe the effects of modifying rates of excretion. These experiments were carried out at the University of Rochester, Atomic Energy Project.

The experiments are described in UR-37, dated June 1948, which apparently was a project report to the Atomic Energy Commission. The human subjects received no medical benefits from these experiments, and in fact the treatment seemed designed to induce kidney injury in at least one patient. It was recognized that uranium salts could damage the kidney, and the experiment planned to identify the concentration that would produce "just detectable renal injury." (UR-37, p. 7)

The experimental subjects were chosen from a large group of hospital patients; those selected had reasonably normal kidney function. In addition, "The probability that the patient would benefit from continued hospitalization and medical care was also a factor in the choice. When higher levels of dosage were contemplated, individuals from the older age groups were preferred in view of the remote possibility that late radiation effects might occur . . ." (UR-37, pp. 8, 9).

Patient 1 was in the hospital because of rheumatoid arthrithis and urethral strictures. Patient 2 was hospitalized because of acute alcololism, "hallucinatory state," cirrhosis of the liver, and possible neural damage. Patient 3 was a young woman "in fairly good physical condition except for mild chronic undernutrition which was thought to be secondary to an emotional maladjustment." (UR-37, p. 18) Patient 4 entered the hospital because of chronic alcoholism and bleeding from the gastrointestinal tract; 12 days after uranium injection, patient 4 was injected with citrate to examine its effect in further removal of uranium. "Unfortunately, this solution was so hypotonic" that blood appeared in the patient's urine and his temperature rose to 39.5 degrees C [103 degrees F]." (UR-37, p. 29).

Patient 5 suffered from chronic cough, had a history of rather high alcohol consumption, and was diagnosed as having pneumonia when he entered the hospital. Uranium doses had been successively increased with each new patient. Patient 5 showed trace amounts of protein in his urine, a sign of kidney disfunction, on the last day before leaving the hospital. He was not followed up. Patient 6 remained in the hospital from October 1946 to April 1947. This was his fifth admission to the hospital. Previous diag-

noses had included heart disease, chronic alcoholism, and pneumonia; the present admission was for an ulcer. "As he had no home, he [Patient 6] agreed willingly to enter the metabolic unit for special studies." (UR-37, p. 41) Patient 6 received the largest dose, 70 microgram of uranium per kilogram weight, and clinical analysis suggested that "tolerance had been reached" for kidney injury. (UR-37, p. 55)

The summary factsheet which the Department of Energy submitted to the subcommittee reports no follow up on the experimental subjects. Funding for the experiment is not specified, but it presumably would be from the Manhattan Project, since the AEC was not established until 1947.

### *Category 2. Testicular Irradiation*

#### CATEGORY 2.001, NUMBER 2

#### *Testicular irradiation of inmates at Oregon State Prison*

From August 1963 to May 1971, 67 volunteers at the Oregon State Prison were subjected to testicular irradiation by x-rays. Radiation doses ranged from 8 to 600 roentgen in single acute exposures, except that six prisoners were irradiated a second time, one a third time, and one was given weekly irradiations of 5 roentgen per week for eleven weeks. For comparison, the present occupational limit for exposure to reproductive organs is 5 roentgen per year. These experiments were carried out by the Pacific Northwest Research Foundation, Seattle; the Atomic Energy Commission provided a total of $1.08 million for these studies.

The objective of this experiment was to obtain data on the effects of ionizing radiation on human fertility and the function of testicular cells. It was considered that data from animals could not be readily extrapolated to humans. Studies included examination of testicular tissue, sperm counts, and evaluation of urinary or blood steroids and hormones.

Prisoners ranged in age from 25 to 52. Each inmate agreed to have a vasectomy at the end of his irradiation; consent of wives was required for this procedure. All prisoners in the Oregon group did eventually have vasectomies. All volunteers were required to sign statements of informed consent. Consent procedures involved an explanation of short term and long term effects, including the possibility of testicular cancer. No Catholics were allowed as subjects. Small sums of money were paid to prisoners: $5 to $10 for each treatment, and $100 at the time of vasectomy. However, according to the Energy Research and Development Administration "records suggest that the prime incentive to participate may have been the feeling that they were making important contributions to the state of medical knowledge." (ERDA background information on AEC human testicular irradiation projects in Oregon and Washington state prisons, March 1976, p. 2)

The prisoner irradiation program was terminated in 1973 after the principal investigator suffered an incapacitating stroke, and because of "subsequent state re-evaluation of correctional institutional involvement in experimental programs." (C.G. Heller et al., "Protection of the rights of welfare of prison volunteers: Policies

followed throughout a 17-year medical research program," unpublished manuscript, p. 7) The same document noted that the vasectomies on subjects after the experiment were necessary "to avoid any possibility of contaminating the general population with irradiation-induced mutants." (Ibid., p. 5)

In a summary factsheet provided the Subcommittee in January 1985, the Department of Energy described the follow up of experimental subjects:

> Complete recovery as shown by a return to pre-irradiated sperm concentrations and germinal cell numbers was found to be within 9-18 months for doses of 100 rad and below, 30 months for doses of 200 and 300 rad and 5 or more years for doses of 400 and 600 rad.

The need for follow up over a longer term was recognized as early as 1971, in a letter from an AEC official to Carl Heller, the principal investigator for the experiments. The letter concluded,

> Thus, I am suggesting that you prepare a protocol for the long-term follow-up of the irradiated volunteers after their release from the research program. (Frank T. Brooks, Division of Biology and Medicine, AEC, to Carl G. Heller, Pacific Northwest Research Foundation, November 30, 1971.)

In its 1976 background information material, the Energy Research and Development Administration noted:

> ERDA believes that there is a need for continued medical surveillance of prisoners involved in both sets of experiments [Oregon and Washington], and will explore with prison officials the best methods to achieve this. Among health effects which should be monitored is the possibility of testicular tumors, occurring after a long latency period (25-30 years). (ERDA background information, March 1976, pp. 2-3.)

However, at the request of the U.S. Attorney in Portland, Oregon, this follow up program was cancelled after several irradiated inmates filed suits against state and federal governments. In September 1976, the District Court for the District of Oregon dismissed the suit against federal defendants.

The experiments resulted in the publication of several scientific papers. The most recent one cited was M.J. Rowley et al, Radiation Research 59, 665-678, 1974.

CATEGORY 2.002, NUMBER 189

*Testicular irradiation of inmates at Washington State Prison*

During the period June 1963 to May 1970, 64 inmates at the Washington State Prison received testicular irradiation from x-rays. Each subject was irradiated once, and doses ranged from 7 to 400 roentgen. Following irradiation, tissue samples and sperm were examined for indications of damage; urine samples were examined for hormone levels. The Atomic Energy Commission granted $505,000 to support these studies, which were conducted by University of Washington researchers.

The objective of these studies was to determine the effects of radiation on gonadal function. The studies were reportedly proposed after a radiation accident at the AEC Hanford facility. Three men were overexposed, and no clear scientific data was available to advise them on possible sterility effects. The experiments were designed to determine the minimum effective dose that would render an individual temporarily sterile.

The criteria for selection were similar to the experiments with Oregon inmates: Participants had to agree to vasectomies after completion of the experiment. However, several of the Washington inmates subsequently did not receive vasectomies: 2 declined and were released from prison; 1 declined and remained in prison; 1 was released before the scheduled vasectomy; 1 did not undergo surgery for psychiatric reasons after mutual agreement with the prison physician; 1 who had heart problems and a life sentence was not vasectomized after mutual agreement (AEC Contract AT(45-1)-2225, Task Agreement 6, Terminal Report, January 1973, p. 3) Because of the lack of follow up information, it is not known if any experimental subjects subsequently fathered any children.

The experiments were terminated after a Human Subjects review board at the University of Washington refused in July 1969 to authorize further irradiation of prisoners. (George W. Farwell, University of Washington, to John R. Totter, Director, Division of Biology and Medicine, Atomic Energy Commission, July 16, 1969)

In the factsheet submitted to the Subcommittee in January 1985, the Department of Energy had this description for follow up: "Recovery of cell morphology and function were found after a maximum of 501 days. It was concluded that man is very sensitive in regard to temporary sterility, but is very resistant to complete sterility." As with the Oregon prisoners, there was no long-term follow up of subjects

Several scientific publications resulted from these experiments. The most recent cited was T.W. Thorslund and C.A. Paulsen, in Proceedings of the National Symposium on Natural and Man-Made Radiation in Space, NASA Document NAS No. 2440, pp. 229-232, January 1972.

### *Category 3. Whole Body Irradiation*

In most of the cases in this category reported to the Subcommittee, whole body irradiation was used as treatment for diseases which were resistant to more conventional methods. Most frequently, whole body irradiation was used in attempts to treat leukemia, cancer, or polycythemia vera (a disorder characterized by excessive levels of red blood cells in the blood). The Subcommittee staff does not question the propriety of these particular applications, since patients were irradiated in an attempt to treat their diseases, and in some cases the treatment was successful. However, one case covered below appeared questionable.

#### CATEGORY 3.001, NUMBER 49

*Blood changes in human beings following total-body irradiation*

During 1943 and 1944, three groups of persons were given whole body irradiation doses from x-rays. The first group was eight persons with cancer. The second group consisted of one cancer patient and two persons with arthritic conditions. The third group was three normal volunteers. The objective of the study was to observe the changes in blood or blood cells following treatment. Although whole body irradiation was a recognized treatment for malignancies, it provided no benefit to the normal subjects, who received

doses which were greater than maximum allowable occupational exposures at the time. In addition, the treatment seemed of little use for arthritis, and the Department of Energy reported in April 1986 that x-ray irradiation for arthritis "is not considered to be standard practice." The experiments were conducted at the University of Chicago and were funded by the Manhattan Project.

The experiment is described in a scientific publication, J.J. Nickerson, Blood changes in humans following total body irradiation, in Industrial Medicine on the Plutonium Project, National Nuclear Energy Series, Vol. IV-20, pp. 308-337, McGraw-Hill, 1951. Page 309 contains the following comment on clinical treatment:

> The people used in groups 1 and 2 were individuals to whom the medical profession could offer no treatment that was at all specific or known to be helpful. The x-ray exposures that were given were as likely to benefit the patient as any other known type of treatment, or perhaps even more likely than any other. Since this manuscript is concerned only with the effects on the blood, the clinical condition of the patients is not discussed at any length.

Group 1 consisted of 8 patients with cancer of the throat, mouth, breast, or larynx. These patients received total body doses of 27, 60, or 120 roentgen in single doses from x-rays. Group 2 consisted of one patient with cancer of the hand, one patient with chronic arthritis who had received no previous known radiation therapy, and one patient with joint stiffness and pain who had received local radiation therapy to the knee. These patients received 500, 300, and 100 roentgen, respectively of total-body doses in multiple doses from x-rays. The radiation produced no significant change in the arthritis of those two patients. Group 3 consisted of three young male subjects who were normal in every known respect. These subjects received 7 roentgen (r) on three successive days, for a total of 21 roentgen from x-rays to each of them. Patients in groups 1 and 2 showed a decrease in the number of lymphocytes in the blood following radiation treatment. Group 3 showed no change in blood elements. For Group 3, the experimenters commented that:

> These cases were of particular interest to us inasmuch as they indicated that acute exposure to far more than the maximum permissible level of 0.1 r per working day could not be expected to produce diagnostic changes in the elements of the peripheral blood which were studied. (Ibid., p. 336)

The summary factsheet which the Department of Energy submitted to the Subcommittee in January 1985 reported no follow up on these subjects.

### *Category 4. Teletherapy with Particle Beams*

These experiments consist of applications of cyclotron beams in attempts to treat patients suffering from cancer or other malignancies. The treatment was applied because conventional methods of therapy had often been unsuccessful in arresting the spread of disease. In some cases, the beam therapy proved more effective than conventional methods. In other tests, this therapy offered no advantages over existing methods and was discontinued. One item reported to the Subcommittee did seem disturbing, because experimental subjects received no apparent medical benefits. This item, in Category 4.006, is discussed below.

CATEGORY 4.004, NUMBER 179

*Neutron therapy facility*

The follow up provisions of this experiment should be noted with approval. The objective of this activity is to determine the effectiveness of neutron beam irradiation as compared to standard irradiation for the management of certain malignant tumors. This project is carried out at the Fermi National Accelerator Laboratory, a facility owned by the Department of Energy, and is funded by the National Cancer Institute.

The project began in 1975 and is continuing. Approximately 1400 patients have been referred to the program. Prior to treatment, patients must agree to comply with long-term follow up requirements, which include regular physical examinations and laboratory tests. Every effort is made to contact patients who miss scheduled appointments, and fewer than 1 percent of patients treated at this facility are currently considered lost to follow up. The benefits of radiation therapy, when expressed as enhanced survival rates, may be obvious. However, information on longer-term effects of radiation treatment will be useful in comparing results with other techniques in use presently or which may be developed in the future. The follow up efforts at the Fermilab project should be applauded, and should serve as a model that can be duplicated in other DOE investigations of medical therapy.

CATEGORY 4.006, NUMBER 93

*Biological effects of heavy ions on human nervous system and vision*

During the early 1970s, human subjects were placed within neutron and ion beams at accelerators in Berkeley and Seattle. These experiments arose because astronauts had observed visual light-streak effects while exposed to cosmic rays in space flight. One objective of the experiments was to explore "visual sensations" in humans from exposure to ions. Two subjects observed light flashes in neutron beams of peak energy of 640 million electron volts (MeV); six subjects observed light flashes and dim but definite streaks of 25 MeV peak energy; and two subjects observed light flashes and streaks due to helium ions impinging upon human retina.

These experiments were conducted by the Lawrence Berkeley Laboratory and were funded by the Atomic Energy Commission. They were reported in Nuclear Science Abstracts in 1972 and 1973. The summary factsheet provided by the Department of Energy reports no long term follow up on the human subjects.

*Category 5. Other Teletherapy*

Projects in this category involved cases where patients whose cancer was not responding to conventional treatment were treated with various types of radiation from accelerators. As before, the Subcommittee staff does not question the propriety of these experiments because they contained a real possibility of benefit for patients.

### *Category 6. Treatment of Polycythemia*

This project was a ten-year attempt, beginning in 1939, to treat polycythemia vera with radiation. The radiation therapy seemed more successful than conventional means of treatment.

### *Category 7. Hematological Effects*

Most of the experiments in this category involved examinations of blood changes of patients who were being irradiated for purposes of diagnosis or treatment. The Subcommittee staff does not question these experiments, since the patients benefited or potentially benefited from the treatment, and the examination of blood changes could provide useful information in designing future treatment.

### *Category 8. Neutron Capture Therapy*

Projects in this category involved the use of beams of neutrons to treat patients with brain tumors. The Subcommittee staff does not question these experiments, since the radiation treatments were meant to benefit patients.

### *Category 9. Other Radiation Therapy*

Most of these projects involved the examination of radioactive isotopes for their ability to treat malignant diseases or to assist diagnosis by concentrating in tumor cells. One experiment, however, raised issues of concern and is discussed below.

#### CATEGORY 9.001, NUMBER 166

*Uranium injected into brain tumor patients*

From 1953 to 1957, approximately 12 terminal brain tumor patients were injected with uranium to determine the dose at which kidney damage began to occur. These experiments were conducted at Massachusetts General Hospital, Boston, with assistance from the Oak Ridge National Laboratory, and were funded by the Atomic Energy Commission.

The experiments were conducted to gain data in deriving tolerance doses for workers in uranium processing and fabrication plants. Inhaled or ingested uranium salts are known to produce kidney damage; these experiments were designed to identify the doses at which kidney damage began to occur. Data were also obtained during these experiments on the excretion and retention of uranium in the body. All subjects were terminal brain tumor patients who died within 18 months of the experiments.

An additional stated reason for conducting the experiment was as an initial evaluation of uranium toxicity in developing therapy to treat brain tumor patients with U-235. However, this does not in fact seem to be an important reason for the experiment, since no effort was made to actually treat the brain tumor patients with this isotope. Moreover, neutron capture therapy with U-235 has never been proven as an effective treatment for brain tumor patients.

Several scientific papers resulted from this experiment. One paper, Bernard et al., Proc. Health Physics Soc., 33-48, June 1956, reported the injection of 11 patients, 10 of whom were in coma or semi-coma. One of these patients died in 2.5 days, and one died 18 days after injection. Doses ranged from 4 to 50 milligrams (mg) of uranium. A second paper, A.J. Lussenhop et al., Am. J. Roentgenol. 79, 83-100, 1958, reported on the injection of five patients, four of whom "were in coma or semicoma and remained so until their demise." Patients were injected with 4 to 15 mg uranium. The three patients with the highest doses, 0.12 to 0.28 mg uranium per kg body weight, showed evidence of kidney toxicity. Based on comparisons with animal data, the experimenters determined that a lethal dose for humans would have been 1 mg uranium per kg.

Another paper, S.R. Bernard, Health Physics 1, 288-305, 1958, reports on the injection of eight terminal brain tumor patients, six of whom were comatose. Doses ranged from 4 to 50 mg uranium. There may be some overlap among the patients covered by the three scientific papers. This last paper referred to earlier studies (which were the experiments reported in Category 1.003, Number 119), and notes that these studies lacked some information: "autopsy data were not obtained since none of the subjects were terminal patients." (S.R. Bernard, Ibid., 288) Using terminal subjects thus provided the "advantage" that the distribution of uranium in the body could be determined after autopsy.

## *Category 10. Biological Effects of I-131*

### CATEGORY 10.001, NUMBER 69

*Study of changes in thyroids irradiated with radioactive iodine*

This project, begun in 1951, is a retrospective study of the health of humans exposed to I-131, chiefly for medical reasons. The study has been carried out at Case Western Reserve University, and has been funded sequentially by the Atomic Energy Commission, the Energy Research and Development Administration, and the Department of Energy. This is not considered an experiment, but the project shows clearly the necessity and usefulness of long term medical follow up of irradiated populations.

The significant non-patient population in this study is the group of Marshallese Islanders who were exposed to radioactive iodine from atomic bomb test fallout. The findings on this population were described in TID-27160, a June 1976 Progress Report to the Energy Research and Development Administration. The report noted the long latency period for the onset of clinical effects, and commented on the likely relation between exposure and thyroid nodules:

> The lengthy interval in man is clearly shown in the Marshallese where in spite of thorough annual physical examinations the first palpable nodule was not found for 9 years and neoplasms are still appearing at 22 years. (p. 4)
>
> To date 6 carcinomas have been removed from 10 individuals from several atolls, 3 from an atoll with extremely low exposure. Since this is a population which seldom if ever develops thyroid nodules, the relationship to the radiation which was primarily radioiodine is most impressive. (p. 4)
>
> At the time of the last annual report we described a 21 year old Marshallese who we had just operated for multiple benign adenomas. He was 6 months in utero when his mother was exposed to fallout. The special studies of that thyroid tissue showed

the bizarre nuclear forms recognized as evidence of radiation effect. At the time of preparation of this report, we have just operated and removed several benign but atypical adenomas from the thyroid of his mother who had developed masses in the last year. (p. 5)

The factor of long delay in the development of neoplasms is emphasized in both animals and men . . . . The first Marshallese lesion did not develop for 9 years. Many of the early lesions came from the atoll with the highest fallout (Rongelap). It was quite some years later that lesions began appearing in people who were on the next nearest atoll (Alingnae) where the dose had been somewhat less. While lesions were appearing on the nearer atolls, the low dose received on an atoll much further away (Uterik) seemed to have produced no lesions, but in the most recent years, 8 individuals have been operated and 3 carcinomas found. These observations seem to emphasize the risk of the low dose range. (p. 5).

Nine years after the 1954 thermonuclear bomb accident, the first thyroid neoplasm appeared. (p. 6).

CATEGORY 10.001, NUMBER 165

*Milk containing I-131 fed to humans*

In 1962, five human subjects drank milk containing radioactive Iodine-131, for periods of time ranging from 1 to 63 days. In the first experiments all subjects drank daily doses of I-131 milk for periods from 4 to 63 days. Doses each day were 150 or 1840 picocuries. The largest dose was 1840 picocuries per day for 63 days, for a total of 115,920 picocuries. In a second experiment, two of the same subjects drank singie doses of 92,000 picocuries each. These experiments were funded by the Atomic Energy Commission and carried out by Oak Ridge National Laboratory.

The objective of the experiment was to validate calculations which standard setting organizations were using to establish occupational radiation exposure limits. Subjects drank the milk, radioactive iodine uptake was measured by counting the area around the thyroid, and excretion of iodine was also measured. Cows milk containing radioactive iodine was obtained from an AEC Agricultural Research Laboratory. The Department of Energy reported that no follow up of subjects was conducted. These experiments were reported in a scientific paper, S.R. Bernard et al., Health Physics 9, 1307-1323, 1963.

CATEGORY 10.001, NUMBER 173

*Planned radioiodine exposures to humans*

From May 1963 to November 1965, radioactive iodine was released intentionally on seven separate occasions. On three occasions, human subjects were exposed. The experiments were funded by the Atomic Energy Commission and were conducted at the National Reactor Testing Station in Idaho.

The experiments were designed to improve knowledge of the transport of radioactive iodine, which is produced by nuclear reactors and nuclear bomb tests, through the air-vegetation-cow-milk sequence in the human food chain. This information was considered desirable in developing reactor siting criteria, in the preparation of safety analysis reports, and as an aid to planning for emergency action after a radiation accident.

Seven separate experiments were conducted. The general design was that radioactive iodine was released in gaseous form, and prevailing winds took the iodine over an area designated the "hot pas-

ture." Monitoring devices in the pasture determined the radioactivity deposited. A herd of cows was then led to the pasture to graze for several days. The cows were milked and the milk monitored for radioiodine. Humans were exposed either by drinking the milk or by direct exposure to the released iodine gas. The experiments collectively were called the Controlled Environmental Radioiodine Tests (CERT).

During Experiment CERT-1, conducted in May 1963, one curie of radioactive iodine was released into the hot pasture. Six cows were placed on the contaminated pasture. Cows were milked twice a day, and the milk from one cow saved for human ingestion. Seven human subjects each drank 0.5 liter of radioactive milk over a period of 18 days. Radioactive iodine uptake was determined by counting the thyroid of each subject. (IDO-12035, Controlled Environmental Radioiodine Tests at the National Reactor Testing Station, U.S. Atomic Energy Commission, June 1964).

Experiment CERT-2 was conducted in September 1964. Approximately one curie of radioactive iodine was again released over the hot pasture. Milk samples were again tested, but were not consumed by humans. Instead, three human subjects were placed on the pasture during iodine relase, and their thyroids counted after exposure. This was not a food chain experiment, but was designed to measure the direct iodine dose from inhalation.

During Experiment CERT-3, conducted in December 1964, and CERT-4 and -5, both conducted in June 1965, no cows or humans were exposed, and measurements were only made on the pasture. Amounts of iodine released were lower than in previous tests. CERT-4 released 0.01 curie; CERT-5 0.1 curie; and the amount released in CERT-3 was not specified. (IDO-12047, Controlled Environmental Radioiodine Tests at the National Reactor Testing Station, 1965 Progress Report, U.S. Atomic Energy Commission, February 1966)

During Experiment CERT-6, conducted in summer 1965, radioactive iodine in the methyl iodide form was released. As the experiment progress report states:

> Unfortunately, several of the vials, each containing 2 curies of methyl iodide-131, were accidentally broken in transit or were leaking when received. Those that were not broken were subsequently opened in the hot cell of the Idaho Chemical Processing Plant (ICPP) and the methyl iodide (2 to 6 curies) escaped to the atmosphere from a 75-meter stack. The stack was located 4 kilometers upwind of the test grid at the Experimental Dairy Farm (EDF). (IDO-12053, Controlled Environmental Radioiodine Tests, Progress Report Number Two, U.S. Atomic Energy Commission, August 1966, p. 2).

Six cows grazed over the 27 acre area of the EDF, and iodine concentration in their milk was determined by counting. In addition, "Several individuals were inadvertently exposed to airborne radioiodine from the leaking and broken containers, and efforts were made to obtain data on the retention of this form of iodine in humans." (Ibid., p. 2) These exposures from ruptured vials occurred over a four-day period, and a few people received multiple exposures; thyroids of these individuals were counted.

Experiment CERT-7 was conducted in November 1965; 1 curie of I-131 in the gaseous molecular form was released over the pasture at the EDF. Six cows grazed, and milk samples were counted. In

addition, seven human volunteers were placed seated on the exposure area. Uptake of radioactive material was determined by counting the subjects' thyroids.

The Department of Energy reported to the Subcommittee that no medical follow up of the experimental subjects in the CERT tests was performed.

## *Category 11. Other Biological Effects*

### CATEGORY 11.001, NUMBER 51

*Reactions of human skin to beta rays*

During April and May 1945, two groups of 10 human subjects were exposed to plastic disks containing Phosphorus-32, which emits beta rays. These disks were placed directly on the skin to expose subjects. In one set of experiments, 10 persons were exposed to 140 to 250 rep (roentgen equivalent physical); in a second set of experiments, 10 subjects received a series of four exposures each in doses varying from 635 to 1180 rep. In most instances the forearm was the point of exposure, except for three cases in the second series where the inner mid-thigh was exposed. These experiments were funded by the Manhattan Project and were carried out in Clinton Laboratory, Oak Ridge, Tennessee. (One roentgen equivalent physical of beta rays is approximately one rem. For comparison, present occupational exposure limits are 30 rem per year to the skin, and 75 rem per year to hands and forearms.)

The objective of this experiment was to determine the beta ray dose at which skin erythema (reddening of the skin) would first be seen. In the first set of experiments, 8 of 10 subjects showed a "visible reaction" of mild tanning at a dose of 250 rep. In the second set of experiments, 6 subjects showed erythema at 635 rep, and 8 showed erythema at 813 rep. These experiments were reported in J.E. Wirth and J.R. Raper, Chapter 12, Biological Effects of External Beta Radiation, National Nuclear Energy Series, Volume IV-22E, McGraw-Hill, 1951.

The Department of Energy reported no follow up on these subjects.

### CATEGORY 11.001, NUMBER 53

*Studies of radium applied to human skin*

During 1955, experiments carried out on human subjects demonstrated that the biological effects of Thorium X (Radium-224), as judged by erythema and skin pigmentation, can be increased by using an electrical current to cause greater penetration of the skin by radioactive material. These experiments were carried out at New York University and were funded by the Atomic Energy Commission.

Three subjects were exposed in these experiments. During the experiment, squares of blotting paper saturated with Radium-224 were placed on the forearms of each subject. An electric current was applied for 20 minutes to the paper on the left forearm, and no current was applied to the right forearm. For each patient, the left forearm showed intense reddening after 48 hours, and some skin

pigmentation at 75 days after exposure; the right forearms showed no visible reactions at the same times. The Department of Energy estimated that doses to the right forearm were 350 rem, and 1000 rem to the left forearms. Irradiated tissues were surgically removed, and no medical follow up on subjects was conducted. For comparison with the doses, present occupational exposure limits are 75 rem per year to the hands and forearms. These experiments were reported in AECU-3061, Atomic Energy Commission, a publication presented at the Sixteenth Annual Meeting of the Society for Investigative Dermatology, 1955. This publication discusses the application of Thorium X to certain skin diseases, but there is no indication that any of the subjects received medical benefit from the experiment.

CATEGORY 11.001, NUMBER 83

*Analysis of illness of children receiving fetal irradiation*

In 1948, a program of routine pelvis examination by x-ray early in pregnancy for 1008 mothers who were to bear their first child was carried out at Chicago Lying-In Hospital. The objective of the exposures was to make delivery and labor more predictable and easier by measuring the sizes of pelvis and fetal head. In preceding and succeeding years, no such measurements were made and these groups serve as a control population. The estimated tissue dose to the pelvis for irradiated mothers was 1.5 to 3 rem. About half of these children were also exposed to 5 x-ray films during the first day of life. The estimated dose to new-born infants was 0.5 rem.

The Atomic Energy Commission subsequently funded the Argonne Cancer Research Hospital to conduct analyses of health of the exposed children. Between 1962 and 1965 the parents of these children were contacted and asked for information on diseases and hospitalization. The first study found an increase in benign hemangiomas, a tumor which produces skin discoloration, but no increase in congenital malformations, eye diseases, or malignant tumors. A second survey made between 1966 and 1970 confirmed the results of the first follow up. The Department of Energy commented in 1985 that, "It is hoped that further data will be obtained from these subjects and if possible from their children."

CATEGORY 11.001, NUMBER 112

*Human absorption of tritium oxide through skin*

During 1951, 14 human subjects were exposed over a small area (about 10 square centimeters) on the forearm (12 subjects) or abdomen (2 subjects) to a water-vapor atmosphere labeled with tritium oxide (HTO). A single subject was in addition exposed over his total skin area while breathing uncontaminated air. Absorption of tritium oxide was estimated by measurments of tritium excreted in urine. The data from these experiments indicated that humans absorbed tritium at a rate 4 times faster than measured for rats. These studies were funded by the Atomic Energy Commission and were conducted by the General Electric Company, Richland, Washington

The objective of these experiments was to determine the rate of absorption of tritium oxide through human skin. This information would assist in evaluating the hazard to individuals who might handle tritium, which had promise of becoming a widely used tracer isotope for hydrogen. The Department of Energy reported that no medical follow up was carried out on these subjects. These experiments were reported in C.W. DeLong et al., Am. J. Roentgenol. Radium Therapy Nucl. Med. 71, 1038-1045, 1954.

CATEGORY 11.001, NUMBER 121

*Effects of x-rays on human fingers*

During 1947, fifteen subjects were exposed in the nail fold area of the left fourth finger to doses of 200 to 600 roentgen. (For comparison, present occupational exposure limits are 75 roentgen per year to the hands.) Fourteen of these subjects were patients being treated by x-rays or radium for other purposes, but none of them had received previous irradiation to the hands. The other subject was a staff member who occasionally prepared radium material for treatments. He was observed before and after the preparation of an item containing 130 milligrams of radium. These experiments were funded by the Atomic Energy Commission and were conducted at the University of Chicago.

The objective of the experiment was to examine the changes which may occur in the fingers of persons occupationally exposed to radiation. The left fourth finger was chosen for irradiation because the skin is fairly thin as compared to other fingers, and this finger is "less likely to have been subjected to previous trauma." Microscopic observations were made of the fingers before and immediately after treatment, and for up to two weeks after treatment. Some irradiated patients showed temporary symptoms such as enlarged or broken blood vessels, or reddening of the skin. The report on the experiment noted no permanent changes to the skin of the finger, and concluded with the statement, "It is proposed that test doses be given at higher levels." (CH-3833, Effect of Single Dose X-Ray to the Nail Fold Area of Human Subjects, Preliminary Report, July 1947, p. 4) However, no further experiments were reported. The Department of Energy reported no medical follow up of the subjects.

CATEGORY 11.001, NUMBER 123

*Human absorption and excretion of tritium*

During 1950, human subjects were exposed to tritium in several different experiments. Subjects were exposed to tritium in air for two hours, and the increase in tritium in body fluids was followed over time. In a second experiment, the arm of a man was immersed up to the elbow in water containing tritium, and the tritium in body fluids was again followed. In a third experiment, a man drank tritium in 0.2 liters of water and absorption into the blood stream was followed. Amounts of tritium administered were up to 3 millicuries. (For comparison, the maximum permissible body burden for occupational exposure is 2 millicuries.) These experiments were

funded by the Atomic Energy Commission and carried out at Los Alamos Scientific Laboratory.

The objective of the experiment was to obtain information on the human absorption and excretion of tritium, to aid in the setting of occupational exposure limits. The exact number of subjects exposed in not clear, but it appears that one subject immersed an arm in tritiated water, one subject drank tritiated water, and seven subjects were exposed to air containing tritium. These experiments were summarized in AECU-937, The Absorption, Distribution, and Excretion of Tritium in Men and Animals, U.S. Atomic Energy Commission, November 1950. The Department of Energy reported no medical follow up of subjects.

CATEGORY 11.001, NUMBER 125

*Human absorption of tritium liquid and vapor*

During 1952, the lower arms of subjects were exposed for variable lengths of time to tritiated water vapor and tritium in liquid water. Tritium activity in subjects' urine was monitored. The Department of Energy provided no further details on this experiment, and reported no follow up of subjects.

CATEGORY 11.001, NUMBER 126

*Human absorption of tritium by lung*

During 1952, three subjects were exposed in five experiments to tritiated water vapor. Subjects breathed tritium-saturated oxygen for 4 to 5 minutes. The tritium retained in the body during the exposure was obtained by comparing the tritium inhaled with the tritium exhaled. Retention and excretion of tritium with time were monitored through blood and urine samples. This experiment was funded by the Atomic Energy Commission and carried out at Los Alamos Scientific Laboratory.

Subjects inhaled from 0.8 to 1.0 millicuries of tritium. This can be compared with the maximum permissible body burden of 2 millicuries.

The objective of the experiment was to obtain information on absorption and retention of tritium to aid in establishing occupational exposure standards. The experiment is reported in LA-1465, Lung Absorption of HTO by Man Upon Inspiration of HTO Water Vapor, Los Alamos Scientific Laboratory, June 1952. The Department of Energy reported no medical follow up of the subjects.

CATEGORY 11.001, NUMBER 127

*Human absorption of ingested tritium water*

During 1952, five experiments were conducted on three subjects in which the subjects drank water containing tritium. Retention of tritium in the body was examined by taking blood and urine samples over time and counting. The experiments were funded by the Atomic Energy Commission and were carried out at Los Alamos Scientific Laboratory.

The objective of the experiments was to obtain data that would assist in evaluating the hazard of ingested tritium. Two subjects

each drank 1.6 millicuries of tritium; the third subject drank 6.2 millicuries in three separate experiments. For comparison, the occupational body burden is 2 millicuries. The experiments are reported in LA-1464, The Absorption of Ingested Tritium Water and the Water Dilution Volume of Man, Los Alamos Scientific Laboratory, June 1952. The Department of Energy reported no follow up on the subjects.

CATEGORY 11.001, NUMBER 133

*Radiation exposure of aircrews in mushroom clouds*

The U.S. Air Force sent manned planes through radiation clouds ("mushrooms and stems") from atomic bomb tests to measure radiation doses in the clouds and to the crews. The detonations were part of Operation Redwing, a series of 17 nuclear tests in the multimegaton range, at Eniwetok and Bikini Atolls in the Pacific, from May-July 1956. The planes, five different B-57Bs, made 27 passes through clouds from six different nuclear explosions, at times from 20 to 78 minutes after detonation. 16 passes were earlier than 45 minutes and 7 were earlier than 30 minutes after detonation.

Maximum radiation doses in the cloud were 800 roentgens per hour. Total radiation doses to crew members were as high as 15 roentgens by film badge. (For comparison, the present maximum annual dose for workers is about 5 roentgen; one chest x-ray represents 0.02 to 0.04 roentgen.)

The objective of the project was to obtain radiation dose information, in the event that an "operational situation" required flights through such clouds. The information was to assist Air Force commands in planning to insure the "most-effective utilization, consistent with crew safety, of aircraft in cloud areas."

Earlier operations had been conducted where drone aircraft were sent through clouds to obtain dose information. The report also mentions manned penetrations made during Operation Teapot. These passes were made from 17 to 41 minutes after detonation. The report on Redwing deletes information on doses measured during the Teapot flights, and gives no reference to any other published report on Teapot. The Redwing flights are described in ITR-1320, Preliminary Report, Operation Redwing: Early Cloud Penetrations, Armed Forces Special Weapons Project, May-July 1956.

On November 13, 1985, the Subcommittee chairman released this document to make it available for a hearing before the Senate Veterans Affairs Committee the following day on compensation for veterans exposed to atomic tests. The document was described in subsequent press accounts.

The Department of Energy reported no medical follow up on the exposed aircrews. However, subsequent correspondence between the Subcommittee and the Defense Department provided more information. The Defense Nuclear Agency (DNA) reported that seven of the Redwing crew members received doses greater than five rem by film badge, and were notified by the Nuclear Test Personnel Review (NTPR), a program to identify veterans exposed during atomic testing. Under this program, persons with exposures greater than five rem per year are notified and encouraged to undergo a special physical examination at the nearest Veterans Administra-

tion hospital. None of these seven have reported medical problems attributable to radiation exposure.

In addition, the Redwing aircraft were contaminated with radioactive material as a result of flying through the clouds. The planes were subsequently decontaminated by ground personnel. The DNA retains the exposure records of these personnel, as well as those of all aircrew members, and all these personnel are recorded as part of the NTPR. The DNA maintains a toll free number which veterans who believe they were exposed to atomic tests can call to report their circumstances. (Letter from Lieutenant General John L. Pickitt, Director, Defense Nuclear Agency, to the Subcommittee Chairman, December 11, 1985.)

In December 1985, Chairman Markey joined with Senator Cranston to request a General Accounting Office investigation on atomic cloud fly-through operations. GAO was asked to determine how many air crew members and how many ground presonnel were exposed during Redwing and other such operations, what doses these personnel received, and what follow up the Defense Department has conducted on all personnel.

CATEGORY 11.001, NUMBER 134

*Radioactive material placed on human skin*

In 1953, Foster D. Snell, a consulting firm, placed synthetic radioactive soil on the palms of over one hundred human subjects, and examined the ability of different cleaning agents to remove the radioactive material. The objective of this experiment was to determine the efficiency of various cleaning agents in removing radioactive contaminants from "human skin and hair."

These experiments were performed for the Chemical and Radiological Laboratories of the Department of the Army, and were reported in a U.S. Atomic Energy Commission technical publication, Removal of Radioactive Contaminants from Human Skin, NP-4935, June 15, 1953. It appears that at least part of the reason for conducting the experiments was to provide information that could be used on a battlefield during a nuclear exchange, since there is a reference to decontamination "from the point of view of the soldier in the field." (NP-4935, pp. 165,166)

For the experiments, a drop of a liquid mixture of radioactive material was deposited on the palms or arms of human subjects, allowed to dry, and counted with a Geiger counter. The contamination was then washed off with various cleaning agents, and the skin counted again to determine efficiency of removal. Initial experiments were conducted on metallic surfaces, then on rabbits and pigs. Preliminary work was also done on hair removed from humans, and then on 16 human subjects. Most of this work was done with a suspension of "synthetic soil," a mixture composed chiefly of soil, sand, and clay, mixed with fission products. Some experiments were performed with synthetic soil which had been irradiated in a nuclear reactor, synthetic soil mixed with Carbon-14, or a sample of soil from the Nevada test site. These other mixtures did not adhere well to skin, and were not used in later experiments. In these first human experiments, solutions registering up to 2,900 counts per minute were placed on subjects' forearms or

palms. These experiments showed that it was most difficult to wash radioactivity from palms, and most subsequent experiments placed the radioactive material on palms only.

Subsequent experiments were conducted on about 102 different human subjects, placing larger amounts of radioactivity, typically 10,000 to 20,000 counts per minute, on subjects' palms. A variety of detergents and hand creams were examined for their ability to remove the radioactive contamination. One set of experiments was conducted with "radiological warfare agents," composed of small pellets of zinc bromide which contained radioactive Tantalum. Droplets containing 13,000 to 49,000 counts per minute of these agents were placed on the palms of six human subjects.

One set of experiments was conducted with employees at the Monsanto Chemical Company's Mound Laboratory, Miamisburg, Ohio. A mixture of contaminants containing alpha emitters, and not further identified, was placed on the palms of four employees and detergents tested for removal. In addition, detergents were tested on the hands of three other employees "whose hands were contaminated in the normal course of work." (NP-4935, p. 152).

Except for the experiments at Mound Laboratory, the Department of Energy has not been able to identify where these experiments were conducted or how the 118 human subjects were obtained. Subjects were male and female, and ranged in age from 18 to 66. The Department of Energy reported no medical follow up on any of these subjects.

**CATEGORY 11.001, NUMBER 183**

*Medical follow up studies*

In its factsheet on this project, the Department of Energy described follow up studies to assess the long range health of several different populations which have been exposed to radiation. These studies have been funded by the Atomic Energy Commission, the Energy Research and Development Administration, and the Department of Energy. Some of them started in the 1950s, and they continue at present. The studies are being carried out at the Argonne Cancer Research Hospital (ACHR), Argonne National Laboratory. The studies are described below:

1. For 20 years, a joint study of more than 400 persons bearing a considerable body burden of radium has been under way. Most of these persons were painters of the radium dials on luminous watches at various plants in the Illinois River valley region during 1920-1930; others received radium chloride by injection or orally as a medical treatment between 1920 and 1933. Persons with a considerable body burden of radium were found to have characteristic defects, destructive changes, and tumors in the skeleton. These studies include accurate estimates of the body content of radium by using a total body counter; through analysis of the expired breath for the gas radon, a radium decay product; by film exposure from subjects' bodies; and through studies of the blood to reveal if destructive or malignant changes have taken place.

2. A long term follow up study is under way to examine about 1000 children who were exposed before birth to x-rays during pelvic

examinations of their mothers. This study, which extended over about 25 years, is described as Category 11.001, Number 83.

3. A follow up study is under way on patients who had received radiation therapy for stomach ulcers. This study was funded by the Department of Energy, and revealed "some positive findings," which are not further specified. The study is now to be resumed under support from the National Institutes of Health.

4. During the 1950s, persons who received short treatments with low-voltage x-rays for benign conditions of the head, neck, and upper thorax during childhood were studied for possible development of carcinoma of the thyroid. All of the children with cancer of the thyroid who had been treated or seen by the investigator had been irradiated previously in such a way that the thyroid gland or portions of it had been included in the radiation field.

CATEGORY 11.001, NUMBER 186, PART A

*Human ingestion of fallout*

Concern about problems from the ingestion of fallout led to studies using real fallout from the Nevada Test Site; simulated fallout particles that contained Strontium-85, Barium-133, or Cesium-134; and solutions of Sr-85 and Cs-134. During 1961 to 1963, real and simulated fallout and solutions of strontium and cesium were fed to 102 human subjects. Absorption and retention of the ingested radioactivity was measured by counting the bodies of subjects. These experiments were funded by the Atomic Energy Commission and were carried out by the University of Chicago and the Argonne National Laboratory. Subjects were university students or members of the researchers' staffs.

Several different fallout or simulated fallout materials were prepared. One set of experiments used microscopic spheres of radioactive strontium, cesium, or barium. A total of 27 volunteers ingested the spheres. Transit time of the spheres through the gastrointestinal tract was measured by counting excreted matter. A second set of experiments used real fallout, obtained from the Nevada Test Site following land detonation of the nuclear test Small Boy, on July 14, 1962. Fallout samples were placed in gelatin capsules and were fed to 10 subjects. In these and subsequent experiments, retention of activity was followed by counting subjects' bodies.

Two types of simulated fallout were also prepared. They were distinguished by the size of microscopic spheres used, which simulated the size of fallout particles close to or far from the site of detonation. 21 subjects were fed simulated local fallout, and 22 simulated distant fallout. Finally, 22 subjects were fed solutions of strontium or cesium. The amounts of radioactive material fed to subjects in all experiments ranged from 0.4 to 2.5 microcuries of Strontium-85, or 0.5 to 14 microcuries of Cesium-134. These values can be compared with the maximum permissible occupational body burdens of 60 microcuries for Strontium-85, and 30 microcuries for Cesium-134.

The Department of Energy reported no long term medical follow up on these subjects. These experiments were reported in a scientific paper, G.V. LeRoy et al., Health Physics 12, 449-473, 1966.

CATEGORY 11.001, NUMBER 186, PART B

*Lanthanum-140 administered to humans*

The paper cited in Number 186, Part A, G.V. LeRoy et al., reported an earlier study in which 54 hospital patients were fed radioactive Lanthanum-140, and the passage of material through the gastrointestinal tract was measured by counting excreted matter. It appears that the Department of Energy did not report to the Subcommittee on this experiment, but it was published in R.L. Hayes et al., Health Physics 9, 915-920, 1963, and the Subcommittee obtained a copy of the original reference from the Library of Congress, Congressional Research Service. This experiment was carried out at the Oak Ridge Institute of Nuclear Studies, and was funded by the Atomic Energy Commission.

The objective of this experiment was to measure the movement of radioactive material through the human body, and estimate the dose to the lower large intestine from materials that the body does not absorb. The experimenters noted that movement through the body varied with individuals, and these experiments attempted to measure the extent of such variation.

Subjects were fed 10 or 20 microcuries of Lanthanum-140. (For comparison, the maximum permissible body burden for occupational exposure is 10 microcuries.) Movement of this substance through the body was examined by collecting fecal samples and counting. Subjects were patients from the clinical program at the Oak Ridge Institute, and ranged in age from 7 to 76. All subjects were selected because they had normal intestinal tracts, which were not affected by their diseases. Subjects thus received no medical benefit from the experiment. To measure variability in individuals, 8 subjects were fed lanthanum twice, and one was fed three times.

*Category 12. Metabolic and Physiological Studies*

CATEGORY 12.001, NUMBER 15

*Strontium and calcium injected in terminal cancer patients*

The material which the Department of Energy submitted to the Subcommittee on this project included ANL-6104, a 1959 report from the Argonne National Laboratory. This report summarized data on the retention by humans of calcium, strontium, and radium. One of the references cited was Schulert et al., Int. J. Applied Radiation and Isotopes 4, 144-153, 1959. The Department of Energy did not supply this reference, but the Subcommittee obtained a copy of the original through the Library of Congress, Congressional Research Service.

In these particular experiments, radioactive Calcium-45 or Strontium-85 were injected into twelve terminal cancer patients, and the distribution of each substance in tissue and bone was determined at autopsy. These experiments were carried out at Columbia University and the Montefiore Hospital, Bronx, New York.

The objective of these experiments was to measure the absorption by different parts of the body of strontium, a product of nuclear fission and a component of nuclear weapons fallout. In order to help evaluate the hazards of strontium to humans, the experiment-

ers desired to determine the retention by different tissues of strontium compared to calcium; strontium mimics calcium chemically and concentrates in bone. As the scientific paper explained, subjects were chosen so they could be autopsied fairly soon after injection: "Since autopsy analyses were employed, the patients were, of necessity, of limited life expectancy with cancer involvement, and cannot be considered as normal healthy adults." (Schulert et al., 145)

Ten patients were injected with about 1.5 microcurie per kilogram body weight of Strontium-85, and about 0.4 microcurie per kilogram of Calcium-45. Total doses would have been 64 to 114 microcuries of strontium, and 17 to 30 microcuries of calcium. For comparison, the occupational maximum permissible body burdens are 60 microcuries for Strontium-85, and 200 microcuries for Calcium-45. These patients lived from 3 hours to 124 days. An additional terminal patient injected with strontium only survived for 251 days, and one patient injected with calcium only survived for 960 days. Patients ranged in age from 49 to 72.

CATEGORY 12.001, NUMBER 109

*Technetium administered to humans*

During 1965, Technetium-95 (metastable) and -96 were administered to 8 subjects. Retention and absorption of technetium were monitored by counting the bodies of subjects and by counting excretions. Doses were administered to subjects at the University of Washington, counting was carried out by the Pacific Northwest Laboratory, Richland, Washington. The Atomic Energy Commission funded the work of the Pacific Northwest Laboratory.

Technetium is a product of nuclear fission and is present in rather high concentrations in wastes from nuclear reactors. At the time of these experiments, technetium was being separated from nuclear wastes at the federal facility near Richland, Washington. In addition, technetium was also used for medical diagnoses. The objective of these experiments was to obtain information on the retention of technetium in the body, to help assign occupational exposure limits.

Four subjects were injected, and four subjects were fed technetium. Each subject received 20 microcuries of Tc-95m and 60 microcuries of Tc-96. (For comparison, the occupational maximum permissible body burdens are 70 microcuries for Tc-95m and 10 microcuries for Tc-96.) Samples of sweat, plasma, tears, urine and feces were collected, and observations were made for up to 60 days on some subjects.

These experiments were reported in a scientific paper, T.M. Beasley et al., Health Physics 12, 1425–1435, 1966. The Department of Energy reported there was no long term follow up of these subjects.

CATEGORY 12.001, NUMBER 110

*Promethium administered to humans*

In 1967, Promethium-143 was administered to 14 subjects. Absorption and retention were followed by counting the bodies of subjects, and by measuring the activity in blood and excretion sam-

ples. 6 subjects were injected with promethium and observed for retention. 2 subjects drank orange juice with promethium in solution. 6 subjects were injected with promethium and then injected with the chelating agent diethylenetriaminepentaacetate (DTPA), and the ability of DTPA to remove promethium from the body was examined. These experiments were funded by the Atomic Energy Commission and were carried out by the Hanford Environmental Health Foundation and the Battelle Memorial Institute, both at Richland, Washington.

The experiments were conducted to determine the uptake, retention, distribution, and excretion of promethium in humans. The information obtained would help to develop an excretion model for diagnosis of promethium in humans, to form a basis for radiation exposure, and to determine the dose from accidental exposures. These considerations were relevant to occupational exposure of persons handling promethium.

Injected subjects received 0.1 microcuries of promethium. Two subjects drank 10 microcuries of promethium. Administered preparations were mostly PN-143, but some Pm-144 was also present. Little promethium was retained by the two subjects who drank it. However, about half of the injected promethium deposited in the liver within a few minutes, and most of the remaining promethium deposited in the bone within the next 5 hours. Subjects were followed for one year, during which this distribution remained unchanged. The effectiveness of DTPA in enhancing excretion of promethium declined with time: When DTPA was injected 30 minutes after promethium, it removed 90 percent of the radioactive material; after 24 hours, it removed only 25 percent; and after 80 days, it removed only 5 percent.

These experiments were reported in a scientific paper, H.E. Palmer, I.C. Nelson, Health Physics 18, 53-61, 1970. The Department of Energy reported that no follow up was conducted beyond the one year observation after the experiment.

CATEGORY 12.001, NUMBER 111

*Phosphorus-32 injected into humans*

During 1963, five subjects were injected with Phosphorus-32. Three of the subjects were patients at the University of Oregon Medical School who received the P-32 as part of the therapy for blood diseases. The other two subjects were injected at the Swedish Hospital in Seattle for purposes only of calibrating equipment. These experiments were funded by the Atomic Energy Commission and carried out by the Battelle Memorial Institute, Richland, Washington.

The reasons for carrying out these experiments were described in a scientific paper:

Fish and waterfowl that feed in the Columbia River downstream from the Hanford reactors acquire some radionuclides that enter the river with the effluent water (1). $^{32}P$ and $^{65}Zn$ are the principal nuclides found, and suckers and whitefish usually contain the greatest concentration of these nuclides. Since sportsmen obtain and eat the waterfowl and fish from the Columbia River below Hanford, a method of measuring the low level body burden of these nuclides in humans is needed. Since $^{65}Zn$ is a gamma emitter, body burdens down to 1 nc [nanocurie] can easily be measured in a whole-body counter. Foster (2) has described an experiment in which

a subject ate a weekly meal of whitefish and the accumulation of the 65-Zn in the body was studied. 32-P does not emit a gamma ray and it is much more difficult to measure. This paper describes a method by which body burdens of 32-P down to 40 nc can be measured. (H.E. Palmer, Health Physics 12, 605–608, 1966. References 1 and 2 are publications designated HW-80991, 1964; and HW-SA-3060, 1963. These are probably Atomic Energy Commission documents.)

One subject was injected with 425 nc of P-32. A second subject was injected with 500 nc, then reinjected after 28 days with 425 nc more. Injection doses for the other subjects were not reported. This same scientific paper reported another experiment where humans ate radioactive fish:

One reason for developing a sensitive, in vivo counter for 32-P was to measure people who eat Columbia River fish. The significance of this intake with relation to the maximum permissible body burden has been discussed in another publication. (1) Five subjects ate ¾ lb each of whitefish which had been caught in the Columbia River. After allowing 1 day for absorption of the 32-P, the subjects were measured for 20 min with the [radiation] counter and showed body burdens of 70, 110, 89, 72, and 93 nc . . . . The maximum permissible body burden for occupational exposure is 6000 nc.: (Ibid., 607. Reference 1 is HW-80991.)

The Department of Energy reported that no follow up was conducted on these experimental subjects.

CATEGORY 12.001, NUMBER 128

*Humans inhaled tritium*

During 1950, six subjects each inhaled "a few" millicuries of tritium. (For comparison, the maximum permissible occupational body burden for tritium is 2 millicuries.) Tritium concentration in urine was monitored for the following 15 days. These experiments were funded by the Atomic Energy Commission and were carried out at the Los Alamos Scientific Laboratory, New Mexico.

The objective of this experiment was to investigate the rate of appearance of tritium in urine. This knowledge would help in the establishment of occupational exposure limits. No follow up on these subjects was reported.

CATEGORY 12.003, NUMBER 174

*Radioactive material administered to humans to calibrate equipment*

Between 1965 and 1972, 8 individuals were involved in 13 different human experiments. All eight were employees of the Idaho Division of the Atomic Energy Commission. In four experiments, subjects inhaled Argon-41; in nine experiments, subjects swallowed capsules containing microcurie amounts of radioactivity. These experiments were funded and carried out by the Atomic Energy Commission.

The objective of this experiment was to calibrate instruments that measure radioactive substances inside the human body; such instruments are usually used to examine workers accidentally exposed or hospital patients receiving radioactive material for diagnostic purposes. A secondary objective of the experiments was to examine the metabolism of radionuclides ingested or inhaled by humans.

Some of these experiments were reported in scientific papers. In the first set of experiments, one subject was fed one microcurie of

Manganese-54; another subject was fed an unspecified amount of Iodine-131 (J.I. Anderson and D.G. Olson, Health Physics 13, 719–732, 1967). In a second set of experiments, individual subjects were fed 3.5 microcuries of Cesium-132, 1.9 microcuries of Potassium-42, or 1.1 microcuries of Manganese-54. In addition, 4 subjects inhaled Argon-41 in amounts of 1.3 to 2.2 microcuries (D.G. Olson, Health Physics 14, 439–447, 1968). In a third experiment, one subject was fed 1.5 microcuries each of Cobalt-60 and Cesium-137 (J.I. Anderson and D.G. Olson, Health Physics 23, 325–332, 1972).

The Department of Energy reported there was no medical follow up of any of these experimental subjects.

# APPENDIX

## Current Federal Regulations on the Protection of Human Subjects

Current regulations on the use of human subjects for experiments are described in Title 45, Code of Federal Regulations, Part 46 (45 CFR 46) revised as of October 1, 1985. These regulations call for special requirements when prisoners, children, or other specified categories of persons are used as subjects.

### GENERAL PROVISIONS

Experiments on human subjects must satisfy the following criteria:

(1) Risks to subjects should be minimized.

(2) Risks to subjects should be reasonable in relation to anticipated benefits, and the importance of the knowledge that may reasonably be expected to result.

(3) Subjects should be selected in an equitable manner.

(4) Informed consent shall be sought from each prospective subject or the subject's legally authorized representative. Informed consent includes a clear description of the risks and benefits of the experimental procedure. (45 CFR 46.111).

### PRISONERS

Biomedical or behavioral research may involve prisoners as subjects only if the purpose of the proposed research is to:

(1) study the possible causes, effects, and processes of incarceration or of criminal behavior;

(2) study prisons as institutional structures or prisoners as incarcerated persons;

(3) conduct research on conditions particularly affecting prisoners as a class (for example, vaccine trials or other research on hepatitis, which is more prevalent among prisoners than the general population);

(4) examine practices, both accepted and experimental, which have the intent and reasonable probability of improving the health or well-being of the subject. (45 FR 46.306)

### CHILDREN

A child is an individual who has not attained the legal age for consent to treatments or procedures involved in the research, under the applicable laws of the location where the research is to be conducted (45 FR 46.402).

A child may be used as a subject only upon receipt of permission from parents and assent from the child, under conditions where the child is judged capable of providing assent (45 FR 46.408). If permission and assent are obtained, research can be conducted only if one of the following conditions is met:

(1) The research poses no greater than minimal risk (45 FR 46.404).

(2) The research presents more than minimal risk, but the procedure holds out the prospect of direct benefit for the individual subject or is likely to contribute to the subject's well-being (45 FR 46.405).

(3) The research presents more than minimal risk, does not hold out the prospect of direct benefit to the subject, but the procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for understanding the disorder or condition (45 FR 46.406).

(4) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children (45 FR 46.407).

OTHER SUBJECTS

Where some or all of the human subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards must be included in the study to protect the rights and welfare of these subjects. (45 FR 46.111)

It should be noted that under these regulations, the experiments previously described with prisoners, and which used minors as subjects, would have been strictly prohibited. In addition, many other experiments used patients with severe illnesses or who were disadvantaged, and there is no indication that safeguards were incorporated into the experiments to protect these subjects.

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