

Wm. R. Bell - DoF
C. Luchins - ORA
H. Vadopich - OR Med Dir
K. Hübner - ORA / Rehab
J. Comar - VT mem. corp
Ann Tipton - ORA

Witnesses
DAR Ridge
before the

Investigation of Orery
Subcommittee on

(Mother Jones Hearing)
Washington, D.C.
Sept 23, 1981

707565

FILE
ORIGINALS

REPOSITORY DAR Ridge Ops. (ORO)
COLLECTION Public Information, M-4
BOX No. Active Records Gathered from Human
Radiation Exp. R.F.
FOLDER

1022120

Statement By

William R. Bibb, Director

Research Division

Oak Ridge Operations Office

U. S. Department of Energy

before the

Subcommittee on Investigations and Oversight

Committee on Science and Technology

U. S. House of Representatives

September 23, 1981

1022121

Mr. Chairman and members of the Committee: My name is William Bibb. I am Director of the Research Division at the Department of Energy's Oak Ridge Operations Office. From 1965 until 1970, I was a member of the Medical Research Branch, Division of Biology and Medicine of the Atomic Energy Commission in Germantown, Maryland.

As a member of the Medical Research Branch, I was the technical representative responsible for monitoring the AEC funded research at the ORINS/ORAU Medical Division. My supervisor was Dr. William Burr, Jr.

The various operations of the Atomic Energy Commission involved the production and handling of large amounts of radioactivity. Associated with these operations was potential and actual exposures of the workforce to radiation. In recognition of the potential hazards of such exposures, the Atomic Energy Commission and its predecessor, the Manhattan Engineering District, had, from the beginning, conducted research programs designed to enhance basic understanding of the nature of these exposures and of the associated biological risk.

The Biomedical Research Program of the AEC was conducted through the Division of Biology and Medicine. The general objectives of the program were:

1022122:

Mr. Chairman and members of the Committee: My name is William Bibb. I am Director of the Research Division at the Department of Energy's Oak Ridge Operations Office. From 1965 until 1970, I was a member of the Medical Research Branch, Division of Biology and Medicine of the Atomic Energy Commission in Germantown, Maryland.

As a member of the Medical Research Branch, I was the technical representative responsible for monitoring the AEC funded research at the ORINS/ORAU Medical Division. My supervisor was Dr. William Burr, Jr.

The various operations of the Atomic Energy Commission involved the production and handling of large amounts of radioactivity. Associated with these operations was potential and actual exposures of the workforce to radiation. In recognition of the potential hazards of such exposures, the Atomic Energy Commission and its predecessor, the Manhattan Engineering District, had, from the beginning, conducted research programs designed to enhance basic understanding of the nature of these exposures and of the associated biological risk.

The Biomedical Research Program of the AEC was conducted through the Division of Biology and Medicine. The general objectives of the program were:

1022123

1. Increased knowledge of the biological effects of radiation in order to provide basic information to those concerned with developing radiation protection standards.
2. The development of increased information useful in the control of biological hazards of radiation, either through minimization of exposure or protection against biological effects.
3. Exploitation of nuclear radiations and of radioactive materials in studies of basic biological processes.
4. Improving and developing techniques for the use of radiations in medical diagnosis and therapy.

The research was carried out largely at the Commission's government-owned contractor-operated (GOCO) laboratories and facilities and by contract with universities, hospitals and other institutions. Research conducted at the GOCO facilities was technically monitored by the AEC staff in Washington, D. C. The various contractors submitted scientific proposals for research to AEC and, if approved and funded, the work was conducted by the proposing contractor. The contracts were management-type contracts whereby the AEC staff technically monitored the performance of approved work but was not involved in supervising the work which was carried out by contractor employees.

1022124

Shortly after the AEC was created in 1947, the Advisory Committee on Biology and Medicine was formed by the Commission to advise them on organizing the Division of Biology and Medicine. The Advisory Committee subsequently reviewed periodically the biomedical program of AEC and reported to the Commission on the quality of these research projects. As the new Division's initial major program, the Advisory Committee recommended establishing at each national laboratory a clinical research facility to take advantage of the unique radioactive material in diagnosing and treating cancer. The primary facility was to be the Argonne Cancer Research Hospital as an adjunct to the School of Medicine of the University of Chicago, with smaller hospitals at Oak Ridge and Brookhaven National Laboratory. Early in 1948, the AEC moved to implement the Committee's recommendation.

The AEC already had a contract with the Oak Ridge Institute of Nuclear Studies (ORINS), a nonprofit, educational corporation whose membership was composed of universities and colleges in the Southern Region*. Under the existing contract, ORINS was training scientific personnel from institutions throughout the country in the use of radioisotopes and was arranging for graduate students and university faculty members to come to Oak Ridge to participate in research programs.

1022125

*ORINS Member Institutions - 1948

University of Alabama

University of Arkansas

Auburn University

Catholic University of America

Duke University

Emory University

University of Florida

University of Georgia

Georgia Institute of Technology

University of Kentucky

Louisiana State University

University of Mississippi

University of North Carolina

University of Tennessee

University of Texas at Austin

Tulane University

Vanderbilt University

University of Virginia

1022126

In February 1948, the Division of Biology and Medicine asked ORINS to consider establishing and operating an Oak Ridge clinical research facility. In March 1948, ORINS convened a meeting of representatives of each Southern Medical School to determine the feasibility of establishing such a clinical research facility in Oak Ridge for the study of neoplastic diseases using the exceptional research tools available there. At the end of the conference, a recommendation was made to AEC that ORINS proceed with the proposed clinical facility to be housed in an unused wing of the AEC-owned and contract-operated community hospital. Following approval of the ORINS proposed operating plan by AEC, construction of a laboratory building and renovation of the adjacent existing hospital wing was begun. ORINS appointed Dr. Marshall H. Brucer as Chairman of the Medical Division. In May 1950, the first patient was admitted to the Medical Division. The floor plan of the original clinical facility operated by ORINS is shown in Figure 1. For reference purposes, the location of the AEC community hospital is also shown.

During the early fifties, the ORINS Medical Division developed methods of synthesizing radiolabelled compounds and preparing them for clinical trials. Early attempts at radioisotope therapy were largely unsuccessful. At the same time that internally administered therapeutic radioisotopes were being studied, ORINS was also conducting an active program to develop external radioisotope sources to be used in place of x-rays to produce an

1022127

external beam that could be directed into the body as a treatment of cancer. By late 1951, an efficient cobalt-60 teletherapy machine had been designed and placed in a specially built room at ORINS. After testing, it was moved to M. D. Anderson Hospital in Houston for clinical trials. Early in 1952, the ORINS Medical Division began a teletherapy evaluation program to determine which of several potentially useful radioisotopes would prove most useful in teletherapy. Cobalt-60 became the most widely used teletherapy source and before long this form of therapy was common all over the world.

During this period, radioiodine-131 had become available from Oak Ridge National Laboratory and, as a result, numerous clinics throughout the United States were using it for the diagnosis and treatment of thyroid cancer. Unfortunately, there was no uniformity in methods used to measure the administered dose or the amount of radioisotope localized in the thyroid gland. In 1954, ORINS initiated a radioiodine uptake calibration program. Several fashion store mannequins were purchased and artificial thyroid glands with accurately known levels of mock iodine were placed in their necks. These calibration kits were sent from one laboratory to another around the country where each clinician used his own instruments to measure the thyroid dose and uptake of the mannequin. All results were reported to the Medical Division where they were compared with expected values. As anticipated, there were wide discrepancies from

1022128

FACILITIES 1940's—60's

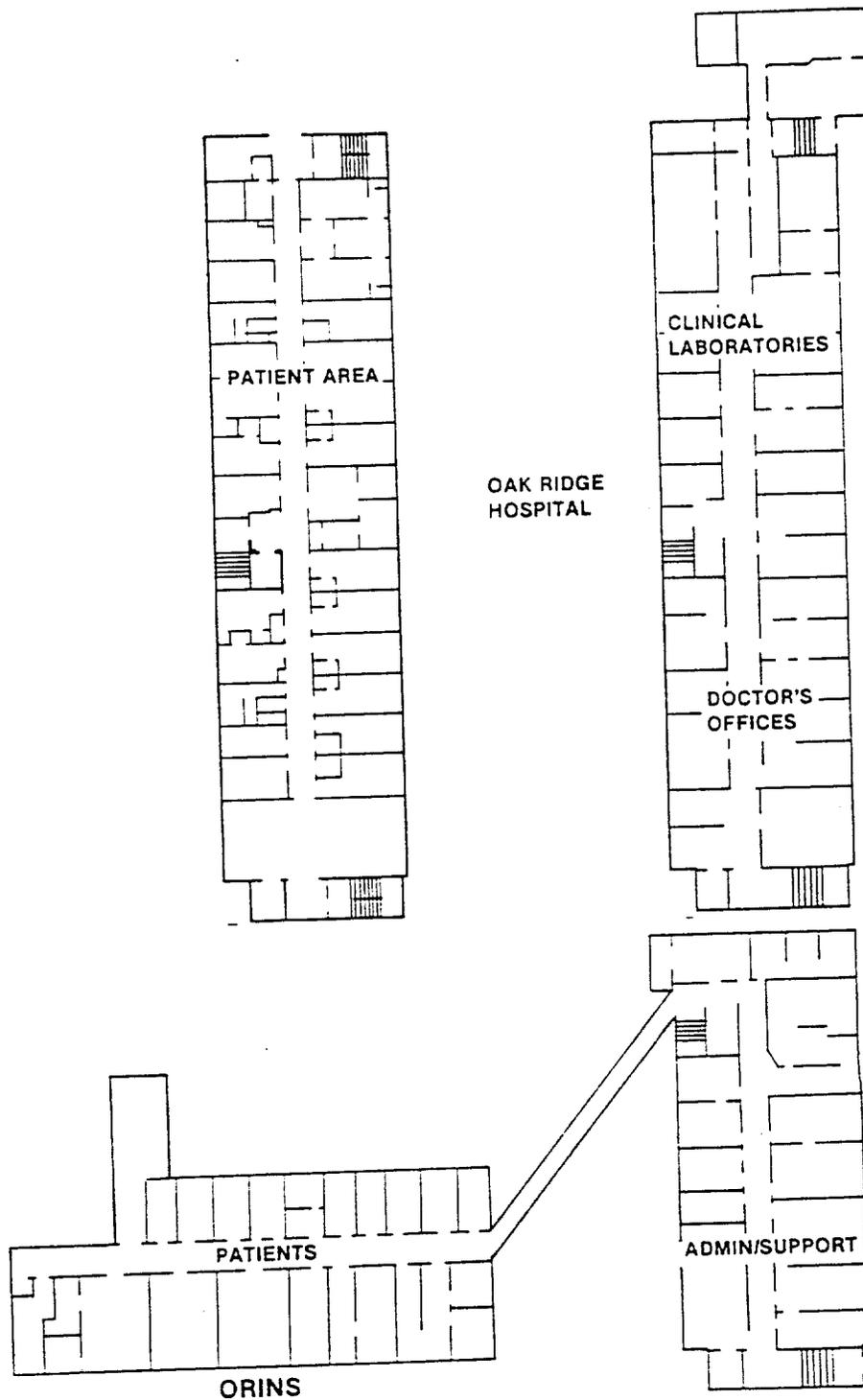


Figure 1

1022129

the standard in the results obtained. Through collaboration between Oak Ridge National Laboratory and ORINS a new instrument was designed which soon became widely available commercially and made radioiodine thyroid diagnosis and treatment a reliable and standard clinical procedure.

The Medical Division also devoted a major effort to human total body irradiation studies to improve the treatment for certain types of leukemia and lymphoma. Prior to 1960, the total body irradiation was given to the patients using a cobalt-60 teletherapy unit.

In June 1958, eight workers at the AEC Y-12 plant in Oak Ridge were involved in a radiation accident. Their doses ranged from 23 to 365 rads, with five of the men receiving more than 225 rads. All of the men were treated at the ORINS Medical Division and subsequently recovered uneventfully.

As a result of the Y-12 accident, it became clear that more information on the response of the human to radiation was needed. The film badges worn by the workers were unreliable indicators of actual exposure and a biological measure of exposure was needed to aid the clinician in handling such cases.

Dr. Gould Andrews who began his career at ORINS in 1949 as Chief of Hematology developed a special interest in the hematologic effects of radiation and studied the Y-12 men over the next 21 years. He also developed an acute interest in the hematologic response of patients exposed to total-body irradiation therapeutically to better learn how to predict and treat these effects in exposed workers. As a result of this knowledge, Dr. Andrews was usually called to consult at other institutions where accidents had occurred. The ORINS Medical Division was the designated hospital for handling any radiation accident at the AEC plants in Oak Ridge. In order to provide the best possible care in case of an accident the AEC expected that hematologic data from patients being treated with total body irradiation, in addition to being used to benefit other patients, would also be used to benefit any radiation accident victim.

In 1960, the new Oak Ridge hospital was completed and the patients moved out of the AEC community hospital. The old hospital was renovated and the ORINS Medical Division patients moved into this facility.

The teletherapy machines available in the late 1950's did not give uniform radiation fields such as one would prefer for total body radiation therapy. During irradiation treatment using teletherapy, the patient had to be moved

to try and provide for a fairly uniform exposure. To solve this problem, ORINS designed and constructed a new facility which was a concrete shielded room containing eight radiation sources and delivered a uniform dose to the patient. This facility, called Medium Exposure Total Body Irradiator (METBI), was completed in 1959 and began operation in 1960. In the METBI facility, patients would lay on a bed located in the center of the room during radiotherapy. Radiation sources were operated remotely and the patient was monitored visually by specially arranged mirrors at the control panel in an adjacent room. The patient was able to communicate with the technician during treatment by means of an intercom system.

Figure 2 is a schematic of the ORINS Medical Division in 1968 showing this renovation and includes the whole-body counter and METBI and LETBI facilities.

In 1960, an immunology program was started at ORINS to study the effects of radiation on immune responses and the immunology of bone marrow transplantation. In order to study the types of infections that occur in patients with bone marrow damage from radiation and chemotherapy, a research program in microbiology was also initiated in 1960.

FACILITIES IN 1968

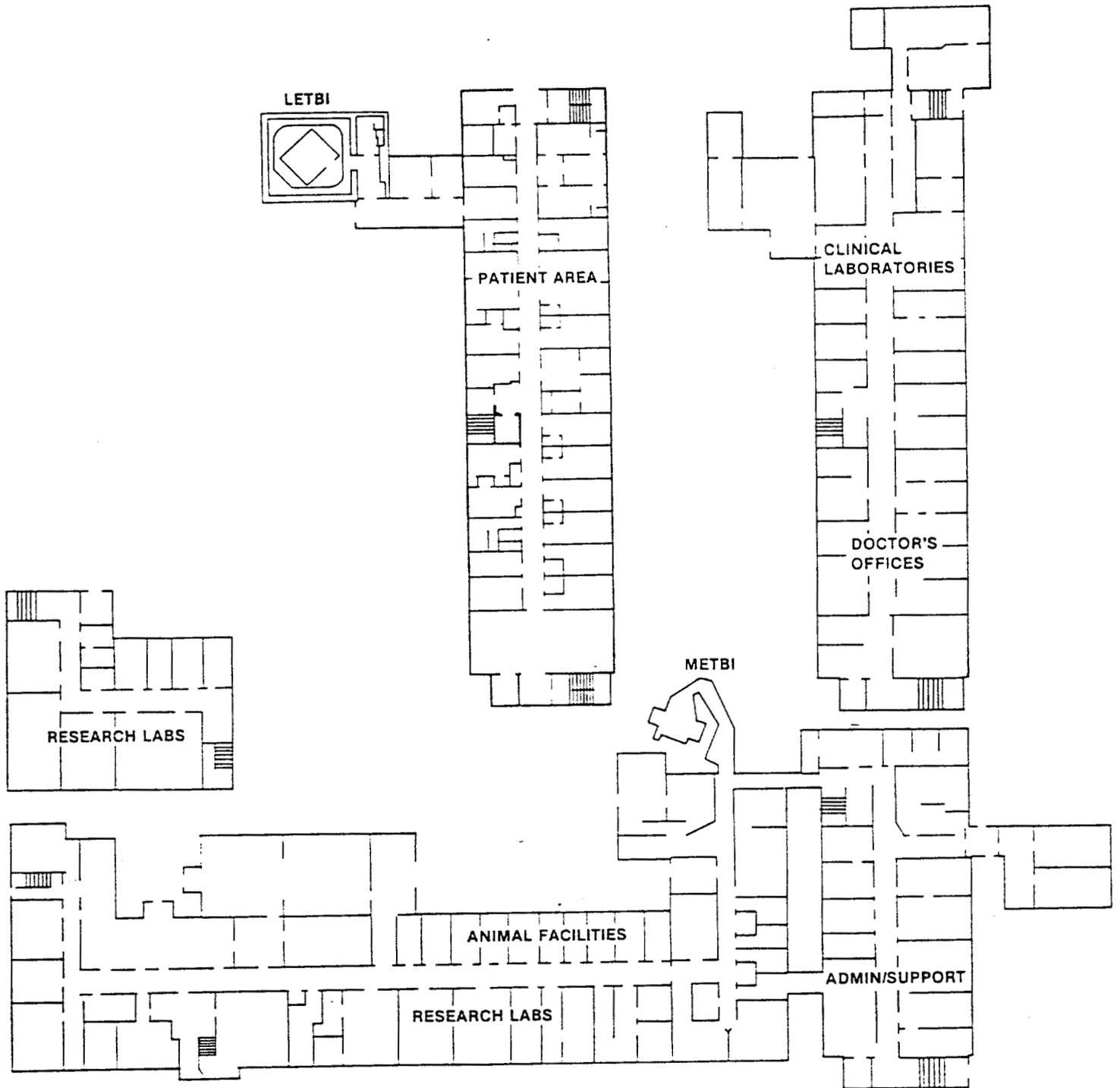


Figure 2

1022133

In late 1961, Dr. Brucer retired as Chairman of the ORINS Medical Division and the following year Dr. Gould Andrews was appointed as his successor.

As the Federal Agency responsible for developing the basic biological knowledge for use by other organizations and institutions in developing radiation protection standards it was normal for the National Aeronautics and Space Administration to approach AEC in 1963 for assistance in determining biological risks astronauts might encounter during space travel. Such data were needed by NASA in order to determine the amount of shielding required to protect the astronauts. It was agreed that AEC would be responsible for collecting radiobiological information from hospital records of patients who had received therapeutic whole-body irradiation and for analyzing the data for NASA. In return, NASA would reimburse AEC for costs incurred in conducting the study. Under the existing AEC-NASA interagency agreement, the project was assigned to ORINS Medical Division by AEC. Following a feasibility study in which medical records at ORINS were examined to determine if useful data could be obtained from patients' charts, the ORINS study was expanded to 45 hospitals and eventually included radiobiologic information from over 2,500 therapeutic exposures. The results of this initial study were made available to the National Academy of Sciences and were published in 1967 in "Radiobiological Factors in Manned Spaceflight".

As a result of animal studies on repair mechanisms, it was becoming obvious that radiation delivered at a slower rate had the potential for providing the same therapeutic benefit to the patient without causing the undesirable side effects observed at faster delivery rates. However, to get the same dose, the patient would need to be exposed for much longer periods of time. Such a facility to be known as the Low Exposure Total Body Irradiator (LETBI) to test this idea in a clinical environment was proposed by ORINS to AEC in 1965.

At the time LETBI was first proposed to AEC, ORINS suggested that in addition to the clinical studies for AEC, subsequent analysis of the stored data might be of value to NASA. For the AEC, LETBI was intended to provide information on the possible benefit of low-dose rate total body irradiation as opposed to the more conventional higher dose rate facilities. The construction of LETBI was funded by AEC to provide this information in a one-of-a-kind facility. Should LETBI prove more beneficial than conventional methods, this concept would have been expected to be picked up by other clinical centers using whole body irradiation for cancer therapy. Since LETBI did not prove to be more beneficial than conventional means, only one such facility was constructed by AEC.

The Low Exposure Total Body Irradiation (LETBI) facility provided a comfortably furnished inner room 16 feet square in which there was an almost uniform radiation field. The radiation sources were positioned in a larger, outer, heavily shielded room.

Patients were able to move about comfortably during irradiation periods prolonged over several days. The exposure rate was 60 times less than that of the METBI facility. Equipment was installed for watching for undesirable side effects and for measuring and recording various physiologic changes of patients during irradiation. An IBM 1800 computer was used to provide on-line monitoring and analysis of physiologic changes much as in a modern Intensive Care Unit. In 1965, this was state-of-the-art instrumentation and AEC relied on NASA for the knowledge they had acquired in developing such instrumentation for astronaut monitoring. The monitoring equipment in LETBI cost \$65,000 and was funded by NASA.

A diagram of the LETBI facility is shown in Figure 3.

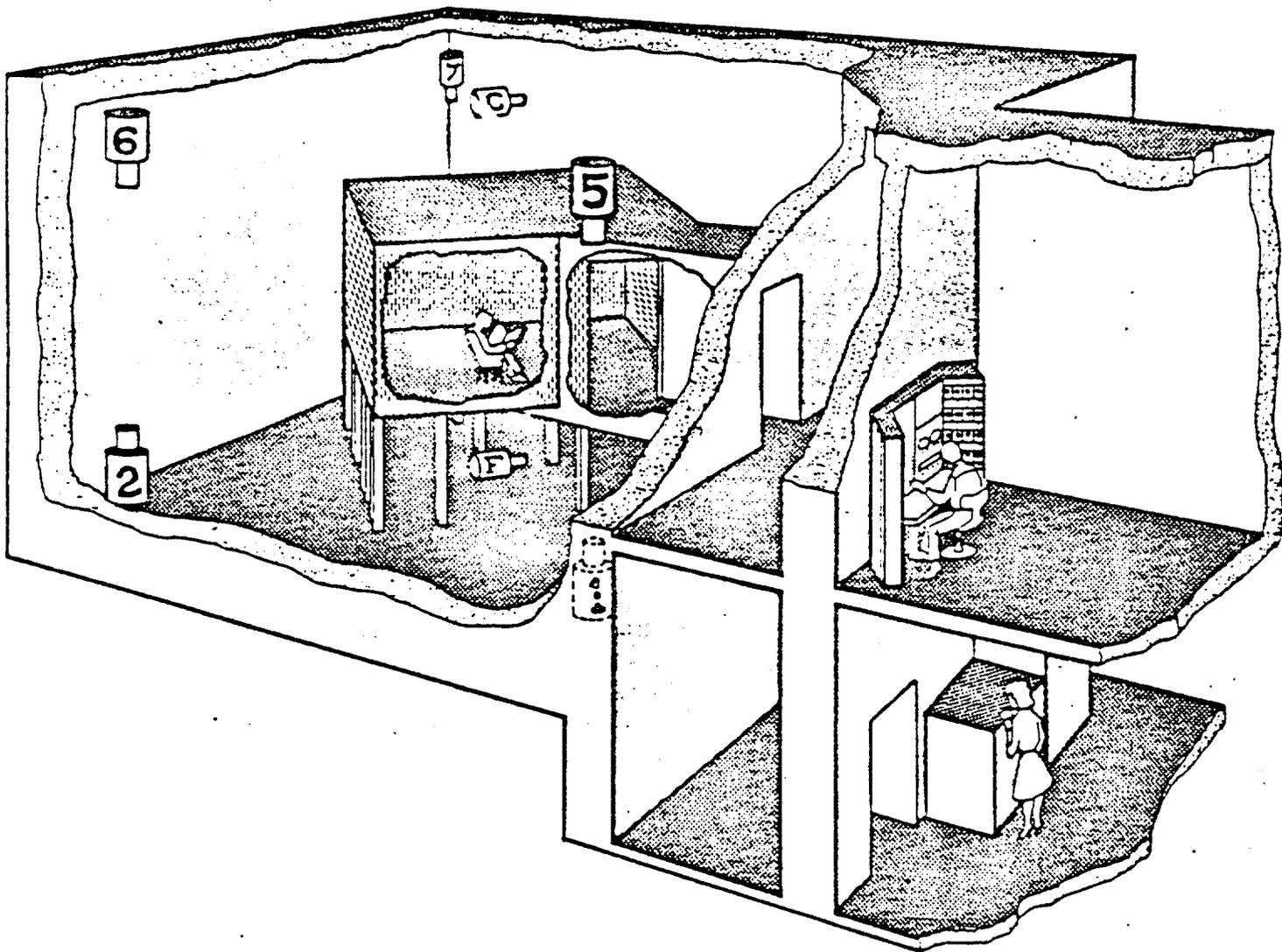


Figure 3 - Cut-away drawing of the Low Exposure Total Body Irradiation (LETBI) facility. Eight cobalt-60 sources provided a uniform radiation field. Sources C and F were not used.

1022137

With the completion of the Low Exposure Total Body Irradiator (LETBI) in 1967, it became possible to collect continuous patient monitoring data during long exposure periods to low dose rate radiation.

Although the elaborate physiological monitoring was designed to monitor the patient continuously during treatment, it was also possible to simultaneously preserve the same data on tape for subsequent analysis.

The storage and analysis of patient data collected as part of the AEC funded LETBI program was beyond the scope of the AEC program and all AEC costs for this activity were reimbursed by NASA. It should be emphasized that all activities related to the clinical treatments using the LETBI facility were funded by AEC.

In January 1966, ORINS underwent a name change to the current Oak Ridge Associated Universities.

By the early 1970's, it was becoming clear that while the treatment of patients at the ORAU Medical Division was excellent, the number of cases treated was too small to be statistically significant in evaluating various

modalities of therapy. Moreover, since all costs related to patient care were borne by AEC, it was becoming increasingly difficult to justify the continued operation of this, and other, AEC hospitals. In the early fifties and sixties, these AEC hospitals were responsible for developing the whole new field of nuclear medicine; by the late sixties, their influence had spread and nuclear medicine was well advanced at most major medical centers. Physicians who had been trained at these AEC hospitals had returned to their universities and were now conducting the training. The AEC hospitals had, in effect, put themselves out of business.

The ORAU clinical cancer research program was terminated in 1974 with the closing by AEC of the inpatient care facility. In 1975, Dr. C. C. Lushbaugh became the Chairman of the newly named ORAU Medical and Health Sciences Division. Following the closing of the clinical inpatient facility, the building was again renovated and its current configuration is shown in Figure 4.

All ORAU patients that were part of the cancer treatment program were notified prior to closing the hospital that:

PRESENT FACILITIES

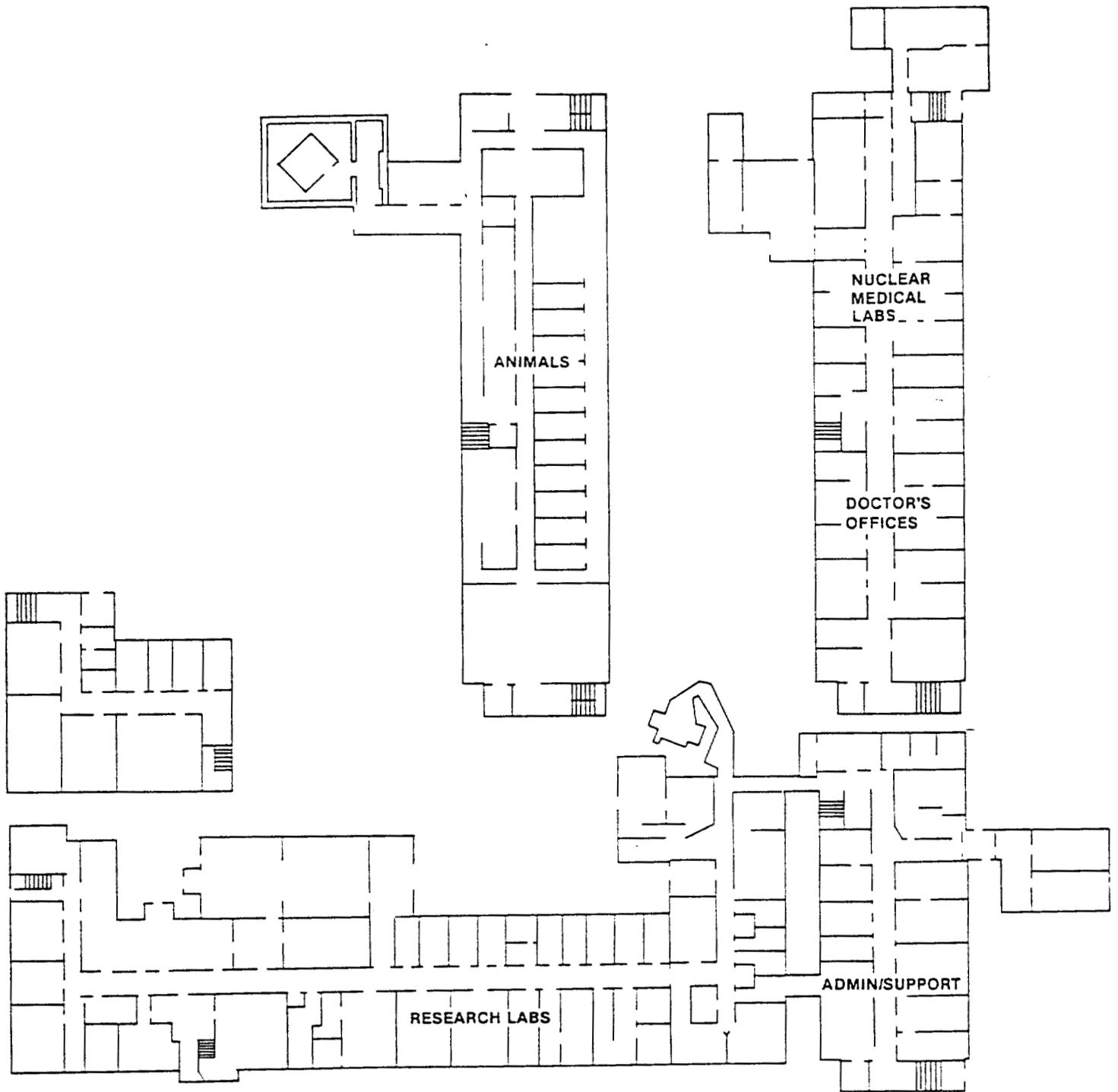


Figure 4

1022140

1. If they wished to have their treatment continued by private physicians in Oak Ridge, DOE would reimburse any difference in costs between their insurance and the doctor's fees.
2. Should they choose to be hospitalized in Oak Ridge Hospital of the United Methodist Church, DOE would pay any charges over and above those the patients' insurance would pay.

This commitment is still in place and this fiscal year DOE paid \$38,000 for care of former patients.

In 1975, the third floor which formerly housed patients was converted to a modern animal care facility to support the ongoing basic research and radiopharmaceutical development programs.

ORAU is continuing its long standing program in the development of radioactive labeled compounds for the diagnosis of disease. With joint funding from the National Cancer Institute and DOE, ORAU is using a special device designed for what is known as Emission Computerized Axial Tomography (ECAT) in out-patient clinical trials.

Mr. Chairman, this concludes my statement. I would be pleased to answer any questions.

STATEMENT BY

Frank V. Comas, M.D.

CHIEF, DEPARTMENT OF RADIATION ONCOLOGY
UNIVERSITY OF TENNESSEE MEMORIAL HOSPITAL

before the

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
U. S. HOUSE OF REPRESENTATIVES

September 23, 1981

1022142

Mr. Chairman and members of the Committee: My name is Frank Comas. I am Chief of the Department of Radiation Oncology at the University of Tennessee Memorial Hospital.

I was associated with the Oak Ridge Institute of Nuclear Studies, later Oak Ridge Associated Universities, between 1958 and 1969. One of my activities was supervising the treatment of patients who were given total body irradiation.

In the course of those studies data was gathered on the side effects of total body irradiation, and some of that information was made available to NASA. It has been alleged that it was the purpose of our studies to generate data for NASA, but this is not true. The total body irradiation program started well before NASA came into the scene, and it continued for several years beyond the termination date for data collection for NASA.

The purpose of our studies was to define the role of total body irradiation in two different settings. One was the heroic use of rather large doses of radiation in the treatment of acute leukemia in children. In those years that was a fatal disease, and much experimental work had been done to the effect that maybe the disease could be treated by wiping out the leukemic cells with radiation. I do not consider myself an expert in this field and will comment no further on the merits of this

1022143

approach. I did not make the decisions whether to irradiate or not, but I did administer the actual radiation treatment in almost all patients that were so treated, and I felt justified in doing so when nothing else appeared to be of much value.

The other much larger group of patients were those with chronic leukemias and disseminated lymphomas. These are diseases which follow a more chronic course, sometimes with possibility of survival for several years. Here, the object of the treatment was to prolong life, and make it as comfortable as possible. Those patients were treated with total body irradiation exposures of 50 to 100 R which is a moderate amount of total body irradiation, with hardly any danger to life from the treatment itself, and usually with rather mild side effects.

Our efforts met with limited success. We did not salvage a single child with acute leukemia given total body irradiation. We obtained a few short remissions, but cures did not appear until the state of the art had improved to effective combination of drugs around 1970. By then, my colleagues were doing very well without any radiation in some types of acute leukemia. Even before then, our overall results compared favorably to the national experience. (See Fig. 1)

With the other group we obtained lots of partial remissions; and a few complete remissions. That is when the disease appears to disappear but comes back after a period of time. In terms of a phase I study - which tests for tolerance by the patient - the treatment went well without significant toxicity. In terms of a phase II study - when tests for how effective that treatment may be - I only know that it worked but cannot say how well because that data has not been analyzed for survival and remission induction, other than for patients with chronic myeloid leukemia. In terms of a phase III study, we never intended to compare total body irradiation versus another form of treatment. We did not have the number of patients to do such a study.

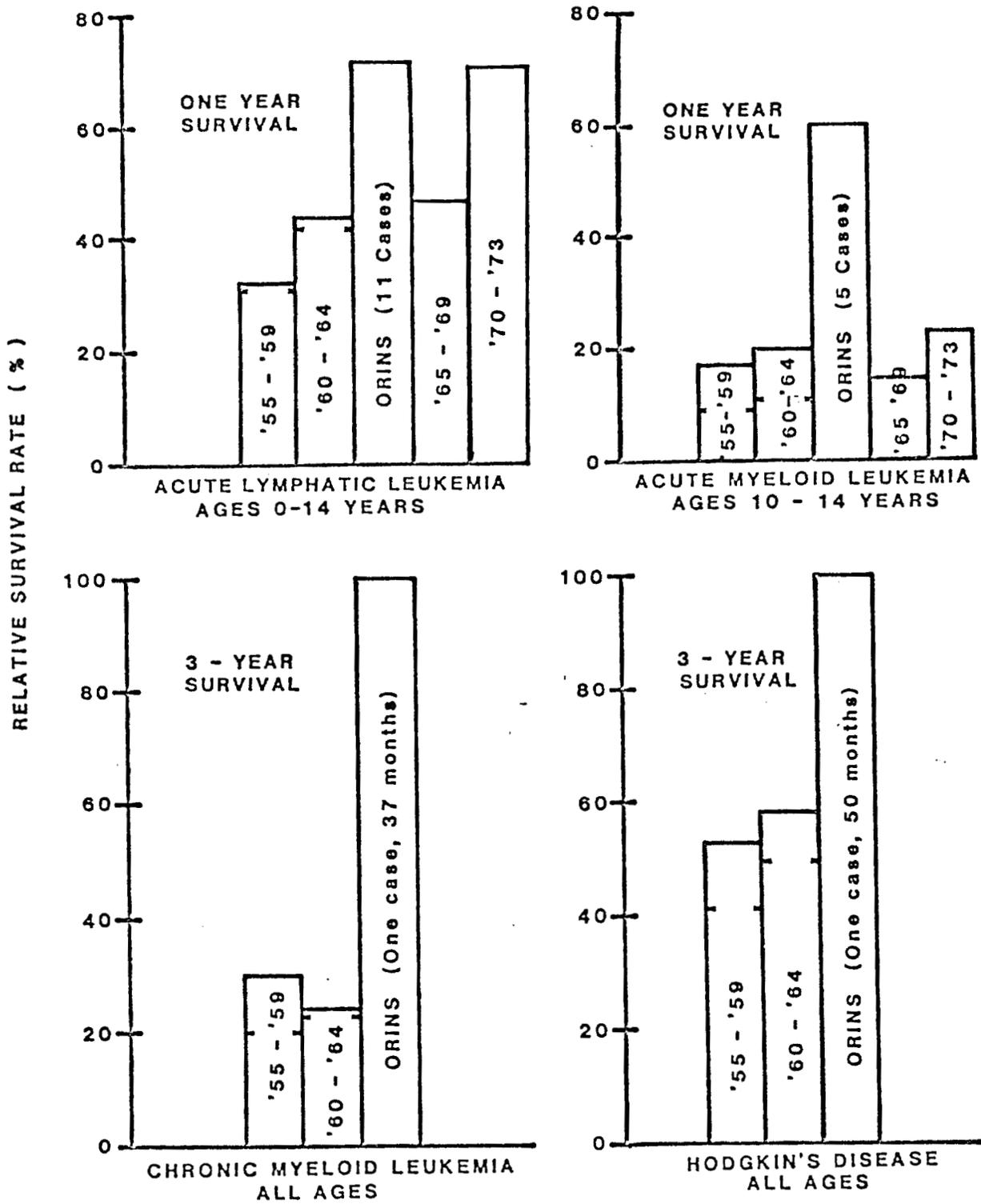
If we look for the perspectives of the 1980s to our efforts of the 1960s this is what I find. Total body irradiation for acute leukemia is still being tried in an experimental way but with radiation doses much larger than those we used. Total body irradiation for lymphomas is now much more prevalent than it was during my years at ORAU. It is given nowadays in fractionated rather than single doses, and in much larger amounts than we did then. In retrospect we did not dare enough. But, then, we were exploring new frontiers, and it was the feeling of our group the first thing was not to harm.

Mr. Chairman, this concludes my statement.

1022145

END RESULTS IN CANCER (US DHEW) IN OVER 100 U. S. HOSPITALS AND ORINS

Relative Survival Rates by Calendar Periods of Diagnosis



ORINS cases treated with TBI and chemotherapy

1022146

Fig. 1

Statement by

Clarence C. Lushbaugh, Ph.D., M.D.

Medical and Health Sciences Division

Oak Ridge Associated Universities

before the

Subcommittee on Investigation and Oversight

Committee on Science and Technology

U. S. House of Representatives

September 23, 1981

Mr. Chairman and members of the Committee: My name is Clarence Lushbaugh. I am the Chairman of the Medical and Health Sciences Division of Oak Ridge Associated Universities, formerly known as the Oak Ridge Institute of Nuclear Studies. Before I begin, I would like to introduce my colleagues who are with me today. They are: Dr. Helen Vodopick of the Oak Ridge Medical Clinic, Dr. Frank Comas, Chief, Department of Radiation Oncology, University of Tennessee Memorial Hospital, Dr. Karl Hübner, Chief Clinician and Director of REAC/TS, and Mrs. Ann Sipe, LPN, Radiation Emergency Assistance Center/Training Site.

Mr. Chairman, I appreciate the opportunity the committee has provided me to present factual information concerning analytical studies carried out under my and Dr. Gould Andrews' direction for the Atomic Energy Commission (AEC) with the support of the National Aeronautics and Space Administration under an interagency agreement in force from 1964 through 1974. Dr. Andrews, now deceased, was Chairman of the Medical Division, ORINS,

1022147

and I was a member of his staff, heading a research group in applied radiobiology, studying the effects of total-body radiation exposure on man. I also directed AEC-funded research projects on whole-body counting and red cell sizing.

You have heard from previous testimony how the NASA/AEC Interagency Agreement came to be, its purpose and objectives. Because of my research background and non-clinical interest in assessing the relative radio-sensitivity of animals, including humans, Dr. Andrews assigned me the task of measuring as precisely as possible human radiation dose-response relationships using data obtained from clinical experience with radiation accident victims and patients who had received total-body irradiation (TBI) therapy in the course of their natural diseases.

This subsequently came to be known as the NASA Study. Previous testimony has described for you how these analytical studies were carried out using hospital charts, the results of the analyses and their inclusion in the National Academy of Science book, published in 1967; which still is used world-wide as a reference text whenever questions of human radiation tolerance arise.

I want to emphasize that clinical data on children under 12 were not considered for analysis since the medication given before total-body irradiation would have biased any conclusions regarding nausea.

You have also heard the history of the development of the low-dose-rate radiation exposure facility which was designed to extend the clinical use of TBI and hopefully to improve its therapeutic usefulness while decreasing the toxicity common to rapidly delivered radiation exposures.

The use of this facility by the clinical staff in the treatment of their patients afforded the NASA study group the opportunity to observe in real time the signs and symptoms of radiation exposure that we had previously had to study in retrospect from medical histories and charts. The use of remote surveillance equipment developed by NASA for monitoring astronaut performance afforded the ORINS clinical staff a means of constantly keeping a check on the well-being of the patient being irradiated (20 hrs a day) in LETBI. It should be noted that patients in LETBI were watched by closed-circuit television and the monitoring was critical when the patient was asleep. This also afforded my staff and me the opportunity to study tapes of these signals (EKG, heart rate, and respiratory movements) to better understand the pathophysiology of the patient. As you are no doubt aware, ten years later such equipment became commonplace in the best intensive care units and allowed one nurse to monitor constantly the status of a ward full of seriously ill persons.

It might be expected that the newer LETBI facility would cause the clinicians to shift their therapy plans to its use over that of the older METBI facility where the dose rate was 60 times as rapid. During the first two years of its operation, the clinicians did use the LETBI facility much more often than the METBI. However, after a relatively short while the clinicians went back to using the METBI facility to deliver the so-called "LETBI dose" of 30 R in 20 minutes instead of the 20 hours required in LETBI. They found that with the METBI facility, the 30 R/day radiation treatments could be given on an outpatient basis. As a result, in 1973, the METBI treatments numbered 168, whereas in the LETBI unit, the number was only 15. (Figs. 1 and 2). Since the therapeutic

1022149

effects were the same, and since the METBI fractionated therapy also avoided radiation sickness, the METBI facility proved to be efficient and more acceptable to the patients. The clinical use of the LETBI facility declined progressively in the last 5 years of its operation and at the time of the closure of the ORAU hospital unit, the LETBI facility was in a standby status.

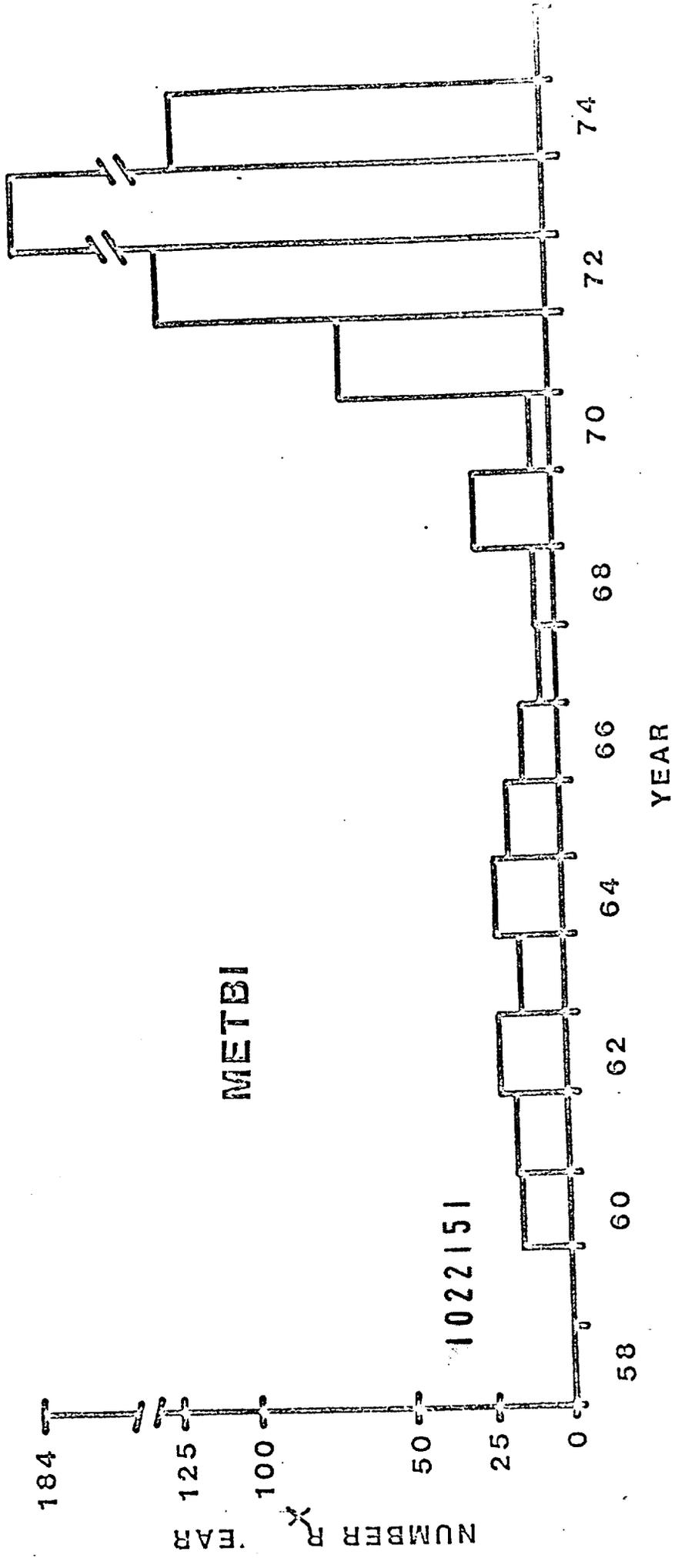
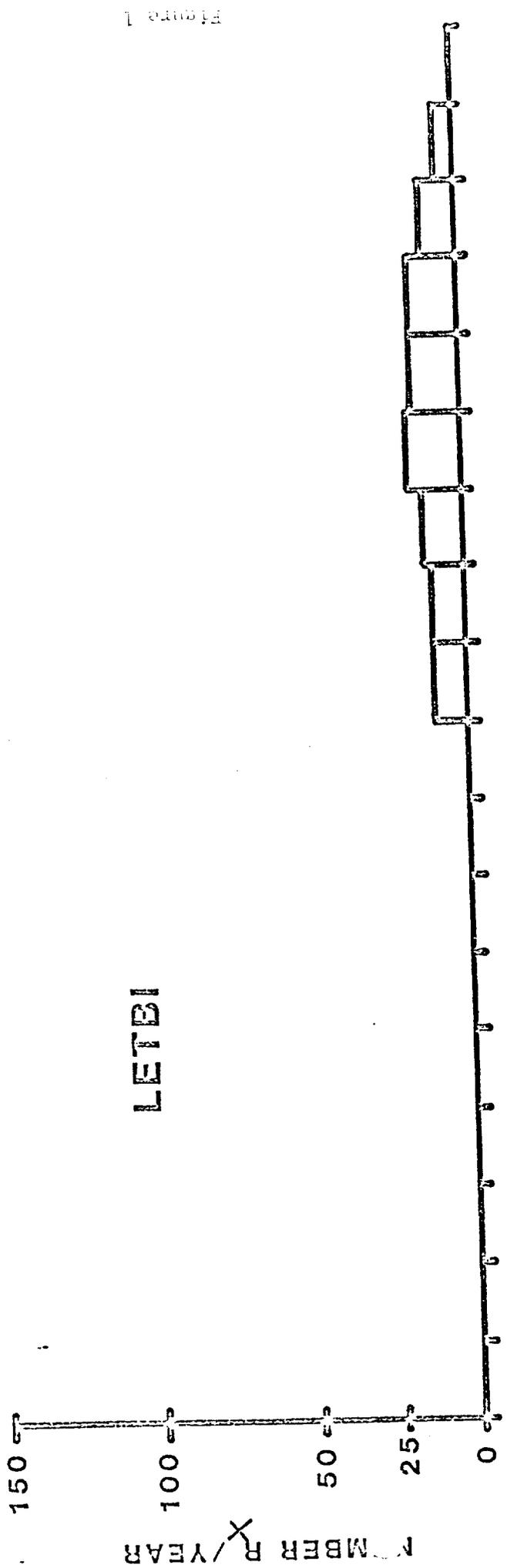
In light of concerns which have been expressed, I would like to clear up two points.

First, neither NASA nor AEC program monitors, to my knowledge, ever attempted to become involved directly or indirectly with the treatment of patients at ORINS/ORAU Medical Division.

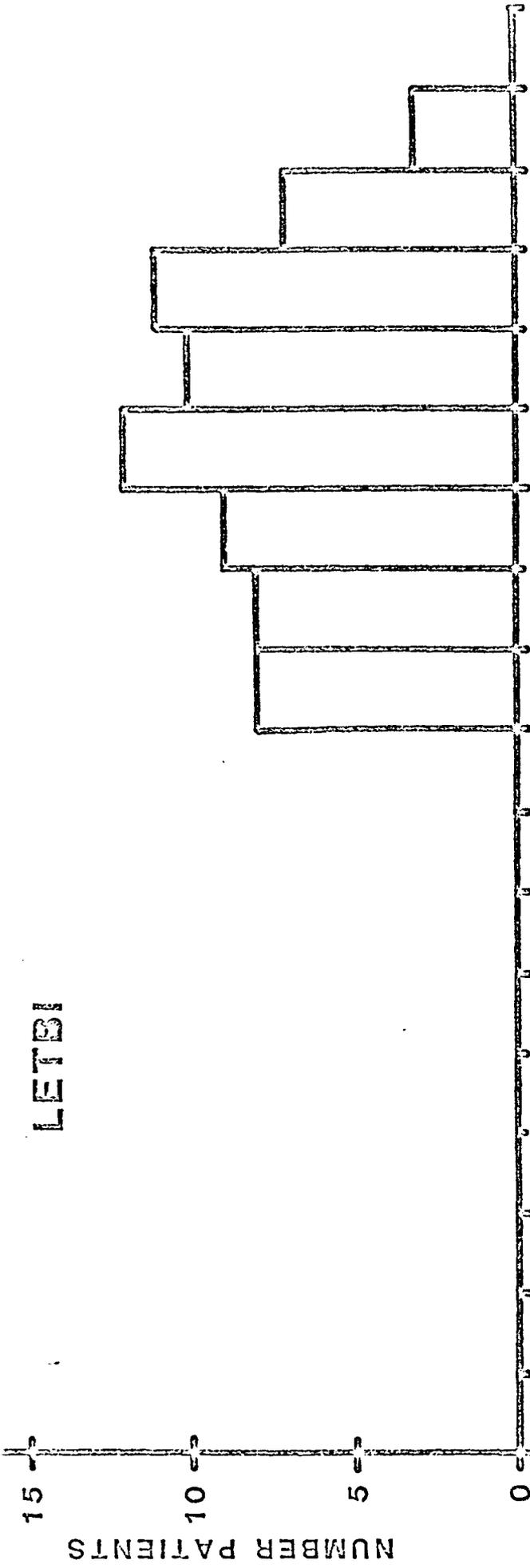
Second, the ORINS/ORAU NASA study group never influenced the clinicians in their selection of patients or the prescriptions of the exposure dose and dose rates. In fact, I studiously avoided making any such recommendations and Dr. Andrews and his clinical staff never requested such recommendations.

Mr. Chairman, that concludes my testimony. I will be pleased to answer questions.

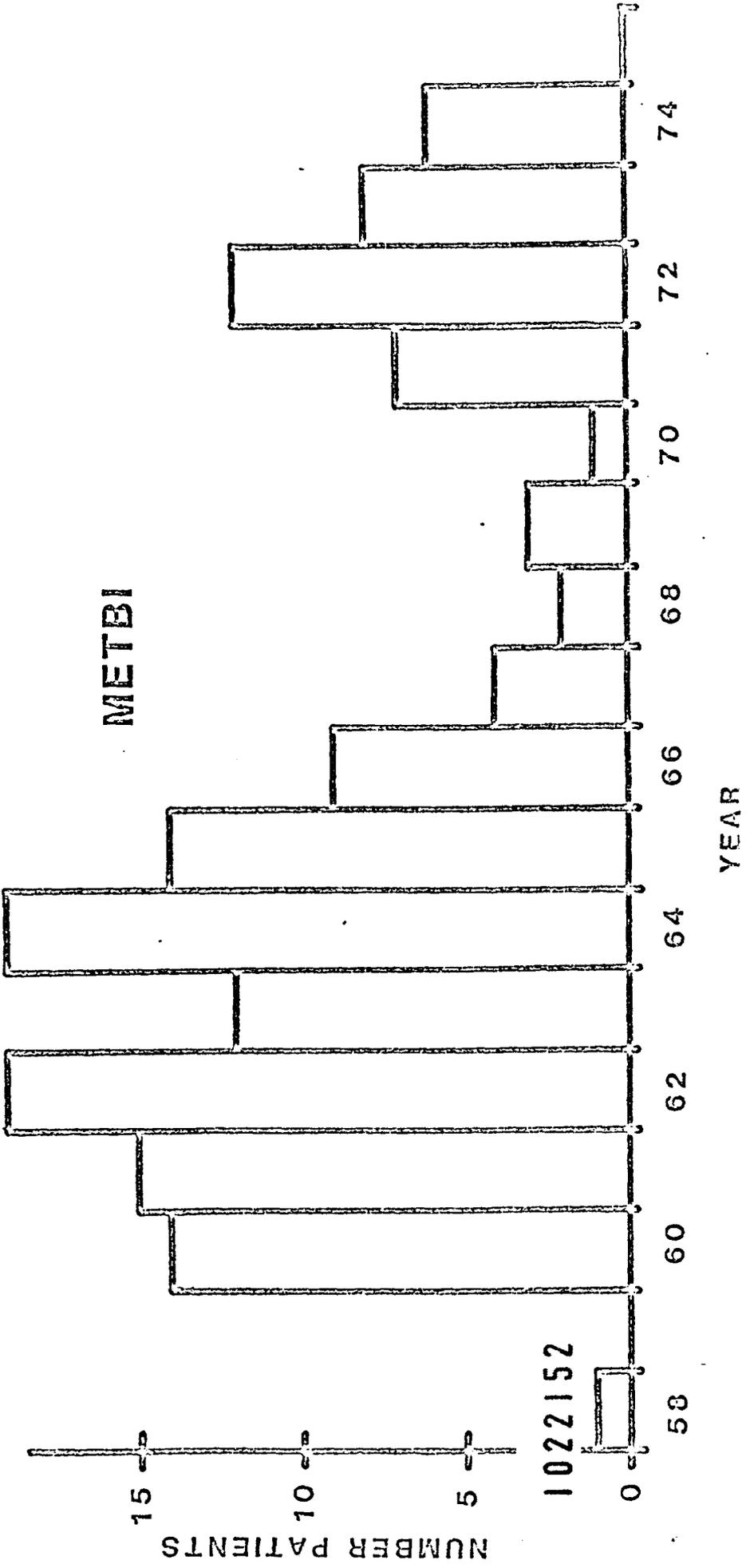
1022150



LETBI



METBI



STATEMENT BY

Helen Vodopick, M.D.
OAK RIDGE MEDICAL CLINIC

before the

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
U. S. HOUSE OF REPRESENTATIVES

September 23, 1981

1022153

The overall radiation program at ORAU was best described by Dr. Gould Andrews, then Medical Division chairman, in a preface of the 1966 year report of the ORAU Medical Division:

"This is a long range continuing program which has as its objective the improved treatment of disease by means of radiation, both internal and external. Main areas of effort are, (1) the best use of total-body irradiation in the treatment of lymphoma, leukemia and polycythemia; (2) local external irradiation therapy for certain types of cancer, including application of experimental methods based on animal studies..."

Since this was a new method of treatment, experimental protocols were developed to evaluate the effectiveness and potential toxicity of this type of irradiation much like protocols now used to assess new drugs in people. Such protocols were reviewed by a human use committee. Lymphomas and chronic leukemias were already known to be sensitive to radiation given in large doses to localized areas. It was still to be determined what the least dose of total-body irradiation administered at various intervals could be used to control these diseases. According to protocol, treatment was titrated to the patient's response. The aim and prime intent of this therapy was to control the lymphoma, leukemia or myeloproliferative disorder.

1022154

Mr. Chairman and members of the Committee: I am Helen Vodopick, a specialist in Hematology and Medical Oncology in Oak Ridge, TN. From July 1965 to January 1975, I was a member of the Clinical Staff at the ORINS/ORAU Medical and Health Sciences Division.

In order to evaluate the type of treatment given to patients at Oak Ridge Associated Universities (ORAU) we must turn back the calendar to the late 1950's and early 1960's. At that point in time the main modalities of treatment of cancer were surgery, irradiation and very few chemotherapeutic drugs. Surgery played the greatest role in the treatment of solid tumors where bulk disease could be removed en masse. However, such an approach most often failed because the tumor had spread beyond the confines of the surgical field. At times radiation was used as a supplement to eradicate residual disease. Unfortunately there were also malignant diseases not amenable to surgery. These diseases were too widespread in the case of lymphomas (tumor of the lymph glands) and inaccessible to surgery in the case of leukemia. Therefore, it seemed logical to control these latter malignancies with irradiation. A new method was devised to administer this irradiation called total-body irradiation (TBI) whereby the widespread disease would be uniformly treated. The investigation of this treatment method became one of the primary goals of the ORAU Medical Division.

1022155

With this intent, only patients with these diseases were accepted to the Medical Division of ORAU for treatment with TBI. These patients were informed of this experimental approach on their initial admission and were required to sign an admission form attesting to this fact (submitted copy). In addition, the chief of the medical service would again explain the procedure before its actual implementation. Therefore, the patients were fully informed of the type of therapy and the investigational nature of it.

Children with acute leukemia and lymphoma, 19 and 1 cases respectively, were also accepted for TBI treatment. These 20 children treated between 1957 and 1968 were irradiated in the medium exposure TBI unit. The majority of these children had been treated with drugs which failed to arrest their disease.

It must be remembered that between 1965 and 1969 according to American Cancer Society statistics, the one year survival rate for children with acute leukemia under 15 years of age was 40% and five year survival rate was 3%. The statistics prior to that time were even more dismal. Therefore, it was hoped that by irradiating the whole bone marrow with a high total dose the leukemic cells could be eradicated. Twelve such children were treated in the METBI facility between 1961 and 1968. These children were also treated with chemotherapy. The leukemia was

1022156

brought under partial control in some cases but re-occurred in all instances. Achieving a remission was possible but maintaining it was not.

Since neither drug therapy nor irradiation had succeeded in curing leukemia in a significant number of children, a new completely different approach was tried. Immunotherapy had worked in animals as proven by Delorme and Alexander. This therapy was based on using a donor's normal sensitized lymphocytes (killer cells) to attack and kill leukemic cells in a recipient. One of the four patients in whom this new therapy was tried was a 3-year-old boy found to have acute lymphoblastic leukemia. After the type of therapy was discussed with his parents, his mother agreed to serve as the lymphocyte donor (consent form enclosed). She was told of the possible risks to her including early sensitivity reaction to injected bone marrow cells or depletion of the constituents of her own thoracic lymph. Another risk was directly related to the type of surgical procedure that needed to be done, i.e., putting a cannula (small tube) into her thoracic duct in her neck. In order to sensitize her lymphocytes, leukemic cells obtained by bone marrow aspirate from the patient were irradiated with 10,000 R, a dose sufficient to kill all these leukemic cells, and were injected into several muscle sites of the mother. The patient was then started on conventional chemotherapy consisting

1022157

of methotrexate and prednisone. It should be emphasized that chemotherapy was begun within nine days of his first admission to ORAU and was continued for 17 days until his marrow was showed to be hypocellular and evidenced the beginning of a remission (August 23, 1965).

It was then that lymphocytes via the thoracic duct were obtained from the patient's mother and given intravenously to the patient. No adverse reaction was recorded during this period. Indeed the patient's bone marrow did show evidence of remission by September 10, 1965, but this recovery in retrospect was attributed to his chemotherapy rather than to the lymphocyte transfusions although one cannot be absolutely certain about this conclusion. We were all extremely disappointed that four months later his leukemia re-emerged.

(The results of this experimental immunologic approach were published in the medical literature in 1966 and 1967.) The patient was then begun on another course of chemotherapy, consisting of vincristine and prednisone. This first relapse of leukemia was complicated by a severe Staphylococcal infection in his blood stream. Both leukemia and infection responded to specific therapy. When a remission was evident, he was begun on weekly maintenance drug therapy which kept his leukemia under control for 13 months, when another relapse of leukemia

and another blood stream Staphylococcal infection occurred. Once again he responded to drug treatment which induced another eight month remission.

When his leukemia relapsed for the fourth time in November 1968, the situation was desperate since his leukemia had become refractory to all current anti-leukemic drugs available. We had only two options: give only blood transfusions to sustain his life for a few days or weeks longer or try total-body irradiation to possibly induce another remission. Total body irradiation as mentioned previously had induced temporary remission in acute leukemia. After consultation with his mother who was told of the hazards and options, the medical staff chose to give him total-body irradiation. It was not our intent to generate data for the Atomic Energy Commission, or for the National Aeronautics and Space Agency (NASA). Our concern and only concern was to keep the patient alive for as long as possible.

Because of his proven propensity to infection, he was taken to a secluded sheltered area (the patient room in the LETBI facility) after he was irradiated in the METBI facility. In addition the principle of reverse isolation was applied in his medical care. In LETBI he could be watched closely via closed circuit television. Initially a monitoring device (referred to as an umbilical cord)

which recorded his pulse rate and respirations was used to reduce his exposure to hospital personnel, a very potential source of infection. Since the monitoring device which was put around his waist was uncomfortable, it was removed in one and a half hours. Data were never collected for any reason other than to monitor vital signs as a routine hospital procedure.

Twenty-four days after his radiation exposure in METBI, the patient died with overwhelming Staphylococcus aureus and Streptococcal infections. These organisms were undoubtedly a part of his own bacterial flora which had become unresponsive to antibiotics and which were unchecked in his body because of his poor immune response. Indeed he had two previous blood stream infections with Staphylococcus aureus during the course of his illness, both during times of leukemic relapse.

After 1966, as the drug armamentarium became larger and more effective, patients were treated with a combination of drugs and local irradiation or with drugs alone. After this date, all children with acute leukemia at ORAU were started on chemotherapy and continued on maintenance drug therapy. Two children also received whole brain irradiation which is now a routine accepted procedure. Of the 23 children with acute lymphatic leukemia treated at ORINS/ORAU by drug and/or brain irradiation four are still living, 14 years, 11 years and 9 years (2 patients) respectively.

1022160

In the present year, 1981, the survival statistics of acute lymphocytic leukemia have improved significantly but still only 50% of the children treated are alive at five years and only one of two of these children are expected to live beyond 10 years.

In conclusion, a program at ORAU was begun to evaluate the therapeutic effectiveness of total-body irradiation in various hematologic diseases. The administration of this irradiation was given in specially constructed facilities called METBI and LETBI. The results of these studies showed that patients so treated lived as long as those patients treated with drugs and with local irradiation. After analysis of the data, there appeared to be no therapeutic advantage nor disadvantage (life was not shortened) to the total-body irradiation. Total-body irradiation remains a viable form of therapy in the palliation of a limited number of hematologic diseases. Further studies should be done to assess whether total-body irradiation could complement or potentiate the effectiveness of various drugs now being used.

Mr. Chairman, this concludes my statement.

1022161

STATEMENT BY

Karl F. Hübner, M.D.

CHIEF, OUTPATIENT NUCLEAR MEDICINE
DIRECTOR, RADIATION EMERGENCY ASSISTANCE CENTER/TRAINING SITE
OAK RIDGE ASSOCIATED UNIVERSITIES

before the

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
U. S. HOUSE OF REPRESENTATIVES

September 23, 1981

1022162

When the ORINS Medical Division began admitting patients in 1950, a special application form for admission had to be signed by the patient or his legal guardian in order to be admitted to the clinical research program. This early patient admittance agreement spelled out some of the essential statements required for today's (1981) consent forms: the treatment may be experimental, the patient is given no promises regarding improvement of his physical condition, there may be certain risks involved in the experimental treatment, the patient may refuse to participate as a patient in the hospital, and the patient understands the agreement and participates of his/her own free will and choice. A copy of this consent form is included as Appendix A.

In 1957, the ORINS Medical Division initiated consent forms for special procedures. These forms were tailored to the case and procedure concerned and were used in addition to the general admittance agreement which was also revised in 1957. A copy of each is attached as Appendix B.

For patients scheduled for total body irradiation, the Chief of Clinical Services of the ORINS Medical Division would discuss with the patient or their legal guardians the nature of the procedure, the amount of TBI, and possible risks and would obtain a signed consent form.

In 1964, the Declaration of Helsinki emphasized that clinical research should be (1) based on laboratory and animal

1022163

experiments or other scientifically established facts, (2) conducted by scientifically qualified persons under the supervision of a qualified medical person, (3) preceded by careful assessment of inherent risks vs benefits, and (4) done only with full information to the patient and with free consent. The Helsinki document differentiated between clinical research in which the aim is therapeutic for the patient and the purely scientific aim without benefit to the patient subjected to the research.

In November of 1966, the American Medical Association (AMA) adopted the ethical principles of the Declaration of Helsinki to aid physicians to fulfilling their responsibilities while engaged in clinical investigations of new drugs and procedures. According to the AMA's guidelines, consent is only attained after disclosure of an investigative new drug or experimental procedure, explanation of the risks involved, indication of possible therapeutic benefits, discussion of alternate drugs or procedures, an offer to answer any questions and the signing of a consent by the patient.

In late 1966, Dr. Gould Andrews decided to revise and formalize a Code of Ethics for Human Experimentation for the ORAU Medical Division. In early 1967 with the assistance of Dr. Heyssel of Vanderbilt University and Dr. Lange of the University of Tennessee, ORAU drafted guidelines for a Human Use Committee, developed new consent forms and officially formed a Human Use Committee. In 1969, ORAU's "statement of assurance" was accepted by the

1022164

U. S. Department of Health Education and Welfare. Appendix C contains the 1967 guidelines, revised consent forms and Human Use Committee membership. Subsequently, ORAU was, and still is, included in the Cumulative List of Organizations and Institutions in Compliance with DHEW Policy and Regulations on Protection of Human Subjects.

In reviewing the ORINS/ORAU Medical Division consent forms used over the years, I believe them to be fully consistent with reasonable medical practice during the time period.

My review also indicated that the choice of therapy in the ORINS/ORAU clinical program was dictated by the potential benefit the therapy offered the patient. In a paper* published in 1950, Dr. Andrews stated, "The Welfare of the patients takes precedence over every other consideration." I believe that guiding principle has continued ever since.

That concludes my statement Mr. Chairman. I will be pleased to answer questions.

* SOUTHERN SURGEON, V. 16, pp. 577-583, 1950.

1022165

We are signing this statement to indicate our understanding and approval of the special treatment planned for our son,

1. We realize that he is seriously ill with acute leukemia and that the outlook for him is extremely poor under any circumstances. We are willing to have him given a special experimental form of treatment consisting of total body irradiation in a dose that is much larger than that used ordinarily, to be followed by transfusion of bone marrow. We understand that there is a serious risk in this treatment.

Signed: _____

Attest:

Gail Anderson
Mary G. Sestini
1 10

Dated this 25 day of May, 1957.

Report of Meeting to Consider Establishment of Committee on Human Use

April 6, 1967

Present: Dr. Robert Heyssel, Dr. Robert Lange, Dr. Lowell Edwards, and
Dr. Gould Andrews

A meeting was held at the Medical Division on April 6, 1967, to discuss the establishment of a committee on clinical investigation which would serve to advise and monitor the Medical Division program in relation to the ethics of research in human beings and the suitability, from this viewpoint, of research going on at the Medical Division. It was pointed out that this committee would be a replacement for more informal arrangements that had previously existed in the Medical Division. The desire to have two outside consultants - Dr. Lange and Dr. Heyssel - had been stimulated by a suggestion from the Atomic Energy Commission which followed the meeting of their Advisory Committee in November, 1966. It had been pointed out by the Advisory Committee and the Commission that they did not wish to imply any criticism of our past practices, but that because of the widespread concern over ethics of human experimentation, and the possibility that some criticism, either valid or not, might arise, they believed it would be desirable to have some outside, disinterested consultants who were familiar with what we were doing, and who had passed on each individual research proposal.

A rather general discussion was held. We considered at some length the function of the committee. It was our opinion that the committee would serve to review research proposals and decide whether or not they were justifiable from the viewpoint of any risk that might be involved in studies done on human

1022168

beings. If no risk is involved, the committee would not make any effort to evaluate the research proposal from the point of view of its scientific value. However, if there are significant hazards, the committee would need to evaluate the scientific merit of the proposal and balance it against the possible risks.

Name of the Committee

We chose the title, "Committee on Human Studies."

a. Composition of the Committee

It was decided to have, in addition to Dr. Lange and Dr. Heyssel, three members of the Medical Division staff on the committee. These would probably include one Ph.D. and two M.D.s. Andrews would be one of the Medical Division members and Edwards would sit in on the meetings without being an active member of the committee. We discussed at some length the fact that the people from the Medical Division would probably be involved to some degree with any research that was under consideration, and decided that in spite of this possible problem the proposed composition of the committee would be satisfactory.

b. Officers of the Committee

The committee would need a chairman, who would probably be from the Medical Division, and a secretary who would be one of the consultants. Dr. Lange has agreed to serve as secretary for at least an initial period.

Decisions of the Committee

It was our consensus that the decisions of the committee would probably need to be unanimous to allow a research proposal to go forward, or at least to

have the approval of both of the outside consultants. In the event that one consultant objects to a research proposal, if there is otherwise considerable support for it, other consultation would be sought. It is our impression that in most instances the committee would be able to reach an essentially unanimous opinion on each research proposal.

Relation of the Committee on Human Studies to the Existing Radioisotope Committee at ORAU Medical Division

It was our opinion that the new committee would not replace the existing radioisotope committee. Proposed studies involving radioisotopes would need to be approved first by the ORAU Isotopes Committee and then by the Committee on Human Studies. Minor changes in research involving radioisotopes could be approved by the Isotopes Committee without further ratification by the Committee on Human Studies. Copies of the minutes of the Isotopes Committee will be sent to Dr. Lange and Dr. Heyssel.

Function of the Committee on Human Studies

The Committee on Human Studies would have meetings called by the chairman at whatever frequency seemed necessary - perhaps two or three times per year. Certain problems not requiring a full meeting of the committee could be handled by telephone communications, preferably by a three-way hook-up with Dr. Lange and Dr. Heyssel. New research proposals would be written up by the senior investigator. A form for this was developed, based upon the one used at the University of Tennessee in Knoxville with suitable modifications. After the form is filled out, the proposal will be evaluated by the administrative office of ORAU Medical Division.

If approved by the chairman of the Medical Division, or considered worthy of serious consideration by the Committee on Human Studies, copies will be sent to Dr. Lange, Dr. Heyssel, and other members of the committee previous to the meeting of the committee. At the time of the meeting, further questions may be asked of the investigator and then the committee will either approve or disapprove the research proposal.

What is to be Considered by the Committee?

The committee is to review all research at the ORAU Medical Division involving human patients in which there is believed to be a significant risk to the patients or a significant possibility that criticism might be leveled at the scientists for their manner of doing studies in human beings. The decision about whether or not a specific investigative procedure involves any risk and therefore requires action by the committee would rest with the Medical Division. The Medical Division should bring to the committee's attention by name and brief description those experiments in human beings believed to have negligible risk, i. e., a systematic survey of hemoglobin and hematocrit values in thyroid patients. Considerable discussion was held about the suitability of undertaking a rather unconventional form of treatment in a single seriously ill patient, partly with the objective of immediate benefit to the patient and partly as a preliminary research effort that might be the basis for a future controlled investigation. Here the group felt that considerable leeway rests with the physician who is responsible for the patient's care. Ordinarily the Committee on Human Studies would not be involved with decisions concerning a single patient but rather with policy matters or research on groups of patients. However, if circumstances were such that the staff of the

Medical Division wanted some consultation on the suitability of a study in an individual patient it might be quite reasonable to seek telephone discussion on this.

Scope of the Committee's Work:

It was decided that the committee should concern itself with all studies done in human beings, whether these subjects are patients in the research hospital or normal volunteers of some type.

Approval of the Previously Prepared ORAU Medical Division Document on Human Volunteers and the Function of the ORAU Isotopes Committee:

Dr. Lange and Dr. Heyssel are in agreement with the document as presented. It was pointed out by Dr. Heyssel that there are certainly some risks in using employees, and that careful protection should be given to employees used as research subjects. Students are quite unsuitable for most research procedures unless the risk is nil since they are not really free to refuse to participate. Dr. Heyssel has serious reservations about using prisoners in research because here too it is very difficult to establish a situation which is free of any suggestion of coercion.

Future Meetings:

It was decided that we would try to have another meeting, perhaps in May or June, and begin to review research proposals. We decided that we should eventually review all of the significant human research at the Medical Division, including those projects that are already under way, with highest priority to review of any studies that might be of questionable suitability or subject to criticism.

Gould Andrews
Acting Secretary

OAK RIDGE ASSOCIATED UNIVERSITIES

Oak Ridge, Tennessee

Authorization for the Administration of Radioactive Substance

I hereby authorize the staff of the ORINS Medical Division to administer to _____ the following radioactive substance _____
Nuclide Chemical

_____ Dose _____ Route of administration

The purpose of this procedure has been explained to me as being:

Its relevance to my condition, the risks and any possible alternatives have been explained to me.

Name of patient

Date

OAK RIDGE ASSOCIATED UNIVERSITIES
Oak Ridge, Tennessee

Consent to Experimental Treatment

I authorize the performance upon myself
(myself or name of patient)
of the following treatment: Total Body Irradiation
for treatment of my lymphoma
(State nature of treatment)

The nature and purpose of the treatment, possible alternative methods of treatment, the risks involved, and the possibilities of complications have been explained to me. I understand that this treatment is not the usual treatment for my disorder and is therefore experimental and remains unproven by medical experience so that the consequences may be unpredictable.

DATE: 6 April 70
(Patient or person authorized to consent for patient)

WITNESS: E A Syce

I have talked with _____ about
the proposed course of treatment to be given himself
including the following: * Total Body Irradiation 100R
= LET 131

O. L. Edwards 6 April 70
Physician / Date

*Physician should indicate experimental drugs, radioisotopes, radiation therapy, and/or possible placebo or sham therapy.

OAK RIDGE ASSOCIATED UNIVERSITIES
Oak Ridge, Tennessee

Consent to Experimental Treatment

I authorize the performance upon _____
(myself or name of patient)
of the following treatment: Total body irradiation
in the medium dose rate facility for control
of my chronic granulocytic leukemia
(State nature of treatment)

The nature and purpose of the treatment, possible alternative methods of treatment, the risks involved, and the possibilities of complications have been explained to me. I understand that this treatment is not the usual treatment for my disorder and is therefore experimental and remains unproven by medical experience so that the consequences may be unpredictable.

DATE: 15 Nov 71 _____
(Patient or person authorized to consent for patient)

WITNESS: _____

I have talked with _____ about
Name
the proposed course of treatment to be given MET 61 150 R
fractionated (30R/da x 5) Name
including the following:*

William Joseph Garity 15 Nov 71
Physician Date

*Physician should indicate experimental drugs, radioisotopes, radiation therapy, and/or possible placebo or sham therapy.

1022175

010001

OAK RIDGE INSTITUTE OF NUCLEAR STUDIES
Oak Ridge, Tennessee

APPLICATION FOR ADMISSION TO THE MEDICAL DIVISION HOSPITAL

The Oak Ridge Institute of Nuclear Studies, Medical Division, has a 30-bed hospital unit as a part of its research facilities in Oak Ridge. The purpose of the hospital is to seek and develop new methods of diagnosis and treatment and to study fundamental problems of certain diseases in the hope that the information obtained can be used for the practical treatment of these diseases and the benefit of patients. The hospital, which is staffed by qualified physicians and nurses, is especially designed for the use of radioactive isotopes. Because of the nature of the facilities, only certain types of diseases can be studied and treated.

The applicant recognizes the right of the hospital to determine the eligibility of all persons for admission as well as the right to refuse admission to any applicant. Moreover, the hospital reserves the right to discharge the patient at such time as it deems advisable.

No charge is made for hospitalization and treatment in the research hospital. The hospital endeavors to provide the most complete care for the patient and the patient's welfare is the primary concern of the hospital. No treatments are employed except those which the hospital feels will benefit the patient. However, the applicant must understand and appreciate the fact that some of the treatments used and that will be used are new, are based upon experiments on animals and that the degree of probable benefit, if any, cannot always be predicted in advance. The applicant is expected to fully cooperate at all times with the hospital and its staff. The applicant hereby grants permission for such operations, and biopsies as are deemed necessary and advisable by the hospital. It is agreed that the hospital may take photographs of treatments, procedures, operations, etc. which are performed upon the patients while in the hospital and use the same in scientific publications. At the time of admission to the hospital the applicant will be required to sign such further entrance agreements as may be required by the Institute and at all times comply with the rules and regulations of the hospital.

On the basis of the foregoing, admission to said hospital is requested by

the Man 15 day of 1950

Walter G. Anderson M.D. Applicant

ADDRESS:

Wm. & Mary - W.A.

This application should be submitted to the nearest participating medical school listed in the patient information pamphlet. It should not be sent directly to Oak Ridge.

APPROVED BY:

Walter G. Anderson M.D.

Member, Hospital Committee - U. of Tenn. Hospital

Title

Medical School

1022176

regarding my physical condition or the probable results of any treatments therefor, and I hereby expressly assume all risks thereof.

I further understand that but for this agreement on my part, I would not be accepted by the Oak Ridge Institute of Nuclear Studies as a patient in its said hospital.

I covenant that I have carefully read the foregoing and know the contents thereof.

IN WITNESS WHEREOF, I have hereunto set my hand on the 14th day of

May, 1943.

[Redacted signature area]

ATTEST:

Roberta P. [unclear]
[unclear]

Father or Guardian

Mother

STATE OF TENNESSEE)
COUNTY OF Anderson)

Personally appeared before me, Mary E. Russell, a Notary Public in and for the State and County aforesaid, the within named bargainer, Mrs. C. A. [unclear], with whom I am personally acquainted, and who acknowledged that he executed the foregoing instrument for the purposes therein contained.

WITNESS my hand and official seal in Anderson County, Tennessee of this, the 15th day of May, 1943

Mary E. Russell
Notary Public

My notarial commission expires: _____

STATEMENT BY

Ann Sipe

CLINICAL NURSE, OUTPATIENT NUCLEAR MEDICINE
TECHNICIAN, RADIATION EMERGENCY ASSISTANCE CENTER/TRAINING SITE
OAK RIDGE ASSOCIATED UNIVERSITIES

before the

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
U. S. HOUSE OF REPRESENTATIVES

September 23, 1981

1022179

Mr. Chairman and members of the Committee: My name is Ann Sipe. I am clinical nurse with the ORAU Outpatient Nuclear Medicine program and technician at the Radiation Emergency Assistance Center/Training Center.

From 1967 until 1974, I was lab technician for the Low Exposure Total Body Irradiator (LETBI) at ORAU. My job was to familiarize the patients scheduled for LETBI with the facility and to collect data on magnetic tape from patients who were being monitored during treatment in LETBI.

As part of the familiarization procedure, I would take the patient on a tour of LETBI, show them the sources, explain how the intercom, closed-circuit television and "umbilical" monitoring system worked. In discussing the umbilical cord, I always discussed how this was similar to those worn by astronauts and that monitoring data collected during their exposure would be analyzed by ORAU for NASA.

Every LETBI patient from whom monitoring data was collected was informed by me before treatment of the possible use of their data for NASA.

Mr. Chairman, that concludes my statement.

1022180

STATEMENT BY

Ann Sipe

CLINICAL NURSE, OUTPATIENT NUCLEAR MEDICINE
TECHNICIAN, RADIATION EMERGENCY ASSISTANCE CENTER/TRAINING SITE
OAK RIDGE ASSOCIATED UNIVERSITIES

before the

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
U. S. HOUSE OF REPRESENTATIVES

September 23, 1981

1022181

Mr. Chairman and members of the Committee: My name is Ann Sipe. I am clinical nurse with the ORAU Outpatient Nuclear Medicine program and technician at the Radiation Emergency Assistance Center/Training Center.

From 1967 until 1974, I was lab technician for the Low Exposure Total Body Irradiator (LETBI) at ORAU. My job was to familiarize the patients scheduled for LETBI with the facility and to collect data on magnetic tape from patients who were being monitored during treatment in LETBI.

As part of the familiarization procedure, I would take the patient on a tour of LETBI, show them the sources, explain how the intercom, closed-circuit television and "umbilical" monitoring system worked. In discussing the umbilical cord, I always discussed how this was similar to those worn by astronauts and that monitoring data collected during their exposure would be analyzed by ORAU for NASA.

Every LETBI patient from whom monitoring data was collected was informed by me before treatment of the possible use of their data for NASA.

Mr. Chairman, that concludes my statement.

1022182

STATEMENT BY

Ann Sipe

CLINICAL NURSE, OUTPATIENT NUCLEAR MEDICINE
TECHNICIAN, RADIATION EMERGENCY ASSISTANCE CENTER/TRAINING SITE
OAK RIDGE ASSOCIATED UNIVERSITIES

before the

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
U. S. HOUSE OF REPRESENTATIVES

September 23, 1981

1022183

Mr. Chairman and members of the Committee: My name is Ann Sipe. I am clinical nurse with the ORAU Outpatient Nuclear Medicine program and technician at the Radiation Emergency Assistance Center/Training Center.

From 1967 until 1974, I was lab technician for the Low Exposure Total Body Irradiator (LETBI) at ORAU. My job was to familiarize the patients scheduled for LETBI with the facility and to collect data on magnetic tape from patients who were being monitored during treatment in LETBI.

As part of the familiarization procedure, I would take the patient on a tour of LETBI, show them the sources, explain how the intercom, closed-circuit television and "umbilical" monitoring system worked. In discussing the umbilical cord, I always discussed how this was similar to those worn by astronauts and that monitoring data collected during their exposure would be analyzed by ORAU for NASA.

Every LETBI patient from whom monitoring data was collected was informed by me before treatment of the possible use of their data for NASA.

Mr. Chairman, that concludes my statement.

1022184

STATEMENT BY

Ann Sipe

CLINICAL NURSE, OUTPATIENT NUCLEAR MEDICINE
TECHNICIAN, RADIATION EMERGENCY ASSISTANCE CENTER/TRAINING SITE
OAK RIDGE ASSOCIATED UNIVERSITIES

before the

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
U. S. HOUSE OF REPRESENTATIVES

September 23, 1981

1022185

Mr. Chairman and members of the Committee: My name is Ann Sipe. I am clinical nurse with the ORAU Outpatient Nuclear Medicine program and technician at the Radiation Emergency Assistance Center/Training Center.

From 1967 until 1974, I was lab technician for the Low Exposure Total Body Irradiator (LETBI) at ORAU. My job was to familiarize the patients scheduled for LETBI with the facility and to collect data on magnetic tape from patients who were being monitored during treatment in LETBI.

As part of the familiarization procedure, I would take the patient on a tour of LETBI, show them the sources, explain how the intercom, closed-circuit television and "umbilical" monitoring system worked. In discussing the umbilical cord, I always discussed how this was similar to those worn by astronauts and that monitoring data collected during their exposure would be analyzed by ORAU for NASA.

Every LETBI patient from whom monitoring data was collected was informed by me before treatment of the possible use of their data for NASA.

Mr. Chairman, that concludes my statement.

1022186

STATEMENT BY

Ann Sipe

CLINICAL NURSE, OUTPATIENT NUCLEAR MEDICINE
TECHNICIAN, RADIATION EMERGENCY ASSISTANCE CENTER/TRAINING SITE
OAK RIDGE ASSOCIATED UNIVERSITIES

before the

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
U. S. HOUSE OF REPRESENTATIVES

September 23, 1981

1022187

Mr. Chairman and members of the Committee: My name is Ann Sipe. I am clinical nurse with the ORAU Outpatient Nuclear Medicine program and technician at the Radiation Emergency Assistance Center/Training Center.

From 1967 until 1974, I was lab technician for the Low Exposure Total Body Irradiator (LETBI) at ORAU. My job was to familiarize the patients scheduled for LETBI with the facility and to collect data on magnetic tape from patients who were being monitored during treatment in LETBI.

As part of the familiarization procedure, I would take the patient on a tour of LETBI, show them the sources, explain how the intercom, closed-circuit television and "umbilical" monitoring system worked. In discussing the umbilical cord, I always discussed how this was similar to those worn by astronauts and that monitoring data collected during their exposure would be analyzed by ORAU for NASA.

Every LETBI patient from whom monitoring data was collected was informed by me before treatment of the possible use of their data for NASA.

Mr. Chairman, that concludes my statement.

1022188

STATEMENT BY

Ann Sipe

CLINICAL NURSE, OUTPATIENT NUCLEAR MEDICINE
TECHNICIAN, RADIATION EMERGENCY ASSISTANCE CENTER/TRAINING SITE
OAK RIDGE ASSOCIATED UNIVERSITIES

before the

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
U. S. HOUSE OF REPRESENTATIVES

September 23, 1981

1022189

Mr. Chairman and members of the Committee: My name is Ann Sipe. I am clinical nurse with the ORAU Outpatient Nuclear Medicine program and technician at the Radiation Emergency Assistance Center/Training Center.

From 1967 until 1974, I was lab technician for the Low Exposure Total Body Irradiator (LETBI) at ORAU. My job was to familiarize the patients scheduled for LETBI with the facility and to collect data on magnetic tape from patients who were being monitored during treatment in LETBI.

As part of the familiarization procedure, I would take the patient on a tour of LETBI, show them the sources, explain how the intercom, closed-circuit television and "umbilical" monitoring system worked. In discussing the umbilical cord, I always discussed how this was similar to those worn by astronauts and that monitoring data collected during their exposure would be analyzed by ORAU for NASA.

Every LETBI patient from whom monitoring data was collected was informed by me before treatment of the possible use of their data for NASA.

Mr. Chairman, that concludes my statement.

1022190

STATEMENT BY

Ann Sipe

CLINICAL NURSE, OUTPATIENT NUCLEAR MEDICINE
TECHNICIAN, RADIATION EMERGENCY ASSISTANCE CENTER/TRAINING SITE
OAK RIDGE ASSOCIATED UNIVERSITIES

before the

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
U. S. HOUSE OF REPRESENTATIVES

September 23, 1981

1022191

Mr. Chairman and members of the Committee: My name is Ann Sipe. I am clinical nurse with the ORAU Outpatient Nuclear Medicine program and technician at the Radiation Emergency Assistance Center/Training Center.

From 1967 until 1974, I was lab technician for the Low Exposure Total Body Irradiator (LETBI) at ORAU. My job was to familiarize the patients scheduled for LETBI with the facility and to collect data on magnetic tape from patients who were being monitored during treatment in LETBI.

As part of the familiarization procedure, I would take the patient on a tour of LETBI, show them the sources, explain how the intercom, closed-circuit television and "umbilical" monitoring system worked. In discussing the umbilical cord, I always discussed how this was similar to those worn by astronauts and that monitoring data collected during their exposure would be analyzed by ORAU for NASA.

Every LETBI patient from whom monitoring data was collected was informed by me before treatment of the possible use of their data for NASA.

Mr. Chairman, that concludes my statement.

1022192

STATEMENT BY

Ann Sipe

CLINICAL NURSE, OUTPATIENT NUCLEAR MEDICINE
TECHNICIAN, RADIATION EMERGENCY ASSISTANCE CENTER/TRAINING SITE
OAK RIDGE ASSOCIATED UNIVERSITIES

before the

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
U. S. HOUSE OF REPRESENTATIVES

September 23, 1981

1022193

Mr. Chairman and members of the Committee: My name is Ann Sipe. I am clinical nurse with the ORAU Outpatient Nuclear Medicine program and technician at the Radiation Emergency Assistance Center/Training Center.

From 1967 until 1974, I was lab technician for the Low Exposure Total Body Irradiator (LETBI) at ORAU. My job was to familiarize the patients scheduled for LETBI with the facility and to collect data on magnetic tape from patients who were being monitored during treatment in LETBI.

As part of the familiarization procedure, I would take the patient on a tour of LETBI, show them the sources, explain how the intercom, closed-circuit television and "umbilical" monitoring system worked. In discussing the umbilical cord, I always discussed how this was similar to those worn by astronauts and that monitoring data collected during their exposure would be analyzed by ORAU for NASA.

Every LETBI patient from whom monitoring data was collected was informed by me before treatment of the possible use of their data for NASA.

Mr. Chairman, that concludes my statement.

1022194

STATEMENT BY

Ann Sipe

CLINICAL NURSE, OUTPATIENT NUCLEAR MEDICINE
TECHNICIAN, RADIATION EMERGENCY ASSISTANCE CENTER/TRAINING SITE
OAK RIDGE ASSOCIATED UNIVERSITIES

before the

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
U. S. HOUSE OF REPRESENTATIVES

September 23, 1981

1022195

Mr. Chairman and members of the Committee: My name is Ann Sipe. I am clinical nurse with the ORAU Outpatient Nuclear Medicine program and technician at the Radiation Emergency Assistance Center/Training Center.

From 1967 until 1974, I was lab technician for the Low Exposure Total Body Irradiator (LETBI) at ORAU. My job was to familiarize the patients scheduled for LETBI with the facility and to collect data on magnetic tape from patients who were being monitored during treatment in LETBI.

As part of the familiarization procedure, I would take the patient on a tour of LETBI, show them the sources, explain how the intercom, closed-circuit television and "umbilical" monitoring system worked. In discussing the umbilical cord, I always discussed how this was similar to those worn by astronauts and that monitoring data collected during their exposure would be analyzed by ORAU for NASA.

Every LETBI patient from whom monitoring data was collected was informed by me before treatment of the possible use of their data for NASA.

Mr. Chairman, that concludes my statement.

1022196

STATEMENT BY

Ann Sipe

CLINICAL NURSE, OUTPATIENT NUCLEAR MEDICINE
TECHNICIAN, RADIATION EMERGENCY ASSISTANCE CENTER/TRAINING SITE
OAK RIDGE ASSOCIATED UNIVERSITIES

before the

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
U. S. HOUSE OF REPRESENTATIVES

September 23, 1981

1022197

Mr. Chairman and members of the Committee: My name is Ann Sipe. I am clinical nurse with the ORAU Outpatient Nuclear Medicine program and technician at the Radiation Emergency Assistance Center/Training Center.

From 1967 until 1974, I was lab technician for the Low Exposure Total Body Irradiator (LETBI) at ORAU. My job was to familiarize the patients scheduled for LETBI with the facility and to collect data on magnetic tape from patients who were being monitored during treatment in LETBI.

As part of the familiarization procedure, I would take the patient on a tour of LETBI, show them the sources, explain how the intercom, closed-circuit television and "umbilical" monitoring system worked. In discussing the umbilical cord, I always discussed how this was similar to those worn by astronauts and that monitoring data collected during their exposure would be analyzed by ORAU for NASA.

Every LETBI patient from whom monitoring data was collected was informed by me before treatment of the possible use of their data for NASA.

Mr. Chairman, that concludes my statement.

1022198