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The United States Transuranium and Uranium Registries

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THE UNITED STATES TRANSURANIUM AND URANIUM REGISTRIES

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ABSTRACT

This paper describes the history, organization, activities and recent scientific accomplishments of the United States Transuranium and Uranium Registries. Through voluntary donations of tissue obtained at autopsies, the Registries carry out studies of the concentration, distribution and biokinetics of plutonium in occupationally exposed persons.

Findings from tissue analyses from more than 200 autopsies include the following: a

greater proportion of the americium intake, as compared with plutonium, was found in the skeleton; the half-time of americium in liver is significantly shorter than that of plutonium; the concentration of actinide in the skeleton is inversely proportional to the calcium and ash content of the bone; only a small percentage of the total skeletal deposition of plutonium is found in the marrow, implying a smaller risk from irradiation of the marrow relative to the bone surfaces; estimates of plutonium body burden made from urinalysis typically exceed those made from autopsy data; pathologists were unable to discriminate between a group of uranium workers and persons without known occupational exposure on the basis of evaluation of microscopic kidney slides; the skeleton is an important long term depot for uranium, and that the fractional uptake by both skeleton and kidney may be greater than indicated by current models. These and other findings and current studies are discussed in depth.

INTRODUCTION

The United States Transuranium and Uranium Registries are unique human tissue research programs whose origins date back more than four decades. In 1949, what the initiators described as ". . . a modest program of postmortem tissue sampling at autopsy . . ." was begun at what was then the Hanford site of the United States Atomic Energy Commission (1-3). This program called for collection of samples bone, lung, liver, and occasionally other tissues at autopsy from both Hanford workers and other residents of Richland, Washington, where most of the Hanford workers resided. Samples thus collected were radiochemically analyzed for plutonium with the goal being to evaluate sites of preferential deposition of plutonium within the body, and to compare what was observed in the tissues postmortem with what was predicted based on the application of biokinetic models to excretion data.

Not too surprisingly this study revealed very low levels of plutonium in the tissues of the local residents and Hanford site workers. Perhaps somewhat surprisingly, it also revealed that at least since 1962, most of the plutonium found in the tissues resulted from fallout from nuclear weapons tests, rather than occupational exposures. Although the highest individual tissue concentrations of plutonium were observed in the pulmonary lymph nodes of a worker with a history of occupational exposure, liver depositions were, in general, greater than those in the lung. Data for the bone samples collected were equivocal, and this initial report of nearly 20 years concluded with a plea for further investigation and collaboration with other plutonium handling facilities.

The initial formal presentation of the Hanford autopsy study was presented at the Seventh Annual Hanford Symposium on Biology Symposium held in Richland in May 1967, nearly twenty years after the study had begun (3). Coincidentally, the concluding paper at that same meeting was given by H. D. Bruner of the Atomic Energy Commission Division of Biology and Medicine, who while graciously noting that the idea was not his or any one persons, but rather "occurred to many men about the same time", proposed formation of a national Plutonium Registry and described progress towards that goal within the AEC (4). The primary purpose of the Registry as outlined by Bruner would be to ensure that the details of an accidental intake of plutonium could be correlated with the subsequent health record of the worker. In addition to sketching the basic information and operating requirements for such a registry, he also listed seven additional purposes, noting among these that the Plutonium Registry should not be limited to plutonium but should also consider other transuranium elements as well (4).

HISTORY OF THE REGISTRIES

The USTUR thus grew out of a desire to better understand the potential health effects from plutonium incorporated into the human body, gaining not only improved understanding of the health effects of plutonium but also of the efficacy of control measures based on actual human experience. The progenitor of what is now the USTUR was formally established in August 1968 as the National Plutonium Registry by the Hanford Environmental Health Foundation (HEHF) under contract to the United States Atomic Energy Commission (AEC).

W. Daggett Norwood, a physician whose undergraduate education was in electrical engineering, and who had figured prominently in the establishment of the medical program at the Hanford site, was appointed the founding director. He was ably assisted by Carlos E. Newton, Jr., Battelle-Northwest, a board certified physicist who carried the title of consultant and who directed the health physics aspects of the program. Rounding out the staff was Dorothy Potter, who served as secretary and general administrative assistant.

Even before the contract award had been finalized, Philip A. Fuqua, then medical director of HEHF, sent out invitations in an effort to set up a blue ribbon Advisory Committee to help guide the fledgling Registry. The six initial Committee members included J. H. Sterner, a physician from the University of Texas, and Robley D. Evans, the MIT physics professor noted for his studies of the radium dial painters were elected as Chairman and Vice-Chairman, respectively. The other Committee members were toxicologist Lloyd M. Joshel, Dow Chemical Company; physician Clarence C. Lushbaugh, Oak Ridge Associated Universities; Thomas F. Mancuso, another physician, University of Pittsburgh; and noted medical and health physicist

Herbert M. Parker, Battelle-Northwest. Wright Langham, the Los Alamos National Laboratory biophysicist who many acknowledged as "Mr. Plutonium" was added the following year.

By the end of its first year, the Registry had, with the aid of the Advisory Committee, established its basic operating and had begun recruitment of registrants, signing up three individuals that year. The following year, 1970, the name was changed to reflect the broader programmatic concern with the other transuranic elements as had been suggested in the prescient talk by Brunner a few years previously (4).

With the passing of the AEC in 1972, support for the program was continued, first by the U.S. Energy Research and Development Administration, and most recently by the Office of Health and Environmental Research of the United States Department of Energy (USDOE). The United States Uranium Registry (USUR), was established as an administratively separate although similar program, ten years later in 1978 by HEHF for the USDOE. The USUR is concerned with understanding the biokinetics, dosimetry and health aspects of exposure to uranium and its daughters, with emphasis on the uranium fuel cycle.

Although there were considerable overlaps in function and staff, each Registry was operated as a separate program administered by a half-time physician-director with scientific support for both Registries provided by a half-time health physicist consultant from Battelle-Northwest. With the exception of tissues obtained from cases originating at the USDOE Rocky Flats Facility, which were analyzed at that facility, radiochemical analyses of tissues were initially performed by Battelle. However, in 1978, responsibility for radiochemical analysis of tissues was turned over to Los Alamos National Laboratory (LANL) under a separately administered program; the Rocky Flats Facility continued to perform the analyses on tissues

originating there until the late 1980's when funding and other considerations dictated their withdrawal from this activity.

Early efforts of the Transuranium Registry were directed towards identifying suitable populations of persons with occupational experience with plutonium and the higher actinides. Once these populations had been identified, workers were informed of the purposes of the Transuranium Registry and their voluntary participation as registrants solicited. More than 1000 persons were ultimately registered (a number that has been reduced over the years as additional knowledge and experience were gained) and by 1975, the results of 30 autopsies and tissue analyses were reported in the refereed literature. (5) As of October 1, 1991, the Transuranium Registry had 467 living active registrants, including five whole body donors with depositions estimated to be greater than 1.5 kBq, and had received tissues (autopsy or surgical specimens) 265 donors, including 9 whole body donations.

A similar strategy of recruiting registrants was adopted by the Uranium Registry subsequent to its establishment, but has not been nearly so successful. As of October 1, 1991, the Uranium Registry had 32 living registrants, and had received tissues from one surgical case and 12 postmortem donors, including one whole body donor. The total cohort of registrants, summarized by individual registry and birth decade, is presented in Table 1.

Table 1

BIRTH COHORT DISTRIBUTION OF LIVING REGISTRANTS

Birth Decade	Number in Cohort Total	USTR	USUR
1900-1909	13	10	3
1910-1919	97	89	8
1920-1929	192	178	14
1930-1939	85	84	1
1940-1949	32	32	0
1950-1959	7	7	0
No Birth Date	73	67	6
TOTALS	499	467	32

THE REGISTRIES: 1992 AS A YEAR OF CHANGE

In February, 1992, the USDOE awarded a three year grant for $3.76 million to Washington State University (WSU) for management and operation of the Registries. This was an important step in the continuing evolution of the Registries and brought with it significant changes. The grant calls for management and operation of the Registries as a single entity rather than as parallel but administratively separate research programs. In addition, the radiochemistry support now provided by Los Alamos National Laboratory under separate contract to the USDOE will be carried out under subcontract with the University beginning with the second year of the grant, thereby providing fully integrated management for the entire program.

Combined management and operation of the Registries and the radiochemistry operations at LANL should not only provide for better integration and centralized control of the programs, but should also reduce overheads and direct operating costs. One obvious benefit is the elimination of redundant efforts, forms, and other duplications arising from the existence of two separate Registry entities.

In addition, there are significant other advantages. These include enhanced opportunities for collaboration with the broad spectrum of faculty available at a major research university. In particular, WSU offers some unique opportunities in this regard through its Health Research and Education Center (HREC) of which the Registries are part. The HREC was created by the Washington State legislature in 1989 to carry out research in biomedical and social health. Medical support for the Registries is provided through HREC, which, in conjunction with the WSU Electron Microscopy Center, offers unique opportunity for histopathology studies utilizing the Registries collection of microscopic pathology materials. Other opportunities include the

specialized analytical capabilities including an ICP mass spectrometer and a 1 MW TRIGA-fueled reactor for neutron activation analysis.

Perhaps the most innovative and potentially advantageous aspect of the transfer of the program to WSU is the integration of the Registries into the academic programs of the University, thereby providing a mechanism for training students in health physics and radiobiology, two disciplines historically in short supply. Conventionally, support for students in health physics has been via a grant or fellowship directly to the student, normally (but not always, depending on the fellowship) with an equal amount provided to the institution. The USDOE fellowship program is by far the largest, and supports about two dozen graduate students annually. Each receives $15,000 per year for support, with the institution receiving a similar amount. Typically, only one or two fellowship students attend any given institution, and the institutional grant, although generous on a per student basis, is insufficient in toto to support even a single faculty member let alone an entire program.

By providing direct faculty research support, as is the case with the Registries grant, a critical mass of faculty can be readily achieved, and the opportunity for student thesis research is created. Hence, students can be more readily informed of and attracted to these disciplines. In addition, the grant provides support (including tuition) for two half time student research assistants, with the actual annual outlay for each of these students is about $15 thousand or half of what the cost would be if the conventional fellowship mechanism were used. And, as an added bonus, these two students provide invaluable assistance in furthering the research carried out by the Registries.

Finally, mention should be made of one additional benefit attributable to the location of the program at a major university: enhanced credibility and academic freedom. In recent years, government and government funded programs have been subjected to increasing scrutiny from the public as well as their peers. Not surprisingly considering the nature of the research, which involves postmortem collection and analysis of tissues from workers known to have had intakes of plutonium or other actinides, the Registries have not been immune from such scrutiny and inquiries by the media. Therefore, it is essential to ensure that the scientists performing the work are unfettered by the funding agency in the scientific conduct of the program, and that the research is carried out in an open and ethical fashion. As the USDOE has recognized, this is best accomplished through a grant to an independent and recognized research university.

Administratively, the Registries are centered on the Tri-Cities campus of Washington State University, with specialized laboratory and medical support staff located in Spokane. The Registries staff includes three full time faculty members -- two radiobiologists and a health physicist who serves as Director. This nucleus of researchers is supported by two half-time graduate student research assistants and a full time administrative assistant. Medical support is provided by the Director of the WSU Health Research and Education Center, a full time faculty member who devotes a portion of his time to serve as the Registries medical director. Radiochemistry support is provided by LANL under direct contract to the USDOE, and includes two professional radiochemists with special expertise in actinide chemistry and one technician. As noted above, with the commencement of the second year of the grant in February 1993, the radiochemistry operations will be administered directly by the Registries via a subcontract with LANL.

The grant also provides for the addition of a fourth faculty member and third half-time student research assistant in the third year of the grant. Plans are also now being considered to add another faculty member and half-time research assistant to manage and operate the National Human Radiobiology Tissue Repository.

RESEARCH OBJECTIVES OF THE REGISTRIES

The primary objective of the Registries is to ensure the adequacy of radiation protection standards for the actinide elements, verifying or modifying, as appropriate, the existing biokinetic and dosimetry models on which the standards are based. This is accomplished by a carefully structured program of research designed to evaluate the distribution, concentration, and biokinetics of the actinide elements in human. Tissues collected at autopsy from volunteer donors with a history of exposure to the actinides are radiochemically analyzed to determine their content of actinide nuclides. These results are evaluated along with radiation exposure and medical histories, and compared with estimates of body, lung, and other organ burdens made during life with measured postmortem deposition to assess the validity of biokinetic and dosimetric models on which the standards are based, and to develop refinements or modifications to these models based on actual human experience. In addition, the Registries also compare the results of animal experiments with those obtained from the human tissue studies to gauge the validity of interspecies comparisons. Another important function is the evaluation of histopathology slides and other specific human data to assess toxic changes possibly attributable to actinide exposure, and to provide basic data for the determination of risk coefficients for radiation exposure.

Finally, the Registries act as a repository for information on internal deposition of actinides in man, and encourage and carry out collaborative research with other scientists. During the 1991-92 time frame, active collaborations were being carried on with no less than 15 institutions (Figure 1). Collaboration with and direct assistance to other researchers will be facilitated through the creation of the National Human Radiobiology Tissue Repository for

radiological specimens. In addition to solutions of tissues, histopathology slides and blocks and remaining analyzed tissues from USTUR cases, this Repository will contain tissues collected by Argonne National Laboratory for the Radium Dial Painter Study. This unique collection of human tissue materials, plus other donated tissues collected from persons with a history of radioactivity intake, will be available for collaborative or individual study, to scientists studying the effects of radioactivity in man, or working in other areas.

U.S. Transuranium & Uranium Registries

Collaborating Research Institutions, 1991-92

- Argonne National Laboratory
  - Surface Deposition of Actinide in Human Bone
  - Oncogene Studies
- Georgetown University
  - Postmortem External Radioactivity Measurement, Case 1001
- Inhalation Toxicology Research Institutute
  - Autoradiography and Microscopic Examination of Respiratory Tract, Case 246
  - Histopathology Study of Osteosarcoma, Case 262
- Lawrence Berkeley Laboratory
  - Soft Tissue Autoradiography, Case 246
- Los Alamos National Laboratory
  - Radioochemical Analysis of Tissues
  - Numerous Special Projects and Studies
- National Cancer Institute
  - Risk Estimates and Epidemiology of Thorotrast
  - Evaluation of Case 1001
- National Institute of Standards and Technology
  - Radiochemical Intercomparison Studies and Development of Standard Reference Material—Human Bone
- National Naval Medical Center
  - Medical, Autopsy and Postmortem Radioactivity Measurements, Case 1001
- National Radiological Protection Board (Great Britain)
  - Distribution of Actinide in Human Bone
  - Autoradiography of Bone
- Pacific Northwest Laboratory
  - Biokinetic Modeling of Uranium
  - Actinide Distribution in the Human Skeleton
  - Comparison of Skeletal Actinide Distribution in Humans & Animals
  - Distribution of Actinide in the Respiratory Tract
  - Postmortem Direct Radioactivity Measurements, Cases 246 and 1001
  - Soft Tissue Autoradiography Studies
- Saint Mary's Hospital
  - Data Base Automation, Uranium Miner Lung Cancer Study
- United Kingdom Occupational Radiation Exposure Study (UNIKORNES)
  - Assistance with Establishment of British Registry
- University of California, Davis
  - Scanning Bone Density Study
- University of Pittsburgh
  - Distribution of Actinide in the Respiratory Tract
- University of Washington
  - Diurnal Excretion of Uranium

Figure 1

OPERATION OF THE REGISTRIES

The basic Registries operation can be described in terms of a five step process. The first step, identification of potentially suitable donor populations or individuals, has historically been accomplished through contacts made via the employer of the potential registrant, since virtually all exposures of interest are incurred in the workplace. Whether done on a group or individual basis, as might be the case with an individual specifically identified by the plant medical or health physics staff as of potential interest to the Registries, the mechanism is essentially the same. Through their employers, potential registrants are provided with general information about the Registries, and invited to contact the Registries directly, either by collect telephone call or postage paid card, if interested.

The next step is the actual enrollment process. Once a positive expression of interest has been received by the Registries, the purposes and operations of the Registries are again explained orally and in more depth, and the individual is provided with a detailed written description of the program. If the potential registrant remains interested, specific information regarding his/her exposure history is sought to determine if he/she will make a suitable donor. Suitability is largely a matter of prior exposure history; acceptance criteria are based on a documented and confirmed deposition or intake of one or more actinide nuclides, typically at levels of a few tens of Bq or greater. If the potential donor desires to become a registrant and is acceptable to the Registries, formal voluntary donation and acceptance is accomplished through the completion of informed consent, permission for autopsy, and medical and health physics records release forms.

Registrants enrolled in the program are sent a brief letter annually to update them on the status of the Registries and to request updated information regarding changes in address or employment. Autopsy permissions or whole body donation forms are renewed on a five year cycle at which time new informed consent forms are also obtained. Each registrant is issued a personal dated identification card, and, if desired, a Medic Alert registration and identification bracelet or necklace is obtained.

Registrants are enrolled as either routine autopsy or whole body donors. Whole body donors are volunteers with depositions typically exceeding 150 Bq and who have a well documented exposure history or other characteristics that would make them of scientific interest. This, along with a natural reticence to make a whole body donation as compared with an autopsy, severely limits the pool of potential whole body donors, and most volunteers are therefore accepted as routine autopsy donors.

The next step in the process involves the actual collection of tissues. This is normally accomplished postmortem except for those few instances in which surgical specimens may be collected, or the individual may be a participant in a special study that involves the collection of excreta or blood during life. The postmortem tissue collection protocol of the USTR evolved on the basis of experience and availability of cases. Initially, samples were routinely obtained of lung, tracheobronchial lymph nodes, liver and bone. (1,6,7). After the first few autopsies, the collection protocol was expanded to include the entire liver and both lungs plus samples from one or more of the following: thyroid, kidney, spleen, gonads, muscle and fat. Further experience with the autopsy procedure and subsequent radioanalytical results led the development

of an expanded formal autopsy tissue collection protocol as described by Breitenstein (1) and Kathren (8) which has recently been refined and is detailed in Table 2.

The Registries also request paraffin blocks or prepared histopathological slides of the various tissues collected. These are typically examined at autopsy by the private pathologist performing the autopsy. Slides and blocks are saved and made part of the National Human Radiobiology Tissue Repository.

All tissues collected are subject to radiochemical analysis to determine their actinide content. These data, are accordingly entered into a newly developed computerized data base and evaluated on an individual case basis as well as collectively along with relevant information relating to exposure, excretion and bioassay data collected during life, medical history and autopsy results to gain additional understanding of the distribution, biokinetics and dosimetry of the actinides from actual human experience.

Table 2

Routine Autopsy Tissue Collection Protocols of the U.S. Transuranium and Uranium Registries

Tissue

- Lungs (entire, with associated nodes)
- Lymph Nodes (Hilar)
- Liver (whole or minimum of 400g)
- Bone:
  - Ribs (one or more, typically
    - left 6 and 7 and
    - excluding 1,2,11,12)
  - Sternum (whole)
  - Vertebral wedge (lumbar, 3 contiguous)
  - Patella (both)
  - Clavicle (one)
- Spleen (whole)
- Kidneys (both)
- Ovaries or testes (both)
- Prostate
- Rectus muscle*
- Body fat*
- Stomach*
- Esophagus*
- Thyroid*
- Heart*
- Tumor *
- Wound Site and Associated Nodes

*Sample: ≥ 20g

TOWARDS IMPROVED BIOKINETIC MODELS FOR PLUTONIUM AND AMERICIUM

To assure the adequacy of radiation protection standards for the actinides and thus achieve the basic goal of the Registries, it is essential that the standards be based on sound biokinetic models. Accordingly, much of the research effort of the Registries has been directed towards biokinetic, or, as they have sometimes been called in the past, metabolic models. A major step was taken with the evaluation of the first whole body donation, which was published as a compendium of five papers constituting the entire October 1985 issue of Health Physics. (8) This case, identified as USTUR Case 102, involved a chemist who had incurred an accidental deposition of ^{241}Am as a result of a wound some 25 y prior to death. At the time of death, his measured total body burden was 5.5 kBq (147.4 nCi) of ^{241}Am, of which more than 80% was resident in the skeleton with only about 7% in the liver. (9) This distribution pattern differed significantly from that predicted by the then current ICRP model, which predicted more nearly equal amounts in the skeleton and liver. (10) The postmortem radioassay data, along with bioassay and other health physics information obtained during life were used to develop and evaluate a new five compartment model for ^{241}Am based solely on human data. (11) One of the key features of this model was a retention half-time of only 2-3 years for ^{241}Am in the liver, as contrasted with the then accepted values of 40 years based on analogy with Pu and animal data.

Further support for a retention half-time of 2-3 y for ^{241}Am in liver, was obtained from a subsequent study of the relative distribution of ^{238}Pu, ^{239}Pu and ^{241}Am in the skeleton and liver of occupationally exposed individuals, using tissues obtained at autopsy by the USTR. (12) This finding of a shorter effective clearance time for ^{241}Am in liver has significant implications for

the dose delivered to the liver from a given intake of Am and hence the radiation protection standards for that nuclide.

Other recent and continuing work of the Registries deals directly with the application and evaluation of the validity of existing biokinetic models. (13-15) One such study compares estimates of systemic deposition made by six laboratories using urinalysis data on a series of 17 individuals were compared with estimates made on the basis of postmortem radiochemical analysis of tissue. (13) Typically, the estimates made by the six laboratories were in good agreement with each other, but were consistently greater than the estimates made from postmortem tissue analysis. The deviation between the urinalysis and autopsy estimates appeared to be inversely related to the level of Pu in the body -- i.e the smaller the estimated deposition, the greater the ratio of the urinalysis to autopsy estimate with convergence of the two occurring at estimated burdens of about 1 kBq.

Another recent study involving comparison of premortem and postmortem estimates of plutonium in skeleton and liver was carried out jointly by the Registries and the Pacific Northwest Laboratory. (14) Skeletal and liver depositions of six former workers at the Hanford site were evaluated using an empirically developed model for internal use based on that of Jones (15) and ICRP Publication 48 (16). Organ burdens estimated from urinary excretion data were found to be roughly consistent with those made from postmortem tissue analysis. Individual estimates were within a factor of 3 for skeleton and a factor of 5 for liver, and were within a factor of 2 for skeleton and liver combined. However, in general, urinalysis estimates of skeletal deposition tended to be greater than autopsy estimates, while the converse was true for the liver.

A more recent study compared estimates of plutonium deposition calculated with various biokinetic models with actual measurements of the plutonium content of the whole body after death (13). This was done with five whole body donations to the Registries. The urinary excretion data from these cases were used with several models to obtain estimates of systemic deposition, and these results compared with the values measured in the tissues by postmortem radiochemical analysis. In general, the estimates made with the earlier models were severalfold greater than the comparable postmortem measured values, and consistent with what would be expected on the basis of the previous intercomparison study. Estimates made with more recent models such as those put forth by Jones (15), Leggett (17) and Leggett and Eckerman (18), were generally in close agreement with the measured postmortem values.

Recently, the Registries utilized date from postmortem analysis of whole body donations to develop a new biokinetic model for ^{241}Am. The new model can be compared with that put forth in ICRP Publication 48, which is the generally accepted model (16). The ICRP 48 model assumes that once the ^{241}Am reaches the transfer compartment -- i.e. is absorbed -- 45% is deposited in the skeleton and 45% in the liver with half-times of 50 and 20 years respectively. The remaining 10% is characterized as going to early excretion. Thus, the fractional long term deposition, R(t) at t years after intake can be characterized by the following two compartment exponential equation:

$$R(t) = 0.45e^{-0.014t} + 0.45e^{-0.035t} \qquad (1)$$

By contrast, the Registries model (19), based on actual human data, uses the parameters expressed in Table 3, and can be expressed in terms of a three compartment exponential equation:

$$R(t) = 0.45e^{-0.014t} + 0.025e^{-0.28t} + 0.30e^{-0.069t} \qquad (2)$$

Table 3

Biokinetic Parameters for ^{241}Am

Compartment	Fractional Uptake	Residence Half-time
Skeleton	0.45	50 y
Liver	0.25	2.5 y
Muscle	0.20	10 y
Rest of body	0.10	10 y

Similarly, a new model can be developed from the whole body data for plutonium as reported and compared with the ICRP Publication 48 model in current use (16). ICRP 48 uses the same biokinetic constants for both Am and Pu, and hence the mathematical representation is identical for both and is characterized by Equation (1). Using the radiochemical data from five whole body cases (20) along with health physics measurements and information of when the intakes may have occurred, the biokinetic parameters shown in Table 4 were developed for plutonium, and lead to the mathematical representation shown in Equation 3:

$$r(t) = 0.4e^{-0.014t} + 0.4e^{-0.035t} + 0.2e^{-0.069t} \qquad (3)$$

The differences between the ICRP model for both Pu and Am characterized by Equation (1) and the Registries Equation (2) for Am and Equation (3) for Pu are significant, and should lead to refinement and improvement in the estimation of in vivo deposition and dose estimates.

Table 4

Biokinetic Parameters for ^{239}Pu

Compartment	Fractional Uptake	Residence Half-time
Skeleton	0.4	50 y
Liver	0.4	20 y
Muscle	0.2	10 y

IN CONCLUSION

The human tissue studies of the Registries are important to understanding the mechanisms by which the actinide elements move throughout the body and are of potential immediate practical application to the safe use of uranium and the transuranium elements by man. Perhaps the most important application is the verification or indicated refinement of existing biokinetic models upon which internal dose calculations and radiation protection standards are based. Another important practical application is the verification of operational health physics estimates of deposition made by in-vivo counting or other bioassay techniques. Tissues from persons with radioactivity uptakes are of enormous potential value in the study of oncogenes and biomarkers, as well as for more traditional studies of possible radiation induced pathology. The increased understanding of the biokinetics, measurement, dosimetry, and biological effects of actinides in man promised by the human tissue studies of the Registries is essential to maintaining and ensuring a suitably safe workplace for those involved with the various actinide elements; no amount of animal data, circumstantial evidence, or calculation can provide the assurance that the radiation protection standards applied to humans are, in fact, both safe and reasonable. We can only be certain that our understanding of the actinides in humans is correct if it has in fact been gained from the proper study and interpretation of actual human experience.

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APPENDIX A

UNITED STATES TRANSURANIUM AND URANIUM REGISTRIES MANAGEMENT (April 1991)

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APPENDIX B

1991 REPORT OF THE ADVISORY COMMITTEE TO THE U. S. TRANSURANIUM AND U. S. URANIUM REGISTRIES

Meeting Held On November 13-14, 1991
Richland, WA

The following members of the Advisory Committee were present: George L. Voelz (Chairman), Keith Schiager, J. Newell Stannard, Langan W. Swent, and Roy C. Thompson. Dr. Kenneth G. W. Inn was absent. Dr. Willard Meader, HEHF President, attended most of the sessions. Dr. Ross Ronish, newly appointed HEHF Director of Research; Ronald Kathren, Director of the Registries; Dr. Scott Dietert, Medical Director of the Registries, and Ronald Filipy attended all sessions. Barbara Brooks represented the Office of Epidemiology & Health Surveillance, Dept. of Energy . The DOE/Richland Operations Office representatives were Gerry Yesberger and Diane Clark. Outside participating collaborators of the Registries were James McInroy, Principal Investigator of the Los Alamos Tissue Measurements program, and Robert Bistline, Representative from the Rocky Flats facility. The meeting was conducted as an informal working session of the Committee and the staff of the combined Registries in order to encourage an unrestricted exchange of information and ideas. The agenda is given in Appendix I.

Noteworthy administrative items brought to the attention of the Advisory Committee are listed here.

- Kathren's responsibilities during the past year included those as the Acting HEHF Research Director. This appointment took a significant amount of his personal time from Registry activities. This situation has changed with recent appointment of Dr. Ronish as HEHF Research Director.
- The offices of the Registry will soon be moved from the main HEHF medical building to commercial office space.
- A significant effort by the staff involved an audit on the status of individual registrant records and autopsy permits. It was noted that many registrants had been dropped because of changes in criteria through the years, but they are still carrying early undated Registrant membership cards. Confusion can result when workers and worker's families find out later that they are no longer listed as registrants.
- Two new Registry policies were approved during 1991. The subjects are Guidelines for Scientific Research Practices and Scientific Advisory Committees. Draft policies reviewed at this meeting were Criteria for Registrant Selection, Autopsies on Registrants, Communications (response to queries), Registrant Enrollment and Renewal.
- Awareness of biosafety for persons working with human tissue was increased in the past year. Protection

against hepatitis B and HIV viruses is principally through the use of protective clothing and conduct of safe work procedures. Immunization against hepatitis B is offered to workers at risk as an additional protection.

- Recruitment activity has been low and more needs to be done. Examples of possible attractive registrants are two workers with curium exposure at Savannah River.
- Currently there are 499 living registrants: 467 in USTR and 32 in USUR. A total of 29 workers have given whole body permits; 19 of these persons are now over 70 years of age. Of the whole body volunteers, about 12 cases are considered to have good scientific prospect based on work histories and exposure.
- Program protocol has been submitted to the HEHF Institutional Review Board for annual review and approval. Authorization has not yet been received but no problems have been identified. Subsequently, the protocol is also reviewed by DOE staff and consultants.
- The Registry staff is involved in an effort to publish a collection of WWII statements and memories on the history of plutonium research from Dr. Glenn Seaborg.
- The potential impact of publicity by news media reports on work of the Registry has been considerable this year. Two major examples of television programs include a program on 60-Minutes and the Geraldo Riviera program entitled "Invasion of the Body Snatchers". These two programs were viewed by the Advisory Committee.

The HEHF staff has been made aware that the DOE Office of Health is considering an unsolicited proposal from Washington State University to administer the activities of the Registries program for the DOE. The proposal is stated to include an intention of the University to transfer the Registry staff persons with the program, if they are agreeable to this. This informal and limited information was received by the Committee without consideration or recommendation.

Actions taken on recommendations made by the Advisory Committee at the 1990 meeting were reviewed. Most of recommendations had favorable action and details were included in presentations. Several recommendations with little or no action during the year are listed:

- No. 2: The need for a tissue dissection laboratory has not been satisfied because the proposed use of a portion of the Emergency Decontamination Facility was not approved. No action is proceeding at the present time. Existing freezer equipment cannot be moved into their new office quarters and a suitable new freezer needs to be obtained.
- No. 5: The recommended staff visits to relevant DOE contractors on behalf of Registry programs were not

accomplished this past year and remain on the "to do" list.

- o No. 6: Separate budget proposals by the Los Alamos Radiochemistry Group for necessary special work as a means to enhance funding for the analytic program was not tried during the year. Progress is being made on some of the special work, such as, calcium analyses on bone samples.
- o No. 8: More work needs to be done to develop a file of procedures used by the Registry and its collaborators.
- o No. 15: Advice on the manner of publication of bone sample data until calcium analyses are available was a moot point because no publication of this nature was made.
- o No. 17: A few USUR registrants were added in FY 1991, but progress on recruitment has been slow.

Ron Filipy presented an update on the development of a Registry database using Paradox PC software. General features and requirements of the system were presented. The database currently consists of three individual data partitions: administrative data, premortem data, and postmortem data. Screen prints from each part were used to illustrate the current set of data items planned for the system.

Brief presentations were made on several technical projects and possible areas of new work. The principal topics were:

1) Results of the thorotrast study on USUR Case 1001 will be published in Health Physics (June or July 1992 issues).

2) Excretion of uranium in urine is the subject of a student project. Variables include diurnal and individual variations.

3) Data on Pu transfer through the placenta may be attained through study of an exposed female who had a miscarriage in late 1990. Internal deposition in this case appeared to be very low.

4) Development of human bone standard for various radionuclides (^{239}Pu, ^{238}Pu, ^{241}Am, ^{232}Th, ^{228}Th) is a collaborative effort between staffs at the National Institute of Standards and Technology, Environmental Measurements Laboratory (DOE), Los Alamos, and the Registries. The current plan is to produce about 1000 bottles containing 15 g of bone ash with 1 mBq/g of activity for each nuclide.

5) Ideas for potential new projects included studying bone densitometry measurements for correlation with calcium analyses and DNA analyses of tissue blocks.

6) The Registries are evaluating the pros and cons for developing a Human Tissue Repository. The concept considers some 14,000 samples (mostly in solutions) from Los Alamos, about 6000 tissues of radium dial painters at Argonne, and perhaps uranium tissues and pathology slides (St. Mary's Hospital, Grand Junction).

7) The prioritized project list was reviewed and discussed.

James McInroy reviewed the progress of radiochemistry analyses done at Los Alamos in FY1991. During the year, the

laboratory received 8 routine autopsy cases and 3 whole body cases. The whole body cases involve osteogenic sarcoma (Pu exposed), primary liver cancer (Am exposed), and a person with uranium exposure history. Analytic work on the thorotrast whole body case has been finished and results are being written up. Funding continues to be a serious problem with a FY 1992 budget of $520k, a reduction of about 20% from FY 1991. As a result of the Tiger Team recommendations, a shutdown of analyses for about 6 months will be necessary.

Robert Bistline, EG&G Rocky Flats, reported on recent developments at Rocky Flats, which include a major effort on beryllium surveillance of present/past employees and a revised radiation monitoring program. He is now working in a newly organized Health Effects Department (Dr. Duane Hillnus, Director). Bistline requested that an updated list of registrants be sent to him because he does not know which RF persons are currently on the Registry books. A new whole body case of special interest (^{239}Pu systemic burden and lung burden of 217 and 30 nCi respectively) has been registered. A walk-in freezer previously used for Registry purposes has been assigned to the environmental program and is no longer available. He has a serious concern that a transfer of the Registry program to Washington State University may cause case recruitment problems because of a perception of potential privacy issues.

At the end of the meeting, tentative recommendations were presented in a verbal report to the HEHF staff. Based on the presentations and discussions of the agenda items, which are not all summarized here, the Committee makes the following recommendations.

General Recommendations:

1. FIVE-YEAR PLAN

The Committee believes planning of staffing, budget proposals, and work schedules might be improved by careful preparation of a five-year work plan. This projection should include an estimate of the workload based on projected death rates of current registrants. The plan should also develop a long range set of priorities and major scientific questions to be addressed by work of the Registry. Key obstacles and difficulties in meeting objectives should also be addressed.

2. NEED FOR TISSUE DISSECTION LABORATORY SPACE

This holdover recommendation from last year emphasizes the need to identify and procure suitable space for handling Registry samples. This unsatisfied physical requirement should be treated as an important obstacle to performing the necessary and unique work of the Registry.

3. DETERMINATION OF SUITABLE WHOLE BODY CASES

Individual registrants for whole body donations should be evaluated in a timely fashion as to the importance and suitability of the case in addressing the scientific questions under study by the Registry. It is thought that this review could be expedited by using a limited set of data on work history, dosimetry, and items of special, relevant medical history. The purpose of this evaluation is to avoid a last minute determination that a particular case is not suitable. It would be preferable to make this decision at an earlier time and notify the registrant if the Registry does not plan to accept the donation. This evaluation could be included in paragraph 4 of the draft policy on "Autopsies on Registrants".

4. DOCUMENTATION FILE ON AUTOPSY PERMITS

Permission to obtain tissue samples for research from either autopsy or surgical cases has been receiving increasing scrutiny and public sensitivity for several decades. Through the years the Registry has collected data on Pu measurements in human tissues from a number of collaborators and outside investigators in addition to Registry permitted cases. It is important in all cases to assure that appropriate permission was obtained for autopsy and surgical samples and the history of permission is recorded.

It is recommended that the Registry review its procedures for documenting the permit authority used to obtain autopsy and surgical samples. On outside cases or special cases from collaborators, the record should provide details on the source of the case and the type of permit authority used in each case, such as routine pathology/hospital permission forms, Registry permission forms, coroner's case, or others. For Registry cases, the file should contain the signed permit for each case as well as details as to any unusual circumstances under which Registry samples were procured, including any special arrangements or constraints.

5. RELATIONSHIP WITH DOE CONTRACTOR'S MEDICAL, HEALTH PHYSICS, AND MANAGEMENT PERSONNEL

This holdover recommendation recognizes again the need for the Registry staff to visit the relevant DOE contractor sites in order to increase awareness of the Registry programs, explain objectives of the programs, upgrade contacts with DOE contractor personnel, explain the current criteria for registrants, and discuss the need for premortem exposure histories. During the past few years there has been significant turnover of both the Registry staff and the DOE contractor staff in medical and health physics departments, which makes this recommendation particularly timely. The site visits should be made jointly by medical and health physics staff. The Registry should give the Contractor

management a current list of registrants. The list should be marked and maintained as an "Official Use Only" confidential document. An awareness should also be kept to identify persons of special interest to the Registry. It is hoped that this activity would lead to a review of current and potential registrants at these sites.

6. REVIEW OF AUTOPSY PERMIT RENEWALS

The Committee feels the renewal period for autopsy authorization should not be shortened to less than the current 5 year period, a consideration under current discussion by the Registry staff. In fact, consideration might be given to possibly lengthening the renewal period. This suggestion is based on the assumption that an outdated approval may result in the potential loss of cases or at least some administrative embarrassment of renewal at the time of a registrant's demise. Contact with registrants with news or reports on registry activities can and should be done at shorter intervals and not be regulated by the renewal period.

At times of contact with registrants or renewal of authorizations, the Registry should try to ascertain an estimated date of retirement or any known plans for termination of employment. This information would allow the Registry to request health physics and medical record information from the DOE contractor at a time when it is still readily accessible and complete.

7. DEVELOPMENT OF REGISTRY DATABASE

Review of the current screens of the registry database resulted in discussion of a large number of suggestions, too many to reiterate here. A few more important examples are:

a) include former Registry identification numbers and the Comprehensive Epidemiology Data Resource (CEDR) number,
b) improve flexibility for multiple values in various fields, such as, multiple work sites (contractors), multiple exposure histories, renewal dates (retain former dates), and autopsy types (allow use of surgical specimens and autopsy types for same individual).
c) include original registration date
d) include current status (active, inactive)
e) include data on known significant accidental exposure and mode of intake (wounds, inhalation, ingestion).
f) add information on significant occupational exposures other than radiation (Be, asbestos, etc.)

The Committee sensed that more fundamental work on the database is needed. Such work would include a statement of the proposed uses of the database(s); evaluation of the input, analytical, and output requirements for these uses; and an estimate on the number of cases needed for various applications.

The work on the database would probably benefit by involving reviewers of several disciplines. One means of achieving this result might be to form a technical review committee that could be sent proposed plans periodically for review and comments.

Another area of concern was the issue of computer security, particularly as it relates to modem access. Modem access is proposed for communication with the Los Alamos tissue laboratory. Continued use of a computer security specialist is needed throughout the planning and development of the database.

8. SAMPLING PLANS FOR WHOLE BODY CASES

A review of the appropriate sampling plan for future whole body cases should be made. The Committee feels this issue is becoming more urgent each year, because of increasing limitations on analytical capacity. Each whole body case results in 300 to 400 samples for multiple radionuclide analyses. The effective use of the analytical resources depends on use of a sampling plan that will produce the needed information and yet not result in excessive numbers of samples. Such decisions are tied to the scientific questions being addressed.

The Committee recommends that Registry assign a responsible staff person to develop plans and arrangements to address these issues. The organization of an ad hoc technical subcommittee of staff, Advisory Committee member(s), and possibly outside consultants/collaborators is recommended.

9. REGISTRY FILE OF PROCEDURES

As a holdover recommendation, the Committee recommends that the Registry maintain a record of past and current procedures used to collect data. The procedure descriptions should include historical summaries and updates on sample preparation, storage, preanalysis procedures as well as analytical and counting procedures. Such a file may help future data interpretation in which there arises questions of possible changes in radiochemical and radiological measurement techniques with time.

10. NATIONAL HUMAN TISSUE ARCHIVE

After limited discussion on the idea of developing a Human Tissue Archive, the Committee agrees that the objective of this proposal is valid and useful. It cautioned, however, that the work is a major effort and there are no specific funds for support of this activity. Some support services, including a functional database and minimal analytical laboratory support, are thought to be necessary for successful archive activities. It was suggested that this activity should not be undertaken until a specific project is approved and funded.

11. PRIORITY SETTING

Review of the 1991 priority list indicates significant differences exist depending on the effort required of various projects, stage of the work, and the staff and/or facility assigned to the work. It was concluded that the priorities cannot be represented fairly as a single list. As a minimum, a separate list should be made for the HEHF projects and the Los Alamos analytic laboratory work respectively. It is recommended that future priority lists could be meaningful if divided to represent independent, major areas of work.

For the 1991 priorities, the Committee suggested that the work on analyzing the four whole body cases should be moved up to high priority. Other items that should be listed as high priority include the visitations to contractor facilities (Recommendation #5) and evaluation of sample selection, pooling for whole body cases (Recommendation #7), and development of standard bone reference material.

12. BONE DENSITOMETRY

The use of clinical measures for bone density on Registry bone samples was proposed as a potential new research area. The Committee felt the proposal may be a project of opportunity given the access to Registry samples, but felt the Registry must weigh the value and product of this research against the purpose and resources of the Registry. Calcium analyses of bone samples will give adequate data for interpretation of bone measurements without direct bone density measurements. It was suggested that given current resources, it was probably wise to promote separate funding for this project.

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