4B2, SAS, PHL, ROF, DBH, SC file

South Carolina
DHEC
Department of Health and Environmental Control
2600 Bull Street, Columbia, SC 29201

January 13, 1994

Rosetta Virgilio
Office of State Programs
Mail Stop WF-3-D-23
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Ms. Virgilio:

This is in reference to the All Agreement States letter (SP-94-011) from your office dated January 10, 1994. The Division of Radioactive Materials Licensing and Compliance of the South Carolina Agreement State Program has not identified any files under our authority which contain information on experiments in which humans were deliberately exposed to radiation for purposes other than radiopharmaceutical therapy.

If you have any questions regarding this information, please contact me at (803) 737-7400.

Very truly yours,

James K. Peterson

James K. Peterson, Director
Division of Radioactive Materials
Licensing and Compliance
Bureau of Radiological Health

/em

RLB2, SAS, PHL, ROQ, OBH, CO file

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To Lloyd Bolling	From Bob Quillin
Co. USNRC	Co. CDH
Dept. State Programs	Phone # 303-692-3038
Fax #	Fax #

Colorado State University

Environmental Health Services
C206 Rockwell Hall
Fort Collins, Colorado 80523
(303) 491-6745
FAX: (303) 491-4864

January 14, 1994

Mr. Robert Quillin, Director
Radiation Control Division
Colorado Department of Health
4300 Cherry Creek Drive
Denver, Colorado

Dear Mr. Quillin,

In response to your fax dated January 11, 1994, we are conducting a search to determine if any individuals were deliberately exposed to radiation, for purposes other than radiopharmaceutical development, at Colorado State University during the years prior to 1975. To the extent possible, we have interviewed former faculty members and students and are in the process of reviewing files.

The interest in radiation bioeffects and use of tracers in biological research at CSU dates back to 1959. Dr. William Carlson was the principal researcher involved in these areas at that time. The Department of Radiological Health Sciences (formerly Radiation Biology) was established in 1964. Dr. Carlson was the first department head. He later became Dean of the College of Veterinary Medicine and Biological Sciences. Dr. Carlson left CSU to become President of the University of Wyoming in 1968. He and other current and former CSU faculty members were interviewed by telephone this week in regard to possible use of radionuclides in human volunteers in the past.

Only two such incidents have been identified. One involved administration of 1.0 microcurie of K-42 each to approximately six faculty members and, possibly, a graduate student, sometime between 1965 and 1967 for the purpose of calibrating the "Whole Body Counter". This is a device which is used to measure radioactivity in humans and animals. The CSU "Whole Body Counter" was originally used for fallout and body composition studies.

The second involved exposure of several individuals to Rn-222 to determine distribution of radon daughters in the body in conjunction with research on radon daughter exposure to uranium miners.

In both cases records have been requested. More information will be available within the next two weeks. Each of these cases involved knowledgeable individuals performing functions with which they were familiar on the basis of their occupation and

professional training. Doses to these individuals were within the occupational radiation dose limits in effect at that time.

Two other incidents have been reported on an anecdotal basis, but we have found no evidence to verify them. According to Dr. Carlson, at one time one or more animals were injected with radioactively labeled steroids. The beef from the animals apparently was ingested by volunteers and the radioactivity in the volunteers measured in the "Whole Body Counter". One other individual recalled getting permission of the Colorado Department of Health to consume meat from an animal used previously in research simply so the meat would not go to waste. An incident involving voluntary ingestion of milk containing I-131 for the purpose of calibrating the "Whole Body Counter" has also been identified, although the individual who has been responsible for the "Whole Body counter" since the time of its construction does not recall either incident. Other individuals who would have known about such studies do not recall these particular incidents. At this time, we have not located any written record of these incidents.

No other radiation exposures pertinent to your request have been identified in the interviews conducted to date. We are still examining files, but are unlikely to uncover any other incidents since most of the individuals who would have been involved in research using radionuclides and can be contacted, have already been interviewed.

After a review of the records, we will supplement the information regarding the foregoing incidents. In addition, if we identify additional information that is relevant to this request, we will make it available to you. Please call me if you have any questions.

Sincerely yours,

Janet A. Johnson

Janet A. Johnson, PhD, CIH, CHP
Interim Director

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To: Dennis Sollenberger / Rosetta Virgilio | From: Bob Quillen
Co.: Co Dept Health

KLG
VHL
SAS
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UNIVERSITY OF COLORADO HEALTH SCIENCES CENTER

Department of Environmental Health and Safety

Container C-233
4200 East Ninth Avenue
Denver, CO 80262

Telephone (303) 270-5890
FAX (303) 270-8026

RECEIVED
JAN 13 1994
RADIATION CONTROL DIVISION

DATE: January 13, 1994

TO: Dr. Robert Quillen, Radiation Control Division, Colorado Department of Health

FROM: Harry M. Cullings, Radiation Safety Officer

SUBJECT: Information Regarding Human Subjects Research with Radiation/Radioisotopes Prior to 1975

Pusuant to your request, I have reviewed all of the relevant license and committee files in my custody, with regard to the subject of possible early research involving radiation exposure to human subjects. I spoke with Dr. Conrad Riley, who was Chair of the very first "Human Research Committee," beginning in the late 1960's, at what was then the University of Colorado Medical Center. An even more important resource is Dr. Marvin Daves, who is still with our Department of Radiology, and was the Chairman of the Department of Radiology beginning in 1961, for over a decade, with continuing major involvement in the "Institutional Radiation Committee."

The earliest document in my licensing files is Amendment No. 24 to AEC License No. 5 902-5, which was issued by the AEC on January 4th, 1962. The license file appears complete from this point forward in time. By this indication, one would assume that the original AEC license was probably issued in the late 1950's. These licensing documents from the 1960's indicate authorizations to use byproduct materials at several off-campus locations, including the State Home and Training School in Wheatridge, the Colorado State Penitentiary, and Regis College. Based on the nature of these locations of use, especially the first two, one might logically surmise that human study populations at those institutions would have been involved.

The Committee files in my custody go back to 1969, with a complete summary log of authorized protocols beginning in 1970 (date, investigator's name, radionuclide, amount authorized, designation of human vs. non-human use), although I am not sure that we can locate the text of the related applications. The files beginning in 1969 indicate that, at least by that time, the University of Colorado Medical Center committees were very progressive with respect to radiation protection, including that of human subjects. An example document from 1974 and 1975 is attached here.

Please let me know if further effort is necessary. Based on my understanding of the files that are available, any detailed information on the early studies would probably require ardous efforts at locating and interviewing faculty members from those times, in order to determine the names of the responsible investigators, and considerable research work in followup, if any records can be located at all. A more expeditious way to locate relevant records might be to locate the letters from the University of Colorado Medical Center to the AEC to request license amendments to License No. 5-902-5, if they are in the AEC files, wherever those files are located. Unfortunately, we do not possess copies of these letters, to my knowledge.

Sincerely,

Harry M. Cullings, M.S.
Radiation Safety Officer

cc: UCHSC Committee on Ionizing Radiation; UCHSC Environmental Health and Safety Committee; Associate Dean for Research Affairs, Director, DEHS

March 6, 1975

TO: Harry P. Ward, M.D.
Dean, School of Medicine

John W. Singleton, M.D.
Associate Dean for Faculty Affairs

FROM: Radiation Safety Committee and Human Subject Committee

SUBJECT: Use of Radioisotopes

The Radiation Safety and Human Subject Committees met jointly on November 1, 1974 and January 10, 1975. There was general agreement on the following points:

(1) All radiation exposure is potentially damaging and will affect the well-being of the general population by increasing the incidence of cancer and the frequency of genetically derived conditions. These effects have been documented by the Committee on Biological Effects of Ionizing Radiation (BEIR Reports), of the National Academy of Sciences.

(2) The consensus of various radiation advisory groups such as the International Commission on Radiological Protection (ICRP), the National Council on Radiation Protection and Measurements (NCRP), is that healthy people (i.e. members of the general public) should be subject to a maximum whole body dose limit of 500 millirems per year, not to exceed 300 millirems per quarter, excluding natural background and medical radiation exposure. Ideally, the average annual exposure should not exceed the natural background radiation of 170 millirems per year and not more than 5000 millirems (5 rems) per lifetime. This limit can be compared to the background radiation level of 200 millirems per year in Colorado. Persons on a transcontinental airplane flight receive an additional 3-4 millirems per round trip.

(3) With respect to the actions of the Radiation Safety and Human Subject Committees, certain common criteria are used by both committees in the evaluation of applications for use of x-rays or radioisotopes in studies involving human subjects.

a. An important consideration is whether the subjects are patients or healthy individuals. In a patient with serious illness, one might be less hesitant to employ radiation for diagnosis or treatment, or as part of an experimental protocol, than in a patient with a less serious or self-limited illness, at least if one were reasonably assured that the exposure to radiation would have no adverse effect upon the patient's condition or chance of survival. Because diagnostic x-rays or radioactive isotopes are used in healthy control subjects, the "need to know" must be great enough

to justify the risk from radiation exposure. The use of laboratory personnel as "controls" is to be discouraged.

b. Another consideration is the age of subjects. For example, there would be less hesitation to use radioisotopes in an individual near the end of his life span, and more reluctance to use radiation in individuals during the reproductive years, and greatest reluctance in children.

c. When equally valid data can be obtained with similar rapidity by methods which do not require the exposure of individuals to radiation, then there is little justification for an investigator to use a procedure requiring radiation exposure.

(4) In any procedure involving the exposure of individuals to radiation, the attending physician or the investigator must make a special effort to explain to the patient or research subject why radiation exposure is necessary for the study, that there is no reasonable alternative procedure to acquire the same information, and that a small but real risk accompanies the exposure to radiation. In the absence of better quantitative criteria for radiation exposure, this type of detailed explanation is essential for "informed consent". The explanation should not rely upon misleading statements or comparisons such as "...equivalent to the exposure from a chest x-ray examination..." or "...so small an exposure as to be negligible..."

(5) The Radiation Safety Committee and Human Subject Committee will continue to review and evaluate research protocols on an individual basis with the question of benefit versus risk kept foremost in mind. This review and evaluation will be conducted without establishment of specific limits for radiation exposure, except that for guidance, reference will be made continuously to recommendations of radiation advisory groups such as the ICRP and the NCRP. We shall require that all persons who use radioactive materials weigh carefully the consequences of the radiation exposure for patients and research subjects.

Kedar N. Prasad

Kedar N. Prasad, Ph.D.
Chairman, Committee on
Ionizing Radiation

Melvin M. Newman

Melvin M. Newman, M.D.
Chairman, Human Subject Committee

cs

BEN NIGHTHORSE CAMPBELL
COLORADO

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ROV
DBH
Cofile

United States Senate

WASHINGTON, DC 20510-0608

January 14, 1994

Mr. Bob Quilin
Division Director of Radiation Control
Colorado Department of Health
4210 E. 11th Avenue
Denver, Colorado 80220

Dear Mr. Quilin,

I am writing this letter to express my support of President Clinton's and the Nuclear Regulatory Commission's efforts to commence a full and comprehensive review of the nation's nuclear medicine activities and records.

As you know, this records search is part of an interagency effort to identify intentional experimentation on humans with ionizing radiation from 1944 to the present. I believe it is necessary to determine whether such research was performed in the past in Colorado.

I recognize this task is difficult, especially in light of the tremendous demands placed on health care and research staff. I would greatly appreciate it if your office would provide my office with the results of records searches in Colorado as soon as possible.

Across the nation, citizens are looking to you and the federal government for leadership during this challenging time. Thank you for your attention to this matter.

Sincerely,

Ben Nighthorse Campbell
U.S. Senator

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To DENNIS MILLENBERGER	From BOB QUILIN
Co. USNRC	Co. CO DEPT OF HEALTH
Dept. STATE PROGRAMS	Phone # 303-692-3231
Fax #	Fax #

RECEIVED
JAN 24 1994
RADIATION CONTROL
DIVISION

1128 PENNSYLVANIA STREET
DENVER, CO 80203
303/868-1900

19 OLD TOWN SQUARE
SUITE 238 #33
FT. COLLINS, CO 80524

145 GRAND AVENUE #F
GRAND JUNCTION, CO 81501
303/241-6831

105 S. WEBER
SUITE 800
COLORADO SPRINGS, CO 80903

835 E. 2nd AVENUE
SUITE 238
DURANGO, CO 81301

720 N. MAIN STREET
SUITE 270
PUEBLO, CO 81003