

Title: EPIDEMIOLOGY OF MAGNETIC EFFECTS ON HUMANS

Principal Investigator: Thomas F. Budinger

Location of Study: Donner Laboratory, Lawrence Berkeley Laboratory

I. SCOPE

This is a retrospective epidemiological study on the effects, if any, of the stationary and alternating magnetic and electromagnetic fields produced by controlled thermonuclear reactors (CTR), high-voltage transmission lines, magnetic energy storage, and magnetohydrodynamic (MHD) systems. Programmatic objectives include acquisition of data for the eventual establishment of allowable exposure standards for CTR and MHD workers, and for the population at large incidentally exposed to environmental changes in magnetic and electric fields. There are contradictory reports and literature on the effects of high and low magnetic fields and electromagnetic fields, on growth and development as well as on behavior. Thus, in order to proceed with an understanding of the impact of various power producing and transporting devices on human health, it is important to establish the hazards, if any, of static and alternating magnetic and electrical fields. The evaluation of the benefits and risks of atomic energy required very extensive and long-term studies of radiobiology. Similarly, previous work on magnetobiology must be evaluated and extended for the eventual establishment of maximum permissible exposure levels for magnetic device workers and the population at large.

Our approach involves a study of 2000 scientists and technicians who have been occupationally exposed to cumulative doses for over 4,000 gauss-days per year for at least 5 years. (A "gauss-day" is defined as exposure to a magnetic flux density of 1 gauss for 1 working day.) The majority of these subjects are cyclotron workers and researchers who have been in fields of 5 gauss for 4 or more hours each day. In addition we will investigate the possible data base obtainable from high tension linemen, and power station operators. The study includes acquisition of medical data on exposed subjects, as well as matched controls from 8 facilities in North America. If warranted, studies will extend to exposed subjects in Europe where an additional 2000 cases will be easily obtainable. The studies of latent effects from acute exposures will include an additional group of about 1000 subjects exposed to greater than 100 gauss fields at the Calutrons in Berkeley and Oak Ridge during World War II.

Retrospective Study of Persons Occupationally Exposed to High Magnetic Fields

Cyclotron workers and high energy physicists around the world have been exposed to magnetic fields and in addition have excellent medical data recorded as a part of the medical program given to radiation workers. Our overview of the potentials of such a retrospective study indicates that about 2000 case histories are available with integrated exposures of each individual up to 20,000 gauss-days. In addition to the proposed protocol detailed below, it is of some importance to evaluate A. H. Vyalov's report of 1500 workers who had ill effects from magnetic field exposures. These workers were occupationally exposed to magnetic fields of 350 to 3500 gauss. Their hands were exposed to these fields for 20 to 60 percent of the work day, and their heads were exposed to less than 250 gauss (Novitskiy et al., 1971). The symptoms reported were headache, fatigue, low blood pressure, decreased white count,

BEST COPY AVAILABLE

<b>copy</b>	Accession No. _____
	File Code No. _____
	Canon No. (7) _____
	Folder No. Old 189.5 _____
	Notes Found By <i>Robert Holmes</i> _____
Date: <i>11-19-75</i> _____	
<b>DOCUMENT SOURCE</b> Lawrence Berkeley Laboratory Archives and Records Office Biology & Medicine Division	

3005219

and skin effects such as sweating, edema and hyperkeratosis.

A careful evaluation of this report with personal contact, if necessary, will be made during FY 78. If comparable data can be obtained, records from these workers will be studied along with case histories from workers at the facilities listed below.

Initially, 1000 subjects with an exposure of greater than 4000 gauss-days per year for 5 years will be identified at 8 locations on the North American continent. At each location we expect to identify 30 to 300 scientists and technicians with intermittent exposures to greater than 5 gauss during the working day. A matched group of employees from the same installation who were not exposed will be selected at random by age, sex, period of employment, and salary range. The expected results in FY 77 will be medical data on at least 200 exposed subjects and 200 matched controls. With this size sample we cannot expect to discern any significant abnormalities because the incidence of cardiovascular disease and the incidence of cancer are only about 10 per 1000 and 3 per 1000 respectively. Thus during FY 78 we will proceed to obtain the additional data from the facilities listed below:

*sample local*

- Lawrence Berkeley Laboratory (LBL)
- National Accelerator Laboratory (NAL)
- Stanford Linear Accelerator Laboratory (SLAC)
- Los Alamos Scientific Laboratory (LASL)
- Brookhaven National Laboratory (BNL)
- Oak Ridge National Laboratory
- Chalk River Canada
- Other Cyclotrons - Penn.-Princeton Accelerator
- University of California, Davis
- University of Washington
- University of Chicago
- Harvard
- Michigan State

In FY 78-79, if indicated, at least 2000 additional exposed individuals can be identified from CERH, Sweden, France, England, Germany and Russia.

II. DATA CASE

The data will be collected in a format which was developed by us for occupational medical purposes at the Lawrence Berkeley Laboratory and successfully adapted to the thyroid cancer and leukemia epidemiology work. A reduced copy of the encoding sheet accompanied by an explanation sheet are attached. The protocol for data collection is as follows:

1. A letter stating the purpose of the study will be sent by the ERDA regional operations office to the director of the facility being visited.
2. A physician-epidemiologist will contact the medical department at the appropriate facility and set up a convenient time during which he can visit the facility to abstract data from employee charts.
3. In most cases Dr. T. F. Budinger, the project coordinator, will make personal contact with a lead physician-scientist at the facility with whom he is acquainted in order to elucidate the objectives and motives

**DOCUMENT SOURCE**  
Lawrence Berkeley Laboratory  
Archive and Records Office  
Biology & Medicine Division

**Records Series Title**  
Biology & Medicine Division

**Accession No.** 44-92-0065  
**File Code No.** 1-1-1  
**Card No.** (17)  
**Folder No.** 014 104's  
**Notes** Karen Holmes  
**Found By** M. W. 1985  
**Date:**

**copy**

3005220

of this work and share ideas on how best to conduct the data collection at that facility.

4. The physician-epidemiologist will brief the occupational medical director on his objectives which include recording data on a format similar to that attached. The usual procedure will be to identify the exposed individuals through job categories and this information will be obtained through the personnel department. Armed with a list of likely exposures the physician-epidemiologist will contact the head of the accelerator division or physics department who can help identify other exposed individuals and provide information regarding the fields around the working areas so that an estimate of the exposure each subject has received can be made.
5. All medical records at the local facility are under the supervision of a medical staff consisting of physicians, RNs and medical technologists, and only professional health personnel will have access to the medical records from which data are abstracted. A Biostatistician/Data Analyst and a Medical Research Analyst will be reviewing the charts and abstracting the required data.
6. This study involves several phases.

Chart Review - If approved by the Campus Committee for the Protection of Human Subjects, the initial phase of chart review will not require informed consent as it will involve abstracting data from existing employment records and occupational health records of the exposed individuals. Only properly authorized professional staff members will have access to the records. They will be fully cognizant of the confidentiality of client/patient information and will be required to sign an Oath of Confidentiality (copy attached). They will encode the information using an identification number. The key to this code will be held by the Custodian of Medical Records (LBL).

Selection of Matched Controls - Using the encoded data on exposed subjects, a matched list of unexposed subjects will be compiled on the basis of distribution as to age, sex, time of employment, and other factors. An encoded number will be utilized for each of the controls.

Subject Questionnaire - Further information will be sought from both the exposed subjects and their matched controls in the form of a questionnaire (copy attached). To ensure voluntary participation and confidentiality, the following system has been worked out.

A postcard will be sent to individuals on these two lists, asking if they would like to participate in this study, and mentioning the questionnaire they would be required to answer. If their answer is positive they would so indicate by signing and returning the postcard.

<b>COPY</b>	Accession No. _____
	File Code No. _____
	Carton No. _____
	Folder No. _____
	Notes _____
	Date Found By _____
<b>DOCUMENT SOURCE</b> Lawrence Berkeley Laboratory Archives and Records Office Biology & Medicine Division	

3005221

A second postcard would be sent as a follow-up to those who had not returned the first card. After this no further attempt would be made to contact individuals. (Copies of the postcard formats are attached.)

Next, a letter will be sent to all individuals who agreed to participate in the study, requesting them to complete and return an attached questionnaire. (Copies of each of these documents are attached.) It may be necessary to personally interview some subjects for clarification or additional information to the questionnaire, but this will only be done at the discretion of the P.I. This may include both subjects and matched controls. The applicable consent form is attached.

The above procedures will require 2 to 3 days at the facility. Once the questionnaires have been returned, either of two procedures might be followed:

- a. Copy each relevant medical record and encode the data at LBL.
- b. Return to the facility and encode the data on site.

The second procedure is preferred because it gives the opportunity to personally contact the cooperating patient to clarify the exposure as well as the medical record. We anticipate we can encode a maximum of 30 patients each day.

7. Following are the safeguards to be used in the course of this study:

- a. Oath of Confidentiality in connection with abstracted medical data.
- b. Identification code which will consist of a 6-digit numerical code using initials, birth date and sex.
- c. Postcard inviting participation in the study.
- d. Letter of consent and questionnaire.
- e. Evaluation by physician of personal medical data from questionnaires.
- f. Interview, if necessary, to be conducted by a physician member of the team.

3005222

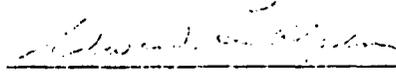
<b>COPY</b>	Accession No. _____
	File Code No. _____
	Canon No. _____
	Folder No. _____
	Notes _____
	Found By _____
Date _____	_____
<b>DOCUMENT SOURCE</b> Lawrence Berkeley Laboratory Archives and Records Office Biology & Medicine Division	

III. DATA ANALYSIS

The data organization and collection will be supervised by a biostatistician/data analyst in the Donner Research Medicine group. Biostatistical consultation will be performed by a senior Ph.D. biostatistician and an epidemiologist in the Department of Public Health, University of California at Berkeley. Additional consultation will be sought from the State of California Department of Public Health.



Thomas F. Dudinger, M.D., Ph.D.  
Principal Investigator



Edward L. Alpen, Ph.D.  
Responsible Administrator

<b>DOCUMENT SOURCE</b> Lawrence Berkeley Laboratory Archives and Records Office Biology & Medicine Division	Records Series Title	
	Accession No.	99-492-0205
	File Code No.	26-1-1
	Carton No.	(7)
	Folder No.	100 107's
Notes		
Found By	Karen Thimmes	
Date	11/10-1985	

**COPY**

3005223

OATH OF CONFIDENTIALITY

As a condition of doing research and having access to private medical information, I \_\_\_\_\_ agree not to divulge any information concerning human subjects obtained in the course of such research to unauthorized persons and not to publish or otherwise make public any information regarding such subjects such that the person is identifiable.

I recognize that unauthorized release of confidential information may make me subject to civil action.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

<b>copy</b>	Accession No. _____
	File Code No. _____
	Canon No. _____
	Folder No. _____
	Notes _____
	Found By <u>KAREN THOMAS</u>
Date: <u>1/18/85</u>	
Lawrence Berkeley Laboratory Archives and Records Office Biology & Medicine Division	

3005224

CONSENT FOR PERSONAL INTERVIEW

Dear \_\_\_\_\_:

In connection with the study of the effects of magnetic and electromagnetic fields on growth, development and behavior, for which you answered a questionnaire, we would like to arrange for a personal interview in order to obtain further information. This interview will be conducted by a physician and, as with the questionnaire, all information will be used anonymously.

Sincerely,

I, \_\_\_\_\_, agree to be interviewed by a physician in connection with the study of the effects of magnetic and electromagnetic fields on growth, development and behavior. I further consent to the use of information obtained in this interview for data purposes only. I understand my name will not be used.  
I further understand that any questions I may have will be answered by personnel conducting this study, and that I may withdraw my participation at any time without any prejudice to my rights.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

3005225

<b>copy</b>	Accession No. <u>44-110-2</u>
	File Code No. <u>7-1</u>
	Folder No. <u>(7)</u>
	Notes <u>Old 1475</u>
	Found By <u>Green Holmes</u>
Date: <u>1/19/75</u>	
Records Series Title <u>Biological &amp; Medicine Division</u>	
Lawrence Berkeley Laboratory Archives and Records Office Biology & Medicine Division	
DOCUMENT SOURCE	

CONSENT TO SEE RECORDS

In the event we wish to examine the patient's medical record after the interview to confirm or clarify medical aspects of the subject, we will ask specific permission to examine this record. The proposed consent form is similar to that used by the Medical Department at the Lawrence Berkeley Laboratory, shown below.

RECORDS RELEASE

DATE \_\_\_\_\_

TO \_\_\_\_\_ DOCTOR OR HOSPITAL

\_\_\_\_\_ ADDRESS

I HEREBY AUTHORIZE AND REQUEST YOU TO RELEASE

TO \_\_\_\_\_ DOCTOR OR HOSPITAL

\_\_\_\_\_ ADDRESS

THE COMPLETE MEDICAL RECORDS IN YOUR POSSESSION, CONCERNING MY ILLNESS AND/OR TREATMENT DURING THE PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_

SIGNED \_\_\_\_\_ (PATIENT OR LEGAL RELATIVE)

\_\_\_\_\_ RELATIONSHIP

HL-922-2

<b>copy</b>	Accession No. <u>44-410-20</u>
	File Code No. <u>10-1-1</u>
	Carton No. <u>(A)</u>
	Folder No. <u>114 1895</u>
	Notes <u>Green Holmes</u>
Found By <u>110-1985</u>	
Date: _____	
Records Series Title <u>Biological &amp; Medicine Division</u>	
Lawrence Berkeley Laboratory Archives and Records Office Biological & Medicine Division	
DOCUMENT SOURCE	

300522b

Name of Institution: \_\_\_\_\_

CARD NO.	ENCLOSURE	ENCLOSURE	ENCLOSURE	ENCLOSURE
L.D. NO.				
BIRTH DATE				
SEX				
FOR CLASS.				
HEIGHT				
BLOOD GROUP				
FAMILY HISTORY				
CUMULATIVE RADIOACTIVE DOSAGE				
MEDICAL HISTORY				
TYPE				
DIRECT				
BACK FILLED				
GAUSS-DAY				
TYPE				
DIRECT				
INTENSIVE FILLED				
GAUSS-DAY				
PARTS OF BODY				
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				
31				
32				
33				
34				
35				
36				
37				
38				
39				
40				
41				
42				
43				
44				
45				
46				
47				
48				
49				
50				
51				
52				
53				
54				
55				
56				
57				
58				
59				
60				
61				
62				
63				
64				
65				
66				
67				
68				
69				
70				
71				
72				
73				
74				
75				
76				
77				
78				
79				
80				

**DOCUMENT SOURCE**  
 Lawrence Berkeley Laboratory  
 Archives and Records Office  
 Biology & Medicine Division

Records Series Title: \_\_\_\_\_  
 Accession No.: \_\_\_\_\_  
 File Code No.: \_\_\_\_\_  
 Carton No.: (A)  
 Folder No.: (118)  
 Notes: \_\_\_\_\_  
 Found By: Karen Holmes  
 Date: 1/16-1985

**COPY**

125003