MRI REPORT

Further Studies of 60-Hz Exposure Effects on Human Function

Final Report Summary
July 3, 1989, to September 15, 1993

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MASTER

PREFACE

This document summarizes the work performed under U. S. Department of Energy Grant No. DE-FG01-89CE34025 (Midwest Research Institute Project No. RA-111-C) entitled "Further Studies of 60-Hz Exposure Effects on Human Function." The project goal was to follow up and extend previous findings indicating that heart rate in human volunteers is affected by exposure to 60-Hz electric and magnetic fields. Research activities were conducted in the laboratory of the Biobehavioral Sciences Section of Midwest Research Institute (MRI) under the general supervision of Mary R. Cook, Section Head. The project was directed by Charles Graham and Harvey D. Cohen, and staff members Mary M. Gerkovich, Donald W. Riffle, and Steven J. Hoffman contributed significantly to this effort. We wish to thank Dr. Imre Gyuk of the Office of Energy Management, who served as Project Officer for this work, and the DOE review team (William Wisecup, Emanuel Landau, Fred Dietrich, and Dick Phillips), for their many helpful comments and suggestions.

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SECTION 1

INTRODUCTION

There is growing public concern about the possible health risks associated with exposure to the electric and magnetic fields generated by power distribution systems. Environmental risk is often a function of effects that accumulate over time and interact with dose level. Thus, the primary goal of our ongoing laboratory research program has been to determine if brief periods of exposure to ambient-level, 60-Hz electric and magnetic fields has effects on established measures of human physiology and performance. Our research strategy has been (1) to identify which human functions appear to be affected by exposure; (2) to determine if these effects are reproducible; (3) to understand the specific circumstances under which they occur; and finally (4) to identify the underlying mechanisms involved.

Project studies are performed in the unique exposure test facility at MRI. This facility is specifically designed for exposure research with human volunteers. Uniform, corona-free, 60-Hz electric and magnetic fields can be presented in the facility under controlled conditions of ambient temperature and relative humidity. Electric fields up to 16-kV/m and magnetic fields up to 400 mG can be presented together or separately. The facility has two capabilities that make it unique. The first is a double blind control system that allows volunteers to be exposed to real or sham fields without either the volunteers or experimenters being aware of which condition is in effect at any given time. Thus, effects due to field exposure can be distinguished from effects due to an individual's expectations about exposure. The facility also is capable of recording human physiological activity during, as well as before and after, exposure to high-voltage fields. This capability aids in tracking the time course of any effects observed.

Participation of human volunteers in this research effort was approved and monitored by the MRI Human Subjects Committee in accordance with Federal regulations on the protection of human subjects (45 *CFR* 46 as amended). Volunteers were recruited for paid participation in the research by posting informational notices at local colleges, universities, and research institutions. Individuals who telephoned about a study were given a complete and accurate description of the purpose, procedures, risks, and benefits of participation, and were screened to assure they met specific criteria (male, 18 to 35 years of age, no chronic disease or disorder, no recent acute illness, not taking medications,

and able to read, write, and speak English). Volunteers who met criteria came to the laboratory where they were again given an explanation of the study, and the operation of the exposure facility was demonstrated. Written informed consent was obtained prior to participation.

Prior to the present effort, multiple human exposure studies were performed in the facility to evaluate effects at different levels of combined electric and magnetic field strength, and under both constant and intermittent exposure conditions. The results of these studies demonstrate that exposure has statistically significant and replicable effects on human heart rate. The cardiac response, however, is not a simple linear function of exposure duration or field strength. Continuous exposure to the fields slows the heart; intermittent exposure can result in both speeding and slowing. Differences between field and sham exposure conditions appear to be greatest shortly after the fields are either turned on or turned off. In other words, the heart seems to be influenced more by changes in the exposure environment than by its constancy. Our results also suggest that human cardiac activity may be differentially sensitive to certain combinations or "windows" of field strength. The slowing response occurred in four studies of exposure to combined fields of 9-kV/m and 200 mG. The response did not occur in two studies of exposure to stronger fields (12-kV/m and 300 mG), and it failed to occur when subjects were exposed to weaker fields (6-kV/m and 100 mG).

These results raise many questions. The precise field conditions most effective in altering human cardiac activity are unknown. Even within the homogeneous sample of volunteers we tested, some individuals appeared to be more susceptible to field effects than others. The factors associated with greater sensitivity to field exposure need to be delineated. The changes observed in heart rate may reflect more important alterations occurring elsewhere in the cardiovascular system. Finally, the mechanisms by which power-frequency electric and magnetic fields interact with human biological systems are unknown. In order to provide the basic data necessary for adequate risk assessment, these issues must be clarified.

The studies summarized here were designed to identify the field components responsible for the changes observed in heart rate, determine whether other cardiovascular variables are also affected by field exposure, and to further explore individual differences in response to exposure. Progress toward these research objectives has been communicated to the Department of Energy through quarterly progress reports, and to the scientific community through publications and presentations at annual meetings. DOE-sponsored research on this topic has continued at MRI after the expiration of this Grant, with technical oversight transferred to Oak Ridge National Laboratory. The final technical report, which will integrate the findings of the final study of the series summarized here with previous work at MRI, as well as in other laboratories, is being prepared under Task 1 of the existing contractual arrangement.

SECTION 2

PROJECT ACTIVITIES

EXPLORATORY STUDY

The objective of the exploratory study was to determine whether the electric or magnetic field, presented separately in an intermittent fashion, would produce the same pattern of heart rate increases and decreases seen in the original intermittent exposure study. In addition, time of day and baseline heart rate were explored in an attempt to clarify design issues that arose from previous studies.

Twenty-four healthy young men 21 to 35 years of age participated in the study. Half were exposed to a 9-kV/m electric field, and half to a 200-mG magnetic field. Within each of these groups, half were exposed in the morning and half in the afternoon. Each subject served as his own control, and order of exposure to real and sham fields was counterbalanced. Each session consisted of five periods (pre-exposure, field-on, field-off, field-on, post-exposure); within the 45-min, field-on periods, the magnetic field was switched on and off four times/minute. Data analysis indicated that the rotating magnetic field was sufficient to produce the "saw tooth" pattern of heart rate speeding and slowing seen in the original combined field study. The electric field alone did not produce the effect. Subjects with low heart rates showed a more marked "saw tooth" pattern than subjects with fast heart rates. Time of day did not appear to be an important variable.

PROBE STUDIES

A number of factors are involved in the seemingly uncomplicated exposure situation used in the original exploratory study. While the total exposure time was 45 min, the period of actual exposure to the fields was 22.5 min, and the maximum period of continuous exposure was 15 sec. In addition, during this time, the fields switched on and off 180 times, and the volunteer was exposed to combined horizontal and vertical magnetic fields each set at a selected level of field strength. Thus a basic issue in need of resolution is to identify which factor, or combination of factors, is the primary stimulus for cardiac change. The objective of the probe studies was to identify the most effective magnetic field conditions for future exposure studies. The variables manipulated were: field type

(horizontal, vertical, rotating); field strength (25, 100, 200 mG); intermittency period (15, 30, 60, 120 sec.) and exposure duration (15, 30, 45 min).

The probe studies were performed under single-blind experimental control conditions, and a standardized testing protocol was followed. All studies involved repeated testing of individuals under a variety of exposure conditions. Test sessions typically included periods of intermittent field exposure intermixed with periods of sham exposure. Measures of heart rate, the electrocardiogram, and abdominal and thoracic respiration were recorded and monitored in real time. Cardiac data were stored in computer files for later analyses designed to evaluate specific hypotheses derived from our previous research.

All conditions produced some slowing of the heart, although the effect was not always significant. The greatest speeding of heart rate at the switch points (which is responsible for the "saw-tooth effect" occurred with rotating fields of 25 and 200 mG, and horizontal fields of 200 mG. Results for intermittency periods were complex and appeared to depend on the combination of field strength and field type employed; overall, there was a trend for longer intermittency periods to have larger effects. Exposure periods of less than 30 min did not produce significant effects.

INDIVIDUAL DIFFERENCES

Data from our previous studies indicated that response to intermittent magnetic fields depends, in part, on the individual's heart rate prior to exposure. We further explored this relationship using data from almost 100 men who were exposed to sham and to continuous wave, combined electric and magnetic fields. Multiple regression analysis was performed to predict the percent change in heart rate as a function of exposure to real and sham fields. The variables used to predict change in heart rate included: pre-exposure heart rate; field strength (6-kV/m, 100 mG, 9-kV/m, 200 mG, 12-kV/m, 300 mG); exposure type (real or sham); and order of exposure to real and sham fields.

When subjects were exposed to 9-kV/m, 200-mG fields, pre-exposure heart rate significantly ($p < .007$) predicted the magnitude of field-related heart rate slowing. No such relationship was found when subjects were sham exposed, and order of exposure was not a significant predictor of the cardiac response for either sham or real exposure. Adding the change in systolic blood pressure to the regression equation increased the percent variance explained from 21% to 29%.

The results indicate that a continuous measure of blood pressure should be added to future studies, and that such studies should focus on cardiovascular responses including, but not limited to, heart rate. Another implication of the results is that people likely to have faster heart rate—older people, smokers,

people who are overweight, sedentary people—might be more sensitive to the effects of the field than the relatively healthy population we have been studying.

CONFIRMATORY STUDY

The objective of the confirmatory study was to test specific hypotheses derived from the exploratory and probe studies performed earlier under this grant. The exposure Facility at MRI was modified to perform detailed cardiovascular studies. Computer programs were written to control and monitor exposure characteristics under double-blind test conditions. Software-controlled instrumentation systems were developed to continuously record pulse transit time (a blood pressure correlate) respiration, and the electrocardiogram from three leads, and to do so at selected time periods during real and sham exposure. An experimental design to evaluate the effects of intermittent exposure to 60-Hz magnetic fields was prepared. Preliminary tests were performed on the test protocol and the exposure and data collection systems. The MRI Human Subjects Committee reviewed the research plan for the study, and approved the participation of human volunteers. Prior to study initiation, a site visit was held at MRI to review and discuss the study. The DOE site visitors included Mr. Paul Gailey (ORNL), and Drs. William Wisecup and Richard Phillips (W/L Associates).

Human Subjects: Sixty healthy young men (aged 18 to 35, no chronic disease or disability, no medication, nonsmoker) were recruited from local colleges, universities, and the general public for paid participation in the study. Written informed consent was obtained prior to participation.

Experimental Design and Procedures: Subjects participated initially in a brief session to become familiarized with the physiological recording procedures, and to provide baseline cardiovascular data. They also completed questionnaires designed to measure their present-day exposure to various electromagnetic devices. Vital signs (blood pressure, temperature, pulse) were recorded, and sensors attached to measure the electrocardiogram (ECG), heart rate, pulse transit time and respiration. These measures were taken several times to allow the subject to become familiar with the recording procedures. Subjects with high or low blood pressure or ECG irregularities were not continued in the study. Following familiarization, the subjects were assigned at random to either a sham exposure group (30 men), or a magnetic field exposure group (30 men). Individual differences in heart rate were equally represented in each group.

Each subject then participated in a morning (0800 to 1230) exposure test session. They were instructed to eat balanced meals and to not drink alcohol for 24 hr before the session. Self-report and vital sign data were collected at the start of the session. Physiological recording sensors were attached as in the familiarization session. The subject then sat and read in the exposure facility for

3 hr. For subjects in the sham exposed group, the magnetic field was not turned on during this period. For subjects in the field-exposed group, exposure to the magnetic field was intermittent. Exposure comprised alternating 45-min "field-on" and "field-off" periods. During "field-on" periods, the magnetic field cycled on and off every 15 sec. During "field-off" periods, the generating equipment was not turned on. Magnetic field strength was 200 mG. The study was performed double blind to control for the effects of expectation, and physiological measures were obtained at multiple matched points throughout sham and field exposure.

Data Analysis: The data are being analyzed to provide information about exposure effects on a variety of cardiovascular measures. These include: cardiac interbeat interval; amplitude and latency changes in major components of the electrocardiogram; pulse transit time; sinus arrhythmia; spectral analysis of the heart period; and vital signs. The results will help us understand how (or if) exposure influences the electrical potentials generated by the heart, or the timing of significant events in the heart cycle, and they will provide new data on the relationship between cardiac activity and other important cardiovascular variables.

Data analysis, integration and interpretation are being performed as Task 1 of Subcontract No. 85X-SN602C to DOE Prime Contract No. DE-AC05-840R21400 with Martin Marietta Energy Systems, Inc.

SECTION 3

PUBLICATIONS AND PRESENTATIONS

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Graham, C., M. R. Cook, H. Cohen, M. Gerkovich, and D. W. Riffle, "Human Cardiac Response to 60-Hz Fields: Exposure Parameters and Individual Differences," Presented at the 1st World Congress for Electricity and Magnetism in Biology and Medicine, Orlando, Florida (June 1992).

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