Abstract for EMF RAPID Program Engineering Project #4: Recommendations for Guidelines for EMF Personal Exposure Measurements

This project developed recommended guidelines for electric and magnetic field (EMF) personal exposure (PE) measurement studies in order to ensure reliable and comparable data across PE measurement studies. These flexible recommendations are intended to provide guidance for investigators with varied research objectives, rather than to dictate specific methodologies. The report presents general guidelines for planning a study, and specific guidelines for developing a detailed study design and protocols.

The purpose of establishing general guidelines for exposure studies is to ensure that valid data are collected and that the data meet the study objectives including, if appropriate, any risk assessment requirements. To accomplish these goals, investigators should employ the following steps when planning an EMF PE measurement study:

1. Develop a clearly stated purpose for the EMF PE measurement study.
2. Complete a written study plan before developing specific protocols or beginning measurements.

A study plan should include seven elements: resource assessment, an exposure model, study design, subject issues, quality assurance, uncertainty evaluation, and an archival plan. Pilot studies are also recommended as central to a research effort.

The recommended specific guidelines for developing detailed plans and protocols for a PE measurement study apply to six elements of a study: study design, subject issues, quality assurance, uncertainty evaluation, archival plans, and pilot studies. The specific guidelines for study design provide recommendations for selecting the field characteristics to be measured, selecting appropriate PE measurement instrumentation, developing a sampling strategy, establishing time-activity record-keeping protocols, and developing plans for data management, data analysis, and documentation of the study's methods and results. The investigators recommend that, at a minimum, a time-weighted average (TWA) exposure of the resultant magnetic field should be measured and reported.

The investigators carried out two pilot studies as part of their work: one with high-school physics students, the other with employees at an electronic manufacturing plant. They report on success of the protocols used, as well as on results.

The report contains a literature review of PE measurement studies; selected references have been summarized in a standard format and included as an appendix.

Study Limitations

The guidelines reflect the technology that was available at the time of writing.

The guidelines represent judgements regarding study design. They cannot provide a definitive approach to personal exposure monitoring for EMF. Approach will depend on the purpose of the study and resources available.

Areas for Future Research

Improvements in instrumentation: reduction in size, ability to capture spectral information.

Better information or approach to time/activity recordkeeping as it relates to EMF.

EMF RAPID Program Engineering Project #4:
Recommendations for Guidelines for EMF Personal Exposure Measurements

Purpose and Focus

This project developed recommended guidelines for electric and magnetic field (EMF) personal exposure (PE) measurement studies in order to ensure reliable and comparable data across PE measurement studies. Such studies may have a variety of objectives: to characterize exposures of subjects in epidemiologic studies, to characterize exposures of specific groups or components of exposure, or to investigate issues of EMF exposure assessment. PE measurements can also be used as part of a response to questions from employees or the public about EMF exposures.

The guideline recommendations are flexible and are intended to provide guidance for investigators with varied research objectives, rather than to dictate specific methodologies. The guidelines fall into two categories: general guidelines for planning a study, and specific guidelines for developing a detailed study design and protocols. Supporting discussions, and suggested implementation procedures are also included.

General Guidelines

The purpose of establishing general guidelines for exposure studies is to ensure that valid data are collected and that the data meet the study objectives including, if appropriate, any risk assessment requirements. To accomplish these goals, investigators should employ the following steps when planning an EMF PE measurement study:

(1) Develop a clearly stated purpose for the EMF PE measurement study.

(2) Complete a written study plan before developing specific protocols or beginning measurements.

Statement of Purpose. By succinctly stating the purpose of the study at the outset, and referring to it frequently, questions regarding the overall study design and the written study plan can be addressed without ambiguity. The purpose statement may evolve as the study design develops and resource constraints are addressed, but any changes or compromises in the purpose will be clearly known. Before beginning measurements, there must be a purpose statement that is understood and accepted by the investigators, their managers, and all sponsors of the study.

Written Study Plan. The written study plan is a general descriptive document and should address the following elements of the EMF PE measurement study:

Resource Assessment. Are there sufficient personnel, instrumentation, financial support and organizational support to adequately address the purpose of the study?

Exposure Model. How are the physical-exposure measurements related to a hypothetical biological endpoint?

- **Study Design.** What general study design is likely, including proposed exposure measurements, instrumentation, sampling strategies, data-collection protocols, data-management plan, and documentation?
- **Subject Issues.** What requirements are there for consent, confidentiality, level of effort by subjects, communication with subjects and dissemination of a subject's PE data?
- **Quality Assurance.** What steps will be taken to ensure adherence to protocols, instrument accuracy, and data integrity?
- **Uncertainty Evaluation.** What are the anticipated sources of error and what limits do they impose on the study's ability to achieve its purpose?
- **Archival Plan.** How will the study data and documentation be archived?

Specific Guidelines

Study Design. Specific recommendations are provided for: selecting the field characteristics to be measured; selecting appropriate PE measurement instrumentation; developing a sampling strategy; establishing time-activity record-keeping protocols; and developing plans for data management, data analysis, and documentation of the study's methods and results. It is recommended that, at a minimum, a time-weighted average (TWA) exposure of the resultant magnetic field should be measured and reported. Sample size, sampling parameters, and resource considerations are discussed along with a presentation of the sampling strategies: simple random sample, systematic sample, stratified sample, cluster sample and multi-stage sample. The following methodologies for time-activity record-keeping are presented: diary, self-administered or interview questionnaire employing retrospective, prospective or concurrent record-keeping. Table 1 [see rapid4b.pdf] shows a simplified decision tree for choosing an activity protocol.

Subject Issues. Guidance is provided for managing subject-related issues such as: obtaining organizational approvals for the participation of subjects; developing the forms to obtain a subjects informed consent; developing the procedures to maintain the confidentiality of subjects; developing clear, unambiguous PE measurement protocol instructions for the subjects; developing a plan to provide subjects with their PE measurement data; and developing PE measurement procedures that minimize the possibility of protocol violations.

Quality Assurance. Recommendations to ensure the quality and integrity of the data from a PE measurement study include: the implementation of appropriate and generally accepted procedures for the sampling process, data collection, data management, and data analysis; the implementation of a plan for verifying the calibration and confirming the functionality of PE measurement meters on a regular basis; the development of methods for assessing the consistency of the PE measurement and its associated data and the completeness of all data soon after each observation; and the introduction of automated and/or manual procedures for verifying the accuracy of the data entered into data bases.

Uncertainty Evaluation. An uncertainty evaluation of a PE measurement EMF study should be performed to determine the magnitude and acceptability of factors likely to contribute to

uncertainty; and to plan for an estimate of both the observed uncertainty introduced by various factors and overall observed uncertainty. The evaluation will assist in planning and implementing data validation procedures.

Archival Plan. Guidance is provided to develop specific plans for the archiving of raw data, processed data, study documents, and other study materials such as forms; written protocols; instructions to subjects and data collectors; and software tools.

Pilot Studies. The specific recommendations include pilot studies of all aspects of the study design. This includes testing protocols for: sampling, instrumentation, PE measurement, time-activity record-keeping, subject participation, and quality assurance.

Testing the Guidelines in Pilot Studies

The guidelines were tested in two pilot studies by an independent investigator. One pilot study measured EMF PE for 50 high school students who kept concurrent time-activity diaries and completed questionnaires regarding their activities. The three classes of students successfully recorded information about their locations while monitoring magnetic-field exposure. Common errors in accounting for sleep time (and thus in exposure data) were corrected by the investigator, and results were compiled with both corrected and uncorrected data. The retrospective questionnaire (completed immediately following measurement) provided more reliable information than the prospective questionnaire. Analysis of the exposure data indicated that, for each class, the overall average exposure was 0.7 to 0.8 mG. Maximum exposure was 10 mG for one group and about 190 mG for the other two. Average exposures were 0.2 - 0.4 mG in one school and 0.9 mG in the other. The highest exposure measured within a school was 110 mG. Table 2 shows the protocol checklist for the pilot study with students.

TABLE 2: Pilot Study #1: High School Students INVESTIGATOR'S PROTOCOL CHECKLIST

ONE WEEK BEFORE MEASUREMENT

Introduction to participants: attend classes to introduce project

_____ 1. Introduce self
_____ 2. Describe project purpose
_____ 3. Illustrate use of meter and holster
_____ 4. Illustrate use of diary
_____ 5. Hand out and discuss consent forms
_____ 6. Discuss confidentiality issues
_____ 7. Discuss how project will fit into class lessons
_____ 8. Answer questions

NIGHT BEFORE MEASUREMENTS

Measurement session preparation

_____ 1. Check and resupply field kit
_____ 2. Put together EMDEX packages: diary, pencil, EMDEX
_____ 3. Install fresh battery and perform EMDEX functional check
_____ 4. Identify EMDEX serial numbers on diary cards and questionnaires

MORNING OF MEASUREMENTS

Measurement session preparation

_____ 1. Initialize EMDEXes

DEPLOYMENT PERIOD

Project Introduction and Setup

_____ 1. Verify voluntary status: collect consent forms
_____ 2. Hand out meters and questionnaires
_____ 3. Demonstrate the placement of the holster on the body
_____ 4 Start meters (must get going quickly in order to gather 24-hour data by beginning of next class)
_____ 5. Request that each participant make up a four-digit code and mark it on the diary and questionnaires
_____ 6. Describe the purpose of the questionnaires and diaries with respect to the study purpose.
_____ 7. Answer any questions

Prospective Questionnaires

_____ 1. For one group hand out prospective questionnaires and ask for their completion.

Describe Use of Meters

_____ 1. Wear on waist for 24-hour period

CONTINUED

TABLE 2 (CONTINUED): Pilot Study #1: High School Students INVESTIGATOR'S PROTOCOL CHECKLIST

DEPLOYMENT PERIOD (CONTINUED)

_____ 2. Meter is measuring every 60 seconds
_____ 3. Only take off for sleep, showers, sporting events etc, or other times when might effect the safety of the wearer
_____ 4. During sleep: lie at bedside, away from electric clock, etc.
_____ 5. Very expensive instruments: need to take care.
_____ 6. Illustrate event marking: have all students try it.

Explain Diaries: Each time the student changes environments the new environment should be recorded as follows

_____ 1. Time registered should be that time on the EMDEX LCD
_____ 2. The EMDEX "event" button should be pushed, and the Event number shown on the LCD recorded in space provided.
_____ 3. The appropriate environment code should be recorded:
   a. **SC- School Classroom**: inside the walls of a classroom
   b. **SO** - School Other: on school property, but not inside the walls of a classroom
   c. **H** - Home: inside the individual's home, or the yard of that home
   d. **T - Travel**: in any environment where traveling from location to another, by foot, bike, or vehicle
   e. **W - Work**: on work premises
   f. **O - Other**: in any environment other than those listed
   g. **ZZ - Sleeping:** while sleeping, meter will not be worn, but will be in proximity to the bed.
   h. **XX - Not wearing**: other than sleeping, any time during which the meter is not worn
_____ 4. If the student forgets an entry, he should record the new environment, enter the estimated time of the event, and write "est" ion the "event number" column. The event marker need not be pushed
_____ 5. The comment column is for anything the student wishes to clarify or record.

RETRIEVAL

Retrieval:
_____ 1. Confirm that 24-hours have past since each meters deployment by checking the time on the LCD.
_____ 2. Collect the meters, holsters and diaries
_____ 3. Confirm that the codes on all forms match.
_____ 4. Log in all consent forms, questionnaires, diaries, evaluations, and EMDEX data.

Downloading Data (Steps 1-3 on site at School A)
_____ 1. Download each meter, naming the eight-digit number selected for the student.
_____ 2. Print graphs for each student
_____ 3. Request that each student compare their diary to their graph and note what they think are sources of the peak exposures.

CONTINUED

TABLE 2 (CONTINUED): Pilot Study #1: High School Students INVESTIGATOR'S PROTOCOL CHECKLIST

ACTIVITY PATTERN REVIEW

Retrospective questionnaires

_____ 1. For two of the groups, hand out retrospective questionnaires and ask for their completion.

QUALITY ASSURANCE AND DATA MANAGEMENT

_____ 1. Perform quality assurance on the EMDEX Data
   a. Confirm that there are no flat lines in the graph, indicating a possible meter disorder.
   b. (Further assurance will be included on a questionnaire, asking if the meter was dropped or otherwise abused, or if the students wore the meter as stated.)

_____ 2. Save the data on floppy disks, as the eight-digit file name.

_____ 3. Make copies of all data and forward to project headquarters.

The subjects for the second pilot study were two groups of employees at an electronics manufacturing plant. Either they kept a time-activity diary or their activities were recorded by an observer during work hours. Several steps were taken during the pilot study to ensure reliability of the data: calibration of instruments was verified before and after the project; functionality of each axis of the meter was verified before measurements were taken; forms were designed to be clear, succinct, and straightforward; the investigator emphasized the importance of data accuracy to participants; the data were reviewed immediately following collection; each participant was assigned a unique six-digit code that was recorded on all forms and data files; and PE measurement EMDEX files were reviewed for quality and backed up on floppy disks before being sent for production of summary data. Average exposure for all professional employees during the study was 0.9 mG. Two employees had substantially higher mean exposures than the other five employees: 1.26 mG and 2.06 mG vs. 0.49 - 0.74 mG. These two employees worked in the same general area and were exposed to the fields from the same printer.

Background Materials

The document contains a literature review of PE measurement studies that provides background information and reference to works presenting PE measurement protocols and related issues. Selected references have been summarized in a standard format and included as an appendix.

To illustrate the effects of subject characteristics on activities possibly related to EMF exposure, existing time-activity survey data for children and adults in California were examined. The largest and most consistent differences in locations and activities observed in these data were related to age and gender. The differences suggest that these should be important subject attributes in an EMF PE measurement study.

Summary

The combination of the general guidelines, specific guidelines, and background materials provides a prospective investigator of EMF PE with a foundation for developing, implementing and reporting a scientifically sound, valid PE measurement study.