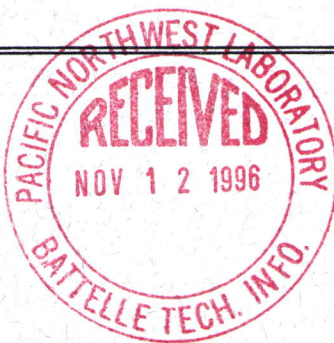




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Final Letter Report

CRADA with Teledyne Electronic Technologies and Pacific Northwest National Laboratory (PNL-096): The Exposure-to-Risk Monitoring System

K.D. Thrall

October 1996

**Prepared for U.S. Department of Energy
under Contract DE-AC06-76RLO**

**Pacific Northwest National Laboratory
Operated for the U.S. Department of Energy
by Battelle**

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The Exposure-to-Risk Monitoring System

Purpose/Objective

The purpose of this project was to demonstrate the "Exposure-to-Risk" monitoring system in an actual occupational environment. The system is a unique combination of existing hardware with proprietary software to create an integrated means of assessing occupational exposures to volatile organic compounds. One component of this system utilizes a portable mass spectrometer developed by Teledyne Electronic Technologies. Integration of the system was accomplished under Laboratory Directed Research and Development (LDRD) funding. Commercialization of the system will take place following demonstration in an actual occupational environment, and will include, in part, Teledyne Electronic Technologies.

The Exposure-to-Risk monitoring system will benefit DOE by overcoming present-day limitations in worker health protection monitoring. There are numerous sites within the DOE complex where many different hazardous chemicals are used on a routine basis. These chemicals range from paint strippers and cleaning solvents to chemical warfare agents, each having its own degree of potential adverse health risk to a worker. Thus, a real concern for DOE is to ensure that a worker is properly monitored to assess any adverse health risk from exposure to potentially hazardous chemicals. With current industrial hygiene technologies, this is an arduous task.

The Exposure-to-Risk monitoring system integrates a patented breath-inlet device connecting a subject's exhaled breath directly with a field-portable mass spectrometer with physiologically based pharmacokinetic (PBPK) modeling to estimate the target tissue dose following a chemical exposure. Estimation of the adverse health risk prediction follows from the exposure/dose calculation based on currently accepted methodologies. This new system can determine, in the field, the possible adverse health risks on a daily basis to an individual worker.

Summary of Activities Performed

Task 1: Development of an informed consent form.

An informed consent form to document worker solicitation and voluntary participation in the field demonstration was developed and approved by Battelle Human Subjects Committee and representatives of Bechtel Hanford legal council (Appendix A).

Task 2: Solicitation of worker participation in the demonstration phase.

A meeting was held with representatives from the Bechtel Environmental Compliance Review Team, and DOE to detail the specifics on the demonstration site. There are three active carbon tetrachloride (CCl_4) vapor pumping sites, two with trailers that would be suitable for our needs. At the time, all three sites were active 24 hours/day, 7 days/week. Four people were identified at the ZP-2 field site that could be potential demonstration participants.

A worker orientation briefing was held with the potential participants to discuss the mechanisms of how the Exposure-to-Risk monitoring system operates to solicit the workers participation, and, if the workers agree to participate, to have informed consent documentation completed. All four workers agreed to participate.

Task 3: Obtain physiological information on participating workers

At the time of informed consent, all participating workers completed HEHF consent forms to release the most current pulmonary fitness test results. Each worker also completed an occupational exposure/medical history questionnaire (Appendix B). A representative from HEHF met with each participant and recorded body weight, body height, and determined percentage of body fat using a seven-point caliper skinfold method. Each participant was assigned an identifying code number. All personal physiological, occupational, and medical information was stored in a locked cabinet with each worker identified only by code number.

Task 4: Construct individual PBPK models for each demonstration participant

This task individualized, a CCl_4 PBPK model, that was experimentally validated under a previous LDRD project, to depict the unique physiological characteristics of each participating worker. The actual program code and validating data files are shown in Appendix C. The model program parameters that were individualized based on data obtained in Task 3 included body weight (BW) and fat volume (VFC). Other tissue volumes (liver, lung, slowly perfused, rapidly perfused) are allometrically scaled by an equation that is based on body weight. The resulting models were designed to allow for actual exposure time (in seconds) and exposure level data from the chemical sensor information (in ppb) to be inserted as model run time commands. The PBPK models and optimization and simulated software, SimuSolv (DOW Chemical Company) are located on an HP9000 workstation that is housed in the RTL building. During field demonstration activities, a phone line was used to access the workstation.

Task 5: Exposure-to-Risk monitoring system readiness.

The timing of the actual field demonstration was delayed significantly from initial forecasts due to difficulties in instrument readiness. The atmospheric sampling glow discharge ion source (ASGDI) initially supplied with the Teledyne 3DQ Discovery ion trap mass spectrometer needed to be installed with extensive modifications. Teledyne contracted separately to have this performed, and the instrument was shipped to Ohio. Laboratory tests performed with the ASGDI/3DQ instrument showed comparable sensitivity to other more complex instruments. Using carbon tetrachloride as the test compound, the instrument ASGDI/3DQ instrument demonstrated a detection limit of 5 ppbv. After installation of the modified ion source and testing, the instrument was shipped back to Richland and set up in the laboratory. Subsequent testing in Richland showed similar results to those achieved during installation.

Funding was received from DOE-EM-6 to design, build and test a chemical sampler analyzer "front-end" that was built on the mass spectrometer to allow for analysis of chemical lapel samplers in the field. The hand held device was tested on the ASGDI/3DQ instrument, which was found to have a detection limit for carbon tetrachloride on the order of 1-2 ng. As a comparison, analysis for carbon tetrachloride at a certified analytical laboratory using charcoal tubes has a limit of quantitation of 10 ng.

Significant Accomplishments

The Exposure-to-Risk monitoring system was successfully transported to Hanford's 200W area and used to monitor workers for CCl₄ exposures during their normal work routine (photos are provided in Appendix C). A small portable trailer was located at the ZP-2 site and the instrument was set up and tested on location several days prior to the start of the demonstration. A phone line was used to transport analysis data to a work station and to access the modeling software located in the RTL building in the 3000 area. Calibrations of the breath analyzer and chemical sampler analyzer were performed immediately following set up and in the morning of each day of the demonstration. The instrument sensitivity was on the order of 5 ppb.

The volunteer workers reported to the trailer immediately upon arrival at the work site each morning for a background analysis of their exhaled breath. If a worker entered the controlled environment, dual lapel samplers were placed on the worker by the industrial hygienist (charcoal tube for analysis at a certified laboratory, Tenex tube for analysis by the Exposure-to-Risk monitoring system). The sample tubes were removed from the worker and a breath sample was collected immediately upon exit from the controlled environment. If only office activities were anticipated for a particular day, the worker wore dual lapel samplers which were removed and a breath sample was collected at lunch time. Replacement sampler tubes were put on the worker immediately following lunch.

No exposures were found when monitoring the workers' exhaled breath or the lapel samplers. Duplicate lapel samplers sent to a certified laboratory for analysis reported results "below the limit of quantitation". The field demonstration provided valuable experience on moving and setting up the system in a field setting, operating under less than ideal weather situations, and provided valuable feedback on worker acceptance.

Significant Problems

The greatest difficulty encountered during the field demonstration was ensuring that the worker population remained at the demonstration site. The personnel involved in activities at the ZP-2 site were continually being pulled off that site to temporary assignments at other sites during the demonstration. Although the supervisor was aware that the demonstration was going on, he was short-handed at other sites and was forced to pull our volunteers. If the demonstration at the carbon tetrachloride sits is to be repeated in the future, it is suggested that the Exposure-to-Risk monitoring system be placed in a trailer and left at the ZP-2 site until significant activities are identified on a day-to-day basis.

DOE/Laboratory Benefits Realized

This project is related, and could benefit, all DOE health and safety programs. Subsequent to the field demonstration, programmatic funding has been received from DOE-EH-5 for development of additional models for 3 additional compounds during FY-96, and extensive field demonstration of the system at Savannah River targeting benzene during FY-97.

Industry Benefits Realized

Teledyne Electronic Technologies will realize a benefit from development of the Exposure-to-Risk monitoring system as the system is marketed and sold to industry and governmental agencies as an integrated industrial hygiene tool.

Recommended Follow-On Work/Potential Benefits from Pursuing Follow-On Work

The Exposure-to-Risk monitoring system needs to be more extensively field demonstrated for a wider variety of chemicals in different environmental settings. These field demonstrations should also be used as a marketing opportunity to bring industry and governmental health and safety leaders to observe the system in action and learn about the potential usefulness. In addition, automation of the system needs to take place to eventually enable a technician to calibrate and operate the system rather than the skilled analytical chemist needed today. This will enable more widespread placement of the system in the workplace.

APPENDIX A

INFORMED CONSENT

Exposure-to-Risk Monitoring System Demonstration

Researchers at the Pacific Northwest Laboratory (PNL), in conjunction with Battelle Columbus Operations, are developing a prototype system to evaluate an individual worker's exposure to hazardous chemicals. This demonstration will consist of field testing the prototype system in an environment where the potential for human exposure to carbon tetrachloride exists. We believe that field testing is a vital part of the development of the technology. As of yet, no risk-based standard exists that is based on this new, novel method for occupational monitoring.

WHAT YOU ARE ASKED TO DO

If you agree to participate we will ask you to do the following:

1. Wear the two chemical samplers that we provide during your normal work routine at the carbon tetrachloride integrated demonstration site.
2. Breathe into the breath-analysis instrument for approximately 2-3 minutes immediately upon arrival each morning to establish the baseline "residual" amount of carbon tetrachloride, if any, in your body prior to entering the control area.
3. Breathe into the breath-analysis instrument when exiting the control area.
4. Provide us with your body weight and height and complete the occupational exposure history questionnaires.

We will be at the carbon tetrachloride integrated demonstration site for approximately 1 week collecting and analyzing chemical sensors and breath samples. We will be available at all times during the study to answer any questions you may have.

WHAT ARE THE RISKS

There are essentially no risks to you if you agree to participate. We are not asking you to perform any work-related activity other than your normal routine. In theory, a slight risk of respiratory infection could exist in an instrument used by several different people. However, to overcome this slight risk, we have added a control valve to ensure that you can only breathe in fresh air, and only exhale out through the mass spectrometer. In addition, we will insert a clean, disposable, mouthpiece prior to each person breathing through the instrument.

WHAT WE WILL NOT BE MONITORING

The mass spectrometer used in this prototype system has the capabilities to detect a whole spectrum of volatile chemicals, including alcohol and volatile components of illicit drugs. However, the ion source used during this demonstration will be specifically set to selectively quantitate the concentrations of carbon tetrachloride that may be present in your exhaled breath. We will demonstrate this selectivity to you upon request. There is no way to reanalyze any of the data for other compounds that might have been exhaled after the sample has been collected.

IT'S ALL CONFIDENTIAL

All personal physiological characteristics (your body weight and height) and any exposure findings will be kept confidential. Only members of the research group will have access to your breath-analysis records in which you will be identified only by a code number.

YOUR COOPERATION IS VITAL

The routine sample monitoring currently used at your work site suggests that you are not being exposed to significant concentrations of volatile carbon tetrachloride, if you are being exposed at all. Therefore you may be wondering why we are asking you to participate. The system under development needs to be demonstrated in a working environment in order to focus and drive additional research.

Your participation is voluntary, of course, and you may withdraw from the study at any time, and you are free not to participate or to withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled. If you have any questions about the study, please have them answered before you sign the consent form, or you may call Dr. Karla Thrall at 375-6702 at any time. Please keep one copy of the consent form for your records.

INFORMED CONSENT

I have read the announcement and have had my questions about this study answered. I understand the purpose of the study. I agree to participate with the understanding that I may withdraw at any time without penalty or jeopardy to my job, and that there are no penalties or loss of benefits upon withdrawal from the research. I understand that all information will be kept confidential, and that my name will not appear in any publication. I have had an opportunity to ask questions and understand that future questions I may have about the research will be answered by the investigator, Dr. Karla Thrall.

Your Signature

Date

Principal Investigator

Date

APPENDIX B

**Occupational Exposure, Medical History
Questionnaire**

Your participation is voluntary

All answers will be kept confidential

Please answer the following questions as accurately as possible. If unsure about any of the medical problems, please answer NO.

1 PERSONAL INFORMATION

2 PERSONAL MEDICAL HISTORY

Name _____

Date of Birth _____

What city do you live in?

- ☐ Kennewick
- ☐ Richland
- ☐ Pasco
- ☐ West Richland
- ☐ Other _____

Occupational or Job Title:

Specific Job Duties:

Sex: ☐ Male ☐ Female

Race: ☐ Caucasian

☐ Hispanic

☐ Black

☐ Oriental

☐ American Indian

☐ Other

IF FEMALE:

No Yes

☐ ☐ Are you pregnant?

GENERAL Do you feel your present health is:

- ☐ Excellent
- ☐ Good
- ☐ Fair
- ☐ Poor

Do you now, or have you ever, had any of the following?

NO	YES		YEAR
☐	☐	Persistent Fevers	_____
☐	☐	Fatigue easily	_____
☐	☐	Bruise easily	_____
☐	☐	Night sweats	_____
☐	☐	Measles	_____
☐	☐	Mumps	_____
☐	☐	Chicken Pox	_____
☐	☐	Whooping Cough	_____
☐	☐	Diphtheria	_____
☐	☐	Scarlet Fever	_____
☐	☐	Rheumatic Fever	_____
☐	☐	Polio	_____
☐	☐	Tuberculosis	_____
☐	☐	Malaria	_____
☐	☐	Anemia	_____
☐	☐	Polycythemia	_____
☐	☐	Meningitis/Encephalitis	_____
☐	☐	Lupus Erythematosus	_____
☐	☐	Leukemia	_____
☐	☐	Hodgkins Disease	_____
☐	☐	Infectious Mononucleosis	_____
☐	☐	Cancer	_____
☐	☐	Alcohol/drug problem	_____
☐	☐	Sarcoidosis	_____
☐	☐	Scleroderma	_____

3 PERSONAL HABITS

Do you now, or have you ever used:

No	Yes				
☐	☐	Cigarettes	IF YES for how many years?	_____	
		Packs	☐ Presently		
		_____ per day	☐ In past	Age started?	_____
☐	☐	Cigars	IF YES for how many years?	_____	
		Cigars	☐ Presently		
		_____ per day	☐ In past	Age started?	_____
☐	☐	Pipe	IF YES for how many years?	_____	
		Pipes	☐ Presently		
		_____ per day	☐ In past	Age started?	_____
☐	☐	Chewing Tobacco			
		Pkgs	IF YES for how many years?	_____	
		_____ per day	☐ Presently		
			☐ In past	Age started?	_____

Have you ever consumed any of the following beverages?

	No	Yes	Daily	Weekly	Occasionally
Coffee	☐	☐	☐	☐	☐
Tea	☐	☐	☐	☐	☐
Soft Drinks	☐	☐	☐	☐	☐
Beer	☐	☐	☐	☐	☐
Liquor	☐	☐	☐	☐	☐
Wine	☐	☐	☐	☐	☐

Do you do any of the following exercises?

	No	Yes	Regularly (3 or more times/week)	Occasionally/ Seasonally
Walking	☐	☐	☐	☐
Jogging	☐	☐	☐	☐
Swimming	☐	☐	☐	☐
Bicycling	☐	☐	☐	☐
Golf	☐	☐	☐	☐
Hand/Racquetball	☐	☐	☐	☐
Football/Soccer	☐	☐	☐	☐
Skiing	☐	☐	☐	☐
Tennis	☐	☐	☐	☐
Weight Lifting	☐	☐	☐	☐
Calisthenics	☐	☐	☐	☐
Basketball/Softball	☐	☐	☐	☐
Other _____	☐	☐	☐	☐

4 MEDICATIONS

Are you now, or have you ever taken any of the following prescription or non-prescription drugs?

	No	Yes	Regularly	Occasionally
Aspirin	☐	☐	☐	☐
Antihistamines	☐	☐	☐	☐
Cold Tablets	☐	☐	☐	☐
Asthma medicine	☐	☐	☐	☐
Antacids	☐	☐	☐	☐
Laxatives	☐	☐	☐	☐
Ulcer drugs	☐	☐	☐	☐
Thyroid drugs	☐	☐	☐	☐
Tranquilizers	☐	☐	☐	☐
Antidepressants	☐	☐	☐	☐
Diet pills	☐	☐	☐	☐
Sleeping pills	☐	☐	☐	☐
Antabuse	☐	☐	☐	☐
Seizure medication	☐	☐	☐	☐
Insulin	☐	☐	☐	☐
Diabetes medication (oral)	☐	☐	☐	☐
Birth control pills	☐	☐	☐	☐
Estrogens	☐	☐	☐	☐
Male hormones	☐	☐	☐	☐
Cortisone/Steroids	☐	☐	☐	☐
Diuretics	☐	☐	☐	☐
Blood pressure medication	☐	☐	☐	☐
Blood thinners	☐	☐	☐	☐
Digitalis	☐	☐	☐	☐
Nitroglycerin	☐	☐	☐	☐
Other _____	☐	☐	☐	☐

5 OCCUPATIONAL HISTORY

Are you currently under care of a physician for any reason? ☐ No ☐ Yes

If yes, explain: _____

Have you ever held a job that was considered hazardous or dangerous to your health? ☐ No ☐ Yes

If yes, please complete the following section:

No Yes

☐ ☐ Was protective clothing/equipment provided

☐ ☐ If yes, did you use it?

Did you inhale (breath) any:

☐ ☐ Chemical solvents IF YES, what (if known) _____

☐ ☐ Fumes IF YES, what (if known) _____

☐ ☐ Dust

☐ ☐ Radioactive materials

☐ ☐ Other _____

Did any of the following materials come in contact with your skin:

☐ ☐ Solvents IF YES, what (if known) _____

☐ ☐ Oils

☐ ☐ Dust

☐ ☐ Radioactive material

☐ ☐ Other _____

6 HAZARDOUS MATERIAL EXPOSURE

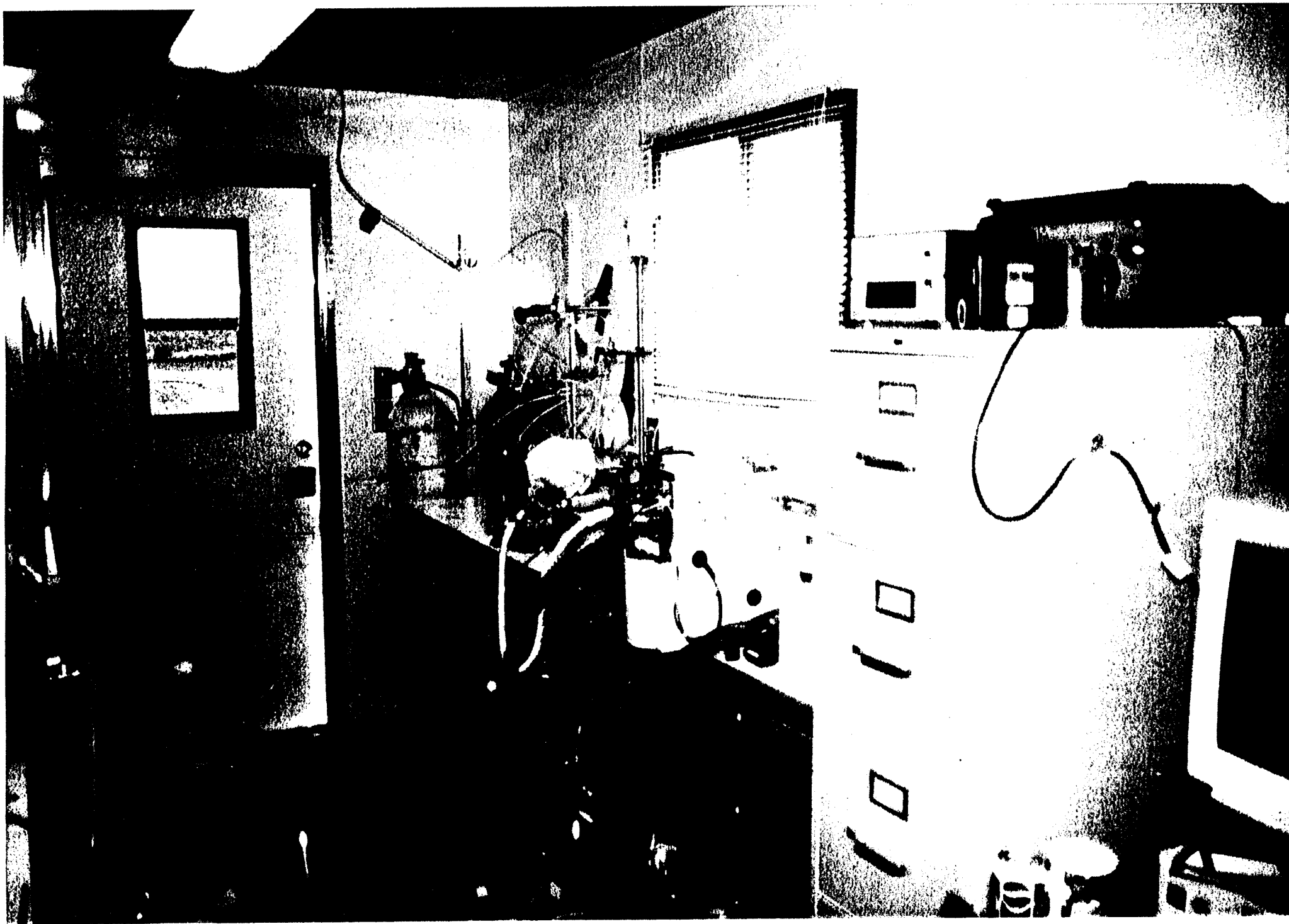
Have you ever worked with any of the following materials either on the job or recreationally such as hobbies?

	No	Yes	Regularly	Recreationally
Arsenic	☐	☐	☐	☐
Beryllium	☐	☐	☐	☐
Chromium	☐	☐	☐	☐
Lead	☐	☐	☐	☐
Mercury	☐	☐	☐	☐
Nickel	☐	☐	☐	☐
Other metal dusts/fumes (Specify) _____	☐	☐	☐	☐
Asbestos	☐	☐	☐	☐
Cutting oil	☐	☐	☐	☐
Dyestuffs	☐	☐	☐	☐
Fiber glass/glass wool	☐	☐	☐	☐
Pesticides	☐	☐	☐	☐
Petroleum products	☐	☐	☐	☐
Plastics processing	☐	☐	☐	☐
Silicone	☐	☐	☐	☐
Solvents	☐	☐	☐	☐
Spray paints	☐	☐	☐	☐
Paints/Lacquers	☐	☐	☐	☐
Wood dust	☐	☐	☐	☐
Wood preservatives	☐	☐	☐	☐
Other hazardous chemicals (Specify) _____	☐	☐	☐	☐
High intensity electrical fields	☐	☐	☐	☐
Laser equipment	☐	☐	☐	☐
Microwave Equipment	☐	☐	☐	☐
Excessive/unusually loud noise	☐	☐	☐	☐
X-ray equipment	☐	☐	☐	☐

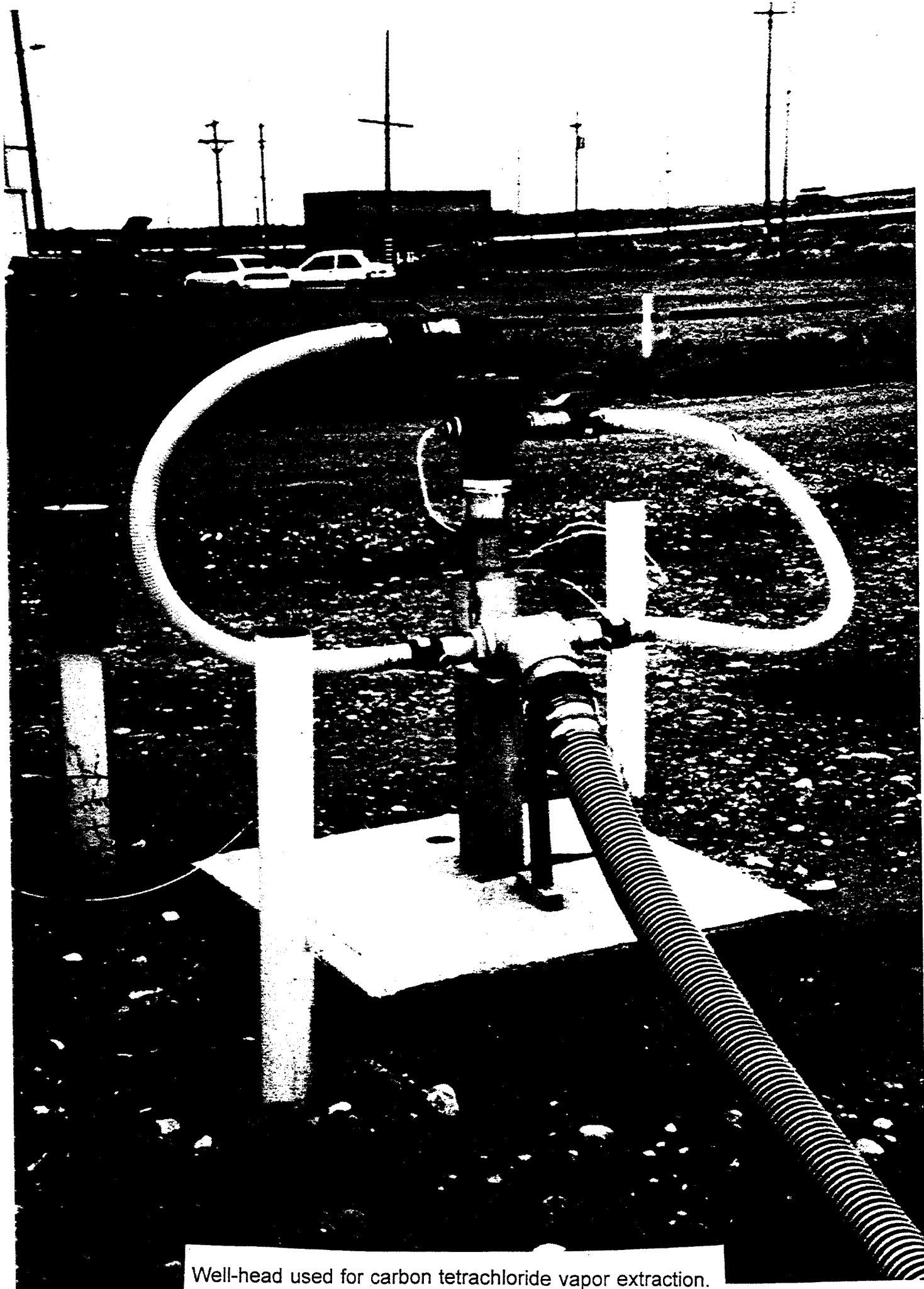
APPENDIX C



"Crew" and trailer used for the demonstration.



Exposure-to-risk monitoring system set up inside the trailer in the field.



Well-head used for carbon tetrachloride vapor extraction.

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