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13. ABSTRACT *(Maximum 200 words)*
Characterization and analysis of combustion products resulting from firing the JAVELIN missile were performed. Of those combustion products analyzed, it was determined that airborne lead concentrations exceeded the OSHA PEL of 50 ug/m^3 each time the missile was fired while in the enclosure. Since the OSHA PEL standard is based upon a continuous rather than a short-term exposure, blood lead concentrations were sought to ascertain the relationship between a short duration airborne exposure and its physiological effect on the body. Blood lead levels were taken on 49 test subjects prior to various JAVELIN missile test firings. Of those 49, 21 were outfitted with personal sampling equipment to determine airborne concentrations at the Assistant Gunner and Gunner positions. Periodic blood sampling after a single exposure showed an average increase of 2.27 ug/dL for all test subjects. Recommendations were made to consider changes in the positioning of the enclosure inhabitants to minimize airborne lead concentrations, to limit the number of missiles fired (situation dependent), and replacement of the lead

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ABSTRACT (continued)

B-resorcyolate with a non-lead containing burn rate modifier for the launch motor.

(end of abstract)

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EXPOSURE ASSESSMENT OF JAVELIN MISSILE COMBUSTION PRODUCTS

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February 1994

EXECUTIVE SUMMARY

The JAVELIN missile, formerly the Advanced Anti-Armor Weapon System - Medium (AAWS-M), is a man-portable, shoulder-fired, fire-and-forget, anti-armor weapon. Employment of the system will utilize standing, sitting/kneeling, and prone firing positions from launch environments including the open, room-sized enclosures, and fighting positions.

The launch motor contains about 1.4 grams of lead β-resorcylate as a burn rate modifier. Although the flight motor also contains lead, it was determined that the contribution of the flight motor to the gunner and assistant gunner exposures was minimal to non-existent. In 1987 Oak Ridge National Laboratory (ORNL) had been requested by the U.S. Army Biomedical Research and Development Laboratory (USABRDL) to study combustion products by use of test firings and model simulations; results at that time indicated that lead might be a problem. Systematic sampling and evaluation of the various combustion products under a variety of conditions during the test and development phases of the system were undertaken in order to assess any human health effects.

Preliminary sampling was conducted using real-time carbon monoxide monitors, high volume sampling pumps using cellulose ester filters, and low volume sampling pumps using impregnated molecular sieve sampling tubes. An eight stage micro-orifice uniform deposit impactor was used to determine particle size distribution. Carbon monoxide (CO), nitrous oxide (NO), nitrogen dioxide (NO_2), lead (Pb), copper (Cu), iron (Fe), and tin (Sn) were analyzed for. Airborne Fe, Cu, and Sn concentrations were all low to non-detectable and therefore did not exceed the OSHA PELs nor the ACGIH TLVs in any firing position. Carbon monoxide monitoring in the enclosure and fighting position revealed exposure concentrations ranging from 40 ppm for a period of 16 seconds to 140 ppm for a period of 10 seconds; well within acceptable standards. All nitrous oxide and nitrogen dioxide samples were below detectable limits. Airborne lead concentrations did not exceed the OSHA PEL for open air firings and for firings within the fighting position, but did exceed the standard for every sampling location within the enclosure.

Follow-up sampling evaluated airborne lead concentrations in the enclosure. The time-weighed average (TWA) airborne lead concentrations for the Gunner and Assistant Gunner remained in excess of the OSHA standard. Since the OSHA standard was based upon continuous rather than short-term exposure, blood lead concentrations were determined. Blood lead levels in the test subjects increased an average of 2.27 $\mu g\ dL^{-1}$ for a single firing of the JAVELIN; well below the OSHA blood lead limit of 50 $\mu g\ dL^{-1}$. Modeling for a large number of firings within the enclosure indicated that up to twelve missiles (the maximum number

available to a Company) could be fired in a short time without the airborne concentration resulting in excessive blood lead levels.

Sampling in the open produced results that all parameters measured (CO, NO, NO_2, Fe, Cu, Sn, and Pb) were below detectable limits indicating no potential for health hazards to personnel. Sampling in the fighting position indicated that none of the potentially toxic components studied were present in amounts capable of producing harmful effects.

Conclusions drawn from the USAMRD testing program are that the JAVELIN missile can be safely fired from the open, fighting position, and enclosure with respect to toxic combustion products; that breathing with the mouth open may lead to increased blood lead levels; and that additional research is needed on short-term exposures to lead from weapons systems in order to arrive at a military standard.

Recommendations include: that consideration be made of positioning the Assistant Gunner in enclosure firings close to the Gunner and at his left, facing away from the missile exhaust; that the personnel leave the enclosure as soon as practical; that as much ventilation be provided as the situation allows; that as few missiles be fired as the situation warrants but no more than twelve Javelins from the same enclosure with maximum time allowed between firings; that personnel do not breathe through their mouths; that use of the system in a training environment require the use of protective masks; that consideration be given to replacing the lead β-resorcylate with a non-lead containing burn rate modifier in any redesign of the missile; that additional studies take place on human exposures to short-term airborne concentrations of lead from weapons systems with the ultimate goal of defining a military-unique standard; that studies be performed investigating the effects of nose versus mouth breathing of lead; that additional studies be conducted on quantification of actual lead exposures in other Army weapon systems; and that consideration be given to study of the toxicity and exposure potential of the vent gases from the CLU battery.

NOTICE

Disclaimer

The findings in this report are not to be construed as an official Department of the Army position unless so designated by other authorized documents.

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Human Subjects

The investigators have adhered to the policies for protection of human subjects as prescribed in Army Regulation 70-25. The approved Human Use Protocol and associated affidavit (DA FORM 5303-R) are attached as Appendix A.

Disposition

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Completion of this study would not have been possible without cooperation on the part of many individuals. The authors wish to acknowledge the following people and organizations for their specific contributions to this effort.

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The entire JAVELIN Project Office, Redstone Arsenal, and Join Venture (Martin Marietta and Texas Instruments) personnel for their cooperation and help during the study.

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ABBREVIATIONS

μg	micrograms
AAWS-M	Advanced Anti-Armor Weapon System - Medium (former name of JAVELIN)
ACGIH	American Conference of Governmental Industrial Hygienists
ACM	Advanced Composite Material
BCU	battery coolant unit
BEI	Biological Exposure Index (ACGIH)
BLL	blood lead level
CLU	Command Launch Unit
cm	centimeter
COHb	carboxyhemoglobin
EED	electroexplosive device
ESAF	in-line electronic safe, arm fire
GER	the gas exchange region of the lung
GEU	guidance electronics unit
ICRP	International Commission on Radiological Protection
I^2R	*imaging infrared*
LBE	load-bearing equipment
LTA	Launch Tube Assembly
m	meter
MCE	methyl cellulose ester
mg	milligrams
mL	milliliter
mm	millimeter
MICOM	U.S. Army Missile Command
MTBB	maximum total body burden
NIOSH	National Institutes for Occupational Safety and Health
OHRB	Occupational Health Research Branch
ORNL	Oak Ridge National Laboratory
OSHA	Occupational Safety and Health Administration
Pb	lead
PbB	blood lead concentration
PEL	Permissible Exposure Limit (OSHA)
ppb	parts per billion
ppm	parts per million
PU	propulsion unit
RF	radiofrequency
TBB	total body burden

TBR	the tracheobronchial region of the lung
TECOM	U.S. Army Test and Evaluation Command
TLV	Threshold Limit Value (ACGIH)
TWA	time-weighed average
USABRDL	U.S. Army Biomedical Research and Development Laboratory
USAMRD	U.S. Army Medical Research Detachment
WRAIR	Walter Reed Army Institute of Research

INTRODUCTION

The JAVELIN missile, formerly called the Advanced Anti-Armor Weapon System - Medium (AAWS-M), is a man-portable, shoulder-fired, fire-and-forget, anti-armor weapon identified to replace the currently fielded DRAGON system. The missile plus launch tube weighs approximately fifty pounds, and it possesses increased range, lethality, and performance compared to its predecessor. The system (Figure 1) consists of the missile, launch tube assembly (LTA), and command launch unit (CLU), each of which will be discussed in a following section. Employment of the system (Figure 2) will utilize standing, sitting/kneeling, and prone firing positions from launch environments including the open, room-sized enclosures, and firing positions (foxholes).

The U.S. Army Biomedical Research and Development Laboratory (USABRDL) Occupational Health Research Branch (OHRB), now the U.S. Army Medical Research Detachment — Wright-Patterson Air Force Base (USAMRD), was asked by the JAVELIN Project Office to assess the potential exposure hazards from exposure to the combustion products of the missile when fired from each of the possible positions. In 1987, Oak Ridge National Laboratory (ORNL) was requested by USABRDL to study the potential combustion products of the missile by use of test firings and model simulations; results indicated that airborne lead concentrations might be a problem. Beginning in 1991 and continuing through 1993, USABRDL, and later USAMRD, conducted systematic sampling and evaluation of the various combustion products under a variety of conditions during the test and development phases of the system in order to assess the potential for human health effects resulting from firing the missile.

This report describes the methodology, procedures, results, conclusions and recommendations from that study.

JAVELIN SYSTEM

Round. The JAVELIN round (Figure 3) is comprised of the launch tube assembly (LTA) and missile. A reusable container is provided for storage and transportation. The LTA serves both as the single use, tactical field handling container and as the launch platform which is placed on the gunner's shoulder prior to firing. The tube provides the barrier between the environment and the missile prior to use by attenuating moisture, shock and impact, electromagnetic radiation, and electrostatic discharge. The LTA also provides a physical barrier to and directs the effects of the launch motor plume and exhaust away from the gunner during firing. Design considerations are incorporated into the LTA to protect the gunner personnel from accidents such as explosion of the launch motor while in the tube. The launch tube is made of advanced composite material (ACM) and provides increased protection to the gunner personnel in event of an accident.

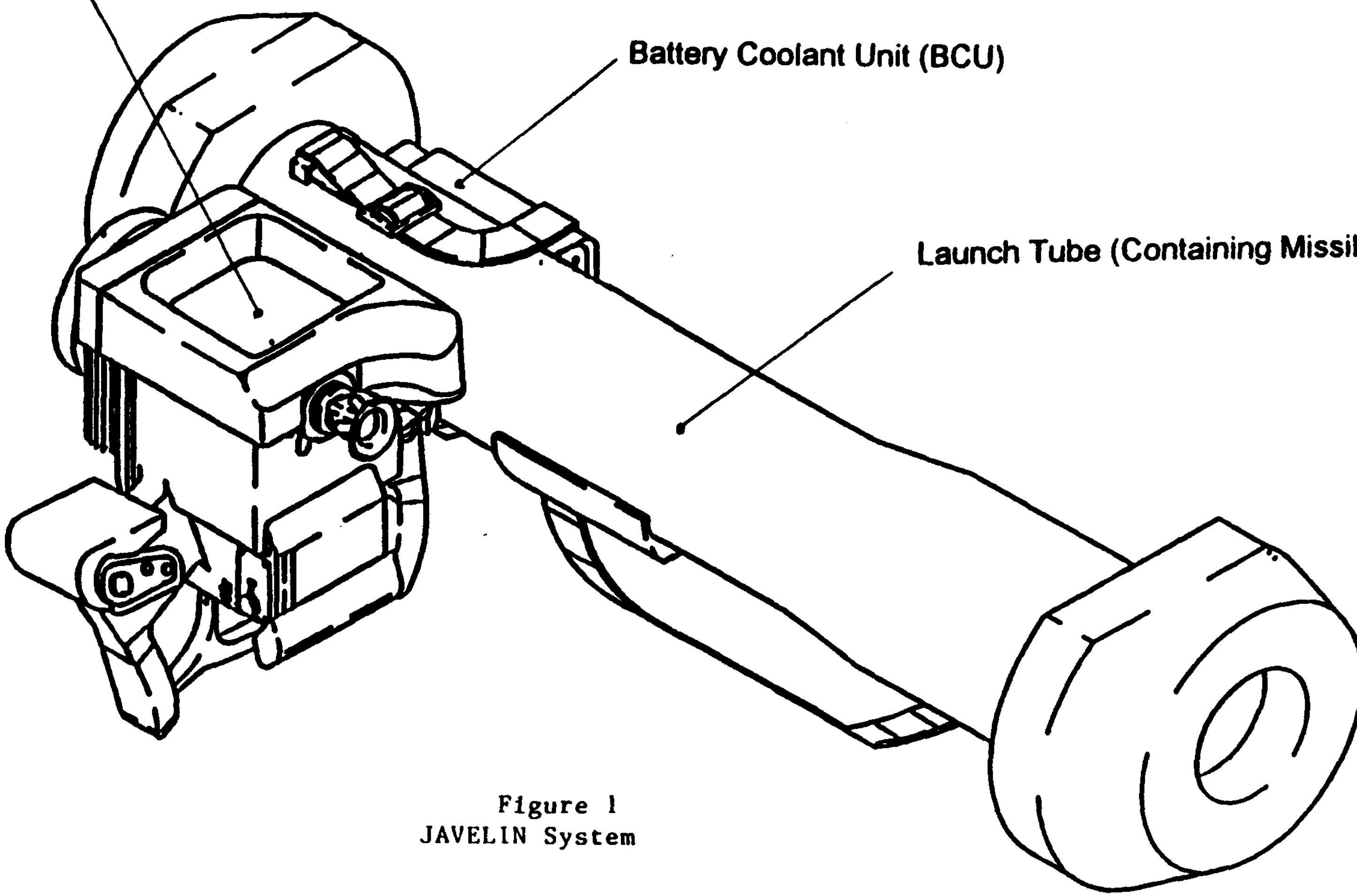
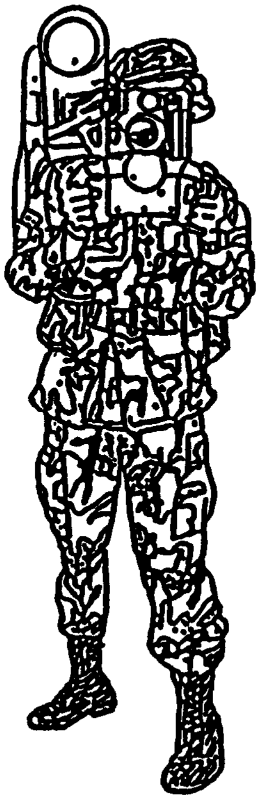
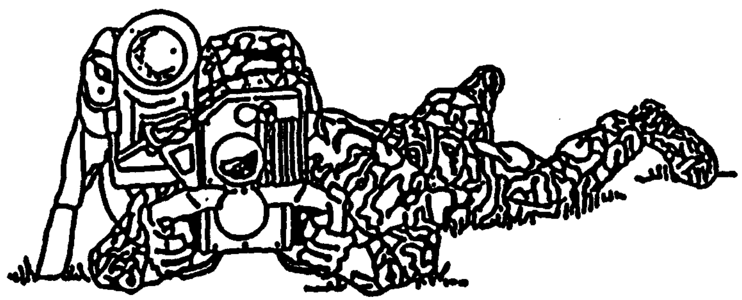


Figure 1
JAVELIN System

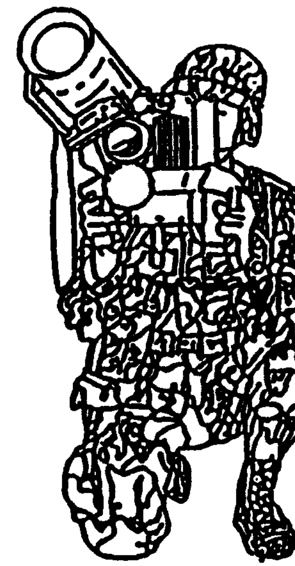
FIRING POSITIONS



STANDING POSITION

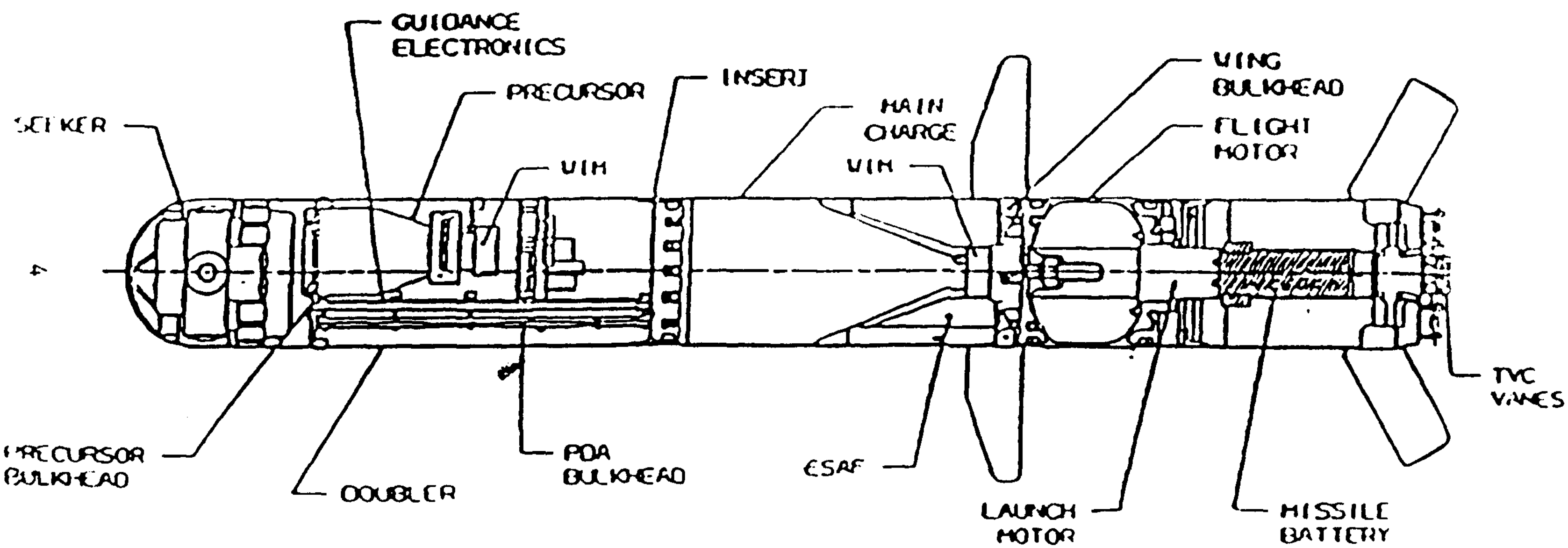


PRONE POSITION



KNEELING POSITION

SITTING POSITION


SEEKER
GUIDANCE ELECTRONICS
PRECURSOR
VIM
INSERT
MAIN CHARGE
VIM
WING BULKHEAD
FLIGHT MOTOR
TVC VANES
PRECURSOR BULKHEAD
DOUBLER
POA BULKHEAD
ESAF
LAUNCH MOTOR
MISSILE BATTERY

The missile is comprised of an imaging infrared (I^2R) seeker with contact fuze; guidance electronics unit (GEU); midbody with eight deployable wings; tandem warheads; in-line electronic safe, arm fire (ESAF) device; two-stage in-line propulsion unit (PU); and an electro-mechanical actuator with four control fins and thrust vector control. The soft-launch missile is expelled from the launch tube by the launch motor which completes its burn prior to tube exit. The launch motor uses M-36 propellant and the flight motor uses a classified formulation (Arcocel 430A). Following completion of sufficient coast distance downrange to ensure gunner safety, the flight motor is fired.

Battery Coolant Unit. The battery coolant unit (BCU) is comprised of a pressure vessel which contains the seeker cooling gases and a thermal battery providing electrical power to the missile during prefire operation. Both items are packaged into the BCU as a single consumable unit mounted to the exterior surface of the LTA. The gas flow and battery activation are electroexplosive devices (EED) initiated by CLU commands; the gas flow can be also initiated by a manual switch.

Command Launch Unit. The command launch unit (CLU) controls all gunner interface with the missile. The controls to initiate missile seeker cool-down, to acquire and lock the seeker on target, and to issue missile launch commands are provided on the CLU. A daysight and a nightsight are incorporated into the CLU to provide surveillance and target acquisition with or without the missile. The CLU is powered by a BA-5590 battery housed in a water-tight compartment. Some concern has been expressed about vent gases from this battery in the event of a short circuit; *this will be addressed later in this report.*

M-36-BASED LAUNCH MOTOR

The launch motor contains 100 grams of M-36 propellant. The M-36 propellant formulation is 49% nitrocellulose (binder/fuel), 40.6% nitroglycerin (oxidizer/plasticizer), 2% 2-nitrodiphenylamine (stabilizer), 3.3% di-n-propyl adipate (plasticizer), 2.5% lead β-resorcylate (burn rate modifier), 2.5% monobasic cupric salicylate (burn rate modifier), and 0.1% candelilla wax (extrusion aid). The JAVELIN launch motor contains approximately 1.4 grams of lead in total.

ARCOCEL 430A FLIGHT MOTOR

The JAVELIN flight motor contains a classified formulation; however, the lead content is not classified. Although the motor contains lead (as lead citrate) and a small amount of zirconium carbide, during the course of the USAMRD study, it was determined that the contribution of the flight motor to the gunner and assistant gunner exposures was minimal to non-existent.

OAK RIDGE NATIONAL LABORATORY STUDIES

The Oak Ridge National Laboratory (ORNL) conducted a study of the M-36 propellant to evaluate potential combustion products.[1] Results indicated that the concentration of lead should be carefully studied.

Analytical validation studies were conducted in a small chamber at ORNL with actual test firings at Redstone Arsenal. Real-time determination of selected species was conducted using non-dispersive infrared spectrometry, chemiluminescence, electrochemical monitoring, and optical scattering. Samples for trace analysis were analyzed using gas chromatography and mass spectrometry. Results indicated measurable quantities of carbon monoxide, lead, copper, and oxides of nitrogen. Carbon monoxide concentrations and resulting predicted carboxyhemoglobin (COHb) values using procedures established in MIL-STD-1472C and MIL-STD-759A did not exceed either then 5% or the 10% criteria in MIL-STD-1472C. Lead concentrations exceeding the OSHA standard were generated, prompting this study. Airborne copper concentrations were below the OSHA time-weighted PEL of 0.1 mg m^{-3} indicating little potential for health effects.

Based upon the ORNL results, a decision was made that USABRDL conduct an investigation into the airborne concentrations of carbon monoxide, oxides of nitrogen, lead, and copper; in addition, it was decided to look at iron and tin since they might also be present.

USABRDL/USAMRD STUDIES

Some concern has been expressed at System Safety Working Group (SSWG) meetings over the potential hazards of inhalation of vent gases from the BA-5590 battery in the CLU. Since this is not a product of missile combustion and the battery is common to many other systems, a separate evaluation will be performed by USAMRD on the exposure assessment of vent gases from the battery and a separate report will be issued. At this point, since venting is away from the gunner's breathing zone, the risk is considered small; however, additional studies should eliminate the uncertainty in this matter.

Initial Health Hazard Evaluation.

Airborne measurements of the combustion products from the Advanced Anti-Armor Weapon System-Medium (AAWS-M) as a result of mechanical test separations were begun in March of 1992. The United States Army Biomedical Research and Development Laboratory sampled for combustion products on five different days.

Six sampling locations were established: four which would most likely approximate the normal positioning of the Gunner and Assistant Gunner(s) within a building or enclosure and in the fighting position; and two to allow for the collection of combustion products approximately 5 meters directly behind the gunner position and general area sampling site located outside and upwind of the test building for use as a control to monitor ambient concentrations of airborne contaminants under study. Results for the latter two positions were below detection limits for all substances studied.

Direct (real-time) reading Neotronics Model CO-101 carbon monoxide monitors were placed at the gunner position and the assistant gunner position. High volume sampling pumps using 37 mm cellulose ester filters in open faced cassettes and having a sampling rate of 4 liters per minute (Lpm) and 14 Lpm (depending upon the location) and two low volume sampling pumps utilizing triethanolamine-(TEA) impregnated molecular sieve sampling tubes for NO and NO_2 with a sampling rate of 0.05 Lpm were placed in the enclosure or fighting position. An eight stage micro-orifice uniform deposit impactor (MOUDI) was used to determine the particle size distribution of combustion products in the 0-15 μm (micron) range.

A number of different analytes were sampled for during these mechanical test firings, to include carbon monoxide (CO), nitrous oxide (NO), nitrogen dioxide (NO_2), lead (Pb), copper (Cu), iron (Fe), and tin (Sn). Averaged concentrations of the metal analytes are listed in Table 1.

Results for Metals. Airborne Fe, Cu, and Sn concentrations were all low to non-detectable and therefore did not exceed the OSHA Permissible Exposure Limits nor did the results exceed the ACGIH TLVs for these analytes. Airborne lead concentrations, however, measured over the 31-39 minute sampling periods exceeded the OSHA PEL of 50 ug m^3 for every sampling location. A majority of the particulate ranged in size between 0.1 and 0.18 μm.

As a result of the possible health hazards of inorganic lead exposure, a more thorough study of the airborne lead concentrations associated with the JAVELIN missile was required.

Results for Oxides. Carbon monoxide monitoring revealed minimal to moderate carbon monoxide concentrations during the test separations. Exposure concentrations ranged from 40 ppm for a period of 16 seconds at the Gunner position to 140 ppm for a period of 10 seconds at the Assistant Gunner position.

All nitrous oxide and nitrogen dioxide samples were Below Detectable Limits (BDL). It was suggested, however, that while NO_2 concentration appeared to be low, a short-term definitive exposure survey for NO_2 should be conducted for full compliance regarding federal work standards since the TEA sampling tubes have an accuracy of only ±25%.

Follow-up Studies.

Sampling was conducted again in September 1992 to evaluate short term airborne lead concentrations in the enclosure. Since there was evidence that each successive firing had higher lead levels, possibly as the result of resuspension of previously deposited material, prior to the follow-up mechanical test separation sampling, efforts were made to eliminate or reduce residual combustion products deposited on the interior walls of the enclosure as a result of previous test firings by washing the floors and walls followed by repainting the walls.

The sampling protocol was consistent with the previous sampling efforts.

Table 1
Metal Results

Thirty-one Minute Sampling Time (Fighting Position)

Location	Total Pb µg/m³	Total Fe µg/m³	Total Cu µg/m³
1	773.00	92.93	231.40
2	721.80	136.93	221.02
3	46.62	58.02	15.26
4	BDL	BDL	BDL

Thirty-five Minute Sampling Time (Enclosure)

Location	Total Pb µg/m³	Total Fe µg/m³	Total Cu µg/m³
1	914.61	22.06	262.59
2	989.60	24.88	272.27
3	1087.93	127.07	252.61
4	30.80	54.60	BDL

Thirty-five Minute Sampling Time (Enclosure)

Location	Total Pb µg/m³	Total Fe µg/m³	Total Cu µg/m³
1	1307.16	21.12	311.71
2	1578.50	64.73	346.69
3	1358.22	32.78	348.58
4	295.91	BDL	BDL

Thirty-six Minute Sampling Time (Enclosure)

Location	Total Pb µg/m³	Total Fe µg/m³	Total Cu µg/m³
1	1208.13	39.81	347.30
2	2262.61	62.47	671.76
3	1696.32	38.36	497.25
4	BDL	BDL	BDL

Thirty-nine Minute Sampling Time (Enclosure)

Location	Total Pb µg/m³	Total Fe µg/m³	Total Cu µg/m³
1	858.24	34.93	201.68
2	988.27	38.13	246.82
3	1386.46	51.50	319.52
4	BDL	13.65	BDL

Low-flow sampling instruments using 37 mm methyl cellulose ester (MCE) filters were calibrated to approximately 2 liters per minute of airflow in accordance with NIOSH standards. Sampling periods were generally on the order of two minutes rather than the approximately half hour of the earlier studies since evidence appeared to support a very brief actual exposure time for the combustion products.

To ensure that the oxides of nitrogen were not a problem, a laboratory nitrogen oxide real-time monitor (Binos model 91 Nitrogen Monitor, Leybold-Heraeus Corporation) was placed 50 cm behind and to the left of the Gunner position. Results for both NO and NO_2 were below detectable limits, confirming the earlier TEA results.

Results of Follow-up Sampling. The averaged 2 minute concentrations for the Gunner and Assistant Gunner were 14,628 $\mu g\ m^{-3}$ and 18,304 $\mu g\ m^{-3}$. Assuming an average inhalation rate of 20.83 liters per minute for a 70 kg man, a Maximum Total Body Burden (MTBB) for inspired inorganic lead would be 500 μg. Based upon the results obtained, the Total Body Burden (TBB) for this test firing equaled an 8-hour time-weighted average (TWA) of 609 μg for the Gunner and 763 μg for the Assistant Gunner. Again these airborne exposures exceeded the OSHA standard for airborne lead.

Additional sampling in the enclosure and the fighting position during March 1993 showed a more favorable exposure concentration at the Gunner location (average 30.5 $\mu g\ m^{-3}$ [enclosure], and 5.6 $\mu g\ m^{-3}$ [fighting position]). The Assistant Gunner showed an airborne lead concentration of 128 $\mu g\ m^{-3}$ in the enclosure and 24 $\mu g\ m^{-3}$ in the fighting position. Since the exposure at the Assistant Gunner position was greater than that at the Gunner position in all cases studied, a recommendation was made to move the Assistant Gunner closer to the Gunner position to (1) create a baffling effect for weapon exhaust back into the Assistant Gunner's breathing zone and (2) diminish airborne lead concentrations in the breathing zone to approximate that of the Gunner. It was further recommended that any additional sampling be conducted using a mannequin or human at the Assistant Gunner position to evaluate the shielding effect of the body from the combustion products during the firing.

Sampling in the open on 24 January 1993 produced results that all parameters measured (CO, NO, NO_2, Fe, Cu, Sn, and Pb) were below detectable limits indicating no potential for health hazards to the Gunner or Assistant Gunner. Since the airborne lead levels in the enclosure were in excess of the OSHA standard for a time-weighed eight-hour workday but the standard was based upon continuous exposure rather than such short-term exposure, it was recommended that blood lead concentrations be determined.

Blood Lead Study (USAMRD). This study was performed to determine the direct effects of short-term exposure to aerosolized lead particles from the JAVELIN missile exhaust on human blood-lead levels. Volunteers were obtained following acceptance of the Human Use Protocol (Appendix A) by the U.S. Army Medical Research and Development Command (USAMRDC).

Computer modeling was also incorporated using the Bert et al. model to estimate the projected blood lead (PbB) concentrations from firing the JAVELIN missile in the enclosure and in the fighting position at the Gunner and Assistant Gunner locations. The computer model also estimated lead accumulation in the bone of exposed personnel for the same firings.

Exposure Scenario. Participants in this study were exposed to the exhaust products resulting from the firing of the JAVELIN missile in a modified enclosure (Appendix B, Figure 1) and a fighting position (Appendix B, Figure 2). Participants were positioned on both the left and right side of the gunner position in the enclosure and directly to the right side of the gunner in the fighting position.

Airborne Sampling Methods. An average of twelve GilAir Personal Air Sampler pumps (Gilian Instrument Corporation) were used during each single-fire sampling period. Six pumps were charged at a time the night preceding the JAVELIN test firing using a Gilian BMWS-200 charger and then calibrated to approximately 2 liters per minute (Lpm) of air using the Bios DC-1 Flow Calibrator (Bios International Corporation). Ten successive flow measurements were taken and averaged for a pre-calibration reading with a 37-mm diameter methyl cellulose ester (MCE) filter for inorganic lead collections placed in the sampling train to simulate the prescribed sampling protocol.

Two personal sampling pumps, associated tubing, and MCE filters were secured to five Load Bearing Equipment (LBE) carriers using clips and tape to prevent the sampling equipment from interfering with the movement of each of the enclosure test subjects. Placement of personnel and sampling devices are shown in Figure x.

Upon completion of the test firing, each pump was immediately post-calibrated to determine flowrate fluctuations. Results were discarded if there were more than 5% variation from the pre-calibration values.

The JAVELIN exhaust general area was sampled with a GilAir Personal Air Sampler pump placed approximately fifteen feet behind the Gunner position. The sampling protocol was consistent with that of the breathing zone and general area described earlier.

Sampling was also conducted outside the enclosure to determine the presence of ambient or background lead concentrations. The location of the pumps are consistent with previous air sampling protocols associated with the JAVELIN test firings.

Soldier Participation. The study group consisted of forty-nine military personnel from Redstone Arsenal, AL, Fort Leonard Wood, MO, Fort Benning, GA, and Wright-Patterson AFB, OH. Blood-lead levels were determined on each soldier to establish a baseline and also to eliminate any personnel occupationally, or by other means, who might have existing blood lead levels near or above the Action Level (30 mg m^{-3}) limit established by the Occupational Safety and Health Administration. Approximately 5 mL of blood was drawn before exposure to establish the baseline blood-lead level, then at 48-hours, 7 days, and 30 days, post-exposure.

Since previous airborne lead sampling data indicated elevated levels of inorganic lead at the Assistant Gunner position, efforts to place study participants in those areas to determine blood lead levels from infrequent, short-duration air exposure were sought.

Each participant was briefed as to the purpose of the research study, the wear of the modified LBE, the sequence of events, and any safety concerns expressed by the Redstone Arsenal, U.S. Army Missile Command (MICOM), U.S. Army Test and Evaluation Command (TECOM), and JAVELIN project personnel prior to the test fire. In addition to the pre-brief, each individual was given a DA Form 5303-R, Volunteer Agreement Affidavit (Appendix A) to review and sign, as well as a survey form to ascertain general current health status and any potential chemical exposures, including lead in any form, including solder.

Airborne Lead Analyses. The used MCE filter cassettes were capped upon completion of each firing and packaged for shipment together with two blank filter cassettes as controls. Analysis for inorganic lead was performed by the United States Army Biomedical Research and Development Laboratory (USABRDL), Ft Detrick, Maryland. All samples were analyzed for lead content using Inductively Coupled Argon Plasma (ICAP) instrumentation in accordance with NIOSH method 7300 for multi-element emission spectroscopy (Department of Health and Human Service [NISOH] Pub. No 84-100, 1984).

All breathing zone, general and blast area samples were analyzed for lead content using the ICAP. The emission source for the ICAP spectrometer was powered by a 2 kw crystal controlled radio frequency (RF) generator. Argon gas is passed through a quartz torch assembly where the gas is scattered with electrons from an external source such as a spark causing the electrons to accelerate within a torroidal path by the RF electromagnetic field. The electrons collide with argon atoms to form more electrons and argon ions, which in turn become excited. This excitation cycle continues until the argon gas becomes extremely ionized (plasma) and a discharge occurs which remains stable as long as the radio frequency field is maintained. What makes the ICAP an excellent choice for elemental analysis is that the temperatures needed to produce emission lines and bands sometime require extreme temperatures. Temperatures within the torrodial plasma can reach 10,000 K. Temperatures produced in a natural gas-air flame may only be sufficient to excite only alkali- and alkaline-earth metals (approximately 1800 °C).

Samples are introduced as solid, liquid, or gas. The analytical method used to determine lead content for the JAVELIN samples was by use of a liquid solution produced by digesting the collection media filter with acid. Liquid samples were introduced into the plasma discharge as an aerosol suspended in the argon gas. The aerosol/gas mixture is then passed through the torroidal torch and atomized producing the an emission of light characterizing the degree of ionic excitation and their return to a ground state. The emitted light is transmitted to an optical system. The signature emission lines and bands are characterized and quantified.

Blood Lead Analyses. Blood samples were taken to determine the concentration of lead from exhaust products resulting from the JAVELIN missile firing. Each study participant who was chosen to complete the study was required to supply three additional blood samples at 48 hours, 7 days, and 30 days post-firing. All samples was collected in lavender top Vacutainer tubes (Becton Dickinson

Vacutainer Systems) with freeze-dried ethylene diamine tetra-acetic acid (EDTA) as a chelating and anticoagulant agent and sent for analysis to the Dwight David Eisenhower Army Medical Center, Fort Gordon, Georgia.

Blood samples are diluted with a matrix modifier solution of dilute nitric acid, Triton X-100, and diammonium hydrogen phosphate to stabilize the lead so that a majority of the blood matrix can be removed before the char step. Clinical analysis of the blood lead samples was determined by electrothermal atomization spectrometry in a graphite furnace using a method developed by Miller et al.[2] The measurement of lead is established by the amount of light absorbed at 283.3 nm by ground state atoms of lead from a lead hollow-cathode lamp using an atomic absorption spectrometer equipped with Zeeman background correction.

HEALTH EFFECTS OF, AND EXPOSURES TO, LEAD

Introduction. Lead was one of the first metals discovered and fashioned by humans.[3] Because of its low melting temperature, malleability, and other characteristics such as high density and highly colored compounds, it has been associated with many industrial uses throughout history. The poisoning potential for lead has been known since ancient times,[4] and some scholars have even proposed that poisoning by lead leached from lead-lined aqueducts was one of the reasons for mental aberrations among the Roman nobility and the eventual fall of their empire.

Some of the earliest recorded occupational health concerns were about lead in mines of the Mediterranean region as far back as Roman times.[5,6] Acute and chronic effects were noted from lead exposure. The symptomatology, clinical presentations, and laboratory studies have resulted in a vast literature of lead effects.[7-17] In brief, the most likely consequences are lung and eye irritation from acute exposures to lead dusts, "wrist drop" and numbness in extremities, mental retardation and nervous system damage from chronic exposures to forms of inorganic lead, decreased growth rates in children, anemia, and possible decreased sperm count and altered sperm morphology in males exposed to lead and lead compounds. Lead can be transmitted via mother's milk to nursing children. Lead interferes with calcium metabolism and is a cumulative poison, accumulating in blood, bone, and kidneys; in bone it can remain for years and may be mobilized upon stress. The most serious effects are probably mental and physical developmental effects in exposed children, decreased fertility in adults, nervous system and kidney damage in adults, and possible hereditary birth defects in offspring of exposed adults.

Inhalation Deposition of Particles. Particulates which enter the nose or mouth may deposit in either the tracheobronchial region (TBR) or the gas exchange region (GER) of the lung. The amount deposited depends upon several factors, including particle size, rate and volume of respiration, and anatomy. Differences appear for mouth breathing versus nose breathing since large particles are generally deposited in the nasal-pharyngeal region in nose breathing but can enter the lungs in mouth breathing. Deposition of particles in the various regions of the respiratory tree is shown in Figures 5, 6, and 7 (from the International Commission on Radiological Protection[18]) for particles of aerodynamic diameters between 0.01 and 100 μm with density of 1 g cm^{-3}. Although lead and inorganic lead particles generally possess densities greater than 1 g cm^{-3}, this chart does give an indication of region of deposition for combustion particles from the JAVELIN missile.

One of the most widely used models of regional deposition versus particle size was developed by the International Commission on Radiological Protection (ICRP) Task Group on Lung Dynamics.[18] Although the purpose of these models was to study the deposition of radioactive particles, the aerosol models are applicable to particles in general. It should be noted that wide variations may occur in the population between adults and children and between males and females. The values used in the ICRP models are for the average adult worker weighing 70 kg with height 175 cm and surface area of 1.8 m^2. The particles are assumed to be insoluble, stable, and spherical with density of 1 g cm^{-3}. Regional deposition was calculated for the average adult breathing at a rate of 15 breaths per minute for tidal volumes of 750 mL (at rest) and 1450 mL (moderate activity).

The major differences in deposition between nose and mouth breathing result from the relatively efficient removal of particles larger than 10 μm by the nasal-pharyngeal region and reduction of particles between 2 μm and 10 μm in nose breathing. For example, for aerosol of unit density with spherical aerodynamic diameters of 0.2 μm, 1 μm, 5 μm, and 10 μm, deep-lung deposition from nose breathing would result in retained fractions of 35%, 25%, 10%, and 0% and tracheobronchial deposition would result in retained fractions of 2%, 3%, 6%, and 0%. For mouth breathing, deep-lung deposition would be 35%, 30%, 55%, and 10%.

Since the majority of the combustion particles from the JAVELIN missile firing are in the range of 0.1 to 0.18 μm, there is the possibility that mouth breathing may alter the deep-lung deposition because there is increased retention of particles of this size from mouth breathing. One of the test subjects in this study (number 6) breathed through his mouth; this might explain the increased blood lead level relative to the other subjects as well as his more rapid decrease in blood lead concentration with time. Additional research is being conducted by USAMRD to investigate this possibility.

Lead in Artillery. With the development of modern gunpowder-based artillery, it was discovered that the rifling in gun barrels was quickly affected by deposition of copper from the rounds with resulting loss of range and accuracy. It was found that the addition of metallic lead, usually in the form of foil, with the powder charge led to a reduction in copper deposition. This use of lead as a decoppering agent in artillery has led to potential exposures of artillery crews to airborne particulate lead.[19] In addition, a number of standard missile propellants used by the military contain lead as a burn rate modifier so that combustion proceeds smoothly and at a controlled rate as in the M-36 propellant of the JAVELIN missile.

Figure 5 - Total and regional deposition fractions for various sizes of inhaled airborne spherical particles with physical density of 1.0 g/cm^3 in the human respiratory tact as calculated by the International Commission on Radiological Protection (ICRP) Task Group on Lung Dynamics[18] for nasal breathing at a rate of 15 breaths per minute (BPM) and tidal volume (TV) of 1450 cm^3

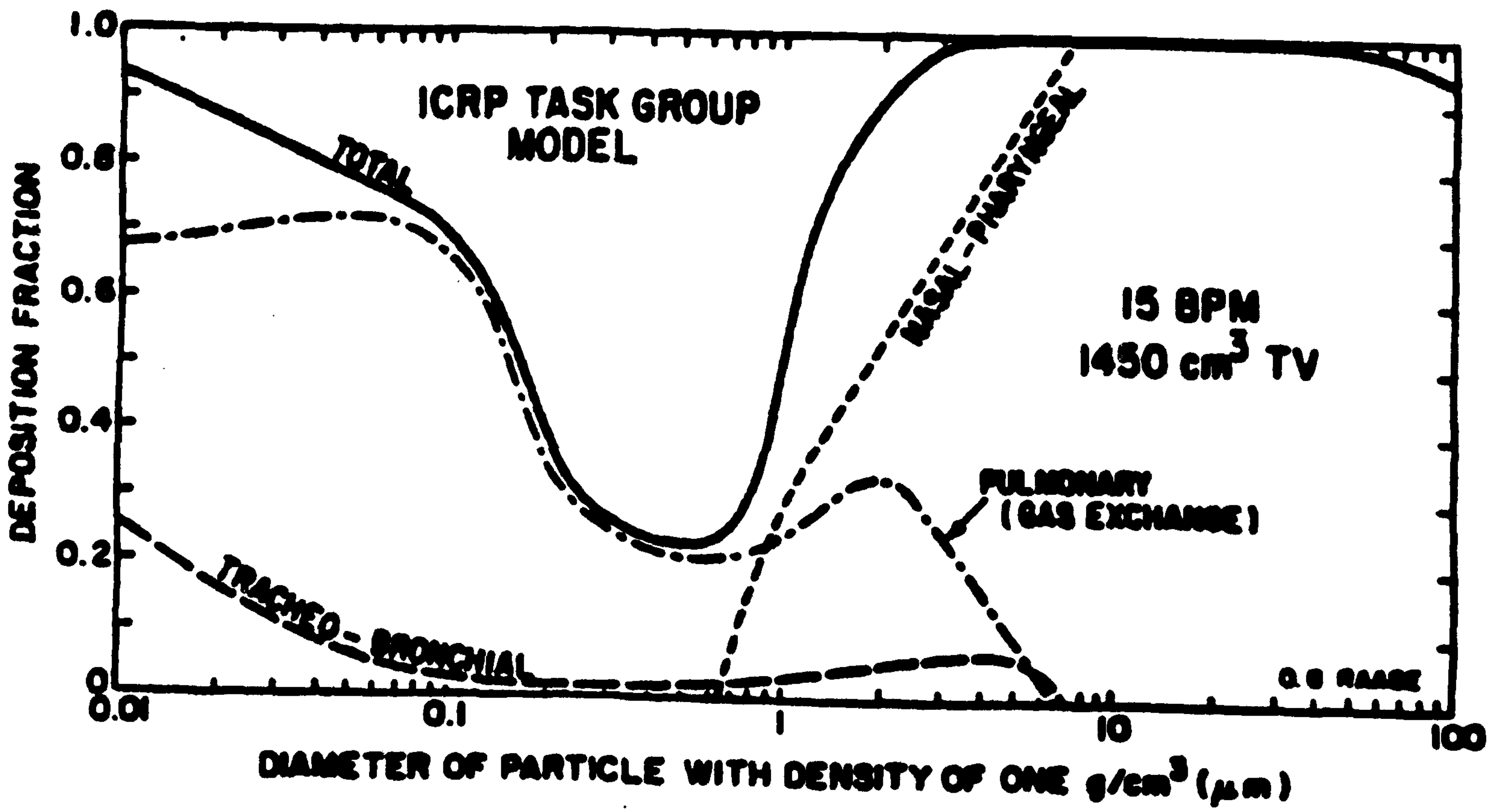


Figure 6 - Selected data reported for the deposition in the entire respiratory tract of monodisperse aerosols inhaled by persons via the nose from various sources compared with predicted values calculated by the ICRP Task Group on Lung Dynamics[18] for tidal volumes (TV) of 750 cm^3 (dashed line) and 1450 cm^3 (solid line).

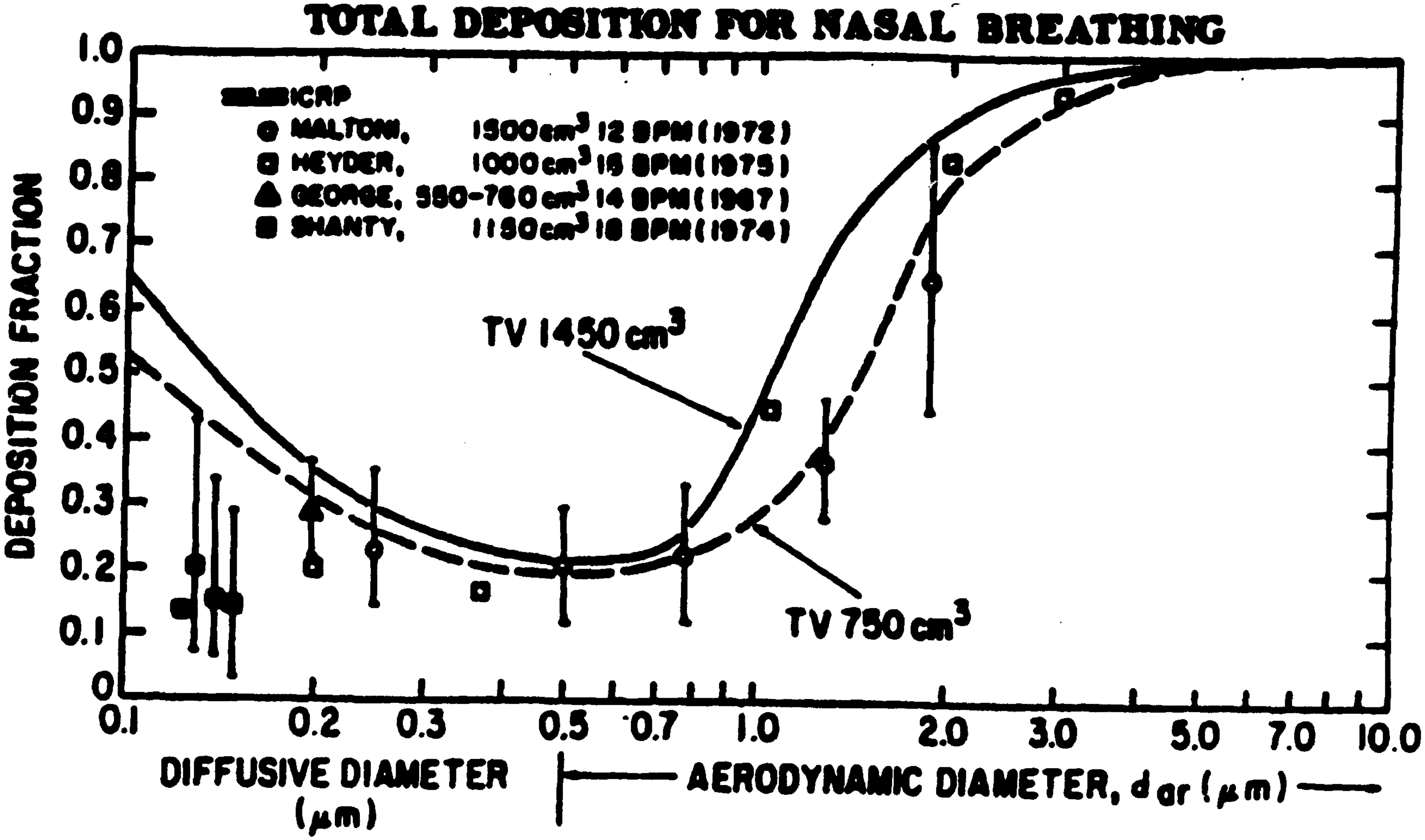
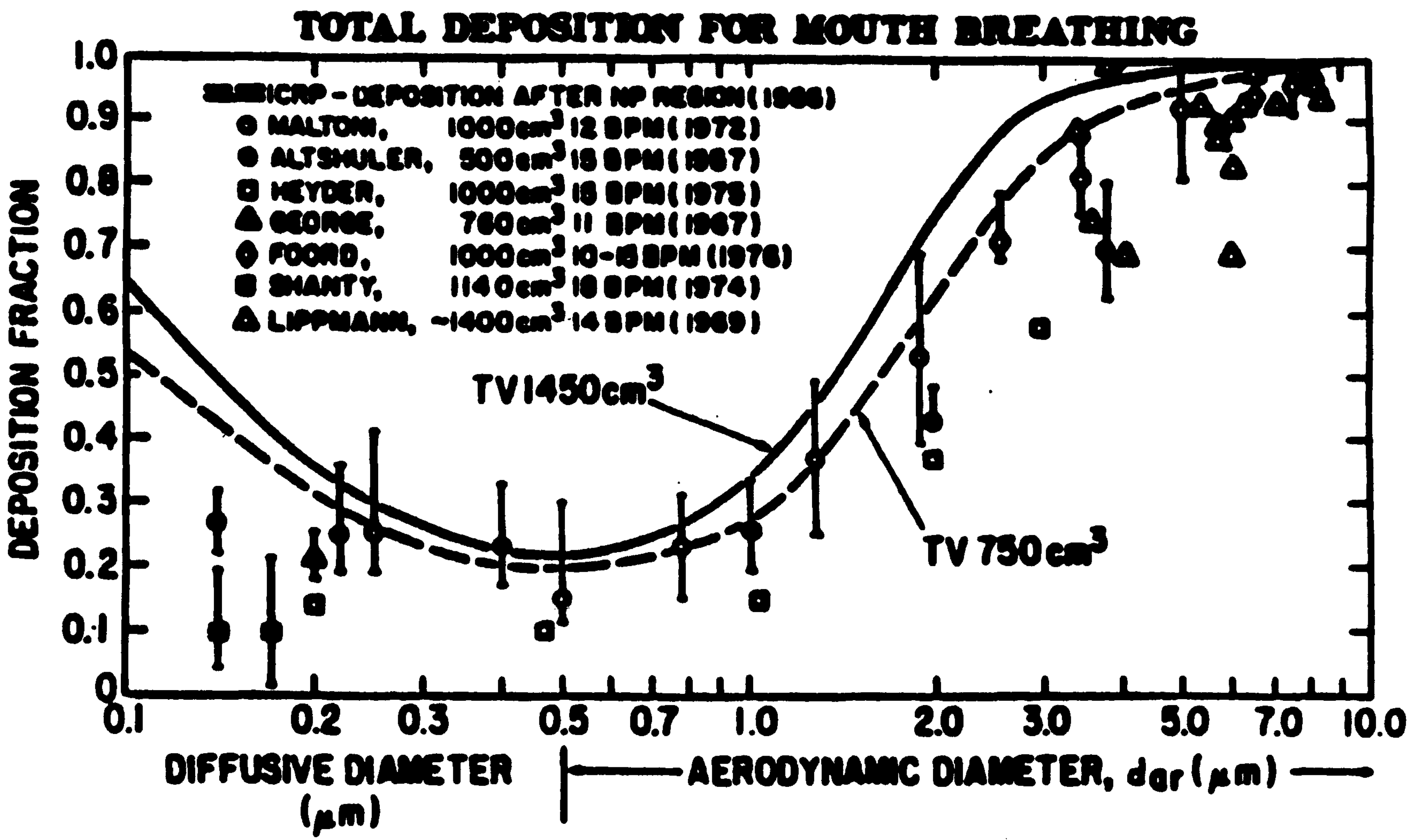


Figure 7 - Selected data reported for the deposition in the entire respiratory tract of monodisperse aerosols inhaled by persons through the mouth compared with predicted values calculated by the ICRP Task Group on Lung Dynamics[18] for tidal volumes (TV) of 750 cm^3 (dashed line) and 1450 cm^3 (solid line).



Other Exposures to Lead. Lead, being ubiquitous in many materials and products, can contribute to exposure and body burden outside of weapons systems firings. Soldiers can also be exposed to lead in solder used in electronics applications. Lead is, or was, contained in many paints and primers used by the military. A current area of interest is the exposure of people, especially children, to lead in paints containing lead pigments which have been in common use since the 1920s. The recent Lead-Based Paint Program of the U.S. Department of Housing and Urban Development has targeted locating and eliminating lead-based paints from any areas whether young children might be exposed.

Exposure Standards. The Occupational Safety and Health Administration (OSHA), using research from the National Institutes of Occupational Health (NIOSH), in 1978 promulgated in 29 Code of Federal Regulations (CFR) Part 1910.1025 an exposure standard for airborne lead together with air concentration monitoring , administrative controls, biological monitoring, and counseling requirements for all employees exposed to lead. This standard defines "lead" as metallic lead, all inorganic lead compounds, and organic lead soaps but excludes all other forms of organic lead. The current 8-hour time-weighted average (TWA) permissible exposure limit (PEL) under OSHA for lead is 50 micrograms of lead per cubic meter of air (50 μg Pb m^{-3} of air). Workplaces exceeding the OSHA "action level" must initiate actions such as notification of both male and female employees with potential exposures to lead in the workplace concerning possible reproductive and other hazards of lead. This action level, currently defined as 30 μg Pb m^{-3} of air or measured blood lead level (BLL) exceeding 40 micrograms of lead per 100 grams (or deciliter) of whole blood (40 μg Pb dL^{-1}), serves to indicate the potential for unacceptable exposure. The lead standard mandates that BLL be maintained below 30 μg Pb dL^{-1} of whole blood for employees of reproductive age who anticipate pregnancy "in the near future". In addition to requirements for special training and education, employees are to be provided with pregnancy tests and laboratory evaluations of male fertility upon request.[20]

The current recommended exposure limit for inorganic lead in industrial settings published as a Threshold Limit Value (TLV) by the American Conference of Governmental Industrial Hygienists (ACGIH) is 0.15 mg PB m^{-3} of air,[21] three times higher than the OSHA PEL. Some concern has been expressed over the wide difference between the OSHA and ACGIH values, but to be conservative, the OSHA value will be used in lieu of a military-unique standard.

Applicability of OSHA Standard. While lead exposure by artillery crews and missile gunners is not covered under OSHA regulations due to its military uniqueness, Executive Order Number 12196 requires that the U.S. military apply the OSHA standard in all cases where there is not an accepted military-unique standard.[22] The Executive Order is implemented in Department of Defense Instruction (DoDI) 6055.1. There are nuances to this requirement since battlefield conditions in war may or may not be covered depending upon conditions of the combat; however, exposures in training scenarios are covered. The relationship between airborne lead and BLL is critical since the physiological effects of lead exposure depend upon the amount of lead that enters the body; this is the reason that biological exposure indices such as BLL are generally considered to be more accurate for evaluation of lead exposure than airborne levels. However, the OSHA airborne PEL was based upon NIOSH and other published research generally related to long-term or, at least, routine exposures to lead in such situations as lead mines, smelters, lead-acid battery work, and paint exposures.[23] This situation may be quite different from military exposures which are generally of high concentration but very brief duration and low frequency.[24]

Military Exposures. There are a variety of potential lead exposures for soldiers. Artillery systems employ lead as a decoppering agent in what are called "high-zone" charges, that is, the larger powder charges known as "green bag" and "red bag" to artillerymen from the color of the powder wrapping. The green bag charges are not as common in training as smaller charges but are still used on a regular basis; red bag charges are very rare in training and are only seen in actual combat. Exposures to lead from the 155mm howitzer have been documented in several reports.[25-27] Airborne levels for total lead have been found which exceed the OSHA twenty-four-hour TWA value of 16.7 $\mu g\ m^{-3}$ in a majority of the sampling periods studied and 86% of one study's concentrations[27] were in excess of the OSHA PEL of 24,000 μg-min m^{-3}. In fact, the twenty-four hour PEL for airborne lead was exceeded by a factor of six times 26% of the time during the three exercises using high zone charges which were studied. In another study,[28] air concentrations were not nearly as high but favorable meteorological conditions together with opened hatches on the howitzers were felt to have been the reason.

Other possible exposures of soldiers to lead include firing missiles. The currently-fielded DRAGON has a launch motor using lead β-resorcylate as a burn rate modifier as does the JAVELIN. Unpublished studies by USAMRD of the missile fired outdoors indicate that the OSHA limit is not exceeded; in fact, air concentrations are below detectable limits. The one scenario where there is some concern is firing the JAVELIN from inside a building, a situation impossible for the DRAGON due to its blast overpressure and noise levels. The exposure duration is very short, averaging only a few minutes at the highest concentration. OSHA allows for time averaging for periods greater than eight hours but not for periods less than this. Thus, there is a quandary: the weapon system, under certain conditions, exceeds the OSHA eight-hour TWA which the Executive Order requires adherence to yet the OSHA PEL may not be the best standard for comparison. To investigate the possibility that another standard be considered, additional studies have been undertaken of the relationship between air concentration and blood lead levels for brief, infrequent exposures and will be published in a separate report.

RESULTS OF USABRDL/USAMRD STUDIES

The Time Weighted Average (TWA) concentrations of lead for the Assistant Gunner positions in the enclosure were exceeded in all firings. At the Gunner position, the exposure averaged 74.32 $\mu g\ m^{-3}$ with the lowest airborne concentration of 42.12 ug m^{-3}, these are presented in Appendix B. Blast area results ranged from 76 ug m^{-3} to 140 ug m^{-3}. Fluctuations may be the result of meteorological influence, given all other pre-existing factors remained constant; in at least one case, the rear door of the enclosure opened and closed during the firing, apparently due to negative pressure developed as a result of the missile firing.

Airborne lead sampling conducted in the fighting position at the Assistant Gunner position were more favorable. The airborne concentration was 16.83 $\mu g\ m^{-3}$ in this posture; well below the PEL of 50 $\mu g\ m^{-3}$.

Results for the airborne and blood lead studies are presented in Appendix B. Blood lead exposures for a single test fire showed only slight increases in blood lead levels. An average increase of 2.27 $\mu g\ dL^{-1}$ from baseline blood lead levels were shown at the 48 hour mark following the initial test fire for all study participants. A return to baseline within 1 $\mu g\ dL^{-1}$ was exhibited within 30 days for 90 percent of all participants completing the study.

The Bert Model[29] was used to predict possible blood lead levels for the Gunner and Assistant Gunner based upon a single fire exhaust exposure. By taking known airborne lead concentrations from each firing and plotting them against a most probable blood lead baseline (in this case 4 $\mu g\ dL^{-1}$ was used and is represented by the first data point of each graph in Appendix C), a projected blood lead concentration may be calculated. The model considers the following parameters: fraction of inhaled lead retained in the lungs, the fraction of ingested lead absorbed into the blood, the daily volume of inhaled air, the mass of lead ingested daily, the residence time of lead in the lungs, and the background level of atmospheric lead. Although the model doesn't take into consideration individual metabolic rates, it has shown some validity in predicting return to baseline blood lead levels in this study.

Using the Bert et al. model and assuming the firing of twelve missile within a brief period of time (on the order of 36 minutes, which would be the maximum rate of fire for a Company-sized unit), the average increase in airborne lead ranged from 90 to 150 $\mu g\ m^{-3}$ and the average 48-hour post-firing increase in bloodborne lead was 2.3 $\mu g\ dL^{-1}$ for one firing so that the increase in blood level of lead should be less than 20 $\mu g\ dL^{-1}$ for twelve firings (approximately one-half the OSHA limit for lead workers). It is felt that this is a safe level of exposure based upon the blood results from this study; however, it should be stressed that this would represent a maximum fire situation both from the standpoint of missile availability and toxic combustion products exposure. Exposures to exhaust gases from the JAVELIN should be kept at the lowest possible under the tactical situation.

CONCLUSIONS

Conclusions drawn from the USAMRD testing program are that the JAVELIN missile can be safely fired from the open, fighting position, and enclosure with respect to toxic combustion products; that breathing with the mouth open may lead to increased blood lead levels; and that additional research is needed on short-term exposures to lead from weapons systems in order to arrive at a military standard.

All toxic substances studied were undetectable for open air firings. For the fighting position, the carbon monoxide, oxides of nitrogen, and lead levels were below applicable standards. For the enclosure, the carbon monoxide, oxides of nitrogen, iron, copper, and tin levels were below applicable standards; however, the airborne lead level exceeded the both the OSHA PEL and the ACGIH TWA-TLV as corrected to eight hour average. The lead exposure did not increase the blood lead levels of the study subjects beyond the OSHA standard; in fact, modeling indicated that even multiple firings would not exceed the blood lead standard.

The one subject (number 6) who used mouth breathing exhibited the largest increase in blood lead level of all the participants. Additional research appears to be needed to evaluate the effects of mouth breathing of the missile combustion products, especially the lead. A majority of the lead particles appeared to range between 0.1 and 0.18 μm, sizes which have between 25 and 50% retained in the respiratory tract for nose breathing and between 30 and 55% for mouth breathing.

Since there is an increase, even though slight, in blood lead levels from firing the JAVELIN indoors, personnel, especially training cadre, firing in a training environment rather than actual combat situations should wear protective masks to prevent exposure to particulates.

Additional research also appears to be needed in order to arrive at a military-unique standard for airborne exposures to particulate lead since the OSHA standard, being based on long-term, continuous exposures, does not seem to adequately address the brief, infrequent exposures experienced by military personnel from weapons systems as may be seen in the lack of relationship between airborne lead levels and blood lead levels in the test subjects.

RECOMMENDATIONS

1. For JAVELIN Operation:

a. For enclosure firings, that consideration be made of positioning the Assistant Gunner as close to the Gunner as possible, facing away from the missile exhaust at the time of firing and to the Gunner's left when facing in the direction of firing, in order to reduce the concentration of lead-containing particulate in their breathing zones.

b. For enclosure firings, that the Gunner and Assistant Gunner leave the enclosure as soon as practical, depending upon the situation, in order to reduce the amount of lead inhaled. Although the exposure to lead particulate appears to occur in a very brief period following the firing, there is evidence that lead-containing materials can be resuspended by activity within the enclosure.

c. For enclosure firings, that as much ventilation be provided (leaving windows or doors open) as the situation allows in order to reduce the concentration of lead present.

d. For enclosure firings, that as few missiles be fired as the situation warrants but no more than twelve Javelins be fired from the same position, and that maximum spacing be provided between firings depending upon the tactical situation.

e. For all firings, that the Gunner and Assistant Gunner do not breathe through their mouths.

f. That personnel firing the missile in a training situation should wear acceptable protective masks as determined by proper health authorities.

g. For future rocket motor redesign, that consideration be given to replacing the lead β-resorcylate with a non-lead containing burn rate modifier.

2. For future medical research:

a. That additional studies be performed on human exposures to short-term but relatively high airborne concentrations of lead from weapons systems with the ultimate goal of defining a military-unique standard.

b. That a study be performed to investigate the relative effects of nose breathing versus mouth breathing of lead-containing particulates from weapon systems.

c. That additional studied be conducted on quantification of actual lead exposures in other Army weapon systems.

d. That consideration be given to a study of the toxicity and exposure potential of the vent gases from the BA-5590 battery in the CLU.

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APPENDIX A

HUMAN USE PROTOCOL
EXPOSURE OF SOLDIERS TO LEAD PARTICULATES
DURING TEST FIRING OF THE JAVELIN MISSILE

1. Purpose of Study: Research studies by the U.S. Army Biomedical Research and Development Laboratory (USABRDL) have identified the generation of potentially harmful concentrations of airborne lead particulates in the exhaust products of the JAVELIN anti-armor missile currently undergoing testing by the U.S. Army Missile Command (MICOM). The JAVELIN is the next-generation missile designed to replace the current DRAGON and TOW missiles. The JAVELIN has a design requirement of being able to be fired from within buildings. Although the airborne concentrations of lead in the combustion products when fired within a small enclosure may potentially exceed the U.S. Occupational Safety and Health Administration's (OSHA's) Time-Weighted Average (TWA) Permissible Exposure Limit (PEL) of 50 micrograms per cubic meter, the OSHA standard was developed based upon 40-hour per week lifetime exposure to lead so as to produce a blood lead level of not more than 50 micrograms per 100 grams of blood. The OSHA standard is used in the absence of a military-unique lead standard. The amount of lead taken into the body from a short duration exposure (probably less than two minutes of maximum concentration as shown by previous studies) may not increase the lead level above the OSHA limit of 50 micrograms per 100 grams of blood. Medical biomonitoring of blood lead is only required for workers exposed at greater than 30 micrograms per cubic meter airborne lead more than thirty days per year. Since the OSHA standard was based upon long-term lead inhalation, it is not known if the airborne PEL is applicable to short-term exposures. This study will provide a scientific evaluation of the relationship of short-term lead exposure in air to blood lead levels. It is planned that 57 JAVELIN missiles will be fired by 16 soldiers during the operational testing phase. Previous USABRDL studies have indicated that the airborne lead results almost entirely from the launch motor rather than from a combination of launch motor and flight motor; not all the launches will be from an enclosure. Also, these USABRDL studies have indicated that there are low airborne lead concentrations when the missile is fired outdoors. Tests are planed in Panama, Alaska, and at Fort Hunter-Leggett, CA in addition to Redstone Arsenal, AL. Specific aims of the proposed study include:

a. To measure the blood lead levels in the subjects resulting from the airborne exposures using standard clinical techniques.

b. To determine the relationship between airborne lead concentration from JAVELIN combustion products and blood lead levels due to the brief concentration of airborne lead particulates inhaled by soldiers located at positions in the enclosure where doctrine requires them to be.

c. To determine whether personal protective equipment is needed for testers and, ultimately, for soldiers when the weapon system is fielded.

2. Justification for the Use of Human Subjects: Plans for the development of the JAVELIN weapon system call for human testers throughout the test phase. Assessment of the blood lead level, which is the real basis of the OSHA lead standard, resulting from the inhalation of particulate lead in the missile exhaust will allow a rational decision to be made as to the level of personal protective equipment required for testers and ultimately the soldiers when fielded. Only the actual test environment can realistically provide such assessment. Firing a JAVELIN missile in the laboratory is not practical. At the same time, the study aimed at these goals can provide valuable scientific information applicable to other military scenarios such as artillery firing. In addition, the JAVELIN missile contains only about one-third the mass of the same propellent used in the DRAGON missile, which is routinely fired in training and was frequently used in the Gulf War; therefore, soldiers have most likely been exposed to even greater amounts of lead from the earlier system although no scientific studies have been done to determine this. Because of the test setting in the field environment and difficulties in studies involving respiratory particulates in animals, the use of test animals would not yield the necessary information. Use of human subjects in actual exposure situations is economical and essential.

3. Scientific Person in Charge of Study: LTC Roland E. Langford, Ph.D., CIH/CPT Donald Lundy, MS

4. Number of Test Subjects Involved: At this time, the JAVELIN Project Management Office (PMO) estimates that between 16 and 32 males will be involved in the planned testing of the weapon system. By doctrine, there is a gunner and an assistant gunner for the missile firing; the assistant gunner's position is behind the gunner. For most of the 57 launches, there will be a gunner and an assistant gunner present although the first firings may involve only the gunner for safety reasons. In order to allow for statistical robustness, it is hoped that at least 20 soldiers will volunteer for the research.

5. Source of Test Subjects: Subjects for the study planned under this protocol will be enlisted, NCO, and officer volunteers who are assigned either to the test unit or to units designated for operational testing. Depending upon when the research is conducted, the soldiers will either be the trained weapons testers (NCOs) or typical infantry soldiers (enlisted). It is believed at this time that the subjects will be NCOs. It is possible that there may be one or more officer volunteers from the PMO due to the high level of interest in this study.

6. Protocol of Proposed Study:

a. It is proposed that the study be performed under actual field conditions during the testing of the weapon system so as to obtain information accurately reflecting the proposed operational scenario. No situations or constraints beyond those previously planned for the testing of the weapon system will be interjected.

b. The procedures to obtain blood samples from the test subjects involve sampling prior to the initial firing(baseline), each day at the end of the shift (not to exceed T+6 days), one week following exercise(T+7), and 30 days following the initial firing(T+30).

c. Subjects will be asked to supply a minimum of four blood samples as discussed above. The total amount of blood required for this portion should not exceed 60ml (about 5 tablespoons). These blood samples will have blood lead analysis performed by a commercial laboratory or by the servicing MEDDAC, depending upon the dates involved.

7. Statement of Risk: The subjects will be involved with the missile as required by operational doctrine. All personnel involved with testing have attested to the fact that they are aware of the dangers involved. Test subjects may, in addition to the discomforts of blood collecting, experience some local bruising at or slight oozing of blood from the collection site. In addition, they will be advised of the possibility of infection or redness at or around the collection site. No testing of the missile will be conducted until the U.S. Army Test and Evaluation Command (TECOM) signs a safety release. The main purpose of the missile firings is to ensure that the missile performs as designed; the measurement of blood lead simultaneously with the testing will allow a determination whether a protective mask will be required when the missile is fired from within an enclosure. The airborne lead levels from JAVELIN firings in enclosures previously measured exceed the OSHA action level of 30 micrograms per cubic meter for any 8 hour period. Although this value was based upon long-term exposure rather than the brief exposure experienced from the launch of a missile. Risk from the planned two to three firings per gunner in enclosures due to airborne lead levels should not be unreasonable.

8. Medical Monitoring: A medical monitor has not been identified at this time. However, name and curriculum vitae will be made available prior to study implementation.

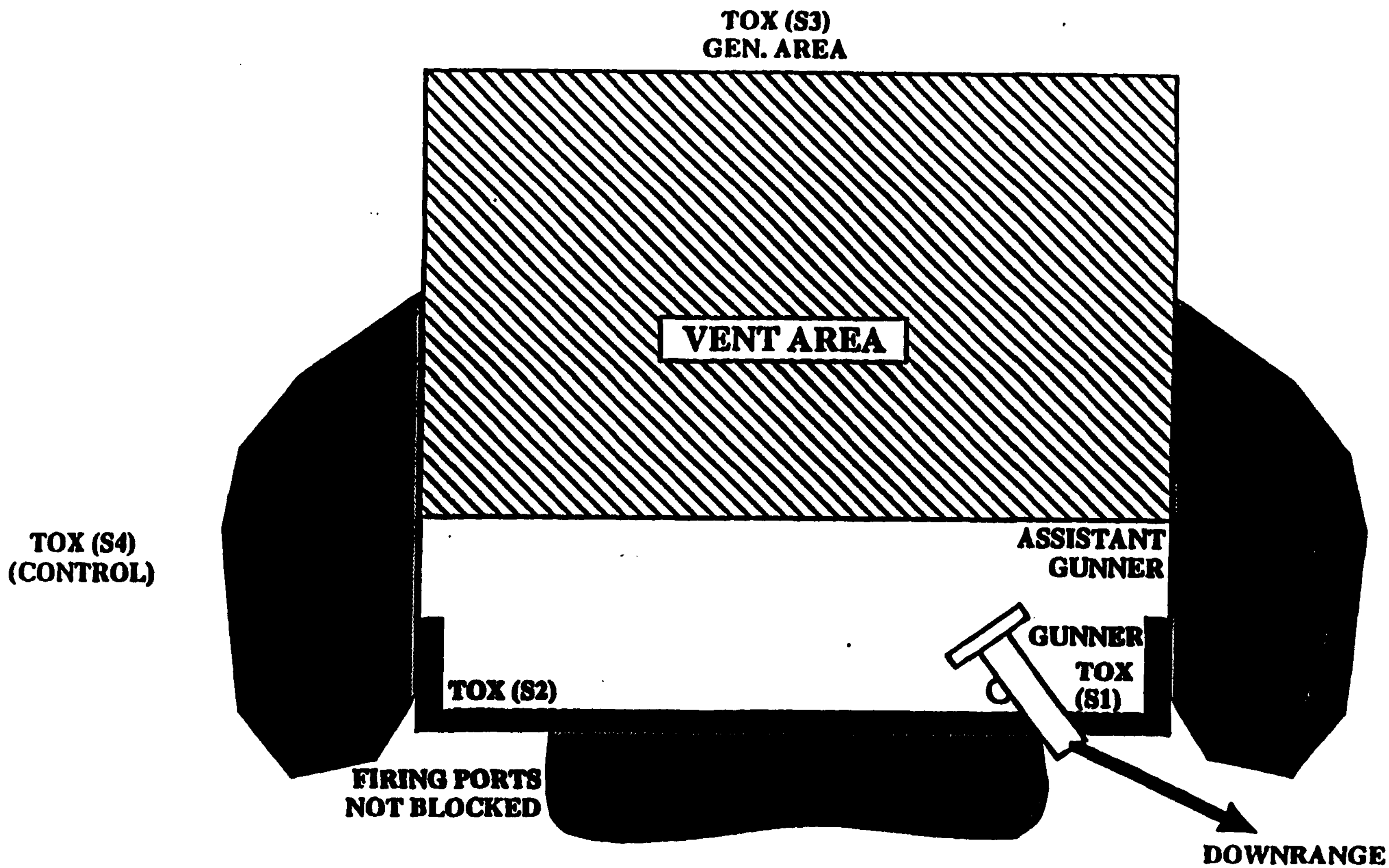
9. Precautions to Safeguard Health and Ensure Safety: No firing of missiles will take place if there is any indication of problems. It is believed that the hazards from testing the missile are greater (explosion of the missile, misfiring, premature warhead detonation, lifting the fifty-pound missile and launch tube, etc.) than those involved in exposure to lead particulates at concentrations slightly above the OSHA PEL for a

brief period. Any soldier with an elevated blood lead level (above 40 micrograms per 100 grams of blood), determined from the baseline blood draw, will not be allowed to participate in the study. A detailed briefing will present the purpose and risks of the study to the subjects. All subjects will acknowledge understanding of the research and the risks involved by signing an informed consent statement.

Test results will not be forwarded to the test subject. However, information bearing on the health of the soldier may be reported to the appropriate medical or command authorities.

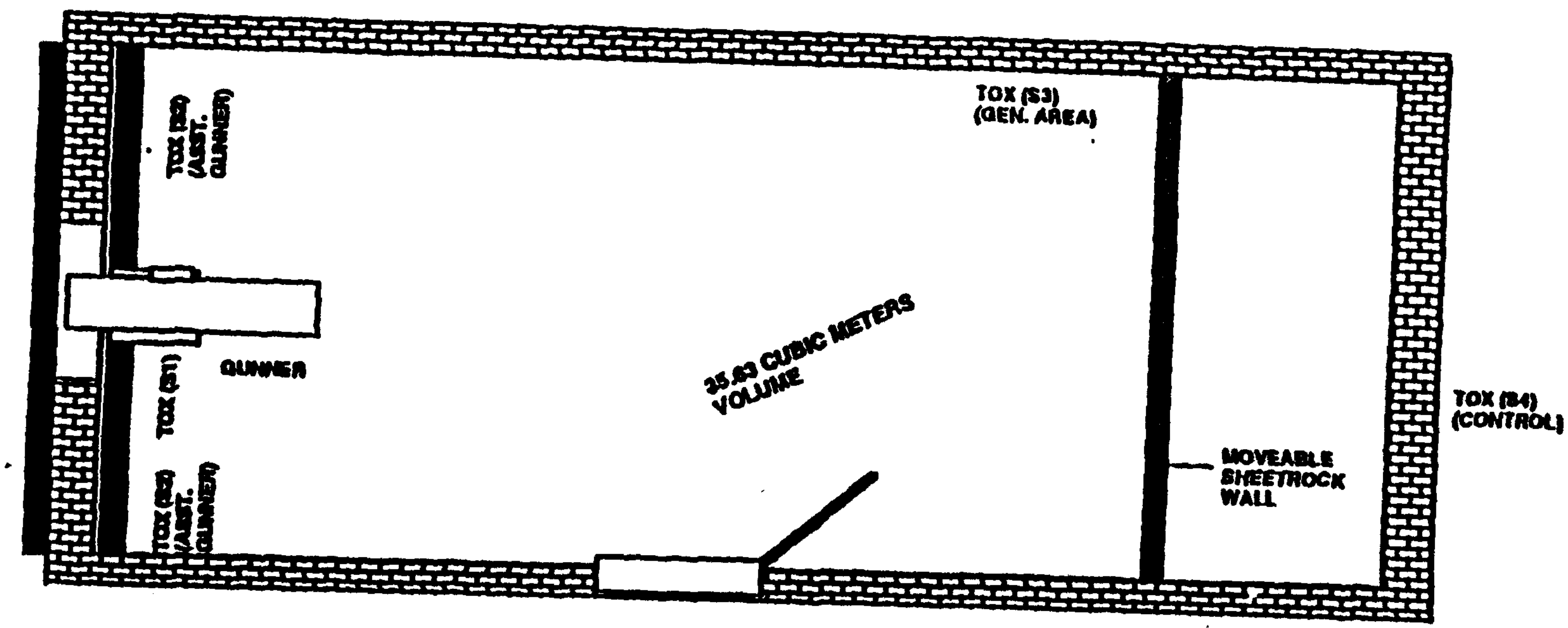
This study will not have any direct benefit for the subjects involved. However, the results obtained will be used to formulate recommendations as a basis to reduce or eliminate unnecessary or potentially hazardous exposures in the training or performance of duties in relationship to this weapon system.

APPENDIX B



TEST SETUP (FIGHTING POSITION).
(ASSISTANT GUNNER STATIONED BEHIND LEFT SHOULDER OF GUNNER)

NOTES:
ALL FIRING CONDUCTED FROM SAME CONFIGURATION
TOX = TOXICITY PICKUP



NOTES:

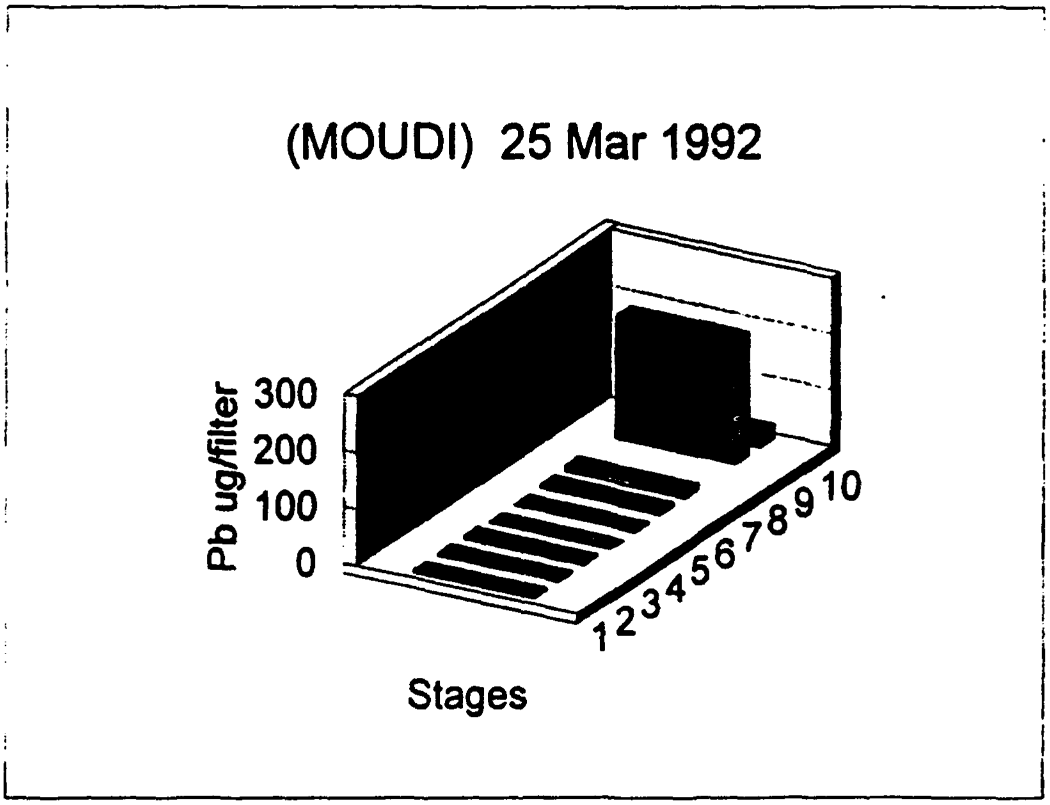
ALL FIRINGS CONDUCTED FROM SAME CONFIGURATION

TOX - TOXICITY PICKUP

TEST SETUP (ENCLOSURE)

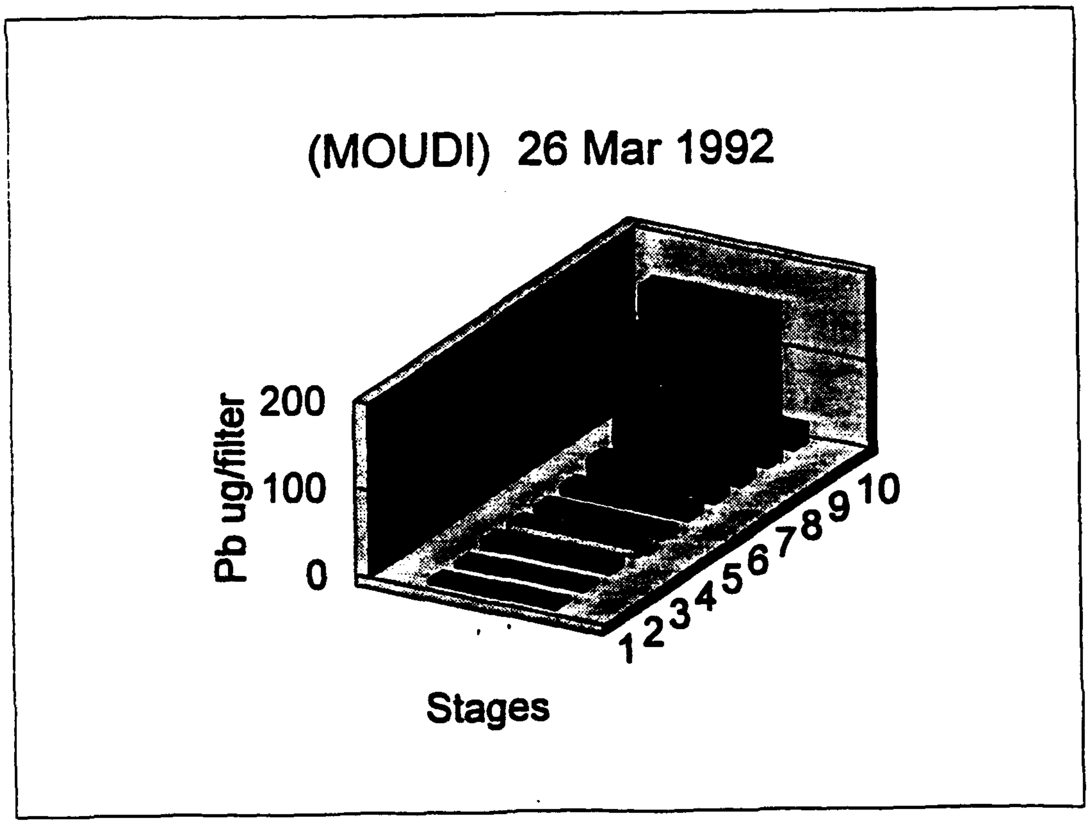
Mirco Orifice Uniform Deposit Impactor
Pb, Cu, Fe, and Sn
25 March 1992

SAMPLE	Pb ug/filter	Cu ug/filter	Fe ug/filter	Sn ug/filter
Stage 1	4.7	2.0	2.2	BDL
Stage 2	5.1	1.8	1.6	BDL
Stage 3	5.2	2.4	2.4	BDL
Stage 4	BDL	3.4	14.3	BDL
Stage 5	2.2	2.4	BDL	BDL
Stage 6	6.7	3.5	BDL	BDL
Stage 7	10.2	3.5	BDL	BDL
Stage 8	SAMPLE	LOST DURING	DIGESTION	
Stage 9	220.0	53.0	BDL	BDL
Stage 10	26.0	1.7	1.7	BDL



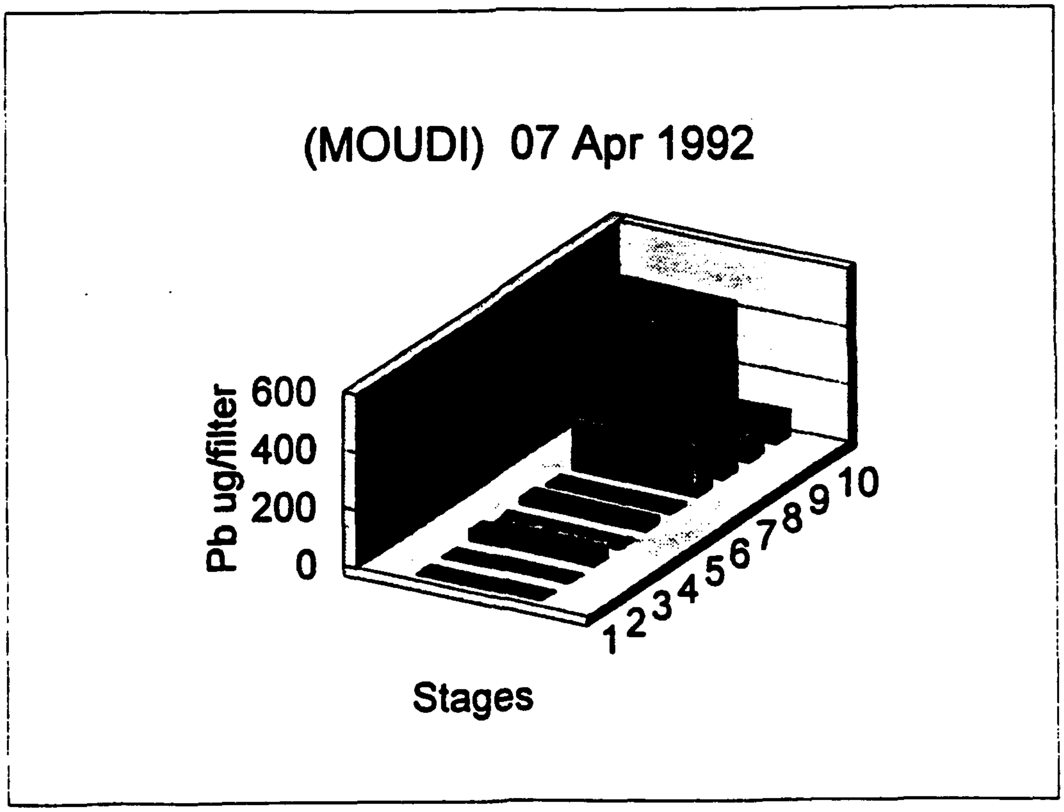
Micro Orifice Uniform Deposit Impactor
Pb, Cu, Fe, and Sn
26 March 1992

SAMPLE	Pb ug/filter	Cu ug/filter	Fe ug/filter	Sn ug/filter
Stage 1	4.9	2.8	2.6	BDL
Stage 2	4.8	5.8	3.7	BDL
Stage 3	11.0	15.0	3.7	BDL
Stage 4	8.7	15.0	4.4	BDL
Stage 5	7.6	10.0	1.5	BDL
Stage 6	12.0	8.1	4.6	BDL
Stage 7	23.0	7.5	1.3	BDL
Stage 8	150.0	24.0	BDL	BDL
Stage 9	180.0	26.0	6.3	BDL
Stage 10	22.0	4.4	BDL	BDL



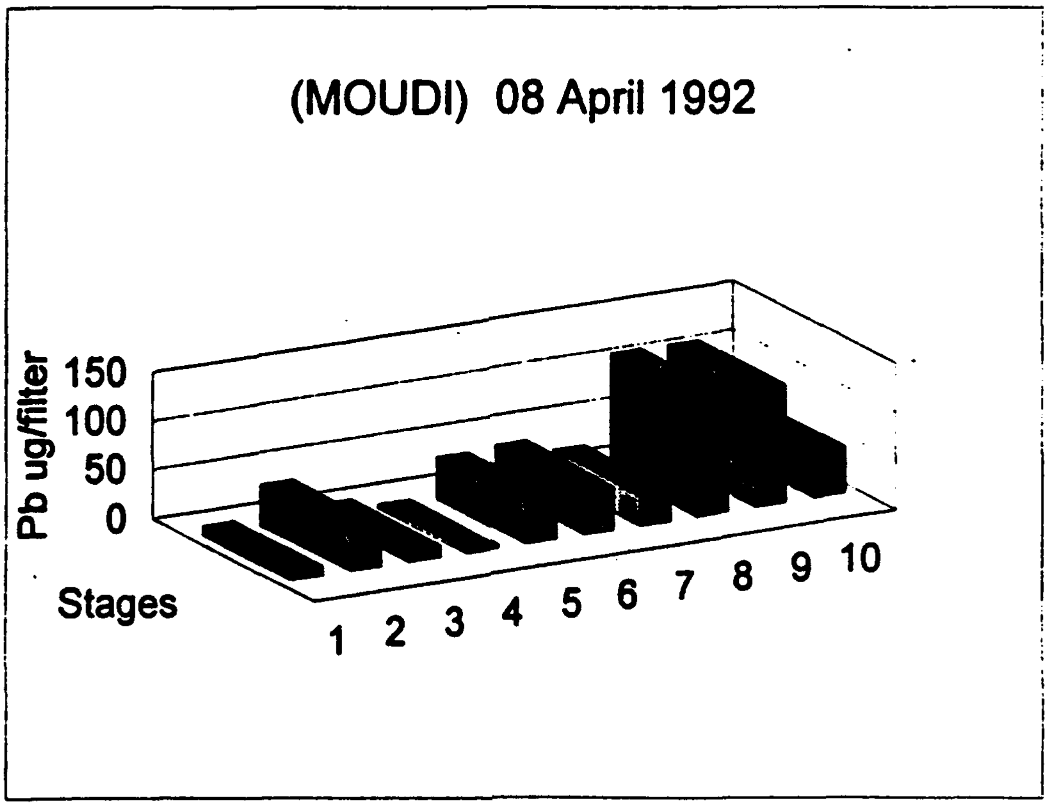
Mircro Orifice Uniform Deposit Impactor
Pb, Cu, Fe, and Sn
7 April 1992

SAMPLE	Pb ug/filter	Cu ug/filter	Fe ug/filter	Sn ug/filter
Stage 1	4.1	3.6	4.8	BDL
Stage 2	1.7	1.7	3.9	BDL
Stage 3	34.0	2.9	3.7	BDL
Stage 4	2.7	4.3	3.7	BDL
Stage 5	24.0	5.6	3.3	BDL
Stage 6	10.0	6.9	3.5	BDL
Stage 7	190.0	13.0	4.6	BDL
Stage 8	590.0	150.0	3.4	BDL
Stage 9	108.0	28.0	2.1	BDL
Stage 10	87.0	5.3	5.3	BDL



Micro Orifice Uniform Deposit Impactor
Pb, Cu, Fe, and Sn
8 April 1992

SAMPLE	Pb ug/filter	Cu ug/filter	Fe ug/filter	Sn ug/filter
Stage 1	10.0	2.0	6.6	BDL
Stage 2	42.0	3.9	7.6	BDL
Stage 3	13.0	8.3	3.3	BDL
Stage 4	3.5	7.6	2.8	BDL
Stage 5	42.0	5.9	4.0	BDL
Stage 6	44.0	4.0	2.6	BDL
Stage 7	30.0	4.0	3.5	BDL
Stage 8	120.0	19.0	2.8	BDL
Stage 9	120.0	20.0	4.3	BDL
Stage 10	47.0	6.0	2.2	BDL



VOLUNTEER AGREEMENT AFFIDAVIT

For use of this form, see AR 70-25 or AR 40-38; the proponent agency is OTSG.

PRIVACY ACT OF 1974

Authority: 10 USC 3013, 44 USC 3101, and 10 USC 1071-1087

Principal Purpose: To document voluntary participation in the Clinical Investigation and Research Prograr SSN and home address will be used for identification and locating purposes.

Routine Uses: The SSN and home address will be used for identification and locating purpose Information derived from the study will be used to document the study; implementatic of medical programs; adjudication of claims; and for the mandatory reporting of medic conditions as required by law. Information may be furnished to Federal, State, and loc agencies.

Disclosure: The furnishing of your SSN and home address is mandatory and necessary to provic identification and to contact you if future information indicates that your health my b adversely affected. Failure to provide the information may preclude your voluntar participation in this investigational study.

PART A - VOLUNTEER AFFIDAVIT

Volunteer Subjects in Approved Department of the Army Research Studies

Volunteers under the provisions of AR 40-38 and AR 70-25 are authorized all necessary medical care for injur or disease which is the proximate result of their participation in such studies.

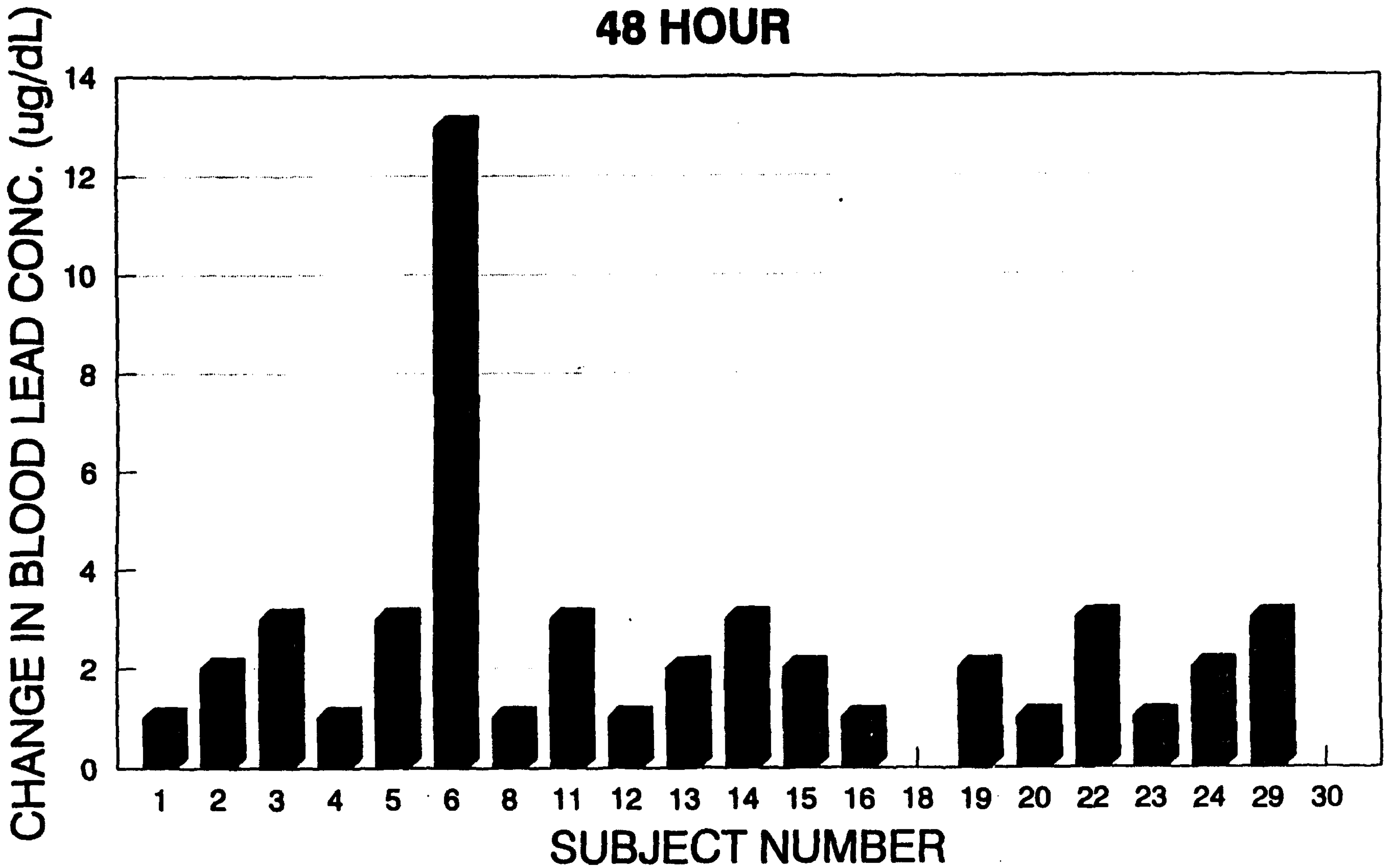
I, ______________________________ SSN ______________________________ having full capacity to consent to having attained my ______________ birthday, do hereby volunteer to participat in the study entitled, EXPOSURE OF SOLDIERS TO LEAD PARTICULATES DURING TEST FIRING OF THE JAVELIN
(Research Study)
under the direction of LTC ROLAND E. LANGFORD, MS / CPT DONALD O. LUNDY, MS conducted by the U.S ARMY BIOMEDICAL RESEARCH AND DEVELOPMENT LABORATORY
(Name of Institution)
The implications of my voluntary participation; duration and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have beer explained to me by LTC ROLAND E. LANGFORD, MS or a member of the research team; DSN 785-0607 OF COMMERCIAL (513) 255-0607

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights or study-related injury, I may contact the COMMAND JUDGE ADVOCATE OFFICE, U.S. ARMY MEDICAL RESEARCH ANC DEVELOPMENT COMMAND MRDC [AT] FORT DETRICK, FREDERICK, MD 21702-5012 DSN 343-2065 OF COMMERCIAL (301) 619-2065
(Name, Address and Phone number - include Area Code)
I understand that I may at any time during the course of the study revoke my consent and withdraw from the study without further penalty or loss of benefits; however I may be required (military volunteer) or requested (civilian volunteer) to undergo certain examinations if, in the opinion of the attending physician, such examinations are necessary for my health and well-being. My refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled.

JAVELIN TOXICOLOGICAL RESULTS

CHANGE IN BLOOD LEAD CONCENTRATION

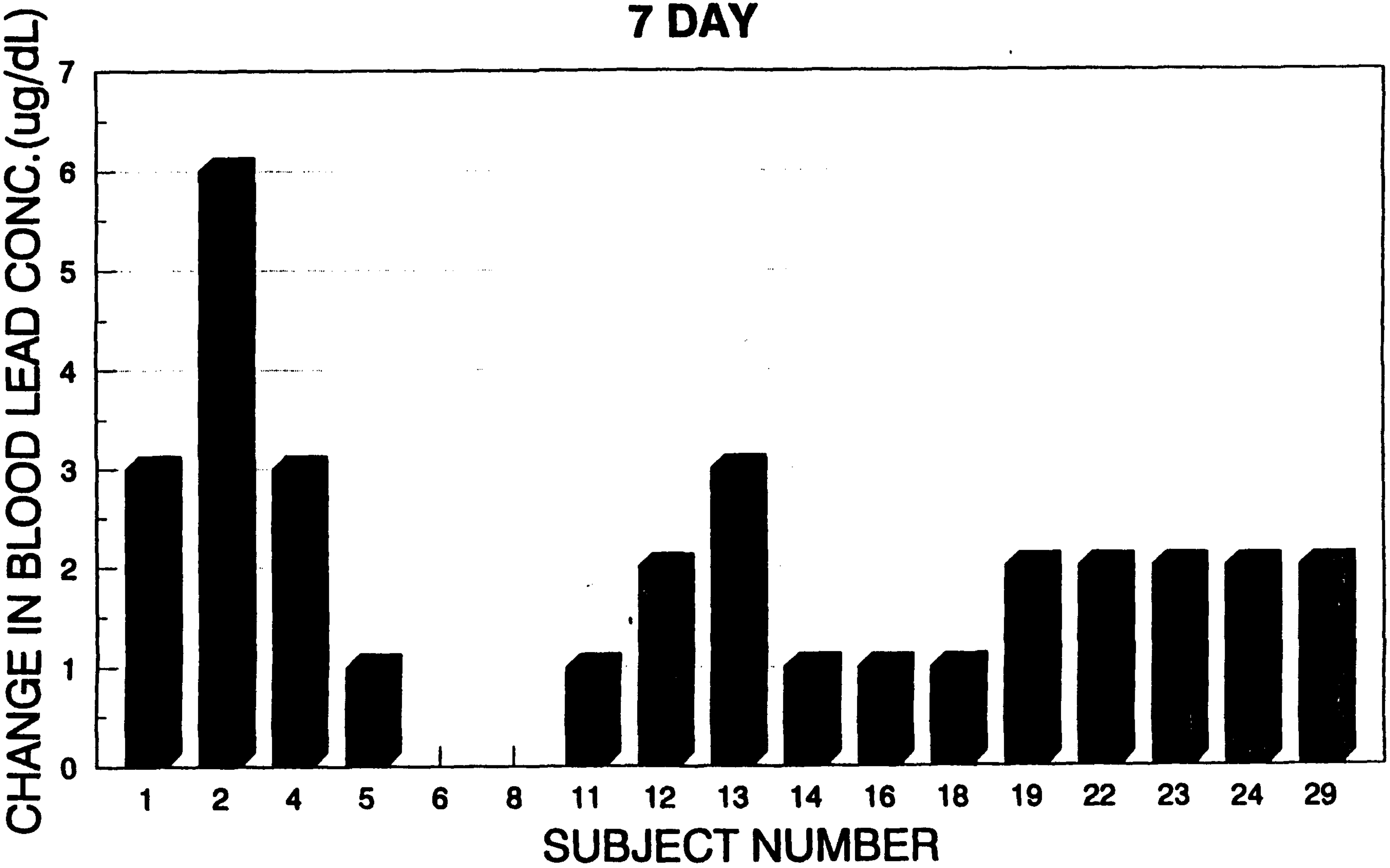
48 HOUR



JAVELIN TOXICOLOGICAL RESULTS

CHANGE IN BLOOD LEAD CONC. (ug/dL)

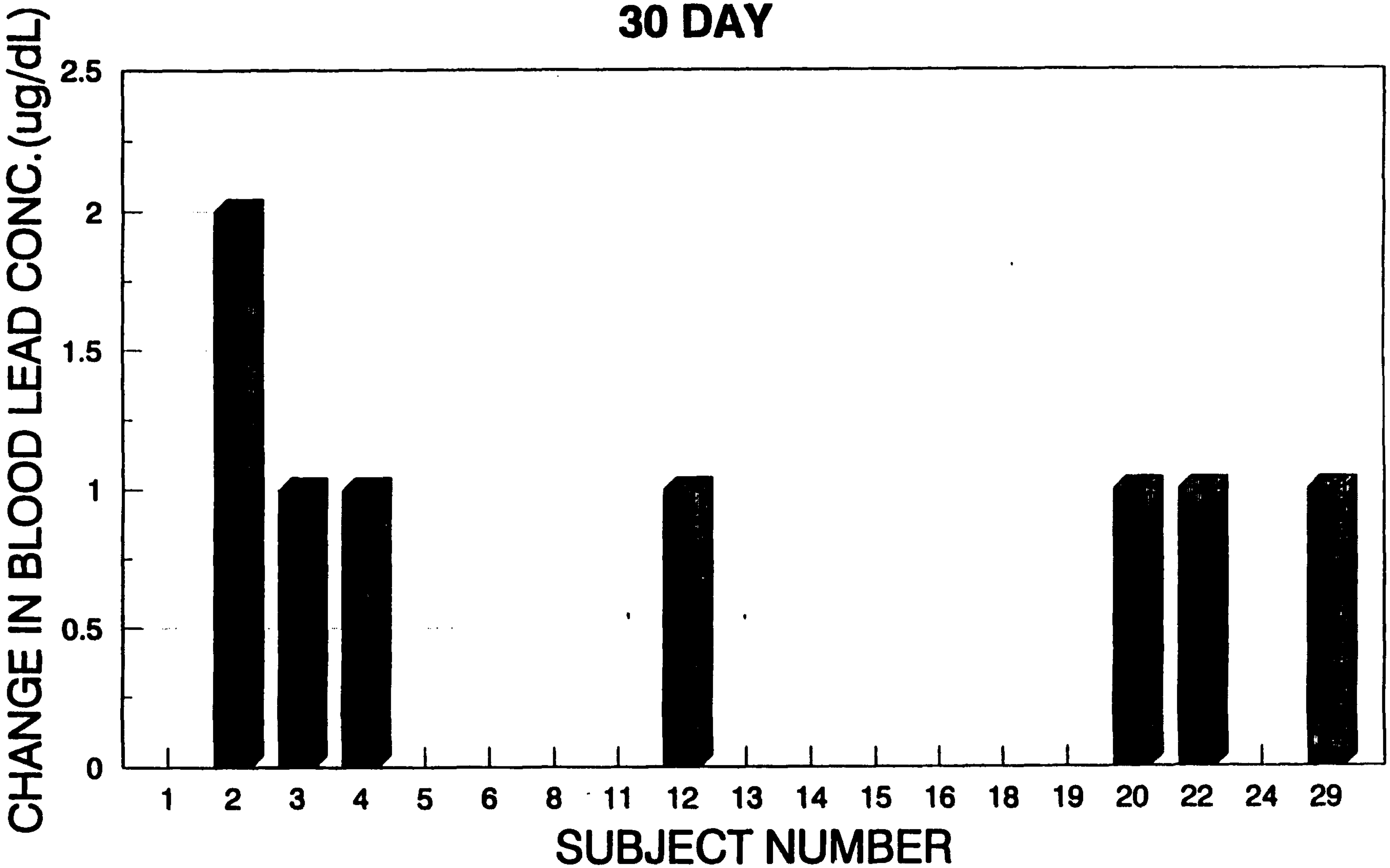
7 DAY



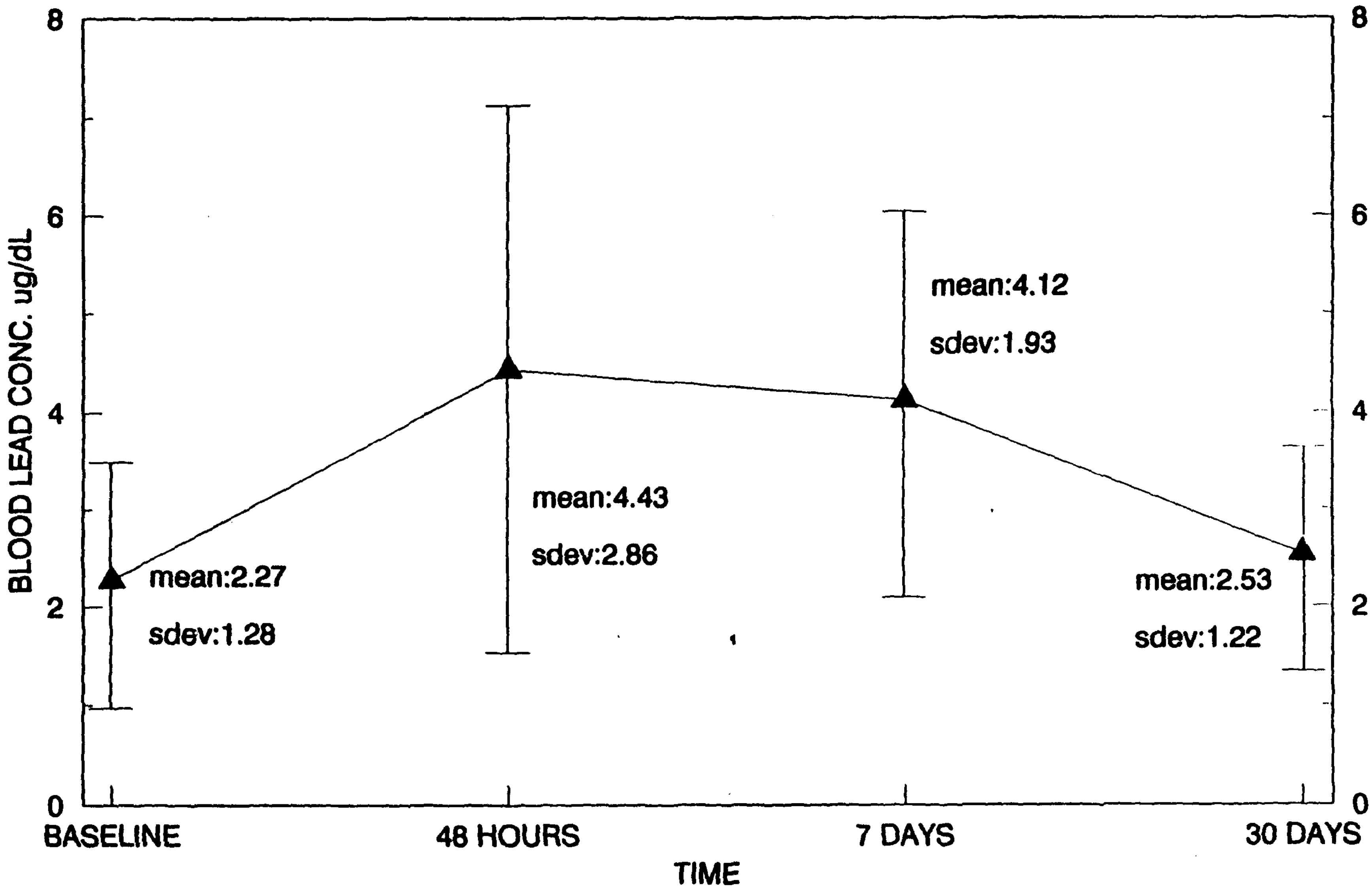
JAVELIN TOXICOLOGICAL RESULTS

CHANGE IN BLOOD LEAD CONC. (ug/dL)

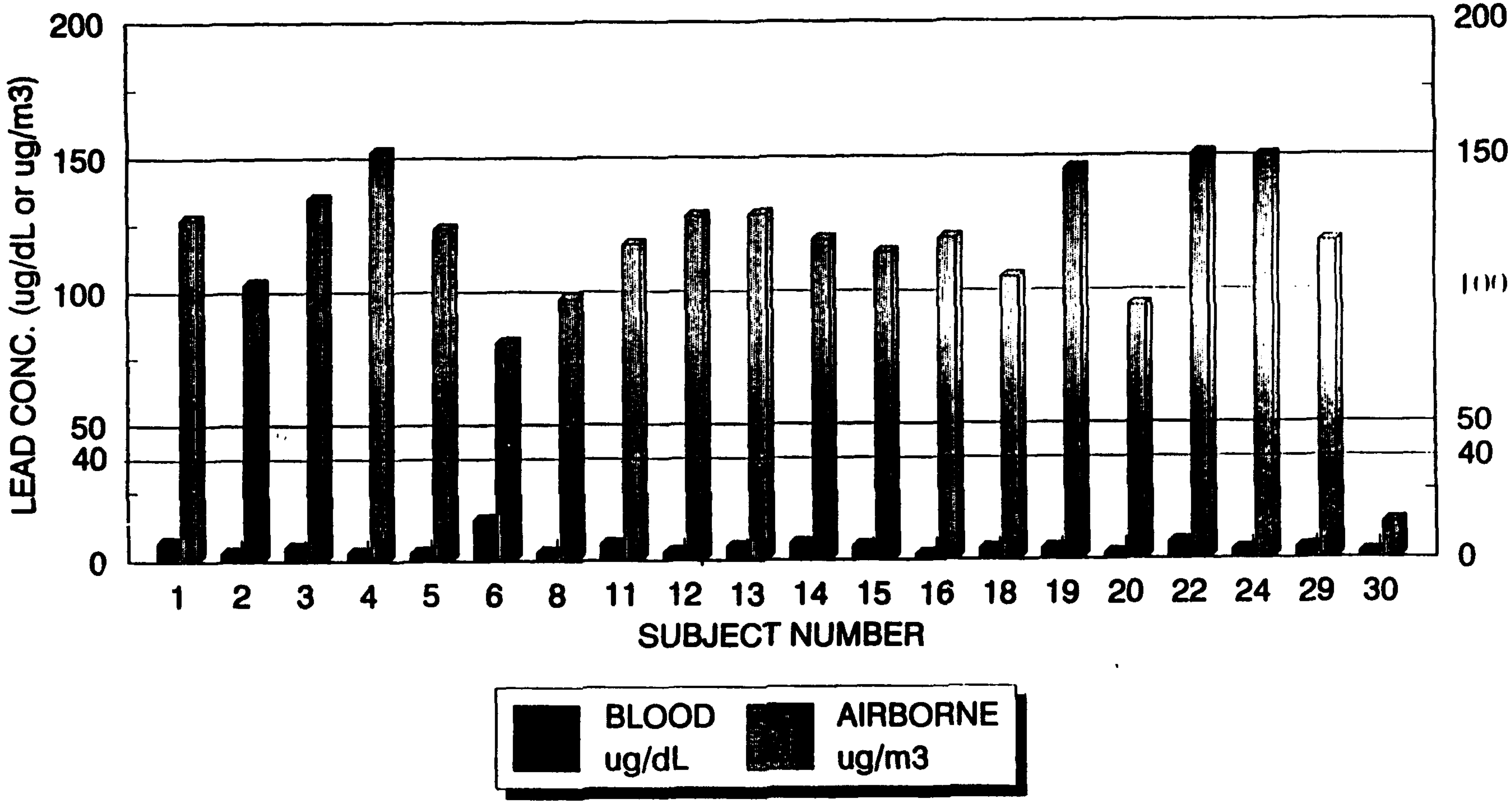
30 DAY



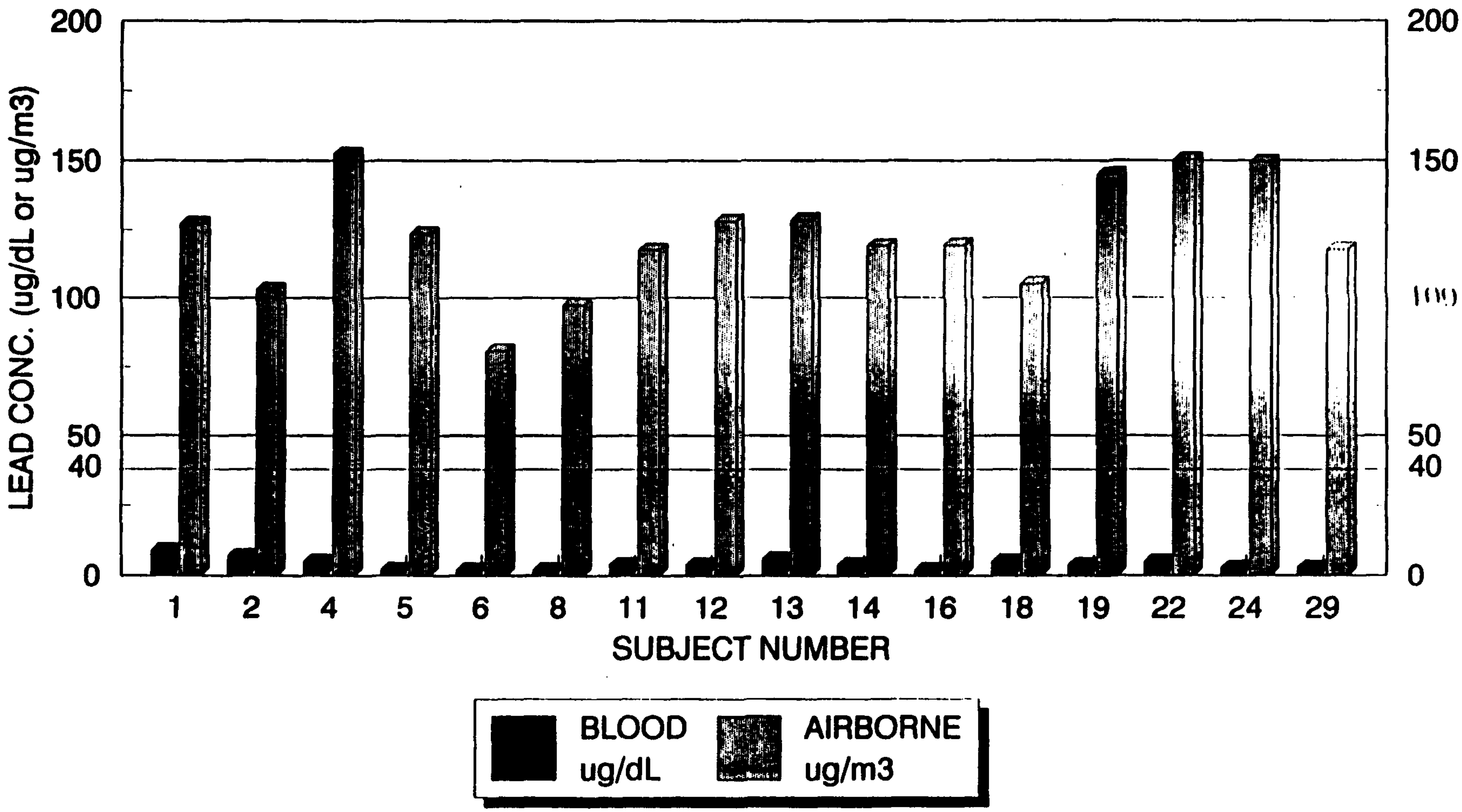
JAVELIN TOXICOLOGICAL RESULTS

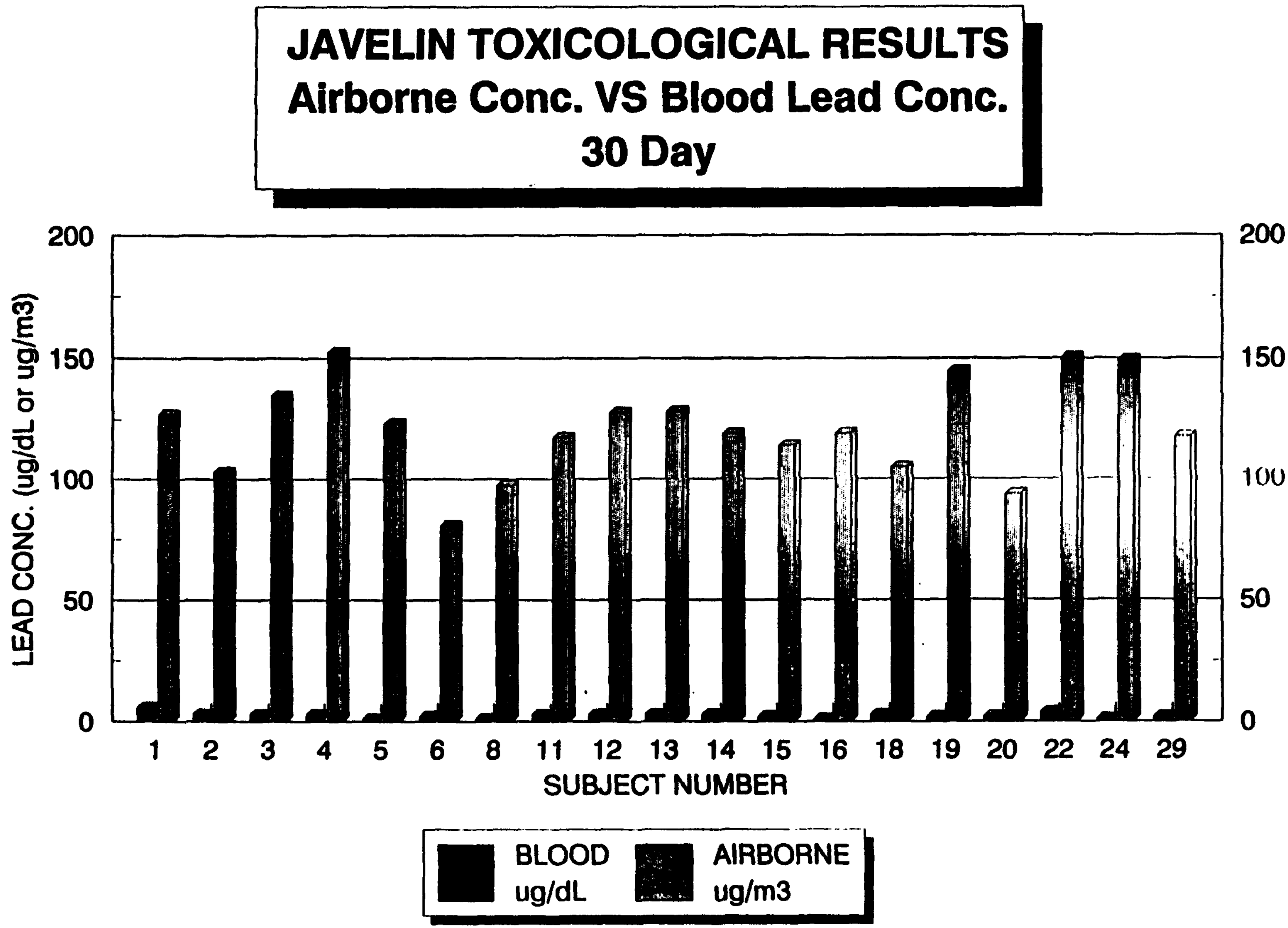


JAVELIN TOXICOLOGICAL RESULTS
Airborne Conc. VS Blood Lead Conc.
48 Hour

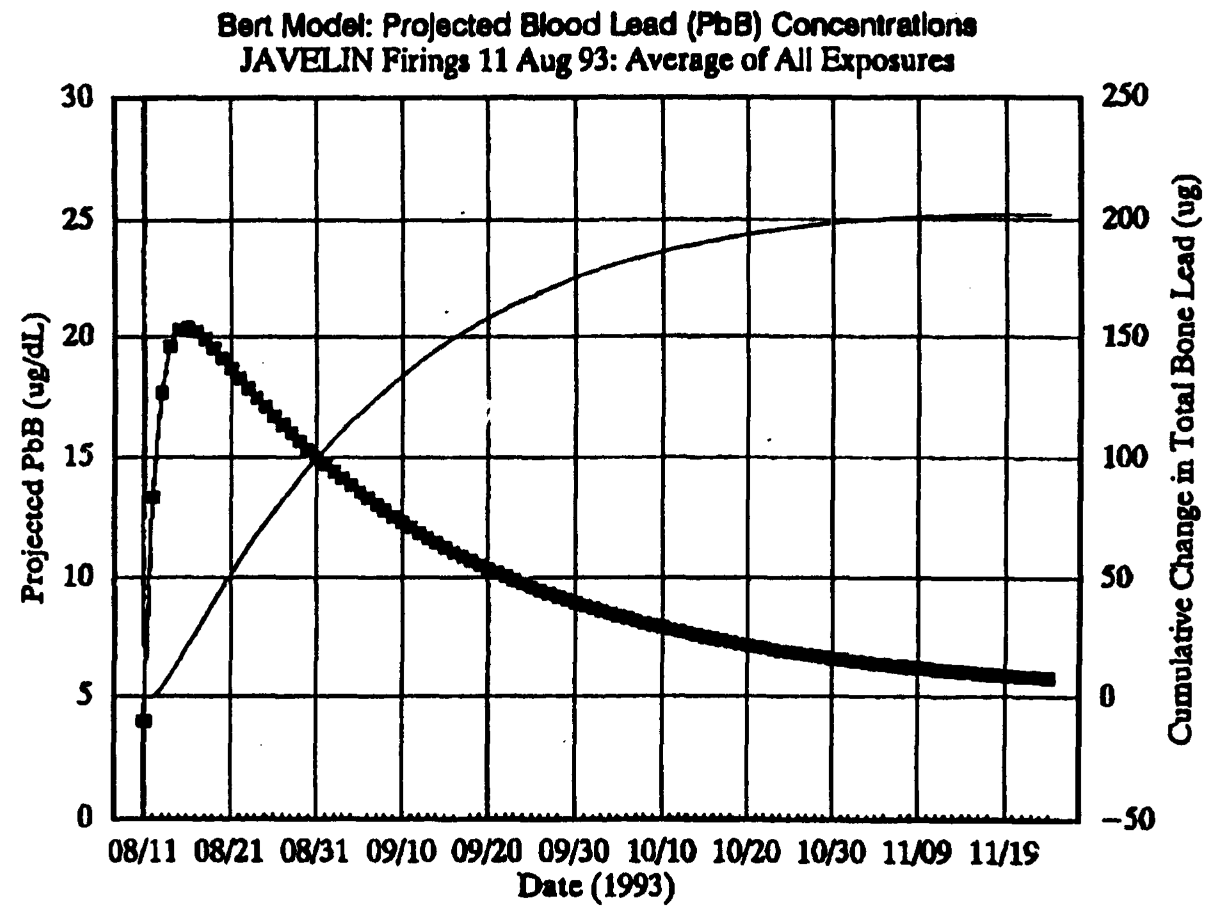


JAVELIN TOXICOLOGICAL RESULTS
Airborne Conc. VS Blood Lead Conc.
7 Day

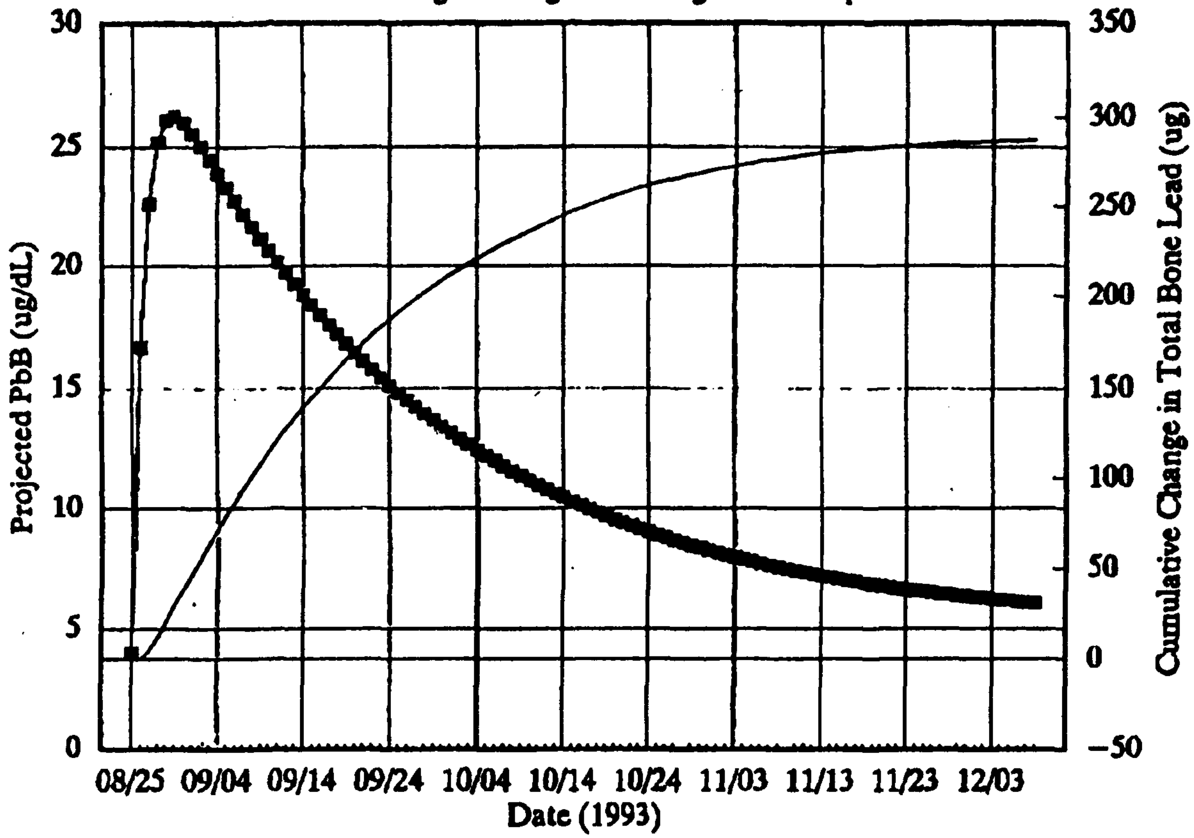


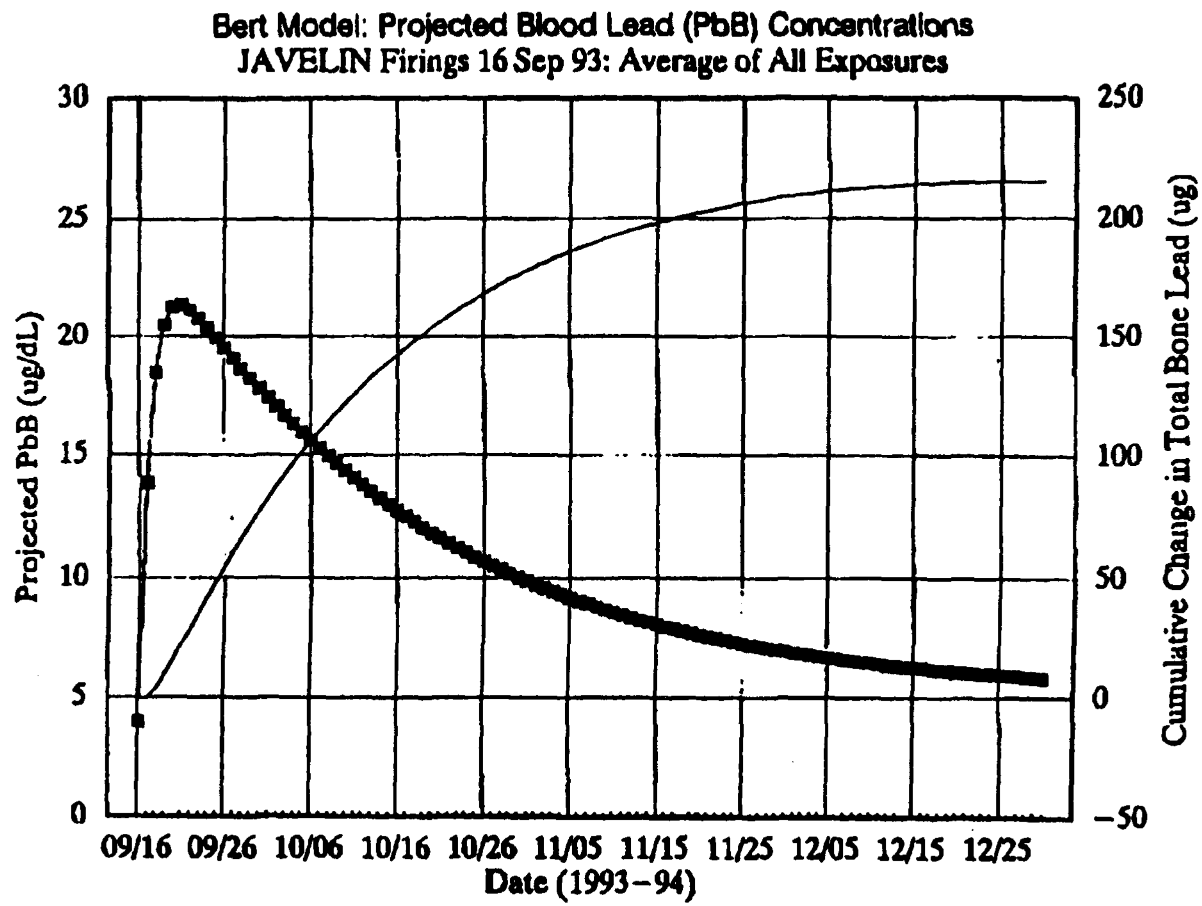

JAVELIN TOXICOLOGICAL RESULTS
Airborne Conc. VS Blood Lead Conc.
30 Day
200
150
100
50
0
LEAD CONC. (ug/dL or ug/m3)
1
2
3
4
5
6
8
11
12
13
14
15
16
18
19
20
22
24
29
SUBJECT NUMBER
BLOOD ug/dL
AIRBORNE ug/m3

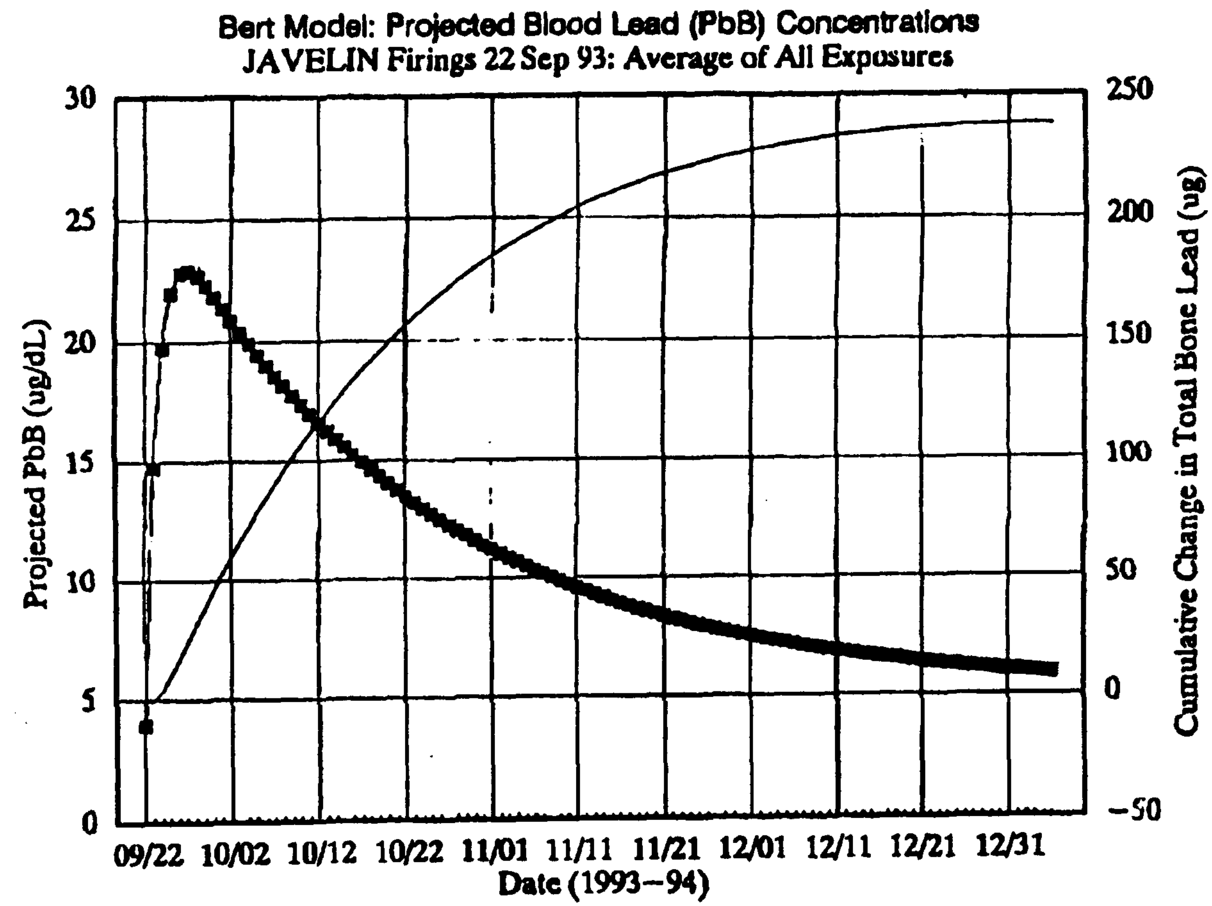
APPENDIX C

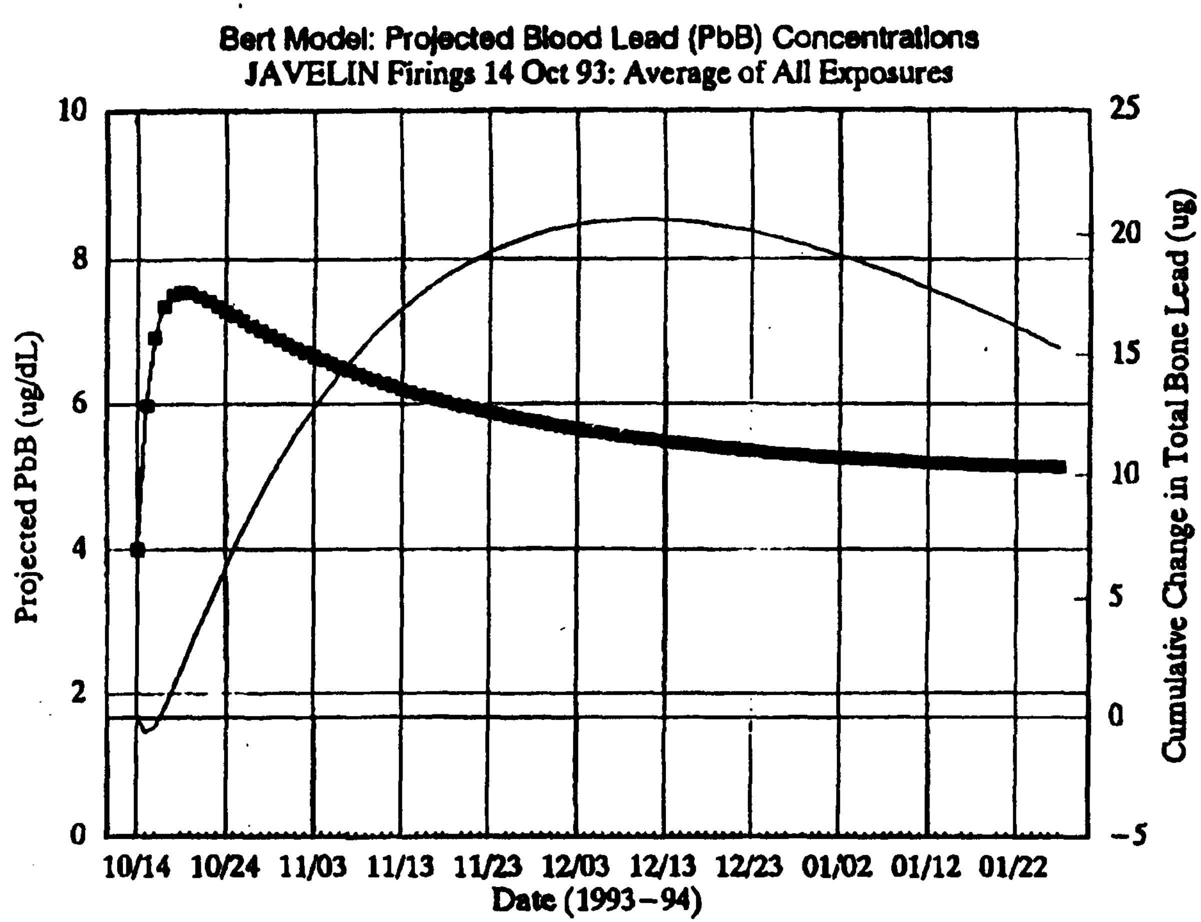

Bert Model: Projected Blood Lead (PbB) Concentrations
JAVELIN Firings 11 Aug 93: Average of All Exposures
30
25
20
15
10
5
0
Projected PbB (ug/dL)
250
200
150
100
50
0
-50
Cumulative Change in Total Bone Lead (ug)
08/11 08/21 08/31 09/10 09/20 09/30 10/10 10/20 10/30 11/09 11/19
Date (1993)

Bert Model: Projected Blood Lead (PbB) Concentrations
JAVELIN Firings 25 Aug 93: Average of All Exposures




Bert Model: Projected Blood Lead (PbB) Concentrations
JAVELIN Firings 16 Sep 93: Average of All Exposures
30
25
20
15
10
5
0
Projected PbB (ug/dL)
250
200
150
100
50
0
−50
Cumulative Change in Total Bone Lead (ug)
09/16
09/26
10/06
10/16
10/26
11/05
11/15
11/25
12/05
12/15
12/25
Date (1993−94)


Bert Model: Projected Blood Lead (PbB) Concentrations
JAVELIN Firings 22 Sep 93: Average of All Exposures
Projected PbB (ug/dL)
0
5
10
15
20
25
30
Cumulative Change in Total Bone Lead (ug)
−50
0
50
100
150
200
250
09/22
10/02
10/12
10/22
11/01
11/11
11/21
12/01
12/11
12/21
12/31
Date (1993−94)


Bert Model: Projected Blood Lead (PbB) Concentrations
JAVELIN Firings 14 Oct 93: Average of All Exposures
Projected PbB (ug/dL)
Cumulative Change in Total Bone Lead (ug)
Date (1993–94)
10/14
10/24
11/03
11/13
11/23
12/03
12/13
12/23
01/02
01/12
01/22
0
2
4
6
8
10
–5
0
5
10
15
20
25