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Region VIII

REGION 8 SUPERFUND TECHNICAL GUIDANCE

No. RA-07: Blood Lead Data Evaluation

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Risk Assessment (Short Title / Key Words)

TITLE: *Criteria for Evaluating Blood Lead Data Quality and Use*

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SUMMARY

The objective of this Regional Guidance is to provide specific criteria along with some general direction for evaluating the quality of the design and the conduct of human blood lead studies (and thereby the level of usefulness for application to specific Superfund sites) in helping to assess exposure and risk from lead at residential areas impacted Superfund sites.

CRITERIA FOR EVALUATING BLOOD LEAD DATA QUALITY AND USE

The objective of this Regional Guidance is to provide specific criteria along with some general direction for evaluating the quality of the design and the conduct of human blood lead studies (and thereby the level of usefulness) in helping to assess exposure and risk from lead at residential area impacted by Superfund sites.

BACKGROUND

Individual blood lead concentrations (measured at a single point in time) are convenient indexes of relatively recent lead exposure and relative risk for related adverse health effects. Data from "well-conducted" and "well-designed" blood lead studies can be useful, in conjunction with site-specific environmental data, in helping to evaluate risk to children from lead at Superfund sites. However, clear guidance or criteria on what constitutes a sufficiently "well-designed" or "well-conducted" blood lead study for the purposes of *risk assessment* have not been adequately addressed. The Centers for Disease Control (CDC) has developed protocols for the standardized collection and analysis of blood, as well as corresponding Quality Assurance/ Quality Control (QA/QC) plans. These CDC protocols present recommended detection limits and control limits for both analytical precision and accuracy. Adherence to these protocols may indicate that a blood lead sample has been adequately collected and analyzed, and the results are acceptable from a clinical perspective; however, they do not necessarily indicate that a blood lead study itself, was adequately designed or the results acceptable for evaluating risk from lead at a Superfund site. Caution with respect to the interpretation of blood lead studies has also been expressed by the Agency from Toxic Substances and Disease Registry (ATSDR, 1992). This guidance will incorporate CDC's protocols for sample collection, analysis, and scientifically defined QA/QC with Superfund's needs for critical elements of sample design to provide specific criteria for evaluating the level of quality and applicability of blood lead data collected for use in risk assessments.

DISCUSSION

The primary elements of a well-designed and conducted blood lead study are:

1. Representativeness of the population sampled.
2. Age of the population tested.
3. Time of year when testing was done.
4. Concurrent characterization of lead sources and exposure pathways.
5. Appropriately defined and executed QA/QC standards.

Elements #1 - #4 are used to evaluate the design of a blood lead study and are briefly presented below. These elements are discussed in greater detail in EPA's Guidance Manual for the Integrated Exposure Uptake Biokinetic Model for Lead in Children (EPA 1994). Element #5 is used to evaluate the conduct of blood lead sampling and analysis and is generally derived from CDC's existing blood lead protocols.

1. Representativeness of the population sampled

It is usually not possible to study all the members of a population. Therefore, epidemiological investigations of childhood lead exposure involve the selection of a *sample*. In order for the investigation to have the most predictive power, this sample should be selected randomly from the population of interest. In this case, random means that each individual selected for the sample has an equal chance for selection. Samples of populations which are not selected randomly may be unusable for predictive or retrospective risk assessment. For example, selective samplings which occur through a medical referral program, a daycare center recruitment, or a community-wide request for volunteer participation, are likely to be non-representative for the whole population and are not generally useable for the purpose of risk assessment. A randomly selected sample can provide two types of information about the population. The sample can be used to: (1) **estimate characteristics** of the population within certain *confidence intervals*. These estimated population characteristics may include the mean blood lead, standard deviation or percentiles. (2) the sample might also be used to **test hypotheses** about the population such as whether females have higher (or lower) blood leads than males.

Many blood lead studies at Superfund sites have tried to include all exposed children less than 84 months of age. At sites where the population was too large, random (statistically significant) sub-samples of that age group have been taken to represent the population exposures and risks. As with any research or epidemiology study, the predictive power of the study is a function of the sample size, true representativeness, freedom from bias, and variability within the population and in measurements.

Representativeness is the extent to which the data define the true extent of exposure, to human health for the population living at that site (EPA, 1992). Sampling that is nonrepresentative may result in biased, false positive (Type I) or false negative (Type II) results for the sampled population.

Sampling designs that do not adequately represent each exposure area and pathway are also likely to be non-representative. Statistically based sampling plans, which specifically consider childhood exposure patterns and are similar to those described in EPA's Guidance for Data Useability in Risk Assessment (EPA, 1992) are needed in order to achieve sufficient representativeness. Development of sampling plans for epidemiology studies in Region VIII must conform to National goals for quality assurance and quality control (QA/R-5).

2. Age of the population tested

Blood lead study participants should generally consist only of those children younger than 84 months of age. This is because: (1) infants and children younger than 84 months of age have been identified as the sub-population most susceptible to the adverse effects of lead exposure; and (2) the measured blood lead data may need to be evaluated against the predictions of EPA's Integrated Exposure Uptake Biokinetic (IEUBK) Model, which predicts blood lead levels only for children less than 84 months of age. If age groups older than 84 months are included in the study, it will be necessary to remove the results for these children from the data set for current use in EPA Superfund quantitative risk assessments. However, professional qualitative assessments of risks for older children and adults can be pursued as indicated.

3. Time of the year when testing was done

Blood lead concentrations show seasonal fluctuations due to factors such as the relatively short half-life of lead in blood, reduced outdoor exposures to lead sources in the wintertime, and physiological (hormonal) changes. Seasonal fluctuations in blood lead concentrations as great as 4 to 6 ug/dl have been observed in some studies (Rabinowitz et al., 1984, David et al., 1982). For these reasons, it is recommended that blood lead studies be conducted during the peak summer months (August-September) when children have had the greatest opportunity to contact outdoor sources of lead and when blood lead levels are expected to be at their maximum.

NOTE: Multiple sampling is more useful than a single time point sample for "capturing" these fluctuations and better characterizing true blood lead levels in a population.

4. Concurrent Characterization of Lead Sources

If a blood lead study is to be properly evaluated in the risk assessment process, it is important that all of the sources of lead exposure to that population at the site be adequately characterized and quantified. The most useful data bases contain "paired" data sets (i.e., each child's blood lead result would be paired with the environmental media data that represents the child's typical, integrated exposure to lead). This pairing of environmental data with blood lead data allows the risk assessor to better examine the relationship between a child's blood lead level and his or her significant sources of exposure. At a minimum, the environmental data would include the soil and house dust lead concentrations (properly sampled for representativeness) at each child's residence.

Information on behavioral factors and demographics that affect lead exposure should be collected concurrently. For example, information on family occupations or hobbies which could be additional sources of lead exposure to a child, or information on excessive mouthing behavior (or pica) which could increase lead intake, would be useful to better evaluate a child's blood lead level in relation to their sources of exposure.

5. Quality Assurance/ Quality Control (QA/QC) Standards

The major function of QA/QC samples is to identify and minimize, or account for, sources of sampling and analysis error (and overall uncertainty). In terms of blood lead measurements, the following have been shown to be major sources of error:

1. Inconsistent sample collection and processing; (i.e., in splitting and diluting blood prior to analyses).
2. Contamination of the specimen during collection, storage, or analysis.
3. Deterioration of the specimen by clotting, denaturation, absorption, or other processes
4. Instability of the measurement system, either over a short (within run/day) or long time span.
5. Improper calibration of the measurement system, including detection limits.
6. Errors in data handling, storage, or reporting.
7. Analyst variability in sample preparation and handling.

QA/QC therefore must include the following elements to minimize or account for these sources of error:

5.a. Specimen Collection

All specimen collection equipment and supplies must be properly screened to define any detectable levels of the analyte and to estimate the variability of this type of contamination. Written protocols for specimen collection which describe in detail all sampling equipment and its use, precautions to avoid contamination, standard and accurate sample processing (dilutions, splits, etc.) and other requirements (time of day, fasting/non-fasting state of subject) which might affect specimen integrity or response. A sample protocol for specimen collection is provided in Appendix A.

5.b. Specimen Preservation and Shipping

Written protocols should include proper packing, storage and shipping temperatures, suggested means of conveyance for timely receipt of specimens, and detailed shipping and specimen log forms to allow description of each specimen to record any variances from collection or shipping protocols and storage times until analyses. A sample protocol for specimen preservation and shipping is provided in Appendix A.

5.c. Analytical Method Performance

The analytical method used must demonstrate acceptable precision, accuracy and reproducibility in the appropriate analytical range. **Precision** is a quantitative measure of variability which can be measured through the analysis of (a) laboratory duplicates and (b) field duplicates, usually expressed as relative percent differences (RPD = Δ/x) or coefficients of variation (CV = SD/x) when three or more replicates are analyzed. **Reproducibility** can be evaluated through multiple analyses of performance evaluation samples. **Accuracy** is a measure of the closeness of a reported concentration to the true value and is usually expressed as a bias (high or low). Analytical bias can be measured by the use of field and lab blanks, known concentrations of the

analyte of interest (control material) prepared in the appropriate matrix and performance evaluation samples. Known values should be represented by a range of acceptable values or by upper and lower *control limits.* Control materials should be stable and available in aliquots or vials which can be sampled over long periods of time. The concentration of the control material should be within the range of interest to the investigation (see below) and presented as a mean and standard deviation for the specific analytical method used to assay the control material. Mean and standard deviations for the control material should also be assessed in the laboratory associated with the specific study being planned. It is recommended that control sample analysis be performed by the laboratory associated with the study on 20 non-consecutive days and prior to initiation of the study. Field and trip blanks should be used to identify the associated bias related to sample collection or shipment.

5.c.(1) RECOMMENDED QA/QC SAMPLES FOR ASSESSING PRECISION AND ACCURACY

5.c.(1)(a) Blind and bench quality control samples

Bench QC standards are blood lead samples with certified values of the analyte of interest KNOWN TO THE ANALYST. We suggest that at least 5% of the total number of samples analyzed be bench QC samples appropriate for the method. Blind QC standards are similar to Bench QC standards, except that the analyst is unaware that they are QC samples. They are submitted to the analyst by a source external to the laboratory (such as a lab supervisor or field investigator) in the same type of container (i.e., Vacutainer) and with the same labels as patient samples so that they are indistinguishable from patient samples. It is suggested that at least 5% of the total number of samples analyzed be blind QC external standard samples. It is also suggested that the blind (and bench) QC standards have at least two concentrations, one in the "expected" range of values for the majority of patient samples and one at or near the "decision level" (i.e., 10 ug/dl) for undue exposure.

Quality control charts similar to those suggested by Levy and Jennings (1950) or Westgard, et al. (1981) should be used to plot the means and ranges of all of the quality control materials and these data should be analyzed by two-way analysis of variance. Limits, such as 95%- and 99%-tiles around the means and ranges (of replicate measurements) allow evaluation of the temporal stability of the measurement system. These charts should be used by the analyst for each run for the evaluation of "bench" or known blood controls (and by the supervisor for blind controls) by use of mean and range control limits, such that any necessary corrective actions can be made in a timely manner.

The quality control measures described above can be used to evaluate the stability of the analytical system by looking at both the "day-to-day" statistical control of the system (i.e., do the controls fall outside of the 95% or 99% limits?) and any long term trends in analytical performance over time (i.e., weeks/months/years).

5.c.(1)(b) Blind and Known Splits

Blind splits are replicate samples (two from the same subject) which are collected and given different ID numbers, yet they are submitted to the lab as separate distinguishable samples. These will allow evaluation of the analytical reproducibility (duplicates) or precision (three or more replicates) by comparing the results between the splits. It is suggested that 5% of samples be submitted as blind random splits to the lab. RPDs or CVs can be reported.

Known splits are generally duplicate samples wherein one of the duplicates is analyzed by the primary lab and the other is submitted to an independent lab for verification of analytical accuracy or comparability. It is suggested that 5% of patient samples be randomly split and sent to the lab as known splits. Criteria should be established as to "acceptable" agreement with the independent lab, and steps to resolve sources of error evidenced by larger discordant results.

5.c.(1)(c) Proficiency Standards

Overall study accuracy can also be evaluated through the regular analysis of reference materials or proficiency testing pools such as those provided by the College of American Pathologists (CAP) or Centers for Disease Control (CDC). Standards of proficiency are +/- 4 ug/dL for the College of American Pathologists (CAP), New York State, and CDC Proficiency Testing programs. Many laboratories are capable of better performance than this. Certain proficiency programs report participating lab performance in comparison to the mean and percentile of all participating lab results.

5.c.(1)(d) Blanks

Both field blanks and laboratory blanks should be used to evaluate any contamination which may occur during the sampling phase or in the laboratory environment. Blanks consist of ultra-pure water which is carried through either the sampling process or the analytical process in a manner which is identical to the actual patient samples. Optionally, certified low-lead samples can be sent from the field to the lab for analysis to demonstrate absence of contamination in the fluid matrix being analyzed (i.e., blood).

5.c.(2) INSTRUMENT AND METHOD DETECTION LIMITS

When evaluating blood lead studies, the instrument (IDL) and method detection limits (MDL) and the number of blood lead results which are below these limits should be noted. The closer the concentration of concern is to the detection limit, the greater the possibility of false negative and false positive error. The IDL includes only the instrument portion of detection, and does not include sample preparation, concentration/dilution factors, or method-specific parameters. As a result, EPA's Guidance for Data Usability in Risk Assessment (USEPA 1992) recommends **against** using the IDL in risk assessment because contaminant concentrations between the MDL and the IDL are considered to be "uncertain" and concentrations below the IDL are considered to be non-quantifiable. The MDL is the minimum amount of an analyte that can be routinely identified using a specific method. The MDL is defined as the

concentration of lead in blood equivalent to 3SD of a whole blood with low (<5 ug/dL) lead concentration. At least ten replicate measurements should be used to calculate the SD.

There are a number of analytical techniques which are capable of achieving MDLs <2 to 5ug/dl, such as atomic absorption spectroscopy, anodic stripping voltammetry, or isotope dilution mass-spectroscopy. Uncertainty in precision and accuracy may be expected to be dependent upon the concentration range being measured and will increase as the concentration decreases. It should be noted that the typical blood lead level in the U.S. today is approximately 3 - 4 ug/dl. Caution should be exercised when assessing blood lead data in which a significant number of the samples are at or below the MDL. These samples must be clearly flagged when data is reported and the appropriate level of certainty or uncertainty should be assigned to those values.

5.d. Calibration

The use of high quality lead standard solution(s) for instrument calibration is essential for reliable blood lead measurements. The National Institute of Science and Technology have such standards available (SRM 3121). Equivalent aqueous standards for lead could also be used, as long as these standards are traceable to those provided by NIST. Standards using blood as the matrix are preferable for some analytical methods (e.g., anodic stripping voltammetry), because of matrix effects observed in these methods. Modern graphite furnace AAS has been shown capable of high accuracy and precision using aqueous (usually matrix matched) standards.

5.e. Data Integrity and Quality

Data should be reported and maintained in a form (preferably electronic and hard copy) in such a way that all data can be independently verified or reconstructed. In addition to the raw data for the patient and QA/QC samples, this information should include instrument operation and maintenance, calibration data for all analytical instrumentation as well as for pipettes, scales, and other commonly employed measurement tools, quality control charts, treatment of missing data or outliers, methods for reporting data below detection limits, etc. A sample protocol for data integrity and quality is provided in Appendix A. (See also: EPA Good Laboratory Practice Standards, 40 CFR, Part 792, subparts A-J.)

RECOMMENDATION

The elements of population representativeness and age, time of year when testing is done, frequency of testing, concurrent characterization of lead sources and pathways, and adherence to blood lead QA/QC standards should all be carefully evaluated according to the criteria above when assessing the quality of the design and conduct of environmental blood lead studies. If a blood lead study has satisfactorily met the listed criteria, the results of the blood lead study should reflect current short-term exposure (with varying degrees of uncertainty) for that site population and the results should be considered in the overall assessment of

exposure and risk (and possibly management of risk) at a site. For example, if the predictions of the EPA IEUBK model differ significantly from the results of that acceptable blood lead study (i.e., geometric mean blood lead levels differ by more than 3 ug/dl, in the range of mean blood lead levels between 3 and 15 ug/dl, or there is greater than 20% difference in the percent population having blood lead levels over 10 ug/dl), attempts should be made to resolve the discrepancy. This discrepancy could be the result of overlooked sources of exposure, interrupted or enhanced pathways of exposure, or incorrect assumptions about intake rates or uptake parameters and may require additional sampling and/or studies to resolve.

Regardless of the level of quality of the blood lead study (ranging from unacceptable to minimally acceptable to fully acceptable), the results of the study should not be used by **itself** to assess long-term risk from lead exposure or consequently, to set remedial goals at a site. Although blood lead concentrations can be fairly accurate indexes of relatively recent lead exposure, they do not take into consideration the source(s) of lead exposure, changes in yard or home maintenance (i.e., intact lead-based paint changing to deteriorated, flaking paint), changes in behavior (more frequent soil contact at age 3, than at age 1), changes in population awareness of lead hazards, etc. For this reason, the results of the blood lead study may not accurately portray future exposures to lead and, especially, should not be used to adjust the inputs and parameters of the IEUBK model *ad hoc*. If the IEUBK model predictions differ significantly from the blood lead results, this should serve as an impetus to better characterize exposure and uptake, and from that empirical data, the parameters and inputs of the IEUBK model should be re-assessed. Given the uncertainty and/or variability associated with both the environmental data (representativeness of actual exposure, sampling, and analysis) and the blood lead data (number of data points near method detection limit, accuracy and precision of QC standards and proficiency standards), it is not likely nor expected that the predictions of the IEUBK model and blood lead data should be in precise agreement.

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APPENDIX A

SAMPLE PROTOCOLS FOR SPECIMAN COLLECTION, STORAGE, AND SHIPMENT AND DATA HANDLING

Appendix A
Collection and Shipping Protocol

The proper collection, processing, storage and shipment of physiologic specimens from participants is critical to the success of the study. The following sections describe the procedures which must be followed for all specimen collections. These procedures must be strictly adhered to in order to avoid contamination, loss, or degradation of the specimens. Please familiarize yourself with the study protocol and insure that you understand the concept of the study, the role of all the personnel involved, and your own role.

Note that subjects are **not required** to report for blood and urine collection in a fasting state although blood collection should be accomplished early in the visit to avoid discomfort to the subject. Blood collection must be completed and processed under carefully controlled conditions of good laboratory practice. Blood separation and processing must be accomplished promptly to avoid degradation of the specimen.

It is extremely important that all records associated with each subject be maintained in an organized and complete manner to ensure that all information is properly collected and accurate. Specimens should be labeled promptly and processed as a unit or "run" and precautions must be taken to avoid patient-specimen-label-record mix-ups. Careful planning and a well organized work area will keep such errors at a minimum. Some of the information required for the specimen label and shipping list will be collected at the time of specimen collection. Problems in blood and/or urine collection should be noted in the sample log and in the comments section of the shipping list.

WHOLE BLOOD COLLECTION AND PROCESSING

NOTE: Universal Precautions - procedures to prevent exposure to HIV; hepatitis; etc., are ASSUMED during all collection and handling of biological specimens. ALL specimens should be considered

POTENTIALLY INFECTIOUS- see CDC Guidelines for specific recommendations and procedures.

Whole blood collection procedure

1. Materials needed per participant.

   - Gauze sponges
   - Alcohol wipe
   - Bandaid
   - 3 mL purple top tube
   - 21g 3/4" butterfly assembly with multiple sample luer adapter, sterile
   - 23g 3/4" butterfly assembly with multiple sample luer adapter for children and difficult sticks.
   - 21g or 22g Vacutainer multiple sample needles
   - 5 cc plastic syringe for children
   - Preprinted labels
   - Tourniquet
   - Vacutainer holder and adapters for pediatric tubes
   - Refrigerator
   - White storage boxes

2. Venipuncture procedure.

   - Locate a suitable table and chair for blood collecting and lay out blood collection supplies.
   - Locate the puncture site. Hold with 2 fingers on one side of the "alcohol wipe" so that only the other side touches the puncture site. Wipe the area in a circular motion beginning with a narrow radius and moving outward so as not to cross over the area already cleaned. Repeat with a second alcohol wipe.
   - Locate vein and cleanse in manner previously described, then apply the tourniquet. If it is necessary to feel the vein again, do so; but after you feel it, cleanse with alcohol prep again, and dry with a sterile gauze square.

- Fix the vein by pressing down on the vein about 1 inch below the proposed point of entry into the skin and pull the skin taut.
- Approach the vein in the same direction the vein is running, holding the needle so that it is at an approximately 15° angle with the examinee's arm.
- Push the needle, with bevel facing up, firmly and deliberately into the vein. Activate the vacuum collection tube. If the needle is in the vein, blood will flow freely into the tube. If no blood enters the tube, probe for the vein until entry is indicated by blood flowing into the tube.
- For collection, loosen the tourniquet immediately after blood flow is established and release entirely as the last tube fills. Collect 1 purple top tube (3 mL).
- If a syringe is required to obtain the blood, attach it to the appropriate size butterfly needle and withdraw 2-3 mLs blood. After withdrawing the needle from the arm, quickly change the needle on the syringe and transfer the blood from the syringe by puncturing the top of the purple-top tube with the new needle and allowing the vacuum to draw the blood into the tube. Mix well with the anticoagulant.
- When the needle is out of the arm, press gauze firmly on the puncture. Heavy pressure as the needle is being withdrawn should be avoided because it may cause the sharp point of the needle to cut the vein.
- Have the examinee raise his arm (not bend it) and continue to hold the gauze in place for several minutes. This will help prevent hematomas.
- Report to the physician any reaction experienced by the participant during the venipuncture procedure.
- Label all tubes with the preprinted labels provided, and use a ballpoint pen to add the date collected and your initials to the label. The tubes should be affixed with the label showing the participant's ID number (e.g., 92-0024-0001-B1).
- Place a bandaid on the subject's arm.

Whole blood processing procedure

General processing instructions

V. SHIPMENT OF SPECIMENS

A. BEGINNING OF STUDY AND GENERAL INSTRUCTIONS

1. Determine the times 'FEDERAL EXPRESS' packages are picked up in order to connect with the best flights to the destination lab. IMPORTANT: SINCE THE MATERIALS PACKED IN ACCORDANCE WITH THE INSTRUCTIONS BELOW WILL REMAIN COOL (WITH REFRIGERANT) ONLY ABOUT 2 1/2 DAYS, SHIPMENTS SHOULD NOT ARRIVE AT DESTINATION LAB ON WEEKENDS OR ON FEDERAL HOLIDAYS.

2. Inquire about regulations in your area concerning shipment of human blood specimens with refrigerant ("Cool Paks") and the quantity of refrigerant allowed per shipper. Also, make sure the specimens will be received at destination lab within 24 hours.

3. For all shipments, do not pack shippers with specimens and refrigerant until just before shipment.

4. Telephone the destination laboratory the day the shipment is mailed.

B. SPECIMEN SHIPPING LIST

1. For each shipment, fill out a blank Specimen Shipping List provided by the destination lab. If the number of specimens in a shipment is too large to fit on one page, please use the continuation sheets provided. Please give the following information on the blank shipping lists (See attached example of a completed Specimen Shipping Lists):

a. Page number - e.g., 1 of 4.
b. Shipment Number- number shipments sequentially

starting with 1.
c. Number of shippers- total number of shippers (containing whole blood specimens) which are being mailed in this shipment.
d. Type of Specimens- whole blood.
e. Number of Specimens- number of each type of specimen shipped.
f. Name, Title, Signature, and Phone Number of person sending shipment or initials as indicated on the continuation sheets.
g. Date shipped.
h. Specimen ID for each participant- e.g. 91-0018-0001. For each participant, check (X) each individual specimen type/aliquot included in this shipment.
i. Date Collected- e.g., 06-25-91.
j. Comments- Specify any deviations from collection, storage, and shipment protocols, and date of occurrence.

Photocopy 2 extra copies of the completed shipping list. As will be described again later, the original will be shipped with the specimens, a copy mailed to the destination lab under separate cover, and a copy retained for your records.

C. REFRIGERATED SPECIMENS

1. Materials needed per shipper.

-1 styrofoam shipper
-2-4 "Cool Paks"- FOAM REFRIGERANT
-Freezer boxes
-Small cardboard shipping boxes (one per 40 specimens)
-Safety glasses or eye shield
-Strapping tape
-Gloves for handling dry ice and frozen specimens
-Sheets of bubble-pack packing material
-'FEDERAL EXPRESS' label, preaddressed to the destination lab
-HUMAN BLOOD-THIS SIDE UP label

-'Specimen Shipping List' (completed)
-Zip-lock bag
-Whole blood specimens (2 tubes per participant)

2. Packing procedure.

-Place the 2 specimens from each participant in the freezer boxes provided. The small cardboard boxes provided can be packed with approximately 40 specimens.

-Pack the cardboard boxes in the bottom of the shipper. If necessary, use sheets of bubble-pack packing material to ensure the specimens are in a vertical position.

-Put one layer of sheet bubble-pack material on top of the specimen boxes.

-Add the 3-4 "Cool Paks", inserting them between the boxes so that they are spaced evenly and the weight of the refrigerant is not directly on top of the specimen boxes.

-Place more bubble material to even the top and place the polyfoam lid on top of the shipper.

-Insert the completed 'Specimen Shipping List' in a 12"x12" Zip-lock bag and secure to the top of the polyfoam lid with filament tape. (Remember to photocopy 2 copies of the 'Specimen Shipping List'. Keep one copy for your records and mail the other copy in a separate envelope to the destination lab).

-Secure the outer cardboard lid on the shipper with filament tape.

3. Shipping procedure.

-Cover or remove previous address labels on all shippers.

-Label each shipper with the following:

Preaddressed, 'FEDERAL EXPRESS' label with the address of the destination lab and the human blood label.

Call the 'FEDERAL EXPRESS' OFFICE AT 1-800-238-5355 to arrange for pick-up.

Telephone the destination laboratory the day the shipment is mailed.

V. SPECIMEN TESTS

ABBREVIATION	TEST NAME
A. BLOOD TEST	
	LeadPb
	Cadmium Cd (or other metal)

Abbreviations will be printed on the participant's label.

LEAD STUDY

CASE 94-00XX

WHOLE BLOOD COLLECTION AND PROCESSING PROTOCOL

BLOOD (6 mL total)

3 mL purple-top tube
B1
"BLOOD PB"

Refrigerate and store at 4°C

3 mL purple-top tube
B2
"BLOOD CD"

Refrigerate and store at 4°C

Both purple-top tubes should be placed in an appropriate box with ice packs and sent to Chamblee for testing

NOTE: ALL ITEMS IN QUOTES AND UNDERLINED ARE "LABELS"

SPECIMEN INFORMATION SYSTEM

FORM 1 LEAD STUDY

SPECIMEN SHIPPING LIST

Case Number: 94-00XX

Shipment Number:_____

Number Shippers (Boxes):_____

Type of Specimens: Number of Specimens:

_____ _____

_____ _____

Shipped By:_____

Signature:_____

Date shipped:_____

Received By:_____

Signature:_____

Date Received:_____

Participant specimen ID number	Specimen collected		Date collected	Comments: specify deviations in collection, storage and/or shipment
	B1	B2	DATE	
94-00XX-0001	__	__	_____	_____
94-00XX-0002	__	__	_____	_____
94-00XX-0003	__	__	_____	_____
94-00XX-0004	__	__	_____	_____
94-00XX-0005	__	__	_____	_____
94-00XX-0006	__	__	_____	_____
94-00XX-0007	__	__	_____	_____
94-00XX-0008	__	__	_____	_____
94-00XX-0009	__	__	_____	_____
94-00XX-0010	__	__	_____	_____
94-00XX-0011	__	__	_____	_____
94-00XX-0012	__	__	_____	_____
94-00XX-0013	__	__	_____	_____

Page 1 of _____

SPECIMEN INFORMATION SYSTEM

FORM 1 LEAD STUDY

SPECIMEN SHIPPING LIST

Participant specimen ID number	Specimen collected		Date collected	Comments: specify deviations in collection, storage and/or shipment
	B1	B2	DATE	
94-00XX-0014	__	__	_____	_____
94-00XX-0015	__	__	_____	_____
94-00XX-0016	__	__	_____	_____
94-00XX-0017	__	__	_____	_____
94-00XX-0018	__	__	_____	_____
94-00XX-0019	__	__	_____	_____
94-00XX-0020	__	__	_____	_____
94-00XX-0021	__	__	_____	_____
94-00XX-0022	__	__	_____	_____
94-00XX-0023	__	__	_____	_____
94-00XX-0024	__	__	_____	_____
94-00XX-0025	__	__	_____	_____
94-00XX-0026	__	__	_____	_____
94-00XX-0027	__	__	_____	_____
94-00XX-0028	__	__	_____	_____
94-00XX-0029	__	__	_____	_____
94-00XX-0030	__	__	_____	_____
94-00XX-0031	__	__	_____	_____
94-00XX-0032	__	__	_____	_____
94-00XX-0033	__	__	_____	_____

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SPECIMEN INFORMATION SYSTEM

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SPECIMEN SHIPPING LIST

Participant specimen ID number	Specimen collected B1	B2	Date collected DATE	Comments: specify deviations in collection, storage and/or shipment
94-00XX-0034	__	__	_____	_____
94-00XX-0035	__	__	_____	_____
94-00XX-0036	__	__	_____	_____
94-00XX-0037	__	__	_____	_____
94-00XX-0038	__	__	_____	_____
94-00XX-0039	__	__	_____	_____
94-00XX-0040	__	__	_____	_____
94-00XX-0041	__	__	_____	_____
94-00XX-0042	__	__	_____	_____
94-00XX-0043	__	__	_____	_____
94-00XX-0044	__	__	_____	_____
94-00XX-0045	__	__	_____	_____
94-00XX-0046	__	__	_____	_____
94-00XX-0047	__	__	_____	_____
94-00XX-0048	__	__	_____	_____
94-00XX-0049	__	__	_____	_____
94-0012XX-0050	__	__	_____	_____
94-00XX-0051	__	__	_____	_____
94-00XX-0052	__	__	_____	_____
94-00XX-0053	__	__	_____	_____

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