The Arizona Border Study

An Extension of the
Arizona National Human Exposure Assessment Survey (NHEXAS)Study
Sponsored by the Environmental Health Workgroup of the Border XXI Program

Quality Systems and Implementation Plan for Human Exposure Assessment

The University of Arizona
Tucson, Arizona 85721

Cooperative Agreement CR 824719

Standard Operating Procedure **UA-G-QSIP1**

Title: Quality Systems and Implementation Plan for Total Human Exposure in Arizona: A Comparison of the Border Communities and the State

Source: The University of Arizona

U.S. Environmental Protection Agency
Office of Research and Development
Human Exposure & Atmospheric Sciences Division
Exposure & Dose Research Branch

QUALITY SYSTEMS AND IMPLEMENTATION PLAN
(UA-G-QSIP 1)

for

TOTAL HUMAN EXPOSURE IN ARIZONA: A COMPARISON OF THE BORDER COMMUNITIES AND THE STATE
(Agreement Number: R824719)

implemented by

UA/BATTELLE/IIT CONSORTIUM

composed of

Arizona Prevention Center
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Tucson, AZ 85724

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REVIEW RECORD FOR QUALITY ASSURANCE PLAN

ID NO: UA-G-QSIP1	REV: 0	ISSUE DATE: June 1997

TITLE: **Total Human Exposure in Arizona: A Comparison of the Border Communities and the State (Agreement #R824719)**

REVIEWED BY: **Susan B. Hopf**

ISSUED BY: Arizona Prevention Center
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☒ Original Issue ☐ Revision

VERIFICATION SCOPE: (check as applicable) "FIRST REVIEW**	SAT	UNSAT	N/A	If UNSAT, explain below or on reverse side
Title Page	X			
Table of Contents	X			
Project Description	X			
Project Organization and Responsibility	X			
QA Objectives for Measurement of Data (DQOs and DQIs)	X			
Sampling Procedures	X			
Sampling Custody	X			
Calibration Procedures and Frequency	X			
Analytical Procedures	X			
Data Reduction, Validation, and Reporting	X			
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Specific Routine Procedures for Assessment of Data Precision, Accuracy, and Completeness	X			
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Quality Assurance Reports to Management	X			
Other:				

COMMENTS: Please see text for typos that might affect interpretation of text. See also pp.30- 32: duplication of text; p.38: subscript/regular case problems: p. 67: incorrect table numbering. Issues addressed and resolved. MMR 9/5/97

Preparer: Please respond to comments above and/or on next page.

☒ APPROVED — Susan B Hopf (Signature) — 19 August 1997 (Date)

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☐ NOT APPROVED — (Signature) — (Date)

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1.0 PROJECT PLANNING AND ORGANIZATION

1.1 Identification of the Problem

Some pollutants pose well-known risks to health, whereas for most pollutants we have insufficient health information. As a result EPA funded 3 consortia to perform the National Human Exposure Assessment Survey (NHEXAS). Members of the Arizona Consortium (listed on the cover) will obtain some information about the population distribution and the determinants of exposure in the State of Arizona (NHEXAS AZ); other consortia will make similar evaluations in EPA Region 5 and the Baltimore/Washington, D.C. urban areas. There is an obvious public health need to try to answer important questions concerning exposure to environmental pollutants that are likely to produce harm and increase the risk of disease in humans. Unfortunately, there are many such questions that are insufficiently addressed to properly enable scientific decisions about management of these risks and protection of public health [Sexton et al., 1992]. There is a major *scientific* need to provide exposure data that are directly relevant to answering these important questions. The NHEXAS concepts are very appropriate to such goals and we will extend them to this study ("Total Human Exposure in Arizona: A Comparison of the Border Communities and the State") which will be referred to as the "Border Study or BORDERAZ " for the sake of brevity in this document.

There are public *concerns* among border communities that exposures are high relative to other parts of the country. These communities believe they encounter elevated exposure related to their proximity with Mexico. Associated with increased exposure is a community-wide fear of increased health effects. Currently, there are no data available to validate this perception of elevated exposure among the border communities. We are undertaking a preliminary, basic research exposure assessment to determine whether there are elevated exposures in the border communities. Some basic research has been undertaken in NHEXAS AZ, a multiple media (air, soil, house dust, skin, food and beverages, water, blood and urine) to determine exposure contributions through various pathways (inhalation, absorption, ingestion). The Border Study is a special, complementary, preliminary exposure assessment study along the Arizona-Mexico border, so for the first time, border exposures can be compared with those from an adjacent non-border area (NHEXAS AZ) [Lebowitz et al., 1995]. Like NHEXAS AZ the "Border Study" will determine the distribution function of exposure to selected metals, pesticides and Volatile Organic Compounds (VOCs). Most of the target contaminants will be the same for the two studies. However, we have added selected pesticides (organochlorines) and Polycyclic Aromatic Hydrocarbons (PAHs) to the analyte list since we have expectations of finding greater concentrations of these along the border.

We will examine these classes of pollutants that are potentially harmful to human health and for which we have little information on population exposure. There are multiple sources (air, water, soil, food, dust, etc.) of exposure to these chemicals. Investigators have the sense that certain populations, including low-income individuals, minorities and the biologically susceptible, are at high risk and their exposures need to be identified. Further, little is known about temporal and spatial distributions, and trends in these distributions. In general, these pollutants have been shown to cause such concern based on limited epidemiological or occupational studies in humans or in animal models utilized for this purpose. Some, considered prototypic, are well-known to cause harm to humans and are considered of major public health significance; the best examples are benzene and lead. As will be seen, almost all have documented concerns that are of public health significance, relating to their different risks -

carcinogenic, teratogenic, etc. (based on reports of EPA, ATSDR, NIOSH, WHO, WHO/EURO). Some health risks and outcomes, like asthma, the clustering of birth defects and some cancers, appear to be increasing [PHS, WHO]. These diseases may be related to the NHEXAS target pollutants (prototypic, priorities 1 & 2) [ATSDR, CDC/Needham et al., 1991]. The need to provide such information is urgent.

1.2 Background of Specific Pollutants & Pollutant Classes Selected for Study

We selected pollutant classes to meet the criteria of i) public health significance, ii) the potential for study in terms of specific areas where high exposures occur and in which high-risk groups (those biologically susceptible, minorities, low income and/or inner city residents) are especially exposed, iii) the cost and feasibility of determining relevant exposures (and sources), and iv) the feasibility of assessing exposure-dose and dose-response relationships to provide the information directly relevant for risk assessment, management and for making public health decisions. The negotiated pollutant classes selected include (in order of priority) metals, pesticides, VOCs and PAHs. The list of target compounds for metals and pesticides were separated into primary and secondary categories. For selected media, we may analyze for multiple analytes. This ranking approach enables us to consistently select the same analytes when confronted with choices due to limitations in sample size or funding. For instance, if the amount of sample is limited the primary targets (metals) only will be analyzed. Further limitations will exclude secondary targets (secondary metals) from analysis. Such limits are not applicable to VOCs or PAHs. Once eluted all compounds are discernible. The following discussion outlines the importance of the specific pollutants selected within each class.

1.2.1 *Target Metals*

Primary Metals: Lead (Pb), Arsenic (As), Cadmium (Cd), Nickel (Ni) and Chromium (Cr)

Secondary Metals: Barium (Ba), Iron (Fe), Manganese (Mn), Selenium (Se), Vanadium (V), Copper (Cu) and Zinc (Zn)

Selection of metals to evaluate, and the rationale for these choices, are based on the EPA Criteria Document for Lead, other EPA documents on metals, and IPCS/WHO Criteria & Guidelines documents. All can produce a variety of health effects, and many are considered definite or probable public health problems. Lead is the obvious prototype metal as it is a NAAQS pollutant, with clearly defined potential human harm. However, there is a lack of sufficient data on population distributions of exposure, especially for all high risk populations.

Arsenic in soil (and dust) appears to be ubiquitous (Arizona & rural California sampling reports), and may be locally ubiquitous in air and water. Given its known health risks for humans (op cit.), and the lack of data on population distributions of exposure, it is a good metal to target.

Cadmium, chromium, and nickel are also of interest for their potential harm to human health and the lack of data on population distributions of exposure. Chromium is of special interest as it is associated with several health outcomes and is a source marker (op cit., below). We are also interested in selenium concentrations, as selenium (a natural ingredient in food) appears to be

protective of cancer in non-toxic amounts. Vast quantities of sulfide minerals are deposited in the rock strata of Arizona. Copper mining and smelting is a major industry in Arizona.

1.2.2 Target Pesticides

Primary Pesticides: Chlorpyrifos, Chlordane (trans or y), DDD, DDE, DDT and Diazinon

Secondary Pesticides: Malathion

Potential Future Evaluation from Stabilized Pesticide Extracts: Acephate, Dieldrin, Heptachlor, Lindane, Methomyl, Methyl Parathion, Pendimethalin, cis/trans-Permethrin, Propoxur and Trifluralin.

Pesticide exposure studies conducted in recent years in the U.S. include the U.S. EPA's Non-Occupational (NOPES) [Lewis et al., 1988], Household Infant (HIPES) [Lewis et al., 1991], and the Second National Health and Nutrition Examination Survey (NHANES II) [Murphy et al., 1983]. On-going pesticide exposure studies include the NCI-EPA Farm Occupational Exposure Study (NEFOES), Lawn Application Pesticide Exposure Study (LAPES) [Nishioka et al., 1992], the Brownsville, TX study and the 3 NHEXAS studies. On the basis of these studies, proximity to Mexico where organochlorines remain available, and pesticide sales figures for the state of Arizona (Merrigan & Baker 1993), we selected the pesticides listed above.

The criteria used here to select representative pesticides for the US population include toxicity, frequency of use, frequency of detection, and existence of highly exposed populations. In our unpublished survey of home in Pima county, Arizona, aside from the pyrethroids which are very unstable, diazinon is the most common pesticide used inside homes. Malathion is used in the western part of the state along the California border to prevent Mediterranean fruit fly infestations of citrus. Current sales, frequency of use, and cost effectiveness of analysis procedures dominated our selection criteria for pesticides. The following discussion is provided as additional rationale for the pesticides selected for study in BORDERAZ.

Each pesticide selected is known to have toxic endpoints and is suspected as having carcinogenic endpoints. Acute toxicity for organophosphate insecticides (organophosphate including phosphate OP and thiophosphate SP insecticides, e.g. diazinon, chlorpyrifos, malathion) involves acetylcholinesterase inhibition, with nausea, vomiting, brachycardia, tachycardia, ataxia, and paralysis [Salem and Olajos, 1988]. Chronic exposure can lead to a "dying-back" of the peripheral nervous system. While both diazinon and chlorpyrifos are SP (thiophosphates), rather than strict OP (organophosphates), both pesticides are oxidized to the corresponding OP (e.g. diazinon) in the environment [Glotfelty et al., 1990] and these OP forms are highly toxic and exhibit about 10,000 fold higher acetyl cholinesterase inhibition [Fujii and Asaka, 1982]. Diazinon use in the garden or orchard has been associated with increased incidence of brain cancer in children, relative to cancer controls and adjusted for ETS exposure, income, and education [Davis et al., 1993]. Diazinon has been banned for use on golf courses and sod farms because of high rates of water-fowl kills related to toxic run-off.

Not only are the toxicity and other adverse health effects of these pesticides clearly established, but these specific pesticides are among the most widely used and frequently detected pesticides in the U.S. The NOPES study found the insecticides chlorpyrifos and diazinon in the indoor air of over 80% of the 260 homes investigated [Lewis et al., 1988]. The HIPES study, which focused on the house dust and indoor air of 9 homes, also found chlorpyrifos to be the most frequently detected pesticide, with the absence of diazinon from the HIPES samples attributed to analytical difficulties [Fortmann et al., 1991]. The results of the NHANES II study, where the urine of nearly 6000 U.S. residents was analyzed for the residues of a variety of pesticides, confirm the exposure of the population to these pesticides [Murphy et al., 1983]. Metabolites of chlorpyrifos and diazinon were detected in 6-7% of the urine samples. Pesticides have also been detected in food and municipal drinking water, indicating numerous routes of exposure [Schattenberg and Hsu, 1992; Lin et al., 1981].

The NOPES study has suggested that outside of the environment defined by farm and agricultural workers, exposure to pesticides is defined primarily by use in and around the home. The pesticides selected here are used extensively for residential and community applications. Because these pesticides are also used for agricultural purposes, farm and non-farm populations can be evaluated in NHEXAS. The NOPES and HIPES studies have shown that for the residential environment, pesticides are present in indoor air and dust at higher levels than are found in outdoor soil and air. These studies suggest that for the non-farm environment, indoor exposure to pesticides is more important than outdoor exposure and that inadvertent dermal contact and ingestion of contaminated house dust may account for significant pesticide exposure in young children.

The highly exposed populations for diazinon and chlorpyrifos are those which routinely treat the home for insect control, either with bombs, sprays, no-pest strips, crack-and-crevice treatments or commercials applications. Those homes located near orchards have been identified as potential highly exposed populations. Homeowners who make their own application may be the more highly exposed population, both from inadvertent misuse and contaminants that brought into the home on clothing.

Chlorpyrifos, Diazinon and Malathion:

Chlorpyrifos, diazinon and malathion are thiophosphate pesticides (SP) used extensively throughout the U.S. in agriculture, on turf [Nishioka et al., 1992], in community pest eradication programs [Weiskopf et al., 1988] and indoors. Malathion attained notoriety when sprayed from aircraft in southern California as part of the Mediterranean fruit fly eradication program. The potential exposure pathways for chlorpyrifos, diazinon and malathion are inhalation, dermal contact and ingestion, particularly since SP are frequently used indoors. The potential pathways of entry from the outdoors into the indoor environment include airborne routes such as spray-drift and resuspension from soil, and track-in of soil residues. Exposure to SP in food may be expected as these insecticides have been detected in diverse produce [Iverson et al., 1975]. Exposure to home-grown produce may represent a dietary exposure route. Although dust-bound residues may constitute a significant source of exposure for young children, indoor use of SPs could result in exposure pathways such as inhalation, dermal contact and ingestion of solid aerosols with higher pesticide concentrations than those in dust- bound residues. These compounds are semi-volatile

organic compounds (SVOCs) with little information currently available on the distribution between the vapor and particle phases and the temporal variability of the phase distribution.

Biomarkers of exposure to chlorpyrifos and diazinon have been established from the NHANES II study [Murphy et al., 1983]. Chlorpyrifos exposure is indicated by the metabolite 3,5,6-trichloro-2-pyridinol, while diethylphosphorothionate (DETP) could result from both diazinon and chlorpyrifos exposure. The phenolic metabolite in urine specific for diazinon, 2-isopropyl-6-methylpyrimidin-4-01, may be detected by a method similar to that used for detecting the phenolic chlorpyrifos metabolite [Grover et al., 1986].

Organochlorines

One comparison of risk to pesticides from indoor exposure has indicated that four chlorinated insecticides (heptachlor, chlordane, aldrin, dieldrin) may pose the greatest risk [Wallace, 1991]. However, this risk assessment used data from only two cities and may have relied too heavily on data from analytical methods that were better suited to detection of these relatively non-polar pesticides rather than to more polar and acidic pesticides. In addition, this risk assessment noted that inadequate information on exposure and potency prevented a calculation of risk for chlorpyrifos and diazinon, which, as noted there, are two of the most frequently detected pesticides in indoor air. Evaluations by the Arizona Department of Environmental Quality indicate that chlordane is found throughout the state at low background levels. This pesticide is no longer sold. It was replaced by chlorpyrifos for treatment of termites. According to the Uniform Building Code (employed throughout the state), the soil under the foundation/slab of all homes must be treated with a termaticide. We selected chlorpyrifos as it is the most common termaticide currently employed.

DDT and related compounds are probably the most effective insecticides in existence. These organochlorines contain carbon, chlorine hydrogen and sometimes oxygen. DDT was first discovered and discarded in 1873 by a German graduate student. It was rediscovered in 1939 by a Swiss entomologist Dr. Muller who ultimately won the Nobel Prize for the discovery. DDT is a low cost broad spectrum insecticide. DDT, DDD, DDE and Chlordane are now banned from sale and use in the US. Residues are still detected in areas that were heavily farmed and we expect to see low levels of the compounds in Arizona. The compounds are still available in Mexico. There is anecdotal evidence that they continue to be used along the US-Mexico Border.

The major urinary metabolite of DDT is *bis*(p-chlorophenyl) acetic acid. p'p DDD and p'p DDE are indicative of exposure to the respective pesticides. Detailed information on Biomarkers is available in the ATSDR report on DDD, DDE, DDT (1993). One of the biomarkers associated with chlordane exposure is heptachlor epoxide detected in the blood.

1.2.3 *Target VOCs*

Primary VOCs: Benzene, Formaldehyde and 1,3-butadiene

Secondary VOCs: Toluene, Trichloroethylene (TCE) and Total VOCs

The selection of our primary and secondary VOCs is based on data gathered by EPA and others [Wallace, 1987; Lofroth et al, 1989; Sheldon and Jenkins, 1990; Wallace, 1991; Cooke, 1991; Hodgson and Wooley, 1991; Dann and Wang, 1992; Lofgren and Petersson, 1992; Sabourin et al., 1991 and 1992; Wallace, 1992].

A number of studies have documented the important contribution of indoor personal activities and consumer products to personal exposures to VOCs [for example, Wallace, 1992; Clobes et al, 1992]. Benzene is one of the VOCs that has been studied most extensively. Personal exposures (personal air and breath) to benzene as well as its indoor and outdoor concentrations have been well characterized [Wallace, 1987]. Although inhalation is the dominant pathway of human exposure [Hattemer-Frey et al., 1990], benzene and other toxic VOCs are also found in water. In certain situations, this exposure can be appreciable. For example, it has been shown that residential use of benzene-contaminated water, such as in a hot shower, may result in significant inhalation and dermal exposures [Shehata, 1985; Lindstrom et al, 1992]. A ubiquitous compound, benzene is considered a human carcinogen and has been estimated to have one of the highest upper-bound lifetime cancer risks of all VOCs evaluated [Wallace, 1991; Dann and Wang, 1992]. One recent study concluded that benzene contributes almost 20% to the computed overall VOC-related lifetime cancer risk [Dann and Wang, 1992].

We have also selected formaldehyde and 1,3-butadiene as primary VOCs for investigation because: (1) they are important as potential health hazards, (2) they are prevalent in air (indoor and ambient) and house dust [Kirchherr et al., 1992], and (3) we lack adequate exposure information on either compound. The individual lifetime cancer risk estimates for formaldehyde and 1,3-butadiene are of the same order as, or possibly even higher than, the airborne risks calculated for benzene Wallace, 1991]. A more recent study suggests that 1,3-butadiene and formaldehyde, along with benzene, make the greatest relative contribution to overall VOC-related cancer risk, namely, 41% for 1,3-butadiene, 18% for benzene, and 15% for formaldehyde. However, there still appears to be uncertainty about the carcinogenic potency of formaldehyde. Also, the lack of personal exposure or indoor concentration data for 1,3-butadiene make the risk estimates for both of these compounds extremely speculative [Wallace, 1991]. Arizona had an extensive aviation industry including major air force bases. In the last 10 years TCE has been identified as a pollutant of ground water, a major component of the domestic water supply. Further, recent malfunctions in the water clean-up site have resulted in atmospheric release of TCE. This is a VOC of major local concern and plays a role in the selection of this locally significant VOC. We expect examination of this VOC to enhance subject participation. The secondary VOCs (e.g., TCE) occur extensively in drinking water in certain locations, and are currently of great concern because of indications that they are potential teratogens [ATSDR; Goldberg et al., 1990]. Information on their occurrence and concentrations may be obtained from city water department records in most larger cities in the U.S. Toluene has

also been included because it is toxic and can be used to determine the sources of benzene (from the benzene/toluene concentration ratio).

Most earlier personal exposure studies employed sampler tubes containing Tenax sorbent through which a known volume of air was drawn with a personal sampling pump. Because Tenax does not retain very volatile compounds, such as 1,3-butadiene, and cannot be used to trap reactive compounds, such as formaldehyde [WHO, 1989], no large-scale personal exposure studies have been carried out to assess exposure to these target compounds.

Benzene:

Exposure to benzene occurs mainly as a result of active and passive smoking, vehicle exhaust (including driving and other personal activities associated with motor vehicles, use of attached garages for parking cars), storing gasoline, the use of certain consumer products, and exposure to aerosolized water-containing benzene. High doses affect the central nervous system, while exposure levels as low as 1 ppm are reported to result in a high risk of leukemia and anemia in children. Studies have shown that children of smokers die of leukemia at more than twice the rate of children of nonsmokers [Wallace, 1991]. Techniques to monitor benzene in indoor and outdoor air are well-established [Wallace, 1987]; benzene also provides clear-cut biomarkers for direct assessment of exposure and risk. The unmetabolized parent compound in exhaled breath [Wallace, 1987; Gordon et al., 1988; Gordon 1990; Gordon et al., 1992; Pellizzari et al., 1992; Wallace et al., 1993] serves as a biomarker of exposure whereas the urinary metabolite trans, trans-muconic acid is a biomarker of dose [Buckley et al., 1992; Ducos et al., 1992].

Formaldehyde:

Because of its widespread use, formaldehyde is one of the most frequently measured compounds in indoor air studies [WHO, 1987; Otson and Fellin, 1992; Moschandreas and Gordon, 199 13. Potential sources of formaldehyde exposure include building materials (urea-formaldehyde foam insulation, pressed wood products, particle board, adhesives, carpeting, new furniture), consumer products (cleaners, fabric softeners), permanent-press fabrics, paper products, cosmetics, and incomplete combustion (vehicle exhaust, emissions from gas stoves, burning cigarettes, wood smoke) [Cooke, 199 1]. Indoor air concentrations are generally significantly higher than outdoor concentrations. Recent emissions test data suggest that the emissions of formaldehyde increase significantly (by 20-75% depending on the emission control technology being used on the test vehicle) when either methyl t-butyl ether (MTBE) or methanol/ethanol blended (alternative oxygenated) fuels are used [Anderson et al., 1993]. These researchers estimate that, in Denver, motor vehicle emissions are the major source of formaldehyde during the winter (>1 ton of formaldehyde per day). Human exposure to formaldehyde is principally through inhalation and skin absorption or less frequently by ingestion [Sittig, 1985]. Two subpopulations have been identified as having particularly high potential for formaldehyde exposure, namely, residents of mobile homes containing particle board and plywood, and persons living in conventional homes insulated with urea-formaldehyde foam. In addition to its designation as a suspect carcinogen and mutagen, formaldehyde in the gas phase is an eye, nose, and throat irritant and a skin irritant in liquid form [WHO, 1989]. Formaldehyde is rapidly metabolized in humans to form formic acid. Although it has

been widely monitored in indoor environments, direct measurements of personal exposure to formaldehyde are relatively sparse [Chan et al., 1991].

1,3-butadiene:

Environmental tobacco smoke from burning cigarettes is an important indoor source of 1,3-butadiene [Lofroth et al., 1989]. Vehicle emissions are a major outdoor source of this compound [Lofgren and Petersson, 1992], and vehicle exhaust and evaporative emissions of fuel from vehicles may enter the living space of houses with attached garages [Hodgson and Wooley, 1991]. Low levels of 1,3-butadiene have been measured in ambient urban air [Lofgren and Petersson, 1992; Cote and Bayard, 1990] and it is regarded as a probable human carcinogen by U.S. EPA [Hallenbeck, 1992]. However, data on indoor concentrations of 1,3-butadiene are very limited. A single pilot study conducted recently to measure indoor concentrations and personal exposures for several air toxics indicated that outdoor concentrations for 1,3-butadiene were generally higher than indoor levels [Sheldon and Jenkins, 1990]. Like benzene, 1,3-butadiene is not very soluble in water.

Thus, unmetabolized parent compound may serve in much the same way as a biomarker of exposure. Urinary metabolites of 1,3-butadiene that may be used as biomarkers of dose are the mono- and diepoxides as well as the recently identified 1,2-dihydroxy-4-(N-acetylcysteinyl)butane [Sabourin et al., 1992].

Our literature evaluation of these pollutants suggests they will be good choices for evaluation within the NHEXAS framework (Table 1). As a result we formed a consortium in response to EPA's NHEXAS RFP consisting of the University of Arizona, Battelle Memorial Institute and Illinois Institute of Technology (aka NHEXAS Arizona). We propose evaluating exposure to the fore-mentioned metals, pesticides and VOCs using a non-stratified, nested sampling strategy. The consortium will **evaluate** a subset of the State of Arizona's population determined statistically as described in Section 1.7.

1.2.4 PAHs

Target Compounds: Acenaphthene, Anthracene, Benz[a]anthracene, Benzo[b]fluoranthene, Benzo[j]fluoranthene (B[j]F), Benzo[k]fluoranthene, Benzo[e]pyrene (B[e]P), Benzo[a]pyrene (B[a]P), indeno[1,2,3- c,d]pyrene, Benzo[g,h,i]perylene, Chrysene, Coronene, Cyclopenta [c,d] pyrene, Dibenzo [a,h] anthracene (DBA), Fluoranthene, Fluorene, Naphthalene, Phenanthrene, Pyrene, Quinoline (air only), Retene

PAHs are generated by incomplete combustion of coal, wood, gas, coal, oil, garbage and other organic substances including tobacco and char-broiled meat. Supplemental diesel traffic in response to NAFTA and the long-standing practice of burning dumps along the US-Mexico border contribute to community concerns regarding these compounds.

PAH exposure has been associated with an elevated risk of cancer in rodents but no definitive studies have been identified regarding cancer in humans (ATSDR, 1995). Chronic exposure resulted in respiratory effects at a dose of 0.0001 ppm and cancer in hamsters at 10 ppm (ATSDR, 1995 p. 18). Acute oral exposure (≤ 14 days) of 100 mg/kg/day resulted in reproductive, renal hepatic and gastrointestinal (systemic) effects in rodents. (ATSDR 1995 p. 32). Similar results were found in rodents with intermediate exposure (15 days to 1 year) of 1000 mg/kg/day. In general the estimated upper bound cancer risk levels are believed to be between 10^{-4} and 10^{-7} or an excess cancer risk of 1 in 10,000 to 1 in 10,000,000. A variety of other reports also describe exposure to PAHs. These include Chuang et al., 1989, 1992; Gist & Burg, 1995; Kuhlman & Chuang, 1988; Lioy et al., 1988; NRC, 1981; RIVM, 1989; Sheldon & Jenkins, 1992; Sisovic et al., 1996; Sittig, 1985; WHO & IARC.

Occupational studies provide evidence that PAHs are absorbed when inhaled and through the skin by exposed humans. However absorption rates depend on the vehicle of administration and the pathway of exposure (ingestion, inhalation or absorption). Becker and Bjorseth 1983 found no relationship between inhalation dose and PAH in urine. Van Rooji et al 1993 examined the respiratory uptake of PAHs in 12 coke plant workers. They evaluated levels of pyrene in the breathing zone of workers (0.1-5.4ug/m3 with uptake of 0.5-32.2ug/day). Further they determined that 75% of the daily uptake occurred through the skin. Of the total dose obtained, 13-49% was excreted as 1 -hydroxpyrene. These results can be confounded by smoking and alcohol consumption. A separate population of smokers was evaluated by Likhachev et al. (1993) who evaluated urinary excretion of PAHs and indicators.

When foods containing PAHs are ingested some of the PAH is orally absorbed (Buckley & Lioy 1992). They also evaluated the urinary metabolites in persons consuming diets with low levels of benzopyrene and detected 1-hydroxypyrene. Hecht et al (1972) failed to detect elevated PAHs found in the feces of 8 volunteers who consumed broiled meat containing 9ug of B[a]P per serving. Animal studies (rats) suggest that intestinal absorption of PAHs varies with the presence of bile (Rahman et al 1986). This confounder may account for differences among study results.

PAHs are both manmade and naturally occurring substances that can be found in most media. Occupational studies demonstrate that PAHs can be carcinogenic when the substances are inhaled or dermally absorbed. In animal studies other adverse health effects are also detected; only cancer has been detected in humans. Minimum risk levels have been reported of the compounds under consideration in this study (ATSDR 1995).

1.3 Project Scope and Work Objectives

Exposure assessment studies are generally limited by the number of media and pathways evaluated for any given pollutant. The NHEXAS projects were exceptions to this statement. In NHEXAS we demonstrate the gains in accuracy and precision of exposure assessment models when multiple media (air, soil, dust, skin, water, food, blood and urine) that accrue and multiple pathways (inhalation, ingestion, absorption) are evaluated for the target contaminants described above. The Border Study will follow the NHEXAS design very closely and provide exposure distribution data for the border

Table 1. Target analytes and their associated Chemical Abstract Service (CAS) Registry Number.

Target Chemicals	CAS Registry Number
Primary Metals	
Lead	7439-92-l
Arsenic	7440-3 8-2
Cadmium	7440-43-g
Nickel	7440-02-o
Chromium	7440-47-3
Secondary Metals	
Barium	7440-39-3
Manganese	7439-96-5
Selenium	7782-49-2
Vanadium	7440-62-2
Copper	7440-50-g
Zinc	7440-66-6
Primary Pesticides	
Chlorpyrifos	2921-88-2
Chlordane (trans or γ)	5 103-74-2
DDD	72-54-8
DDE	72-55-9
DDT	50-29-3
Diazinon	333-41-5
Secondary Pesticides	
Malathion	121-75-5
Potential Pesticide Evaluation	
*Acephate (orthene)	30560-19-l
*Dieldrin	60-57-1
*Heptachlor	76-44-8
*Lindane (γ hexachlorocyclohexane)	58-89-9
*Methomyl	16752-77-5
*Methyl Parathion	298-00-o
*Pendimethalin	40487-42-1
*cis/trans-Permethrin	52645-53-l
*Propoxur	114-26-1
*Trifluralin	1582-09-g

Table l(cont). Target analytes and their associated Chemical Abstract Service (CAS) Registry Number.

Primary VOCs	
Benzene	71-43-2
l, 3-butadiene (hexachlorobutadiene)	106-99-o
Secondary VOCs	
Bromomethane (methyl bromide)	**74-83-9**
Carbon tetrachloride (tetrachloromethane)	56-23-5
Chlorobenzene	108-90-7
m-Dichlorobenzene	541-73-1
p-Dichlorobenzene	106-46-7
o-Dichlorobenzene	95-50-l
1,1-Dichloroethane	75-34-3
1,2-Dichloroethane	107-06-2
1,1 -Dichloroethylene	75-35-4
cis- 1,2-Dichloroethylene	156-59-2
Dichloromethane (methylene chloride)	75-09-2
1,2-Dichloropropane	78-87-5
Ethylbenzene	100-41-4
Formaldehyde	50-00-O
Styrene	100-42-5
Tetrachloroethylene	127-18-4
Toluene	108-88-3
1 , 1,1 -Trichloroethane	71-55-6
1,1,2-Trichloroethane	79-00-5
Trichloroethylene	79-01-6
Trichloromethane	67-66-3
m-&p-Xylene	108-38-3 & 106-42-3
o-Xylene	95-47-6
PAHs	
‘Acenaphthene	**83-29-9**
+Anthracene	120-12-7
+Benz[a]anthracene	56-55-3
+Benzo[b]fluoranthene	205-99-2
+Benzo[j]fluoranthene (B[j]F)	205-82-3
+Benzo[k]fluoranthene	207-08-g
+Benzo[e]pyrene (B[e]P)	192-97-2
+Benzo[a]pyrene (B[a]P)	50-32-8
+indeno[1,2,3- c,d]pyrene	193-39-5
+Benzo[g,h,i]perylene	191-24-2
+Chrysene	218-01-g
+Coronene	191-07-l
‘Cyclopenta [c,d] pyrene	27208-3 7-3

Table l(cont). Target analytes and their associated Chemical Abstract Service (CAS) Registry Number.

PAHs (cont.)	
'Dibenzo [a,h] anthracene (DBA)	*53-70-3*
'Fluoranthene	*206-44-o*
'Fluorene	*86-73-7*
'Naphthalene	91-20-3
'Phenanthrene	85-01-8
'Pyrene	129-00-O
'Quinoline (air only)	91-22-5
'Retene	*483-65-8*

*These pesticides will be analyzed only if sufficient additional funds are provided.
'The PAHs will only be analyzed for a subset of households sampled.

areas similar and comparable to the NHEXAS AZ project, This approach will enable us to directly compare Border and State distribution functions.

The evaluated population in both studies will be selected using a population-based probability design for recruitment (see section 1.7.3). A considerable literature base exists about exposures in the work-place. Our emphasis will be placed on residential exposures; information about occupational exposures will be limited to questionnaire responses by respondents. Our overall project goals are to:

A. Obtain "border" data for exposure and risk assessment to compare with "state" data (NHEXAS).

B. Determine total residential exposure along the border from multiple exposure pathways for comparison with the statewide NHEXAS evaluations.

C. Determine the high end (upper 10%) of the residential exposure from a population-based probability distribution for metals (Pb, As, Cd, Ni, Cr, Ba, Mn, Se, V, Cu and Zn) and evaluate variability in the border region when compared with the state of Arizona.

D. Determine the high end (upper 10%) of the residential exposure from a population-based probability distribution for 3 pesticides collected in the NHEXAS study (chlorpyrifos, diazinon, malathion) and 4 organochlorines reported from Brownsville (DDD, DDE, DDT and Chlordane) and currently available in Mexico.

E. Determine the high end (upper 10%) of the residential exposure from a population based probability distribution for VOC exposures (benzene, toluene, TCE and 1,3-butadiene) in the Nogales area and compare it with the NHEXAS distributions.

F. Determine the high end (upper 10%) of the residential exposure from a population based probability distribution for PAHs in the US-Mexico border region using experimental "real time" collection and traditional techniques.

G. Use available methods and technologies to obtain technically valid distributors of the selected pollutants.

1.3.1 Project Objectives related to scope include:

A. The most accurate way to fulfill the broad-based project objectives is to evaluate all people, at all times, throughout the border region. This is not possible in terms of cost and practicality. As a result we must select a representative subset of our target population. Our sampling strategy to meet this goal is outlined in section 1.7.3.

B. Documenting the occurrence, distribution & determinants of total exposures to selected metals, pesticides, VOCs and PAHs (pollutants) in the general population living along the Arizona-Mexico border.

Specific pollutants include:
metals (Pb, As, Cd, Ni, Cr, Ba, Mn, Se, V, Cu and Zn),
pesticides (chlorpyrifos, diazinon, malathion, DDD, DDE, DDT, and chlordane)
VOCs (benzene, toluene, TCE , formaldehyde and 1-3 butadiene).
PAHs (Acenaphthene, Anthracene, Benz[a]anthracene, Benzo[b]fluoranthene, Benzo[j]fluoranthene (B[j]F), Benzo[k]fluoranthene, Benzo[e]pyrene (B[e]P), Benzo[a]pyrene (B[a]P), indeno[1,2,3- c,d]pyrene, Benzo[g,h,i]perylene, Chrysene, Coronene, Cyclopenta [c,d] pyrene, Dibenzo [a,h] anthracene (DBA), Fluoranthene, Fluorene, Naphthalene, Phenanthrene, Pyrene, Quinoline (air only), Retene)

C. Characterizing the 90th percentiles of total exposures to each of the pollutants in the Border Study population and comparing the distribution with those for the State of Arizona.

D. Comparing any geographic and temporal trends of the multi-media exposures found for the border and the rest of Arizona.

E. Evaluating exposures in a proportionate-based population sample for all media, personal characteristics, time-activity, and geographic factors contributing to total exposure in the Arizona border area for comparison with the rest of the state.

F. Evaluating exposures in a proportionate-based sample as reflected in blood and urine samples (biomarkers) by target pollutant concentrations.

G. Exploring the use of intensive/precise techniques in a nested subset of the population with the goal of generalizing results to the entire population.

Results from the intensive monitoring phase of this study will be projected to the larger but less precise data of the earlier stages and then to the general population living along the Arizona border with Mexico. This project employs cost effective methods used in the NHEXAS Project. It is also a feasibility study comparing some low cost screening methods with costlier analytic methods.

H. Determining whether exposure can be predicted by questionnaire-based predictive models, which can be used to validly formulate relationships between "explanatory variables" of exposure measured by questionnaire or measured in media and exposure as evidenced by biomarker samples. We will evaluate relationships between exposure reports, environmental measurements, and biomarkers of target pollutants in the Arizona Border Study and compare the models with those generated for NHEXAS.

1.3.2 The following Work Objectives and implementation steps must be met to complete the project:

All procedures supporting the work objectives are divided into the following project implementation areas: administrative, field, laboratory, data management and data analysis. Figure 1 provides an overview and Figures 2 - 6 report specific protocols and their relationship to the project. Throughout this document the final digit of each SOP will be "x". "X" will always refer to the latest revision of a given SOP. We present this number as "x" in this document to minimize the need for QSIP revision. Appendix A lists all SOPs needed to complete work for this project in their current version.

A. Preparation--Work Objectives

1. Development of a short addendum to the NHEXAS Questionnaire that examines issues related to cross-border commerce and target analytes. Completion and approval of the of the ICR supplement and approval of the revised consent form with the internal human subjects review board (see Appendix B).

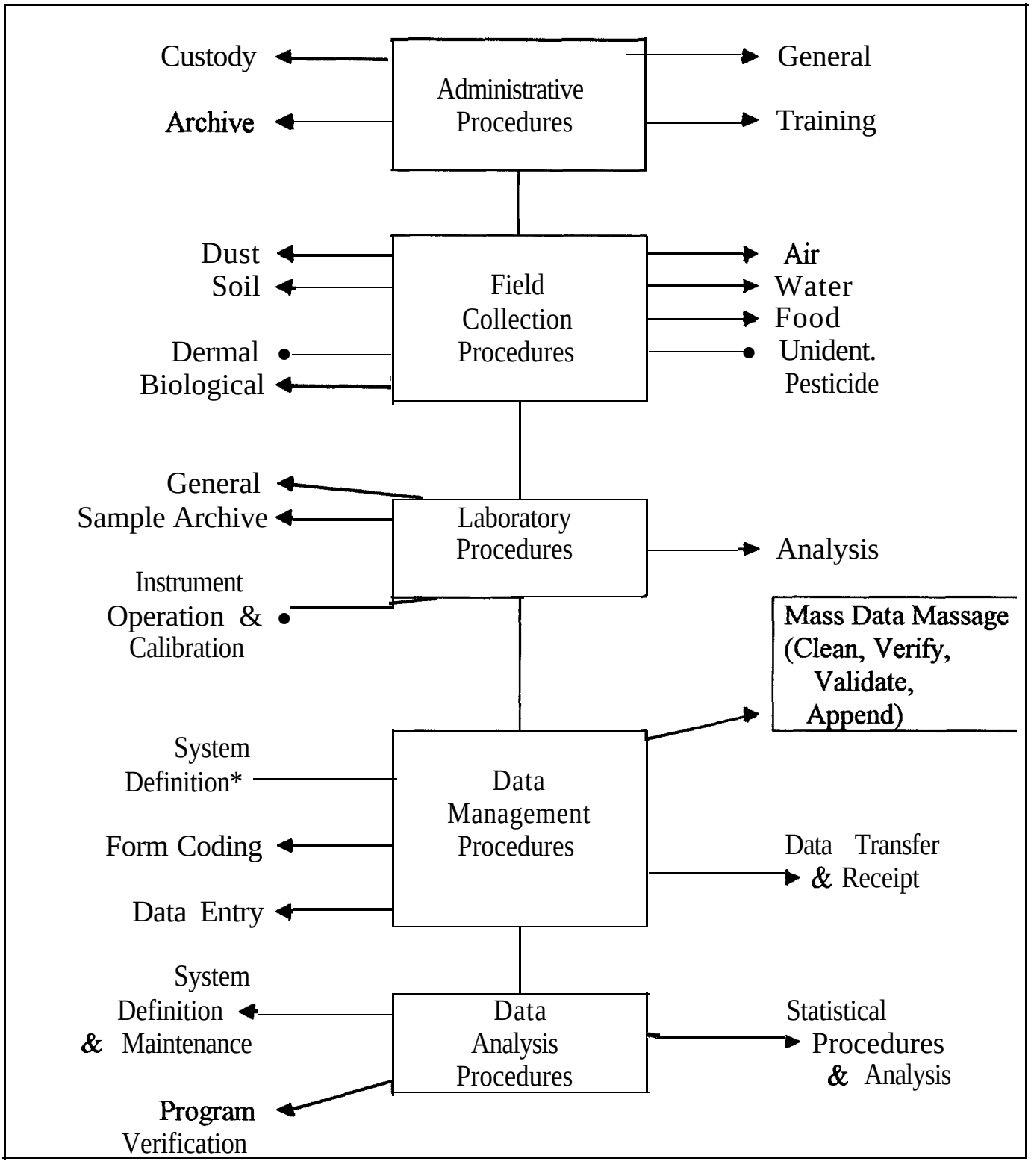
2. Completion of the QSIP and associated Standard Operating Procedures (SOPs; UA-G.X). These documents will define responsibility for all work done in the project and the QA measures required as part of task completion. (The PI and C-PIs of the Arizona Consortium interact with each other and the EPA project officers to develop an appropriate QSIP).

3. The selection of the study population occurs. We will use a three phase sampling approach to identify the housing units to be sampled (see section **1.7.3).** Although the sample design is nested, none of the subsamples (stages) will be stratified by expected pollutant type. Each stage will be a subset of the preceding stage.

4. Assembly of the necessary equipment, sampling and analytical methodologies.

5. Virtually all procedures used in the border study have been used in the NHEXAS project, and traditional sampling of PAHs from air will employ the same procedures already used for air

Figure 1. Major classes of Standard Operating Procedures in support of the Border Study. Each consortium member is responsible for training and certifying its additional support personnel.



Pesticide collection in the field. The laboratory analysis has been used in other studies conducted by Battelle. As a result, only real-time PAH monitoring and mounting a passive sorbent for independent analysis by G. Robertson of EPA are new procedures. These procedures can readily be incorporated into our current household sampling stratagem minimizing the need for extensive trial sampling. None the less, a two house, pre-field evaluation of all equipment and supplies (field, lab & data) will occur. Field forms will be modified as needed.

6. This project was designed to use already trained and available personnel limiting the need for hiring and training new employees. If additional project personnel are required, they will be brought in and trained as needed using the established training protocols (UA-T-6.x & Battelle BCO-T. 1 .x). Training and documentation of the field staff including interviewers and technical support is discussed in SOP UA-T-1 .x through UA-T-4.x. Data assistant and lab training plans are described as UA-T-5.x and UA-T-6.x respectively.

7. Initiate documentation for the Border Study Project Documentation Form Notebooks specified in the SOPs for each area (Packet prep, Field, Lab(s), Data and Analysis). Supplement the Master Project Form Notebook (in the Data Section) that contains a copy of all forms to be used in the project. These will be updated with any new form from field, lab and data sections. Ideally, there should be no form changes within the study. As a fail safe mechanism, a copy of every form (and every version) used in the project should be kept in these notebooks maintained by the Project Field and Data Coordinators, and laboratory Supervisors. (University of Arizona & Battelle, data, field & lab Coordinators cooperation).

8. Complete Dictionaries, Coding and Cleaning SOPs for Submitted Questionnaire Version have already been developed for the NHEXAS Questionnaire and will be completed for the supplemental questionnaire (Appendix B) [UA-D-4.x through UA-D-49.x]; (University of Arizona, Co-PI & Data section, Coding input from EPA through conference calls & personal interaction).

9. A modular, electronic sample/data tracking system was developed for the NHEXAS project. The system is essentially an electronic Chain of Custody record from which summary reports can be compiled and sample handling records can be rapidly traced. The system operates with bar code scanners and "program" written at UA and Battelle (UA-D-28.x). New modules will be created to accommodate new sample types that will be encountered in the Border Study.

10. Pre-assessment--'Evaluation of the PAH monitors and additional Passive Sampler only.

    a. All field procedures have been extensively evaluated during NHEXAS implementation. Only collection of PAH and using the USGS passive sampler are new. For these 2 new procedures we will implement pre-field evaluation of the methodology in terms of equipment use, timing and practicality. Streamline the field process to minimize the impact on project respondents and maximize the amount, quality, precision, accuracy, and integrity of

Figure 2. SOPs included in Administrative Procedures. Each SOP addresses internal QC requirements for that procedure. (Appendix contains descriptive titles' of each SOP.)

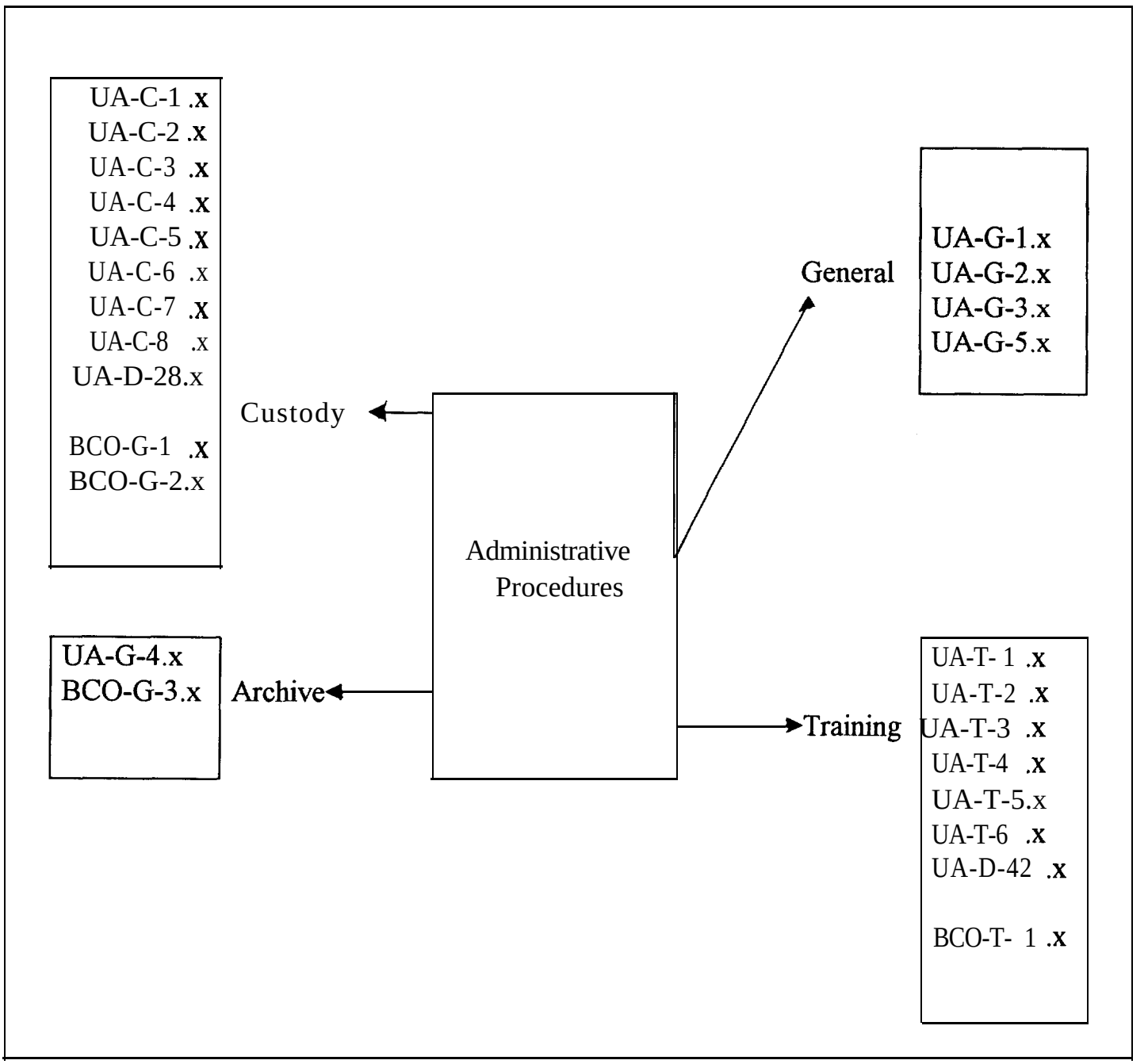
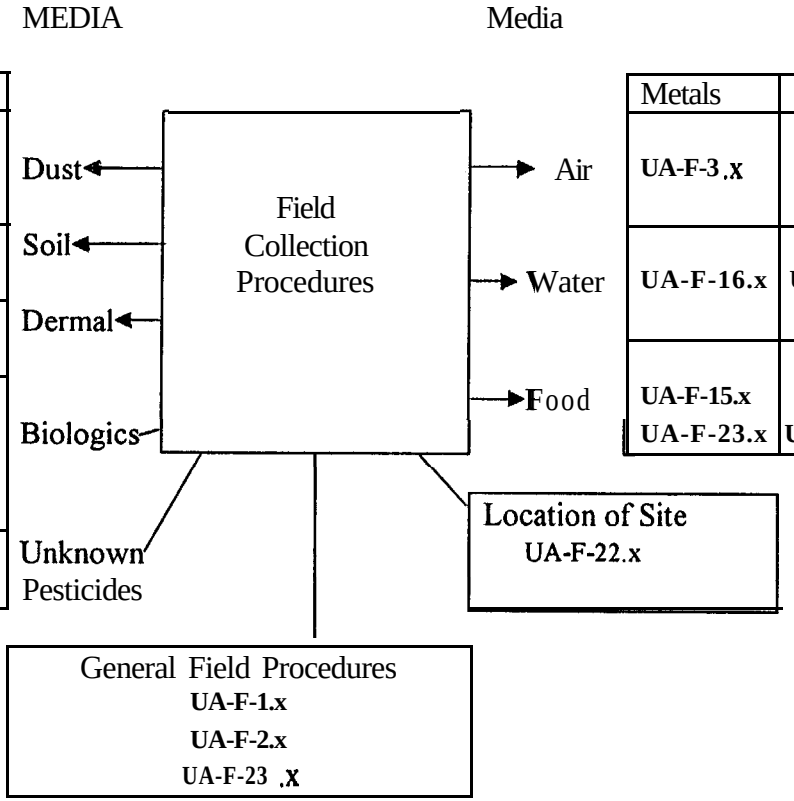


Figure 3. SOPs included in Field Collection Procedures associated with Metals, Pesticides, VOCs and PAHs. Each SOP addresses internal QC requirements for that Procedure. (Appendix A contains descriptive titles of each SOP.)

PAHs	VOCs	Pesticides	Metals
UA-F-7.x UA-F-8.x	N/A	UA-F-7.x UA-F-8.x	UA-F-7.x UA-F-8.x
UA-F-5.x	N/A	UA-F-5.x	UA-F-5.x
N/A	N/A	UA-F-9.x	UA-F-9.x
N/A	UA-F-19.x	UA-F-19.x UA-F-20.x	UA-F-19.x UA-F-20.x UA-F-26.x
N/A	N/A	UA-F-25.x	N/A



Metals	Pesticides	VOCs	PAHs
UA-F-3.x	UA-F-28.x UA-F-27.x	UA-F-11.x UA-F-12.x UA-F-27.x	UA-F-24.x UA-F-28.x UA-F-27.x
UA-F-16.x	UA-F-17.x	UA-F-18.x	N/A
UA-F-15.x UA-F-23.x	UA-F-15.x UA-F-23.x	N/A	N/A

Figure 4. SOPs included in Laboratory Procedures associated with Metals, Pesticides, VOCs and PAHs. Each SOP addresses internal QC requirements for that Procedure. (Appendix A contains descriptive titles of each SOP.)

Analysis of Media

PAHs	VOCs	Pesticides	Metals
BCO-L-26.x BCO-L-27.x BCO-L-30.x	BCO-L-17.x BCO-L-18.x BCO-L-22.x BCO-L-3 1.x	BCO-L-21.x BCO-L-27.x BCO-L-15.x	BCO-L-3.x UA-L-9.x UA-L-10.x
BCO-L-26.x BCO-L-28.x BCO-L-30.x UA-L-12.x	N/A	BCO-L-21.x BCO-L-13;15 BCO-L-28.x UA-L-12.x	BCO-L-3.x UA-L-10.x
BCO-L-26; 28 BCO-L-30.x UA-L-11.x	N/A		UA-L-10.x BCO-L-3.x
N/A	N/A	BCO-L-12;15 BCO-L-2 1.x	BCO-L-3.x
N/A	EPA 524.2	EPA 525.2 EPA 531.1	EPA 200.8
N/A	N/A	UA-L-13.x RTI Protocol	UA-L-13.x RTI Prot.
N/A	CDC Protocol	CDC Protocol	CDC Protocol

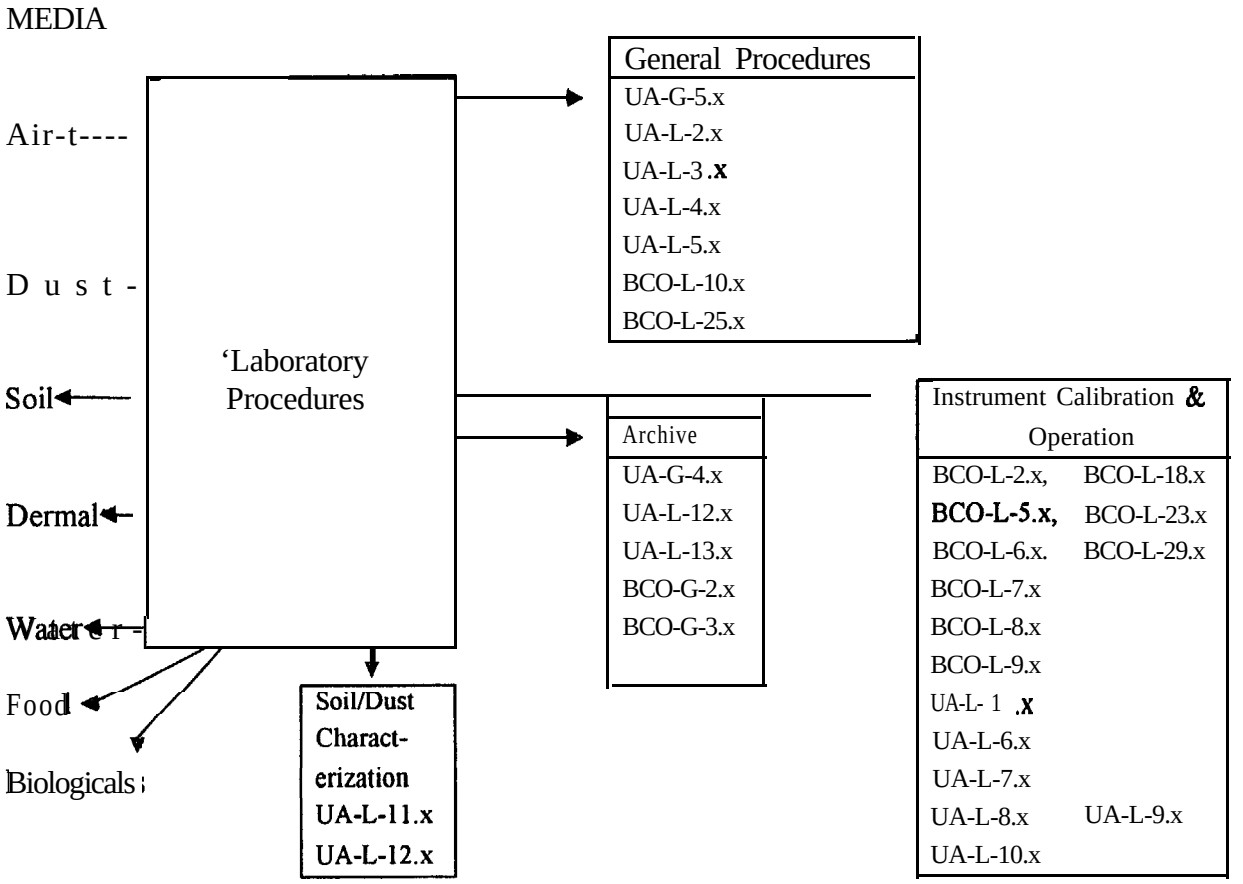


Figure 5. SOPs included in Data Management Procedures. Each SOP addresses internal QC requirements for that procedure. **(Appendix A contains descriptive titles of each SOP.)**

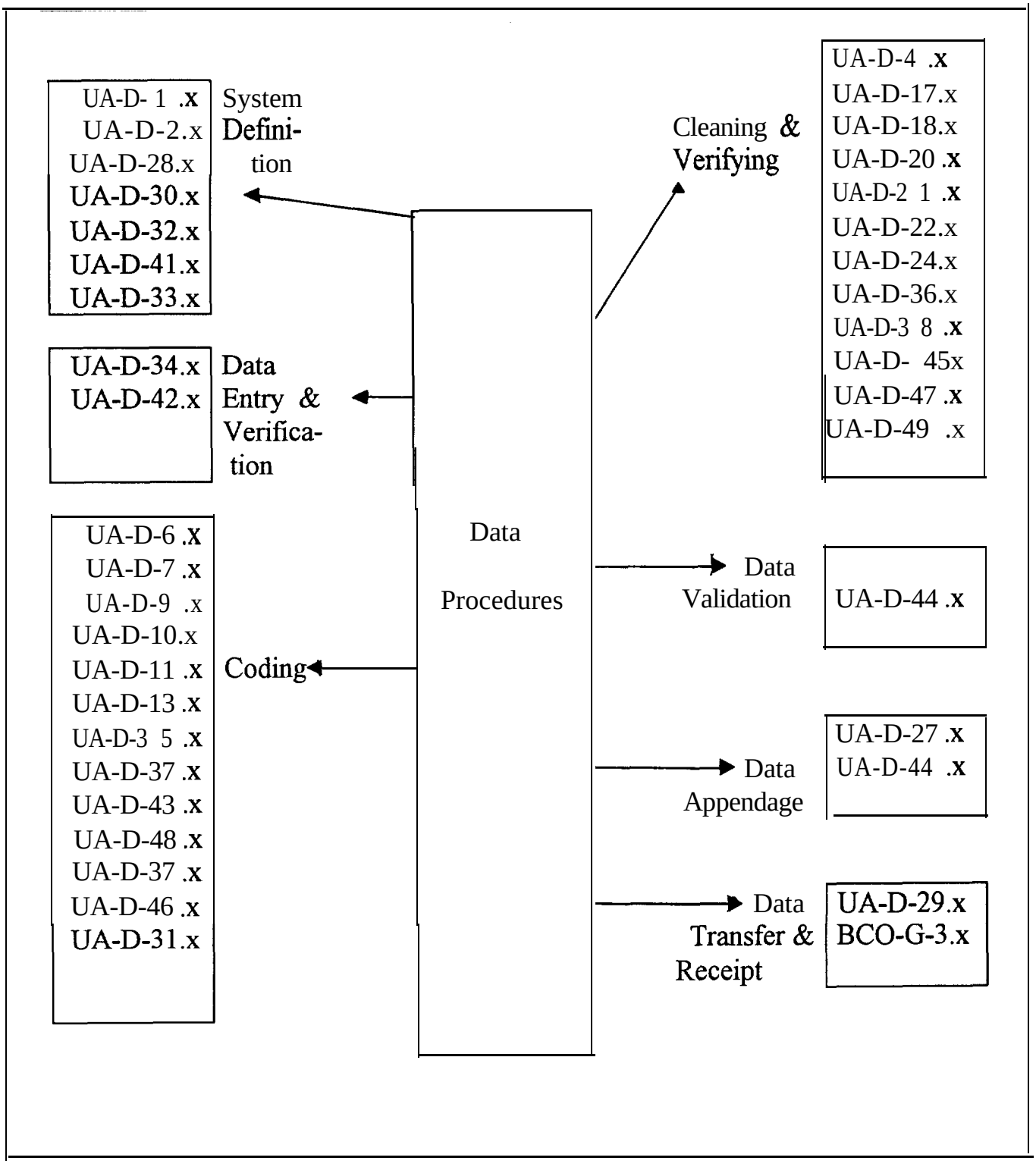
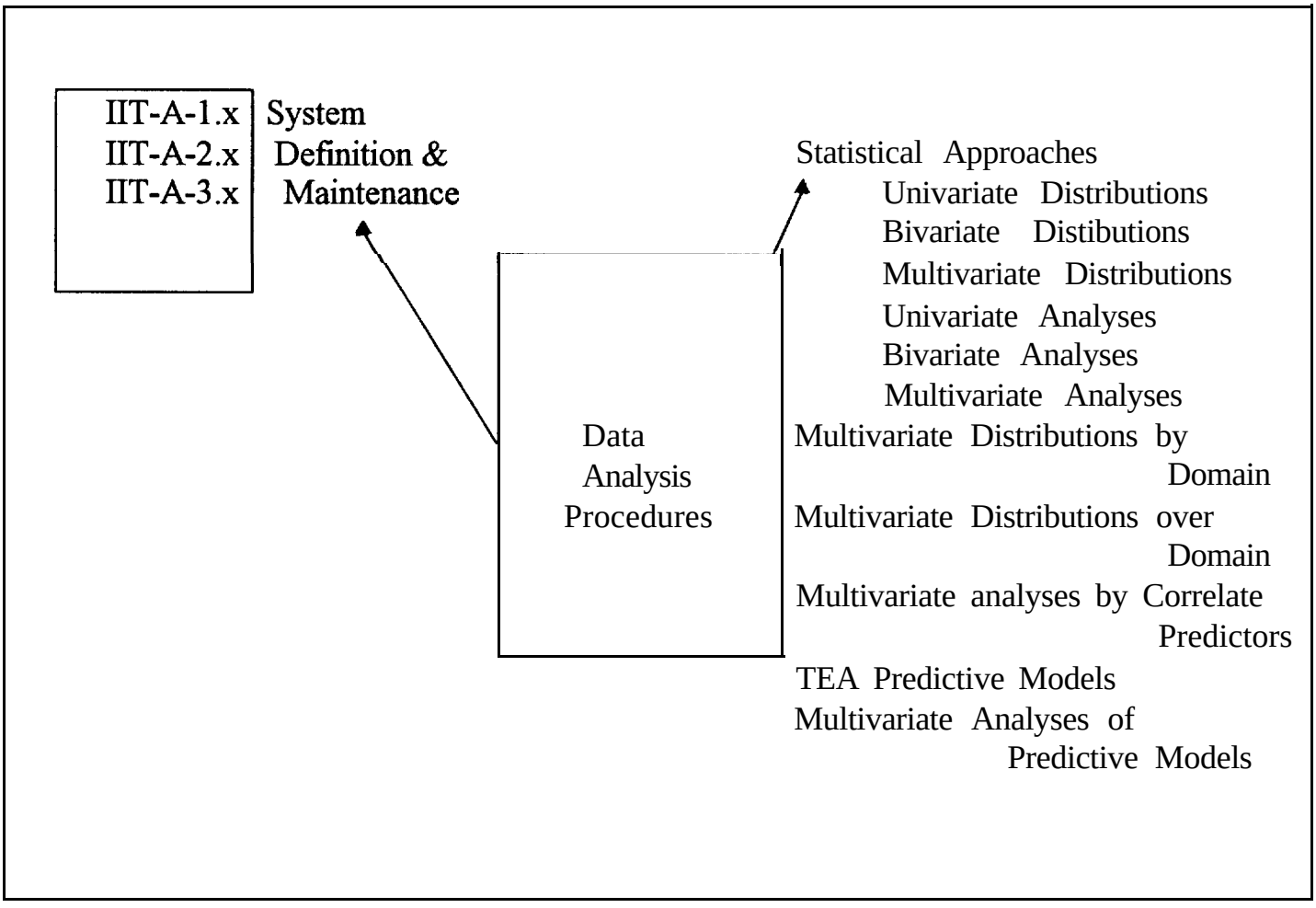


Figure 6. Data Analysis Procedures. Each SOP addresses QC internal requirements for that procedure. (Appendix A contains descriptive titles Of each SOP.)



data and samples gathered in the field. (University of Arizona, Co-PI & Field Coordinator, Interaction and discussion within the Consortium and with EPA consultation).

b. The entire NHEXAS survey and the food NHEXAS comparability project serve as storage and shipping trials of all sample types that will be encountered in the Border Study (see SOPs UA-G-1.x through UA-G-4.x plus handling procedures described in Field and Lab SOPs; University of Arizona Co-PI & Field Coordinator; Interaction within the consortium and with cooperating labs analyzing food, water and tissue).

c. The entire NHEXAS survey serves as an in-house lab trials to evaluate custody transfer, sample storage and pre-coded laboratory forms (UA-C-1 .x through UA-C-8.x; University of Arizona--Field Coordinator and Lab Supervisor & Battelle; Interaction and discussion within the consortium).

d. Revision or further development of the QSIP or any associated SOPs including revised field forms as needed. (PI & Co-PIs University of Arizona, Battelle & IIT; Interaction within the consortium and with cooperating labs analyzing food, water and tissue).

e. Review and finalize field and lab forms and determine those that must be maintained as databases (as opposed to filed field records).(Internal University of Arizona).

11. Define Teleform variable names for any new forms added to the project. Complete Dictionaries, Coding and Cleaning SOPs for any field forms. (UA-D-30.x; University of Arizona, Interaction and discussion within the Consortium and with EPA consultation).

12. Define or revise any in-house laboratory data forms. Complete Coding, Dictionaries and Cleaning SOPs for any in-house lab data (see Figure 5; coding & cleaning).

13. Retrieve and manipulate data collected by other sources that may complement or supplement NHEXAS data and be used in modeling. This includes databases like weather, County and State Department of Environmental Quality regional pollutant databases. Build dictionaries, complete appropriate documentation and build Master Databases. (UA-D-4.x through UA-D-27.x; Data Section, University of Arizona, Interaction and discussion within the Consortium).

14. Revise "Adult" and "Minor Child" written consent forms describing additional protocols suggested by OMB (i.e., collection of human hair for unspecified future metal analysis and collection of unmarked stored pesticides). Enumerate the respondent risks and benefits. Outline precisely respondent burden in terms of time, environmental and biological samples. State in broad terms the analyses to be performed on the samples. If the respondent cannot read, read the consent form to him/her. Be sure the respondents understand what they are

agreeing to do. Describe the specifics of subject confidentiality. Obtain the signature of the adult or the minor child and legal guardian prior to collecting the Baseline Questionnaire. All communications, consents, assents and questionnaires will be available in English and Spanish.

*Note: Completion of the preliminary work should coincide with the completion of the NHEXAS project. This will minimize field delays and therefore, costs.

15. Complete the application for the Internal Review Board (Human Subjects) and attach the questionnaires and the consent forms.

16. After IRB approval, employ the approved English and Spanish versions of the NHEXAS and Border supplement questionnaires. (Field Coordinator, University of Arizona).

B. Implementation of Field Survey--Work Objectives:

1. Field Sampling

a. Recruitment (Arizona, PI Co-PI & Field Coordinator): In the 4 border counties (i.e., Cochise, Santa Cruz, Pima, and Yuma). 300 households will be asked to participate in the Border Study. They will be mailed a letter describing the study and informing them that an interview team will visit their home. The interview team will visit the home and a short Descriptive Questionnaire will be completed at these homes (10% will be readministered using a telephone follow-up). A minimum of 75% response is mandatory (225 homes). Interview techniques and questionnaires completion are covered in UA-T-l .x through UA-T-2.x. Recruitment will be representative of the population groups living in the border counties. The 1990 census statistics are presented in Table 2. Population projections of 1995 will also be evaluated where data is available.

b. Baseline Questionnaire Administration (Arizona, PI Co-PI & Field Coordinator): Of the 300 homes invited to participate, Baseline Questionnaires will be administered to the Primary Respondent in a minimum of 225 homes.

c. Initial Sampling (UA-F-1.x through UA-F-2.x; Arizona, PI Co-PI & Field Coordinator): Households will be selected for sampling to minimize the sample design effect (section 1.7.3). Using this strategy, All 225 homes will be approached for environmental sampling using less intensive sampling procedures and additional questionnaire administration.

d. Intensive & Temporal Sampling (UA-F- 1 .x through UA-F-28.x; Arizona, PI Co-PI & Field Coordinator): 100 homes will be selected to minimize the sample design effect (section 1.7.3) from the 225 homes of Stage 2 and asked to participate in the more intensive standardized environmental sampling (see Table 3). They will be subject to environmental monitoring and asked to complete all questionnaires.

Table 2. Race and ethnicity by county based on the 1990 census data.

	Census Race Response by County					Spanish Descent	
Arizona County	% Caucasian	% African American	% Native American	% Asian or Pacific Islander	% Other	% Hispanic	% Non-Hispanic
Apache	20.3	0.2	77.6	<0.1	1.9	3.9	96.1
Cochise	81.5	5.2	1.2	2.2	10.0	28.4	71.6
Coconino	64.5	1.3	29.3	0.7	4.2	10.1	89.9
Gila	76.6	0.2	13.3	0.3	9.8	18.4	81.6
Graham	77.6	1.6	14.7	0.6	5.3	24.6	75.4
Greenlee	86.4	0.3	1.9	0.6	10.7	42.8	57.2
La Paz	74.7	0.3	17.7	0.6	6.7	24.7	75.3
Maricopa	84.9	3.5	1.8	1.7	8.1	16.0	84.0
Mohave	95.3	0.1	2.3	0.7	1.6	5.0	95.0
Navajo	44.0	1.0	52.2	0.3	2.5	7.1	92.9
Pima	78.9	3.1	3.0	1.8	13.1	12.4	87.6
Pinal	74.9	3.1	9.6	0.6	11.8	29.4	70.6
Santa Cruz	74.9	0.2	0.2	0.4	24.3	77.1	22.9
Yavapai	95.8	0.2	1.6	0.5	1.9	6.4	93.6
Yuma	75.7	2.8	1.5	1.3	18.8	41.8	58.2

2. Analysis of Samples--Lab Processing (UA) and Sample Shipment to Battelle & Other Labs (Arizona), These procedures run concurrently with Field sampling (Section 1.3.2, B 1)--Work Objectives.

   a. Sample Custody & Integrity (UA-C-1 .x through UA-C-8.x; Arizona, Battelle and other Labs): All samples are accompanied by custody sheets and signed by the relinquisher and the recipient at each stage after collection. Custody of samples collected in the field transfers to the Project Field Coordinator. He (or his designee) is responsible for transfer of the samples and custody forms to the appropriate labs and for sample integrity evaluation and maintenance prior to shipment or transfer.

   b. Sample Analysis (Arizona): Samples to be analyzed weighed and/or aliquoted in Arizona (soil and dust) are transferred to the Lab Supervisor who assigns analysis and QC checks the analysis and completed data forms (UA-L-9.x through UA-L-10.x). Sample residue is appropriately stored or shipped to Battelle (BCO-L-1 .x through BCO-L-3 1 .x) by the laboratory supervisor for further analysis. The lab Supervisor provides the data coordinator with a copy of the custody form indicating sample shipment or transfer to storage.

c. Sample Analysis (elsewhere, e.g. Battelle (BCO-L-1.x through BCO-L-3 1 .x) or the Federal Labs): Interim sample storage will conform with requirements specified in the various SOPs. Samples will be batched and shipped in a timely fashion according to specifications in the SOPs by the Project field Coordinator at Arizona. Samples to be shipped to Battelle will include: soils, dust, air filters ($PM_{2.5\&10}$, PUF, Carbo traps, OVM badges, PAHs).

d. Lab Data Processing (UA-D-24.x; Arizona): Laboratory data are copied by the Lab Supervisor and copies are placed in the lab notebook. Most data is downloaded directly from instruments in data batches. These data are transferred to master data bases by the Project Data Manager. In the case of paper forms, original, scannable, data sheets are assembled by type and transferred to the Project Data Coordinator at weekly to monthly intervals.

e. Lab Data Processing (UA-D-27.x; UA-D-29.x; BCO-G-3 .x; from elsewhere): Laboratory results will be sent to the Project Data Manager at the University of Arizona from other labs. Data can be sent in two forms. (1) Copies of the laboratory data sheets are given to the Project Data Coordinator, assembled into packets and batches and processed as the Arizona Lab data. (2) Electronic data and data format definition are provided to the Project Data Manager for creation of appropriate master data bases. Outside labs will transfer data to Arizona in a mutually agreeable format.

3. Reduction and Preparation of Data--Questionnaires, Laboratory Data and Field forms [These procedures run concurrently with work described above (Section 1.3.2, B 1 & B 2)]--Work Objectives.

a. QC & QA checks of forms: Questionnaires, Laboratory Data and Field forms will be QC checked in the field by field staff for accuracy and completion. A copy of the field form is retained in the field office. All Questionnaires and Field forms will be QA checked by the Project Field Coordinator within 1 week of return to the Field Office. These checks will ensure Field QC was adhered to and the forms are complete. Laboratory Data will be QA checked by the Project Laboratory Supervisor at the end of each day of laboratory analysis for adherence to all QC/QA procedures specified in the individual SOPs (see all Field and Laboratory SOPs, Arizona & Battelle).

b. Data Packet Assembly: Field Forms and Questionnaires will be collected into household packets and passed to the Project Data Coordinator at the end of each month minimally (UA-C-3 .x, Arizona).

c. Data Processing: The Project Data Coordinator will batch data Field and Arizona lab data (UA-C-4.x through UA-C-8.x) assign data coding, entry/scanning, verification and validation tasks. Processed data batches are assembled into master databases by the Project Data Manager (UA-D-44.x; Arizona).

At Battelle the project Lab supervisor will assign the task of data coding, entry, verification, validation and creation of a master data base of laboratory measurements. Battelle (and National Labs) will calculate concentrations of pollutants and transfer the completed data set, plus formatting and all key variables to Principal Investigator at the University of Arizona. These data will be handled as a supplemental data base by the Project Data Manager (D).

d. Data Processing of Supplemental Data Bases: Public record data will be sought for various analysis. This will mean re-formatting databases created by others to make them compatible with our NHEXAS and Border databases. Databases currently identified include: weather data (NOAA), data bases from Air Quality Districts in the State of Arizona, data from FDA reporting contaminants in commonly consumed food using a mini-market basket approach and complete analysis databases provided by cooperating laboratories. These data may be used in modeling (UA-D-4.x through UA-D-49.x as specified in Figure 5; Arizona--Project Data Manager).

e. Final Data Base QA Check: Logged, batched data and appropriate custody forms are filed in the project data offices. Each processed data batch is examined for errors. Ten percent of the forms are randomly selected for final 10% data checks. The batch is deemed to be accurate if no more than 5% of the data is erroneous. If systematic errors are found they can be documented and corrected. More than 5% error rate requires examination of 50% of the data batch. If the 50% check has more than a 5% error rate, the entire batch is re-processed as per step c (above) (UA-D-44.x; Arizona-- Project Data Coordinator).

f. Data Delivery: The project Data Manager will deliver data bases to EPA (and others) in the specified format as instructed by the Principal Investigator.

4. Analysis of Prepared Data--Questionnaires, Laboratory Data and Field forms [These procedures run concurrently with work described above (Section 1.3.2, B1; B2 & B3)]--Work Objectives.

a. Sample Population Representativeness (Arizona): Several forms of analysis will be run throughout the project to ensure proportional representation of all groups evaluated. Recruited population within census blocks and tracts will be compared with the census data. Available demographics of nonparticipants will be compared with census data to determine any bias in sampling. Participation in each of the environmental sampling stages will be evaluated relative to census statistics (Table 2) to evaluate potential bias due to non response.

b. Appropriateness of Methods (including internal Questionnaire Evaluation) (Arizona & IIT): Intensive and less intensive methods will be used in different study stages. Exposure distributions generated using these different techniques will be compared and the increment of "improvement" in the exposure assessment will be evaluated.

c. Exposure Assessment (Arizona and IIT): "Body burden" measures of target pollutants,

as measured by the biomarkers, integrate cumulative exposures over long periods of time. We will compare the biomarker values with the models derived for individual multimedia exposure using different levels of data collection intensity (including the inter and intra-individual variability). There will be many iterations of this process. One will consider the entire population. Others will examine possible "explanatory" relationships. These models will be particularly important in examining the high end of the distribution. These analyses will integrate all the data collected.

d. A project implementation overview is presented in Figure 7.

1.4 Project Description

This effort is a special study to assess exposures on the Arizona side along the US-Mexico Border. This "Border Study" was fimded by the United States Environmental Protection Agency.

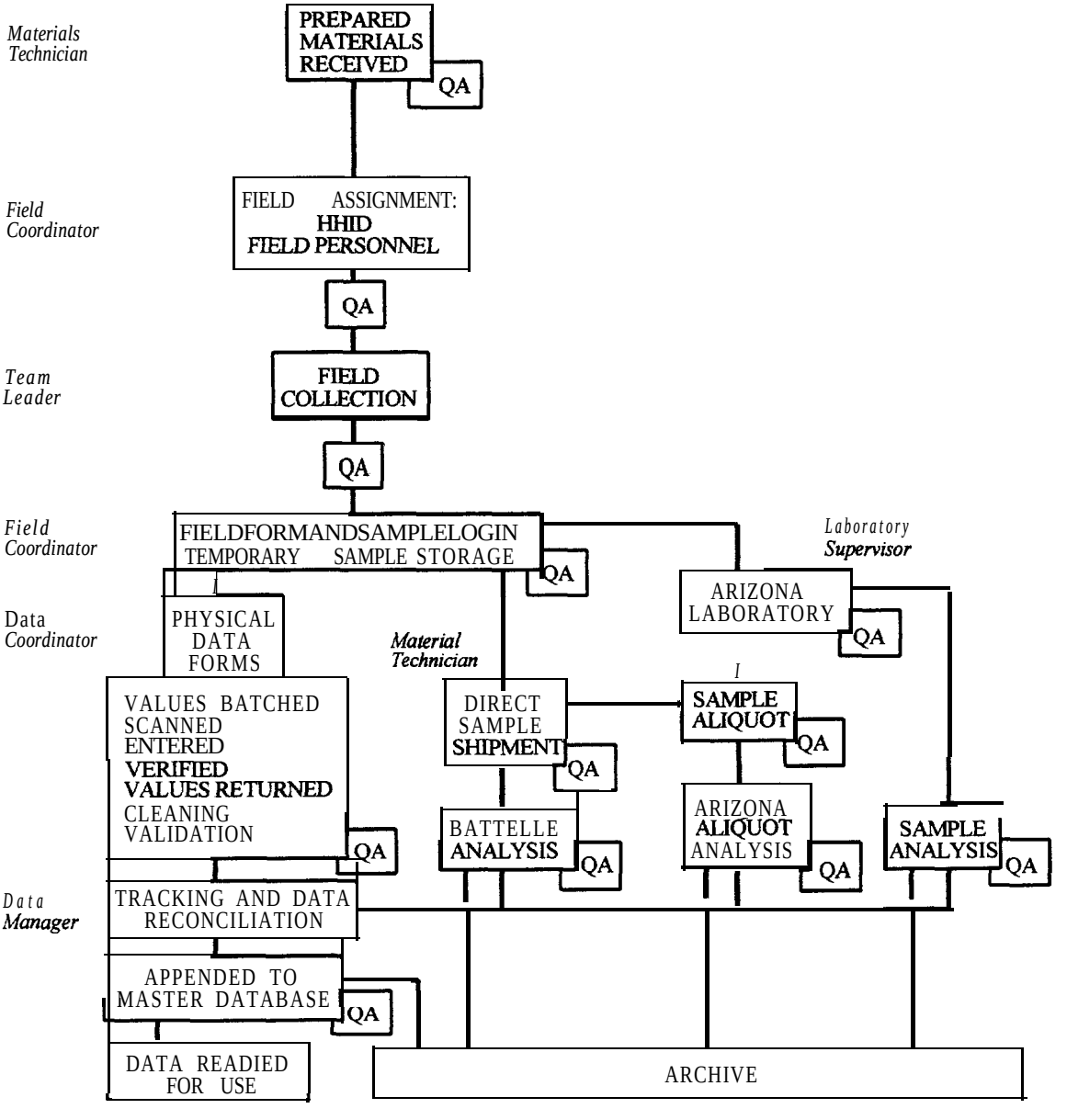
The Border study will assess exposure to selected metals, pesticides, VOCs and PAHs. Exposure information will be gathered directly from subjects, from environments frequented by subjects (primarily subject home environments) and from public records. Questionnaires will be employed to characterize the study population, evaluate common practices believed to contribute to exposures, and evaluate potential bias in the study due to non participation. Blood and urine samples will be collected directly from the subjects and concentrations of target pollutants will be measured. Additional concentrations of target pollutants will be measured from the air, dust, soil and water of the home environments of subjects. Duplicate food diets (regardless of food source) will also be collected. (If funding is available beverage will also be collected, if not then beverage data will be modeled from pre-existing NHEXAS data.) Public records containing usable information on target pollutants (soil, air, and water could be employed. Exposure assessment models will be generated using direct and surrogate measures varying in the intensity of detail.

The Border Study is broken into a series of field stages reflecting the work objectives. The staged approach enables us to maximize the number of samples analyzed while minimizing cost. Thus, for certain key media, like house dust or soil, we will gain more statistical power. This is important when exploring effects like temporal variability of contaminants in a small geographic area. For further cost effectiveness and efficiency of sampling, all 3 stages will be operational at the same time in the field. Forms (or questionnaire covers) and sample buckets will be coded to help keep protocols straight within each household. Concurrent stage sampling is planned.

STUDY PHASE 0 (pre-study population recruitment): Identification of sample design components to sample proportionately, subject geographic locations, and demographic characteristics.

STUDY PHASE l/FIELD Stage 1: 300 households will be selected as described in section 1.7.3 Any adult household resident will be interviewed to complete the Descriptive Questionnaire. The primary

Figure 7. An overview of NHEXAS Arizona Implementation.



complete the Baseline Questionnaire. This is a survey of the permanent population of Arizona; part time residents will be excluded. A 90% response rate for the first Q would yield 270; the requirement of a 75% (or better) response rate for the second level, the Baseline Q, would yield a total of 225 plus houses. (125+ homes will be evaluated using Stage 2 methods and 100 of these homes will be evaluated using Stage 3 methods.)

STUDY PHASE 2 (INITIAL SAMPLING)/FIELD Stage 2: For this stage, the target population is the 125 (plus) households who completed Descriptive Questionnaires, and they are asked if they would like to participate further. Incentives offered include free information about themselves and their micro-environment, in relationship to the study as a whole. Work-ups include procedures documented in Table 3.

- Questionnaires (Q): These Stage 2 questionnaires are self-completed or completion-assisted as requested by the subject. They include the Baseline Questionnaire; The Time-activity Log (for 1 day recall and reports of an idealized weekday and weekend day as a separate record); the Diet Diary (l-day recall), and the Technician Questionnaire. All questionnaires are available in English or Spanish at the choice of the respondent(s).

- Environmental Sampling (inside & outside of residences): Metals in dust, and soil. The sampling is described in greater detail in Section 3.

- Other residents of selected households will be asked if they wish to continue being part of the study, and they could complete the Questionnaires used in this Stage. As other members of the household have different exposures, related mostly to different time-activities, secondary/tertiary individuals will be identified among those in the household with different time-activity patterns to be asked to also complete all the Q's, the Time-activity Log, and the Diet Diary as specified above. Participation of multiple household members may optimize participation of the primaries of the households (as shown in our other studies and by other investigators), and will maximize the number of individuals on whom information is obtained without major cost increases. (Nevertheless, secondary and tertiary participants will be identified as such and analyzed distinctly.)

STUDY PHASE 3/FIELD Stage 3 - INTENSIVE SAMPLING: A randomly selected subset of households (n = 100) will be evaluated for metals, pesticides, VOCs and PAHs using methods (Table 4) with greater resolution and reliability. As appropriate, the less intensive measurements used in stage 2 will be employed as an internal side by side calibration approach. All follow-up NHEXAS/Border questionnaires will be completed by at least the target respondent in the household; secondary/tertiary household respondents will be asked to complete the questionnaires. Questionnaires are available in English and Spanish at the choice of the respondent(s).

Media sampled will include air, dust, soil, water, food (and beverages?), skin (dermal), blood, and urine.

Table 3. Sampling and Analysis Methods to be employed in Stage 2 (n=125). These sampling methods will be employed side by side in Stage 3 (n = number of households).

Media	Site/Type	n	Analyte	Collection	Analysis Method
Dust	Indoors-Carpet	125	Metals	Vacuum Cleaner & Filter	XRF
Soil	Outdoors-Yard Composite	125	Metals	Mixed aliquots collected by trowel to a depth of 2.5 cm	XRF
Questionnaires	Descriptive	125			
	Baseline	125+			
	Time/Activity	125+		1 -day recall (Plus typical week day & typical weekend day; l-day each on a separate; qx in a separate data file	
	Diet	125+		1 -day recall	
	Border				
	Supplement				

Table 4. Sample Collection methods of Stage 3.

Media	Contaminant Class	μ Environment or Type	Collection Method	Sample Description
Air	Metals & $PM_{2.5\&10}$	In & Out	Active - Teflon filter	7-day integrated
	Pesticides	In only	Active - Sorbent & 2xAD	2-day integrated
	v o c	In only	*Active- Carbotrap Passive- OVM3 500	1 -day integrated 7-day integrated
	PAH	In & Out	Active - Sorbent & 2xAD	2-day integrated
			Active- Real Time	l-hour integrated
	Pest, PAHs & VOCs		USGS-Sampler	3 O-days integrated
Dust	Metals, Pesticides & PAHs	Indoors	Vacuum & Filter Surface wipe	Defined Area
Dermal	Metals, Pesticides	Hands to wrist	Wipe	Area
Soil	Metals, PAHs	Outdoor Soil Composite	Cornposited Aliquot	Defined Area
Water#	Metals, Pesticides & VOCs	Kitchen tap & Drinking Water	Cubitainer, glass vials	post-flush as stored
Biological#	Metals, OC Pesticide VOCs	Blood	Vacutainer	Venous Blood
	Metals. Pesticides	Urine	Specimen cup	morning catch
	Metals	Hair	Scissors	nape of neck
Food#	Metals, Pesticides	Duplicate Diet	Ziploc bags & plastic containers	Composite (l-day)
Beverage#@	Metals, Pesticides	Duplicate Bev. Excludes water	Gallon containers	Composite (l-day)
Questionnaires	All Analytes	Home & Work		
Descriptive			Administered	General
Baseline			Administered	General
Supplement			Administered	General
Time/Act.			Self-completed	1 -week
Diet Diary			Self-completed	4-days
Food Follow			Self-completed	1 -day
Follow-up			Self-completed	1 -week
Technician			Technician	General

*Subset of 25 homes
#Analyzed through IAG or EPA Contract with outside Lab
@ if sufficient funds are available

- Air monitoring for $PM_{2.5 \& 10}$, and metals will be done for residential indoor and outdoor air, a subset will be done for VOCs. Pesticides will be collected in indoor air only. PAHs will be done inside and outside each home.

- Dust will be obtained from carpets/rugs and window sills for metals, pesticides and PAHs. Metals and pesticides will also be evaluated from dermal samples.

- Soil will be obtained from the residential yard (as a composite) for metals & PAHs.

- Water monitoring will be of both tap (all homes) and separate source drinking water (estimated as 50% of homes) for metals, pesticides & VOCs (specific on sample collection methods are outlined in SOP numbers UA-F-16.x - UA-F-17.x).

- Food will be collected as a one-day duplicate diet (excluding beverage ?). Food will be collected in Ziplock Bags. Specifics of food collection and storage are outlined in SOP # UA-F-15.x. Specifics for collection and storage are outlined as UA-F-15.x. FDA has conducted a mini-market basket analysis in the US/Mexico border that included Arizona.

- Biological samples (blood and urine) will be obtained for metals VOCs and pesticides in the primary and a subset of secondary respondents. Urine will be collected as the first morning void not a 24-hour sample. Hair samples will be collected and archived to evaluate metals in the future.

STUDY PHASE 4 - Data analysis, including exposure assessment: All analyses will be hypothesis specific. General classes of analyses and the statistical approaches that will be taken are listed in Table 5. All analyses (except prediction models) are standard statistical techniques found in textbooks and computer software package manuals.

In general alpha will equal 0.05, except when corrected to accommodate multiple comparisons. (However, since initial univariate evaluations are not part of the hypothesis testing, they do not require correction for multiple comparison.) The power (l-beta; type 2 error) will be deemed satisfactory between 0.8 and 0.9 for the hypothesis testing. Power calculations are generally made prior to designing a study to determine the number of measurements needed. Our initial power calculations were based on needed sample sizes for detecting exposures above the 90th percentile, starting at the last stage then expanding to each earlier stage. Calculations were based on the delineation of population subgroups [within the design chosen] with a power of 0.80 and a type-1 error (p-value) of 0.05 for the detection of specific groups and those at the 90th percentile of exposure - $p1=0.50$ & $p2=0.10$ for the final stage [Fleiss, 1981]). Such calculations are valuable when the distribution of the target pollutant is known. When unknown, assumptions are made about the variance and covariance of the distribution and the resulting power determination may or may not be valid. So, if the null hypothesis is not rejected, a power calculation will be repeated to test the validity of the sample size.

Specific Statistical Approaches

The analyses are dictated by the design features related to exposure-response determinations. All analyses, after data QA/QC (QA) specifics are provided in section 4 and SOPs UA-D-15.0, UA-D-16.0, UA-D-25.0, UA-D-26.0), are reviewed to evaluate the distributions of the variables (and presence of possible outliers). Depending on the demands of the analysis, the purpose being descriptive or to test specific hypotheses and the method/model chosen to perform the tests, we determine if removal of outliers and/or transformations of variables are necessary. These analyses will be performed at the University of Arizona on the Local Area Network (LAN) consisting of

Table 5. Classes of Hypotheses and Statistical Approach taken.

Types of Hypotheses	Statistical Analyses	Chemical	Media
Char./Compar Popultns	Univar.& Bivar. Analyses	None	None
1 st Distributions	Univariate Distributions	Each Every Domain	Each
Domain Distributions	Bivariate Distributions	Each Every Domain	Each
Correlates	" "	Each Every Domain	Each
Chem.-for all media	Bivar./Multivar. Distributions	Each	All
Chem. Sub-Classes	Multivar. Analyses	Each	All
Methods Eval./Compar.	Bivar./Multivar. Analyses	Each	All
Compare Domains	Multivar. Distrib. by Domain	Each	All
Total Exposures(TEA)	Multivar. Distrib. over Domains	Each	All
Corr./Predn of TEA	Multivar. Analyses by Corr/Preds.	Each	All
Predictive Models	TEA Predictive Models	Each	All
Corr./Pred.-pred.TEA'	Multivar. Analyses of Pred.Models	Each	All

several PCs linked to two UNIX based SUN-System work stations (with a combined disk of 5.5 gig). This LAN and associated programming are described in UA-D-1.x. Exposure assessment will be performed on the computer system at Illinois Institute of Technology; its system is described in SOP # IIT-A-1.x.

Univariate analyses: Use of these methods assumes that measurements are above the detection limits for each pollutant. First, frequency distributions will be determined and histograms plotted (with descriptive distribution statistics). Continuous distributions will be examined; if they are non-Gaussian with skew around the mean (third moment); then we will use transform functions (e.g., logarithmic) to normalize the data.

If the data can not be normalized, then we will use a variety of non-parametric statistics including rank correlation, nonparametric linear models for regression and ANOVA (1 & 2 factor). If the variables to be evaluated are categorical, we will use binomial or multinomial approaches (e.g. contingency tables, X^2).

Bivariate analyses include bivariate frequency distributions and histograms for sub-classes of key variables, scatter diagrams, contingency (e.g., chi-square) tables, and analysis of variance, with appropriate simple statistics (as above, also t & F tests, chi-square tests, correlation coefficients and regression slopes with intercepts). Common indices of variable expression, known (or expected) bivariate distributions, cell sizes, and other, similar factors, influence our choice of approaches. Our choices are influenced by the nature of the alternate hypotheses, whether we are testing primary or secondary hypotheses, or performing exploratory (hypothesis-generating) analyses.

The next step is to examine the relationships between intervening/ confounder variables and the dependent variables (e.g., relations with chronic occupational exposure reports, daily exposure events, SES factors), and to evaluate the relationships between confounder and intervening variables with independent indoor and outdoor pollution variables (e.g. relations with time-activities, meteorological conditions, etc.), using similar univariate and bivariate approaches.

The univariate and bivariate relationships of dependent and independent variables are analyzed during this phase, without and then with appropriate co-, intervening, and confounding variables. Often within these stages of analyses we will evaluate such concerns as homogeneity of sub-group variances (or homoscedasticity in regressions), linearity, and trends. Results therefrom determine the approaches to the next phases of analysis. [Such analyses precede all multivariate approaches, and dictate what approaches and what variables are to be considered for each specific aim addressed.]

As for the multivariate analyses, our first choice is linear (or nonlinear) parametric regression. For interactions we will employ ANOVA and ANCOVA as tools. Discriminant analysis will include principal components analysis, and possibly analysis of variance (with tabulated coefficients and adjusted variables, and significance results). For certain outcome variables, we will use multiple logistic regression and regressive logistics; the latter has been used recently and very effectively in analyzing time-dependent relationships. (Odds ratios from multiple logistics are useful.)

Prediction models for total exposure can take various forms. Estimates of the average exposure experienced in each location can be derived from the time budget information and the integrated samplers in that location. An average partial exposure component for the i-th location can be calculated, $E_i = [t_i \times c_i] / T$, where T is the total elapsed time. The distribution of this average partial exposure component as a proportion (P) of the measured total integrated personal exposure (E), $P_i = E_i / E$ can be used to summarize (mean or median percentage) the relative importance of each component (location) to total personal exposure in this population. Since this average partial exposure does not use the actual concentration average specific to the time(s) an individual was present for locations sampled with integrated samplers, these proportions may over- or under-estimate the individual's actual exposure component.

Differences between the integrated average concentration in a location and the actual concentration to which an individual is exposed may be due to the uneven spatial distribution of the pollutant within the compartment, building/room or geographic area and topography (for outdoor samples). Further, responses to questions on the Time/Activity diary and the Follow-up questionnaire provide information facilitating evaluation of sources of variation and the times of source use recorded by the participants, so that the temporal relationship between the presence of the sampled individual and source being used can be assessed.

Time Weighted Average (TWA) estimates of personal exposure will be calculated based on the time and location information derived from the daily diary. This contains a discrete sequence of time periods (j) that are spent in the limited number (7) of location categories; each period having a unique duration, t_j. For each of these time periods a concentration, c_j, can be estimated from the passive sampler or from continuous data (if available) for that location and time period. The TWA is calculated as:

$$TWA = \Sigma\, p_j * c_j, \text{ where } p_j = t_j / T \text{ and } T = \Sigma\, t_j \text{ for } j = 1,\ldots, \text{number of time periods.}$$

Information from questionnaires and diaries influencing exposures will be included as covariates in relating concentrations to exposures. The calculated TWA will be compared with the integrated personal exposure measurement using an analysis of covariance (ANCOVA) procedure to assess the agreement between the estimated and measured exposure, and to estimate the average pollutant concentrations in non-measured locations and their importance from the value and relative significance of the regression coefficients (Quackenboss, 1982; Tosteson, 198 1; Spengler, 1985; Quackenboss, 1987).

Assessment of exposure from multiple media can be evaluated by adapting a general Personal Exposure Assessment model which states that:

$$\text{Avg. daily exposure} = \left\lceil \frac{C_i}{C_k} \right\rfloor \times \left\lceil \frac{IU_i}{BW} \right\rfloor \times EF \times \frac{ED}{AT} \times C_k$$

where C_i is the contaminant concentration in the exposure media i, C_k is the concentration in environmental media k; IU_i is the intake/uptake factor (per body size [SW]) for exposure media i; EF is the exposure frequency (day/year) for this population, ED is the exposure duration(years), and AT is the

averaging time for population exposure (days). These models help define the process linking sources to routes of exposure. Human activity patterns associated with exposure are critical to these single and multiple media models.

The specific exposure assessment modeling approach will be decided through collaboration with EPA. In addition, we would like to explore exposure assessment modeling using: (a) mass balance models, (b) other non-mass balance models previously attempted in exposure assessment, (c) beta and gamma distributions with multinomials approximating the alpha level, and compound pdfs involving different Pearson-type characteristics. These attempts will be time and resource dependent.

1.5 Personnel Qualifications

The Principal Investigator and Co-Principal Investigators (Co-PI) all have doctoral degrees and additional experience in their field(s). Each Co-PI will be responsible for determining the education and experience level required for employees performing tasks overseen by the consortium member. Each Co-PI will be responsible for determining and documenting the qualifications of local project employees. Overall 30 to 35 people will work on the project. This includes PI's; staff coordinators; field personnel; lab personnel; data personnel; and analysis personnel. Specific of training and job responsibilities are outlined in Sections 1.6 and 3.3.

1.6 Training Required

Training requirements will be task dependent and determined by each Co-PI. Training requirements will be appropriately defined by the job description and job responsibilities. Qualification and supplemental training records will be maintained by each Co-PI for those serving on the project in accordance with the Training SOPs (UA-T-1 .x through UA-T-6.x).

As part of the quality assurance program, the project has an independent Quality Assurance Officer who will, in conjunction with Co-PIs and appropriate Project Coordinator(s)/Supervisor(s), define the need for formal project-specific training and indoctrination programs and will supervise their conduct.

Training and indoctrination programs will involve familiarization of key personnel with:

* Technical objectives of the project
* Project communication chain
* Project control documents
* Project QA requirements
* Project QA responsibilities
* Project documentation requirements

Coordinator/Supervisor Training: Each of these individuals will have appropriate degree qualifications and a minimum of two years experience in his/her area of expertise. Additional training will be provided

by self study, individual instruction as needed, and monthly area specific and joint staff meetings (one each per month).

Field Interviewer(s)/Technician(s): Each person will have a degree in an area related to his/her task assignments. Additional training will be provided by self study, individual instruction, and monthly area specific and joint staff meetings (one each per month). Supplemental training specific to this project will be provided by the Field Coordinator as outlined in UA-T-l .x through UA-T-4.x.

Data Assistants: Each person will have course work in a data intensive field leading to a degree. Additional training will be provided by self study, individual instruction, and monthly area specific and joint staff meetings (one each per month). Supplemental training specific to this project will be provided by the Data Coordinator as outlined in UA-T-5.x.

Laboratory Assistants: Each person will have course work in a laboratory based discipline leading to a degree. Additional training will be provided by self study, individual instruction, and monthly area specific and joint staff meetings (one each per month). Supplemental training specific to this project will be provided by the Laboratory Supervisor as outlined in UA-T-6.x.

The QA Officer will inspect documented evidence (see UA-T-1.x through UA-T-6.x) of all project-specific training and indoctrination activities maintained by the Co-PIs and the various Project Coordinator(s)/ Supervisors.

1.7 Experimental Design

1.7.1 Fundamental Objectives and Specific Hypotheses to be tested:

A. The primary objective is to compare the distribution of human environmental exposure for the Arizona border region with that of the State of Arizona. Thus, the primary focus of this investigation is the comparison of exposures to border residents with those of other state residents (as determined by the NHEXAS Arizona field study). Specific aims supporting this objective include the comparison of concentration distributions for each analyte/media measured. The primary objective will be scientifically achieved by testing the hypothesis, namely:

   Primary Hypothesis: The distribution of exposure for the population residing in the border region does/does not differ from that for the State.

B. As a secondary objective, we will investigate differences in the way (sources and pathways) the border population is exposed (to environmental contaminants) relative to the State's non-border population (as represented in non-border homes of the NHEXAS AZ study). This objective will be supported through specific aims where inter-media analyte relationships (e.g. Pb in blood and dust) will be examined and compared for the two populations. This secondary objective will be scientifically achieved by testing the following:

Secondary Hypothesis: The inter-media analyte relationships do/do not differ between the border and the rest State's (non-border) population.

C. A third, exploratory objective is to compare the EPA LRGV (Lower Rio Grande Valley) Study findings, to those from the proposed Arizona Border Study. This tertiary objective will be achieved by comparisons in the nature of the following:

Exposure estimates from the LRGV Study will fall within the confidence intervals of the estimates from the Arizona Border Study.

1.7.2 Survey Design

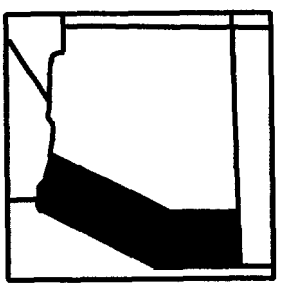
Overview: Throughout this document the Border Study "FIELD STAGES" refer to specific sampling protocols that will be performed at the selected household subsets. To minimize confusion, we refer to each component of the survey design as a design phase. The design phases were initially described for the NHEXAS Study (Lebowitz et al. 1995). We have built the Border study design using the same population based probability research design.

Arizona is the fifth largest state in the United States and is composed of 15 counties, only 4 of which are located on the US-Mexico Border. Although the Border is defined at 100 km from the line, we will evaluate only those areas 40 km or closer. The Border Study employs a multi-phase probability sampling design. The border area was divided into 4 "regions" (counties). Each region contains a number of "combined census block groups" either entire or partial census tracts, that will serve as the primary sampling unit (PSU) for the first design phase of the study. We allowed each of the 48 census tracts along the border to be selected up to two times making 96 possible PSU along the border. We then ranked the tracts by occupied housing units and randomly selected 25 PSU across 3 size classes. The PSU were divided into area segments containing, on average, 20-30 houses each based on 1990 census "blocks"; 4 area segments were selected from each of the subdivided PSUs; these will become secondary sampling units (SSUs) making up the second design phase. Each house in the selected SSUs will be listed; houses will be randomized and sequentially selected until 3 participating households are obtained for each area segment, thus completing the third phase selection. This will result in 300 houses chosen for recruitment. Each chosen household is enrolled by completion of the Descriptive Questionnaire (the same QX used in NHEXAS). Figure 8 provides a graphic representation of this study design.

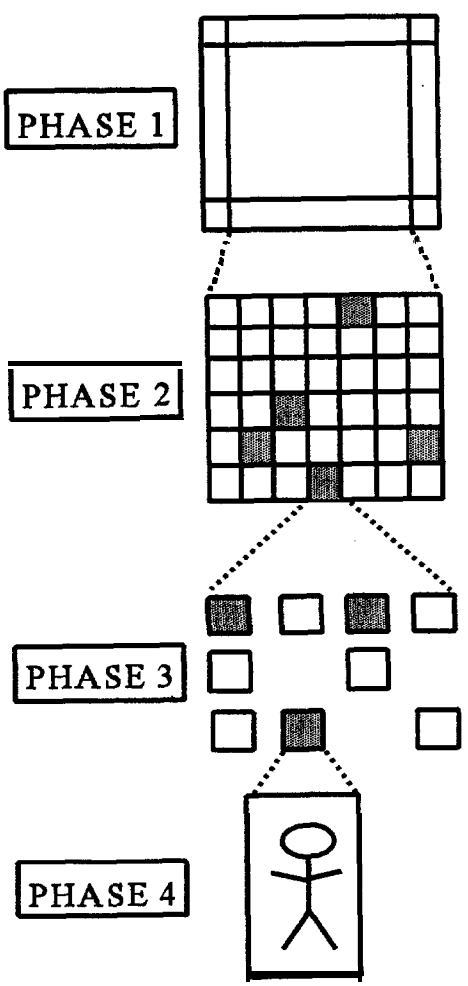
After each sample household has completed the Descriptive Questionnaire, including a roster of all people living in the household, a single "individual respondent" will be selected at the fourth design phase of sampling for monitoring within the sample household. One- and two-persons households will be sub-sampled to achieve approximately equal person-level probabilities of selection in spite of unequal number of persons in sample households. Sample households will be selected in random waves until the appropriate number of participants have been recruited.

Figure 8. Diagrammatic of the Survey Design Phases.

IDEALIZED ARIZONA AND BORDER SAMPLING DESIGN



Arizona Border: 4 Counties



Primary Sampling Units
Select 25 of a potential 96 primary sampling units (census **tracts).**

Secondary Sampling Units ("Blocks ")
Select 4 area segments from the division of the Primary Sampling Units into Secondary Sampling Units.

Housing Units
Select 3 Housing Units from each selected Secondary Sampling Unit.

Primary Respondents

A. First Design Phase: Sample of Combined Census Block Groups (cf. "tracts")

Sampling frame - As in NHEXAS, the sampling frame for the first design phase sample will be constructed from the 1990 Census Summary Tape File 1A (STF 1B). The sampling units will consist of combined census block groups derived from census block-level records.

Sample size - A survey design study employed for NHEXAS (Clickner 1993), and selected for use in this study to ensure comparability, recommends a relatively large sample of PSUs to reduce the possibility of high intracluster correlations (i.e., tendency for measurements to be more alike within counties). Therefore, Border AZ uses a field data collection protocol intended to maximize the number of PSUs (combined census block groups) while maintaining a relatively efficient field data collection protocol within each PSU to minimize costs.

In keeping with the NHEXAS study survey design, environmental data will not be used for stratification in both the NHEXAS Arizona study and the Border survey design. Although we anticipate no stratification, only stratification based on general population characteristics (age, gender, and ethnicity) potentially related to analysis domains and/or general population differences in exposures to toxicants with proportionate sampling rates will be undertaken in the study design phase.

Sampling method - We will select sample PSUs with probabilities proportional to size (pps) using a sequential probability minimum replacement (pmr) sampling algorithm [Chromy 1979]. Use of pps sampling facilitates an approximately equal probability sample of housing units with equal numbers of sample housing units per combined census block group (PSU). The frame units will be sorted within the Border Region in a geographical order by size and one-third of the PSUs will be randomly selected from each size class. This will result in implicit stratification with exactly proportionate sampling rates based on the frame ordering because of the sequential nature of the sampling method.

B. Second Design Phase: Sample of Area Segments (cf. "blocks")

Sampling frame - We will select 25 PSUs in Design Phase 1. The sampling frame for the second phase sample will be constructed from the 1990 Census Summary Tape File 1B (STF 1B) block-level data records within each of these PSUs. Eligible blocks within a PSU are sorted into 4 size classes based on the number of occupied housing units. One census block is chosen randomly from each of the four size classes. Blocks are field truthed and combined as necessary to obtain sufficient size for sampling (on average 20-30 homes). In no case will the combination of blocks forming an SSU cross census block boundaries. Also, none of SSUs cross block group or block numbering area (tract) boundaries. Prior to proceeding to the third decision phase, each SSU will be checked against census data to insure that all possible housing units are considered. Each missed housing unit identified in this manner will be included in the sample. Each missed housing unit that produces a study participant will count toward the requisite number of participants in the sample segment. This procedure ensures maximum coverage of occupied housing units in the target population.

Sample size - The recommended NHEXAS survey design study suggested minimizing sample clustering because of the high cost of collecting and analyzing environmental samples and because of the possibility of high intracluster correlations (i.e., tendency for the measurements of some chemicals in some media to be more alike within PSUs and within area segments). Based on this criteria and logistical considerations, the NHEXAS Arizona field studies will select 4 area segments or SSUs per PSU.

Demographic variables from the Census STF 1B data base will be used to evaluate the secondary sampling units. They are (1) percent urban population; (2) percent Hispanic population; (3) average housing unit value; and (4) percent single family residences. The distributions of these variables will be examined within each of the PSUs to assure that the sample segment reflects the characteristics of the census block group. This analysis will define the extent of representativeness with regard to (1) homes in rural and urban areas, (2) representation of Hispanics and Native Americans, and (3) representation of households from all socio-economic strata relative to the 1990 and incremental census data. Deviations will be evaluated and reported relative to representativeness of the population.

C. Third Design Phase: Sample of Households (Housing unit)

Sampling frame - The third phase sampling frame consists of a list of all potential housing units in each selected area segment. This list is compiled by the field interviewers assigned to the PSU.

Sample size - A multinomial sampling procedure will be implemented in each sample segment to achieve a pre-assigned number of participants in each segment. Hence, the sample size will be a random variable, the number of sample housing units needed to produce "m" successes (participants) (see below).

Three housing units will be selected from each of the four area segments located in a SSU. This will yield a total of 300 houses to be surveyed using the Demographic Questionnaire (3 houses x 4 area segments x 25 PSU= 300 housing units). Up to 2 housing units per area segment will be evaluated for environmental monitoring [Stage 2 environmental monitoring will total (125) housing units; Stage 3 monitoring will be completed in 100 housing units].

Sampling method - Use of the multinomial sampling procedure requires that all housing units listed for each sample segment first be placed in a random order so that the first "x" sample housing units constitute a simple random sample of size "x," for every integral value "x." To achieve "m" participants in a segment, we will begin by fielding the first "m" housing units on the randomly ordered list (a simple random sample of size "m"). When the final result for one of these sample housing units is a "refusal," an ineligibility, or an incapacity, the field coordinator will increase the size of the simple random sample by one housing unit. The increase is accomplished by accessing the next housing unit on the randomly ordered list (a supplemental sample of size one).

The third design phase sample size for each segment will be the number of sample housing units activated for data collection. Each refusal will count against the survey response rate. Therefore, sample housing units beyond the initial "m" housing units will be activated only by the field supervisor who has verified that all possible attempts to obtain a response have been completed. Whenever a sample housing unit is released for contact, the interviewer will check for missed respondents within the sample housing.

D. Fourth Design Phase: Sample of Persons for Monitoring (Primary Respondent)

Sampling frame - The fourth phase sample frame will be derived from the roster of household members compiled in the Descriptive Questionnaire discussed above. The interviewer will use appropriate probes to check for completeness of the roster and will remove any household members not eligible for the study (see section 3.1.1).

Sample size - Housing units will be recruited in each sample segment until an appropriate number of persons willing to participate in the environmental and biological monitoring stages (Stages 2 & 3) have been recruited (3 people per SSU). One person in each selected house will be designated as the primary respondent. The Border study (as NHEXAS Arizona before it) will enhance participation by asking all household residents to participate in the survey. We will evaluate the differences among exposures detected from those sharing a common residence. Since the greatest cost of the survey is encountered in the environmental sampling and "getting into the house," the potential for evaluating exposures among family members should not be overlooked. Further, if autocorrelation among residents is low, then the power available for some analyses is enhanced. Data obtained from the Primary Respondent can be readily identified and kept separate for transfer to EPA.

Sampling method - If one person were selected at random from every sample household, the survey design effect, or variance inflation factor, due to unequal probabilities of selection within households of different sizes would be approximately 1 .5. Therefore, the design calls for selection of a person from about 25% of the one-person households, from about 32% of the two-person households, and the remainder (43%) from all other households. This reduces the survey design effect for unequal person-level probabilities of selection to less than 1.1. Within those households chosen to have a sample member recruited, one eligible household member will be selected at random using the appropriate (unit size dependent) random selection table. Accounting for the survey design effect will improve the capture chances a small amount. This proposed design is a compromise between equal probabilities of selection for monitored households and for monitored persons with an unequal weighting design effect of about 1.1 expected in each case (see Table 6 below).

Table 6. Person-level sampling weights for NHEXAS Arizona (HH = households)

Housing Unit Size	*% Arizona Households*	*HH Completing Descriptive Qx*	*Asked to Participate*	*Expected to Participate in the Activity*
One person	25%	75	75	56
Two people	32%	96	96	72
> Three people	43%	129	129	97
Total	100%	300	300	225

1.7.3 Precision Requirements

A. Survey errors are dichotomous; some result from sampling, other errors result from nonsampling. Sampling errors are observation errors resulting from an observation of the survey population only. These would not occur if the entire population was evaluated. All other errors in the survey measurement process are nonsampling errors.

B. Precision Targets: The precision of statistics based on a given sampling design is often discussed in terms of estimates of population proportions (e.g., frequency of occurrence of elevated levels of VOCs in air or arsenic in water) because the standard errors of proportions depend only on (1) the population proportion being estimated, (2) the sample size available for the estimate, and (3) the survey design effect for the estimate. In particular, no independent sources of information regarding population variability are needed for estimates of proportions. The survey design effect for a statistic is the ratio of the sampling variance for the statistic under the actual sampling design divided by the variance that would have been achieved with a simple random sample of the same size. It can be factored into components associated with the effects of (1) stratification, (2) multistage (phase) sampling (clustering), and (3) unequal weighting (unequal probabilities of selection and weight adjustments for unit nonresponse). Stratification tends to decrease the design effect (increase precision), whereas multistage sampling and unequal weighting increase the design effect. Multistage sampling effects usually predominate.

C. Sample Size: Table 7 presents power calculations for samples sizes of 50, 75 and 100 at significance levels of 0.10, 0.05 and 0.01. These power calculations are aimed at satisfying the primary objective of this study, detecting significant differences in the log-normal distributions of pollutant concentrations in the border versus the 175 HUs in rest of the state. The coefficient of variation (CV) was assumed to be 100% for both populations (about = CV for blood lead). Thus, it will be possible to test our hypotheses based on Stage 3 results with 100 HUs in the border region, with statistically significant differences in pollutant concentrations at $p<0.05$ with a power of >0.77 or better if the difference in geometric means of pollutant concentrations is at least 1.5, as we envision. A greater ratio of geometric means results in greater power.

Nonresponse Error. Nonresponse can occur at several levels in the NHEXAS Arizona study design. The first opportunity for nonresponse is to the Descriptive Questionnaire, which we expect to complete for a minimum of 75% of the occupied sample housing units. We will test for significant differences between respondents and nonrespondents for all characteristics known for both, such as the "key" Descriptive Questionnaire items.

Adjustments to the sampling weights (reciprocals of the probabilities of selection) will also be computed to reduce the potential for nonresponse bias for each phase of nomesponse to in the study. The ability to compensate by making meaningful weight adjustments for the potential nonresponse bias depends heavily on the availability of sufficient data for the nonrespondent to adequately model the response propensity (probability of responding). This must be balanced against the essential need for informed consent from each respondent. Preceding collection of questionnaire information from any potential housing unit, we must secure the respondent's signature on an "Informed Consent Form." This form has been approved by the University of Arizona's Human Subjects Review Board for use in both the NHEXAS & Border Studies (UA-IRB # 95-86).

We will have the Descriptive Questionnaire data to model nonresponse against the Baseline Questionnaire. We expect that standard weighting-class nonresponse adjustments will be sufficient to compensate for the lower levels of nonresponse to the Descriptive Questionnaire and the Baseline Questionnaire. However, logistic regression models for the probability of responding will also be explored for nonresponse in the monitoring phase because these models have the potential to make greater use of the data available in the Baseline Questionnaire and produce greater reduction of nonresponse bias.

Questionnaire Measurement Error. Problems associated with questionnaire construction were evaluated for the NHEXAS project by the RTI/EOHSI Consortium and corrected where possible prior to OMB approval. We will use the same questionnaires in the Border Study. Further, errors will be limited by hiring people with some training or experience in interviewing technique. We will provide additional training for new and inexperienced interviewers. Interviewers will ask the questions exactly as written and not use leading probes. These procedures should reduce questionnaire measurement errors to the extent practicable. All questionnaires will be available in English and Spanish at the choice of the respondent and at least 1 member of each field team will be fully bilingual.

Field Sampling Error. Arizona will hire the most qualified and experienced monitoring personnel possible. They will all be cross-trained in all sampling techniques. The Field Team Leader has the authority to make field based decisions, Each field procedure has a complete SOP written to cover appropriate sampling methods and ensure consistent quality sampling. Field personnel are certified as being competent to perform these procedures through training protocols (UA-T-1.x through UA-T-4.x) before they independently collect field samples. If a protocol does not cover the situation confronted in the field, the technician will consult with the Field Team Leader. The Field Team Leader will determine whether a sample should be taken

(and how). If the need for consultation arises, the Field Team Leader can call the project office. Any non-conforming collections will be noted on the sample and field form.

Analytical Chemistry Measurement Error. National Institute of Science and Technology (NIST) performance calibrations and standards were available for the NHEXAS Study. Where available, these same solutions will be used in the Border Study. We will also employ field blanks, co-located field duplicate samples, replicate sample extract analyses, etc. to quantify measurement error variance and bias for the collection and analysis methods employed in the study. Overall, this will amount to a 10% collection of field and lab blanks/spikes/ duplicates/replicates. We expect to find that each field and laboratory measurement procedure has no significant bias. Standard errors of survey statistics will be based on the estimated total survey variance, which includes all sources of variation without separately estimating each variance component. If any significant measurement biases are detected, survey estimates will be statistically adjusted to produce unbiased population estimates.

1.7.4 Dependent and Independent Variables

All analyses will be hypothesis specific. In general:

Dependent Variables = all values measured from samples. This includes measured amounts of each metal, pesticide, and VOC from each of the media sampled. Detection of target pollutants in blood or urine ("biomarkers") are independent variables.

Independent Variables = all data obtained from questionnaires, the geographic location (including elevation), and time of sampling.

After the exposure assessment model is complete, a dose model will be created. At that point the biomarkers are the independent variables and the exposure model results are the dependent variables.

1.7.5 Discriminating Power of Tests

A. Statistical

Sample Size Determinations: Sample sizes for target populations and nested sub-samples were calculated based on needed sample sizes to compare differences in geometric means of exposure along the Border and within the State of Arizona as defined in NHEXAS. Power calculations and sample sizes are discussed in section 1.7.5.

Choice of Statistical Models: Based on the hypothesis being tested and the study design there will be a limited choice of statistical models that can be used. We will choose the most robust, most discriminating model amongst them, such as a general linear model. In general, the relationships will be viewed as significant if $p < .05$. Multiple comparisons will be taken into account. More detail has been provided in Section 1.4 Stage 4.

B. Instrument, Laboratory & Chemical Assays:

Equipment and analyses performed in the laboratory must meet some minimal standards for each of the procedures performed. Outlined below (Tables S-10) are the methods and the expected detection levels attainable for procedures and target pollutants. This section is in terms of General Techniques followed by Detection Limits (DL) of the target pollutants. When available, accuracy is established based on standard reference material. The detection limits and the ability of any evaluation to measure the presence of a contaminant are also outlined in the Laboratory SOPs.

Table 8. General Field Assays-Method Precision

Media	**Object to Calibrate**	**Purpose**	**Calibration Method**	**Quantitative/ Qualitative**	**Tolerance**
Air	Pumps	Field Calibration Checks	Sierra Top Trak Digital Mass Flow Meter	Quantitative	± .2 L
Air	Relative Humidity		Psychrometer	Quantitative	±10% RH
Air	Temperature		Thermometer	Quantitative	± 2 °F
Location	GPS Meter	Site Location in terms of Latitude and Longitude	Readings in both Lat and Long and Military coordinates: Cross reference with available Address coordinates in Arc Info	Quantitative	± 200 m
Distance	Tape or Ruler	Distance from Reference Points	Repeat Measures	Quantitative	± .25 cm
Dust	Collection	Vacuum Cleaner	fixed point anemom.	Quantitative & Qualitative	± 10% of original flow

Table 9. General Laboratory Procedures-Method Precision

Media	Evaluation Method	Instrument	Quantitative/ Qualitative	Tolerance
Air—$PM_{10\&2.5}$	Weight	Balance	Quantitative	± .Olmg
Soil	Sieves-- 3 size fractions	Standard Soil Sieves	Quantitative	± 5%
Soil	pH	pH meter	Quantitative	± .2
Soil	Electro-conductivity	ohm meter	Quantitative	± .2
Soil	Color Character	Munsell Soil Chart	Qualitative	
Dust	Weight/ Unit Area	Balance	Quantitative	± .Olmg
Dust	Aliquot Splits	Balance	Quantitative	± .01mg
Food	Veracity Assessment-Comparison of food sample with diary report	Visual Verification	Qualitative	
Food	Food Mass	Balance	Quantitative	± 1g
Food	FDA Assay	GC/MS or GC/ECD	Quantitative	2-50 µg/kg metals 2-50 µg/kg pesticides
Beverage(?)	Veracity Assessment-Comparison of food sample with diary report	Visual Verification	Qualitative	
Beverage(?)	Volumetric Assessment	Visual Verification	Quantitative	± 1 cc
Beverage(?)	FDA Assay	GC/MS or GC/ECD	Quantitative	.001-.025 mg/kg metals .5-.3 ng/g pesticides

Table 9 (Cont). General Laboratory Procedures-Method Precision

Media	Evaluation Method	Instrument	Quantitative/ Qualitative	Tolerance
Water	Water Lab Assay	GC/MS or GC/ECD	Quantitative	0.2-1.0 µg/L metals 0.2-O. 10 µg/L pesticides 0.05 µg/L VOCs
Blood	CDC Assay	CDCs Choice	Quantitative	6-10 µg/L metals l-5 ug/L Pesticides 0.10-1.0 µg/L VOCs
Urine	CDC Assay	CDCs Choice	Quantitative	2-6 µg/L metals 1-5 µg/L pesticides

Table 10. Quality Assurance Objectives for Media/Analyte Class from Battelle Laboratories.

Expected Precision, Recovery, and Detection Limits for Chemical Characterization Methods.

Medium	Analyte Class	Sample Location/Type	Analytical Laboratory	Analytical Method	Precision %RSD	Recovery %	MDL
Air	Metals	Indoor/Filter[h]	Battelle	ICP-AES	±30%	70-130%	17.4-1,400 ng/m^3
			UA	XRF (Stage II)	±30%	70-130%	0.1-3.5 µg/m^3
		Outdoor/Filter[h]	Battelle	ICP-AES	±30%	70-130%	17.4-1,400 ng/m^3
			UA	XRF (Stage II)	±30%	70-130%	0.1-3.5 µg/m^3
	Pesticidcs	Indoor/Filter/PUF	Battclle	GC/MSD	±15%	70-130%	3-20 ng/m^3
		Outdoor/Filter/PUF	Battelle	GC/MSD	±15%	70-130%	3-20 ng/m^3
	PAHs	Indoor/Filter/XAD-2	Battelle	GC/MS (SIM)	±15%	70-130%	0. I-O.05 ng/m^3
		Outdoor/Filter/XAD-2	Battelle	GC/MS (SIM)	±15%	70-130%	0.1-0.05 ng/m^3
	VOCs	Indoor/whole air	UA	PID[g] (Stage II)	±20%	75-125%	ΣVOCs -500 ppb
		Indoor/PSD (OVM3500)	Battelle	GC/MS[g]	±15%	95-100%	0.5 µg/m^3
		Indoor/multisorbent tubc	Battclle	TD-GC/MSD[g]	±20%	80-120%	0.1 ppbv
		Outdoor/whole air	UA	PID (Stage II)	±20%	75-125%	ΣVOCs -500 ppb
		Outdoor/PSD (OVM3500)	Battelle	GC/MS	±15%	95-100%	0.5 µg/m^3
		Outdoor/multisorbent tube	Battelle	TD-GC/MSD	±20%	SO-120%	0.1 ppbv
	Formaldehyde	Indoor/PSD (PF-1)	Battelle	Colorimetric	±15%	75-125%	IO ppbv
		Outdoor/PSD (PF-I)	Battelle	Colorimctric	±15%	75-125%	IO ppbv
Dust & Dermal	Metals	Carpet Dust*	Battelle	ICP-AES	±30%	70-130%	0.1-s µg/g
			UA	XRF (Stage II)	±30%	70-130%	0.1-2.5 µg/g
		Surface Wipe'	Battelle	ICP-AES'	±30%	70-130%	2- 160 µg/m^2
		Hand Wipe'	Battelle	ICP-AES	±30%	70-130%	0.1-8 µg/sample
	Pesticidcs	Carpet Dust[a,d]	Battelle	GC/MSD	±15%	70-130%	0.02-O. 1 µg/g (0.003-0.01 µg/m^2)
		Surface Wipe'	Battelle	GC/MSD	±15%	70-130%	0.4-2 µg/m^2
		Hand Wipe	Battellc	GC/MSD	±15%	70-130%	0.02-o. I µg/sample
	PAHs	Carpet Dust'	Battelle	GC/MS (SIM)	±15%	70-130%	0.001-0.005 µg/g

Table 10 (cont). Quality Assurance Objectives for Media/Analyte Class from Battelle Laboratories.

Medium	Analyte Class	Sample Location/Type	Analytical Laboratory	Analytical Method	Precision %RSD	Recovery %	MDL
Soil	Metals	Yard/Foundation[j]	Battelle	ICP-AES	130%	70-130%	0.1-8 µg/g
			UA	XRF (Stage II)	±20%	70-130%	0.1-2.5 µg/g
Water	Metals	Tap; drinking	EPA-Ci	ICP-AES	110%	85-115%	0.2-I µg/L
	Pesticides	Tap; drinking	EPA-Ci	GUMS	±15%	85-115%	0.02-O. I µg/L
	VOCs	Tap; drinking	EPA-Ci	GC/MSD	±25%	75-125%	0.05 µg/L
Food	Metals	24-Hour diet	FDA	ICP-AES	±20%	80-120	0.002-0.05 mg/kg
		Pre-/post cooked	FDA	ICP-AES	20%	SO-120	0.002-0.05 mg/kg
	Pesticidcs	24-Hour diet'	FDA	GC/MS	125%	70-130%	l-5 ng/g
		Prc-/post cooked	FDA	GC/MS	±25%	70-130%	l-5 ng/g
Blood	Metals	Venous blood	CDC	ICP-AES	110%	70-130%	6-10 µg/L
	Pesticidcs (persistent)	Venous blood	'CDC	GC/MS	±25%	50-120%	0.1-I µg/L
	VOCs	Venous blood	CDC	GC/HRMS	±25%	75-125%	0.03 µg/L
Urine	Metals	I st Morning void	CDC	ICP-AES	±10%	70-130%	2-6 µg/L
	Pesticides	1st Morning void	CDC	GC/MS	±15%	50-130%	1-5 µg/L

[a] Assumes 1 g of dust and 8 m^2 area vacuumed.
[b] Chlorpyrifos analysis only.
[d] Analysis of target pesticides.
[e] Variable surface area (calculated here in units of $\mu g/m^2$, assuming 0.05 m^2 sill area wiped.
[f] Assumes 25 g aliquot of food extracted.
[g] PID = photoionization detector; GC/MS = gas chromatograph/mass spectrometer; TD = thermal desorption-GC/MSD (mass selective detector).
[h] Assumes 200 mg dust sample.
[i] Assumes air sample volume of 1,920 L over 8-hour sampling period.
[j] Assumes 1 g sample.

1.7.6 Acceptable limits on false positives and false negatives

Acceptable limits on false positive and false negative data depend on data type. Our project has two major types of data and different approaches are used to determine false positive and false negative values.

A. Questionnaire data: In general, a question will be regarded as not valid and not usable if more than 5% of the responses are found to be false. This determination will be made **in two** ways.

1. For the Descriptive Questionnaire: 10% of the responses of non-participating subject families will be verified by readministration by phone.

2. For all other Questionnaires: At least 10% of the Stage 2 questionnaires will be readministered to respondents in Stage 3. These results will be compared to evaluate discrepancies. If any question has more than 5% non-explained and inconsistent responses, the question will be eliminated from the data base for all respondents.

B. Measurements (Physical or Chemical): Tables 8-10 describe methods and associated known detection limits. Since the primary Border Study goals is to compare geometric means of exposure distributions between the Border Study population and that of the of the State of Arizona (as represented by NHEXAS) for each common of target pollutant, comparable limits of detection are important between the studies. Blanks and spiked samples will be needed for analysis of each sample batch in every sample lab (including the Federal Contract Labs). These will detect major lab errors. Other false negatives and false positives most frequently occur at or near the detection limit. These are not likely to be a problem. Their detection would generally place the sample in the lower half of the distribution. Critical false positives are those falling as upper end outliers. When sufficient sample with adequate integrity is available, then outliers in the upper 2% of the distribution will be re-evaluated to confirm the value validity.

The laboratory SOPs outline the accuracy, precision and acceptance limits for all lab generated data. Method Detection Limits are reported in Table IO.

2.0 MANAGEMENT ASSESSMENT

2.1 Assessment Responsibility

A. The Principal Investigator will perform overall direction of the project (and coordination with the appropriate outside agencies (i.e., County Departments, etc.). The Principal Investigator is ultimately responsible for all aspects of the project. The On-Site Co-principal Investigator will be responsible for ensuring that project control documents are prepared by the project staff in a timely manner. The Principal Investigator and/or On-Site Co-principal Investigator will be responsible for reviewing and approving all project control documents as well as all final project deliverables to ensure their compliance with the project requirements. Responsibility may be delegated to project personnel for implementation of the Quality Assurance program.

B. The On-Site Co-principal Investigator and/or Coordinator(s)/Supervisor(s) will be responsible for preparing or delegating responsibility for the preparation of project documents. Responsibilities include ensuring that proper quality control activities are implemented in the research program, in the office, field, laboratory and data offices.

C. The Director of Quality Assurance is responsible for the maintenance of this QA Plan. Responsibilities include verifying the proper implementation of project control documents through the performance of planned and scheduled quality assurance audits/inspections (see Appendix C).

D. The Director of Quality Control is responsible for the overall implementation of this QA Plan and for all QA/QC activities within the project. Responsibilities include assisting the project technical staff in the development of the required project control documents. The Director of Quality Control is further responsible for developing and implementing a plan for regularly monitoring the quality aspects of project activity and providing periodic documentation of monitoring activities to the On-Site Co-Principal Investigator and Project Coordinator(s) and to the Principal Investigator as appropriate. The Director will assist the project staff, as required, in the resolution of quality related problems (Appendix C).

E. The appointed in-house quality assurance personnel are responsible for verifying that quality control and quality assurance activities are being implemented regularly by the laboratory and field personnel as prescribed in the Standard Operating Procedures. They will notify the appropriate Project Coordinator and/or On-Site Co-Principal Investigator upon discovery of any quality related problems or non-compliances.

2.2 Assessment Types

A. Informal QA Audits: Each Project Coordinator/Supervisor has specialized QA responsibilities defined in the SOPs. Each will perform routine in-house QA Audits on appropriate QA records and report in writing to the On-Site Co-Principal Investigator. These audits will be performed on a quarterly basis. Reports are due the last day of each quarter.

Errors will be sought in:

* technician understanding of procedures,
* equipment performance,
* recording data,
* compiling data, and
* analysis of data.

Mechanisms of error searches include:

* direct visual inspection,
* comparison of forms, and
* statistical evaluation.

B. Formal QA Audits: These will be performed by the QA Unit of the University of Arizona for all members of the Consortium. The QA audit will pertain to the specific QA requirements for each member. Field audits will occur once during the first 3 months; then at 6, and 12 months. Laboratory and Data audits will occur annually.

2.3 Assessment Usage

Quality assurance assessment procedures will be used in all aspects of the project including: document development, procedure evaluation, procedure implementation, sample collection, sample shipment, sample analysis, data reduction and data analysis, Quality assurance audits will be performed to identity and correct faulty conduct within the project.

2.4 Assessment Criteria

The University of Arizona, Office of Arid Lands Studies contains qualified scientists certified as QA reviewers. This University of Arizona department is independent. They will perform formal audits on all aspects of the project.

Documents that will be enforced include this QSIP, all appendices and all Standard Operating Procedures identified within this QSIP.

2.5 Assessment Documentation

Internal QA audits will be submitted to the on-site Co-Principal Investigator on the last Friday of each month. All notebooks containing QA documents as described in the SOPs will be checked, signed and dated by the appropriate Coordinator/Supervisor. Each Coordinator/Supervisor will write a memo to the On-Site Co-Principal Investigator disclosing the results of the audit in their area and proposed corrective action in accordance with the SOPs if needed. Documentation of the informal QA audits will reside with the On-Site Co-Principal Investigator.

Copies of all publications and associated peer reviews of articles, theses or dissertations must be kept on file with the principle or On-Site Co-Principal Investigator(s).

Results of the External QA Audits (as specified in Appendix C, QA-02 section 7.2 B) will be provided to the on-site Co-Principal Investigator and the Principal Investigator.

3.0 PROJECT IMPLEMENTATION PLAN

3.1 Project Design Criteria

3.1.1 Siting Criteria

Information and physical samples will be collected only from homes under the jurisdiction of the State of Arizona. These homes will be selected using a population-based probability design (see section 1.7.3). We have approached the Tohono O'Odham Nation for permission and cooperation in sampling residents on their lands. Sampling will only occur with the Nation's consent. We will work with EPA Region 9 to facilitate this process.

Exclusionary criteria include: Military bases, institutions and residences occupied by more than 9 unrelated persons and part time residents with a permanent residence elsewhere. Once a home is selected for monitoring, equipment will be sited inside and outside the home to obtain specific measurements. Siting criteria for each procedure are defined in the specific Field SOPs (see Figures 1-6). A summary is presented below (Table 11).

3.1.2 Project Quality Objectives (PQOs)

Measurements never reflect the condition being measured perfectly. Project Quality describes the uncertainty associated with any measurements taken whether by questionnaire, description or an actual measurement. Project Quality Objectives describe the degree of uncertainty that will be acceptable for each portion of the project. A single analyte obtained from a given medium may have several PQO measures associated with it. All must fall within the defined limits for the sample to have validity. Some types of uncertainty can be reported quantitatively; other conditions can only be described qualitatively. The following discourse will describe PQOs as they pertain to our study.

A. Representativeness of the Evaluated Population.

Our study design outlines the selection of the subjects to be evaluated through a 4 phase process and characterizes the adequacy of the number of households (primary respondents) that will be evaluated at each study phase. Please refer to section 1 for details. The PQO for each stage of our study is 75% of the targeted population. We expect to exceed this for the Descriptive Questionnaire and all of our Stage 2 sampling.

B. Consistent Application of the Methodology.

Five components play a major role in the consistent application of the study methodology. These are education, experience, training, clear written procedures, implementation and supervision/evaluation.

1. All employees must understand their roles and tasks. Sometimes the education needed is formal. At other times it is implemented through on-the-job lectures, readings and demonstration. The educated project employee will understand why methods must be applied consistently and is more likely to conform.

2. Experienced employees may already possess the skills to perform the job and realize the importance of applying the same techniques throughout the project. They may be easier to train in the specifics of our project protocols and needs.

Table 11. Siting Criteria for samplers at households (M= metals analysis; P = Pesticide Analysis).

Media	Analyte	Equipment	Indoor Location & *Rationale	Outdoor Location & *Rationale
4ir	M	Black Box $PM_{2.5}$ & 10 (or field calibrated SKC pump operated at 4 L/mm)	Main Room/ Family Room--at least 2 feet from any wall. *Location of maximum waking time. Distance minimizes air flow alteration.	North side of house—7'-10' from the midpoint of the n. wall of the house. *the wall provides some protection from direct sunlight; the side of the house is arbitrary but consistent.
	P	SKC/URG PUF	Main Room/ Family Room-at least 2 feet from any wall. *Location of maximum waking time. Distance minimizes air flow alteration.	None
	v o c	OVM 3500 (Within metal shelter)	Main Room/ Family Room-at least 2 feet from any wall. *Location of maximum *waking* time. Distance minimizes air flow alteration.	North side of house—7'-10' from the midpoint of the n. wall of the house. *the wall provides some protection from direct sunlight; the side of the house is arbitrary but consistent. (Santa Cruz co. only)
	v o c	Actively Pumped VOC (Carbotrap sorbent with SKC pump operating at 5 mL/min; an 8 hour sample will be integrated over 24 hours of collection time)	Main Room/ Family Room—at least 2 feet from any wall; opposite side of the room from PM sampler. Try to minimize the likelihood of collecting filtered air. *Location of maximum waking time. Distance minimizes air flow alteration. (Proportional sample of the border.)	North side of house—7'-10' from wall. At least 7 - 10 feet from the PM sampler. *The wall provides some protection from direct sunlight; the side of the house is arbitrary but consistent. (Proportionately sampled along the border).

Media	Analyte	Equipment	Indoor Location & *Rationale	Outdoor Location & *Rationale
Air	PAHS	Actively Pumped PAHs (filter/XAD-2 cartridge assemblies with SKC pump operating at 4 L/min; an 8 hour sample will be integrated over 48 hours)	Main Room/ Family Room-at least 2 feet from any wall; opposite side of the room from PM sampler. Try to minimize the likelihood of collecting filtered air. *Location of maximum waking time. Distance minimizes air flow alteration. (Santa Cruz Co. Only)	North side of house—7'-10' from wall. At least 7 - 10 feet from the PM sampler. *The wall provides some protection from direct sunlight; the side of the house is arbitrary but consistent. (Santa Cruz Co. Only)
	PAHs	Wilson's "Real-Time PAH monitor) (unit requires additional data logger and portable PC for use; 1 hour measurements).	Main Room/ Family Room-at least 2 feet from any wall; opposite side of the room from PM sampler. Try to minimize the likelihood of collecting filtered air. *Location of maximum waking time. Distance minimizes air flow alteration.	North side of house—7'-10' from wall. At least 7 - 10 feet from the PM sampler. *The wall provides some protection from direct sunlight; the side of the house is arbitrary but consistent.
	Broad Spect-rum Volatile Sampler	Passive Semi-Permeable Membrane Devise (SPMD) deployed for analysis by USGS & EPA	Passive sampler exposed inside main VOC room for 1-2 months./ Placed at the convenience of the respondents	Mounted on the passive stand on the north side in 10% of the homes.
Soil	M & PAHs	Ziploc bag stainless steel trowel	None	30-60g collection. One composite sample will be collected from all sides of the home or building. * Provides a composite that is collected in a consistent manner among all homes.

Media	Analyte	Equipment	Indoor Location & *Rationale	Outdoor Location & *Rationale
Dust	M, P, & PAHs	Vacuum Sample	Vacuum Sample Composite of up to 8 m2 from the main room and the bedroom of the Primary Respondent; Precise area sampled is recorded* Maximizes the view of subject exposure.	None
	M	Window Sill Wipe	Composite: 2 square foot of main room window plus 2 square foot of bedroom window sill on each of 2 wipes. * good location for Pb paint. Good view Soil component of house dust.	None
Der-mal	M, P	2X 2 Wipe	Both hands to wrists	None
Water (tap)	M, P & VOCs	Plastic Amber glass Vials	Kitchen tap after 2 min. flush. Aerator removed to minimize gas *Flushed Sample is the majority of consumed water. Water collection will be consistent among houses. Teams will visit houses after variable water use. An "unflushed" sample at one home will not be related to the same sample at another depending on time of day and water use.	None

Media	Analyte	Equipment	Indoor Location & *Rationale	Outdoor Location & *Rationale
Water (drinking)	M, P & VOCs	Plastic Amber glass Vials	Collect as is water from storage container at the house regardless of source. * We expect a greater level of contaminant from the container than from the water.	None
Food	M & P	Ziploc Bags & plastic containers	Duplicate of all food consumed within l-day regardless of source.	None
Beverage (?)	M & P	Ziploc Bags & 1 -gallon plastic containers	Duplicate of all Beverage (excluding water) consumed within 1 -day regardless of source.	None
Blood	M, P VOCs, & PAHs	Vacutainer	Primary Respondent	None
Urine	M, P & Creatinine	Specimen Cups	Primary Respondent-first catch in the morning	None
Hair (OMB Request for future anal.)	M	Ziploc Bag Stainless Steel Scissors	< or = 1 g. trimmed from nape of neck up to 1 inch from scalp	None
unidentified Pesticide (OMB Request for future anal.)	P	Ziploc Bag or HDPE vial	Any pesticide identified as such by the resident but unlabeled and unknown.	None

3. Training is specific to each project regardless of the amount of experience or education an employee may have. All employees will be trained in terms of the specific procedures for the Border project. Each employee will observe new protocols and perform them successfully (without coaching) a number of consecutive times under observation prior to certification in a task. Employee training will be documented and checked periodically. The performance standards and evaluation will be determined for each task as a function of its complexity.

4. Clear, concise, written procedural instructions exist for every task. All employees must follow these procedures; deviations must be documented. Major changes must be documented and released as a revised procedure (SOP). A new raw data base must be created for the data collected under the new procedure clearly marking it as differing from the preceding data collected.

5. Once certified, the employee will perform the work as specified by the supervisor. Employee proficiency will be documented and checked periodically. Failure results in loss of certification and training must be repeated and documented. All tasks performed by the employee since the last evaluation will be evaluated. If problems arise the data will be re-evaluated if possible or voided if they can not be re-evaluated.

Supervisory/professional staff have attained credentials through education, experience and periodic training seminars. Their work should be documented. Qualifications of all personnel must reside with the appropriate Co-P.I. and be updated annually. Training SOPs

Field Staff: QA-T-l .x, QA-T-2.x, UA-T-3 .x, UA-T-4.x

Laboratory Staff: UA-T-6.x, BCO-T-1 .x

Data Staff: UA-T-5.x

Specific SOPs as they pertain to the various project components are illustrated in Figures 1 through Figure 6. We have one SOP that specifically addresses interviewing technique (UA-T-l .x). If a manual for uniform questionnaire administration is developed we will append the manual to this SOP and require that administration of the Descriptive and Baseline questionnaires are performed according to the protocol for the Primary Respondent. (All other questionnaires are self-administered in the Border project. If a subject fails to complete the Follow-up questionnaire, then he or she is aided by the interviewer on the final home visit).

C. Completeness

The Border Study is designed as a comprehensive exposure assessment study. The following possible sources of error will be evaluated.

1. Survey Design, Once the grid is established and sampling units selected, areas must be

completely sampled from the PSU through the individual (see Figure 8) for each sequential PSU. If resources are insufficient a leastwise deletion of PSUs may occur (from the bottom up). If additional resources are forthcoming, the study can be expanded by accessing the subsequent PSUs on the list.

2. Field Collections. All questionnaires, samples and sample forms are to be collected and completed according to the SOPs at all participating houses. ALL information blanks on sample forms and questionnaires should be filled, If data are not collected because the medium is unavailable then that information is recorded *on* the sample form and coded into the data base. If collection is attempted and the item is unavailable or insufficient for analysis then the information is recorded and the house is completed for available aspects. Blood and urine will be requested, they will be permissible nonresponse items. Respondents have the right to refuse all or partial participation at any time. Minimal requirements for household completion are: (1) 75 % of the solicited Descriptive, Baseline and Follow-up questionnaires and (2) 75% of all environmental samples completed for the sampling stage. The completion status at each project stage and phase will be noted in the overall data collection/custody/sample-integrity/analysis tracking management system.

3. Laboratory Analysis. Data will be obtained for 90% of all samples analyzed. Field blanks, lab blanks, spiked and replicate samples will be collectively obtained for 10% of the samples. Initially (first 6 months) all 10% of these QA samples will be analyzed. The QA sample collection will be reduced to a collective 5%.

4. Data Management. Every field in the data base will be filled. If a procedure is not applicable, or data are missing or refused, then the field will be coded accordingly (UA-D-5.x). All batches of data will be appended to the master data bases. Missing data will be tracked and identified.

5. Analysis. The data will be analyzed according to appropriate SOPs (IIT-D-1.x through IIT-D-3.x) and a final report will be written and submitted to the EPA Project Officer.

D. Accuracy

1. Study Design. : Potential errors associated with the study design are discussed in section 1.

2. Field implementation.

a. Housing unit location: all houses will be located by latitude and longitude using GPS equipment. This is accurate within a few hundred meters. To preserve confidentiality the data will be encrypted.

b. Questionnaires: A random selection of 10% of all Descriptive questionnaires collected from each Arizona County will be readministered by phone and accuracy evaluated.

c. Field collection: All data labels will be preprinted bar-codes minimizing errors of identification and transcription. When possible field readings will be stored in a data logger and down-loaded instead of transcribed. Some records will be transcribed to make sure the data has been properly downloaded. When transcription is required, all critical values will be read by one technician and verified by another. QC checks are built into each field SOP.

d. Equipment will be calibrated in the field according to the specifics of each field procedure.

3. Laboratory Analysis:

a. Full QA will be practiced and documented throughout the project.

b. QC samples will be processed. Recovery of spikes will be greater than 50-150%, recovery of surrogate standards (NIST) will be greater than 80-120%. Variability of reference standards will be less than 25% (RSD). NIST NHEXAS standards will be employed if available for the Border project.

c. The laboratory will be asked to re-evaluate the outliers in terms of the QC samples collected and any laboratory spikes evaluated. If a possible error is evident from the QC samples, the sample will be reanalyzed if sufficient sample remains. If the sample can not be reanalyzed, it will be coded as void.

4. Data Management:

a. Data loggers will be down-loaded into prepared data base batches. Values will be compared with selected hand recorded field or lab observations to ensure that the batch was properly downloaded and then appended to the master database.

b. Questionnaires and forms will be set up for scanning, thereby limiting potential data entry errors.

c. Some data will have to be may need to be entered by hand.. These data will be entered, verified (100% re-entry), cleaned, validated and appended to the master data base. The re-entry step usually reduces data error to under 1%. Currently, all data is entered by scanning QC'ed coded forms into databases. Critical hand written fields are visually verified 100% of the time. Data are cleaned, validated and appended to master databases. Errors are consistently less than 1%.

d. Outliers will be checked for data accuracy. If a second value is obtained and both sample results are deemed valid, then a mean of the sample values will reside in the database. If one sample is invalidated, then the reasons for the invalidation error will be documented and the new value will be entered in the database.

E. Internal comparability of our study methods

When finalized, the collection methods and the data management system will remain the same throughout the study. Any unanticipated changes will require a side-by-side methods comparison. If a collection method change occurs, the data will be placed in different master databases. These can be copied and combined for analysis, but the database structure will reflect the field or laboratory procedure used. We are employing both non-intensive and intensive methods within our study stages.

1. Metals: Air, Soil and Dust

We will use a SPECTRACE 9000 XRF for the chemical analysis of particulate matter captured on filters ($PM_{2.5\&10}$), soils and house dust. We can obtain results for all of our target metals. This method will be used on ALL air, soil and dust samples collected. The method is non-destructive. 10% of these samples will be sent to Battelle as method QA analysis using AAS and ICAP-AES analysis.

Our goal with the XRF is to identify the distribution of contaminant using the same methods as the NHEXAS project so we can compare distributions. XRF analysis enables us to maximize our sample numbers while minimizing costs.

2. Pesticides: Dust

We will use GC/ECD to identify target pesticides in stage 3 samples of the Border Study. Our goal with the method is to provide some pesticide information comparable to that collected in NHEXAS so we can compare distributions between the State and Border area. GC/ECD analysis enables us to maximize our sample numbers while minimizing costs.

3. VOCs

During Stage 3, passive VOC badges will be placed inside all homes. In Santa Cruz County they will also be placed outside the homes. The badges will be analyzed using GC/FID techniques. We will also sample Stage 3 homes using actively-pumped multisorbent tubes. The tubes will be analyzed using a thermal desorption GC-MS technique.

4. PAHs

We are involved in a special study to evaluate the real-time PAH monitor developed by Nancy Wilson as a grab sampler. Results will be compared with active PAH collection and residues found in carpets and other media representing periods of longer duration. This is not a validation study, but rather evaluation of a less costly approach to determine whether the sampler is sensitive enough to indicate high end exposures in home environments.

To meet the project goals, we must compare data sets generated by the NHEXAS Project and the border study. Where available we will employ the same NIST solutions provided for the NHEXAS study to facilitate this cross comparison.

F. Precision (Minimum Detection Limits)

These are covered in Tables S-10. Precision is important for defining the distribution function. Precision is a critical consideration when an analysis is performed on readings with different levels of precision. Then, a simple analysis can only be as precise as the least precise measure. In more complex analyses weighted factors can be used to get around this constraint to some degree.

G. Documentation.

Every aspect of the study will be documented to make it verifiable in terms of design, field collection, laboratory analysis and data evaluation.

3.1.3 Types of Samples Required

Up to four classes of samples will be obtained from each sample site (household):

A. Questionnaires and Diaries: Subjects will be asked to respond to written and verbal questions.

B. Environmental samples: Dust, soil, air and household water samples will be collected at homes.

C. Food and (possibly Beverage if finds are available) Samples: For a subset of the recruited subjects, duplicate diet samples will be collected for a 24 hour period. These will include duplicate portions of all food and beverages ingested by a person on a day specified with the respondent and field team collecting the samples. Each food type will be collected in its own sample bag and cornposited upon return to the laboratory. Beverages will be collected as a separate composite in a single container. Beverages include any food that is in a liquid phase at room temperature.

D. Tissue and Body Fluid Samples: Each subject will be asked to provide blood, urine and hair samples during the sampling period.

3.1.4 Collection Media Criteria

A. Air: Outdoor air will not be evaluated in the Stage 2 homes. In Stage 3, indoor and outdoor (100%) air will be collected and analyzed for $PM_{2.5\&10}$ and metals by XRF; "real-time PAH measures and passive VOC s will also be evaluated in all Stage 3 homes. Pesticides will be sampled exclusively from indoor environments. Active collections of PAHs and VOCs will occur in a percentage of homes as funds permit. Indoor air will be sampled in the main room. The volume of air sampled will depend on the collection time, and the flow rate of the pump.

The proposed procedures will collect the volumes of air described in Table 12. Outdoor air will be sampled on the north side of the residence at the same rate and duration as indoor air.

Table 12. Projected volume of air collected by active samplers. The sampling schedule for the intermittent samplers is outlined in the appropriate SOPs.

Sampler	Compound Class	Flow Rate	Duration of Sample Collection	Volume of Air Sampled (m3)
Harvard PM_{10}	Metals	4 L/min	0.50 (168 hours)	20.16
Harvard $PM_{2.5}$	Metals	4 L/min	0.50 (168 hours)	20.16
Sorbent&2XAD	Pesticides	4 L/min	0.40 (48 hours)	4.60
Active VOC (Multisorbent Carbo trap)	v o c	5-10 ml/min	0.333 (24 hours)	0.0038
Active PAH	PAH	4 L/min	0.40 (48 hours)	4.60

B. Dust: Samples will be collected from carpets inside subject homes during Stages 2 & 3. Surface dust will be collected in all Stage 3 homes.

C. Soil: In Stages 2 & 3, soil will be collected outside the homes of subjects as a composite of soil
from all sides of the home; subsamples will be collected to a depth of 1" (2.5 cm).

D. Water: Up to two water sources will be sampled from all Stage 3. These are collected from the kitchen faucet and any treated or independent drinking water source. For NHEXAS we estimate that 50% of the homes have drinking water sources other than tap water and that values appeared **accurate.** In the Border region the numbers may be greater. We will sample alternate drinking water sources up to 50% of the Stage 3 homes. If additional funds become available samples will be collected to that funding level.

E. Food (and possibly) Beverage: The Stage 3 primary respondent will save samples of all foods and beverage consumed during a 24 hour time period.

F. Subject's Body: Dermal wipes will be collected for metals and pesticides from the primary respondents. Hair, blood and urine samples will be requested from all primary respondents participating in Stage 3.

G. An aliquot of any subject identified pesticide of unknown composition will be collected and stored for future analysis at the request of OMB.

H. Target pollutant classes analyzed for each the media are listed in Table 13.

Table 13. Sampling Media for the Pollutant Classes:

Sample/Medium		Pollutant Class			
		Metals	Pesticides	VOCs	PAHs
Air	Indoor	X	X	X	X
	Outdoor	X			X
Dust:	Carpet/Floor	X	X		X
	Surface	X			
	Dermal	X	X		
Soil:	Composite	X	-		X
*Water:	Kitchen tap	X	X	X	
	Drinking	X	X	X	
*Biological:	Hair (curate only for eventual metals analysis)				
	Blood	X	X	X	-
	Urine	X	X		
*Food(Beverage?) 1 -day dupl.		X	X		

* Collection only - Analysis through IAGs or EPA Contracts

3.1.5 Pre-assessment for Field Implementation of the Border Study.

The Border study employs the NHEXAS Questionnaires, the NHEXAS field, analysis and data protocols and parallels NHEXAS as part of the Study design in every possible way. Added protocols including, $PM_{2.5}$, PAH monitoring, USGS sampler placement and collection, collection of hair samples, and collection of unknown pesticides require the addition of one field team member to a home. These procedures can be readily incorporated into the collection strategy followed in NHEXAS. Field trials will occur in July of 1997 and adjustments made as needed. Because the procedure is 85% similar we anticipate few problems.

RTI evaluated the Questionnaire for the NHEXAS study. However, Spanish is widely spoken in Arizona so we have special needs. The draft questionnaire was translated into grammatically correct colloquial Arizona Border Spanish that will be used in the Border Study.

Meanwhile, all previously used equipment is being examined and tested for conformance with operating standards. If any fail to function properly, they will be repaired to specifications (Harvard $PM_{2.5\&10}$, VOC pumps, SKC personal air monitors, vacuum cleaners, particle collectors and GPS recorders). These air, dust and soil samples are typical of samples we expect to encounter throughout Arizona. SOPs written for operation of the older equipment are being re-evaluated and upgraded.

Vast amounts of data will be collected. Our current LAN can accommodate the incoming data. We have identified the "key" and important variables that should be associated with each type of sample and are treating a "tracking" data system (Figure 9). All data, data custody, shipment, integrity, status and archiving issues will be tracked through this system. Battelle Keeps a parallel system and the two systems are reconciled routinely (not less than once in 6 months).

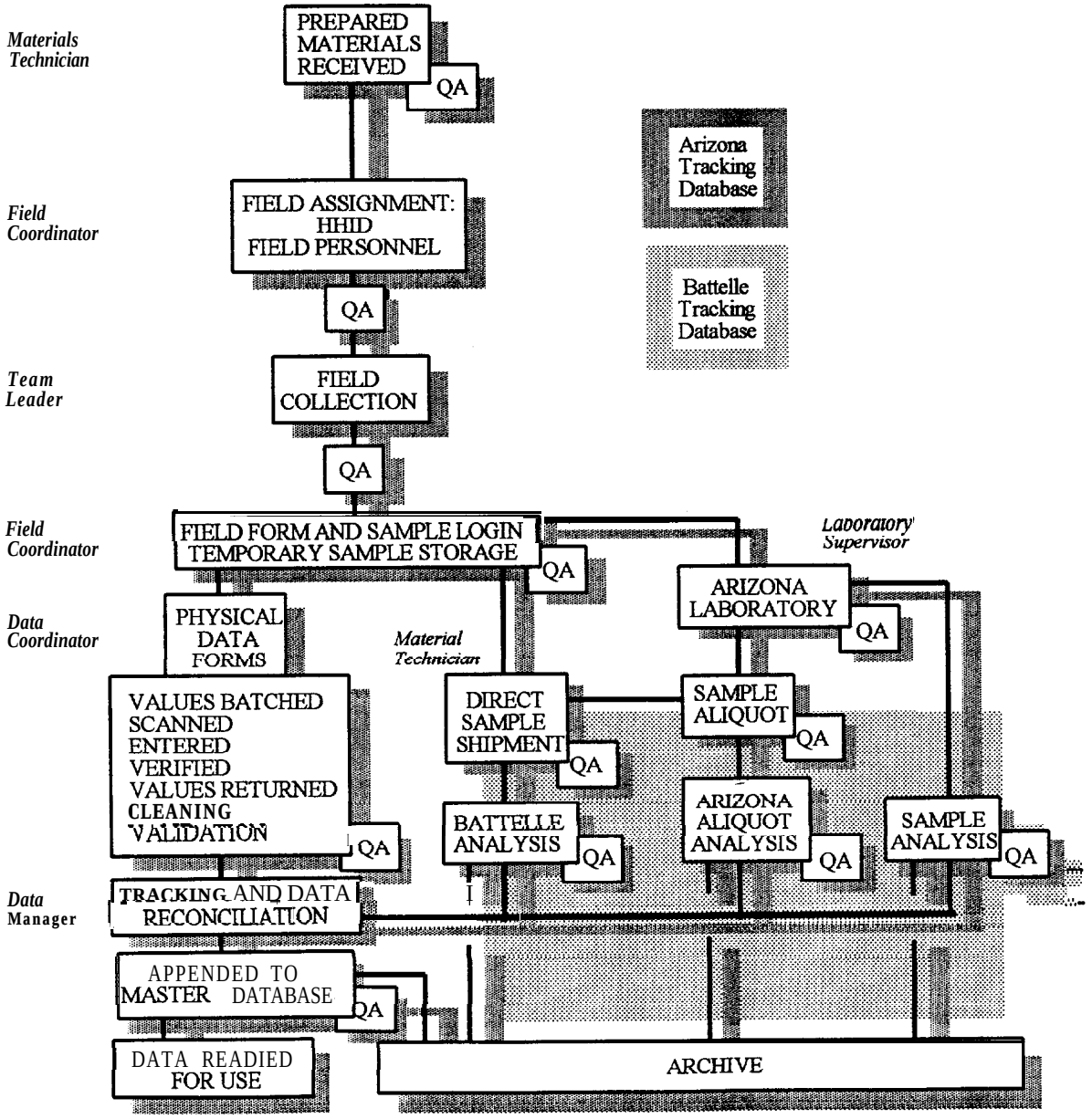
The field, lab and data teams are working together and have evaluated all field forms to be used (performed for NHEXAS). Data shells and dictionaries built for NHEXAS will be employed in the Border Project. Battelle has tested all the materials planned for field use. None of the materials we have used to date appear to contaminate our samples. This is based on evaluations of materials prior to NHEXAS implementation and the non-detects recorded for NHEXAS field collections. Use of bar-codes, sample handling procedures, and scanable forms tested prior to the initiation of NHEXAS and found to be reliable throughout the NHEXAS Project will be used in the Border Study. Prior to entry in the field we mail or deliver an introductory letter to the homes we will contact. All phases of the field operation have been extensively examined and refined in the NHEXAS study (Lebowitz et al., 1995). If any substantive changes to protocols are needed, they will be documented and resubmitted as necessary.

3.1.6 Sampling Time and Frequency

A. General Strategy:

Housing units identified in the sampling design will be sent a letter of introduction (mailed or delivered by hand) followed by a field interview within one week (see section 1.7.3). This letter is

Figure 9. Diagrammatic of the NHEXAS Arizona Project and Data Tracking components.



sent to potential respondents living on an identified "block: and addressed to "Current Resident". The letter defines the project in broad terms and provides respondents with time to consider possible participation. This approach is consistent with obtaining the necessary "informed consent" of the study respondents.

The sampling period will be defined in terms of person weeks. Some measurements will be weekly; others will be collected for shorter periods and weighted to represent a week. Certain techniques represent a "point in time" (pit) sample related to an area (e.g. surface and dermal samples. All data will be presentable in terms of person weeks through direct measurements or a weighting factor applied to lesser measurements. The sampling schedule is designed to permit sample completion in 12 months from onset.

B. Specifics:

Specific operational durations are outlined in the appropriate field protocol. Projected duration of sampling within the field is illustrated in Figures 10-14. Sampling equipment to be used and duration of use are presented in Tables 14-15.

Figure 10 identifies the various implementation stages relative to the questionnaire and provides estimates of respondent burden. Figure 11 illustrates the total technician time needed in each home. The number of technicians can be increased to keep the respondent "contact" hours to a minimum. Figure 12 illustrates time lines for collection implementation in Stages 1 and 2. Figures 13 and 14 illustrates collection scenarios for Stage 3.

3.1.7 Sample Collection

An overview of sample numbers and analysis methods are included in Table 14. Specific aspects of sample collection are outlined in the Field SOP(s) (See Field SOP Volume #2).

Repeated/replicate or same sample splits will be obtained in a random 10% of all homes sampled. All samples will be treated precisely the same and results should be similar. The degree of similarity will be sample type dependent. Some samples will vary by as little as 5% and other samples will vary by as much as 50%. Tolerance limits will be defined in the appropriate Laboratory SOPs. Over the first 6 months all 10% of the QC samples will be analyzed. Once personnel are experienced on this project, the analysis will be reduced by half and the remaining samples will be archived unless problems arise.

3.1.8 Sample Handling

Samples must be handled to preserve identity and integrity. All samples will be appropriately labeled in the field. Prior to leaving the field the team leader will take a sample inventory. All labels will be checked and samples will be transported and stored in accordance with

Figure 10. Study Stages and Questionnaire (Q) Collection burden. N equals the Field Stage estimates of number of completed questionnaires and the time (per individual respondent) required to complete them.

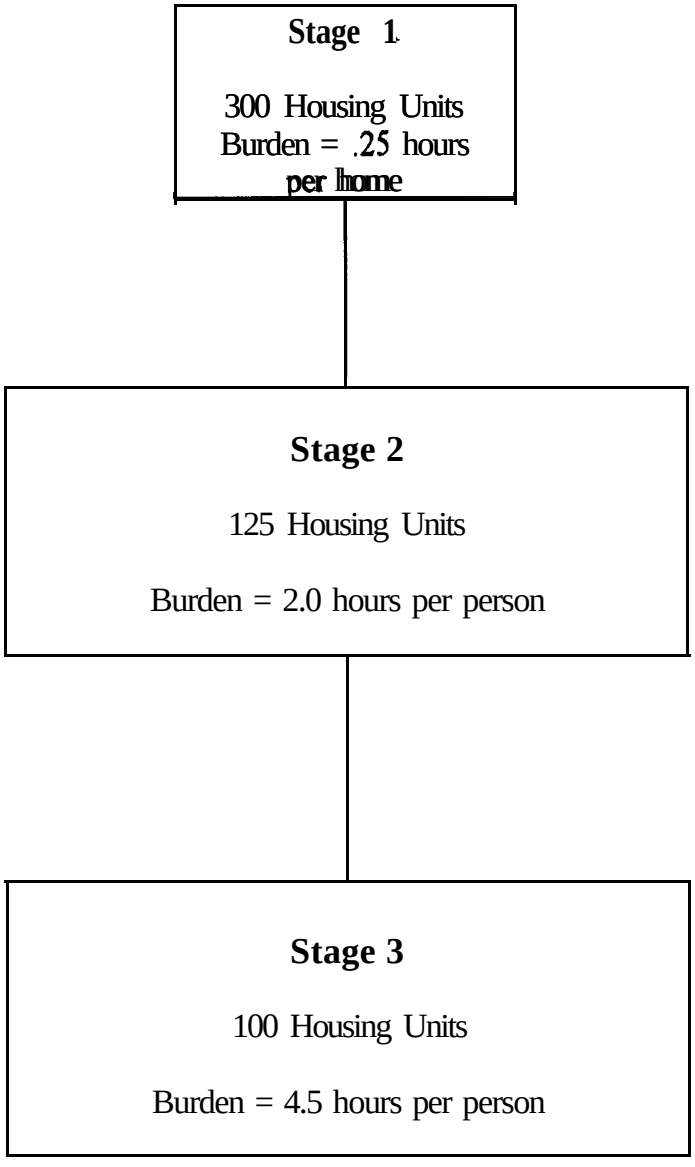


Figure **11.** Study Field Stages **(F)** and Technician Task Completion burden. N equals the number of households a Field team will visit and the time expenditure required to sample the household.

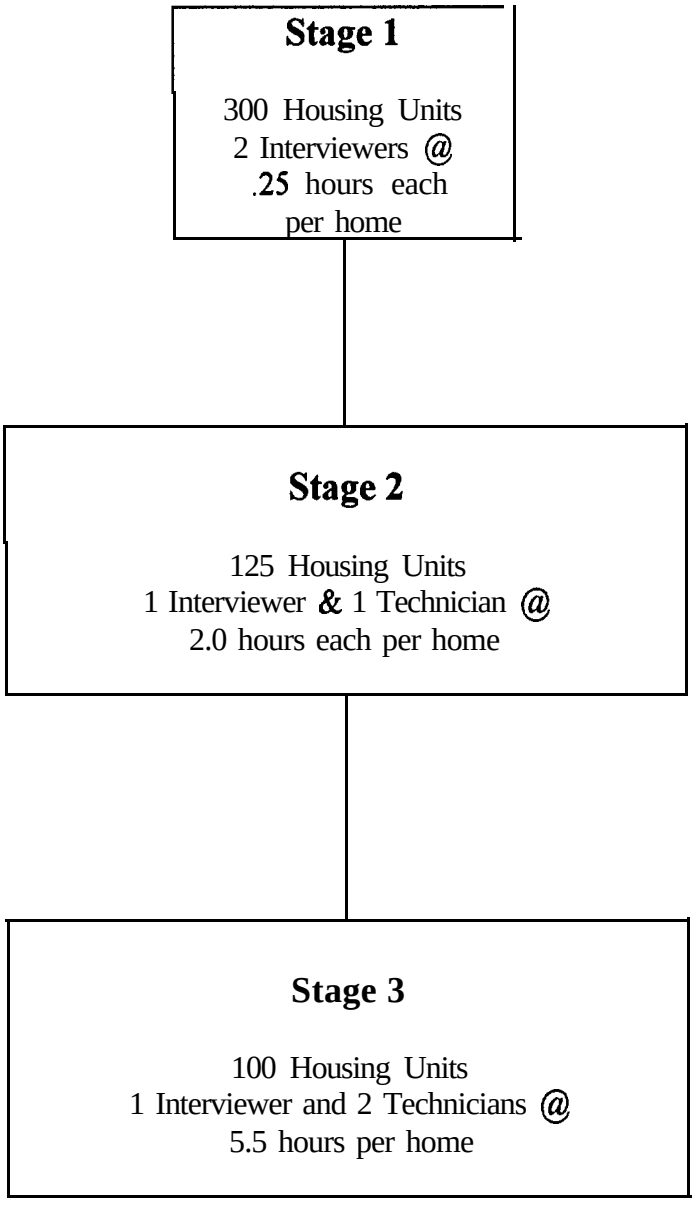


Figure 12. Time lines and information collected in Stages 1 & 2.

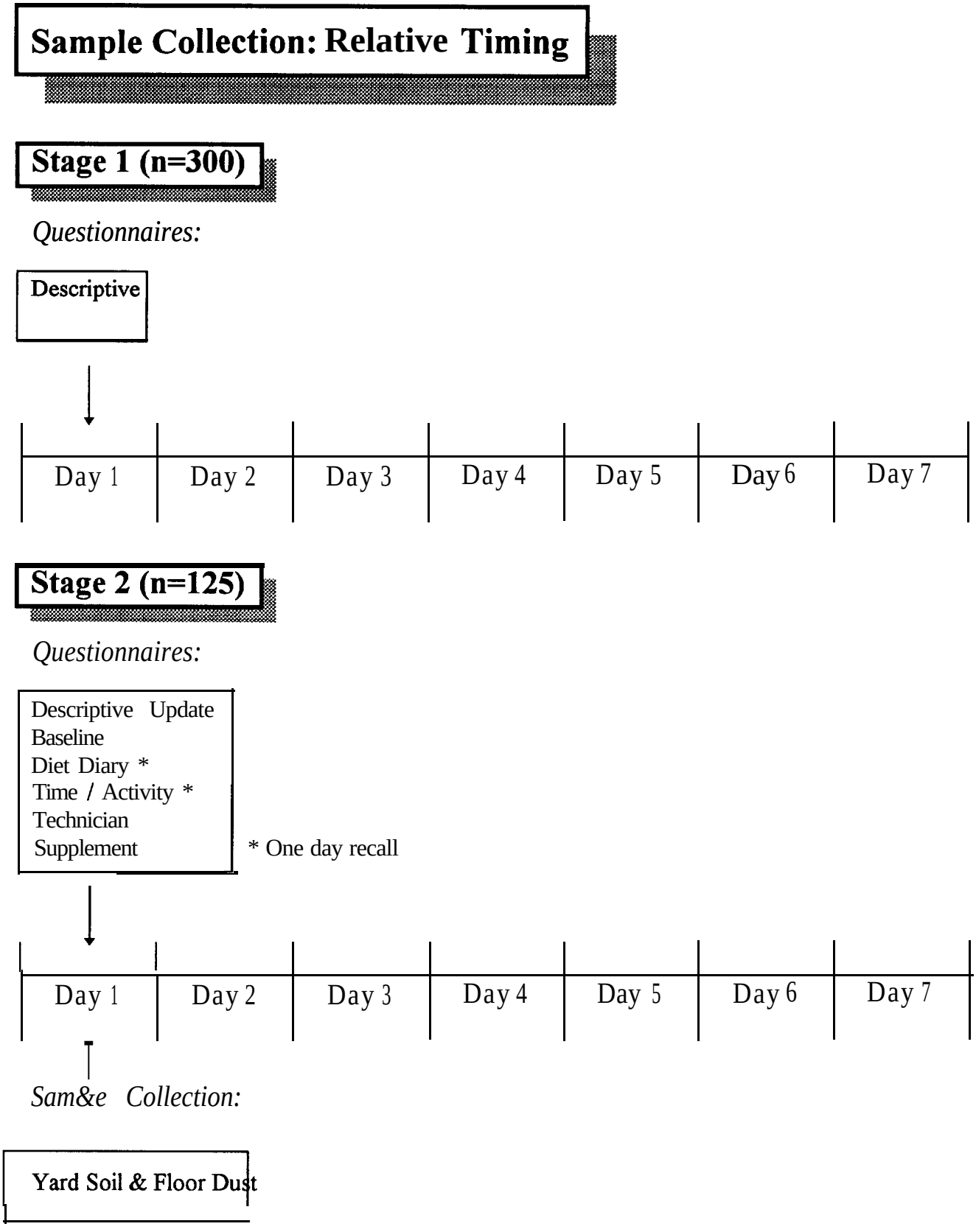


Table 14. Specific Equipment and operation parameters used in Residential Sampling (Stages 2); I = Indoor, 0 = Outdoor, M = Metals, P = Pesticides, PIT = Point in Time Collection.

STAGE 2 (Households evaluated = 125)

INITIAL VISIT (Interviewer + 1 Technician)	Collection Interval	Comments
Vacuum Carpets	(I, M)	PIT
Composite Soil	(0, M)	PIT

Questionnaire Collection
Baseline Questionnaire and Border supplement
Technician Questionnaire
Food Diary-l-day recall
Time/Activity-l-day recall (plus l-day typical weekday; l-day typical weekend; these data will be put in a separate database)

specifications outlined in each Field SOP. In general, sample handling is target pollutant dependent. Filter samples collected for metals analysis are robust, requiring little special treatment. Samples collected for pesticides are semi-stable. Pesticides volatilize. Samples should be kept cold and shipped for analysis within 7 days of collection. VOCs are very volatile and must be kept cold and shipped within a week. Water and food samples must be pretreated and shipped quickly. Serum samples are wrapped in bubble wrap and kept cold at all times; urine samples must be frozen, and shipped on dry ice.

In general, field and laboratory blanks will accompany a random 10% of all homes sampled. Field blanks will be handled in precisely the same manner as field samples. Evaluation of field and lab blanks should not vary from the initial QA measures of the product by more than 10%.

Specific sampling, handling, and shipping requirements are outlined in each of the appropriate Field SOPs (UA-F-3.x through UA-F-26.x). Data flow and control is also illustrated in Figures 15 - 22 for each media collected. The custody is transferred as the data moves from sample to sample. As is evident from these Figures, all samples will be shipped within 7 days.

Stage 3 Sampling can be effected in two ways depending on the availability of resources and time. The 3 visit household scenario ensures greater control over the samplers and sample integrity. When sampling over great distances we do not always have this luxury. In the two visit scenario, we have instituted two household phone call follow-ups and a responsible adult in the household turns off samplers, places the sample in the provided container, and refrigerates the sample. This approach has been utilized with success in selected NHEXAS homes. The action is taken while the field team leader waits on the phone and the collection record is documented by the team leader. Where pumps are involved, the pump is turned off by the subject. On return to the home the pump is restarted by the technician, allowed to stabilize and a record is made of the final flow reading prior to sampler disassembly. These scenario's are diagrammed in Figures 13 and 14.

3.1.9 Sample Custody

At the time of field collection, a sample custody form is completed for each sample. Figures 15-22 illustrate the sample flow through the project and predicted points of custody exchange. The original custody form remains with each sample until it is fully expended. Copies of the custody form are retained by each individual who passes the sample to another person or entity. Aspects of sample and data custody are covered in field and data SOPs. Overall issues of sample custody are addressed in eight separate Custody SOPs (UA-C-1.x through UA-C-8.x).

3.1.10 Sample Preparation

Samples will be prepared in accordance with written Standard Operating Procedures developed for the laboratory evaluation of each sample type. (See Laboratory SOPs; Volume III).

Figure 13. Time lines and information collected in Stages 3 (Three visit Scenario).

Sample Collection: Relative Timing

Stage 3 (n=100)

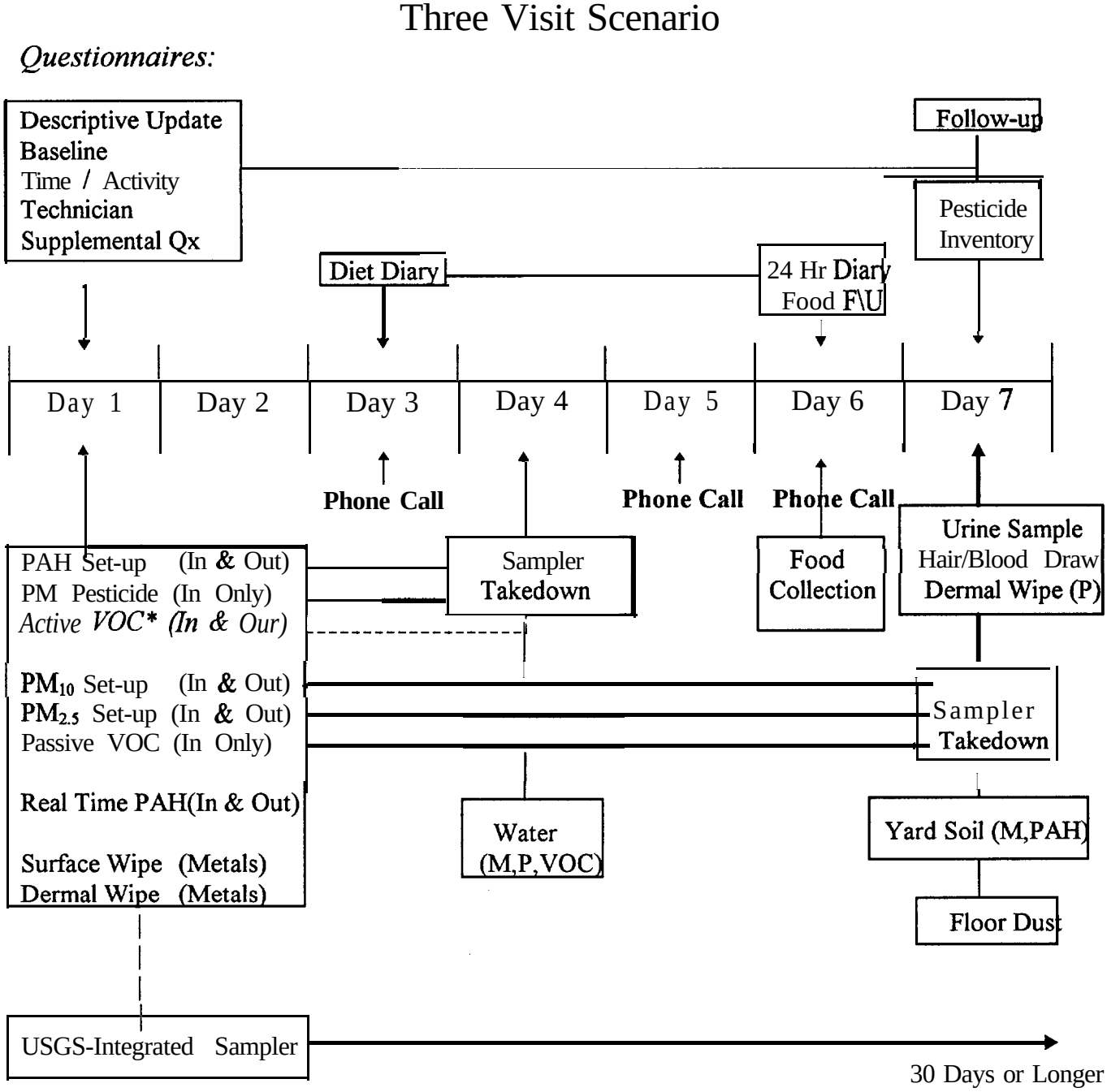


Table 15. Specific Equipment and operation parameters used in Residential Sampling (Stages 3-Three visit Scenario); I = Indoor, 0 = Outdoor, M = Metals, P = Pesticides, PIT = Point in Time Collection.

STAGE 3 (Households evaluated =100 ; Three-day Collection Scenario)
(Performed with 1 interviewer and 3 technicians)

INITIAL VISIT	Collection Interval	Comments
Dual Head Harvard Sampler($PM_{2.5\&10}$)	(I,O,M)	7-day integrated
SKC Pump & URG Head Sorbent and 2XAD	(I, P, PAH)	24 or 48 hour integrated
SKC Pump & URG Head Sorbent and 2XAD	(O, PAH)	24 or 48 hour integrated
Real-Time PAH	(I,O)	1 hour integrated PIT, I & 0
Passive VOC badges	(I)	7-day integrated
Active VOC Sampler (n = 25 homes)	(I,O)	1 -day integrated (deploy)
Surface Wipe	(I, M, P)	PIT
Dermal Wipe	(M)	PIT

Follow-up Phone Call (Day 3): Remind Subject of visit on Day 4.

Mid-Week Follow-up		
Water Sample(s)		PIT
SKC Pump & URG Head Sorbent and 2XAD	(I, P, PAH & o-PAH)	Collection of
Active VOC Sampler	(I,O)	Collection of

Follow-up Phone Call (Day 5): Remind subject of Food/Bev? Collection on Day 6

Follow-up Phone Call (Day 6): Remind subject of Urine Collection on the Morning of Day 7

Concluding Visit:		
Food Collection (Beverage)		1 -day Composite
Urine Sample		Morning Void Post Food Collection
Dual Head Harvard Sampler		Collection of
Passive VOC badges		Collection of
Blood Draw & Hair		Supplemental Med-Tech or Nurse
Dermal Sample	(P)	PIT
Vacuum Carpets	(I, P, PAH, M)	PIT (Follows Collection of Badges)
Composite Soil	(O, P, PAH,M)	PIT

Figure 14. Time lines and information collected in Stages 3 (Two visit Scenario).

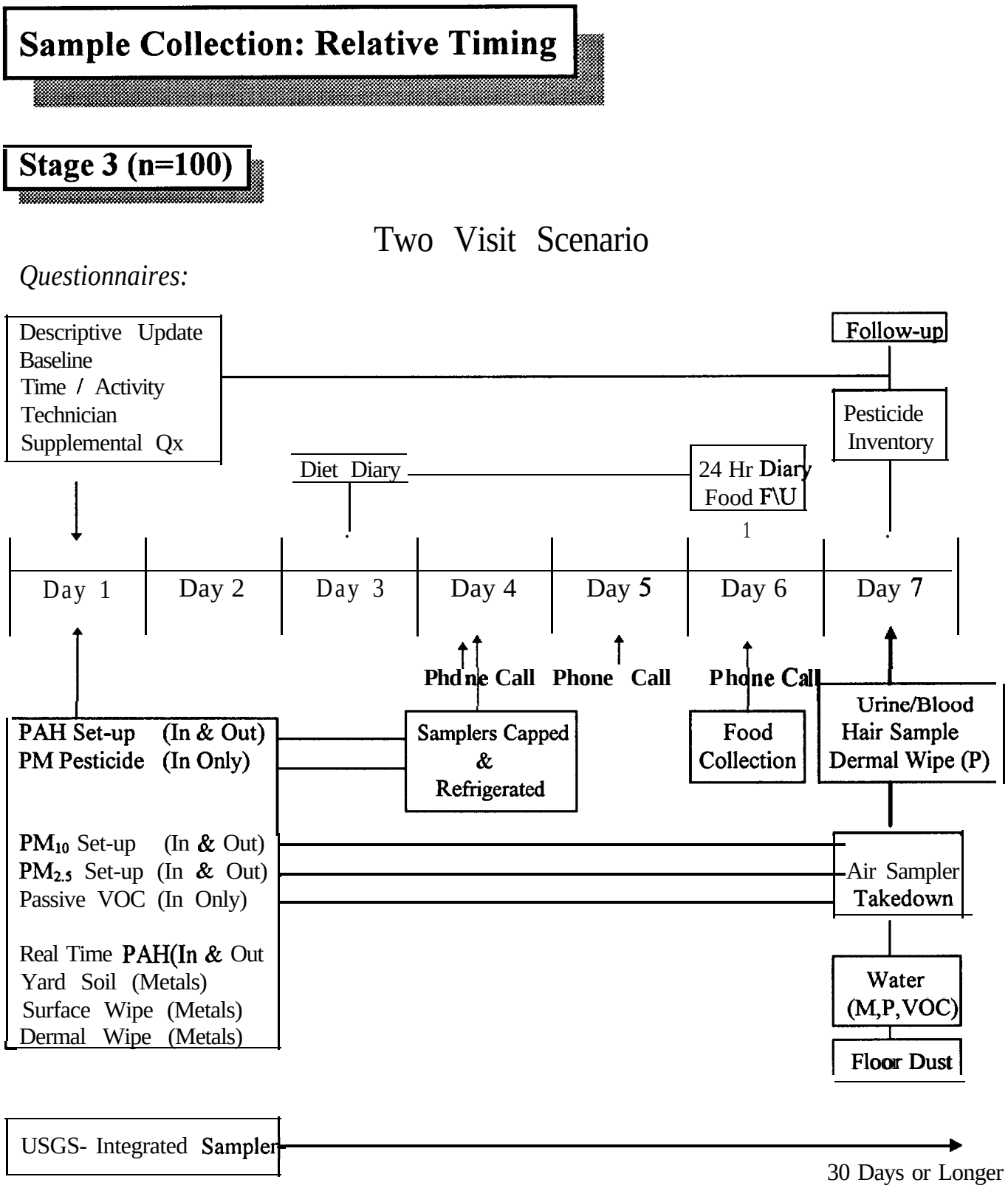


Table 16. Specific Equipment and operation parameters used in Residential Sampling (Stages 3—Two visit Scenario); I = Indoor, 0 = Outdoor, M = Metals, P = Pesticides, PIT = Point in Time Collection.

STAGE 3 (Households evaluated =100 ; Three-day Collection Scenario)
(Performed with 1 interviewer and 3 technicians)

INITIAL VISIT	Collection Interval	Comments
Dual Head Harvard Sampler($PM_{2.5\&10}$)	(I,O,M)	7-day integrated
SKC Pump & URG Head Sorbent and 2XAD	(I, P, PAH)	24 or 48 hour integrated
SKC Pump & URG Head Sorbent and 2XAD	(O, PAH)	24 or 48 hour integrated
Dermal Sample	(M)	PIT
Surface Dust	(I, M, P)	PIT
Composite Soil	(O, P, PAH,M)	PIT
Real-Time PAH	(I,O)	1 hour integrated PIT, I & 0
Passive VOC badges	(I,O)	7-day integrated

Follow-up Phone Call (Day 4): Subject instructed to unplug the Active Pesticide/PAH samplers and place the sampling heads in the container provided and put them in the refrigerator. The technician remains on the phone while this activity occurs. The technician verifies that there were no problems or records any problems encountered.

Follow-up Phone Call (Day 5):The subject is reminded to collect all food on the following day and keep it refrigerated in the containers provided. The technician verifies that the time activity diary is being kept and that there are no problems.

Follow-up Phone Call (Day 6): The technician verifies that all food was collected during the day and has been placed in the refrigerator in the provided containers. The subject is reminded to collect the first morning urine void on the following morning and place the container in the freezer immediately.

Concluding Visit:

Dual Head Harvard Sampler		Collection of
Passive VOC badges		Collection of
Dermal Sample	(P)	PIT
Blood Draw & Hair		Supplemental Med-Tech or Nurse
Vacuum Carpets	(I, P, PAH, M)	PIT Following Collection of Badges
Water Sample(s)	(M, P, VOC)	PIT

Table 17. Summary of samples collected for each medium in each stage .

Sample Designation	Location of Medium	Sampler Type Active/Passive	Contaminant	No. of Homes Stage 2 125	Stage 3 100
Air	Indoor	Active	Metals		100
		Active	Pesticides		100
		Active	VOCs		25
		Passive	VOCs		100
		Active	PAH		100
		Active	Real Time PAH		100
	Outdoor	Active	Metals		100
		Active	VOCs		25
		Active	PAH		100
		Active	Real Time PAH		100
Dust	Carpet/Floors	Vacuum	Metals	125	100
		Vacuum	Pesticide		100
		Vacuum	PAH		100
	Dermal	Wipe	Metal		100
		Wipe	Pesticides		100
	Surface	Wine	Metal		100
Soil	Composite	Grab	Metal	125	100
			PAH		100
Water	Tap	Flush	Metal		100
			Pesticide		100
			VOC		100
	Drinking	As Stored	Metal		50
			Pesticide		50
			VOC		50
Food/Bev?	Duplicate Diet	24-hour	Metals		100
			Pesticide		100
Biologicals	Blood	Venous	Metals (Pb, Cd)		100
			Pesticides (OC)		100
			VOCs		100
	Urine	Morning Void	Metals		100
			Pesticides		100
	Hair	Nape of Neck	Metal (Hg)		optional
Questionnaire*					
	Descriptive			125+	100
	Baseline			125+	100
	Supplement			125+	100
	Technician			125+	100
	Time Activity	1-day recall +		125+	
	Time Activity	Sampling week			100
	Food Diary	1 -day recall		125+	
	Food Diary	4 sample days			100
	Follow up	Sample week			100

*Numbers represent homes; on average 3 people per home will complete questionnaires.

Figure 15. Handling of Soil Composites.

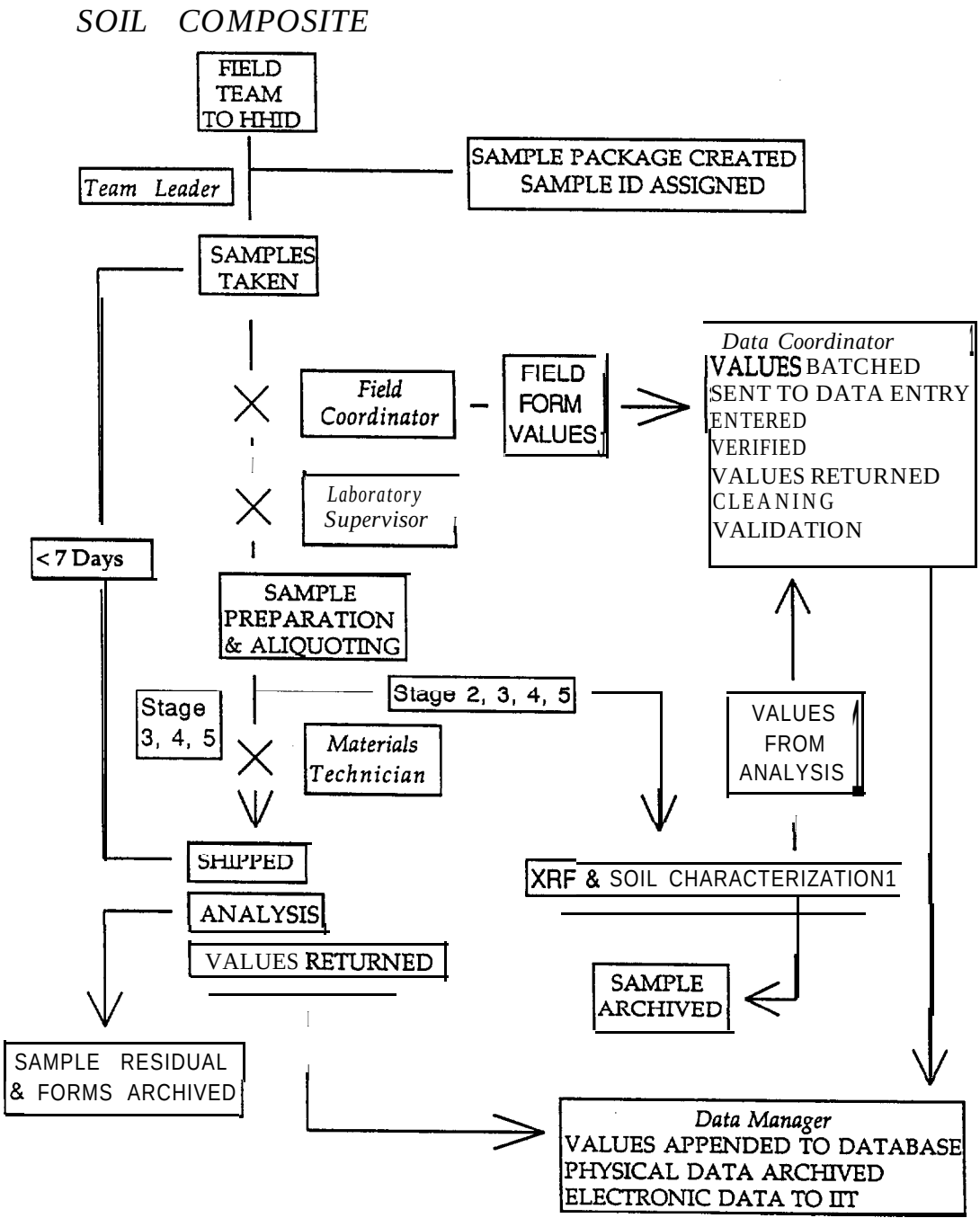


Figure 16. Handling of dust samples from floors collected using a vacuum cleaner.

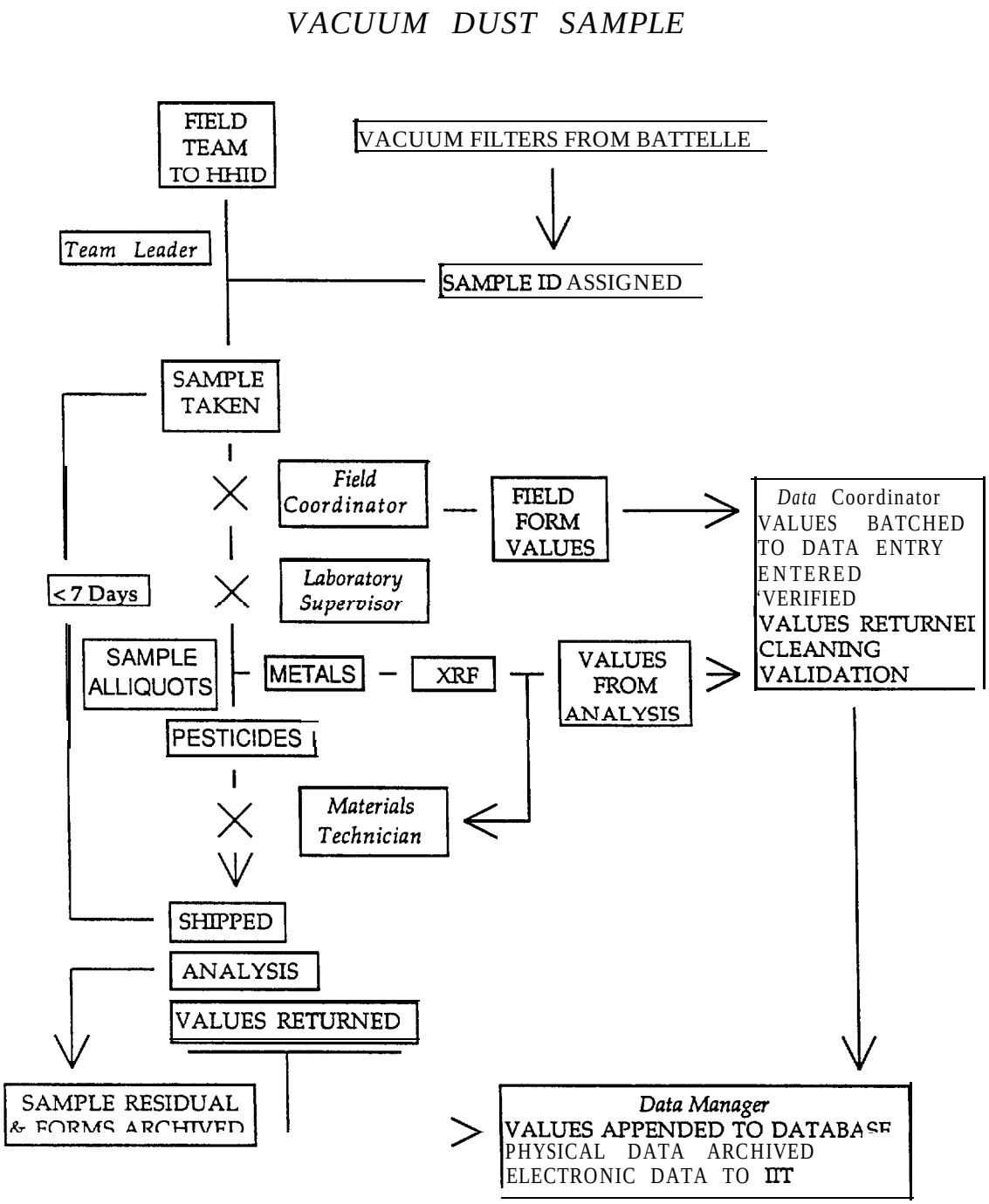


Figure 17. Handling of particulate from the pumped air samplers. (Harvard $PM_{2.5\&10}$, pesticide and active PAH samples).

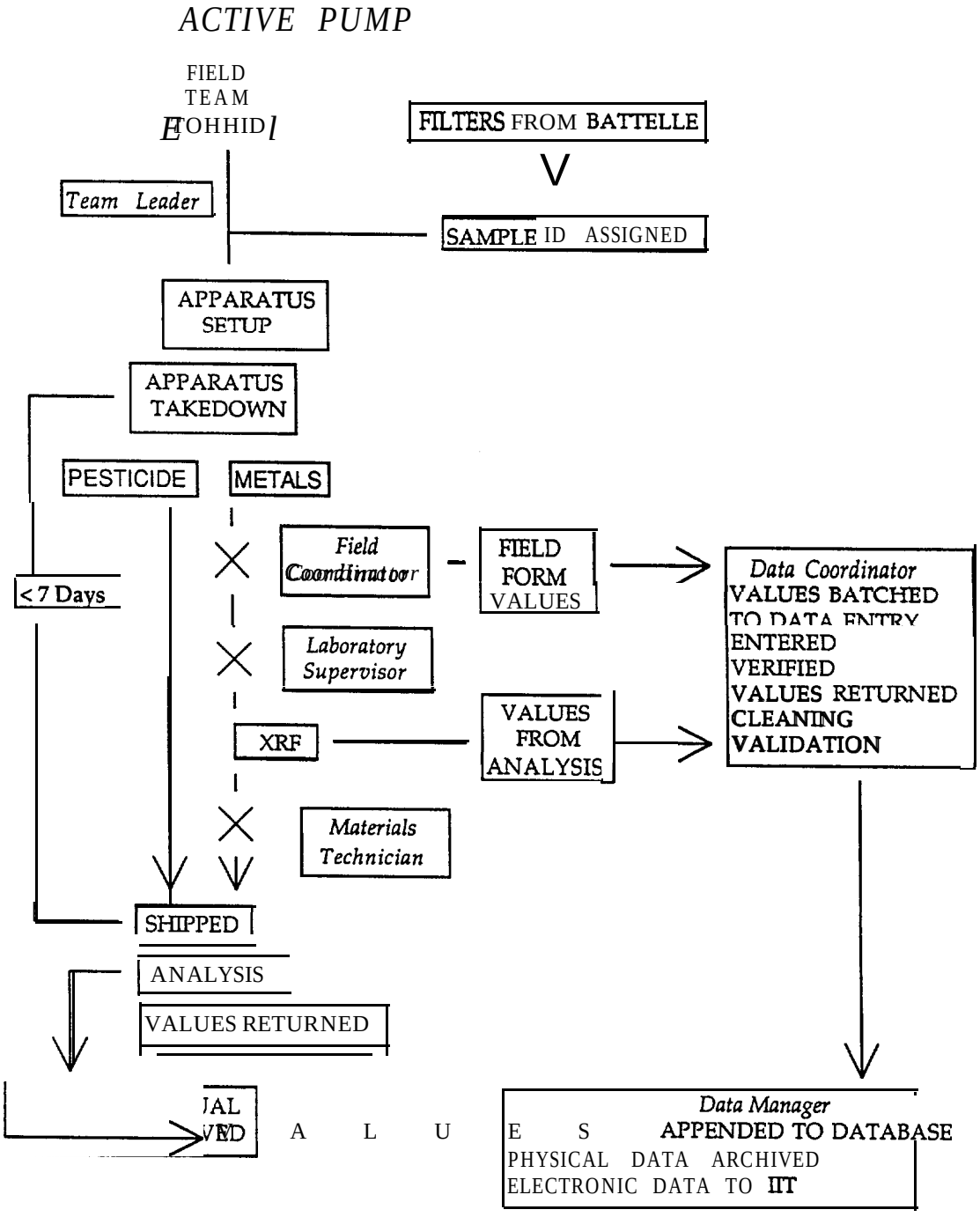


Figure 18. Handling of all VOC samples (active and passive).

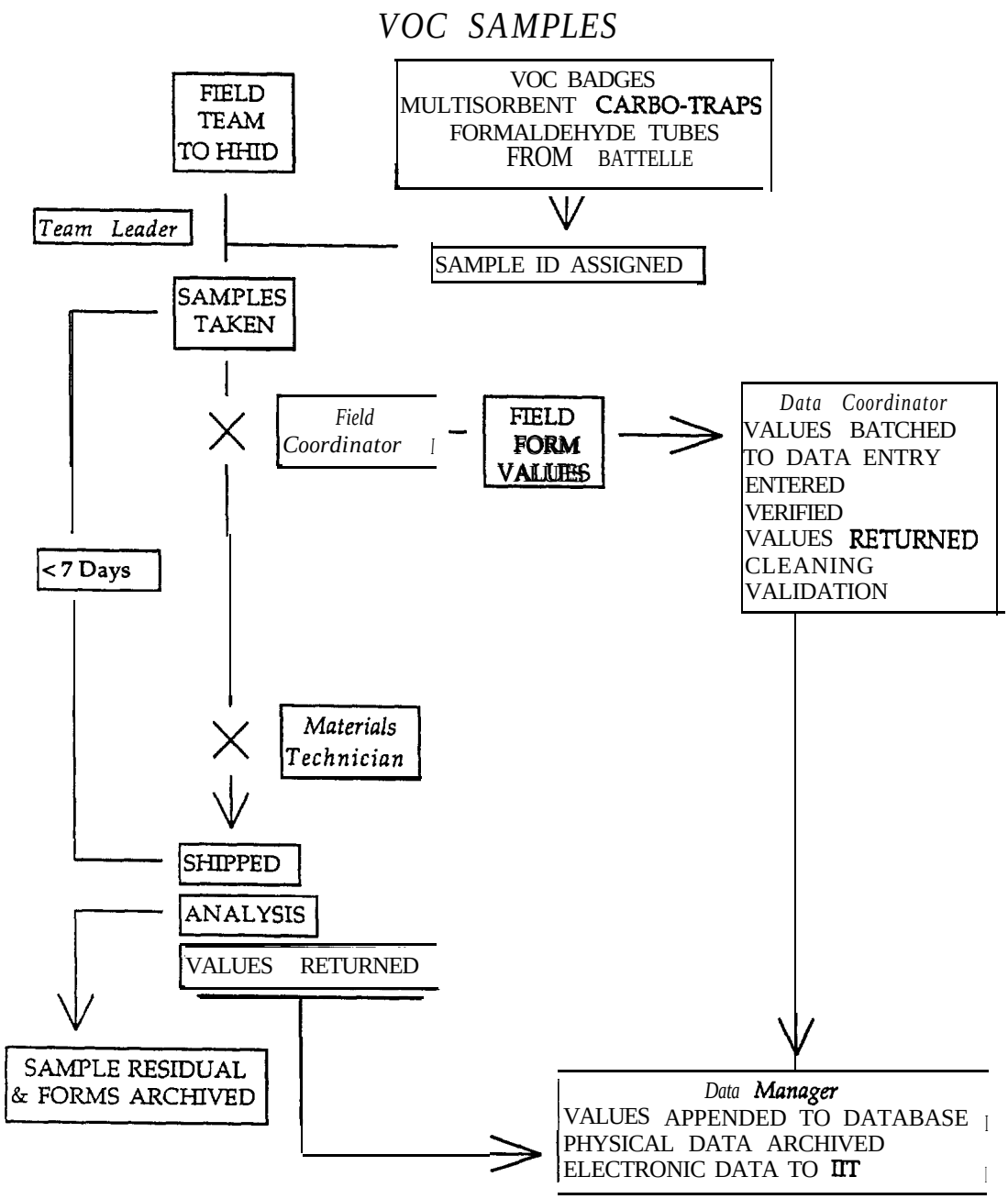


Figure 19. Handling Wipe Samples (Dermal and Sill).

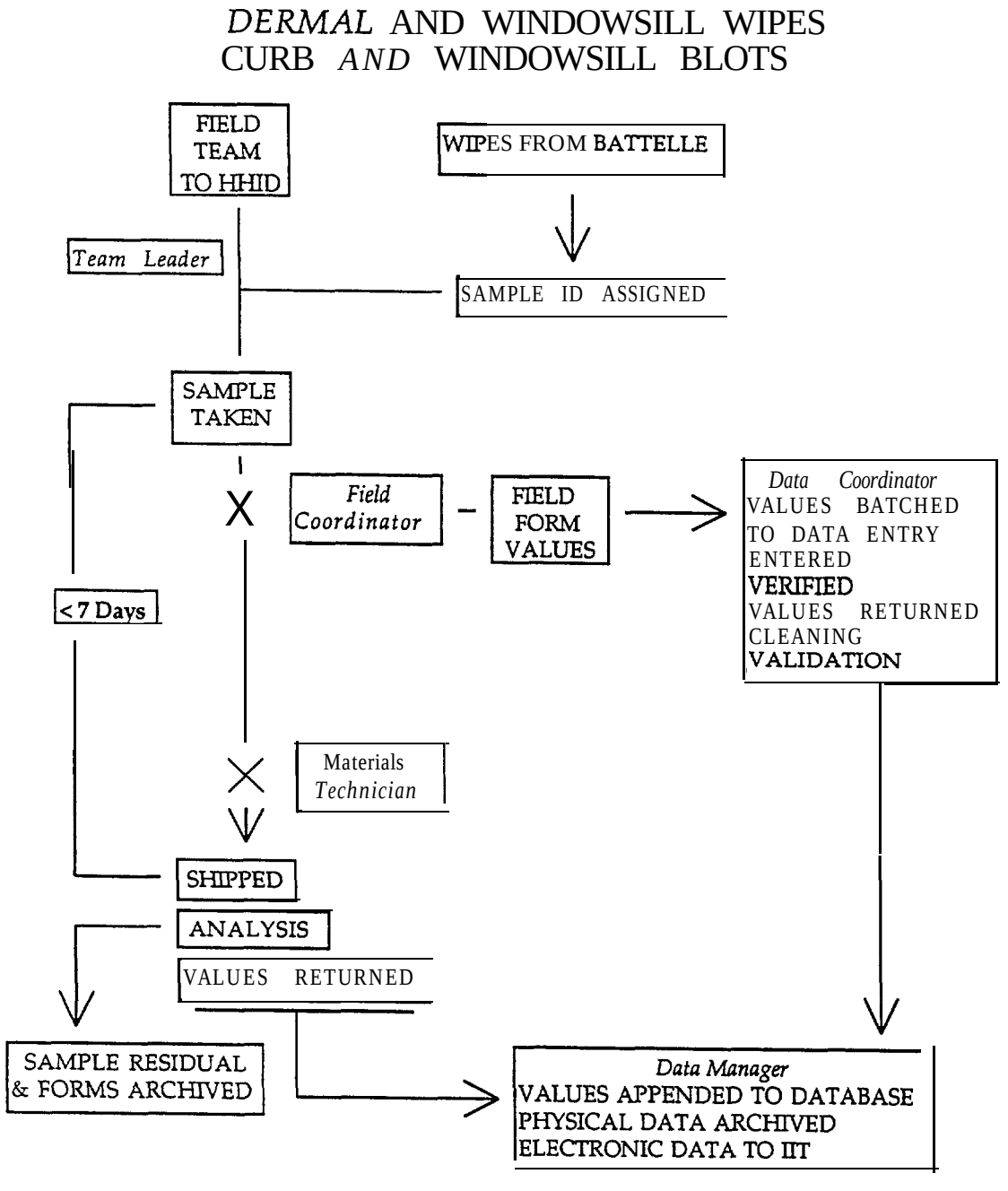


Figure 20. Handling Food (and possible Beverage) Samples.

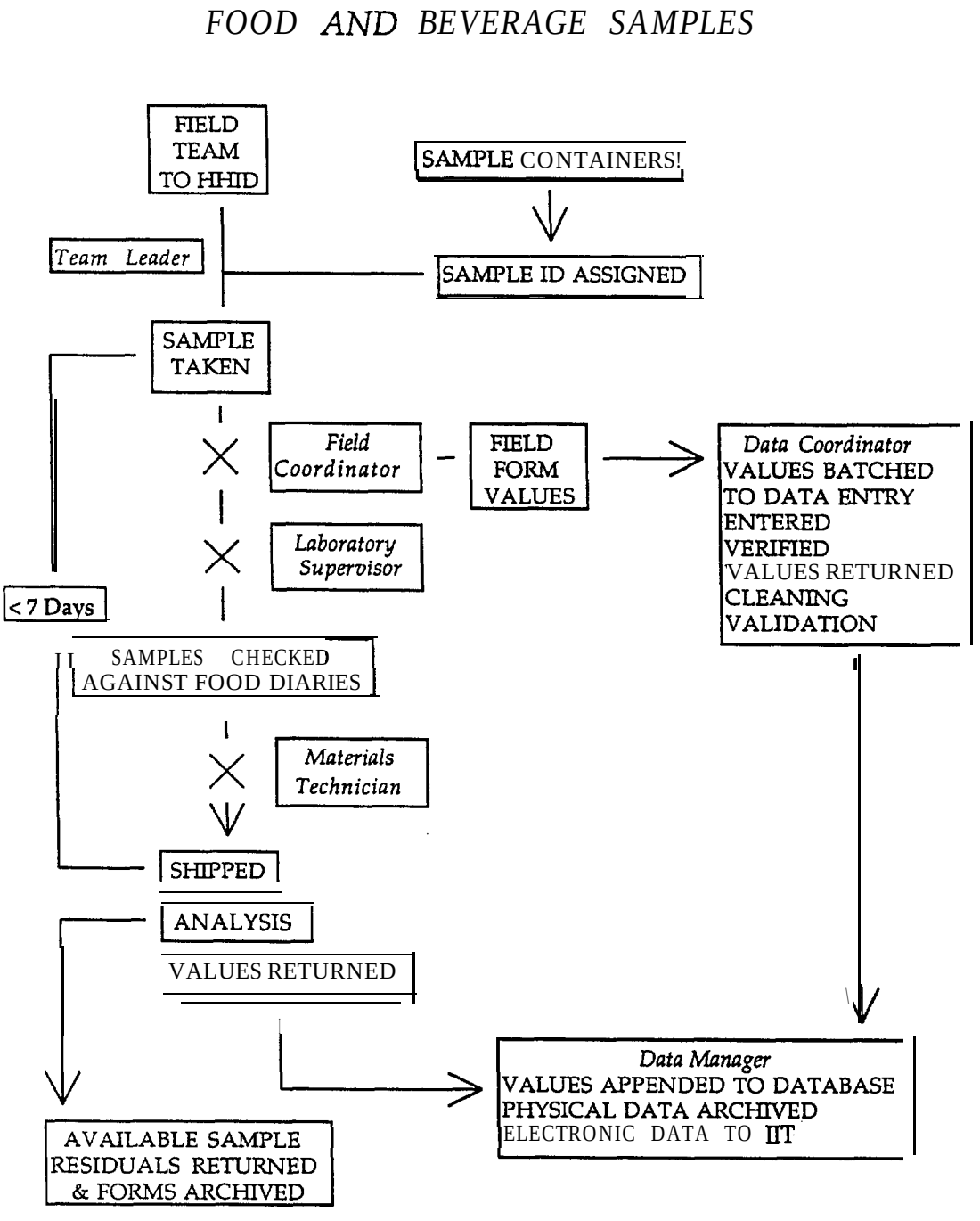


Figure 21. Handling Tap and Separate Drinking Water Samples.

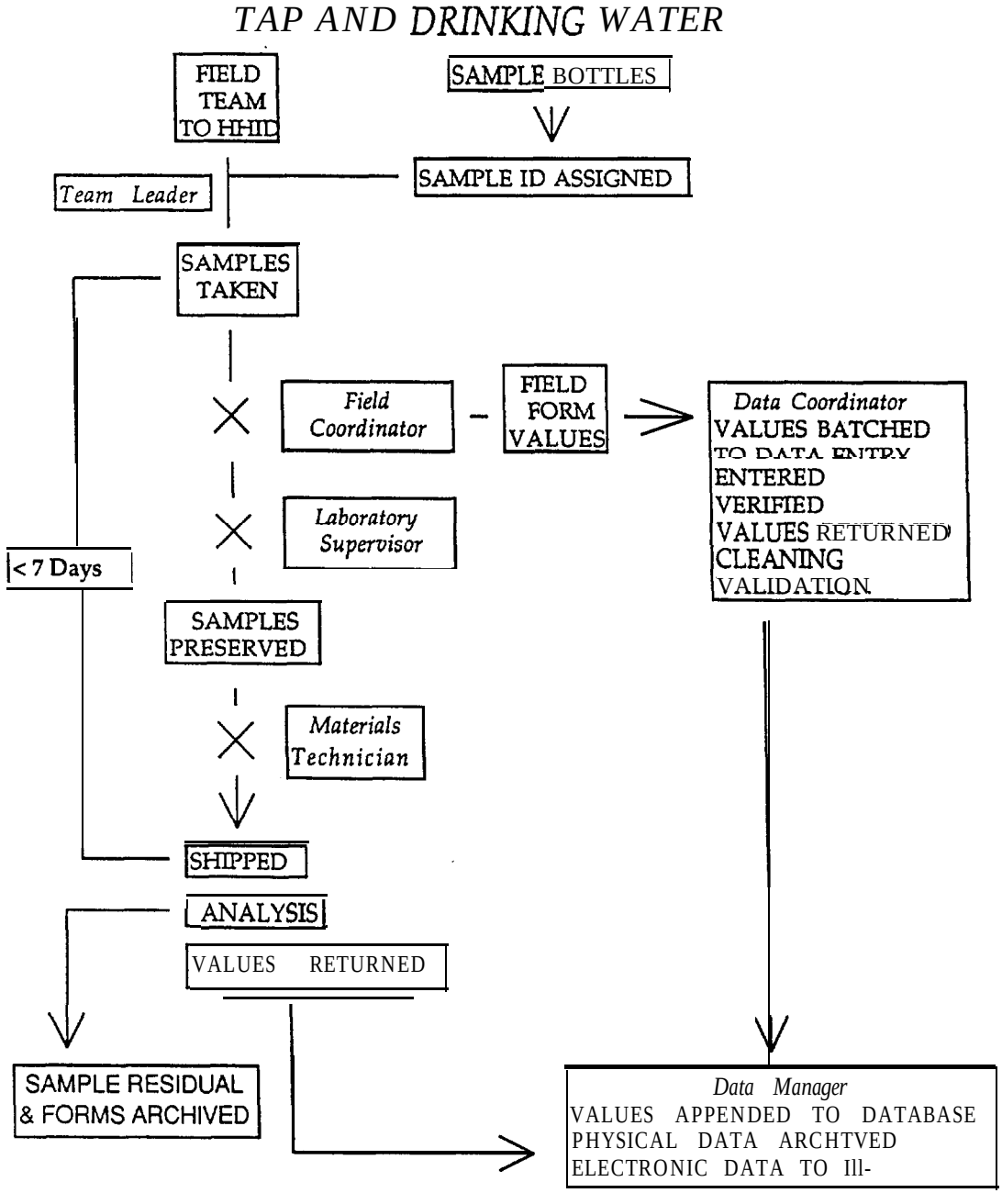
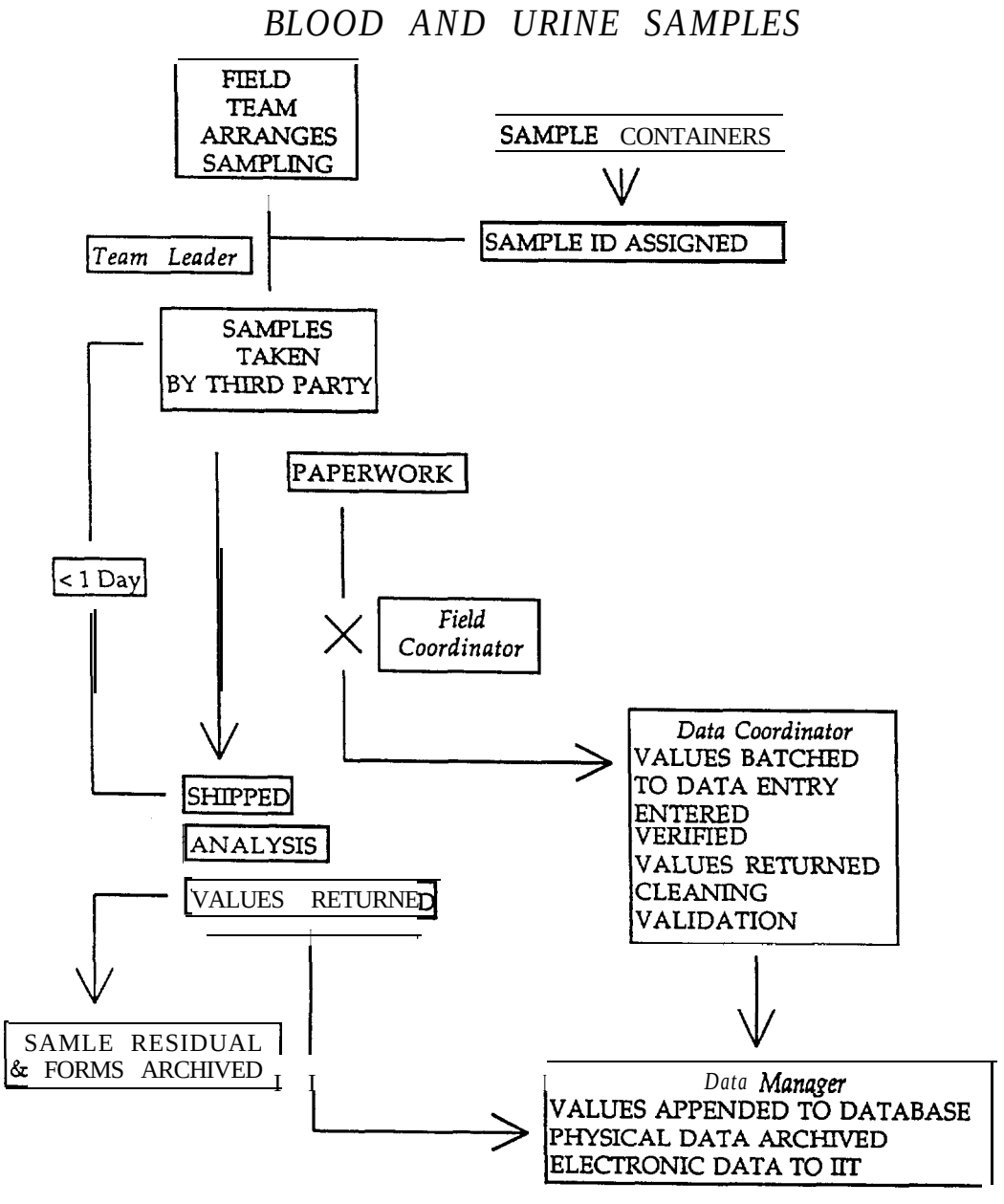


Figure 22. Handling Urine and Blood Samples.



3.1.11 Sample Analysis

Samples will be analyzed in accordance with written Laboratory Standard Operating Procedures developed for each sampling type.

3.2 Data Quality Indicators

Data Quality Indicators flow from the Project Quality Objectives expressed in section 3.1.2. If the **DQIs** are met, then the data has a consistently good high quality. If **DQIs** are not met, then the data is not of sufficient quality to meet the stated objectives.

3.2.1 Planning

All field, laboratory and analysis aspects of the study design will be considered, tested and evaluated prior to field implementation.

A. Collect a functional, creative work team.
B. Define the problem in all of its details.
C. Plan how the project is to be approached. {These steps form an
D. Test the Plan. {iterative do loop.
F. Decide how to handle errors.
E. Document, Document, Document !

3.2.2 Field Data

The following data quality indicators will be documented for the field portion of the project.

A. Training: Each field team member is completely trained in the performance of all field procedures including collection, handling, transport, storage and shipment. Each member is required to know and refer to the **SOPs** governing each field procedure. Appropriate and thorough training results in quality samples. Good training is evidenced in superior performance evaluations and timely corrections in performance. Technicians are evaluated monthly and corrective actions are documented.

B. Field Staff Evaluation: The Project Field Coordinator is responsible for incremental evaluation of all field staff in the performance of sample and data collection. Performance is evaluated and documented on the Field training SOPs. The project Field Coordinator is responsible for maintaining these records for audit.

C. Field Cross Checks: All field technicians are cross trained. Field Team Members are responsible for cross checking each other's work in the field. 100% of all critical data are cross checked in the field and documented on field collection forms. The team leader checks all

sample labels, packaging and transport storage prior to departure from the household being evaluated.

D. Internal QA Audits by the Project Field Coordinator: Within l-2 weeks of sampling, all completed field forms and data sheets are reviewed by the Project Field Coordinator for completeness and appropriateness of response. Sample labels on all questionnaires, forms and samples are inspected for completeness. Custody forms must accompany each sample and be appropriately completed and signed. Field samples must be stored in accordance with the SOPs and shipped or delivered by the Project Field Coordinator or his/her designate.

E. Sample integrity is lost if the chain of custody is broken. (See Custody SOPs). Poor custody transfer records will result in corrective action.

F. Repeated or replicate samples are collected routinely from homes. Similar lab results are indicative of consistent collection techniques. Repeated/replicate or split samples varying by more than 20% are indicative of either poor field or poor lab practice and corrective actions (like training review and increased internal and external audits) will be implemented.

G. External Field Audits: A representative of the University of Arizona's Quality Assurance Unit will perform periodic-field audits. During the first 3 months of field operation, audits will occur monthly. Thereafter, quarterly audits will be performed. Results of these audits will be communicated directly to the Principal Investigator. Appendix C outlines the audit procedures that will be followed.

3.2.3 Laboratory Data

The following additional data quality indicators will be documented for the laboratory.

A. Internal quality control procedures to monitor measurement precision and accuracy will be implemented for sample collection in the field and for sample analysis in the laboratory. These internal quality controls will consist of the analyses of field blanks, lab blanks, lab spikes, and reference matrix samples, in addition to replicate analyses of selected samples. The data reduction for these sample types has been discussed previously. The project quality objectives that will be met through these analyses are listed at the beginning of this document. QA samples (blanks, spikes, reference samples, replicates) will encompass all sample matrices and will constitute approximately 10% of the total sample number. Each lab supervisor will perform an internal monthly QA audit (last Friday of each month) and provide a written report to the Co-PI supervising that section of the project.

B. External Quality Assurance Measures: National Institute of Science and Technology (NIST) provided materials for performance evaluation and standards used for the NHEXAS project. If available in Battelle's residual stock from the NHEXAS project, they will be run with samples as independent QC checks in accordance with Laboratory SOPs.

C. The QA officer will review the results of these control samples. Aspects of each individual

analytical procedure also serve as checks of internal QC. These are discussed below.

D. Pesticides & PAHs: Each sample will be spiked with a recovery surrogate. The recovery of the spiked surrogate standard will be reported for each sample as a running check on the reliability of the extraction and analysis procedures. Recovery of analytes will not be corrected by recovery of the surrogate standard. The same surrogate standard will be spiked into each sample matrix, so that method performance can be assessed broadly, on the basis of its average recovery, for each matrix. Recovery of this surrogate standard will also help to identify samples where data may be suspect due to poor recovery of the surrogate.

The GC/MS instrument performance is also monitored in the laboratory through the use of an internal standard for quantification. Significant differences, during the course of a day, in the area of the internal standard quantification ion (>50% DM) signal instrument difficulties that require operator attention.

E. Metals: The analysis of one or more internal calibration verification standards will be used as a periodic check on instrument drift. These data will be used to signal the need for a new calibration curve, or reanalysis of samples.

F. VOCs: The GC/MS instrument performance will be assessed by comparison of current data with historical VOC data. Peak areas of compounds in reference standards will be used as a check of this performance.

3.2.4 Databases

The following additional data quality indicators will be documented for electronic data.

A. The structure of the databases is defined in the planning phase and all necessary key indicators are recorded on all forms, samples, questionnaires and records.

B. Each database undergoes multiple procedures to ensure that it reflects what is reported in the questionnaire or on the data form. A detailed explanation of these is offered in SOP# UA-D-44.x.

C. Prior to any data analysis, univariate and bivariate analysis are undertaken and the outliers are checked against field and laboratory records for any discrepancies.

3.3 Project Responsibilities

The ultimate responsibility for the success of the project falls on the Principal Investigator. However, he cannot supervise such a large project alone. All project employees are responsible for immediately reporting problems to their direct supervisor. If the problems cannot be readily solved then they are reported further up the chain of command (Figure 23). The solutions must be in conformance with all project documents. The project QA officer can always be consulted for an outside perspective to

resolve problems. Each Co-Principal Investigator (Co-PI) is responsible to the Principal Investigator for a portion of the project.

3.3.1 Overall administrative responsibility for the project will be assumed by the Principal Investigator. The PI in consultation with the Co-PI's and the EPA Project Officer will be responsible for major study design changes.

3.3.2 The Principal and Co-Principal Investigators will supervise and document the implementation of the study and population selection.

3.3.3 Day-to-day field operations will be implemented and documented in Arizona and are the responsibility of the Arizona Co-Principal Investigator and the Project Field Coordinator.

A. Changes in field study design will be made and documented by the Principal and Co-Principal Investigators.

B. Changes in the Questionnaire will be made by the PI in conjunction with the PI's of the other consortia and EPA and conforming with office of management and budget regulations.

C. Major changes in types of equipment used to sample a medium will be made and documented by the Principal and Co-Principal Investigators.

D. Minor substantive changes in field protocol implementation will be made by the Arizona Co-PI and the Project Field Coordinator with documentation sent to the other Co-PIs and the Principal Investigator.

E. Collection, preliminary sample preparation and stabilization, shipping and maintenance of samples and questionnaires surveys and field collections will be the responsibility of the Project Data Coordinator.

F. The Field Coordinator is responsible for the post field transfer, storage and shipment of all collected samples. These are to be performed according to the appropriate protocols.

G. The Field Coordinator is responsible for maintaining and calibrating equipment during the field assessment.

H. The Field Coordinator is responsible for training, supervising monitoring, evaluating, enforcing all QC/QA requirements for his area and assigning tasks to all the field staff.

J. The Field Coordinator is responsible for the field and questionnaire data during the field procedures and transferring all original data records to the data section.

3.3.4 Day-to-day laboratory operations will be implemented and documented in each of the responsible labs and are the responsibility of the Local Co-Principal Investigator and the Laboratory Supervisors. Several labs participate in this study.

A. Major changes in Laboratory Methods either in terms of equipment used or approach will be recommended by the local laboratory to the Principal and Co-Principal Investigators, and decided and documented by them.

B. Minor changes in laboratory protocol implementation will be made by the Arizona Co-PI and the Project Field Coordinator with documentation sent to the other Co-PIs and the Principal Investigator.

1. Arizona and Battelle
   a. The Lab Supervisor is responsible for the post field evaluation/preparation of **all** collected samples. These are to be performed according to the appropriate protocols and include sample storage, shipment, and archiving.

   b. The Lab Supervisor is responsible for maintaining and calibrating support equipment for lab analysis and field assessment.

   c. The Lab Supervisor is responsible for training, supervising monitoring, evaluating, adhering to all QA/QC requirements for his area and assigning tasks to the other laboratory personnel.

   d. The Lab Supervisor is responsible for keeping laboratory data records and providing copies of all data records to the data section.

   e. Equipment and materials evaluation and certification will be performed by Battelle.

2. Laboratories performing Food, Water, Blood and Urine Analysis:

   a. The labs will be responsible for performing all analysis according to the specifications set up by EPA in the various contracts or in accordance with this document at the request of EPA.

   b. Arizona will provide 10% field QA samples for water and food. For water 5% of the QA samples will be replicates and 5% will be blanks. For food 5% will be "blanks" and 5% will be spikes. Sufficient sample is provided to CDC for splits of biological samples for QA.

   c. The Federal Labs will be responsible for adhering to Standard QA procedures.

   d. The labs will run a total of 10% QA samples for field blanks, Lab/blanks and spiked samples.

   e. Unexpended blood will be archived and co-owned by CDC and the Consortium for

future research as we jointly decide. Unexpended urine, food and water samples are owned by the recipient laboratory. We request return of two 125 ml sample aliquots of solid food if available after analysis.

f. NIST is not actively involved in the Border Study. We will employ residual NIST standards for comparability with the NHEXAS project wherever possible in accordance with laboratory protocols as controls.

g. Federal and Contract laboratories will send data to the EPA Project officer who will verify that work has occurred according to the contract specifications. The Laboratory will send electronic or hard copies of results to the Project Data Manager at the University of Arizona for production of appropriate data bases.

3.3.5 Day-to-day data processing operations will be implemented and documented in each of the project areas defined above. The responsible parties will transfer their data to the University of Arizona Data office in a mutually agreeable format.

A. Major changes in data processing methods either in terms of equipment used or approach will be determined by the Principal and Co-Principal Investigators and documented by them.

B. Minor substantive changes in data protocol implementation will be made by the Local Co-PI and the Data Officer and the Arizona Data Manager with documentation sent to the other Co-PIs and the Principal Investigator.

C. The University of Arizona Data Manager will provide EPA with the Border records at the written instruction of the PI or Arizona Co-PI in the format that EPA requests. All data transfers and receipts will be recorded.

D. Once the data is provided to EPA in the specified format, subsequent manipulations are the responsibility of EPA with the cooperation of the Consortium.

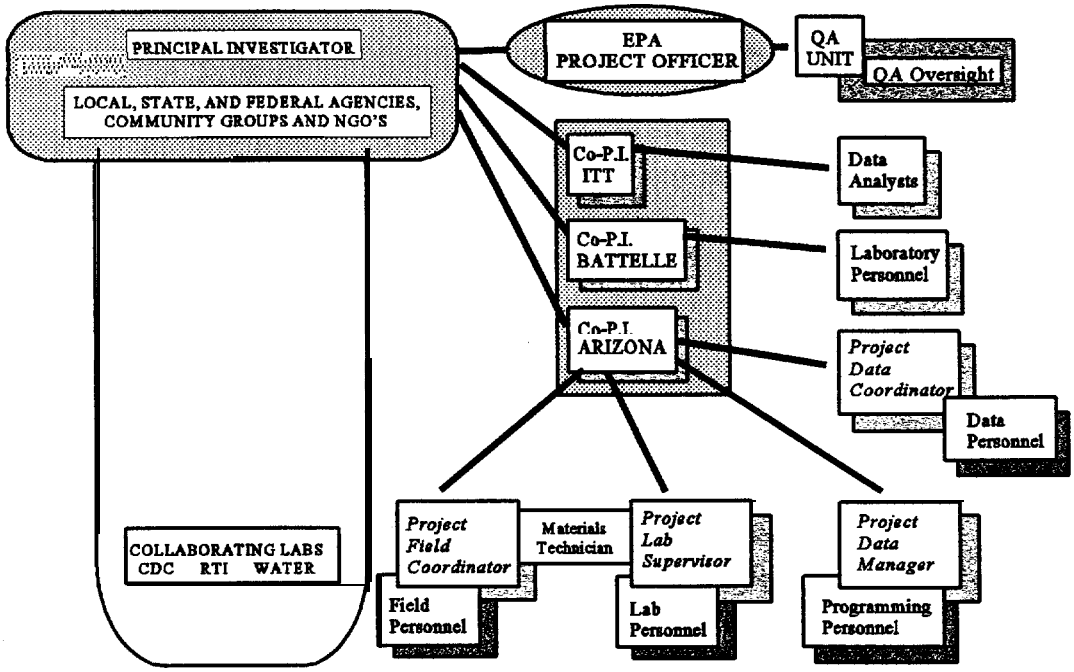
3.3.6 Data Analysis for Exposure Assessment. This responsibility will be fulfilled by Arizona and IIT.

Note: Figure 23 illustrates the organizational structure of NHEXAS ARIZONA and interacting agencies.

4.0 DATA ACQUISITION AND MANAGEMENT

The specific techniques employed for data acquisition, reduction, processing and validation will be dependent on the situations presented. Data reporting methods also may vary. Specific approaches to data acquisition are covered in the Field and Data SOPs. "Key" variables have been identified and combined to form a unique verifiable sample identification number.

Figure 23. The organizational structure of the Border Project. Shading represents those areas subject to QA audit and oversight.



In the context of this discussion, data means all collected and project generated information. This means questionnaires, field forms, samples, lab analysis, tracings or extracts from lab analysis, reports and documents maintained for QA purposes, electronic files, unexpended samples are all data. For discussion purposes these will be characterized as:

QA Documents = Paper documents (i.e. the QSIP) required for or generated by a QA audit. This also includes UA, Battelle and IIT notebooks needed to perform any QA audit. These records are readily accessible at all times. They are kept in ordered, sequentially numbered notebooks and/or files in the area where they are needed.

Lab forms = Paper forms generated in the lab and containing records of results. These are sequentially ordered in notebooks and/or files in the laboratory where they are generated.

Physical forms = Other papers (generated primarily by the field or data) that contain project information. These are filed sequentially by household identification number or topic in file cabinets.

Samples = Raw material collected from the field and evaluated in a laboratory. These are labeled and placed sequentially in storage boxes or other suitable labeled containers.

Lab Data Files= These are primarily downloaded electronic analysis results files, regardless of source. These will be retained in their original batches in a storage directory. After validation they will be sequentially appended into a master database structure. The master data base will reside with others in the electronic file tree.

Archive samples= Retained residue after a sample has been processed. Extracts, tracings, filters; these are materials or records that are a by-product of the analysis. These will be numbered, dated and placed in appropriate containers and suitably stored under the appropriate conditions as specified in the applicable SOP.

To track and archive these data, we have constructed a master tracking system which includes the location of all the data at any point in time. The system has cross programs that match newly entered records against their previous entry components. Location of each unprocessed sample is listed in the system for easy retrieval at a time when processing is possible. This tracking system will facilitate evaluation of sample integrity and sample shipment.

The following will be included in Project Control Documents (SOPs) either directly or indirectly by reference to other approved documents:

A. Methods used for data acquisition.
B. Data reduction scheme(s) for collected data, including all equations used to perform required calculations.
C. Methods used to process raw data.

D. Principal criteria used to validate data integrity during acquisition, reduction, processing, and reporting of data.

4.1 Data Acquisition

A. Data acquisition, instrumentation, analytical standards and methods, and data collection and reduction methods will be controlled. They will be based on recognized standards and techniques, and will be evaluated prior to use and periodically during use, to verify accuracy, stability, and repeatability. This evaluation will be documented by each laboratory performing the analysis.

B. The activities related to field questionnaires, sample collection, analysis and reporting shall be controlled in accordance with the appended SOPs.

4.2 Control and Calibration of Measurements and Testing Equipment

4.2.1 Balances, instruments, and other measuring and test equipment used for activities affecting quality will be controlled and, at specified periods, calibrated and adjusted to maintain accuracy within necessary liits (See Lab SOPs).

4.2.2 The specific measuring and equipment calibration procedures used, will comply with manufacturer's recommendations. If the equipment calibration procedures are complex, or if the equipment is leased, outside calibration services may be employed (See lab and Field SOPs).

4.2.3 The appended SOPs specify the equipment and instrument requirements and the calibration procedures to be employed, their frequency and their sources.

4.2.4 Records of measuring and test equipment calibrations will be maintained by the responsible Project Coordinator or his designee and periodically reviewed by the Project Manager, in-house Quality Control Director and the Director of Quality Control.

4.3 Identification of Data

4.3.1 Raw, reduced, and processed data, whether obtained via literature reconnaissance from the public domain, university sources, or during field and laboratory activities will be identified and controlled to assure that only correct and acceptable items or services are used by the project. Identification will, at a minimum, be maintained on documents traceable to the items, data or services.

4.3.2 Non-detects present a special data challenge. They are usually reported as < some definative number. By contrast true values may be reported as = to the same definative number. In our databases we have created a special symbol field. This allows the data analyst to recode non-detects as suits that analysis. Further it enables differentiation of non-detects from detection of low (but present) values.

4.3.3 Controlled storage shall be provided and maintained for all samples to ensure that only acceptable samples will be used.

4.3.4 Reports: Drafts of reports including calculations and supporting documentation for reviews will be paginated and identified by the author/preparer as to project number, draft or revision number, date of preparation, and total number of pages.

4.4 Control of Erroneous Data

4.4.1 Activities, services or data failing to conform with established requirements will be controlled to prevent their inadvertent use or installation. These controls will provide for the identification, documentation, evaluation and disposition of nonconformances. Nonconforming items will be segregated to prevent their inadvertent use. (See UA-G-2.x, UA-D-2.x).

4.4.2 A nonconformance relating to written material will be defined as an identified or suspected deficiency in an approved or verified document (e.g., technical report, analysis, calculation, computer program) where the quality of the end item itself or subsequent activities using the document would be affected by the deficiency.

4.4.3 All project staff members are responsible for promptly reporting suspected nonconformances in writing to the responsible Project Coordinator, Project Co-Principal Investigator, and the Director of Quality Control. Nonconformances that cannot be readily resolved by the responsible Project Coordinator, Project Co-Principal Investigator, and Director of Quality Control will be reported to the Principal Investigator for resolution.

4.5 Data Evaluation

Once master data bases are generated, 10% of the data will be randomly selected and compared against the questionnaires, field or laboratory forms as a Quality Assurance check. If more than 5 % of the data is erroneous, corrective action will be taken as per the data protocols.

Further, data will be examined for errors using uni- and bivariate statistical procedures. Outliers will be checked for accuracy.

4.6 Procedures

A control document describing each field, data and laboratory procedure will be written and known as a Standard Operating Procedure (SOP) [SOP # UA-G-1.x]. The SOP will describe the Purpose, application, responsibilities, steps of each procedure, the records to be kept and quality control and assurance requirements. Current SOPs are attached and listed in the Table of Contents. SOPs fall into eight major categories, General, Training, Field, Laboratory & Calibration, Custody, Data, Analysis and Miscellaneous.

5.0 RECORDS USAGE AND MANAGEMENT

5.1 Data Records

Records furnishing documentary evidence of data integrity and validity will be specified as appropriate in each SOP under the "Records" (SOP UA-G-1.x Section 8.0) (Project Control Documents). Records will be legible, identifiable, retrievable, and protected against damage, deterioration or loss. Requirements and responsibilities for record identification, storage, and retrieval will comply with recognized procedures.

Project Records fall into two classes: written and electronic.

5.2 Records Management System

A records index (written sign-in and out notebook) will be prepared by the responsible Project Coordinator or his designee using the information in the applicable SOPs. The Project Coordinator or his designee will maintain current working files for documents originating within his/her area of responsibility during the research project. All records will be filed and labeled in accordance with the appropriate SOP descriptions.

Quality assurance records generated by the Quality Assurance Unit and its staff (e.g., audit/inspection reports, corrective action requests, nonconformance reports, personnel quality assurance and indoctrination and training records) will be maintained by the Quality Assurance Unit and/or its designee(s).

The On-Site Co-Principal Investigator (aka local Project Manager) will have copies of all Project Control Documents on file as well as copies of all quality assurance related documentation as enumerated in this document.

Data input received from other individuals or organizations will be retained by the organization using such data.

Access to all data record files written and electronic will be controlled.

Removal of records from the files will be controlled by both access and completion of a sign-out log. Upon return of the document, the responsible custodian will co-sign and date the entry, indicating the document was returned.

Records of external transmittal of all project records will be maintained by the On-Site Co-Principal Investigator or designee.

Generic records such as test procedures, work instructions, software program documentation and verification records will be maintained by the originating organization. Revisions to existing documents such as procedures, work instructions, and computer programs will be filed with the original, together

with any and all previous revisions. Copies of superseded versions will be retained for at least three (3) years.

5.3 Record Validation

Written records: All written records will be maintained by the project for a minimum of three years following project completion. Detailed records are kept in the files by Study, HHID number and form type. Collection of all data is documented, initialed by the technicians and supervisors, dated and has chain of custody forms attached documenting the transmittal of the material. All forms are initially completed in black ink. Any changes are made in red or purple on the form, initialed and dated by the project member making the change.

Electronic records: Changes in data bases are documented extensively. The change must be noted on the original physical form and in the "Data Base Change Log Book". Changes must be approved by the Project Data Coordinator and documented. Errors found in the Master Data Bases must be written up in a memo and passed on the Project Data Manager. Only he/she is authorized to make changes in any Master Data Bases. The Project Data Manager logs the changes on the "Master Data Base Log Form" and files it in the appropriate notebook. Accurate (but suspicious looking) outlier values may be noted in the Data Dictionary to save time during future analyses.

These validation methods are covered in Detail in SOPs # UA-D-4.x, UA-D-16.x, UA-D-44.x.

5.4 Records Identification, Indexing and Retention

A records index will be prepared by the responsible Project Coordinator or his designee using the information in the applicable Project Control Document. The Project Coordinator or his designee will maintain current working files for documents originating within his area of responsibility during the research project. All records will be filed and labeled in accordance with the SOPs.

In general, data packets and laboratory results will be filed by the study stage and household identification number (SOP # UA-F-1.x). Other documents will be filed by type and date; they will reside in each area of the project as defined in the SOPs.

Quality assurance records generated by the Quality Assurance Unit and its staff (e.g., audit/inspection reports, corrective action requests, nonconformance reports, personnel quality assurance and indoctrination and training records) will be maintained by the Quality Assurance Unit and/or its designee(s) .

The On-Site Co-Principal Investigator will have copies of all Project Control Documents on file as well as copies of all quality assurance related documentation as enumerated above.

All records and unexpended samples (retaining integrity) will be kept at least three (3) years after the project ends.

5.5 Records Distribution and Storage

Extensive custody SOPs have been developed to describe how samples, physical forms and custody issues are handled in the project (SOP # UA-C-1 .x through UA-C-8.x). All current and archive locations will be recorded in the Tracking System (Figure 9).

Documents and physical forms will be stored and cataloged for at least three (3) years from the end of the project in the Health and Environment Study offices of the Arizona Prevention Center, at the University of Arizona. Project forms will be placed in a secure, locked, dry storage environment on metal shelving or in metal file cabinets.

At the completion of the project, all master data bases will be transferred to magnetic tape and reside in the control of the Principal Investigator.

Data input received from other individuals or organizations will be retained by the organization using such data.

Access to all data record files will be controlled.

Records of external transmittal of all project records will be maintained by the Principal Investigator or On-Site Co-Investigator or designee. These procedures are outlined in the Data SOPs (Volume IV).

Generic records such as test procedures, work instructions, and software program documentation and verification records will be maintained by the originating organization. Revisions to existing documents such as procedures, work instructions, and computer programs will be filed with the original, together with any and all previous revisions. Copies of superseded versions will be retained for at least three (3) years.

Many of the physical samples lose integrity quickly. These samples are kept refrigerated or frozen prior to shipment and analysis in other laboratories (as specified in the SOPs). Suitable refrigerator and storage space is available in the field lab for short term storage. The recipient laboratories (outside the consortium) may return unexpended samples and they will be archived at the University of Arizona following our general Archiving Procedures UA-G-4.x. Unexpended sample residues will be retained with field and custody forms in the Health and Environment Offices of the Arizona Prevention Center at the University of Arizona for at least 3 years following completion of the project.

6.0 Routine Controls and Procedures

6.1 Maintenance of Equipment

Each piece of equipment used in the study will undergo four classes of maintenance. The maintenance level will depend on the type of equipment employed.

A. Routine maintenance will be performed according to the operating instructions of the equipment document.

B. Preventive maintenance will be performed annually if equipment maintenance is not described in the equipment documentation.

C. Lab checks and equipment calibration will be performed as each piece of equipment is returned from the field and preceding reuse in the field.

D, Field checks and equipment calibration will be performed by the field technician when the equipment is installed in the field.

E. Specifics:

1. Balances, instruments, and other measuring and test equipment used for activities affecting quality will be controlled and, at specified periods, calibrated and adjusted to maintain accuracy within necessary limits.

2. The specific measuring and equipment calibration procedures used will comply with manufacturer's recommendations. If the equipment calibration procedures are complex, or if the equipment is leased, outside calibration services may be employed.

3. The SOPs specify the equipment and instrument requirements and the calibration procedures to be employed, their frequency and their sources.

4. Records of measuring and test equipment calibrations will be maintained by the responsible Project Coordinator or his designee and periodically reviewed by the On-Site Co-Principal Investigator, and the Director of Quality Control.

F. Identification and isolation of non-functioning field and lab equipment is described in SOP # UA-G-2.x, UA-L-1 .x through UA-L-4.x. Identification and isolation of non-functioning data equipment is described in SOP # UA-D-1.x, UA-D-2.x.

6.2 Quality of Consumables

Quality control of consumable products will occur at two levels.

A. A visual inspection of all consumables will occur when received from the supplier and when used.

B. A contaminant analysis of specific scientific consumables will be performed for 1 sample per batch or a sample aliquot per lot number for chemical reagents and standards.

Specific consumable materials to be tested include:

Filters: $PM_{2.5\&10}$ filters, Vacuum filters, Pesticide/PAH Sorbent & Filters

VOC Collectors: Multisorbent Carbo Traps, OVM badges

Other: Gauze for sill and dermal wipes, Ziploc Freezer Bags

Water Containers: Cubitainers, Vials, Bottles

Lab Analysis Containers: Test tubes, vials

Reagents: chemicals needed for field and laboratory protocols

6.3 Labeling

Laboratory labels will be attached to all primary reagents. They will identify the material by composition, stability, storage requirements, safety handling requirements, safety hazards, and date of receipt.

All secondary reagents (and those of subsequent generations) will have labels with materials identification, concentration, date of preparation, identification of preparer and when appropriate, safety information and expiration date.

Sample Labels will be indelible and preprinted. Labels will be attached to all questionnaires and samples collected.

Unlabeled materials will not be used; Unlabeled chemicals will be disposed of through the hazardous waste unit of the cooperating agency.

6.4 Acceptance of Equipment and Materials

All equipment and materials purchased will be evaluated to see if they meet critical specifications as outlined in the project specifications. Changes in the specifications will not be permissible without review and consent by the Principal, Co-Principal and Cooperating Investigators. If changes in materials specifications are agreed to, they will be specified in writing and the specifications signed by the Principal and Co-principal investigators.

6.5 Storage of Equipment and Materials

The storage of equipment and materials, will comply with manufacturer's recommendations.

SOPs indicate storage requirements for some media. These SOP specifications must be followed as some samples loose their integrity.

7.0 TECHNICAL ASSESSMENT AND RESPONSE

7.1 Assessment Procedures

7.1.1 Pre-Field Assessment

A. Equipment: Equipment will be calibrated in the laboratory prior to transport into the field. Equipment must be able to maintain operating standards during the course of operation. Equipment must be tested at the time of set-up and removal to assure that it performed to standards as defined in the specific SOPs. All critical values associated with equipment operation must be 100% independently validated by another field team member.

B. SOPs and Forms: All SOPs must be field tested prior to project implementation. Field forms must be pretested. SOPs and field forms found inadequate will be revised and finalized prior to entry into the field.

7.1.2 Field

A. Duplicates will be collected for 10% of all samples with the exceptions of food, beverage, blood and urine. For the exceptions, the samples will be split in the laboratory (when possible) to provide QA split samples. All samples will be analyzed using the same methods.

B. Field blanks will be used in conjunction with 10% of all samples collected. They will be prepared and analyzed using the same methods as study samples.

C. Questionnaire results obtained during field visits will undergo 100% QC check by technicians in the field, 100% QA check for completeness by the Project Field Coordinator (or designee) acting as an in house QA auditor for field forms.

D. 10% of the subjects contacted during Field Stage 1 will be re-contacted by phone and the Descriptive Questionnaire readministered as a QA check.

E. Coordinator(s)/Supervisor(s) will routinely evaluate technicians as outlined in the Training Procedures (SOP # UA-T-1 .x through UA-T-6.x).

F. The QA Unit will perform periodic field audits as per their protocol presented in Appendix C.

7.1.3 Laboratory

A. Coordinator(s)/Supervisor(s) routinely evaluate technicians as outlined in the Training Procedures (SOP # UA-T- 1 .x through UA-T-6.x & BCO-T-l .x).

B. NHEXAS NIST standards (if available to Battelle) will be used in conjunction with all

laboratory evaluations. Measurement deviations beyond acceptable limits described in the SOPs will be documented, investigated and corrected. Any deviations in field or laboratory procedures will be corrected and documented.

C. Repeated/replicate, split and blank samples (field and lab) will be treated as all study samples and evaluated in accordance with all pertinent SOPs. Values may vary from samples by some designated amount (see appropriate lab SOPs for value). Excessive deviation between samples will result in re-evaluation of the field and lab procedures. All implemented corrective actions will be dated and documented.

7.2 Assessment Evaluation

7.2.1 The QA unit recognizes the need for project data to meet specific criteria for scientific validity and technical defensibility, and to be of defined precision and accuracy. The QA systems to be implemented provide a planned and systematic management approach of procedures and controls to ensure that personnel, equipment, activities, and documentation comply with U.S. EPA requirements. The Consortium and the QA Unit recognize EPA's right to observe and perform additional QA audits at its discretion and welcome these constructive efforts.

7.2.2 To assist in meeting these objectives, the UA maintains a Quality Assurance Program to ensure that activities affecting the quality and integrity of data are appropriately planned and coordinated. The University of Arizona QA Unit will monitor all three members of the consortium. The QA system audits will be used to assure that QA/QC plans are prepared, approved and fully implemented, that QA/QC procedures are fully understood by field and lab personnel, and that data are reported in a manner reflecting the project quality objectives of the program. To assist task leaders in tracking critical QA issues, a Quality Assurance Checklist will be developed for each aspect of sampling and analysis. These will be distributed to field and lab personnel with instructions.

7.2.3 QA performance audits (Appendix C) will be used to assure compliance with the project plan. These audits will have the form of verification surveillances and will be performed by the assigned QA Officer. These surveillances will be performed to ensure that a specified requirement is being met. These audits will include both real time observations during the work or analytical process to ensure that specific applicable procedures are being implemented, and traceability checks through data to ensure that project data can be tracked back through the analytical process, through sample handling and transportation, back to the date, location, staff, and technique used to collect the sample. At least one QA surveillance audit will be performed for each of the following key activities: sampling, sample tracking from field to lab, analytical measurement, and data reporting.

7.3 Assessment Response and Follow-up

A. Field: Conditions adverse to quality, such as variances, unusual occurrences or abnormal conditions, and deviations from the SOPs and contractual requirements will be identified promptly and corrected as soon as practicable. In the case of a significant condition adverse to

quality, the cause of the condition will be determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality will be documented and reported to the appropriate levels of management. Follow-up action will be taken by the Director of Quality Control to verify implementation of corrective action.

B. Laboratory: The need for corrective action will be identified by the technical staff during the course of their work or review of data. We expect that problems will be identified and corrected prior to QA audits, although this additional measure of oversight will provide further opportunity for identification of problems prior to data reporting. Each individual staff performing laboratory or data processing activities will be sufficiently well-trained in their operations that they will be responsible for notifying the appropriate supervisory personnel of any circumstance that would affect the quality or integrity of the data. Deviations from approved procedures that require corrective actions typically result from unforeseen circumstances. All deviations will be documented in field or lab notebooks, and will be dealt with as expeditiously as possible by the responsible task leader.

C. Data: The need for corrective action will be identified by the technical staff during the course of their work or review of data. We expect that problems will be identified and corrected prior to QA audits, although this additional measure of oversight will provide further opportunity for identification of problems prior to data reporting. Each individual performing data processing activities will be sufficiently well-trained in their operations that they will be responsible for notifying the appropriate supervisory personnel of any circumstance that would affect the quality or integrity of the data. Deviations from approved procedures that require corrective actions typically result from unforeseen circumstances. All corrective changes in the data bases must be approved by the Project Data Coordinator (Working Data Bases) or Project Data Manager (Master Data Base). All corrections will be noted on the appropriate "Data Change" form as outlined in the Data SOPs.

DISTRIBUTION LIST AND STATUS

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