RESEARCH TRIANGLE INSTITUTE

March 10, 1977

WORK PLAN

EPIDEMIOLOGIC STUDY CONDUCTED IN POPULATIONS LIVING AROUND NONFERROUS SMELTERS TO DETERMINE BODY TISSUE BURDENS OF SELECTED NONFERROUS METALS

EPA Contract No. 68-02-2442

RTI Project No. 31U-1372

Chemistry and Life Sciences Group
and
Statistical Sciences Group
Research Triangle Institute
Post Office Box 12194
Research Triangle Park, N. C. 27709

Prepared for

Environmental Protection Agency
Research Triangle Park, N. C. 27711

TABLE OF CONTENTS

Page

LIST OF TABLES. vi

LIST OF FIGURES vii

1.0 Survey Design. 1-1

1.1 Sampling Personnel. 1-1
1.2 Overview. 1-2
1.3 Target Population 1-5
1.4 The Sampling Frame. 1-10
1.5 Sample Selection Techniques 1-13

1.5.1 Survey Participants. 1-13
1.5.2 Air Sampling 1-14
1.5.3 Sampling for Soil Contamination. 1-14
1.5.4 Sampling Tap Water 1-15
1.5.5 Quality Control. 1-16

1.6 Sample Sizes and Sampling Error 1-17

1.6.1 Allocation of the Sample of Individuals. 1-17
1.6.2 High-Volume Air Samples. 1-18

Appendix 1.1: Characteristics of Survey Sites 1-23
Appendix 1.2: Sample Sizes and Allocation For Air Sampling 1-42
Appendix 1.3: Wind Roses for Smelter Sites. 1-46
Appendix 1.4: Resumes of RTI Project Staff. 1-53
Appendix 1.5: References. 1-59

2.0 Field Operations 2-1

2.1 On-Site Project Operations (At RTI) 2-1

2.1.1 Project Staff. 2-1
2.1.1.1 Overall Supervision 2-1
2.1.1.2 Survey Director 2-1
2.1.1.3 Site Administrator(s) 2-4
2.1.1.4 Data Receipt Control, Scan-Edit, and Direct Entry. 2-4
2.1.1.5 Training Manual 2-5
2.1.1.6 Training Session(s) 2-5
2.1.2 Data Receipt Control and Entry 2-7
2.1.2.1 Receipt Control 2-7
2.1.2.2 Visual Scan-Edit. 2-7
2.1.2.3 Direct Data Entry 2-8
2.1.2.4 Quality Control 2-8

TABLE OF CONTENTS (Continued)

		Page
	2.1.3 Confidentiality of Project Data	2-11
	2.1.4 Protection of Human Subjects Certification	2-13
2.2	Off-Site Project Operations (At Smelter Locations)	2-14
	2.2.1 Performance Sites	2-14
	2.2.1.1 Selection	2-14
	2.2.1.2 Public Relations	2-14
	2.2.1.3 News Releases	2-16
	2.2.2 Independent Subcontractors	2-17
	2.2.2.1 Recruitment	2-17
	2.2.2.2 Training	2-24
	2.2.2.3 On-Site Consultants	2-25
	2.2.3 Household Data Collection	2-26
	2.2.3.1 Screening	2-26
	2.2.3.2 Participant Consent Form	2-27
	2.2.3.3 Study Questionnaire	2-29
	2.2.3.4 Sample Collection	2-30
	2.2.3.5 Quality Control	2-32
	2.2.4 Central Data Collection	2-33
	2.2.5 Site Administrator's Responsibilities	2-34
	2.2.5.1 Coordination of Field Operations; Data Management	2-34
	2.2.5.2 Sample Collection	2-35
	2.2.5.3 Data Storage, Packaging and Shipment	2-35
	2.2.6 Quality Control	2-37
	2.2.6.1 Training	2-37
	2.2.6.2 Supervision	2-37
	2.2.6.3 Sample Collection	2-38
	2.2.6.4 Duplicate Sample Collection	2-39
	2.2.6.5 Reinterview	2-39
	2.2.7 Respondent/Participant Burden	2-40
2.3	Anticipated Problems	2-41
	2.3.1 Smelter Resistance	2-41
	2.3.2 Recruiting Independent Subcontractors	2-41
	2.3.3 Nonparticipants	2-41
	2.3.4 Incomplete Data Sets	2-42
	2.3.5 Missing Data	2-42
2.4	Schedules for Field Operations	2-43
	2.4.1 Time Schedule	2-43
	2.4.2 Cost Schedule	2-46
Appendix 2.1:	Resumes of RTI Project Staff and Consultants	2-48
Appendix 2.2:	Tentative Training Manual Outline	2-76
Appendix 2.3:	Survey Instruments	2-84

TABLE OF CONTENTS (Continued)

		Page
	Appendix 2.4: Pretest Considerations	2-99
	Appendix 2.5: Relevant Correspondence	2-105
	Appendix 2.6: Sample Collection Methodology	2-109
	Appendix 2.7: References	2-132
3.0	Physical Methods of Analysis	3-1
	3.1 Atomic Absorption Analysis	3-1
	3.1.1 Biological Samples	3-2
	3.1.1.1 Blood	3-2
	3.1.1.2 Urine	3-2
	3.1.1.3 Scalp Hair	3-2
	3.1.2 Environmental Samples	3-3
	3.1.2.1 Tap Water	3-3
	3.1.2.2 Dust	3-3
	3.1.2.3 Air Particulates	3-3
	3.1.2.4 Soil	3-4
	3.1.3 Arsenic Analysis	3-4
	3.1.4 Market Basket Samples	3-5
	3.2 Spark Source Mass Spectrometric Analysis	3-5
	3.3 Free Erythrocyte Protoporphyrin (FEP) Analysis	3-5
	3.4 Quality Control and Analytical Protocol	3-6
	3.4.1 Instrumentation	3-6
	3.4.2 Limits of Detection	3-7
	3.4.3 Routine Analytical Protocol	3-7
	3.4.4 Analytical Priorities	3-8
	3.4.5 Quality Control Procedures	3-8
	3.4.5.1 Instrument Performance	3-8
	3.4.5.2 Accuracy and Precision	3-9
	3.4.5.3 Interlaboratory Comparison	3-10
	3.4.6 Calibration of High Volume Air Samplers	3-10
	3.5 Determination of Total Particulate Solids in Air	3-10
	3.6 Personnel	3-12
	3.7 References	3-12
	Appendix 3.1: Analytical Data Sheets	3-13
	Appendix 3.2: Resumes of RTI Project Staff	3-27
4.0	Statistical Methods of Analysis	4-1
	4.1 Confidentiality of Data Files	4-1
	4.2 Data Analysis	4-2
	4.2.1 Analysis of Environmental Levels	4-2
	4.2.2 Analysis of Tissue Levels	4-3

TABLE OF CONTENTS (Continued)

	Page
4.3 Potential Problems.	4-5
4.3.1 Missing Observations	4-5
4.3.2 Trace Metal Intake Due to Diet	4-8
4.4 Personnel	4-9
Appendix 4.1: Resumes of RTI Project Staff.	4-10
Appendix 4.2: References.	4-17
5.0 Cost and Labor Projection	5-1

LIST OF TABLES

Table		Page
1.1.	Tentative sample allocation for individuals at the study sites.	1-19
1.2.	Tentative sample allocation for air samples. . . .	1-21
1.1.1.	Selected population characteristics of survey sites	1-24
1.1.2.	Population residing in the tentative study area near Ajo, Arizona.	1-27
1.1.3.	Population residing in the tentative study area near Anaconda, Montana	1-29
1.1.4.	Population residing in the tentative study area near Bartlesville, Oklahoma.	1-31
1.1.5.	Population residing in the tentative study area near Bixby, Missouri	1-33
1.1.6.	Population by stratum residing in the study area near Corpus Christi, Texas	1-35
1.1.7.	Population residing in the tentative study area near Herculaneum, Missouri	1-37
1.1.8.	Population residing in the tentative study area near Palmerton, Pennsylvania	1-39
A-1.2.1.	Lead content of air, µg/cu m	1-43
A-1.2.2.	Random assignment of days for high volume air samples: an example	1-45
A-2.6.1.	Tentative sample allocation for air samples. . . .	2-114
A-2.6.2.	Exemplary format for presenting survey and laboratory results for study element: lead	2-116

LIST OF FIGURES

Figure		Page
1.1.	Preliminary distance-stratification for a target population based upon Zn and Cd content of topsoil according to Miesch and Huffman in East Helena, Montana.	1-9
1.1.1.	Geographic location of study smelter and tentative delineation of the study population, Ajo	1-28
1.1.2.	Geographic location of study smelter and tentative delineation of the study population, Anaconda. . . .	1-30
1.1.3.	Geographic location of study smelter and tentative delineation of the study population, Bartlesville. .	1-32
1.1.4.	Geographic location of study smelter and tentative delineation of the study population, Bixby	1-34
1.1.5.	Geographic location of study smelter and tentative delineation of the study population, Corpus Christi.	1-36
1.1.6.	Geographic location of study smelter and tentative delineation of the study population, Herculaneum . .	1-38
1.1.7.	Geographic location of study smelter and tentative delineation of the study population, Palmerton . . .	1-41
2.1.	Research Triangle Institute administrative structure	2-2
2.2.	Project administrative structure	2-3
2.3.	Location and number of interviewers from the current RTI listing living in counties within a reasonable distance of the Ajo, Arizona, performance site . . .	2-19
2.4.	Location and number of interviewers from the current RTI listing living in counties within a reasonable distance of the Bixby and Herculaneum, Missouri, performance sites.	2-20
2.5.	Location and number of interviewers from the current RTI listing living in counties within a reasonable distance of the Anaconda, Montana, performance site.	2-21

LIST OF FIGURES (Continued)

Figure		Page
2.6.	Location and number of interviewers from the current RTI listing living in counties within a reasonable distance of the Bartlesville, Oklahoma, performance site.	2-22
2.7.	Location and number of interviewers from the current RTI listing living in counties within a reasonable distance of the Palmerton, Pennsylvania, performance site	2-23
2.8.	Field operations time table	2-44
2.9.	Field operations cost and labor projections	2-47
A-2.4.1.	Location and number of interviewers from the current RTI listing living in counties within a reasonable distance of the Corpus Christi, Texas potential Pretest site.	2-102
A-2.4.2	Location and number of interviewers from the current RTI listing living in counties within a reasonable distance of the Hayden, Arizona, potential Pretest site.	2-103
A-2.6.1.	Geographic and temporal placement of high-volume air samples: a partial hypothetical example depicting only the first two days of the survey . .	2-115
3.1.	Calibration of Sierra Instrument Orifice, Model 330	3-11
5.1.	Sampling design cost and labor-hour projections . .	5-2
5.2.	Field operations cost and labor-hour projections. .	5-3
5.3.	Field supervision and shipping costs and labor-hour projections	5-4
5.4.	Chemical analysis cost and labor-hour projections .	5-5
5.5.	Statistical analysis cost and labor-hour projections	5-6
5.6.	Projected monthly costs by activity	5-7

1.0 Survey Design

1.1 Sampling Personnel

Professional staff in the Sampling Research and Design Center (SRDC) have a broad range of experience in sampling theory and statistical applications, including unequal probability sampling methods and theory, response error modeling, optimization procedures, controlled selection procedures, variance estimation for complex surveys, data analysis, randomized response techniques, and other areas. Dr. James R. Chromy is Center Director and will have general supervision of sampling in this study, especially for those tasks involving probability sampling techniques.

The selection of the study participants and the survey design for air sampling will be under the direct supervision of Mr. Stephen R. Williams, Senior Statistician in SRDC. Mr. Williams, assisted by Mr. Lanny Piper, Statistician in SRDC, will be responsible for on-site delineation of the target population, its stratification, and the accumulation of pertinent extant information about the study communities. Additional support will be provided by SRDC research assistants and other support staff, who have extensive experience in the preparation of sampling materials and in the selection of probability samples. These and other related tasks will be completed by SRDC staff in close coordination with the Chemistry and Life Sciences Group and the other Research Triangle Institute (RTI) centers that are involved in this study. Résumés of the professional sampling personnel that will be substantively involved in the study are presented in appendix 1.4.

1.2 Overview

Sampling methodology to be used for obtaining a sample of the household population is a stratified area sample in which a sequential sample of persons is to be selected for participation in the study survey. An area sample is commonly used in population surveys that must result in a high degree of accuracy. This is because no complete, current listing is readily available from which to sample the target population; the area frame comprises a complete "listing" of this population. Also, a probability sample of sites and days is to be selected for the purpose of obtaining high-volume air samples. Selective sampling may necessarily be used to collect samples of tap water, house dust, and soil if probability sampling for these data is deemed impractical; several random-sample methodologies are being investigated at the Pretest site.

Note that the specific methods proposed for measuring environment-related factors differ somewhat among the various types of data being sought. These differences reflect several considerations, such as the extent to which surrogate variables reflect the factors of interest, the quality control of data collection, and the suitability and cost of data collecting techniques under actual survey conditions. However, the planned methodology stresses probability sampling techniques wherever possible in order to facilitate valid statistical analyses and to increase the degree of control over data collection. Field enumerators will follow explicit, nonjudgmental procedures throughout. These procedures will range, as outlined in the following sections, from obtaining small, possibly selective samples of relatively homogeneous factors, such as tap water at a particular residence or school, to obtaining large stratified random samples from a highly variable item, such as air quality in a smelter community.

Specifically, the survey will result in the selection of a stratified probability sample of persons who reside at various distances downwind from nonferrous smelters in selected communities. Approximately 240 persons, aged 35 and under, will be selected at varying distances from the emission source in each of six smelter communities (a selective sample of study sites was identified by the Project Officer on the basis of prior investigation). Additionally, 80 residents aged 60 and older will be selected in each of three of these communities. Blood, urine, and scalp hair samples will be obtained and analyzed for these persons and will comprise the basis for estimating community uptake coefficients of lead, zinc, arsenic, copper, manganese, and cadmium. To estimate the exposure levels of the "downwind" residents and an "upwind" control group to these six elements, residence data and samples of soil, household dust, and tap water will be obtained at each of the six communities selected for study. To estimate levels of atmospheric exposure, high-volume air samples will be obtained at random locations throughout the target area and at random points in time throughout the survey period. The number of dust and tap water samples will be equivalent to the number of households that have individuals in the sample--that is, less than or equal to 1,680, the total number of individuals to be selected. Additionally, RTI anticipates that a minimum of 90 high-volume air samples will be taken at each smelter site, a total of approximately 540 (90 x 6) air samples for the study. Two soil samples at each pre-schooler play area, and one composite soil sample at each school playground and high-volume air sampling site will be collected.

Prior to the studies in the six sample communities, a Pretest or pilot study will be conducted at Corpus Christi, Texas. The methodology will be identical to that planned for the survey sites except that a smaller sample of persons will be selected to participate and the survey period will be shorter. Approximately seven persons per age/sex cohort will be selected from each of the two geographic strata representing the extremes of potential exposure and one person per cohort will be selected from each of the remaining six strata. This allocation will result in a total of approximately 120 individuals in the Pretest study and is such that the hypothesis of no significant difference in uptake can be tested with reasonable power. The survey design for air sampling will also be equivalent to that planned for the main study sites except that the period of time sampled will be reduced from 20 to 10 days--that is, approximately 45 high-volume air samples will be collected during the Pretest.

Each study site (community) will be visited prior to the survey in order to ascertain the appropriate delineation of target (high-risk) population and to develop sampling materials. The actual sampling plans will be conceptually equivalent but will necessarily be developed individually to suit the particular circumstances of the community, such as availability of mapping materials, prevailing atmospheric patterns, geographic topography, type and location of the smelter and other major emission sources, and population densities. Tentatively, RTI expects to obtain a balanced sample of five individuals from each cohort from each of approximately eight distance strata (40 persons in each cohort). These strata will generally increase in size (land area) as the distance from the stack emission increases, in order to optimize the sample design according to the usual pattern of particulate fallout.

Although the actual number of high-volume air samples will ultimately depend upon the site circumstances, the number of air samples per stratum will range from approximately two obtained on each of 3 days to three obtained on each of 7 days. The number of observations, both locations and days, will increase as the distance from the emission source increases. The number of electric connections needed to accommodate the air samplers at each of the study sites is expected to range from 8 to 18 depending upon the number of strata used for sampling at the particular site.

Often, studies of environmental quality present emphasis and analyses that are based on purposefully selected samples of population and environmental factors. Such findings are highly susceptible to biases and often are not valid. In contrast, the methodology presented in the present study stresses random probability sampling techniques which will facilitate valid statistical analysis.

The following sections address specific components of the survey design including target population, construction of the sampling frame, sample selection techniques, sample size, and the estimation precision.

1.3 Target Population

The primary target population consists of the relatively high-risk human population that resides "downwind" of lead, zinc, and copper smelters in selected U.S. smelter communities. Specifically, American Smelting and Refining Company (zinc), Corpus Christi, Texas, will be used as a pilot test; the six study smelters consist of:

- St. John Mineral Corporation (lead), Herculaneum, Missouri;
- Missouri Lead Operating Company, Bixby, Missouri;

- Anaconda Company (copper), Anaconda, Montana;
- Phelps Dodge Corporation (copper), Ajo, Arizona;
- National Zinc Company, Bartlesville, Oklahoma; and
- New Jersey Zinc Company, Palmerton, Pennsylvania.

In appendix 1.1, the sites are characterized according to population, migration, and age characteristics. Other neighboring communities, some of which are listed in appendix 1.1, may also be included in the target populations. Also, figures in appendix 1.1 depict the population and its stratification for Corpus Christi, Texas and the tentative population delineations for the study sites. Characterization of the target population presented there is indicative of the technique that will be used on the study sites.

Delineation of the target population will be based largely on prevailing wind patterns. Tentatively, the high-risk population is defined as all persons residing within 30 km of the emission source (this limit may differ according to prevailing fallout patterns) and in sectors that experience winds from the direction of the emission source more than 3 percent of the time. The 3 percent cutoff generally excludes areas receiving 10 percent or less of the total fallout from the study source. It is planned that the target population will comprise all persons in this high-risk population that are members of the categories being studied. Additionally, an "upwind" area segment will be sampled as a control group to facilitate the isolation of effects from the particular emission source under study. The target population is thus restricted so that the available resources can best be utilized to answer questions about the potentially high-risk population, although this restriction precludes valid inferences about the entire population in some of the study communities (in other communities, such as Ajo, Arizona, the wind patterns and the population distribution are such that the entire community comprises the high-risk population.) Wind roses (see appendix 1.3) have been developed for all test sites. These diagrams depict the relative frequency of wind velocity and direction. At Anaconda, for example, westerly winds prevail 85 percent of the time, largely at 7 to 21 miles per hour. The target population for Anaconda, therefore, would ideally comprise all persons (with exceptions noted below) residing in a fan-shaped area to the east of the smelter.

The population in these communities is additionally restricted to the relatively young (preschool, school age, and age 20 to 35), and to the relatively old (age 60 and older) that have not had occupational exposure at the community smelter within the preceding 12 months. The exact delineation of this population will differ by site depending on local circumstances such as those alluded to in the previous section. Presurvey site visits are planned for the purpose of gaining the pertinent local information needed to supplement extant materials in the construction of a sample frame (see section 1.3).

Several aspects of the study present somewhat unique sampling problems. For example, most smelter communities are relatively small (population 1,000 to 5,000) and show net outmigration during the past decade. In this stereotype community, relatively few of the 20 to 35 age group will remain in the community. The minimum size for each stratum will be imposed by the expected number in the population of the most scarce cohort, usually the pre-school group. The approximate stratification guidelines presented in figure 1.1, therefore, will necessarily differ by site. Obviously, sampling from such populations can guarantee adequate cohort representation over the range of distances and potential exposures only to the extent that these cohorts are contained in that population. In other words, RTI anticipates, depending on the community, that virtually all of the families residing near the emission source will need to be screened in order to obtain adequate information about uptake of some of the cohort groups in that area. Figure 1.1 reveals that the area near the smelter represented by the steep portion of the curve contains a highly variable particulate content.

The curve presented in figure 1.1 was developed on the basis of results from several prior studies [Refs. 1.1, 1.2, 1.3]. These works reveal that the particulate dropout rates for varying distances from the smelter follow a somewhat similar pattern for several of the elements to be investigated in the study. Distance-fallout data were compared for zinc, cadmium, lead, and arsenic on the basis of air, surface soil, and blood samples. Surface soil samples reflect the fallout rates and the atmospheric mobility of lead [Ref. 1.4]. The general shape of this curve is useful in describing relatively homogeneous strata, which contain approximately equal variances for element accumulation. Equally spaced readings on the vertical axis, therefore, identify distance strata for which equal-size samples of persons will yield approximately equal reliability for each stratum estimate. Actually, the stratum boundaries are being based on potential exposure according to methodology in appendix 1.1; this refinement is expected to be a more effective stratification and will still serve as a quasi-stratification of distance from the smelter.

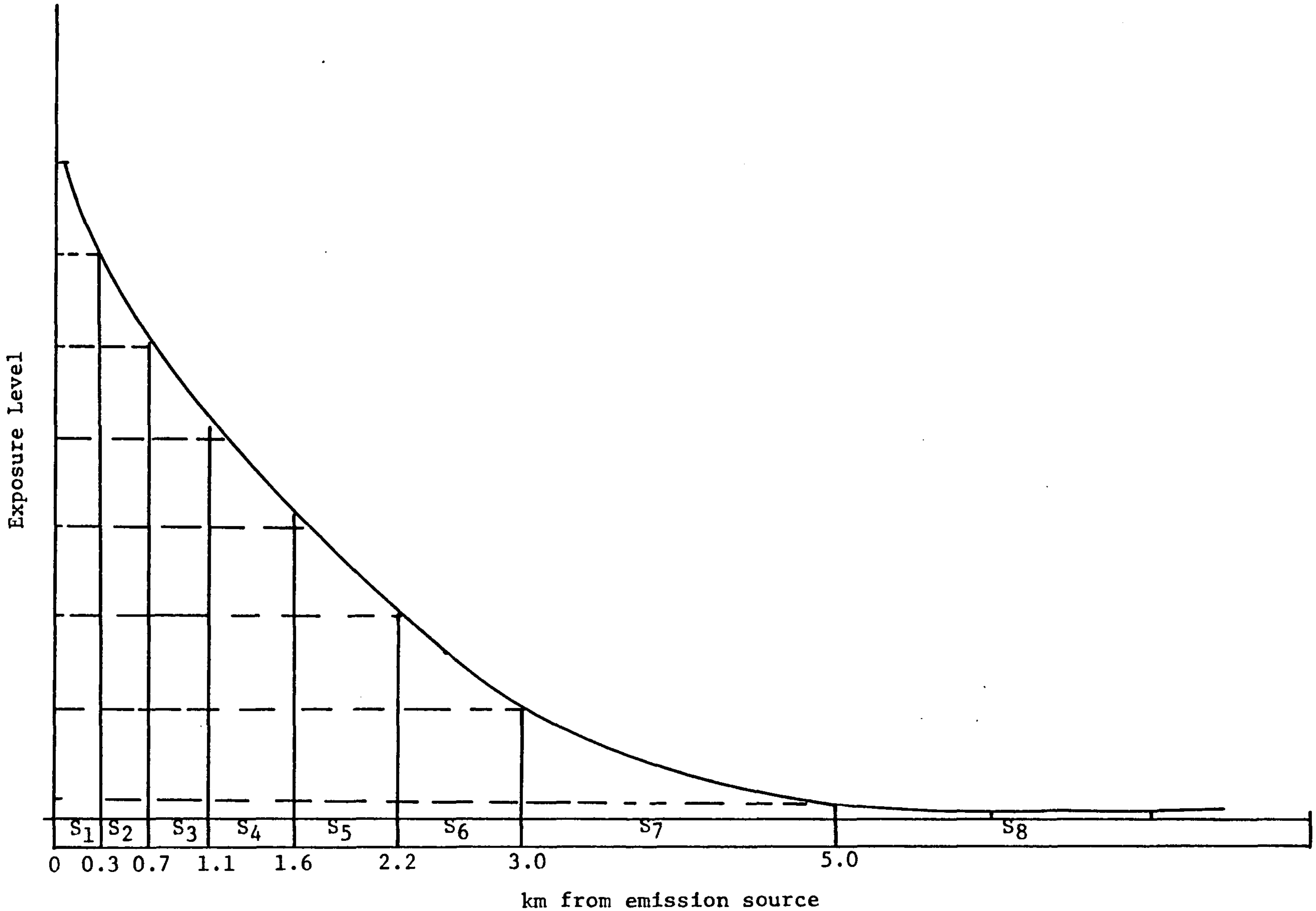


Fig. 1.1. Preliminary distance-stratification for a target population based upon Zn and Cd content of topsoil according to Miesch and Huffman [Ref. 1.1] in East Helena, Montana.

It is noteworthy that stratum 8 in figure 1.1 (from 5 to 8 kilometers downwind of the smelter) is generally considered to be beyond the range of atmospheric transport and, therefore, will serve to some extent as a control group with minimal exposure. More accurately, however, the mobility of individuals in the area can be expected to result in some exposure for most individuals living in the community, thus precluding selection of a true control group from a smelter community. In fact, the exposure levels at Corpus Christi, according to the standard dispersion models, are substantial even beyond 30 km, hence, the decision to sample upwind for the control group.

1.4 The Sampling Frame

The first requirement for a probability sampling of any nature is the establishment of a frame. A frame is a collection of sampling units that may be unambiguously defined and identified. A list of persons, families, or houses might be a sufficient frame for certain types of samples. For the planned survey, one must assume that a complete list of the target population will not be available and will be costly to develop. Therefore, an area sampling frame will be developed. Such a frame will result in a probability sample--that is, all persons in target populations as tentatively defined in appendix 1.1 will have a known, nonzero probability of being selected for the study. The method and materials used to obtain a stratified area sample may vary somewhat by site but will follow the same basic methodology. As shown in appendix 1.1, the sites to be studied are generally characterized by such small populations that Census of Population data are not sufficiently detailed to use as a sampling frame.

Corpus Christi, the one exception to this characterization, is a tracted area for which the Census material constitutes a suitable base for constructing an area frame. The frame construction for Corpus Christi will involve the following tasks:

1. Obtain the pertinent Census materials; these are already available at RTI and include 16 sheets of enumeration district (ED)/block maps and block and ED statistics;

2. Obtain county highway maps showing roads and other boundaries useful for constructing area segments and showing locations of dwelling units outside the urban area;

3. Obtain pertinent stratification information from local sources, such as health departments and weather services;

4. Delineate target area and strata boundaries;

5. Select for each stratum an ED or block with probability proportional to the 1970 population for the ED in which the first sample segment will be located.(a sample segment will comprise a cluster of from 6 to 14 households);

6. Continue task 5 using with-replacement sampling until a sufficient number of segments have been assigned to yield the requisite cohort samples; the procedure of tasks 5 and 6 will be repeated within each sample ED and block to identify specific sample segments and their survey sequence.

The process of developing the sampling frame for less populated areas encompasses the same tasks except that aerial photography, geological survey maps, and street maps will be used to delineate the primary sampling units (PSUs). To facilitate the selection of sample segments, the sample PSUs will be cruised and subsegmented and households will be listed according to methodology developed at RTI [Ref. 1.5].

The information that is expected to be pertinent for stratifying the target population may include several factors as noted earlier in section 1.1. Basically, the target population will be stratified, first according to exposure potential from the emission source (essentially a distance-from-source stratification) and second, according to age and sex within the exposure (or distance) strata. Other factors, which undoubtedly influence exposure and uptake of elements, such as cigarette smoking and proximity to automobile traffic, will be addressed through statistical analysis. Care will also be taken during the statistical analysis to account for the fact that the data result from a stratified cluster sample and not from a simple random sample. Additionally, each stratum should be sufficiently large to yield the requisite sample. The minimum size stratum for each site can be anticipated by viewing the smallest cohort proportion and making allowances for possible nonresponse and occupational exposure. Using Ajo, Arizona as an example, approximately 7 percent of the population is male and 60 or older. According to the 1970 Census, 71 (i.e., 5/.07) persons will be needed to produce the requisite sample of five in this cohort if all participate, if none have had occupational exposure within the preceding 12 months, and if all have lived in Ajo for at least a year. Therefore, the 71 persons plus additional to account for possible nonresponse and occupational exposure suggests that the minimum stratum size may be approximately 125. What actually constitutes a reasonable allowance for these sample losses, however, will be ascertained from local sources and site experience. This minimum stratum size, the relatively small site populations, and the increasing stratum areas as the distance from the source increases suggests that fewer than 8 strata will be feasible for some sites. The actual number of strata used will depend on several factors including what constitutes the downwind population.

1.5 Sample Selection Techniques

1.5.1 Survey Participants

The major considerations outlined in this section involve the need to obtain randomized samples from an adequate representation over a wide range of distances from smelters for 6 to 8 cohort groups. To accomplish this objective, the downwind population in each "distance stratum" will be partitioned, as described in section 1.3, into small segments such as city blocks. Instructions to data collection field staff will contain the following information:

- A list of segments to be surveyed and the order of visiting these segments and households in the sample segments;
- Maps showing segment locations and specific boundaries;
- A form on which a tally will be maintained for each cohort group for each stratum;
- A form for recording a count of all eligible persons in those segments visited, which of them were asked to participate, and which did participate.

The field enumerator will continue to visit segments in the predesigned order in each stratum until either the cohort samples (5 in each cohort group) are obtained or until all households in the stratum have been either contacted or verified as not containing any of the eligible individuals still needed. Except for eligible individuals that do not cooperate, this technique will result in a probability sample of the target populations that will facilitate valid inferences and analyses of the data. The use of cash incentives is expected to hold the nonresponse and hence the departure from a probability sample to a minimum level. In a similar study, the voluntary response rate without the use of incentives was 80 percent [Ref. 1.6].

1.5.2 Air Sampling

The placement of the air sample locations will coincide with the first segments selected in each stratum for the sample of individuals. Also, for each air sample location, a list of days during which the 24-hour samples are to be obtained will be provided to the Site Administrator. This list of days comprises a probability sample of time periods throughout the survey period. From 4 to 6 air samplers will be operating virtually throughout the survey period, and the requisite number of electric connections is expected to range from 8 to 18 for each smelter site depending on the number of strata. Constraints on the allocation require that no more than 2 strata are designated for monitoring on a particular day, and that no stratum will be assigned more than 3 monitors on any single day. The procedure is as follows (see also table 1.2.2):

1. Randomly select 3 days from the first 19 days of the survey period without replacement and assign these to stratum 1--two locations proximate to the first two segments (household sampling units) will be monitored on each of these 3 days;
2. Repeat the procedure of number 1 for stratum 2;
3. Repeat the procedure for the remaining strata except that days already assigned twice are ineligible, and the number of days to be assigned to each stratum increases for strata that are more distant from the smelter.

1.5.3 Sampling for Soil Contamination

Samples of surface soil are to be collected in play areas of all study children. Two soil samples will be obtained from residential play areas for pre-school age study participants at each smelter site, and one composite sample will be taken from each school yard where study children attend (and each air sampling location).

Variation in the soil content of study elements throughout the play areas, both for different locations and times, is expected to be small, relative to variation in the air samples for example, but will undoubtedly be sufficiently large to consider random sampling. For this reason, a methodology is being investigated in the Pretest which would result in a reasonably unbiased sample of the surface soil in play areas of the sample children. This method involves a random point sampling which would essentially ensure that all locations in the play area would have a nonzero (and equal) probability of being selected. Two points will be selected in each play area in the Pretest and will be analyzed before aggregation so that variance components and requisite sample size can be ascertained. If the Pretest reveals that random sampling is impractical, a selective composite sample will be relied upon at the study sites to measure element exposure from soil in the play area. In either case, the enumerators will first establish the boundaries of the most commonly used play area and will then select surface soil samples from scattered points in the play area. These samples, which will be obtained concurrently with the interview, will comprise the soil sample(s) for that play area.

1.5.4 Sampling Tap Water

A sample of tap water will be obtained during the interview at the residence of each study participant. The tap water sample will be obtained from the kitchen tap or other source commonly used for drinking and/or cooking. It is anticipated that two tap water samples will be obtained, one sample taken from the first drawn water and another sample taken after the water has been allowed to run for three minutes. The underlying assumption is that the element content of most ingested water is between these two extremes. The feasibility of this methodology will be investigated at the Pretest site by analyzing the "before and after" samples seperately for a subsample of the households. Random sampling at different locations and times (except the before and after flush sampling) was not proposed for this measure of exposure, because it should be relatively homogeneous within a household, and because what little improvement in data that might result from a suitable randomization of this measure does not appear to justify the accompanying increase in respondent and interviewer burden.

1.5.5 Quality Control

Analytical errors--that is, errors in the laboratory analyses--can constitute a serious problem [Ref. 1.4]. Several methods for controlling these errors are described more fully in the data collection and laboratory analysis sections of this Work Plan, but one aspect of the quality control is described briefly here because it relates to sample randomization. To the extent possible, the sample data will be stored in the laboratory and analyzed in random groups rather than in batch groups as they are sent in from the field in order that analysis error can be identified as error rather than as factor effect. Also, the forms used for tallying eligibles in the sample segments will identify some 10 percent of certain eligibles as quality control individuals; duplicate samples of blood and hair will be obtained for selected adult participants and duplicate samples of tap water and dust will be taken at selected dwellings. Also, duplicate soil samples will be taken for 10 percent of the school yards and air sampling locations. The purpose of these quality control observations is to measure the possible influence of sample acquisition, packaging, shipping, and laboratory analysis. Additionally, 10 percent of the sample individuals will be reinterviewed at a later date to verify the information obtained on the survey questionnaire; the identity of these persons will be unknown to the initial interviewer.

1.6 Sample Sizes and Sampling Error

The sampling errors and sample sizes are presented here in two sections, for individuals and for high-volume air samples. An apparent inconsistency exists between the proposed sample allocation of persons and that for air samples. This apparent inconsistency reflects the anticipated small within-stratum variation of long-range, average conditions, such as element absorption in soil [Ref. 1.1], and the relatively greater within-stratum variation anticipated for certain unstable conditions, such as atmospheric composition at a specific location on a particular day [Ref. 1.2]. This results in a slightly larger sample of high-volume air samples being taken in the strata more distant from the smelter, while, for persons (and soil samples), equal sample sizes are to be taken from each stratum.

1.6.1 Allocation of the Sample of Individuals

If estimates of population totals or averages are sought, the optimum sample allocation in stratified sampling is a function of stratum variances, costs, and stratum sizes, according to the following equation:

$$n_h = n(N_h S_h / \sqrt{C_h}) / \sum^{L} N_h S_h / \sqrt{C_h} \qquad (1)$$

where n_h = the optimum sample size for stratum h for an overall sample of size n, N_h = the number of elements in stratum h of the population, S_h = the standard deviation of stratum h, and C_h = the cost of sampling from stratum h.

To meet the objectives of this study, however, accurate estimates are needed of mean exposure at various distances from the emission source. The N_h, therefore, are dropped from equation 1. Also, C_h in the proposed study will be approximately constant for all strata. The optimum n_h can then be obtained by using equation 1 and the fact that the S_h are also approximately equal (see figure 1.1):

$$n_h = n\ S_h / \sum^{L} S_h$$

$$= n/L$$

$$= 40/8$$

$$= 5$$

where L is the number of strata (8 or less), n is the number of individuals per cohort (40), and other notation is as defined for equation 1. The desired sample allocation of the 1,680 sample persons is described in table 1.1, although, as noted earlier, the actual stratum sizes may differ among smelter sites. Based on prior studies [Ref. 1.7, 1.8, 1.9 and 1.10, for example], this sample size should result in a reasonable capability (Type I and Type II error both at 0.05) for detecting a lead difference, for example, of 5μg/100 ml blood; 40 is commonly accepted as the concentration above which health problems are likely to exist.

1.6.2 <u>High-Volume Air Samples</u>

The high-volume air samples are needed to estimate exposure levels

Table 1.1. Tentative sample allocation for individuals* at the study sites.

Geographic Site	Number of Individuals by Cohort Group in Each Stratum							
	Preschool		School Age		20-35 Years		60 Yrs & Older	
	Male	Female	Male	Female	Male	Female	Male	Female
Lead (1)	5	5	5	5	5	5	5	5
Lead (2)	5	5	5	5	5	5	0	0
Zinc (1)	5	5	5	5	5	5	5	5
Zinc (2)	5	5	5	5	5	5	0	0
Copper (1)	5	5	5	5	5	5	5	5
Copper (2)	5	5	5	5	5	5	0	0

*Assuming, tentatively, eight strata as depicted in figure 1.1: 0.0 - 0.29 km, 0.3 - 0.69 km, 0.7 - 1.09 km, 1.1 - 1.59 km, 1.6 - 2.19 km, 2.2 - 2.99 km, 3.0 - 4.99 km, and 5.0 - 7.99 km.

at varying distances from the emission source, at varying distances from the transit line of the downwind pattern (corresponds to primary wind direction), and at varying wind velocity and direction.

All air samples will be collected by the Chemistry and Life Sciences Group of RTI. Each of these high-volume samples will be collected over 24 hours on fiberglass filters.

Two sampling questions need to be answered about the high-volume air survey:

1. How many sampling points are needed in each stratum?
2. How many locations should be observed during a sample day?

Several 24-hour readings are needed in each stratum in order to measure the variation over time [Ref. 1.2] as well as the need to measure the influence on exposure of different wind velocities and directions. The basic sample size and allocation are presented in table 1.2, but they necessarily will be tailored to suit the individual site circumstances. Methodology for estimation of sample size and allocation is described in appendix 1.2. The per-site sample size totals 87 location-days. This size sample is expected to produce a coefficient of variation for element content of atmosphere of 0.20 or less at the stratum level.

As mentioned above, the stratification and sample allocation will vary somewhat among sites so that the examples presented for clarification--namely, the fall-out curve in figure 1.1, the sample allocation in table 1.2, and the random assignment scheme for air samples presented in table 1.2.2--should be considered flexible. Another noteworthy point on the air sampling is that it is primarily to be used to assess the past average exposure of the target population.

Table 1.2. Tentative sample allocation for air samples*.

Type of Observation	Number of Observations, S_i, in Each Stratum								
	S_1	S_2	S_3	S_4	S_5	S_6	S_7	S_8	Total
Locations (A)	2	2	2	2	2	2	3	3	18
Days (B)	3	3	4	4	5	5	6	7	-
24-hour samples (A x B)	6	6	8	8	10	10	18	21	87
Ratio, days/locations	1.5	1.5	2.0	2.0	2.5	2.5	2.0	2.3	-

*Based on data presented in appendix 1.2 [Ref. 1.2].

Because it samples such a short time period (20 days), little measure of seasonal effect will result. Resource constraints have imposed this relatively short sample period; admittedly a longer time period and even a one-to-one matching between high-volume air samples and sample persons might be desirable. Basically, therefore, what is expected from the proposed design is a measure for each distance stratum of the atmospheric condition during the survey period and of how well the standard dispersion models perform [Ref. 1.11]. This information can be used to adjust these models so that historical climatic data can be used more effectively to estimate average past exposure. The same type of seasonal adjustments will be used on other "seasonal" factors in the analysis to the extent seasonal effects are revealed over the course of the study.

Another characteristic of the air sampling methodology is the continuous sampling of predesignated points on specified days. While one might be tempted to shift the samplers away from "unusual" atmospheric conditions, such variations would result in biased estimates.

APPENDIX 1.1

CHARACTERISTICS OF SURVEY SITES

Table 1.1.1. Selected population characteristics of survey sites.*

State	Smelter town	Neighboring towns	Population number	Net migration since 1960, percent	Age groups, percent			
					1-5	6-17	20-35	60+
Arizona	Ajo		5,881	-16.6	12	25	19	14
		Rowood	-					
Missouri	Bixby		<1,000					
		Bass	-					
		Buick	-					
		Viburnum	520					
	Herculaneum		1,885					
		Festus	7,530					
		Crystal City	3,898					
		Horine	-					
		Povely	517					
Montana	Anaconda		9,771	-18.9	10	22	18	19
		Gregson	-					
		Warmsprings	-					
Oklahoma	Bartlesville		29,683	6.4	10	20	20	17
		Dewey	3,958					
		Tuxedo Park						
Pennsylvania	Palmerton		5,620	-5.4	9	17	20	22
Texas	Corpus Christi (Pretest site)		204,525	22.0	11	26	19	12

*Based on the 1970 Census of Population.

METHODOLOGY FOR CHARACTERIZING THE STUDY POPULATION IN CORPUS CHRISTI, TEXAS

Estimates of particulate concentration surrounding the ASARCO, Inc. smelter at Corpus Christi, Texas were made using the Climatological Dispersion Model (CDM) of the EPA UNAMAP Library. The CDM is described in detail by Calder [Ref. 1.12] and in less detail by Busse and Zimmerman [Ref. 1.13]. A brief description of the model and its application follows.

The average annual concentration (ground level) was estimated for Pb, Mn, Cu, As, and Zn resulting from the nine sources at ASARCO that emit these elements. The models used to estimate these concentrations rely on such information as:

- Relative frequency of wind speed (6 categories) and direction (16) for each of six atmospheric stabilities,
- Mixing height of atmosphere [Ref. 1.14],
- Temperature (outside and stack gas),
- Emission height,
- Stack diameter, and
- Emission rate and velocity.

These concentrations were calculated for a 60 km square area around ASARCO. Concentrations were calculated each 0.8 km up to 8 km from ASARCO and each 1.6 km for the remaining area in the 3600 km^2 area. Gradients of these concentrations were plotted on maps depicting population location and Census defined areas (Blocks, Enumeration Districts [EDs], and Tracts). These gradients revealed several pertinent considerations:

- Most of Corpus Christi's population resides "upwind" of the ASARCO plant.
- Individuals residing downwind (largely to the northeast) are apparently exposed to substantial concentrations (from ASARCO) even beyond 30 km from the source; 75 $\mu g/m^3$ was estimated at 30 km.
- The gradients also revealed useful strata boundaries for use in the sampling components of the investigation.

Based on the concentration estimates, it was concluded that the study population should be taken within 30 km even though this distance will not result in an adequate control group. The control sample will be selected from Corpus Christi residents to the southeast where concentrations of only 10 $\mu g/m^3$ were estimated. Additionally, to obtain the maximum possible information about individuals throughout the full range of exposure potential, the upwind (wind from the direction of the smelter less than 3 percent of the time) population--except for the control--was excluded. Also, to hold the public relations activities to a reasonable level, the study area was restricted to Nueces county; approximately 3,800 persons reside within the 30 km limit in San Patricio county but this constitutes only 4 percent of the total downwind population.

The tentative study populations delineated for the other study sites will probably have similar exclusions--that is, counties with a small proportion of the population will be excluded and the distance limit (30 km) may be reduced or increased depending on particulate dispersion and population location.

Table 1.1.2. Population residing in the tentative study area near Ajo, Arizona*

County	Census Division	Town or Area	Population
Pima	Ajo	Ajo	5,881
		Other	412
Total			6,293

*Based on 1970 Census of Population

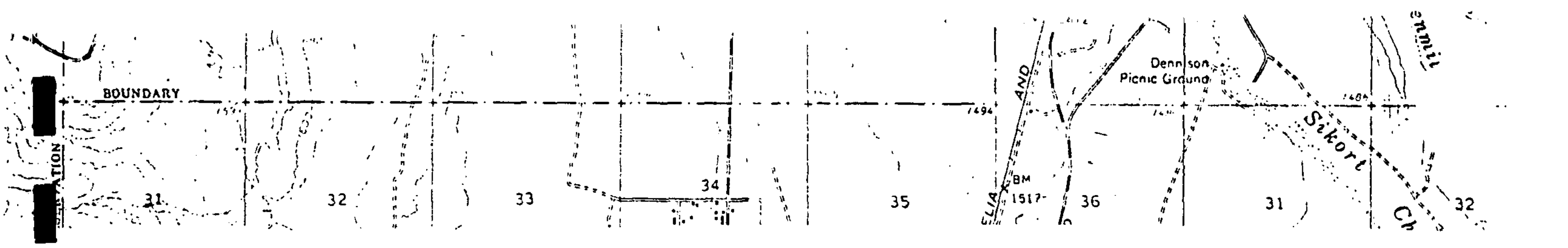
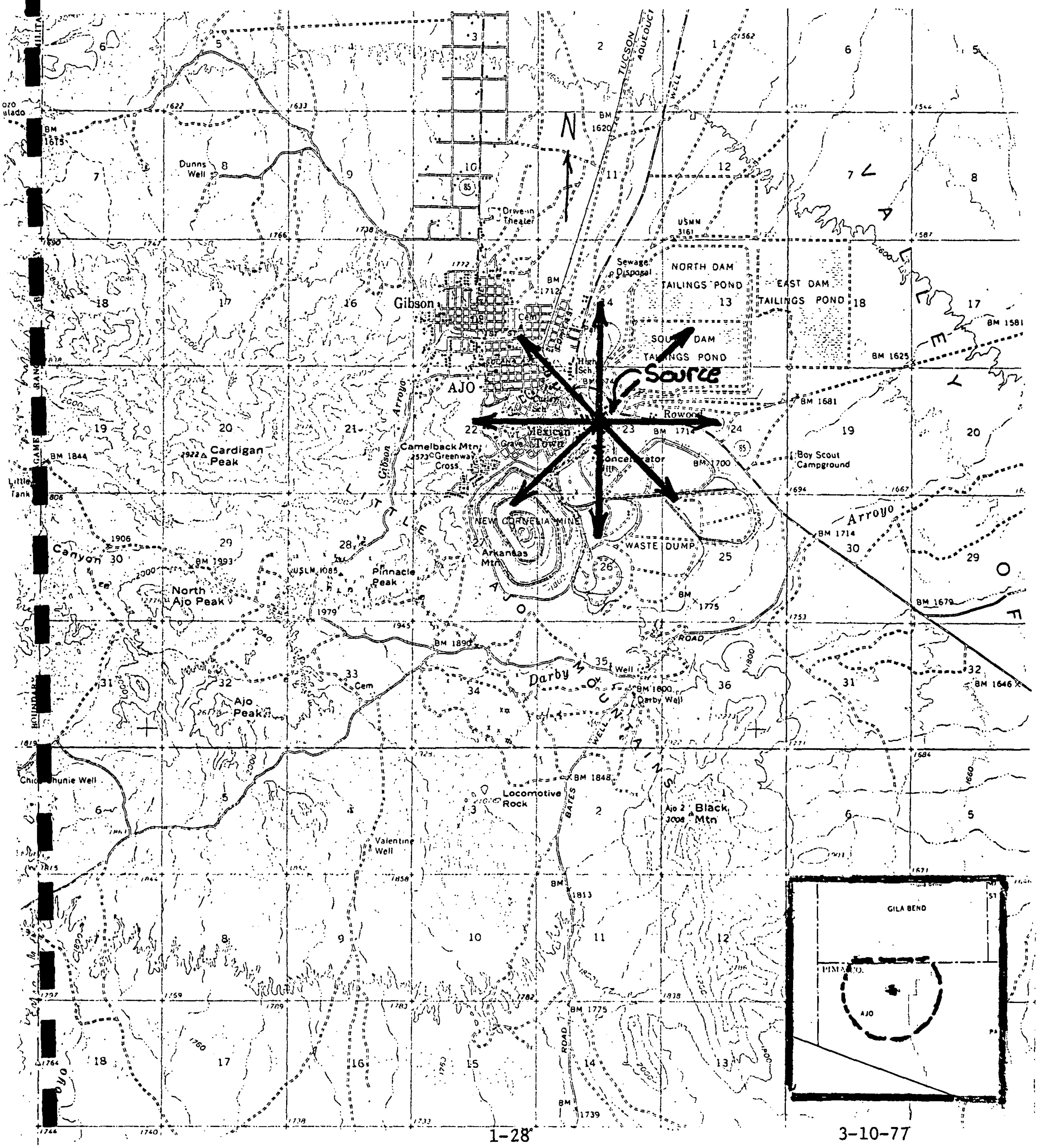


Figure 1.1.1. Geographic location of study smelter and tentative delineation of the study population, Ajo



3-10-77

Table 1.1.3. Population residing in the tentative study area near Anaconda, Montana*

County	Census Division	Town or Area	Population
Deer Lodge	Anaconda	Anaconda	9,771
	Deer Lodge Valley	-	3,255
Silver Bow	Butte	Butte	23,368
	Rocker-Ramsey	-	980
	Walkerville-Browns	Walkerville	1,097
		Other	285
Powell	Cottonwood	-	816
Total			39,572

*Based on 1970 Census of Population

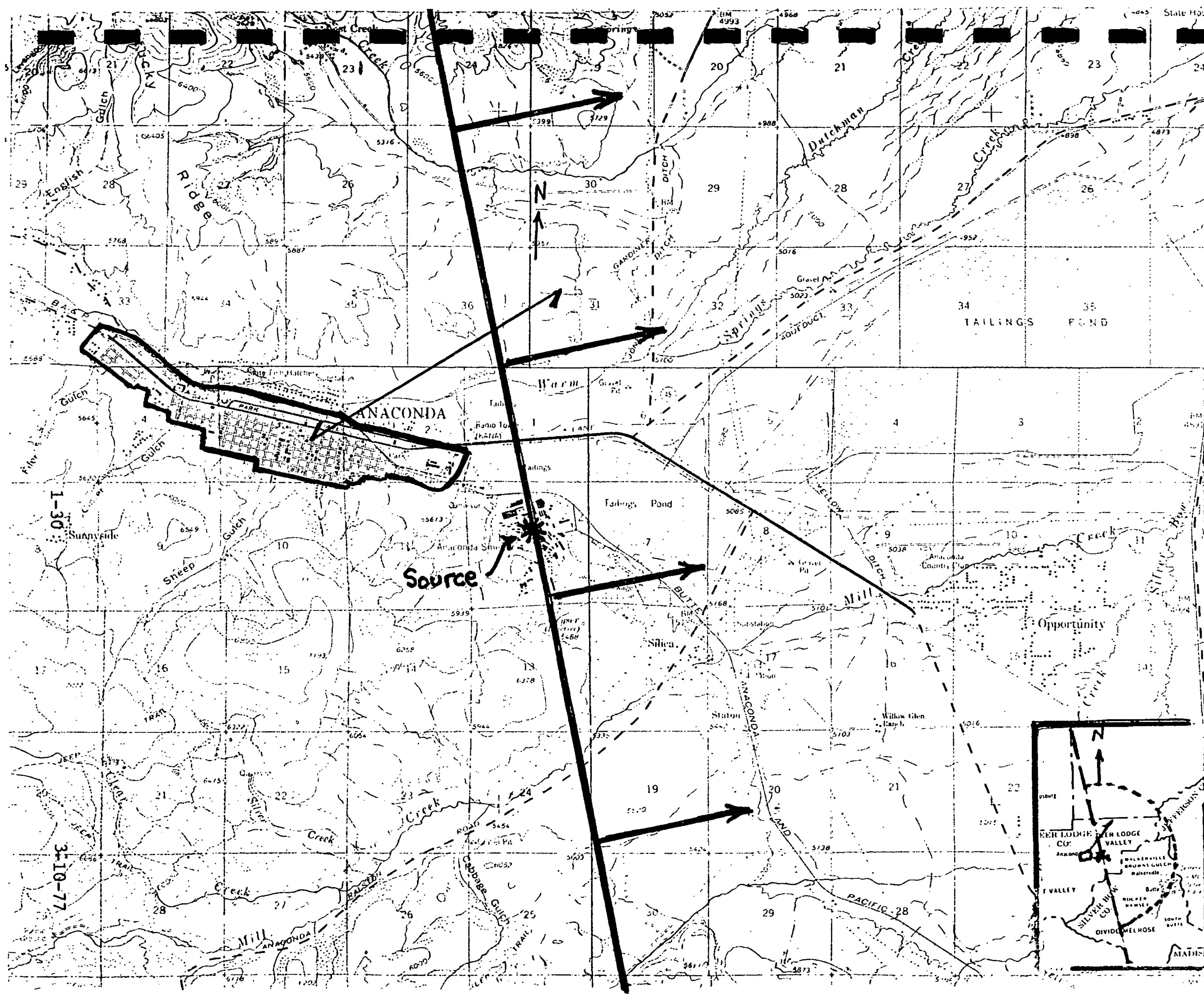


Figure 1.1.2. Geographic location of study smelter and tentative delineation of the study population, Anaconda

Table 1.1.4. Population residing in the tentative study area near Bartlesville, Oklahoma*

County	Census Division	Town or Area	Population
Washington	Copan	Copan	558
		Other	845
	Dewey	Dewey	3,958
		Other	1,240
	Bartlesville	Bartlesville	29,672
	Bartlesville Southeast	-	1,026
	Ochelato-Ramona	Ochelato	330
		Ramona	600
		Other	1,897
Osage	Pawhuska	-	909
	Barnsdall	Avant	439
		Barnsdall	1,579
		Other	485
Rogers	Oolagah-Talalo	-	513
Nowata	South Coffeyville-Wann	Wann	135
		Other	525
Total			44,771

*Based on 1970 Census of Population

Figure 1.1.3. Geographic location of study smelter and tentative delineation of the study population, Bartlesville

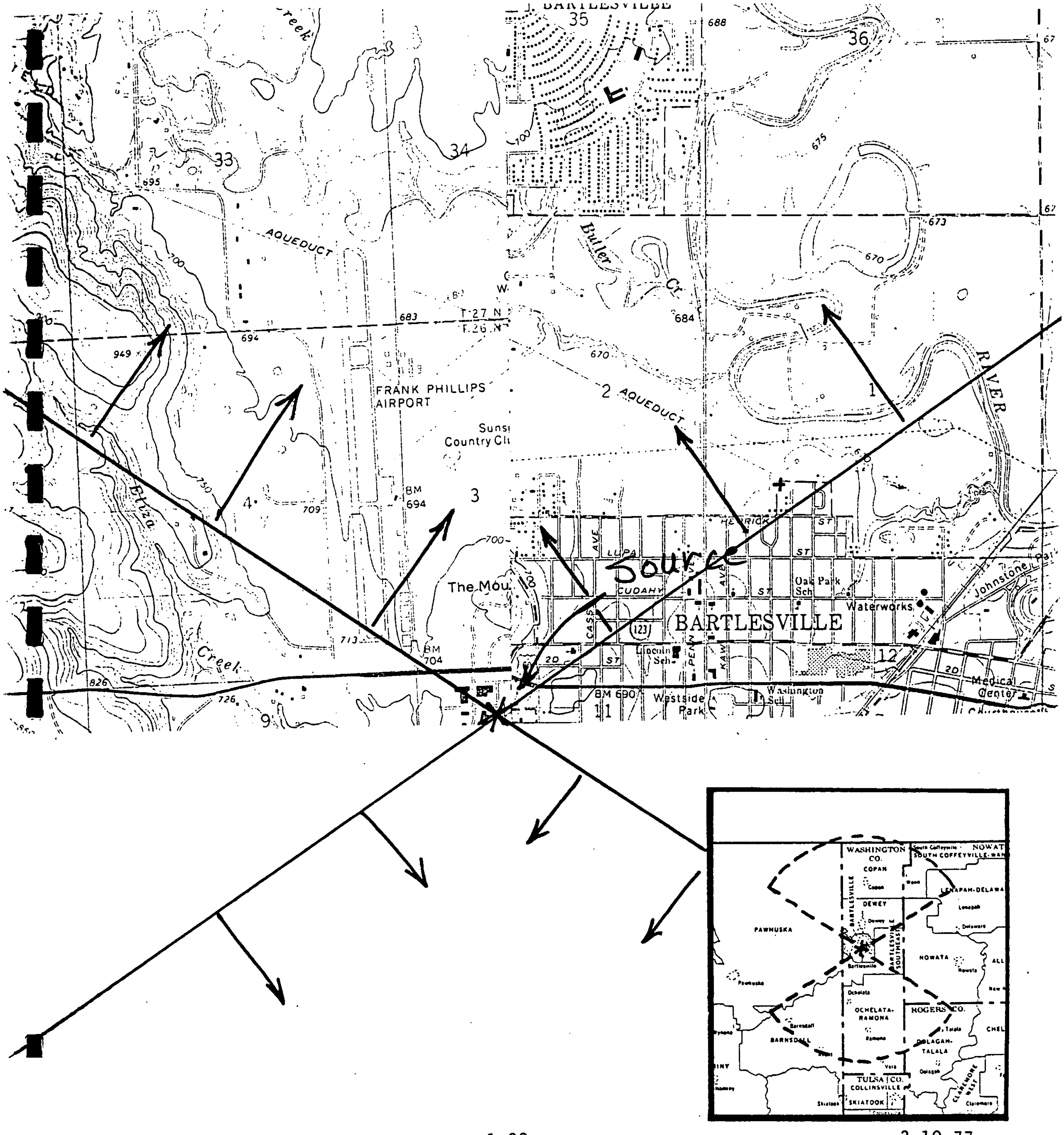
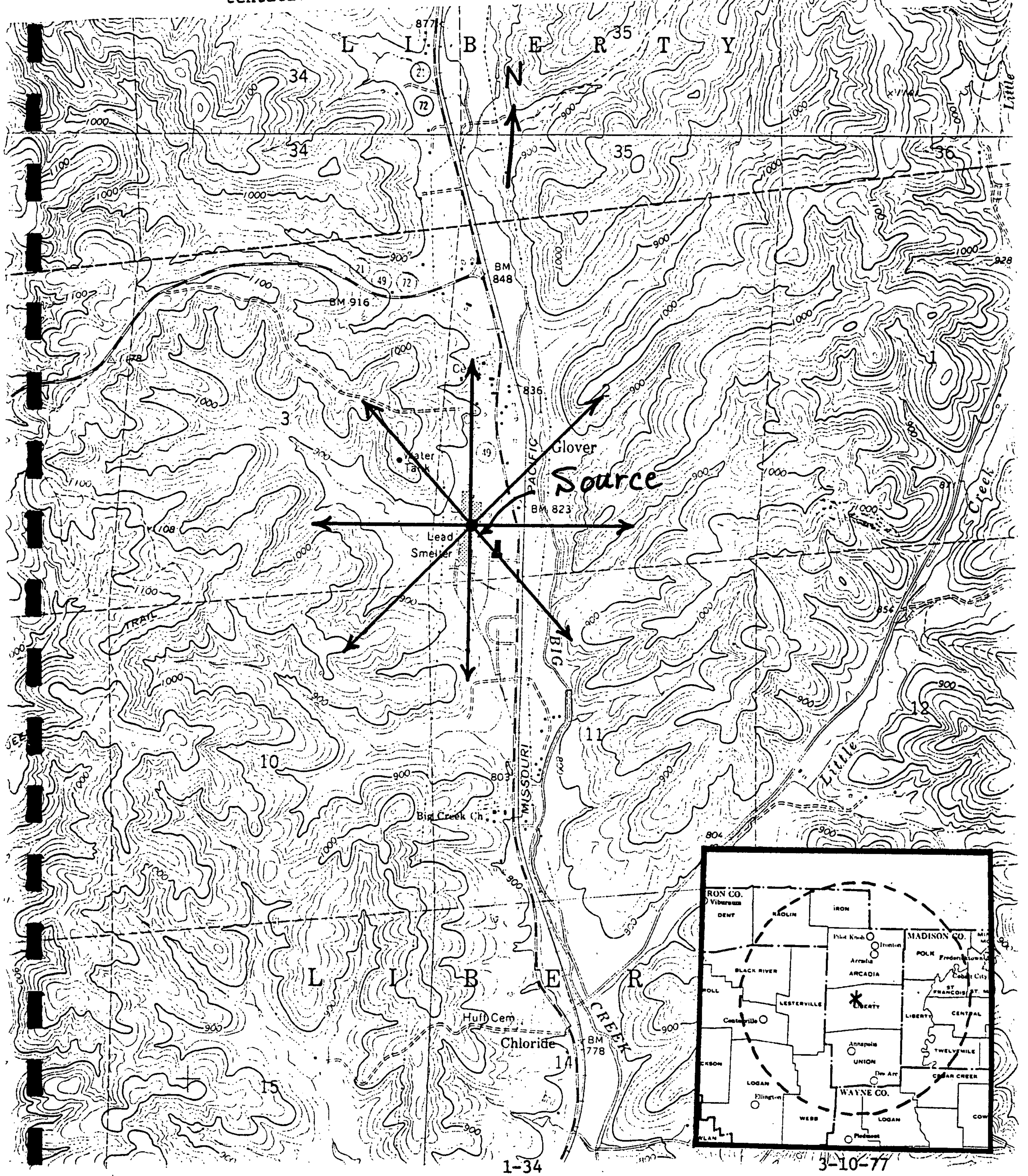


Table 1.1.5. Population residing in the tentative study area near Bixby, Missouri*

County	Census Division	Town or Area	Population
Iron	Arcadia township	Arcadia	627
		Ironton	1,452
		Pilot Knob	582
		Other	2,046
	Iron township	-	1,116
	Kaolin township	-	245
	Liberty township	-	478
	Union township	Annapolis	330
		Des Arc	222
		Other	1,049
Reynolds	Carroll	Centerville	209
	Lesterville township	-	762
	Webb township	-	205
Madison	Polk township	-	398
	St. Francois township	-	268
	Liberty township	-	279
	Central township	-	210
	Twelvemile township	-	129
Wayne	Logan township	-	325
	Cedar Creek township	-	144
Crawford	Osage	Dillard	36
Total			11,112

*Based on 1970 Census of Population.

Figure 1.1.4. Geographic location of study smelter and tentative delineation of the study population, Bixby



3-10-77

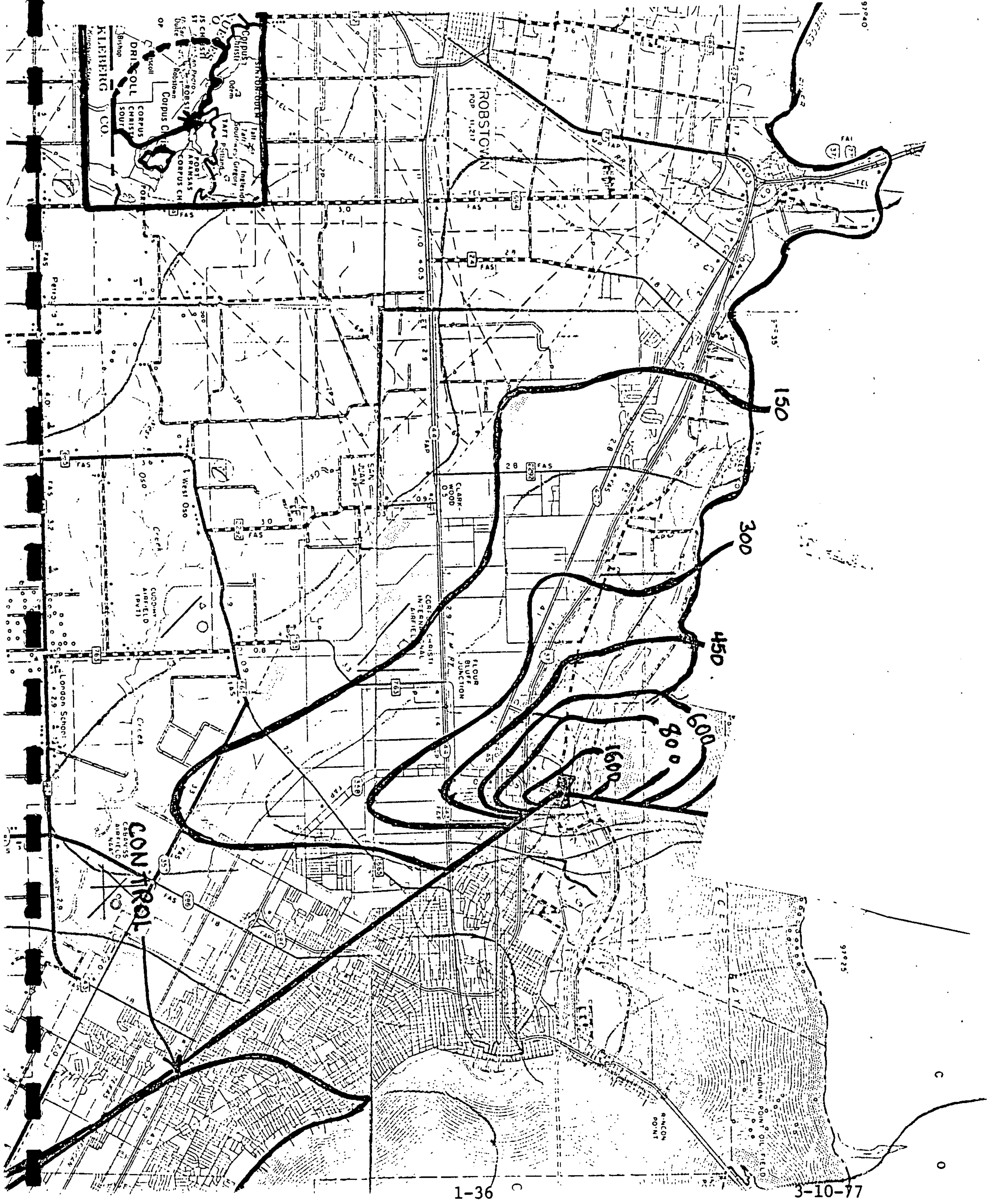
Table 1.1.6. Population by stratum residing in the study area near Corpus Christi, Texas

Stratum	Potential exposure μg/m^3**	Population	Sample size
1 (Control)	<25	54,265	42
2	25 - 150	76,747	6
3	150 - 300	14,296	6
4	300 - 450	872	6
5	450 - 600	302	6
6	600 - 800	356	6
7	800 - 1,600	591	6
8	>1,600	741	42
Total		148,170	120

*Based on 1970 Census of Population.

**Based on atmospheric dispersion model described in appendix 1.1.

Figure 1.1.5. Geographic location of study smelter and tentative delineation of the study population, Corpus Christi



 3-10-77

Table 1.1.7. Population residing in the tentative study area near Herculaneum, Missouri*

County	Census Division	Town or Area	Population
St. Louis	Lemay	Bella Villa	1,419
		Lemay (part)	36,759
		Other	22,381
	Concord	Concord	21,217
		Lemay (part)	3,356
		Sunset Hills	92
		Other	12,979
Jefferson	Meramec	Parkdale	836
		Other	7,640
	Rock	Kimmswick	268
		Other	44,403
	Joachim	Crystal City	3,898
		Festus	7,530
		Herculaneum	1,885
		Pevely	517
		Other	8,108
	Central	Hillsboro	432
		Other	4,995
	Big River	-	1,316
	Valle	De Soto	5,984
		Other	1,995
Ste. Genevieve	Jackson	Bloomsdale	411
		Other	647
Monroe (Illinois)**	all except Prairie DuLong	-	17,491
Total (in Missouri)			189,068

*Based on 1970 Census of Population.

**Tentatively excluded from the study area.

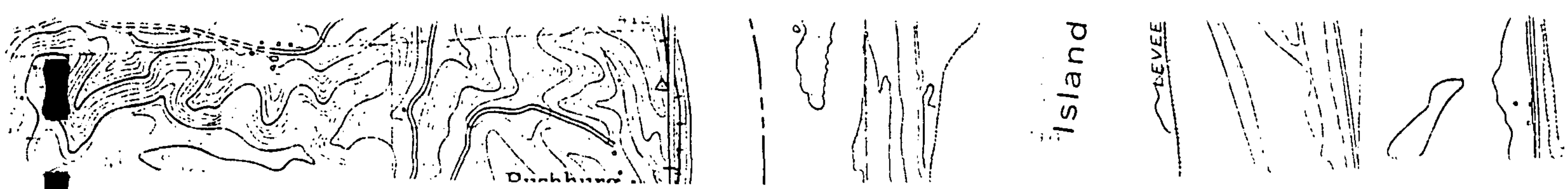


Figure 1.1.6. Geographic location of study smelter and tentative delineation of the study population, Herculaneum

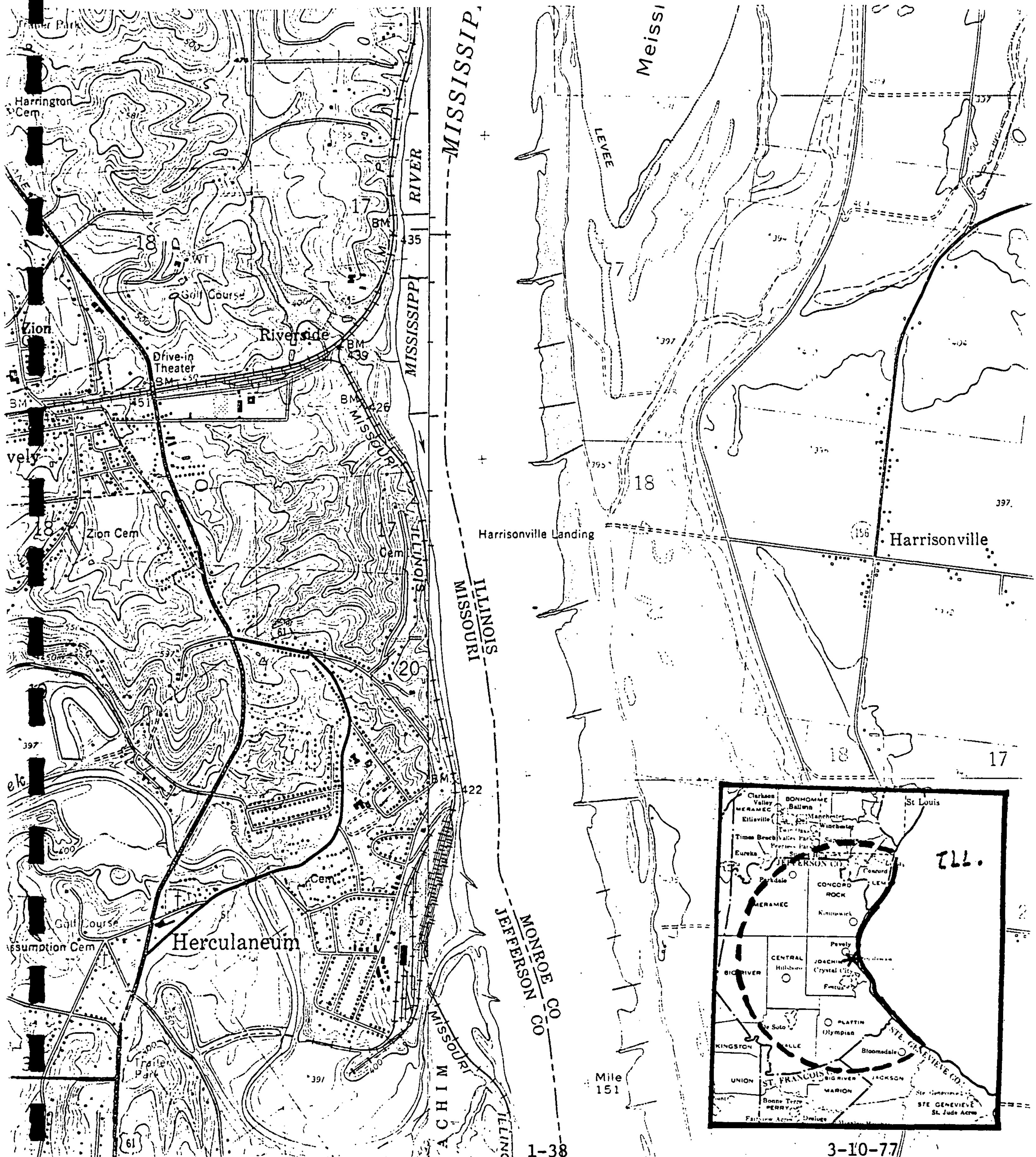


Table 1.1.8. Population residing in the tentative study area near Palmerton, Pennsylvania*

County	Census Division	Town or Area	Population
Carbon	Kidder township	-	298
	Penn Forest township	-	423
	Towamensing township	-	1,096
	Lower Towamensing	-	2,360
	Palmerton borough	-	5,620
	Franklin township	Other than Weissport East	514
	East Penn	-	659
Monroe	Tunkhannock township	-	159
	Chestnuthill township	-	2,021
	Jackson	-	404
	Polk	-	1,284
	Hamilton	-	995
	Ross	-	998
	Eldred	-	990
Northampton	Lehigh township	-	6,086
	Walnut borough	-	1,942
	Moore township	-	3,791
	Chapman borough	-	191
	Bushkill	-	3,387
	Wind Gap borough	-	2,270
	Plainfield	-	2,144
	Slockerton borough	-	753
	Upper Nazareth	Eastlawn Garden	1,613
		Other	1,992
	Lower Nazareth	-	2,091
	East Allen	-	2,737
	Bath borough	-	1,829
	Bethlehem township	-	4,536
	Bethlehem city	-	52,065
	Hanover		5,434
	Allen		1,856
	Northampton		8,389
	North Catasaugua borough	-	2,941

Table 1.1.8.* (Continued)

County	Census Division	Town or Area	Population
Lehigh	Catasaugua borough	-	5,702
	Hanover	-	1,217
	Whitehall	Fullerton(U)	7,908
		Other	10,415
	North Whitehall	-	6,819
	South Whitehall	-	14,210
	Allentown city	-	109,527
	Upper Macungie	-	4,390
	Weisenberg	-	1,737
	Lynn	-	2,047
	Heidelberg	-	1,532
	Lowhill	-	1,002
	Washington	-	3,732
	Slatington borough	-	4,687
	Coplay borough	-	3,642
Berks	Albany	-	555
Schuylkill	West Penn	-	2,636
Total			305,626

*Based on 1970 Census of Population.

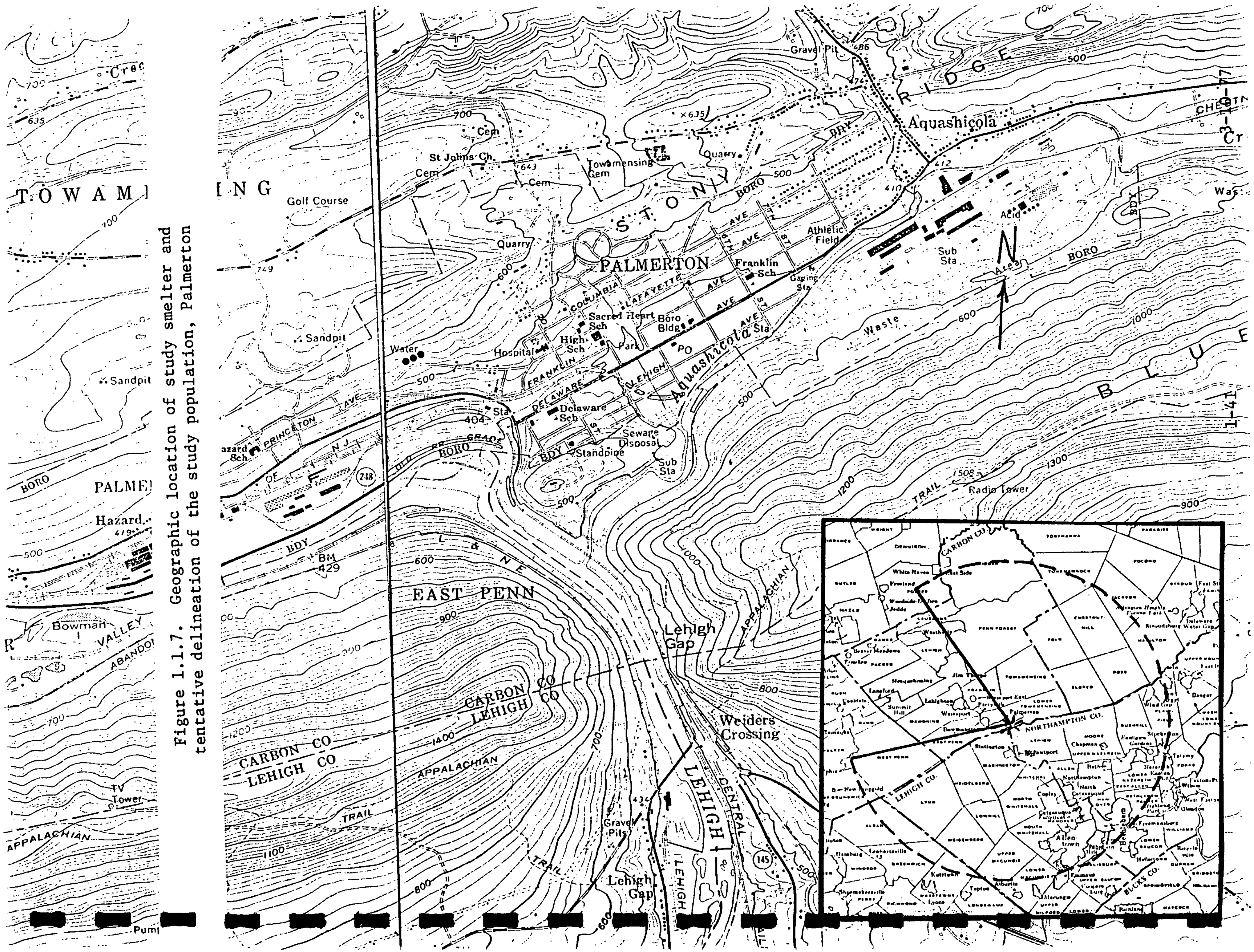


Figure 1.1.7. Geographic location of study smelter and tentative delineation of the study population, Palmerton

APPENDIX 1.2

SAMPLE SIZES AND ALLOCATION FOR AIR SAMPLING

The requisite sample sizes and allocations are based tentatively on data presented in table 1.2.1 [Ref. 1.2]. These allocations will ultimately reflect also the specific smelter-site characteristics, which will be obtained from site visits.

The variances (based on table 1.2.1 data) equal 891 and 305 for strata 6 and 8, respectively. Sample sizes of 10 and 23 for these two strata will yield estimates with less than a 20 percent coefficient of variation (CV). If a regression estimator proves effective, say with a correlation coefficient ($R_y.123...p$) of 0.8, then the CV would be approximately 12 percent.

Table 1.2.1. Lead content of air, μg/cu m.*

Day	Stratum 6; 2 locations (2.2 - 3.0 km)		Stratum 8; 3 locations (5.0 - 8.0 km)		
1	13.0	30.0	1.3	7.6	4.2
2	84.0	68.0	15.0	36.0	25.0
3	18.0	66.0	9.6	3.2	4.2
4	-	-	24.0	60.0	29.0

*Based on reference 1.2.

The variances were calculated according to: $S^2 = \sum_{ij} (X_{ij} - \bar{x})^2/(nm-1)$

where

X_{ij} = Pb readings for day i and location j with i ranging from 1 to n and j ranging from 1 to m.

The coefficients of variation are calculated according to:

$$C = S_e / \bar{x} \sqrt{nm}$$

where

$$Se = S \sqrt{1-R^2_{y}.12...p}$$ and the other terms are as defined above.

Also, the following ratio of standard deviations for each stratum suggests that the sample ratio for day/locations should be approximately 2.2:

$$mn/m = S_D/S_L$$

where

S_D and S_L are the standard deviations for days and locations, respectively.

An example of the assignment of the air samplers by location and day within each stratum is presented in table 1.2.2.

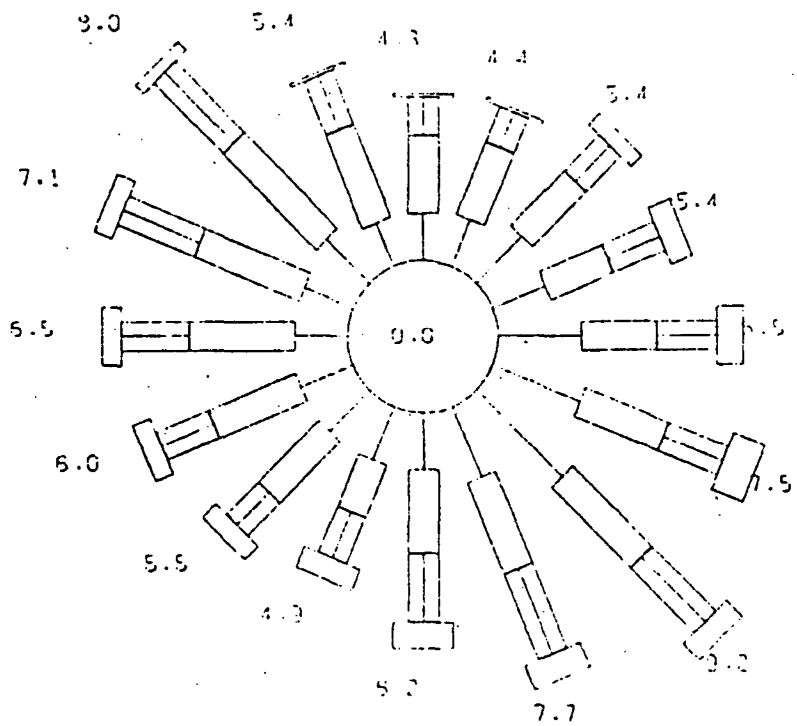
Table 1.2.2. Random assignment of days for high volume air samples: an example*

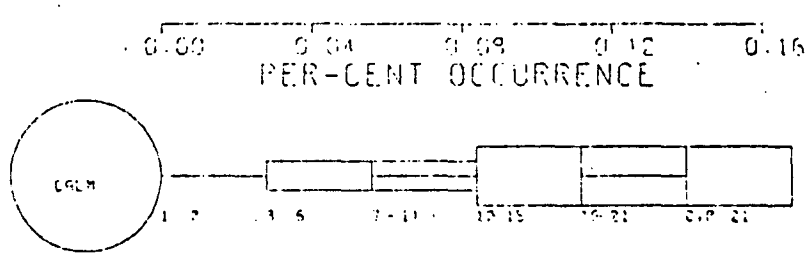
Stratum	Day 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	Electric drops, required number
1						x		x			x									2
2			x										x			x				2
3				x				x		x					x					2
4	x								x		x							x		2
5		x			x		x					x		x						2
6			x			x	x										x	x		2
7		x		x					x	x		x				x				3
8	x				x								x	x	x		x		x	3

*Each x represents 2 or 3 sampling locations for each stratum-day as indicated by the requisite number of electric drops.

APPENDIX 1.3

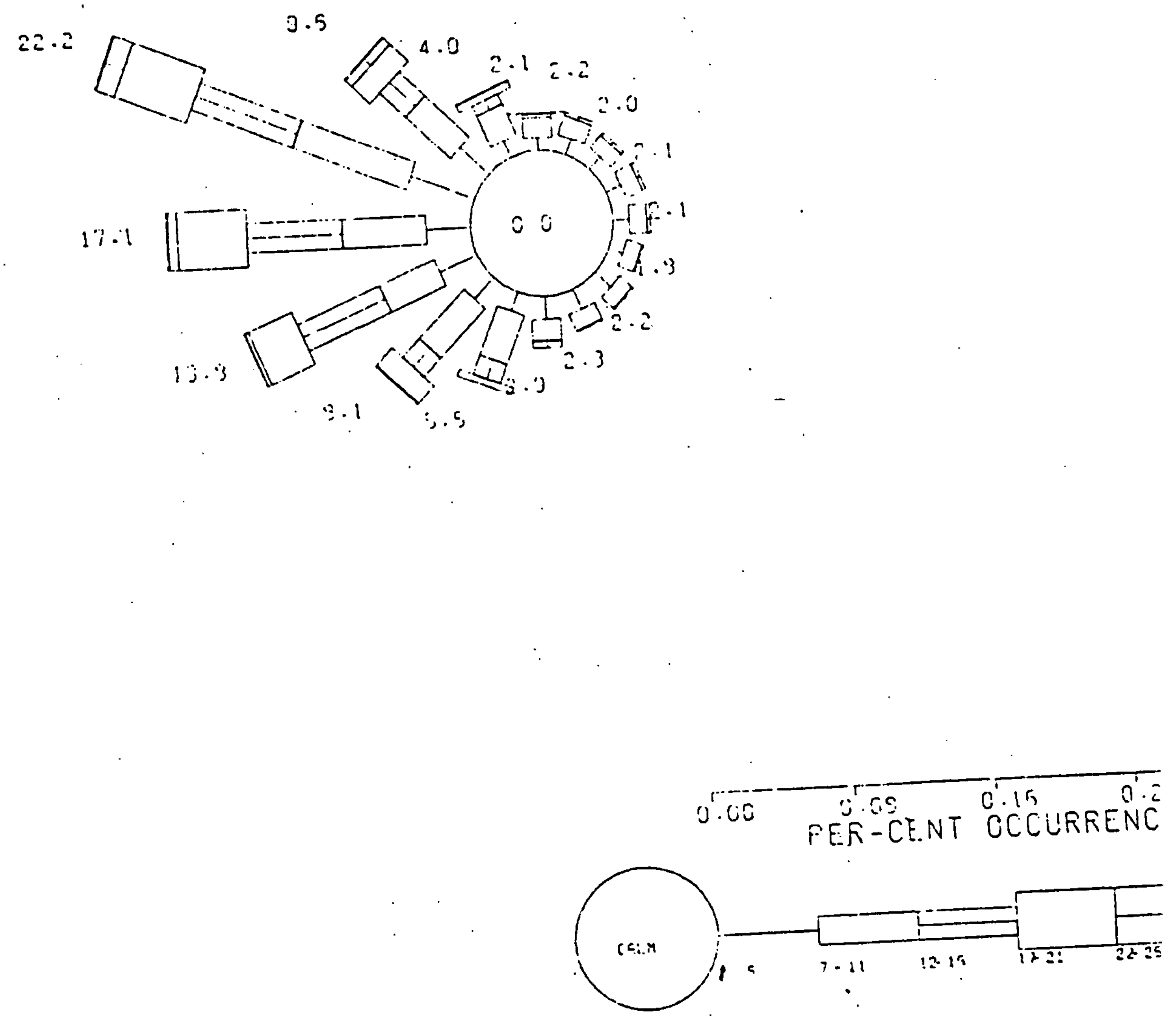
WIND ROSES FOR SMELTER SITES





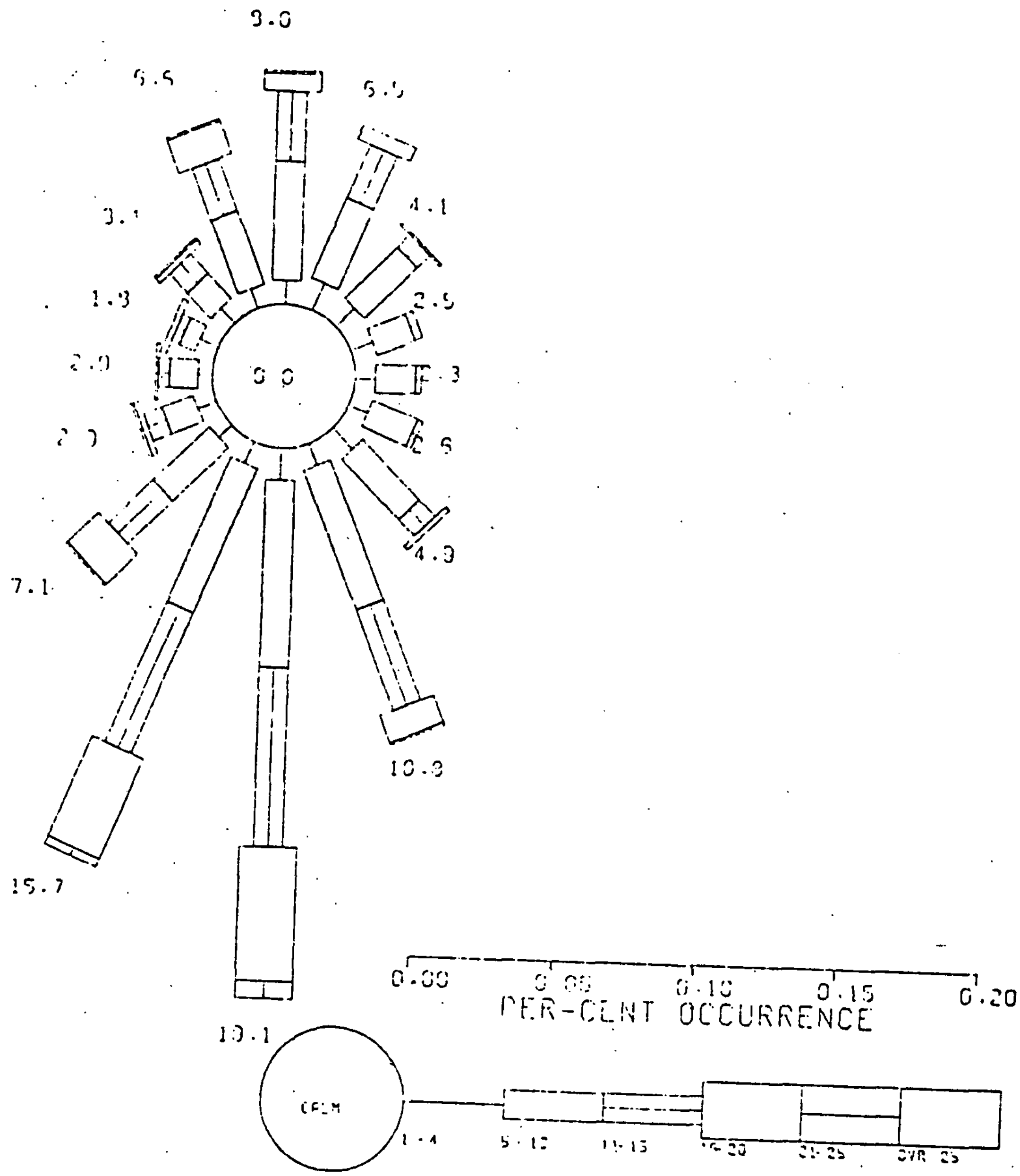
3-10-77

ANACONDA, MONT. 300M

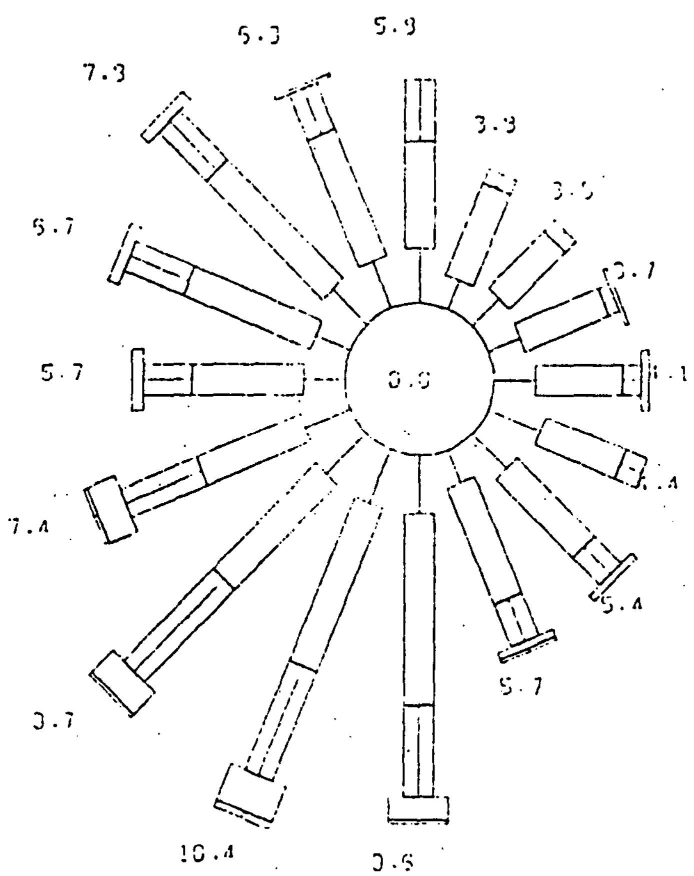


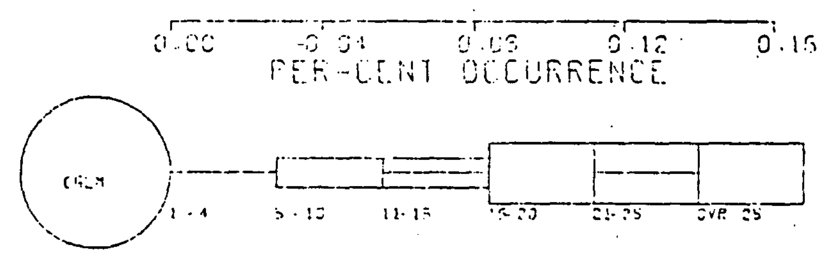
3-10-77

BARTLESVILLE-BLACKWELL, OK. 300M

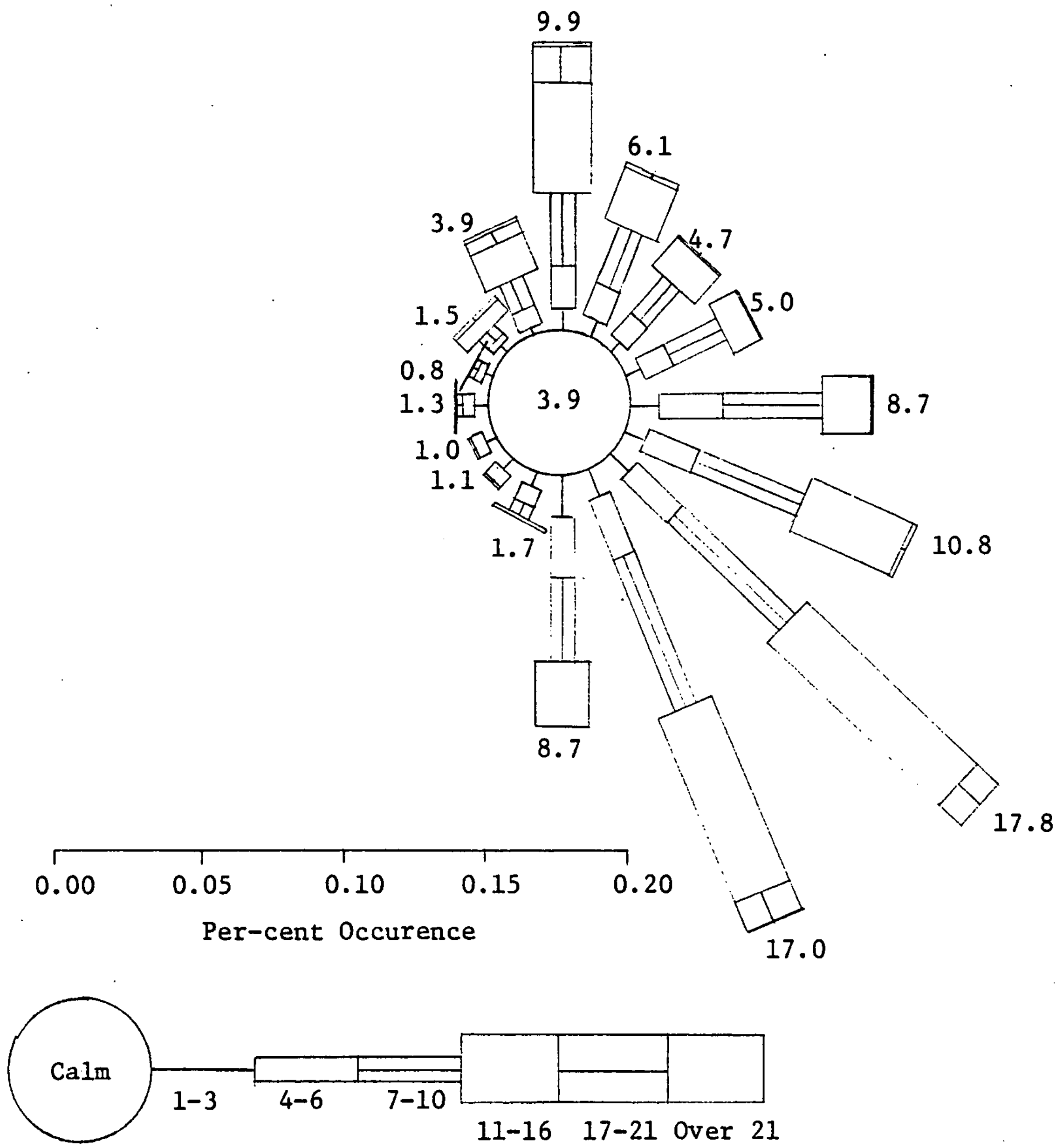


3-10-77

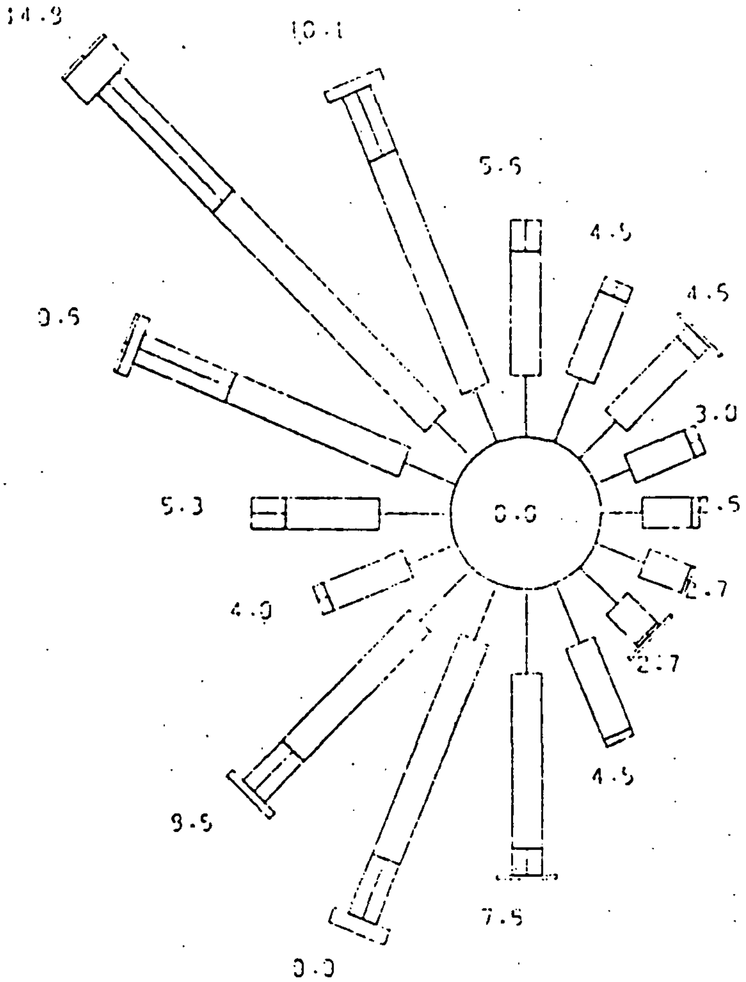

5.3
5.8
7.3
3.8
3.5
5.7
3.7
5.7
0.0
7.4
5.4
5.7
3.7
10.4
3.6

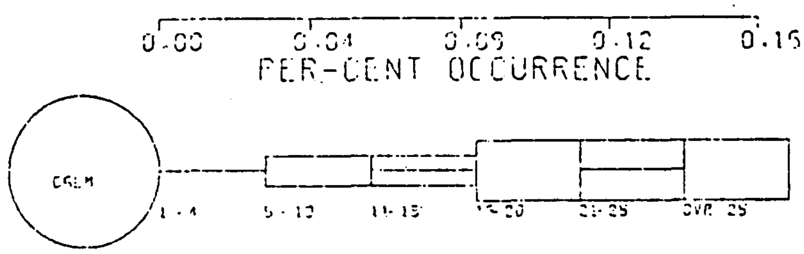

0.00
0.04
0.08
0.12
0.16
PER-CENT OCCURRENCE
CALM
1-4
5-10
11-15
16-20
21-25
OVR 25

CORPUS CHRISTI, TEXAS



3-10-77




PER-CENT OCCURRENCE
CALM

APPENDIX 1.4

RESUMES OF RTI PROJECT STAFF

JAMES R. CHROMY, Senior Statistician and Director,
Sampling Research and Design Center

Professional Experience

1966 to date. Research Triangle Institute, Research Triangle Park, North Carolina 27709.

1976 - date: Director, Sampling Research and Design Center. Responsible for coordinating research program in sampling statistics and for coordinating sampling and other statistical support for a wide variety of projects being conducted throughout the Institute.

1972 - 1975: Manager, Sampling Department and Senior Statistician, Statistics Research Division. Responsible for the development of survey designs and sampling techniques for a wide variety of projects in which data are collected by means of sample surveys. Supervised a permanent staff of thirteen professional statisticians, nine support personnel and many additional temporary support staff at peak periods.

1968 - 1971: Head, Sampling Section and Senior Statistician, Statistics Research Division. Developed sample designs for the National Assessment of Educational Progress in 1969 and 1970. This task included both the selection of 9-year-olds, 13-year-olds, and 17-year-old students in-school by means of a school frame and 17-year-olds and young adults (ages 26-35), out-of-school through an area frame. Was responsible for the design of samples selected for other studies.

1966 - 1968: Statistician, Statistics Research Division. Development of optimal sample designs in terms of minimum cost and maximum precision. Assisted in the development of computer micro-simulation population models.

1962 - 1965. Statistical Reporting Service, USDA, Lincoln, Nebraska. Agricultural Statistician. Assisted in field office operations of agricultural area surveys and objective yield estimates. Conducted monthly cattle-on-feed mail surveys and nonresponse interview surveys.

Education

B.S., Technical Agricultural Economics, University of Nebraska, Lincoln, Nebraska, 1964.

M.E.S., Experimental Statistics, North Carolina State University, Raleigh, North Carolina, 1966.

Ph.D., Statistics, North Carolina State University, 1974.

Professional Activities

Alpha Zeta
American Association for Public Opinion Research
American Statistical Association
Biometric Society
Gamma Sigma Delta
International Association of Survey Statisticians
Phi Kappa Phi

JAMES R. CHROMY (Continued)

Selected Publications

Chromy, J. R. and Hendricks, W. A. [1967]. Further Investigations of Sampling Plans for Estimating NASO Budget Requirements. Project SU-284 Final Report, Research Triangle Institute.

Chromy, J. R. [1967]. Matrices of Transitional Probabilities for a Demographic Simulation Model. Working Paper No. 7 developed for the Demographic Micro-Simulation Model Project. Research Triangle Institute.

Chromy, J. R. [1968]. A Generalization of the Matrix of Probabilities Approach for Population Micro-Simulation. Working Paper No. 19 developed for the Demographic Micro-Simulation Project. Research Triangle Institute.

Chromy, J. R. [1968]. Methods for Assigning Ages in the Initial Population. Working Paper No. 25 developed for the Demographic Micro-Simulation Project. Research Triangle Institute.

Chromy, J. R. and Horvitz, D. G. [1970]. "Appendix C: Structure of Sampling and Weighting," Report 1, 1969-1970 Science: National Results and Illustration of Group Comparisons. Washington, D.C.: Government Printing Office.

Chromy, J. R., Moore, R. P., and Clemmer, Anne [1972]. "Design Effects in the National Assessment of Educational Progress Survey," Proceedings, Social Statistics Section, American Statistical Association, pp. 48-52.

Chromy, J. R. (Editor) [1973]. A Study of the SES and STOC Stratification for NAEP Samples. Project 25U-796-6 Final Report, Research Triangle Institute.

Moore, R. P., Chromy, J. R., and Rogers, W. T. [1974]. National Assessment's Approach to Sampling - Year 02. National Assessment of Educational Progress, Denver, Colorado.

Chromy, J. R. [1974]. Pairwise Probabilities in Probability Non-replacement Sampling. Ph.D. dissertation, North Carolina State University, Raleigh, N.C.

Chromy, J. R. and Horvitz, D. G. [1974]. "The Use of Monetary Incentives in National Assessment Household Surveys." Proceedings, Social Statistics Section, American Statistical Association, pp. 171-179.

Piper, Lanny L. and Chromy, J. R. [1975]. "Design Effects for Alphabetic Cluster Samples." Proceedings, Social Statistics Section, American Statistical Association.

March 1976

LANNY L. PIPER, Statistician

Professional Experience

1972 to date. Research Triangle Institute, Research Triangle Park, North Carolina 27709. Statistician, Sampling Research and Design Center. Design and analyze survey samples.

Education

B.S., Mathematics, Miami University, Oxford, Ohio, 1970.

M.S., Statistics, North Carolina State University, Raleigh, North Carolina, 1972 (National Science Foundation Fellowship)

Professional Activities

American Statistical Association, member.

Selected Publications

Chromy, J. R. and Piper, L. L. [1973]. A Survey of High School Seniors to Determine Responses to the Job Skills Sampling Questionnaire. Project 25U-814 Final Report, Research Triangle Institute.

Mason, R. E. and Piper, L. [1973]. Technical Report Children's Television Workshop Surveys 1972-1973. Project 25U-683, Research Triangle Institute.

Piper, Lanny L. and Chromy, James R. [1975]. Design Effects for Alphabetic Cluster Samples. Presented at the 1975 Annual Meetings of the American Statistical Association.

April 1976

STEPHEN R. WILLIAMS, Senior Statistician

Professional Experience

1975 to date. Research Triangle Institute, Research Triangle Park, North Carolina 27709. Senior Statistician, Sampling Research and Design Center. Involvement in the sample design and analysis for a variety of studies. Project or sampling leader in several large-scale dental surveys.

1970 - 1975. Southern Research Institute, Birmingham, Alabama 35205. Senior statistician, Economic Research and Planning Section. Project leader on a study to design and assist in the implementation of a statewide information system for health planning. Project leader on numerous health studies in the areas of epidemiology, ambulatory-health care, health-facilities planning, information systems, and the characterization of hospital inpatients and their care. Statistics instructor at the University of Alabama. Econometrician and bio-statistician support on numerous and varied studies in the social sciences field.

1960 - 1970. United States Department of Agriculture. Survey statistician and mathematical statistician in the Research and Development Branch. Primary responsibilities in nationwide surveys involving area- and multiple-frame and other types of probability sampling. Mathematics instructor at Rollins College, Winter Park, Florida.

Education

B.S., Economics, University of Wyoming, Laramie, Wyoming, 1958.

M.S., Economics, University of Wyoming, Laramie, Wyoming, 1959.

M.S. coursework requirements in Statistics, Iowa State University, Ames, Iowa, 1963.

Completed additional courses in Statistics at George Washington University and University of Florida, 1963-1967.

Presently pursuing Ph.D., Biostatistics, University of Alabama, Birmingham, Alabama.

Selected Publications

Williams, S. R. [1971]. "Forecasting Florida Citrus Production, Methodology and Development." U.S. Department of Agriculture Bulletin.

Williams, S. R. and Schaffer, S. [1971]. Selected Population, and Housing Characteristics From a Sample Survey of Households in Greene County, Alabama. Project Final Report, Southern Research Institute.

STEPHEN R. WILLIAMS (Continued)

Williams, S. R., Tropper, P., and Schaffer, S. [1972]. A Local-Area Information Generation System for Transportation, Housing, and General Urban Development. Project Final Report, Southern Research Institute.

Williams, S. R. [1974]. Ambulatory Health Care: Survey and Forecasting Methodology. Project Final Report, Southern Research Institute.

Williams, S. R. and Nash, E. [1974]. Factors Associated with the Incidence of Congenital Anomolies: A Localized Investigation. Project Report, Southern Research Institute.

Williams, S. R. and Schaffer, S. [1975]. "Health Information Systems," Southern Research Institute Bulletin, pp. 12-17.

Williams, S. R. and Folsom, R. E. [1976]. Bias Resulting From School Nonresponse: Methodology and Findings. Project Report, Research Triangle Institute.

April 1976

APPENDIX 1.5

REFERENCES

REFERENCES

1.1 Miesch and Huffman, "Abundance and distribution of lead, zinc, cadmium, and arsenic in soils in Helena Valley, Montana." Area Environmental Pollution Study (EPA Office of Air Programs Publication No. AP-91), p. 65.

1.2 Djurie, D., et al., "Environmental contamination by lead from a mine and smelter." Archives of Environmental Health, Vol. 23, pp. 275-279, October 1971.

1.3 Oyanguren, H., and E. Perez, Archives of Environmental Health, Vol. 13, p. 185, 1966.

1.4 Seeley, J. L., et al., "Determination of lead in soil." Applied Spectroscopy, Vol. 26, No. 4, pp. 456-460, 1972.

1.5 Research Triangle Institute, Field Sampling Manual. Research Triangle Park, North Carolina: Research Triangle Institute, 1976.

1.6 Hammer, D. I., et al., American Journal of Epidemiology, Vol. 93, p. 84, 1971.

1.7 Barltrop, D., et al., "Significance of high soil lead concentrates for childhood lead burdens." Environmental Health Perspectives, Washington, D.C.: Government Printing Office, Vol. 7, pp. 78-81, 1974.

1.8 Chisolm, J. J., et al., "Variations in hematological responses to increased lead absorption in young children." Environmental Health Perspectives, Washington, D.C.: Government Printing Office, Vol. 7, pp. 7-12, 1974.

1.9 David, O., "Association between lower level lead concentrates and hyperactivity in children." Environmental Health Perspectives, Washington, D.C.: Government Printing Office, Vol. 7, pp. 17-25, 1974.

1.10 Anderson, D., and J. Clark, "Neighborhood screening in the communities throughout the nation for children with elevated blood lead levels." Environmental Health Perspectives, Washington, D.C.: Government Printing Office, Vol. 7, pp. 3-6, 1974.

1.11 Turner, D. B., Environmental Protection Agency. Workbook of Atmospheric Dispersion Estimates. Washington, D.C.: Government Printing Office, 1970.

1.12 Calder, K. L., "A climatological model for multiple source air pollution." Proceedings Second Meeting of the Expert Panel on Air Pollution Modeling, NA 70 Committee on the Challenge of Modern Society, Paris, France, p. 33, July 1971.

REFERENCES (Continued)

1.13 Busse, A. D., and J. R. Zimmerman, Users Guide for the Climatological Dispersion Model, EPA-R4-73-024. Research Triangle Park, North Carolina, p. 133, 1973.

1.14 Holzworth, G. C., Mixing Height, Wind Speed, and Potential for Air Pollution Throughout the Contiguous United States. Research Triangle Park, North Carolina: Environmental Protection Agency, Office of Air Programs (AP-101), p. 118, 1972.

2.0 Field Operations

2.1 On-Site Project Operations (At RTI)

2.1.1 Project Staff

2.1.1.1 Overall Supervision

Field operations will be under the general supervision of James D. Bates, Director of the Survey Operations Center (SOC) in the Statistical Sciences Group (SSG) of the Research Triangle Institute (RTI). All SSG activities for this research effort will be coordinated under the general supervision of Dr. W. Kenneth Poole, Director of the Statistical Methodology and Analysis Center (SMAC). The RTI and project administrative structures are presented graphically in figures 2.1 and 2.2, respectively, with RTI units likely to be involved in this research effort shaded in figure 2.1.

2.1.1.2 Survey Director

Benjamin S. H. Harris, III, Health Survey Specialist within SOC will serve as Survey Director, assisted by survey assistant Martha L. Smith and other survey specialists and survey assistants as required. Working in close coordination with representatives of SMAC, the Sampling Research and Design Center (SRDC - see section 1.0), and the Chemistry and Life Sciences Group (CLSG - see section 3.0), the Survey Director will be responsible for supervising the Field Operations, including the following tasks:

- Training RTI project staff in study objectives and data collection procedures;
- Public relations at the performance sites;

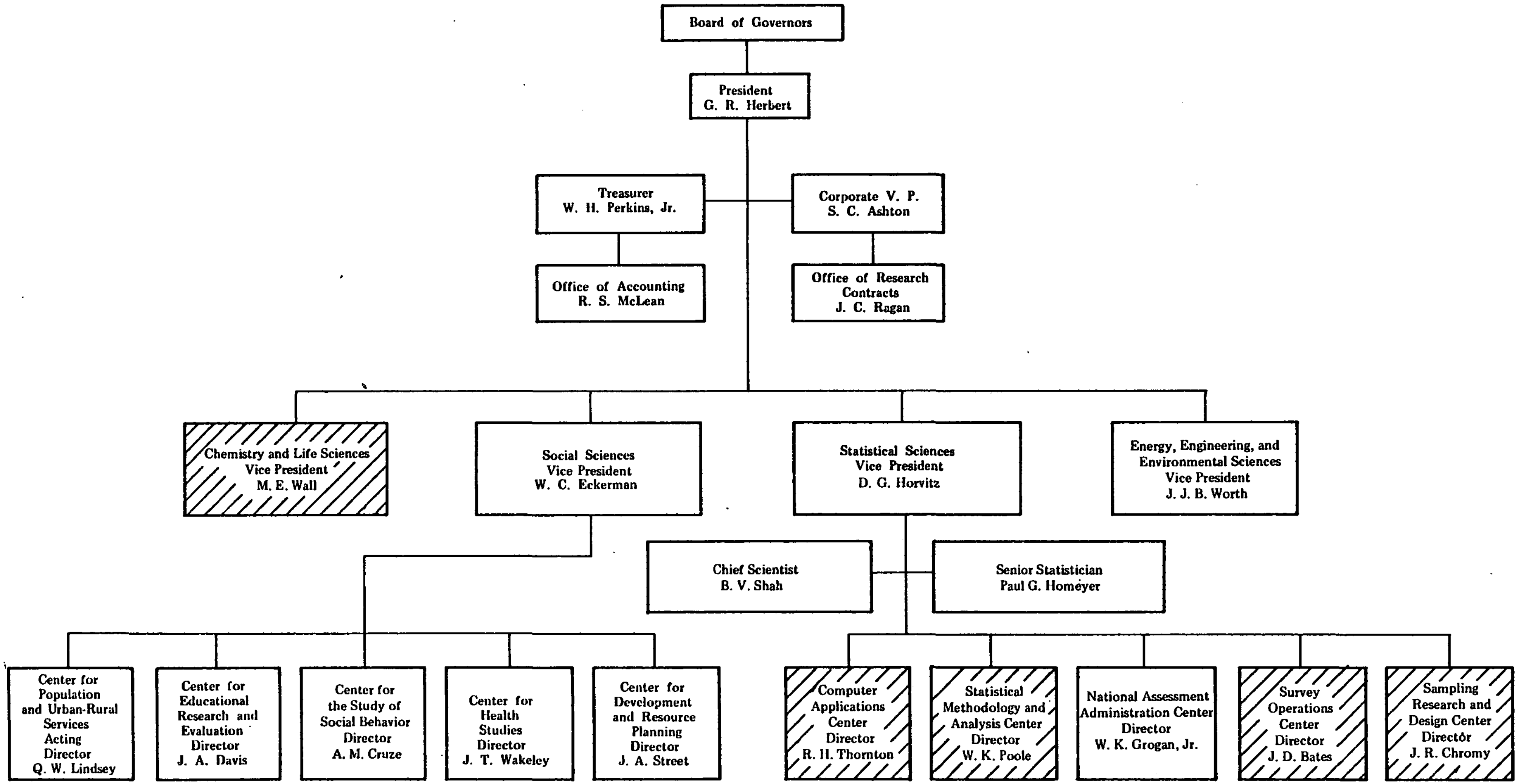


Fig. 2.1. Research Triangle Institute administrative structure.

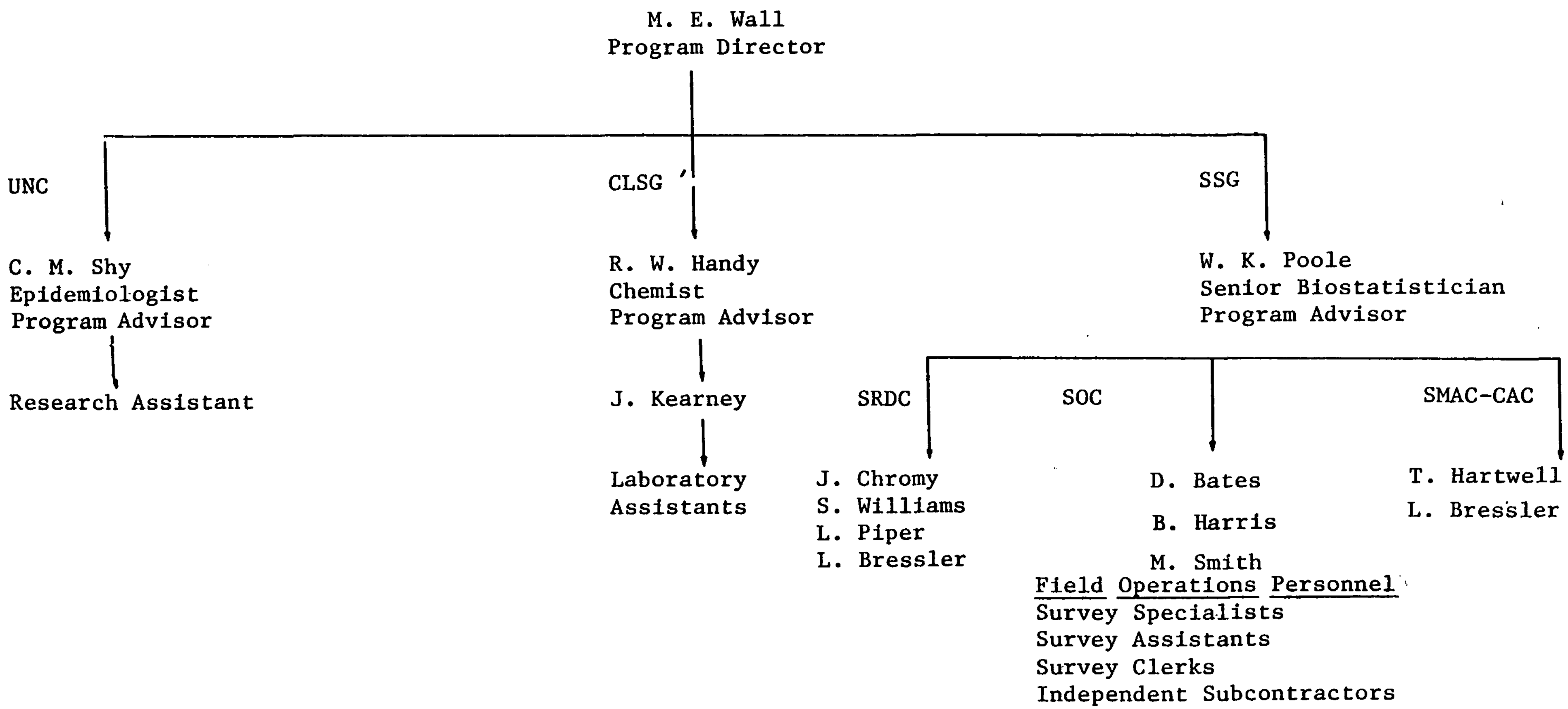


Fig. 2.2. Project administrative structure.

3-10-77

- Recruitment and briefing of independent subcontractors;
- Pretest of data collection instruments and procedures;
- Receipt control, verification, and entry of data; and
- Quality control procedures relevant to the foregoing tasks.

2.1.1.3 Site Administrator(s)

Data collection, coordination and validation at the performance sites will be conducted by a CLSG professional acting as Site Administrator (SA) and independent subcontractors, with overall supervision by the RTI Survey Director and backup administrative assistance available from RTI's national staff of Field Supervisors (see below). The SA will be responsible for overall coordination and quality control of data collection at each performance site; for the collection of all air samples, general soil and water samples, and *market basket* samples (see below); and for coordination and shipment of data from the performance site to RTI. An SA will remain at the site for the duration of data collection; the same SA(s) at the very least will oversee such activities at sites representing the same type smelter. At the present time, RTI anticipates that J. Kearney will be one SA, with backup from Project Leader Handy and Survey Director Harris (see figure 2.2).

2.1.1.4 Data Receipt Control, Scan-Edit, and Direct Entry

Data receipt control, scan-edit, and entry at RTI will be under the general supervision of Mildred C. Pennington. Throughout planning for and conduct of receipt control, scan-edit and entry, one experienced Survey Assistant will be assigned to the project to provide overall supervision of these tasks. Experienced survey clerks will check in survey instruments, perform the scan-editing, maintain manual logs, and refer problem cases to the Survey Assistant or Survey Director for resolution. Direct data entry will also be conducted under the supervision of Survey Assistant Smith, with overall guidance from the Survey Director as needed.

Resumes of individuals named in the preceding paragraphs will be found in appendices 2.1 and 3.1.

2.1.1.5 Training Manual

A training manual will be developed by RTI for use in training RTI project staff and briefing independent subcontractors. This manual will address study objectives; data collection instruments; detailed rationale and procedures for collecting environmental and biological samples; coding and editing instructions for all survey instruments; instructions for administration, coordination, and quality control of all field operations; and discussions of anticipated problems. A tentative outline for this training manual appears in appendix 2.2.

2.1.1.6 Training Session(s)

Before data collection begins at the first performance site, RTI will conduct an intensive one week training session for RTI project staff, in particular the prospective SA(s) who will be responsible for coordination of data collection activities at the performance sites, and staff who will be responsible for data receipt control and entry at RTI. The training session agenda will in general resemble the training manual outline in appendix 2.2 and will address study objectives; data collection instruments; rationale and detailed procedures for collecting environmental and biological samples; instructions for administration, coordination, and quality control of all field operations; coding and editing instructions for all survey instruments; and discussions of anticipated problems. Since data collection at the performance sites will be carried out consecutively and will therefore cover several months, and since some activities will begin immediately while others will follow in sequence, additional briefing sessions may be required as refreshers or as special problems arise.

These training sessions will be conducted by the Survey Director, Project Leader, and other appropriate personnel assisted by RTI project consultant experts in epidemiology, biochemistry, and community health sciences: Dr. Stephen H. Gehlbach, Assistant Professor of Community Health Sciences at Duke University, Adjunct Assistant Professor of Epidemiology in the University of North Carolina (UNC) School of Public Health, and Director of Research for the Family Medicine Program at Duke University [Ref. 2.1]; Dr. Carl M. Shy, Director, UNC Institute of Environmental Studies; and Dr. Boyd R. Switzer, Assistant Professor of Nutrition, UNC School of Public Health. Resumes of these consultants will be found in appendix 2.1.

2.1.2 Data Receipt Control and Entry

2.1.2.1 Receipt Control

Data will be received at RTI/SOC from three sources: the independent subcontractors at the performance site, the SA at the performance site, and RTI/CLSG. From the independent subcontractors, RTI/SOC will receive copies of each day's Household Screening Questionnaires (HSQ's) and Logs (HSL's) and each week's Production, Time and Expense Reports. From the SA, RTI/SOC will receive Participant Consent Forms (PCF's) and Study Questionnaires (SQ's). From RTI/CLSG, RTI/SOC will receive results of chemical analyses. Examples of survey instruments appear in appendix 2.3.

Each completed survey instrument will be checked in by identification (ID) number by project personnel on the day received; at the same time, the document will be assigned to a batch for control purposes. Completed survey instruments will be maintained in batches while they are in RTI's custody.

2.1.2.2 Visual Scan-Edit

Following check-in and receipt acknowledgement, each document will be scan-edited on an item-for-item basis to detect omissions, inconsistencies, and/or illogical or incompatible entries. Specifically, this review is designed to verify:

- That the executor understood and followed the question sequences and intent correctly and that entries seem reasonable and consistent;
- That any sampling or skip sequences were correctly followed and that no applicable items were omitted; and

- That each instrument is properly identified and that all items required for verification of the individual's work were completed.

2.1.2.3 Direct Data Entry

Following scan-edit and error resolution by telephone or other action (see below), complete survey instruments will be coded by use of communications terminals permitting *direct data entry* operations. Direct data entry means simply that programmable terminals with keyboards and cathode ray tube display screens are used instead of manual coding and keypunch. A programmed format specifically designed for the survey instrument appears on the display screen. As the terminal operator looks at the hard-copy documents, he or she keys the responses into the terminal. The keyed data then appear instantaneously on the display screen. The data are recorded on magnetic tape cassettes for transmission to a computer facility. Hence, the direct data entry process accomplishes in one step what previously has taken two steps. In addition, time savings are substantial because of quality control opportunities cited below.

2.1.2.4 Quality Control

RTI will use three types of quality control in processing the survey data: a check of the survey data at the source; at the data entry point, since the data will be entered through programmable terminals; and the traditional concept of verification through re-keying.

- Reinterview: As a quality check of the interview process, RTI plans to reinterview by telephone, personal visit, or mail, in that order of preference, approximately ten percent of the population for whom completed questionnaires are obtained. The actual method of reinterview (mail, telephone, or personal visit) will be determined according to which is more convenient, cost-effective, and/or appropriate; telephone would be the preferred method. RTI does not anticipate that the reinterview process would involve the entire SQ. This procedure will actually permit a two-fold verification: that the interview was conducted, and that responses are consistent. In the event that inconsistent responses are detected, an attempt will be made to determine if the inconsistencies are due to variations in participant response or interviewer error or misinterpretation; in the latter case, the interviewer will be contacted in an effort to resolve the problem.

. Visual Scan-Edit: Should a completed survey instrument *fail* the visual edit check, two procedures will be implemented. First, an attempt will be made to resolve the problem by telephone from RTI/SOC to the site of instrument completion. Second, should the problem be critical enough to necessitate further action, the document will be transmitted to the appropriate person with specific instructions for resolution.

. Direct Data Entry: Programmable terminals, referred to in numerous articles as *intelligent terminals*, have proven to be very effective devices for converting data to machine-readable form. These devices allow *editing* at the point of data entry in a manner that was previously unavailable. Error rates drop because operators can easily correct keystroke errors which are normally left for the verifier when keypunches are used. Even if the operator must go back to a previous field to make a correction, no already keyed data are lost. As the data are entered, the terminal checks the data for proper range or invalid punches, and if an error is detected, locks the keyboard. If necessary, the editing supervisor or survey assistant can aid the data entry clerk in resolving the error.

The basic philosophy associated with direct data entry is to provide a device that allows the operator to make easy corrections of keystroke errors and to detect at data entry time any errors that may be corrected by review of the hard copy instrument. Beyond these checks, it is desirable to have a minimum of ten percent verification by *re-keying* to insure that the data are converted to machine-readable form with a very low error rate. Should an error rate of more than one percent per operator be discovered through re-keying, 100 percent verification of that operator's work will be carried out. The Survey Director will be provided regular reports of the results of direct data entry quality control procedures.

2.1.3 Confidentiality of Project Data

There are two basic areas where there should be concern about maintaining data confidentiality: source documents (survey instruments/questionnaires) and data tape files. RTI recognizes the need to maintain these project documents under strict controls to insure confidentiality and record integrity.

Storage for hard-copy source documents (HSQ, PCF, and SQ) shall be in a secure, well-ventilated, vault-like room in the basement of the Ragland building on the RTI central campus at Research Triangle Park, North Carolina. The room has about 600 square feet of floor space and has both wall and free-standing shelving. Access is by one locked door, with controlled, i.e., signed for, entry only on authority of one of the project staff in charge of receipt control and coding operations. Materials will be stored here, with such working amounts as are necessary being removed, signed for by record identification, and worked on in a secure space under supervision. Materials will be received in the mail on a daily flow basis and, insofar as possible, be dealt with on a flow basis, with real-time receipt control records being maintained for all processing steps. Overnight storage of processing batches will be in a locked and secure work space. When processing has been completed, all source documents will be filed in an ordered, accessible manner. During all stages of processing and storage, project personnel will control access to and removal and replacement of survey instruments from specified working and storage areas.

Data tape files will be maintained on a strict need-to-know basis throughout the extent of the project; at no time will these files be readily accessible except under specific authority of a senior professional working on the project. However, only the PCF will provide a link between the various ID numbers and a specific participant's name, and the PCF will never be converted to machine-readable form - that is, the data tape files will never contain participant's names or addresses.

2.1.4 Protection of Human Subjects Certification

The Department of Health, Education and Welfare has determined that RTI should operate under the special assurance provisions of the Protection of Human Rights regulations. Upon notification, the Institute's Committee on Human Rights is prepared to review the data collection forms and protocol for this study. The membership of the Institute's Committee on Human Rights consists of:

Dr. J. N. Brown

Dr. W. C. Eckerman

Dr. D. G. Horvitz

Dr. M. E. Wall

Mr. S. C. Ashton

Mr. R. L. Welborn

2.2 Off-Site Project Operations (At Smelter Locations)

2.2.1 Performance Sites

2.2.1.1 Selection

The Project Officer has specified the following smelter locations as performance sites for this research effort:

- Anaconda, Montana;
- Palmerton, Pennsylvania;
- Herculaneum, Missouri;
- Bartlesville, Oklahoma;
- Bixby, Missouri; and
- Ajo, Arizona,

most likely in that order (see section 2.4 - Schedules for Field Operations).[2.1]

2.2.1.2 Public Relations

RTI plans to establish communication with certain agencies/organizations at/regarding each performance site. These agencies/organizations will include but not necessarily be limited to the following:

- Various federal agency representatives, including regional EPA representatives, EPA's Industrial Environmental Research Laboratory, and the Center for Disease Control (CDC): These agencies have had various interests and contacts in/with environmental studies of smelter communities, including a recent CDC study [Ref. 2.2]; such contacts/experience may prove useful to this research effort.

- State and local health agency representatives: These agencies may also have had various levels of interest and experience regarding

---

[2.1] In addition, RTI will perform a Pretest at one additional smelter location, probably Corpus Christi, Texas - see appendix 2.4.

environmental/health studies of smelter communities; such interest/ experience is expressed in correspondence such as that reproduced as appendix 2.5 and may prove useful to this research effort. RTI will contact appropriate representatives of these agencies in an attempt to secure their cooperation, assistance, endorsement and participation. In particular, RTI hopes that the assistance of these agencies might be enlisted in securing qualified field staff and sites for training field staff and central data collection (see below). During initial contact with appropriate agencies, RTI hopes to make arrangements for the follow-up of participants for whom study data collected indicate medical attention, and participants will be informed of such arrangements (see below).

. Local education authorities: RTI will contact appropriate representatives of these agencies in an attempt to secure their cooperation, assistance, participation, and endorsement. The cooperation of appropriate education authorities is considered essential since it will be necessary to collect soil and water samples at each school where study children participants attend. In addition, schools are potential sites for training field staff and central data collection.

. Smelter representatives: RTI anticipates meeting with representatives of the smelter industry and individual smelter firms in an attempt to secure their cooperation and inform them of study activities. The role chosen by the smelters may have a significant impact on the cooperation of potential participants in the smelter communities.

. Other: In addition to the agencies listed in the preceding paragraphs, RTI plans early meetings/discussions/investigations regarding other elements in the smelter communities related to the logistics of this research effort, including local electric utilities regarding power drops for air sampling devices; transportation alternatives for independent subcontractors, participants, and in particular the shipment of study materials to and from RTI; hotels/motels for training and accommodation of field staff; and municipal agencies such as the police department to inform them of study activities.

2.2.1.3 News Releases

Once the various levels of public relations have been completed, and the positions and levels of participation of the various agencies have been determined, RTI plans a series of news releases, approved by the Project Officer, through the appropriate federal, State, or local agency to inform the public of the study's objectives and activities in an attempt to improve cooperation by potential study participants. RTI anticipates that all involved agencies, including the smelter(s), will have an opportunity to review these news releases before they are released. RTI anticipates involvement of local and area newspapers, radio, and television in this publicity campaign utilizing news releases and public service announcements which would explain succinctly the reasons for and potential benefits of the study. This publicity campaign will probably start at each performance site approximately two weeks before data collection is to begin.

2.2.2 Independent Subcontractors

2.2.2.1 Recruitment

While at the smelter location to contact appropriate federal, State and/or local agencies related to the study, RTI will initiate recruitment of field staff/independent subcontractors to participate in the actual study data collection. RTI plans to retain two types of staff who will work as independent subcontractors to perform data collection in the field, coordinated by the SA:

. Field Interviewers (FI's) who would be responsible for contacting and screening households, completing questionnaires, measuring paint lead levels, and collecting dust and water samples and some soil samples; and

. Medical personnel such as Registered Nurses or medical technicians to obtain the blood and hair samples, collect the urine samples, and perform the hematocrit and urine protein and specific gravity determinations.

With regard to recruiting the field staff at each location, RTI anticipates three potential sources:

. RTI listings: RTI has been conducting national surveys for over 16 years and has conducted other studies involving surveys in various parts of the nation. As a result, a current list is available of some 2,500 persons who have served RTI on one or more projects or have indicated their availability. This list will serve as the starting point in securing qualified individuals. Many of the persons on this list have at least some health-related training and/or experience. For example, figures

2.3 through 2.7 present graphically the number of interviewers from the current RTI listing living in counties within a reasonable distance of the performance sites in Arizona, Missouri, Montana, Oklahoma, and Pennsylvania, respectively. That is not to say that all of these individuals would be available or suitable for this research effort (see below).

. State and local agency contacts: RTI hopes that some qualified field personnel might be retained through the assistance of State and local agencies, particularly health agencies (see appendix 2.5). RTI may offer such agencies an active role in the collection of biological samples from household survey participants by subcontracting that aspect of the data/sample collection to such agencies, by engaging agency personnel to work for RTI during their off time, or by assisting RTI in retaining qualified individuals to serve as independent subcontractors.

. Newspaper advertisements: Appropriate advertisements will be placed in local or area newspapers.

. Interviews: Once potential field staff have been located, they will be screened and interviewed by RTI staff, most likely the Survey Director, in order to determine their qualifications and availability for this research effort. At each site, RTI anticipates retaining at a minimum three FI's and two medical staff members; an additional FI will most likely be retained at each of the three sites where individuals over 60 years of age will be surveyed, so that data collection can be completed at each site in approximately one month (see below).

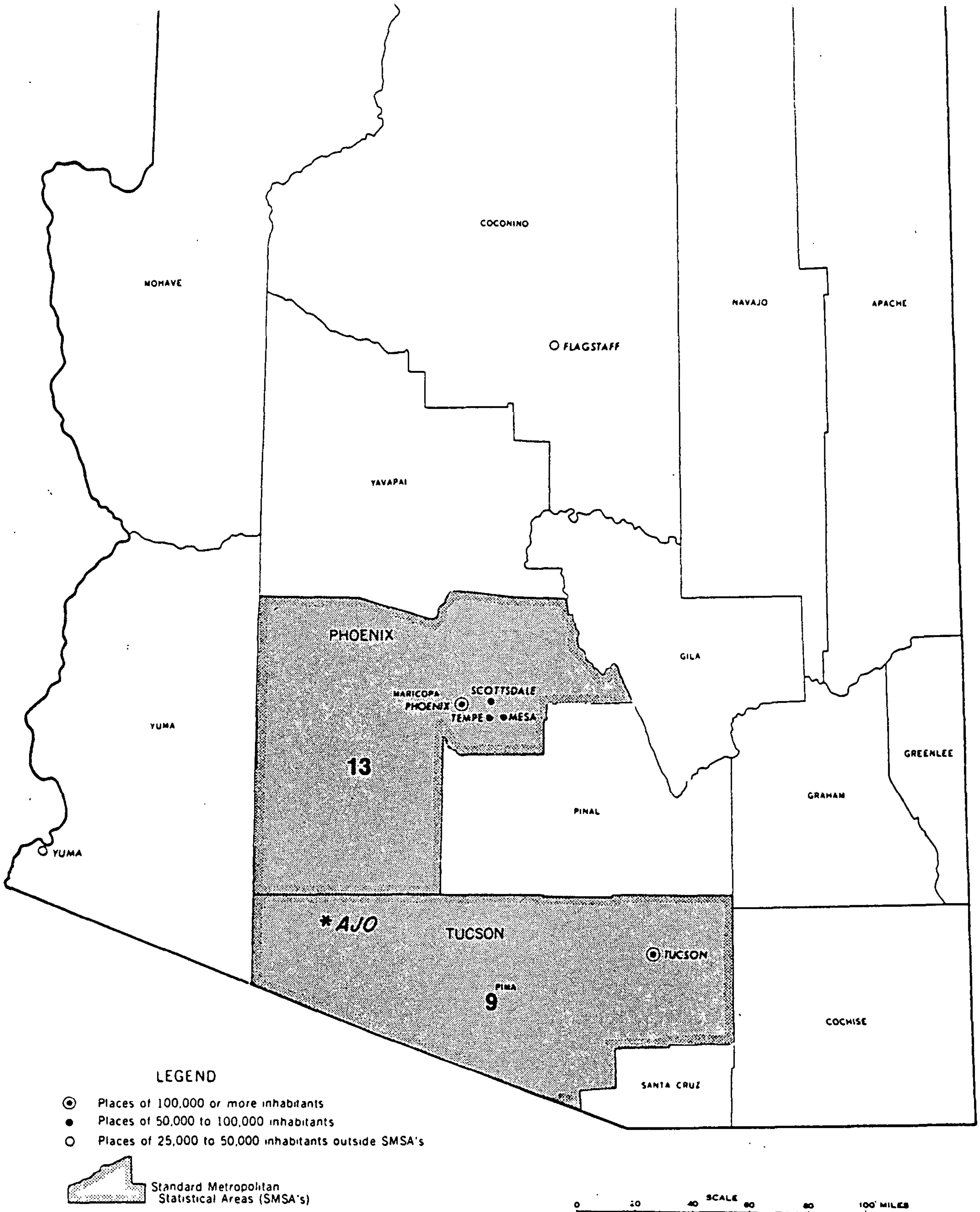


Fig 2.3. Location and number of interviewers from the current RTI listing living in counties within a reasonable distance of the Ajo, Arizona, performance site [Source: Ref. 2.3, p. 972].

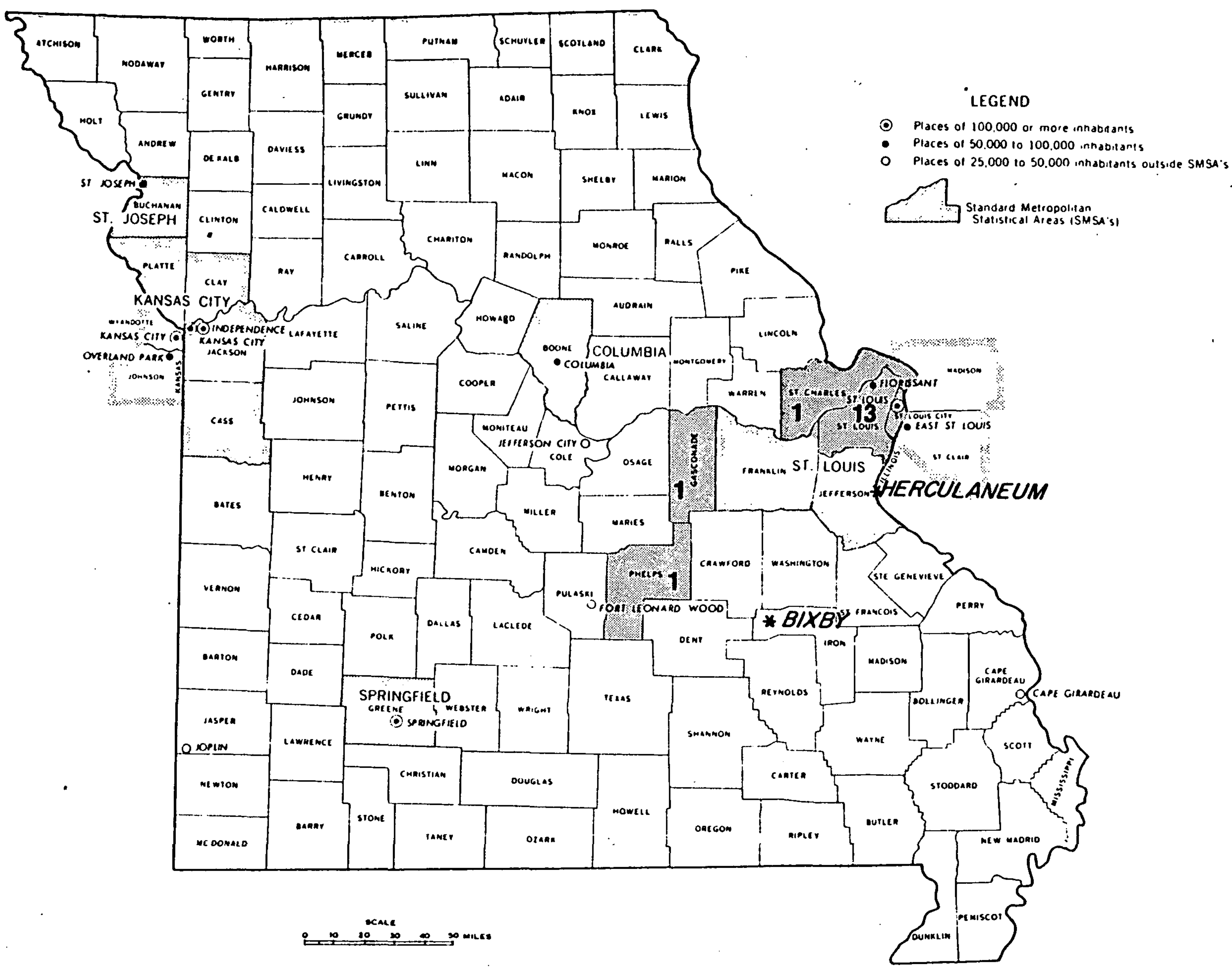


Fig. 2.4. Location and number of interviewers from the current RTI listing living in counties within a reasonable distance of the Bixby and Herculaneum, Missouri, performance sites [Source: Ref. 2.3, p. 995].

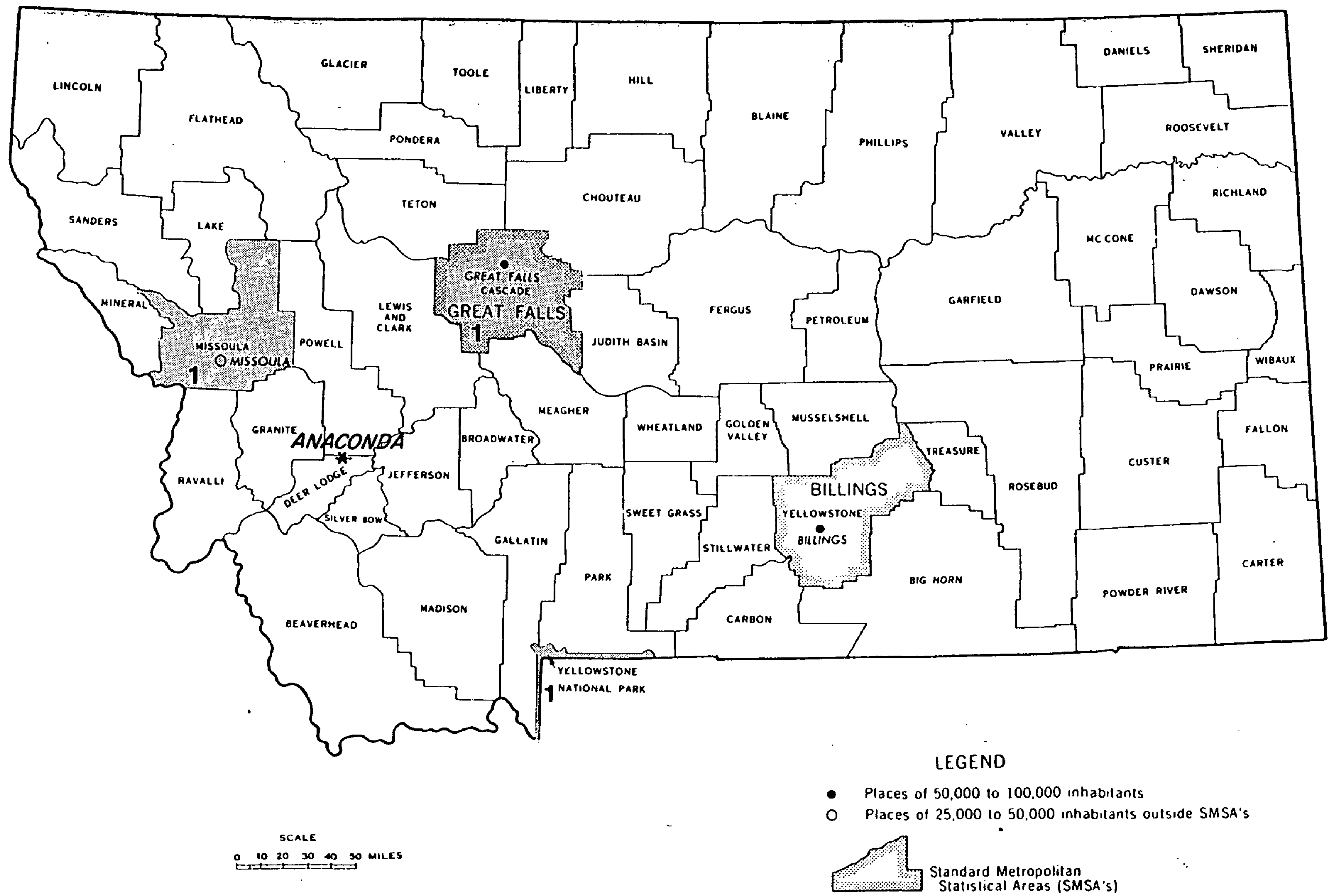


Fig. 2.5. Location and number of interviewers from the current RTI listing living in counties within a reasonable distance of the Anaconda, Montana, performance site [Source: Ref. 2.3, p. 996].

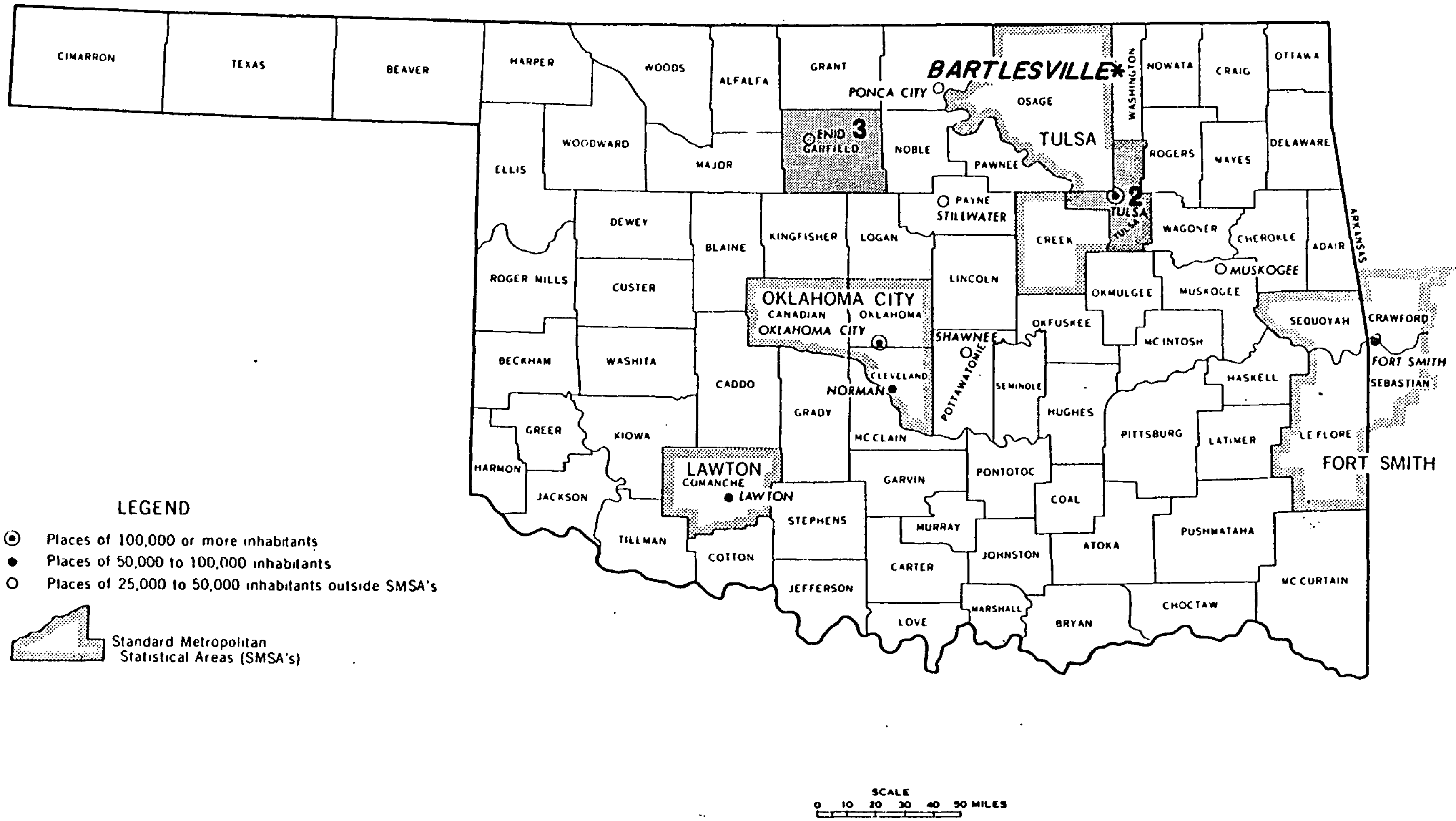


Fig. 2.6. Location and number of interviewers from the current RTI listing living in counties within a reasonable distance of the Bartlesville, Oklahoma, performance site [Source: Ref. 2.3, p. 1006].

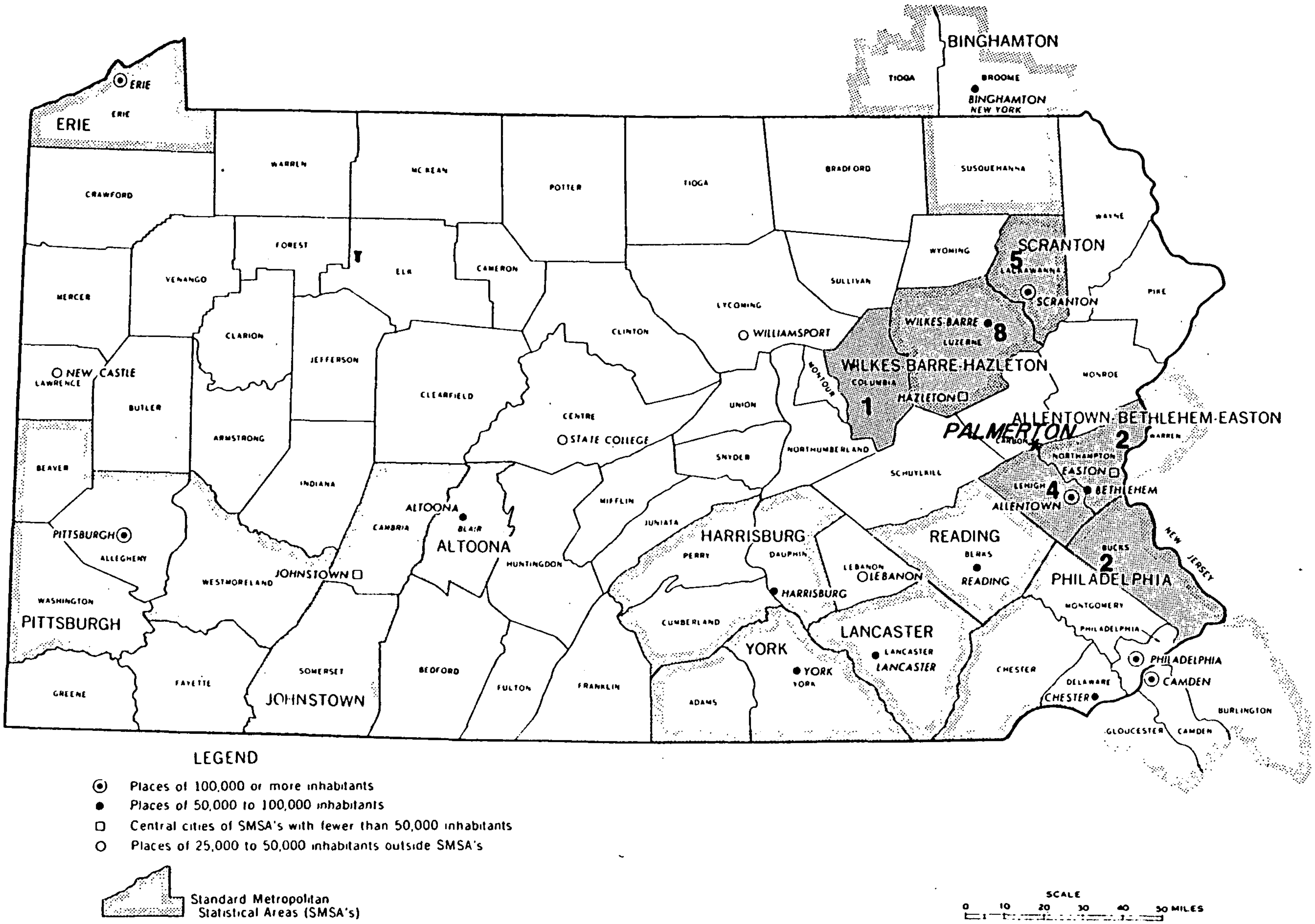


Fig. 2.7. Location and number of interviewers from the current RTI listing living in counties within a reasonable distance of the Palmerton, Pennsylvania, performance site [Source: Ref. 2.3, p. 1008].

. Qualifications: Potential FI's should ideally be known to and/or recommended by RTI, various State or local agencies, and/or similar organizations; present evidence of relevant survey, environmental, and/or health-related experience; live within a reasonable distance of the performance site; have an automobile available; be available to work irregular hours and/or weekends; and be physically capable of carrying the survey equipment and materials. The medical independent subcontractors should ideally meet the above criteria, and be *currently employed* in some area requiring acquisition of blood samples, preferably from children. In certain areas, such as Arizona, RTI will attempt to retain experienced independent subcontractors who are bilingual - that is, speak English and Spanish, although a recent RTI study demonstrated no significant difference in performance between monolingual and bilingual interviewers working with elementary school children and adults with limited English-speaking ability in four areas of the United States, including parts of Texas and Arizona [Ref. 2.4].

2.2.2.2 Training

After the independent subcontractors have been recruited and before data collection activities begin, RTI will conduct two-day briefing sessions at each performance site to acquaint the independent subcontractors with study objectives; survey instruments; rationale and detailed procedures for collecting environmental and biological samples; administrative and quality control considerations; and anticipated problems, in order to increase the relevance and quality of the data collected. The training session agenda will follow closely the outline and content of the training manual, a tentative outline of which is presented in appendix 2.2.

The training sessions will be conducted by the Survey Director, RTI Senior Chemists, and consultants, and will be attended by the RTI professional SA and the independent subcontractors. During the training sessions, the independent subcontractors will be carefully instructed in all aspects of the field work. Considerable emphasis will be placed on the objectives and significance of the study and the nature of the data collection. Practice interviews will be conducted to insure that each FI becomes thoroughly familiar with household screening and interviewing techniques and use of the survey instruments. During the first day of household contact, which will hopefully follow immediately the training session, the Survey Director and SA will accompany the FI's to assist them with their first household contacts. If it becomes apparent that any independent subcontractor needs additional training, such instruction will be provided before the field work assignment is given.

2.2.2.3 <u>On-Site Consultants</u>

As a contingency, RTI plans to enlist the services of physician consultants on-site to serve as points of contact for the field staff in the event that any problems or questions are encountered in the data collection process, particularly in regard to the acquisition of biological samples. For example, the existence of certain disease entities such as bleeding tendencies may preclude the acquisition of a blood sample from a given participant.

2.2.3 Household Data Collection

2.2.3.1 Screening

Once RTI/SRDC has designated the data collection areas/grids within each performance site related to distance downwind from the smelter; data collection instruments and forms have been approved by the Office of Management and Budget (OMB); and the field staff have been retained and trained, household data collection will begin.

FI's will be primarily assigned to specific areas or grids within the smelter community; this procedure should facilitate the FI's familiarity with and recognition within that area or grid. Data will be collected by door-to-door interview. Each residence unit encountered in each data collection grid will be visited in sequence. Within each residence unit so encountered, households will be screened to determine those containing *eligible individuals* - that is, those (1) with no direct occupational exposure to the smelter within the preceding 12 months, (2) who have lived within the smelter study area for at least the preceding 12 months, and (3) who fall within one of the four study age groups: pre-school 1-5 years or 12-72 months of age, school age 6-18 years of age, and adults 20-35 years of age (with an option to age 40), and in three sites 60 years of age or greater. Such eligibility will be determined by the FI as part of the household data collection process. A residence unit within the data collection grid may contain more than one household containing an eligible study participant. Similarly, such a household may contain more than one eligible study participant. Each eligible person in those residence units will be invited to participate in the study until the required number and distribution of participants is obtained.

At the time of first household contact, the FI will introduce himself as a representative of RTI and EPA; present study identification and (hopefully) copies of letters from appropriate federal, State and local agencies; and explain the nature and purpose of the study. The FI will maintain a log record of residence units and households visited and screened on a Household Screening Log (HSL - see appendix 2.3). Screening of the household to determine whether or not it contains eligible individuals will be determined by administration of the HSQ (see appendix 2.3). RTI anticipates a certain number of *nonrespondents*, or households which cannot be screened; *nonparticipants* or refusals; and *ineligibles*, or households which contain no eligible respondents. If an eligible person refuses to participate in the study, the refusal and the reason(s) therefore will be noted on the HSL. Visits to screen potential households or to enlist participants will be limited to three.

2.2.3.2 Participant Consent Form

When an eligible person within a household agrees to participate, the precise location of the residence unit will be noted on a map at the time of the enlistment, so that the distance of the residence unit from the smelter can be accurately calculated. In addition, the individual will be required to sign a *Participant Consent Form* (PCF - see appendix 2.3) in order to participate in the study.

The PCF will introduce the study; explain its objectives, sponsorship (the relationship and roles of RTI and EPA), and requirements of and risks, burdens, and benefits to participants; and stress that participation is completely voluntary and that all data collected will be kept confidential. The PCF will hopefully contain an indication of the support and/or involvement of appropriate State and local agencies; the names and telephone numbers of appropriate authorities so that participants may obtain additional information if desired; and inform the participants of arrangements with these agencies for appropriate follow-up of any study participants for whom study data collected indicate a need for medical attention. The PCF will be signed by the participant or, in the case of persons under age 18, the parent or other responsible guardian, and will contain an agreement to provide the necessary information and samples, including a specific release and arrangements (appointed time and place) to draw blood. Participants may freely withdraw from the study at any time; however, in order to encourage participation RTI will offer an incentive of ten dollars to each participant to be paid after the blood sample is obtained. Again, confidentiality of data will be stressed, including steps taken to disassociate the name of the participant from the data once collected; for example, the PCF is the *only* data collection instrument which will bear the name of the participant and allow its association to study identification numbers, but will be maintained in hard copy only and stored in a restricted area, as indicated in a previous section. To further emphasize this disassociation, the incentive will be paid in cash rather than by check or money order, although the participant or his/her guardian will sign a receipt indicating that the incentive was received. The PCF will make two copies, one for the head of the household and one for the participant or his/her guardian; the original will be attached to the questionnaire until it is received at RTI and verified. Where required, the PCF will be available in more than one language - for example, English and Spanish for Arizona.

2.2.3.3 Study Questionnaire

The Study Questionnaire (SQ - see appendix 2.3) is divided into four parts, Part A related to the *household* and which will be completed only once for each household containing at least one participant; Part B related to the *individual participant;* Part C providing information on the interviewer and respondent; and Part D recording paint lead levels and the results of hematocrit and urine protein and specific gravity determinations, and indicating whether or not corresponding and duplicate environmental and biological samples were obtained, and the date, time, and place of acquisition of such samples. Participants will be identified by a unique study number used to correlate and cross-identify the questionnaires and samples (see below) by way of pre-printed self-adhesive labels.

Household information includes questions related to family socioeconomic status (occupations, educational levels), and questions related to food sources and preparation. Information on individual participants includes demographic characteristics such as age, sex, race, marital status, occupation, and education level; residence information; health information such as current health status and history of exposure to heavy metals, including questions related to symptoms of clinical and subclinical toxicity; personal characteristics such as exposure to cigarettes and various drugs and sundries, and average number of hours spent outside each day; and dietary information such as exposure from foods high in heavy metal content [Ref. 2.5] and history of pica, the ingestion of non-food substances such as paint, clay, and plaster. In addition, for children participants, information will be collected on location of play area(s) and school(s) attended.

2.2.3.4 Sample Collection

The specific methods proposed by RTI for measuring environment-related factors differ somewhat among the various types of exposure. These differences reflect several considerations such as the extent to which surrogate variables reflect the factors of interest, the measurability of factors, the variability of factor measurements, the quality control of data collection, and the suitability of data collection techniques under actual survey conditions. The proposed methodology stresses random sampling techniques wherever possible to facilitate valid statistical analyses and to increase the degree of control over data collection; FI's will follow explicit, nonjudgmental procedures throughout. These procedures will range, as described in appendix 2.6, from obtaining small selective samples of relatively homogeneous items, such as tap water at a particular residence, to obtaining large stratified random samples for a highly variable item, such as air quality in a smelter community.

As indicated in preceding sections, data collection will be divided among the various field staff. The collection of environmental samples will be divided between the SA and the FI. The SA will be responsible for collecting air, market basket, and general soil and water samples such as soil and water samples from each school where study children participants attend; RTI anticipates that more than one school age child participant may attend the same school. The FI will be responsible for the selection and screening of residence units, households, and eligible participants; acquisition of the PCF and administration of the SQ; collection of dust and tap water samples for each participating household, and soil samples from the appropriate play area for each pre-school child participant; measurement of paint lead levels; explanation of the procedure for collecting the urine sample; and arrangements for the participant to go to a central location for acquisition of the biological samples and disbursement of the incentive. At that central location, the urine, blood and hair samples will be collected by the medical independent subcontractor, who will also perform the hematocrit and urine protein and specific gravity determinations.

For each household containing a study participant, paint lead levels will be measured, samples of housedust and tap water will be collected, and the precise location of the residence noted on a map so that the distance of the residence unit from the smelter can be accurately calculated. For each study participant, RTI shall endeavor to obtain a completed PCF and SQ, and samples of blood, urine, and scalp hair; in addition, soil samples will be collected from the appropriate play area for each pre-school child participant and from each school yard where study children participants attend.

2.2.3.5 Quality Control

Two aspects of *quality control* will directly involve the participating households and individuals - *duplicate samples* and *reinterview*. For households/participants for whom duplicate samples are to be collected, the purpose and procedures for collecting the duplicate samples (see below) will be explained. Each person completing an HSQ or an SQ will be informed that they may be selected for reinterview.

2.2.4 Central Data Collection

As indicated in preceding sections and paragraphs, RTI plans to arrange for the collection of biological samples at a central location which would be manned by at least one medical staff member and probably an FI for four hours in the evening Monday through Friday and eight hours during the day on Saturdays. Participants would come to this location to deposit their urine samples and permit the collection of blood and scalp hair samples. In addition, hematocrits and urine protein and specific gravity determinations will be performed at this location. In the event that a participant does not have transportation to the location, RTI will be prepared to provide transportation. In the event that the participant's physical condition makes travel impractical, such as an elderly, disabled, or otherwise infirm person, the medical staff member may have to go to the home in order to obtain the necessary samples. Ideally, the biological samples will be collected the day after the participant is enlisted or during the day on the next Saturday.

2.2.5 Site Administrator's Responsibilities

At each performance site, the SA will have three areas of responsibility: (1) general supervision and coordination of field operations; (2) collection of certain general samples; and (3) data management, handling, and shipment.

2.2.5.1 Coordination of Field Operations; Data Management

As indicated in preceding sections, an RTI professional will serve as SA and as such be responsible for the coordination and quality control of data collection; these individuals will remain at each site for the duration of data collection at that site, and at the very least the same individual(s) will oversee such activities at sites representing the same type smelter. The SA will work in close communication with the Survey Director and other professionals at the RTI central facility at Research Triangle Park, North Carolina, in order to coordinate and supervise immediate field operations at each performance site. The SA will have to coordinate his own project activities with those of the independent subcontractors to ensure that various project activities proceed as effectively and efficiently as possible with regard to both time and cost. The SA will also serve as a trouble-shooter.

Among the field operations which the SA will have to coordinate are:

. Obtaining household mapping information, copies of HSLs, HSQs, and administrative forms, and soil, tap water, and housedust samples from the FI's;

. Scheduling and transportation of participants to the central data collection facility for collection of biological samples, including delivery of the completed PCF and SQ to the central data collection facility; and

. Retrieval of the completed PCFs, SQs and biological samples from the central data collection facility.

2.2.5.2 Sample Collection

As intimated and discussed in preceding sections and appendix 2.6, the SA will be responsible for collecting random air samples in the smelter community, composite soil samples from the smelter community at large as well as from each school yard where study children participants attend, water samples from each school where study children participants attend, and market basket samples.

2.2.5.3 Data Storage, Packaging and Shipment

With regard to survey instruments, the SA will only be responsible for shipping the completed PCFs and SQ's to RTI/SOC, although he will receive copies of HSLs, HSQs, and various administrative forms from the appropriate independent subcontractors for review and reference as needed.

All samples will be chilled to 0°-5°C (not frozen) after collection and will be shipped in this condition via Federal Express. Shipment by Federal Express eliminates the possibility of sample contamination due to pressure gradients in transit. High density polyethylene containers will be used for tap water, urine and soil samples; Poly-Seal caps will be used to provide a leak-proof seal without contamination. Plastic containers will be shipped in styrofoam blocks in which depressions are cut to exactly hold each container. RTI experience with such shippers has resulted in no container damage and a minimum of sample temperature change during transit.

Zip-Loc plastic containers will be used for air, scalp hair and dust samples. RTI experience with Zip-Loc plastic containers indicates that the Zip-Loc seal insures containment protection eliminating sample loss and contamination. The plastic bags will be shipped in a styrofoam-lined box.

Blood samples will be shipped to RTI in specially designed 8-tube Vacutainer shippers. As with other samples, blood samples will be chilled (not frozen) in order to reduce losses due to hemolysis and volatilization.

2.2.6 Quality Control

2.2.6.1 Training

In order to standardize the quality of data collection techniques and procedures from the outset, a training manual will be developed by RTI for use in training RTI project staff and briefing field interviewers. This manual will address study objectives; data collection instruments; detailed rationale and procedures for collecting environmental and biological samples; instructions for administration, coordination, and quality control of all field operations; instructions for data receipt control, scan-edit, and entry; and discussions of anticipated problems (see appendix 2.2). In addition, RTI will conduct training sessions for RTI project staff and independent subcontractors which will address study objectives and procedures in order to increase the quality and relevance of data collected. One major objective of the training activities will be to provide explicit, nonjudgmental procedures for the field staff to follow.

2.2.6.2 Supervision

The RTI Survey Director will supervise and coordinate the field operations, providing flexibility of coverage should additional professional level effort be required at any time during the data collection period. An SA will remain at the performance site until data collection is completed, and the same SA(s) will be used at least for sites of the same smelter type. RTI plans to enlist the services of physician consultants on-site to serve as points of contact for the field staff in the event that any medical problems or questions are encountered in the data collection process, particularly in regard to the acquisition of blood samples.

The Institute has a field operations staff of Field Supervisors (FSs) located at key points across the country who have coordinated the work of field data collection staffs for a variety of projects and will be available to assist with supervision and/or coordination of data collection for this project if required. These area supervisors are currently based in or near the following major metropolitan areas: Boston, New York, Washington, Atlanta, Pittsburgh, Detroit, Chicago, St. Louis, Houston, Los Angeles, and San Francisco. At the very least, the appropriate FSs will be made aware of project activities and provided a copy of the training manual; depending upon time and cost considerations, the appropriate FS may be invited to attend the training session at the performance site.

In order to facilitate supervision, both RTI/SOC and the SA will receive copies of the HSLs, HSQs and various administrative forms completed by independent subcontractors which will provide an opportunity to monitor the production and activity of the field staff.

As indicated in preceding sections, the Survey Director and SA will accompany the independent subcontractors during the first day of data collection at each performance site. The SA will be encouraged to meet frequently with independent subcontractors to review study progress and problems, and independent subcontractors will be observed occasionally in the performance of their duties. Survey instruments will be edited upon receipt at RTI/SOC.

2.2.6.3 Sample Collection

Each sample will be properly labeled as it is collected. Each individual sample will be treated the same as all other samples of that particular type.

2.2.6.4 Duplicate Sample Collection

As a check on the quality or precision of collecting certain of the biological and environmental samples, RTI plans to collect duplicate soil, housedust, tap water, blood, and scalp hair samples (the last two from adult participants only) from ten percent of the sample sources, using the same technique and as nearly as possible the same sites as the original sample (see appendix 2.6). In the event that problems are detected, an attempt will be made immediately to determine the cause and appropriate resolution of the problem.

2.2.6.5 Reinterview

As a quality check of the interview process, RTI plans to reinterview by telephone, personal visit, or mail, in that order of preference, approximately ten percent of the population for whom completed questionnaires are obtained. The actual method of reinterview (mail, telephone, or personal visit) will be determined according to which is more convenient, cost-effective, and/or appropriate; telephone would be the preferred method. RTI does not anticipate that the reinterview process would involve the entire SQ.

This procedure will permit a two-fold verification - that the interview indeed took place and that responses are consistent. In the event that inconsistent responses are detected, an attempt will be made to determine if the inconsistencies are due to variations in participant response or FI error or misinterpretation; in the latter case, the FI will be contacted in an effort to resolve the problem.

2.2.7 Respondent/Participant Burden

The only anticipated *risk* to participants will involve the acquisition of the blood sample, and the *burden* will consist of the *time* to respond to the questionnaire(s), the time and *inconvenience* of allowing the FI into the household to collect the household environmental samples; and the time, inconvenience and perhaps minor discomfort of providing the biological samples (see below). In order to complete household data collection, approximately two hours of time may be required of each participant, including travel and the collection of all relevant samples. More specifically, RTI anticipates that 45 minutes will be required to complete the questionnaire(s) for each participant, 30 minutes will be required to collect the household environmental samples, and 20 minutes will be required to obtain the biological samples, leaving 25 minutes for travel time to the central data collection facility.

To offset this burden, RTI will offer the *incentive* of ten dollars per participant and an opportunity to obtain some health measurements, such as the hematocrit, urine protein, and the various analyses for metal burden. Potential participants will be informed of arrangements with appropriate area agencies for the followup of study participants for whom study data indicate medical attention.

2.3 Anticipated Problems

RTI has identified the following potential problem areas which may have a significant impact on project time, cost or validity.

2.3.1 Smelter Resistance

RTI has assumed that the smelter industry will provide at the very least a promise of verbal cooperation or passive resistance. In the event that the smelter takes a position of active resistance, project performance at a given site might be seriously jeopardized, since most of the performance sites are relatively small communities whose economy is significantly influenced by the smelter.

2.3.2 Recruiting Independent Subcontractors

Since the six performance sites were not specified prior to the signing of the contract, RTI predicated field operations costs on the assumption that qualified independent subcontractors could be retained at, or within a reasonable distance of, the smelter community performance site. Should RTI be unable to find qualified independent subcontractors at, or within a reasonable distance of, the performance site, they will have to be brought into the performance site from more distant points at an additional expense for travel and subsistence.

2.3.3 Nonparticipants

As indicated in preceding sections, RTI anticipates a certain number of nonrespondents, nonparticipants, and ineligibles. However, in some of these small smelter communities, these various categories of nonparticipants may significantly reduce the number of data sets available for analysis. Through callbacks and the incentive, RTI hopes to keep nonrespondents and nonparticipants at a minimum, but eligibility is determined by established criteria. In some of these small smelter communities, for example, the number of adult men without direct occupational exposure may be small.

2.3.4 Incomplete Data Sets

Even though an individual may agree to participate in the study and sign a PCF, a complete set of questionnaires and samples for that individual may not be obtained for a variety of reasons such as baldness, inability or refusal to provide a scalp hair or urine sample, or refusal to provide a blood sample. RTI has anticipated some of the potential problems in obtaining complete data sets and made appropriate provisions, such as offering an incentive to be paid only after collection of the blood sample; transportation to and from the central data collection facility; and arranging for the medical independent subcontractors to visit the participant at home to collect the biological samples if necessary. Nonetheless, participation in this survey is voluntary and the small size of most of these smelter communities limits the number of eligible volunteers. Therefore, RTI will accept as a *minimum data set* a blood sample and completed HSQ, PCF, and SQ.

2.3.5 Missing Data

Since various data elements must be shipped to RTI from the performance site via Federal Express and/or mail, the possibility exists for those data elements to be lost or damaged so as to not be useable. In the past, RTI has had little problem with regular first class mail.

2.4 Schedules for Field Operations

2.4.1 Time Schedule

Figure 2.8 presents graphically a time schedule for the field operations, including preparations, data collection in the field, and data processing. In figure 2.8, tasks at RTI are as follow:

Task 1 - Preparation of work plan and data collection instruments;

Task 2 - Review and revision(s) of work plan and data collection instruments;

Task 3 - Preparation of training manual;

Task 4 - Training session;

Task 5 - Data receipt control, edit and direct entry;

Task 6 - Reinterview; and

Task 7 - Preparation of final report.

For each performance site, Phase I refers to public relations, recruitment of independent subcontractors, and publicity; Phase II refers to training; and Phase III refers to data collection. This time table is predicated on approval of study protocol and data collection instruments by EPA and OMB early in 1977. In order to minimize interviewer and participant burden, RTI anticipates that field operations at each site would be conducted during temperate weather; some studies have indicated that weather plays a significant role in project efficiency and participation. [Ref. 2.6]

At this point in time, RTI anticipates that the performance sites would be studied in the following order:

Pretest - Corpus Christi, Texas;

Performance site 1 - Anaconda, Montana;

2 - Palmerton, Pennsylvania;

3 - Herculanuem, Missouri;

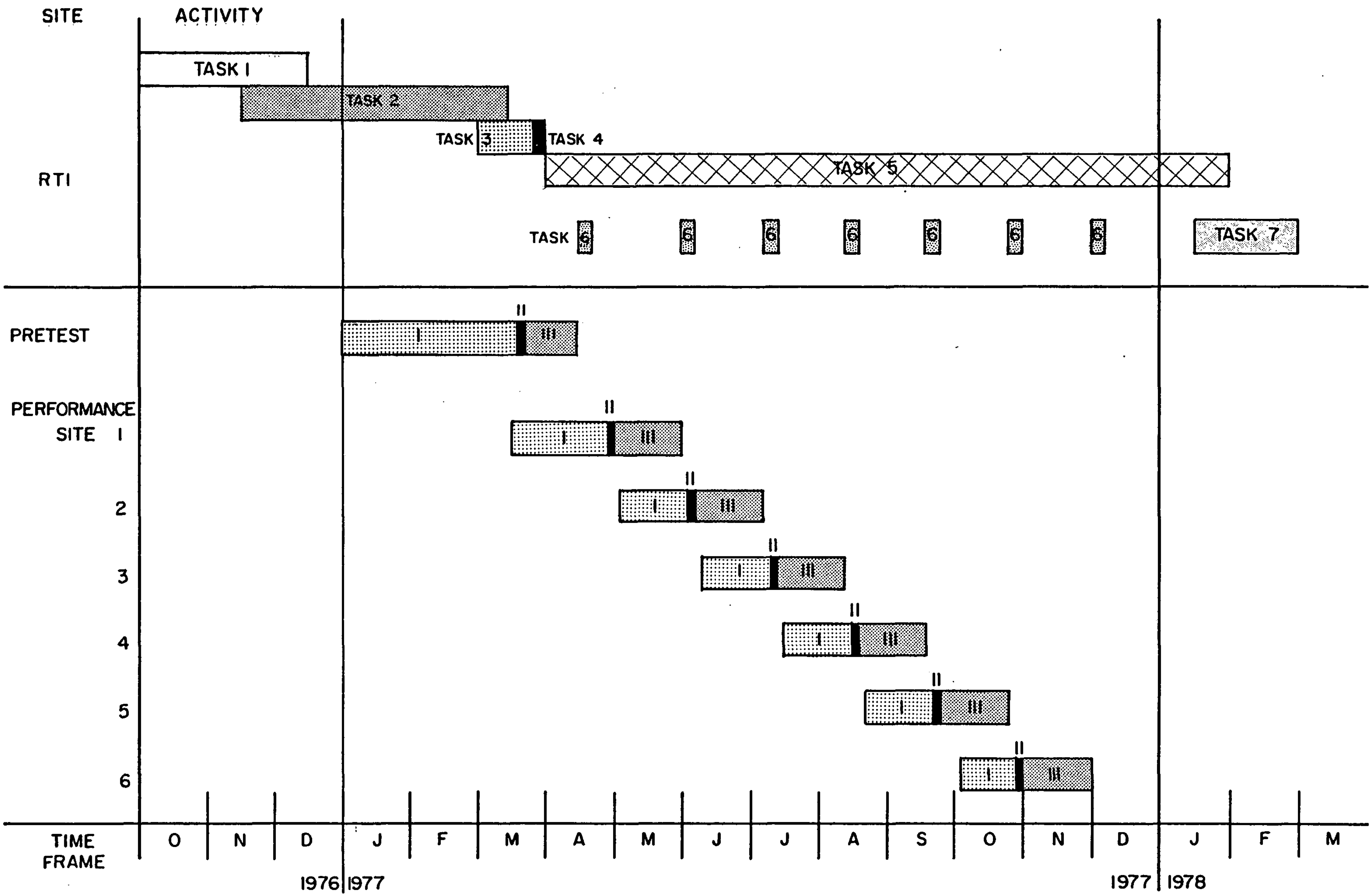


Fig. 2.8. Field operations time table.

4 - Bartlesville, Oklahoma;

5 - Bixby, Missouri; and

6 - Ajo, Arizona.

It is further anticipated that the elderly age group will be studied at Herculanuem, Bartlesville, and Ajo.

2.4.2 Cost Schedule

Figure 2.9 presents graphically cumulative *estimated* cost (exclusive of fee) and labor (man-months) projections by month for the field operations. These cost and labor projections are based on figure 2.8 and predicated on the same assumptions.

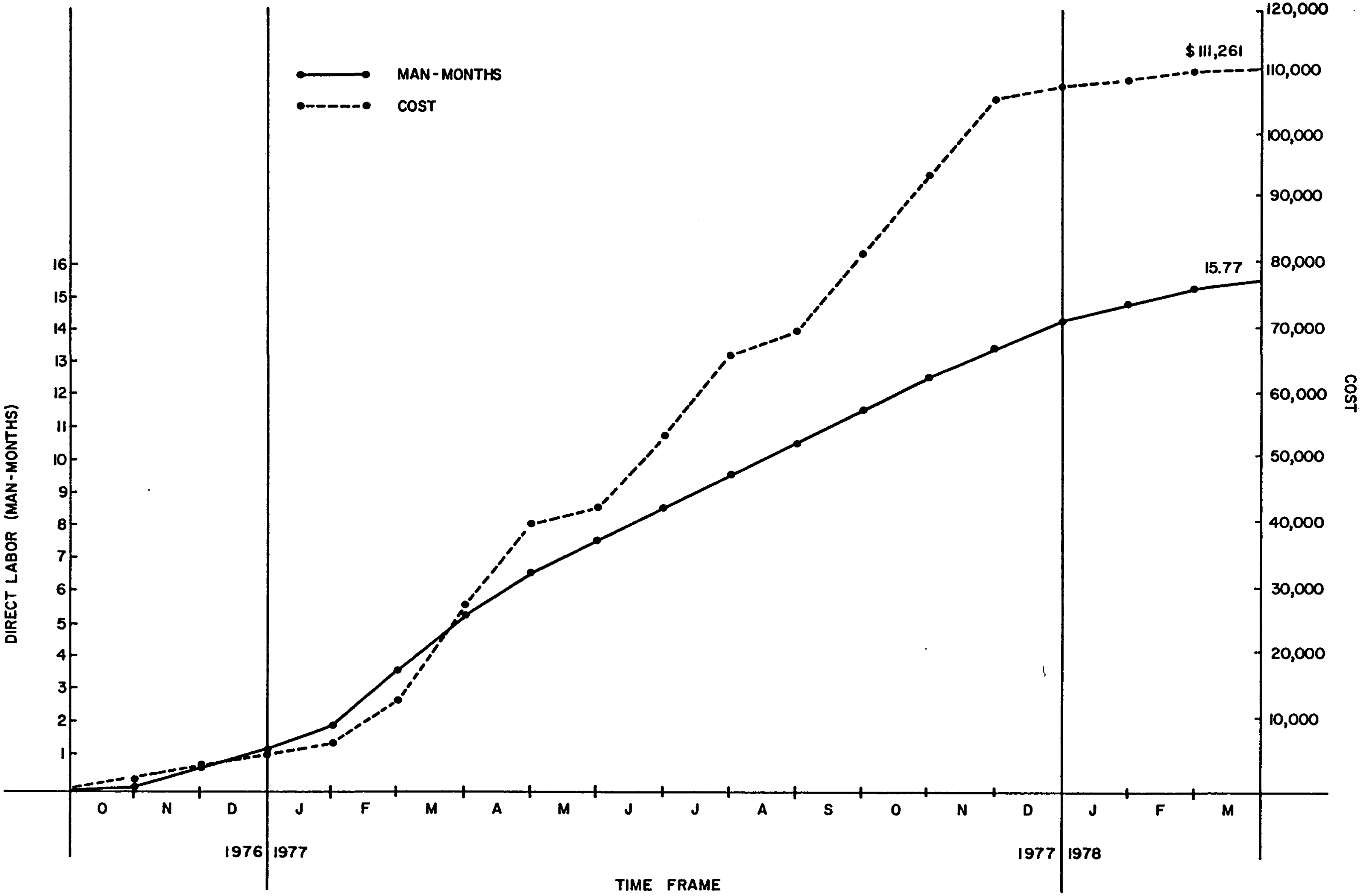


Fig. 2.9 Field operations cost and labor projections.

3-10-77

APPENDIX 2.1

RESUMES OF RTI PROJECT STAFF AND CONSULTANTS

JAMES D. BATES, Director, Survey Operations Center

Professional Experience

1963 to date. Research Triangle Institute, Research Triangle Park, North Carolina 27709.

1976 to date: Director, Survey Operations Center.

1972-1976: Manager, Survey Methodology and Operations Department.

1971-1972: Senior Economist, Center for the Study of Social Behavior.

1968-1971: Head, Economics Section in Social Statistics Group.

1965-1968: Economist in Sampling Group of Statistics Research Division.

1963-1965: Statistics Research Division contract with U.S. Agency for International Development on project as Survey Statistician. Rural Economic Surveys, Federal Office of Statistics, Nigeria, West Africa.

1961-1963. Florida Citrus Commission, Department of Agricultural Economics, University of Florida, Gainesville, Florida. Assistant Marketing Research Economist.

Education

B.S., Agricultural Economics, University of Florida, 1958.

M.S., Agricultural Economics, University of Florida, 1963.

Completed course work toward Ph.D. in Economics at North Carolina State University.

Professional Activities

American Economic Association, member.
American Farm Economic Association, member.
Phi Kappa Phi.
Gamma Sigma Delta.
Alpha Zeta.

Publications and Reports

"Behaviorial Characteristics of Customers Shopping for Fresh Oranges," (with S.W. Williams and M.R. Godwin) Florida Citrus Commission, in cooperation with the University of Florida Department of Agricultural Economics, Agricultural Experiment Station and the Marketing Economic Division of ERS, USDA, Pub. S.C.C.-E.R.D. 65-8, May 1965.

A Study of Job Vacancies and Manpower in Durham County, James D. Bates, Statistics Research Division, Research Triangle Institute, July 1966.

A Study of Financial Assistance to Child Care Institutions by the State of North Carolina, James D. Bates and James A. Street, Statistics Research Division, Research Triangle Institute, March 1967.

Operating Costs in Homes for the Aged and Nursing Homes in North Carolina, D.A. King and J.D. Bates, Statistics Research Division, Research Triangle Institute, March 1967.

An Intensive Investigation of the Problems Associated with Young Men who are Mentally Unqualified for Military Service, A.M. Huq, T.H. Jerdee, J.D. Bates and Don Jackson, Research Triangle Institute, May 1967.

An Index of Economic Status of Individual Rural Families, J.D. Bates, J.V. Rachal and L. Gould, Research Triangle Institute, January 1971.

Alcohol Safety Action Program, Annual Report, J.R. Miller, B.A. Moser, S. Trustman and J.D. Bates, March 1972.

Drug Usage and Arrest Charges, William C. Eckerman, James D. Bates, J. Valley Rachal, and W. Kenneth Poole, December 30, 1971.

North Carolina Survey on Aging, J.D. Bates and D.W. Jackson, March 9, 1972.

An Operational Consumption Measure of Economic Status: With Applicability to United States Rural Families, J.D. Bates, J.V. Rachal, W.K. Poole and R.P. Moore, October 1972.

A Description of Field Procedures and Data Processing for the Household Survey for New Towns, J.D. Bates, and D.W. Jackson, November 30, 1973.

A Review of USAID Projects in Four Major Livestock Producing States in Nigeria: An Assessment of Range Management, J.D. Bates, G. Howze, F.A. Abercrombie, and H. Van Blake, May 1975.

3/76

CURRICULUM VITAE

STEPHEN HUNTER GEHLBACH

Born: January 14, 1942, in Moline, Illinois

Education: Academic: Received A.B. degree, Harvard College 1964.

Graduated from Case Western Reserve School of Medicine (1968)

Internship and Residency: Mixed medical-pediatric internship at the Royal Victoria Hospital in Montreal, Quebec

One year residency in pediatrics at Childrens' Hospital Medical Center in Boston

One year residency in pediatrics at Duke Medical Center

Military Service: Served two years in U. S. Public Health Service assigned to the North Carolina State Board of Health as Field Epidemiologist working primarily in the field of general communicable disease control

Licensure: North Carolina, December, 1971

Publications: (coauthor): "Haemolytic Anaemia in Infectious Mononucleosis Due Inapparent Congenital Spherocytosis," Scand. J. Haemat., 7: 141-144, 1970.

(coauthor): "Clinical Reactions Following Rubella Vaccination," JAMA, 220: 1569-1572, 1972.

(coauthor): "Coccidioidomycosis," Arch. Int. Med., 131: 254-255, 1973.

(coauthor): "Spread of Disease by Fecal-Oral Route in Day Nurseries," HSMHA Health Reports, 83: 320-322, 1973.

PUBLICATIONS: Gehlbach, S., Cooper, B., "Haemolytic Anaemia in Infectious Mononucleosis Due Inapparent Congenital Spherocytosis," Scand. J. Haemat., 7: 141-144, 1970.

Grand, M., Wyll, S., Gehlbach, S., "Clinical Reactions Following Rubella Vaccination," JAMA, 220: 1569-1572, 1972.

Gehlbach, S., Hamilton, J., Conant, N., "Coccidioidomycosis," Arch, Int. Med., 131: 254-255, 1973.

Gehlbach, S., MacCormack, J., Drake, B., Thompson, W., "Spread of Disease by Fecal-Oral Route in Day Nurseries," HSMHA Health Reports, 88: 320-322, 1973.

Gehlbach, S., Williams, W., Woodall, J., Freeman, J., "Pesticides and Human Health - An Epidemiologic Approach," Health Service Reports, 89: 274-277, 1974.

Gehlbach, S., Williams, W., Perry, L., Woodall, J., "Green Tobacco Sickness - Ann Illness of Tobacco Harvesters," JAMA, 229: 1880-1883, 1974.

Roe, C., Schonberger, L., Gehlbach, S., et. al.: "Enzymatic Alterations in Separate Outbreaks of Reye's Syndrome: Prognostic Implications", presented to the Reye's Syndrome Conference, Columbus, Ohio, October, 1974.

Gehlbach, S., Williams, W.: "Pesticide Containers: Their Contribution to Poisoning," Arch. Env. Health, 30: 49-50, 1975.

Landrigan, P.J., Gehlbach, S.H., Rosenblum, B.F., etc."Epidemic lead absorption near an ore smelter, N.E.J.M. 292: 123-219, 1975.

Roe, C. R., Schonberger, L.B., Gehlbach, S.H., Wies, L.A. and Sidbury, J.B., "Enzymatic alterations in Reye's syndrome: Prognostic implications", Pediat. 55: 119-126, 1975.

Gehlbach, S.H., Gutman, L.T., Wilfert, C.M., Brumley, G.W., and Katz. S.L. "Recurrence of skin disease in a nursery: Ineffectuality of hexachlorophene bathing", Pediat. 55: 422-424, 1975.

Gehlbach, S.H., Williams, W.A., et.al.: "Nicotine absorption by workers harvesting green tobacco", Lancet 1: 478-480, 1975.

Gehlbach, S.H., and Williams, W.A.: "Epidemiology of pesticide poisonings in North Carolina", (Abstract) Pediat. Res., 4: 297, 1975.

BENJAMIN S. H. HARRIS, III, Health Survey Specialist

Professional Experience

1964 to Date. Research Triangle Institute, Research Triangle Park, North Carolina 27709.

1974 - date: Health Survey Specialist, Survey Operations Center, Statistical Sciences Group. Currently Project Leader of a follow-back study of children who received diagnostic doses of radioactive iodine over the period 1946-1967; Survey Director of a study of heavy metal absorption by persons living near non-ferrous smelters; Task Leader of tasks related to establishment and coordination of an Advisory Committee, training and quality control of record abstractors, and hospital nonresponse in a national survey of the incidence, prevalence, and costs of traumatic injury to the central nervous system; Task Leader of off-site and data collection activities related to the evaluation of, and exploration of alternatives to, the Hospital Discharge Survey; also involved in a study of the outcomes of alternative modes of treating prostatic carcinoma. Major contributor to the evaluation of the Mecklenburg County, North Carolina, Alcohol Safety Action Project and the establishment and maintenance of a national registry of chronic intermittent dialysis patients; and monitored grant review committees for the National Institute on Alcohol Abuse and Alcoholism (NIAAA).

1971 - 1974: Medical Science Analyst, Center for Health Studies. Project Leader of a study of diagnosis and determination of disability in alcoholism; the preparation of a directory of State and local alcoholism services; and a pilot follow-back study of patients treated for tuberculosis in the North Carolina Sanitorium system during the period 1930-1950 by pneumothorax and pneumoperitoneum with fluoroscopy. Supervised survey of Medicare procedures used by physicians in selected metropolitan areas; major contributor to a study involving the collection and analysis of data relating to civilian techniques in international development assistance, and a survey of attitudes and capabilities of major hospitals in North Carolina regarding the handling of patients involved in radioactive accidents. Coordinated site visits to alcoholism treatment centers sponsored by NIAAA and prepared a summary and evaluation of the site visit process, assisted with the Third Annual Alcoholism Conference of NIAAA, and involved in the medical evaluation of the supplemental food program for Women, Infants, and Children. Assisted in the preparation of new contract proposals related to health services, and served as a consultant to the Craven County (N.C.) Health Department in the preparation of a proposal to the North Carolina Regional Medical Program.

1966 - 1971: Health Services Analyst, Operations Research and Economics Division. Principal Investigator on studies of hospital utilization in the last year of life and the economic costs of kidney disease; major contributor to study of the post nuclear attack prevention and control of communicable respiratory diseases; supervised survey of drug usage among arrestees for serious crimes in selected metropolitan areas; research on the economic costs of alcoholism and excessive fertility.

1964 - 1966: Biologist, Natural Products Laboratory. Responsible for biological assays and pharmacologic evaluation of synthetic and naturally-occurring toxic agents, the immediate operation of the Institute's animal colony, coordinating the Laboratory's bio-assay program, and assisting in the preparation of new contract proposals in bio-medical areas.

1961 to 1964. Duke University Medical Center, Durham, North Carolina 27710. Research Assistant, Department of Psychiatry, Division of Electroencephalography (EEG). Research activities included portable EEG, the EEG in various types of epilepsy, guides for teaching EEG, neurophysiologic changes in the brain of the cat after administration of hallucinogens, and changes in electrical activity resulting from drowsiness and psychopharmacologic agents; preparation of Keysort data cards for classification and condensation of EEG's; and recording EEG's in operating rooms during neurosurgical procedures. During this time also served as junior staff psychiatrist, John Umstead (State mental) Hospital, Butner, North Carolina.

Education

B.A., Zoology, Duke University, Durham, North Carolina, 1960.
Graduate work in medicine, Duke University School of Medicine, 1960-1965.
Course in Operations Research, Georgia Institute of Technology, Atlanta, Georgia, 1968.
San Diego Summer School of Alcohol Studies, University of California, San Diego, 1972.

Honors

President, Pre-med scholastic honorary society, Duke University, 1959-60.
NIMH student research stipends, summers of 1961 and 1963.
Who's Who in North Carolina, 1973.

Selected Publications

"Experience with Portable Electroencephalography in a General Hospital." Electroencephalography and Clinical Neurophysiology, 1963, 15:1047 (Abstract of paper presented to Southern EEG Society, Durham, N.C., November 17, 1962).

"Psychiatric Problems in Children with Frontal, Central and Temporal Lobe Epilepsy." Southern Medical Journal, 1966, 59:49-53, coauthor.

"Murine Toxicity of Cochliobolus carbonum." Applied Microbiology, 1968, 16(11):1710-1722, coauthor.

"Interictal Focal or Lateralized Discharges Occurring in the Electroencephalograms of Patients Suffering From Centrencephalic Epilepsy." Confinia Neurologica, 1968, 30:368-374, coauthor.

The Economic Cost of Kidney Disease and Related Diseases of the Urinary System (PHS Pub. No. 1940). Washington, D.C.: U.S. Government Printing Office, 1970.

"Estimation of a Potential Hemodialysis Population." Medical Care, 1970, 8(3):209-220, coauthor.

"The Number and Cost of Medicines Prescribed for the Treatment of Patients with Selected Diseases." Inquiry, 1970, 7(3):38-50.

Postattack Communicable Respiratory Diseases. Research Triangle Park, N.C.: Research Triangle Institute, 1970, coauthor.

Care in Hospitals and Institutions During the Last Year of Life by Cause of Death: United States, 1962-1965 Deaths. Washington, D.C.: U.S. Department of Commerce, National Technical Information Service, 1972 (NTIS Accession No. PB-208-639).

Military Civic Action Final Report, Volume I: Evaluation of Civilian Techniques in International Development Assistance. Research Triangle Park, N.C.: Research Triangle Institute, 1972.

Medical Facilities - Control of Radioactive Materials in North Carolina Transportation Accidents (RM-24U-754). Research Triangle Park, N.C.: Research Triangle Institute, 1973.

"Alcohol Abuse: An Overview." Adit: Approaches to Drug Abuse and Youth, 1973, 2(1):1-2, 11-15.

Mecklenburg Alcohol Safety Action Project: An Analysis of Ultimate Performance Measures to Determine Total Project Impact. Research Triangle Park, N.C.: Research Triangle Institute, 1974.

"Edgar Allan Poe on Sullivan's Island." South Carolina Magazine, 1975, 39(2):8-15.

Evaluation Reports I and IV: Hospital Discharge Survey Evaluation Study. Research Triangle Park, N.C.: Research Triangle Institute, 1976, coauthor.

MILDRED C. PENNINGTON, Research Assistant II

Professional Experience

1973 to date. Research Triangle Institute, Statistics Research Division, Research Triangle Park, North Carolina 27709. Research Assistant to the manager and supervisor of the clerical staff of the Survey Methodology and Operations Department.

1942-1973. United States Department of Agriculture

1961-1973: United States Department of Agriculture, Statistical Reporting Service and the North Carolina Department of Agriculture, Division of Agricultural Statistics, Raleigh, North Carolina. Statistical Assistant to the statistician and supervisor to the clerical staff of the Input and Collection unit.

1942-1961: United States Department of Agriculture, Standards and Research Division, Statistical Research Laboratory, Institute of Statistics, North Carolina State University, Raleigh, North Carolina. Act as assistant to the statistician and supervisor to the clerical staff of the Survey Operation Group.

Education

Needham Broughton High School, Raleigh, North Carolina 1935

Attend one week course on Supervision and Group Performance, Atlanta, Regional Training Center, Atlanta, Georgia, 1971

Professional Activities

Association for Coordination Interagency Statistics, North Carolina State Departments, 1971-1972; member.

February 1973

CURRICULUM VITAE
Carl M. Shy

I. Born: October 23, 1931 - Milwaukee, Wisconsin
Married: June 6, 1959
Wife: Eve Carol (nee Rudich)
Children: Leslie (3/26/60)
Rosalie (4/2/62)
Ann (6/4/65)

II. Pre-Medical Education:
1. A.B. St. Louis University, 1956
Major in Philosophy and Economics
2. St. Louis and Marquette Universities, 1956-57
Graduate Studies in Philosophy and Economics

III. Medical Education:

	Year	Location	Appointment and Degree
1.	1958-1962	Marquette University School of Medicine	Medical Student, M.D. received June 1962
2.	1960 (Summer)	Marquette University School of Medicine	Student Fellowship (2 months) in Physiology
3.	1962-1963	University of Michigan	Intern (Straight Medicine)
4.	1963-1964	University of Michigan Medical Center	Resident I in Internal Medicine
5.	1964-1965	University of Michigan School of Public Health	Student in Department of Epidemiology: M.P.H. Received May 1965
6.	1965-1967	University of Michigan School of Public Health	Student in Department of Epidemiology: Dr.P.H. Received April 1967

IV. Post-Doctoral Public Health, Medical and Academic Experience:

	Year	Location	Appointment
1.	1967-1971	U.S. Public Health Service National Air Pollution Control Administration (Now the Environmental Protection Agency) Durham, North Carolina	Epidemiologist and Chief, Epidemiology Branch, Division of Health Effect Research

2.	1971-1972	Environmental Protection Agency, Office of Research and Monitoring, Division of Health Effects Research, Research Triangle Park, North Carolina	Deputy Director Division of Health Effects Research
3.	9/72-12/73	Environmental Protection Agency, Office of Research and Monitoring, National Environmental Research Center, Research Triangle Park, North Carolina	Director, Human Studies Laboratory (Final Civil Service Grade was GS-16)
4.	1968-1973	University of North Carolina Department of Epidemiology	Adjunct Assistant Professor
5.	1969-Present	Duke University	Assistant Clinical Professor of Epidemiology (Part-time Appointment)
6.	1970-Present	Journal of Chronic Diseases	Editorial Consultant
7.	1971-Present	Wake County Hospital	Staff Member, Medical Night Clinic (General Pediatric and Internal Medicine Practice)
8.	1968-Present 1971-Present	State of Ohio State of North Carolina	Medical Licensure Medical Licensure
9.	1/74-Present	University of North Carolina	Director, Institute of Environmental Studies Lecturer, Department of Epidemiology, School of Public Health

V. Membership in Scientific Organizations:

1. Alpha Omega Alpha National Honorary Medical Fraternity
2. Delta Omega National Honorary Public Health Society
3. American Association for the Advancement of Science
4. Society for Epidemiologic Research
5. American Public Health Association
6. North Carolina Lung Association, Advisory Committee on Air Pollution

VI. Publications:

1. Shy, C.M. and Meade, R.C.: The hippuric acid radioisotope renogram, Marquette Med. Rev. 26:139-147, 1961.

2. Shy, C.M.: Diagnostic procedures for determining hypertension of renal origin. Marquette Med. Rev. 26:194-199, 1961.

3. Meade, R.C. and Shy, C.M.: The evaluation of individual kidney function using radioiodohippurate sodium. J. Urol. 86:163-170, 1961.

4. Shy, C.M.: A comparison of psychoanalytic and philosophical thought. Marquette Med. Rev. 27:61-67, 1962.

5. Shy, C.M.: Of Man and Machines (Student Editorial). Marquette Med. Rev

6. Associate editor of Vol. 27, No. 3 (March 1962) issue of Marquette Med. Rev.

7. Shy, C.M.: The pituitary-thyroid relationship in Graves' disease. Marquette Med. Rev. 27:162-166, 1962.

8. Shy, C.M.: The determinants of the one-second forced expiratory volume, as a measure of chronic obstructive lung disease, in a total population stud Doctoral dissertation submitted and accepted in partial fulfillment of the requirements for the degree of Doctor of Public Health, April 1967. Disserta is available in microfilm form from University Microfilms, Ann Arbor, Michig

9. Shy, C.M., Creason, J.P., Pearlman, M.E., McClain, K.E., Benson, F.B. and Young, M.M. The Chattanooga School Children Study: Effects of Community Exposure to Nitrogen Dioxide. 1. Methods, Description of Pollutant Exposure and Results of Ventilatory Function Testing. J. Air Pollution Control Assoc. 20:539-545, August 1970.

10. Shy, C.M., Creason, J.P., Pearlman, M.E., McClain, K.E., Benson, F.B. and Young, M.M. The Chattanooga School Children Study: Effects of Community Exposure to Nitrogen Dioxide. 2. Incidence of Acute Respiratory Illness. J. Air Pollution Control Assoc. 20:582-588, September 1970.

11. Shy, C.M.: Health Effects. Chapter in National Emissions Standards Study, A Report to Congress, 1970.

12. Cohen, A.A., Shy, C.M., Benson, F.B., Riggan, W.R. and Newill, V.A.: Air Pollution Episodes: Guides for Health Departments and Physicians. HSMHA Heal Reports, June 1971.

13. Hammer, D.I., Finklea, J.F., Hendricks, R.H., Shy, C.M. and Horton, R.J.M Hair Trace Metal Levels and Environmental Exposure. Amer. J. Epid. 93:84-92, February 1971.

14. Pearlman, M.E., Finklea, J.F., Shy, C.M., VanBruggen, J.B. and Newill, V.A.: Chronic Oxidant Exposure and Epidemic Influenza. Environmental Research, June 1971.

15. Pearlman, M.E., Finklea, J.F., Creason, J.P., Shy, C.M., Young, M.D. and Horton, R.J.M.: Nitrogen Dioxide and Lower Respiratory Illness, Pediatri 47(2), February 1971.

16. Shy, C.M.: Environmental Epidemiology. Chapter in Environmental Handbo for International Students. University of North Carolina, (In Press), 1972.

17. Hammer, D.I., Finklea, J.F., Hendricks, R.H., Hinners, T.A., Riggan, W.B. and Shy, C.M.: Trace Metals in Human Hair as a Simple Epidemiologic Monitor of Environmental Exposure. Trace Substance in Environmental Health, Vol. 5, 1972.

18. Cohen, A.A., Bromberg, S., Buechley, R.W., Heiderscheit, L.T. and Shy, C.M.: Asthma and Air Pollution from a Coal-Fueled Power Plant. Amer. J. Public Health 62:1181-1188, September 1972.

19. Hauser, T.R. and Shy, C.M. Position Paper: NO_x Measurement. Environ. Sc and Technol. 6:890-894, October 1972.

20. Shy, C.M., Hasselblad, V., Heiderscheit, L.T. and Cohen, A.A.: Environme Factors in Bronchial Asthma. Published in Environmental Factors in Respirato Disease, 1972.

21. Love, G.J., Shy, C.M., Calafiore, D.C., Benson, F.B. and Finklea, J.F.: The Strategy for Determining the Effects of Environmental Pollution on Human Health. Environ. Letters 3(1):13-20, 1972.

22. Pinkerton, C., Creason, J.P., Shy, C.M., Hammer, D.I., Bueckley, R.W. and Murthy, G.K.: Cadmium Content of Milk and Cardiovascular Disease Mortality. Trace Substances in Environ. Health, Vol. 5, 1972.

23. Riggan, W.B., Hammer, D.I., Finklea, J.F., Hasselblad, V., Sharp, C.R., Burton, R.M. and Shy, C.M.: CHESS - A Community Health and Environmental Surveillance System. Published in Proceedings of Sixth Berkeley Symposium on Mathematical Statistics and Probability, Vol. VI, Effects of Pollution on Health, University of California Press, 1972.

24. Finklea, J.F., Cranmer, M.F., Hammer, D.I., McCabe, L.F., Newill, V.A. and Shy, C.M.: Health Intelligence for Environmental Protection: A Demandin Challenge. Published in Proceedings of the Sixth Berkeley Symposium on Mathe tical Statistics and Probability, Vol. VI, Effects of Pollution on Health, University of California Press, 1972.

25. Pearlman, M.E., Finklea, J.F., Creason, J.P., Shy, C.M., Young, M.M. and Horton, R.J.M.: Nitrogen Dioxide and Lower Respiratory Illness. Published in October 18, 1971 issue of Modern Medicine. (Abstract)

26. Shy, C.M.: Referee for Article "Air Pollution: A Major Public Health Problem" by Ayres, Evans and Buehler. Published as CRC Critical Review in Clinical Laboratory Sciences, January 1972.

27. Shy, C.M., Hasselblad, V., Burton, R.M., Nelson, C.J. and Cohen, A.A.: Effects of Air Pollution on Ventilatory Function of U.S. School Children: Results of Studies in Cincinnati, Chattanooga and New York. Arch. Environ. Health 27:124-128, September 1973.

28. Nelson, C.J., Shy, C.M., English, T., Sharp, C.R., Andleman, R., Truppi, L. and VanBruggen, J.: Family Surveys of Irritation Symptoms During Acute Air Pollution Exposures: 1970 Summer and 1971 Spring Studies. J. Air Poll. Contr. Assoc. 23:81-86, February 1973.

29. Shy, C.M. and J.F. Finklea. Air Pollution Affects Community Health. Environ. Sc. and Techn. 7:204-208, March 1973.

30. Shy, C.M., J.F. Finklea, D.C. Calafiore, F.B. Benson, W.C. Nelson and V.A. Newill. A Program of Community Health Surveillance Studies (CHESS). Published in Determination of Air Quality - Proceedings of the ACS Symposium on Determination of Air Quality, p. 41-48, Plenum Press, New York-London, 1972.

31. Shy, C.M., C.J. Nelson, F.B. Benson, R.S. Chapman, W.B. Riggan and V.A. Newill. Ventilatory Function in School Children: 1967-1968 Testing in Cincinnati Neighborhoods. Published in Health Consequences of Sulfur Oxides: A Report from CHESS 1970-1971. In press.

32. Shy, C.M., V. Hasselblad, J.F. Finklea, R.M. Burton, M. Pravda, R.S. Chapman, and A.A. Cohen. Ventilatory Function in School Children 1970-1971 Testing in New York Communities. Published in Health Consequences of Sulfur Oxides: A Report from CHESS 1970-1971. In Press.

33. Shy, C.M., W.B. Riggan, W.C. Nelson, R.C. Dickerson, F.B. Benson, J.F. Finklea, A. Colucci, D.I. Hammer, and V.A. Newill. An Overview of CHESS. Published in Health Consequences of Sulfur Oxides: A Report from CHESS 1970-1971. In press.

34. Finklea, J.F., C.M. Shy, G.J. Love, C.G. Hayes, W.C. Nelson, R.S. Chapman and D.E. House: Health Consequences of Sulfur Oxides: Summary and Conclusions Based Upon CHESS Studies of 1970-1971. Published in Health Consequences of Sulfur Oxides: A Report from CHESS 1970-1971. In press.

35. Shy, C.M.: Transportation and Health. In Proceedings of the Connecticut Conference on Transportation, Connecticut Lung Association, 1973, In press.

VII. In-House Technical Reports and Inter-Agency Experience in Federal Government:

1. Shy, C.M., Hammer, D.I., Goldberg, H.E., Newill, V.A. and Nelson, W.C. Health Hazards of Environmental Lead. (To be submitted for publication.) Revised March, 1972.

2. Love, G.J., Shy, C.M., Calafiore, D.C., Benson, F.B. and Finklea, J.F. The Strategy for Determining the Effects of Environmental Pollution on Human Health.

3. Member of combined EPA-DHEW Environmental Health Task Force to prepare a report to Congress entitled "Human Health and Environmental Pollution." April-May, 1971, published in 118 Congressional Record S. 4169, March 17, 1972.

4. Staff member in preparation of Air Quality Criteria documents for nitrogen oxides, carbon monoxide and photochemical oxidants. March-September, 1970.

5. Member of EPA Health Planning Task Force to identify EPA health research needs in relation to legislative mandates and agency directives, and to plan a consolidated EPA health research program: July - November, 1971.

6. Member of EPA Task Force to revise existing air quality criteria for sulfur oxides: May-July, 1972.

7. Assistant to Dr. Vaun Newill, Chief, Health Effects Branch, EPA Headquarters in developing submission to the President's New Technology Initiatives Program, Washington, D. C., November - December 1971. Submission was accepted and funded for FY 1973-1977.

8. Member of Federal Inter-Agency Ad Hoc Committee on Classification of Toxic Substances: November 1972 - present (December 1972).

9. Co-Chairman with Dr. David Rall for Project "Biological and Genetic Effects of Pollution" as part of the US/USSR Environmental Agreement, November 1972 - Present.

10. Submission of contract proposal "Environmental and Familial Determinants of Respiratory Disease in Adolescents" for National Heart and Lung Institute, March 7-April 7, 1972; Shy, Chapman, House and DeSantis.

11. Finklea, J.F., M. J. Cranmer, D. I. Hammer, L. J. McCabe, and C. M. Shy.- Health Intelligence for Environmental Protection: A Demanding Challenge.

12. Love, G. J., C. R. Sharp, J. F. Finklea, C. M. Shy and J. Knelson. Atmospheric Levels of Air Pollution Producing Significant Harm, June 13, 1972.

13. Shy, C. M. Health Effects of Various Ambient Air Concentrations of Lead. EPA Position Paper Developed at Request of Director, National Environmental Research Center, RTP, N.C., October 12, 1971.

14. Shy, C. M. Health Research and Air Quality Criteria. Chapter Written for Revision of Air Quality Criteria for Sulfur Oxides, June 1972 (Unpublished).

VIII. Papers Presented at Scientific and Other Public Meetings

1. The Cincinnati School Children Study. The effects of air pollution on ventilatory performance of elementary school children. Presented at the annual meeting of the Society for Epidemiologic Research, Washington, D.C., May, 1968.

2. The determinants of the one second forced expiratory volume in an epidemiologic study of a total community (Tecumseh, Michigan). Presented at the annual meeting of the American Public Health Association, Detroit, Michigan, November, 1968.

3. The Cincinnati and Chattanooga School Children Air Pollution Studies. Presented at the meeting of the U.S.-Japan Cooperative Science Group, Boston, Massachusetts, February, 1969.

4. An epidemiologic study of the effects of nitrogen dioxide exposure on a population. Presented at the annual meeting of the Tennessee Public Health Association, Nashville, Tennessee, October, 1969.

5. (a) A National Health Effects Surveillance Network.

   (b) Air Pollution and Asthma.

   (c) Air Pollution and Acute Respiratory Disease.

   (d) Cigarette Smoking and Epidemic Influenza. Papers presented at the Arizona Chest Disease Symposium, Tucson, Arizona, March, 20-22, 1970.

6. Monitoring the Health Effects of Air Pollution Control. Presented at the Southeastern Industrial Health Conference, Gatlinburg, Tennessee, October 1, 1970.

7. Health Hazards of Automobile Emissions. Presented at the Mid-Atlantic sectional meeting of the Air Pollution Control Association, Harrisburg, Pennsylvania, October 8, 1970.

8. The Chattanooga School Children Study. Effect of Atmospheric Nitrogen Dioxide Exposure on the Incidence of Acute Respiratory Disease. Presented at the 98th annual meeting of the American Public Health Association, Houston, Texas, October 26, 1970.

9. Air Pollution and Acute Respiratory Disease. Presented at the Third Annual New York State Conference on Air Pollution, Albany, New York, October 29, 1970.

10. Shy, C.M. Health Hazards of Proposed Fossil Fueled Power Plant in Astoria, Queens, New York. Citizens for Clean Air, New York, New York, October, 1970.

11. Shy, C.M. Repeat of above. New York City Common Council Hearings. New York, New York, December, 1970.

12. Shy, C.M. Health Hazards of Carbon Monoxide. West Virginia State Medical Society Annual Meeting, Charleston, West Virginia, January 30, 1971.

13. Shy, C.M. Asthma and Air Pollution. West Virginia State Medical Society Annual Meeting, Charleston, West Virginia, January 31, 1971.

14. Shy, C.M. Community Health and Environmental Surveillance Studies. Colloquim for Foreign Scientist-Visitors, Duke University, January 16, 1971.

15. Shy, C.M. Briefing on Mercury, Cadmium and Lead as Hazardous Substances. Presented to National Air Quality Criteria Advisory Committee, Rockville, Maryland, March 18, 1971.

16. Shy, C.M. A Program of Community Health and Environmental Surveillance Studies (CHESS). Presented at the annual meeting of the American Chemical Society, Los Angeles, April, 1971.

17. Shy, C.M., Hammer, D.I., Hendricks, R.H., Hinners, T. and Finklea, J.F. Hair as an Epidemiologic Tool to Quantitate Trace Element Body Burdens. Presented at the Fifth Annual Conference on Trace Substances and Health, Columbia, Missouri, June, 1971.

18. Finklea, J.F., Cranmer, M.F., Hammer, D.I., McCabe, L.J., Newill, V.A. and Shy, C.M. Health Intelligence for Environmental Protection: A Demanding Challenge. Presented at the Sixth Berkeley Symposium on Mathematical Statistics and Probability, Berkeley, California, July 19, 1971.

19. Burton, R., Norris, C., Shy, C.M., Benson, F.B. and Heiderscheit, L. A Community Survey of Cigarette Smoking and Alveolar Carbon Monoxide. Presented at the 99th annual American Public Health Association, Minneapolis, Minnesota, October 11-15, 1971.

20. Shy, C.M., Hasselblad, V., Burton, R.M., Cohen, A.A., Pravda, M. and Deutscher, S. Is Air Pollution in New York City Associated With Decreased Ventilatory Function in Children. Presented at the 99th annual American Public Health Association, Minneapolis, Minnesota, October 11-15, 1971.

21. Shy, C.M. Chairman, Symposium on Epidemiologic Methods to Measure Biologic Response to Environmental Pollution. Annual Meeting of Society for Epidemiologic Research, Atlanta, Georgia, May, 1971.

22. Shy, C.M. Asthma and Air Pollution. Presented at annual meeting of Southeastern Allergy Association, Asheville, N.C., October, 1971.

23. Shy, C.M. and associates. Effect of Atmospheric Particulate Matter and Sulfur Dioxide on Ventilatory Performance of Children. Presented at annual meeting of American College of Chest Physicians, Philadelphia, Pa., October, 1971.

24. Shy, C.M. Health Effects of Motor Vehicle Emissions. Presented at annual Southeastern Industrial Health Conference, Gatlinburg, Tennessee, November, 1971.

25. Shy, C.M. Evaluation of Health Hazards of Fuels and Fuel Additives. Presented at Annual Public Hearing on Long Range Medical Aspects of Air Pollution, Rutgers Medical School, Piscataway, New Jersey, March, 1972.

26. Report on Health Consequences of Sulfur Oxides: A Report from CHESS 1970-71 to the National Air Quality Criteria Advisory Committee, Washington, D. C., November 16, 1972.

27. Presentation at the EPA Research Seminar for Federal Agencies, Washington, D. C., November 20, 1972.

28. Chairman, Workshop on Multiple Factors in Disease at the New York Academy of Sciences International Symposium on Pulmonary Reactions to Organic Dusts, New York, November 8, 1972.

29. Shy, C. M., et al. Effects of Air Pollution on Ventilatory Function of U. S. School Children: Results of Studies in Cincinnati, Chattanc and New York. Presented at the American Medical Association, Air Pollution Medical Research Conference, Chicago, Illinois, October 2-3, 1972.

30. Shy, C. M. Health Consequences of Environmental Deterioration. Presented at the Conference on the Environment, Chapel Hill, North Carolina, December 1, 1972.

31. Shy, C. M. Testimony at Court Hearing, Tampa, Florida, April 26, 1972, Regarding Health Effects of SO_2 and Particulate Emissions.

32. Shy, C.M. Air Pollution and Its Relation to Respiratory Disease (CHESS). Presented at the Scientific Session, Association of Pediatric Pulmonary Centers, American Academy of Pediatrics, New York, N. Y., October 14, 1972.

33. Shy, C.M. Reported Results of the CHESS Program at Regional Meeting of the Council on Environmental Quality, Public and Occupational Health of the American Medical Association, Washington, D.C., December 1, 1972; and with Dr. Finklea summarized EPA's health research program to the same AMA Council, December 9, 1972.

34. Shy, C.M. Adverse Health Effects of Transformed Products of SO_2 Emissions - Resulted from CHESS Program. Presented at Weather and Air Pollution Committee Session, American Academy of Allergy, Washington, D. C., February 9, 1973.

35. Shy, C.M. Additional Analysis of 7-City Lead Study. Presented to EPA's Hazardous Materials Advisory Committee, Washington, D. C., February 26, 1973.

36. Shy, C.M. Air Pollution Epidemiology. Presented to Sophomore Medica Students, Duke University Medical Center, Durham, N. C., February 27, 1973.

37. Shy, C.M. Briefing on CHESS Program for Science Newswriters, Washing D. C., March 2, 1973.

38. Shy, C.M. Effects of Low Levels of Oxidants and NO_2 Upon Humans. Presented at CRC Automotive Air Pollution Symposium, Washington, D. C March 8, 1973.

39. Shy, C.M. Health Intelligence for Air Quality Standards. Presented Meeting of the President's Air Quality Advisory Board, St. Louis, Mar 27, 1973.

40. Shy, C.M. Assessing Environmental Health Effects in Populations. Presented at Annual Meeting of N. C. Tuberculosis and Respiratory Disease Association, Wrightsville Beach, N. C., April 13, 1973.

41. Shy, C.M. Health Effects of Environmental Contaminants. Presented at Annual Meeting of the American Industrial Health Conference, Denve Colorado, April 17, 1973.

42. Shy, C.M. Transportation and Health, Presented at the Connecticut Conference on Transportation, Hartford, Connecticut, May 16, 1973.

43. Shy, C.M. Human Health Effects of Nitrogen Dioxide Exposure: A Review. Presented at the National Academy of Science, National Research Council Conference on Health Effects of Air Pollutants, October 4, 1973.

IX. Awards and Honors

Superior Service Medal, U.S. Public Health Service, June 1971

Quality Increase (GS 14/2 to 14/3) February, 1970

Delta Omega National Honorary Public Health Society, May 1965

Scientific Writing Award, Marquette Medical Review, June 1962

Alpha Omega Alpha National Honorary Medical Fraternity, June 1961

Second Place, Gramling Memorial Student Medical Essay, September 1960

MARTHA LILLIAN SMITH, Survey Assistant

Professional Experience:

1973 to Date. Research Triangle Institute, Statistics Research Division Research Triangle Park, North Carolina. Survey Assistant on New Towns Study, National Longitudinal Study of High School Class of 1972, Supervisor of Microfilming Department, Survey Assistant on a Thyroid Neoplasm Study and Study of Head and Spinal Cord Injury.

1972 to 1973. Resident Counselor, Smith College, Northampton, Mass. Assisted Dr. Betty Spear, Chairman, University of Mass., Department of Women's P. E. in Developing a historical research project for a national convention of the American Association of Health P. E. and Recreation. President, graduate class.

1965 to 1972. Western Guilford High School, Greensboro, North Carolina, Teacher of health, P. E., and mathematics. Coached varsity track and field, basketball and golf. Chairman of boys and girls P. E. Department. Chaired department's self study for Southern Assoc. of Accredtion. Supervisor of student teachers. Advisory Committee on Girls Athletics of the N. C. High School Athletic Association.

1964 to 1965. Union Pines High School, Cameron, North Carolina. Teacher of health, P. E., and government. Coached varsity and junior varsity basketball.

Summer.

1962 to 1963. General counselor, Camp Lakeside, Hendersonville, North Carolina.

1964. Director of the girls camp, Camp Lakeside, Hendersonville, North Carolina.

1965. Head tennis counselor, Camp Ton-A-Wanda, Hendersonville, North Carolina.

1966 & 1970. Director of programming and counseling, Camp Mountain Lake, Hendersonville, North Carolina.

1971 & 1972. Trip director, Tripp Lake Camp, Poland Maine.

Education

1957 to 1960. Diploma - Central Davidson High School, Lexington, North Carolina.

1960 to 1964. B. S. May, 1964 - Appalachian State University, Boone, North Carolina
Major: Health and Physical Education
Minor: History

1968 to 1969. Graduate Work - University of North Carolina, Greensboro, North Carolina.
Major: Physical Education

1972 to 1973. M. S. May, 1973 - Smith College, Northampton, Massachusetts
Major: Physical Education
Thesis Topic: Survey on Women's Athletics in Massachusetts

Contributing Work

Risk of Thyroid Neoplasms after Receiving Diagnostic Doses of Radioactive Iodine During Childhood. Monthly Technical Progress Reports, Research Triangle Park, N. C.: Research Triangle Institute, September, 1974 to November, 1976. (co-author)

Followup of Patients Receiving Diagnostic Doses of 131 Iodine During Childhood-Summary Report: Pilot Study. Research Triangle Park, N. C.: Research Triangle Institute, February, 1975. (co-author)

Publications

A Study of Interscholastic Athletics in the Springfield, Massachusetts Educational Region. Martha L. Smith, Masters Thesis, Smith College, Northampton, Massachusetts, May, 1973.

11/76

Name: Boyd Ray Switzer, Ph.D.   Sex: Male   Birth Date: October 3, 1943

Title: Assistant Professor in Department of Nutrition, School of Public Health and Assistant Professor in Department of Biochemistry and Nutrition, School of Medicine.

Social Security No: 229-60-0083   Place of Birth: Harrisonburg, Virginia

Martial Status: Janie J. Switzer, wife.   No. of Children: 2

Education

Institution	Discipline	Degree and Year Conferred
Bridgewater College Bridgewater, Virginia	Chemistry	B.A. (cum laude) 1965
University of North Carolina Chapel Hill, North Carolina	Biochemistry	Ph.D. 1971

Professional Experience

June to September 1964	National Science Foundation Undergraduate Research Participant, University of Tennessee, Knoxville, Tennessee. This work resulted in a publication in J. Am. Chem. Soc. 87:4477, 1965.
Sept. 1965-Sept. 1968	National Institutes of Health (NIH) Research Trainee. University of North Carolina at Chapel Hill.
Sept. 1968-Aug. 1970	NIH Predoctoral Fellow. University of North Carolina at Chapel Hill.
Aug. 1970-April 1971	Postdoctoral Research Assistant. University of North Carolina at Chapel Hill.
April 1971-Sept. 1971	NIH Postdoctoral Fellow. University of North Carolina at Chapel Hill.
Sept. 1971-July, 1972	NIH Postdoctoral Fellow. University of Southern California, Los Angeles, California.
July 1972-Present	Assistant Professor, Department of Nutrition.
Dec., 1972-Present	Assistant Professor, Joint Appointee in the Department of Biochemistry and Nutrition.

Membership in Organizations

American Chemical Society
American Association for the Advancement of Science
The Lambda Society at Bridgewater College

Major Research Activities

Study of Collagen Biosynthesis in Human Skin Fibroblasts in Tissue Culture. June 1966 to August 1970.

Ornithine Transcarbamylase: Mode of Fluoride Inhibition. Aug. 1970 to July 1972.

Nutritional Evaluation of the Focus on Optimal Development (F.O.O.D.) Project in Durham Public Schools (biochemical component). May to June 1973.

Diet-Hormone Interaction with Emphasis on the Role of Insulin and Glucagon (collaborative study with Dr. J.C. Edozien). July 1972 to present.

Medical Evaluation of the Special Supplemental Food Program for Women, Infants and Children (WIC). Director of Biochemistry Laboratory. July 1973 to present.

Presentations

Annual Meeting of the American Society of Biological Chemists, San Francisco, California, June 16, 1971.

Annual Meeting of the Tissue Culture Association, Lake Placid, New York, June 7, 1971.

Annual Meeting of the North Carolina Academy of Sciences, Wilmington, North Carolina, May 3, 1969.

Annual Meeting of the Federation of American Societies for Experimental Biology, Atlantic City, April 9, 1974.

Teaching Experience

The University of North Carolina 1972-present.

1. NUTR 200, Cell Biology (lecture) and NUTR 201 Cell Biology Laboratory taught jointly with Dr. John J.B. Anderson.

2. NUTR 202, Nutritional Biochemistry taught jointly with Dr. J.C. Edozien and Dr. John J.B. Anderson.

3. Faculty member of 1973 Summer Program in Health Sciences sponsored by North Carolina Health Manpower Development Program.

4. BIOC 8, Biochemistry for Dental Hygiene Students, taught jointly by several faculty members.

5. BIOC 226, Biochemical Regulations, taught jointly by several faculty members.

Research advisor for 1 or 2 students and have not directed any masters or doctoral dissertation research previously.

Special Assignments

Self-study Report of the Department of Nutrition, 1972.

Self-study Report of the School of Public Health, 1972.

Task Force Report for the Research and Development Board of the North Carolina Public Health Association, March to August 1973.

Member of the Vitamin A Panel of the Institute of Nutrition, Jan. 1973 to present.

Chairman of Doctoral Advisory Committee in the Department of Nutrition, 1974 to present.

Chairman of M.P.H. Comprehensive Examination Committee in the Department of Nutrition, October 1974 to present.

Chairman of the Fellowship and Traineeship Committee, School of Public Health, 1974-75.

Member of the Safety Committee, School of Public Health, 1974-75.

Member of the Board of Scientific Directors, Institute of Nutrition, Feb. 1975 to present.

BIBLIOGRAPHY

1. Bowman, N.S., Rice, D.E., and Switzer, B.R. Magnetic Nonequivalence in Derivative of α-Hydroxy Acids. J. Am. Chem. Soc. 89:4477, 1965.

2. Switzer, B.R., Waters, M.D., and Summer, G.K. Studies on Regulation of Alkaline Phosphatase Activity and Collagen Biosynthesis in Human Skin Fibroblasts (abstract). Fed. Proc. 28:901, 1969.

3. Switzer, B.R., Summer, G.K., and Waters, M.D. Protein Biosynthesis in Mammaliam Cell Cultures (abstract). J. Elisha Mitchell Society 85:115, 1969.

4. Switzer, B.R. and Summer, G.K. Improved Method for Hydroxyproline Analysis in Tissue Hydrolysates. Anal. Biochem. 39:487, 1971.

5. Switzer, B.R. and Summer, G.K. A Modified Fluorometric Micromethods for DNA. Clin. Chim. Acta. 32:203, 1971.

6. Switzer, B.R. Studies on Collagen Biosynthesis in Human Skin Fibroblasts. Dissertation, 1971.

7. Switzer, B.R. and Summer, G.K. Effect of Ascorbate and Medium Change on Human Fibroblasts in Culture (abstract). In Vitro 6:383, 1971.

8. Switzer, B.R. and Summer, G.K. Studies on Collagen Biosynthesis in Human Skin Fibroblasts (abstract). Fed. Proc. 30:1195, 1971.

9. Switzer, B.R. and Summer, G.K. Collagen Synthesis in Human Skin Fibroblasts. Effect of Ascorbate, α-Ketoglutarate and Ferrous Ion on Proline Hydroxylation. J. Nutrition 102:721, 1972.

10. Switzer, B.R. and Summer, G.K. Inhibition of Collagen Synthesis by α,α'-Dipyridyl in Human Skin Fibroblasts in Culture. In Vitro 9:160, 1973.

11. Waters, M.D., Summer, G.K., Switzer, B.R., Moore, R.D. and Heitkamp, D.H. Alkaline Phosphatase Activation and Collagen Synthesis in Human Skin Fibroblasts in Culture. Exptl. Cell Res. 80:170, 1973.

12. Switzer, B.R., Zand, T., Niehaus, N.J., and Edozien, J.C. Effect of Diet on Fasting Plasma Immunoreactive Insulin (abstract). Fed. Proc. 33:669, 1974.

13. Edozien, J.C., Niehaus, N.J. and Switzer, B.R. Effect of Diet on Fasting Plasma Catecholamines in Rat (abstract). Fed. Proc. 34:881, 1975.

APPENDIX 2.2

TENTATIVE TRAINING MANUAL OUTLINE

1.0 Introduction

1.1 Research Triangle Institute (RTI)

1.2 Environmental Protection Agency

1.3 Background: Related and Previous Studies

1.4 Study Objectives

1.5 RTI Project Staff and Structure

1.6 Project Timetable

2.0 Preparations for Field Operations

2.1 Involvement of Other Agencies

2.2 News Releases

3.0 Overview of Field Operations

3.1 Introduction and Purpose

3.2 Sampling Considerations

3.3 Survey Instruments

3.4 Household Data Collection

3.5 Confidentiality

3.6 Quality Control

3.7 Supplies Required for Conduct of Field Work

3.8 Disposition of Supplies

4.0 Household Contact and Data Collection

4.1 Preparation

4.2 Screening

4.2.1 Assignment of Field Staff

4.2.2 Sampling Considerations

4.2.3 Explaining the Study

4.2.4 Household Screening Questionnaire

4.2.5 Household Eligibility

4.2.6 Household Screening Log

4.2.7 Problems

4.2.7.1 Nonrespondents

4.2.7.2 Nonparticipants

4.2.7.3 Ineligibles

4.3 Household Data Collection

4.3.1 Participant Consent Form

4.3.2 Study Questionnaire

4.3.3 Sample Collection

4.3.3.1 Household

- Soil (Pre-school age only)
- Tap Water
- House Dust
- Paint Lead

4.3.3.2 Individual

- Urine
- Scalp Hair
- Blood

4.3.4 Incentive

4.3.5 Liaison with Central Data Collection Facility

4.3.6 Quality Control

4.3.6.1 Labels

4.3.6.2 Duplicate Samples

4.3.6.3 Reinterview

4.3.7 Problems

4.3.7.1 Refusals

4.3.7.2 Incomplete Data Sets

4.3.7.3 Transportation for Participants to Central Data Collection Facility

4.4 Survey Instruments: Administration

4.4.1 Household Screening Questionnaire

4.4.2 Participant Consent Form

4.4.3 Study Questionnaire

4.4.3.1 Household Information

4.4.3.2 Individual Information

4.4.3.3 Interviewer/Respondent Information

4.4.3.4 Sample Information

4.5 Sample Collection Methodology

4.5.1 Soil

4.5.2 Tap Water

4.5.3 House Dust

4.5.4 Paint Lead

4.5.5 Urine

4.5.6 Scalp Hair

4.5.7 Blood

4.5.8 Quality Control: Duplicate Samples

4.6 Central Data Collection

4.6.1 Overview

4.6.2 Scalp Hair Sample

4.6.3 Blood Sample

4.6.4 Hematocrit

4.6.5 Urine Sample

4.6.5.1 Urine Protein

4.6.5.2 Specific Gravity

4.6.6 Quality Control: Duplicate Samples

4.6.7 Problems

4.6.7.1 Incomplete Data Sets

4.6.7.2 Adverse Participant Reaction

4.7 Work Schedule

5.0 Administrative Procedures

5.1 Reporting

5.1.1 Household Screening Log

5.1.2 Production, Time and Expense Reporting

5.2 Contacts

5.2.1 RTI Staff

5.2.2 Site Administrator

5.2.3 Central Data Collection Facility

5.2.4 Local Consultants and Agencies

5.3 Special Problems

6.0 Data Receipt Control and Entry (RTI Staff and Site Administrator(s) Only)

6.1 Survey Instruments

6.1.1 Household Screening Log

6.1.1.1 Receipt

6.1.1.2 Batching

6.1.1.3 Scan-Edit

6.1.1.4 Direct Data Entry

6.1.2 Household Screening Questionnaire

6.1.2.1 Receipt

6.1.2.2 Batching

6.1.2.3 Scan-Edit

6.1.2.4 Direct Data Entry

6.1.3 Participant Consent Form

6.1.3.1 Receipt

6.1.3.2 Batching

6.1.3.3 Scan-Edit

6.1.4 Study Questionnaire

6.1.4.1 Receipt

6.1.4.2 Batching

6.1.4.3 Scan-Edit

6.1.4.4 Direct Data Entry

6.2 Results of Chemical Analysis (Chemical Analysis Report Form)

6.2.1 Receipt

6.2.2 Batching

6.2.3 Scan-Edit

6.2.4 Direct Data Entry

6.3 Quality Control

6.3.1 Scan-Edit

6.3.1.1 Visual

6.3.1.2 Direct Data Entry

6.3.2 Re-keying

6.3.3 Reinterview

6.3.3.1 Household Screening Questionnaire

6.3.3.2 Study Questionnaire

7.0 Site Administrator Responsibilities (RTI Staff and Site Administrator(s) Only)

7.1 Coordination of Field Operations

7.1.1 Training Sessions

7.1.2 Local Agencies

7.1.3 Independent Subcontractors

7.1.4 On-Site Consultants

7.1.5 Field Supervisors

7.1.6 Central Data Collection Facility

7.2 Sample Collection

7.2.1 Air

7.2.2 Soil

7.2.3 Water

7.2.4 Market Basket

7.3 Data Management and Shipment

7.3.1 Survey Instruments

7.3.1.1 Household Screening Questionnaires

7.3.1.2 Household Screening Logs

7.3.1.3 Participant Consent Forms

7.3.1.4 Study Questionnaires

7.3.1.5 Independent Subcontractors' Production, Time and Expense Reports

7.3.2 Environmental Samples

7.3.2.1 Air

7.3.2.2 Soil

7.3.2.3 Water

7.3.2.4 House Dust

7.3.3 Biological Samples

7.3.3.1 Urine

7.3.3.2 Scalp Hair

7.3.3.3 Blood

7.4 Special Problems

APPENDIX: Glossary of Terms

APPENDIX 2.3

SURVEY INSTRUMENTS

OMB No.
Approval Expires

RESEARCH TRIANGLE INSTITUTE

STUDY OF HUMAN TISSUE HEAVY METAL BURDEN IN NON-FERROUS SMELTER COMMUNITIES

HOUSEHOLD SCREENING LOG

Site Number ☐ Segment Number ☐☐ Interviewer Number ☐☐☐

Date ☐☐–☐☐–☐☐ Day of Week ☐
(Month) (Day) (Year)

Household Number	Street Address	Eligible Household Member(s)		Member(s) Agree(s) to Participate		Number of Participants	Reason(s) for Nonparticipation, Nonresponse, or Ineligibility
		Yes	No	Yes	No		

3-10-77

OMB No.
Approval Expires

RESEARCH TRIANGLE INSTITUTE

STUDY OF HUMAN TISSUE HEAVY METAL BURDEN IN NON-FERROUS SMELTER COMMUNITIES

NOTICE: The information recorded on this questionnaire will be held in strict confidence, and will be used solely for medical research into the effects of environmental factors on public health. All results will be summarized for groups of people; no information about individual persons will be released without the consent of the individual. This questionnaire is authorized by law (42 U.S.C. 1857 as amended). While you are not required to respond, your cooperation is needed to make the results of the survey comprehensive, accurate, and timely.

HOUSEHOLD SCREENING QUESTIONNAIRE

1. Site number: ☐ 2. Segment number: ☐☐ 3. Interviewer number: ☐☐☐

4. Household number: ☐☐☐ 5. Date: ☐☐ - ☐☐ - ☐☐ *(Month) (Day) (Year)*

6. What is the exact address of this residence?

____

(Street Number and Name) *(Apartment Number)*

____ ☐☐☐☐☐

(City) *(State)* *(Zip Code)*

7. a. Do you have a telephone? [1] Yes *(Go to Question 7b)* [2] No *(Go to Question 7c)*

b. If yes, what is the number? ☐☐☐ - ☐☐☐ - ☐☐☐☐ *(Go to Question 8)*
(Area Code)

c. If no, what is the number of the nearest telephone? ☐☐☐ - ☐☐☐ - ☐☐☐☐
(Area Code)

[1] Do not know

8. How many persons reside in this household? ☐☐

9. For each person in your household, including yourself, please indicate the age, birthdate, sex, length of residence at this address and in this community, occupation, and relationship to you, beginning with the oldest and proceeding to the youngest:

Household Member Number	Age (Years)	Birthdate			Sex (M or F)	Length of Residence				Occupation(s) During Past 12 Months	Relationship to Respondent	Participant Number
						At this Address		In this Community				
		Month	Day	Year		Units	M,D, or Y	Units	M, D, or Y			
01												
02												
03												
04												
05												
06												
07												
08												
09												
10												

10. a. Has anyone in your household worked at the smelter at any time during the past 12 months?

[1] Yes *(Go to Question 10b)* [2] No [3] Do not know

b. If yes, indicate relationship to respondent _______________________
and household member number(s) from question 9 _______________

If it is apparent that the household contains no persons eligible to participate in this study, thank the respondent and proceed to the next household. However, if persons in the household appear to be eligible to participate in this study, continue to question 11.

11. Would you participate in a health study as a paid volunteer? [1] Yes [2] No

12. In your opinion, would other members of your household participate in a health survey as a paid volunteer?

[1] Yes, all [2] Yes, some [3] No [4] Do not know

3-10-77

OMB No.
Approval Expires

RESEARCH TRIANGLE INSTITUTE

STUDY OF HUMAN TISSUE HEAVY METAL BURDEN IN NON-FERROUS SMELTER COMMUNITIES

PARTICIPANT CONSENT FORM

I understand that the Research Triangle Institute is engaged in a study of heavy metal (arsenic, cadmium, copper, lead, manganese, and zinc) exposure and absorption by persons living in communities near non-ferrous smelters. I understand that this survey is being conducted because increased amounts of heavy metal absorption have recently been discovered among persons living near smelters in the United States, particularly young children. I understand that the survey is being conducted in order to help measure the levels of heavy metal exposure and absorption by persons living in communities near non-ferrous smelters, and is limited to the purpose stated. I further understand that the survey is being conducted under the auspices of the United States Environmental Protection Agency in cooperation with the Center for Disease Control of the United States Public Health Service and the

(State and local health departments) ____________________.

I do hereby freely consent to participate in this study of heavy metal absorption and understand that my participation will consist of providing answers to a questionnaire related to heavy metal exposure and the following environmental and biological samples: (1) two four ounce samples of cold tap water from a source commonly used for drinking and cooking, (2) a sample of housedust from a small area ($0.25m^2$) from the surface of the floor of a room commonly used for family activities using a small vacuum device, (3) a small (approximately four ounces) early morning urine sample, (4) a small sample of scalp hair, (5) a small (approximately 10 cc) blood sample to be taken from an arm vein, and (6) measurement of paint lead levels using a special portable apparatus. I understand that two four ounce samples of surface soil will be taken from the play area(s) of each pre-school child participant and that in some small children the blood sample may be obtained from a finger or heel. I understand that an agent of the Research Triangle Institute will administer the questionnaire in my home and at the same time collect the tap water, housedust, and soil samples, and measure the paint lead levels. I further understand that I am to deliver my urine specimen to

(Address of designated central data collection facility) ____________________

on *(Day of week)* ______________, *(Date)* ____________ at *(Time)* ________ a.m./p.m. where an agent of the Research Triangle Institute will obtain the scalp hair and blood samples and where I will receive an incentive of ten dollars for my full participation in this study. I understand that a small number of households and individuals will be selected for the collection of duplicate tap water, housedust, scalp hair, and blood samples and reinterview, but that such selection would not entitle me to further compensation.

I understand that a report of my test results will be sent to the State and local health authorities. In addition, I would/would not like a copy of this report sent to my family physician, Dr. ____________________

Address: ____________________

I understand that my name will not otherwise be voluntarily disclosed, that all information collected in this study will be compiled into a general summary which will be strictly confidential, and that my name will not be referred to in any way when compiling and evaluating the results of the study.

I understand that participation in this study may result in no direct benefits to me, other than those described herein, and that I am free to withdraw from this study at any time. It has been explained to me that there are no significant risks to me from participation in this study. I further understand that while participating in the study I will be free to ask any questions concerning the study; if I have any further questions about the project, I know that I am free to contact

(Local health department representative) ____________________ telephone number ______________ or

(State health department representative) ____________________ telephone number ______________

or Mr. Benjamin S. H. Harris, III, Survey Operations Center, Research Triangle Institute, Research Triangle Park, North Carolina 27709, telephone number 919-549-8311, extension 2700.

Date: [|] – [|] – [|]
(Month) *(Day)* *(Year)*

Participant's Name: *(Print)* ____________________

Site Number: [|] Segment Number: [|] Participant Number: [|] Household Number: [| |]

Signatures:

____________________ Witness: ____________________

[ ] Participant [ ] Parent, guardian, or other legal representative of participant* Interviewer Number: [| |]

*If the participant is a minor (under 18 years of age), this consent form must be signed by the parent or legal guardian.

3-10-77

OMB No.

Approval Expires

STUDY OF HUMAN TISSUE HEAVY METAL BURDEN IN NON-FERROUS SMELTER COMMUNITIES

Sponsored by:
Health Effects Research Laboratory
Environmental Protection Agency
Research Triangle Park, North Carolina 27711

Conducted by:
Research Triangle Institute
P.O. Box 12194
Research Triangle Park, North Carolina 27709

QUESTIONNAIRE

THE RESEARCH TRIANGLE INSTITUTE OF RESEARCH TRIANGLE PARK, NORTH CAROLINA, IS UNDERTAKING A RESEARCH STUDY FOR THE U.S. ENVIRONMENTAL PROTECTION AGENCY OF LEVELS OF HEAVY METAL ABSORPTION BY PERSONS LIVING IN COMMUNITIES NEAR NON-FERROUS SMELTERS. THE INFORMATION RECORDED IN THIS QUESTIONNAIRE WILL BE HELD IN STRICT CONFIDENCE AND WILL BE USED SOLELY FOR MEDICAL RESEARCH INTO THE EFFECTS OF ENVIRONMENTAL FACTORS ON PUBLIC HEALTH. ALL RESULTS WILL BE SUMMARIZED FOR GROUPS OF PEOPLE; NO INFORMATION ABOUT INDIVIDUAL PERSONS WILL BE RELEASED WITHOUT THE CONSENT OF THE INDIVIDUAL. THIS QUESTIONNAIRE IS AUTHORIZED BY LAW (42 U.S.C. 1857 AS AMENDED). WHILE YOU ARE NOT REQUIRED TO RESPOND, YOUR COOPERATION IS NEEDED TO MAKE THE RESULTS OF THIS SURVEY COMPREHENSIVE, ACCURATE, AND TIMELY.

Study number: ☐☐☐☐☐☐

Site number: ☐ Segment number: ☐☐ Household number: ☐☐☐ Participant number: ☐☐

3-10-77

A. HOUSEHOLD INFORMATION

1. For each person in your household, including yourself, please indicate age, beginning with the oldest and proceeding to the youngest *(Enter responses in matrix below)*:

Household Member Number	Age (Years)		Educa-tional Level	Currently Employed at Smelter 1 = Yes 2 = No	Normally Spend Day at Home 1 = Yes 2 = No	Excess Metal Absorption		Partici-pant Number	
						Screened	Diagnosed		
01									
02									
03									
04									
05									
06									
07									
08									
09									
10									

2. For each person in your household, including yourself, please indicate educational level, again beginning with the oldest and proceeding to the youngest *(Enter responses in matrix above using codes listed below for highest educational level completed)*:

[1] 8th grade or less
[2] High school - incomplete
[3] High school graduate
[4] College - incomplete
[5] College graduate
[6] Graduate school
[7] Technical school beyond high school
[8] Do not know
[9] Other

3. Does anyone in your household currently work at the smelter? *(Enter responses in matrix above.)*

4. Which members of your household normally spend their day at home? *(Enter responses in matrix above.)*

5. Has anyone in your household ever been screened for excess heavy metal absorption?

[1] Yes [2] No [3] Do not know *(Enter response in matrix above.)*

6. Has any member of your household ever been diagnosed as having excess heavy metal absorption?

[1] Yes [2] No [3] Do not know *(Enter response in matrix above.)*

7. For male head of household, indicate:

a. Household member number: [ ][ ]   b. Current occupation: ____________________

8. For female head of household, indicate:

a. Household member number: [ ][ ]   b. Current occupation: ____________________

9. What is the approximate age of your house? [ ][ ] Years [1] Do not know

10. What type of structure is your house? *(51 percent or more of exterior surface.)*

- [1] Solid brick, concrete, or rock
- [2] Brick or rock veneer
- [3] Stucco
- [4] Asbestos
- [5] Aluminum siding
- [6] Composition siding
- [7] Wood frame
- [8] Do not know
- [9] Other *(Specify)* ____________

11. Is there evidence of flaking paint present in the home? [1] Yes [2] No

12. Are paint chips present in the soil surrounding the home? [1] Yes [2] No

Interviewer observation (questions 11–12)

13. Do you cool your home with any of the following appliances? *(Check all that apply.)*

- [1] Central air conditioning
- [2] Window air conditioner(s)
- [3] Evaporative cooler(s)
- [4] Window fan(s)
- [5] Ceiling exhaust fan(s)
- [6] Circulating fan(s)
- [7] None of these
- [8] Do not know
- [9] Other *(Specify)* ____________

14. Are any of the following articles used in storing, preparing, and/or serving food in your household? *(Check all that apply.)*

Articles	Uses								
	Storing food(s)			Preparing food(s)			Serving food(s)		
	No	Yes	*Specify food(s)*	No	Yes	*Specify food(s)*	No	Yes	*Specify food(s)*
1. Unglazed pottery (homemade or craft)	1	2		1	2		1	2	
2. Glazed pottery (homemade or craft)	1	2		1	2		1	2	
3. Hand-painted flatware	1	2		1	2		1	2	

[4] None of these [5] Do not know

15. Does your household grow any of its own food in a home garden? [1] Yes [2] No [3] Do not know

If yes, specify food(s) ____________

16. Where does your household ordinarily shop for groceries? *(Specify)* ____________

17. Where does your household obtain fresh fruit and/or vegetables? *(Specify)* ____________

18. What is the primary source of your water for drinking?

- [1] Bottled water
- [2] Tap - municipal supply
- [3] Tap - community well
- [4] Tap - private well
- [5] Tap - cistern
- [6] Do not know
- [7] Other *(Specify)* ____________

19. Is that the same primary source of water for drink mixes such as coffee, tea, Kool-Aid, etc.?

[1] Yes [2] No If no, how does it differ? *(Specify)* ____________

20. What is the primary source of your water for cooking?

- [1] Bottled water
- [2] Tap - municipal supply
- [3] Tap - community well
- [4] Tap - private well
- [5] Tap - cistern
- [6] Do not know
- [7] Other *(Specify)* ____________

21. Has anyone in your family ever been under medical care for:

	No	Yes	Relationship to respondent and/or household member number:
a. Seizures?	1	2	(Specify) ____ ☐☐
b. Hyperactivity?	1	2	(Specify) ____ ☐☐
c. Mental retardation?	1	2	(Specify) ____ ☐☐
d. Skin conditions other than acne?	1	2	(Specify) ____ ☐☐
e. Kidney stones?	1	2	(Specify) ____ ☐☐
f. Broken bones?	1	2	(Specify) ____ ☐☐

B. PARTICIPANT INFORMATION

IF THE PARTICIPANT IS UNDER 18 YEARS OF AGE, THIS SECTION OF THE QUESTIONNAIRE MAY HAVE TO BE ADMINISTERED IN WHOLE OR IN PART TO THE PARENT OR GUARDIAN, AND MUST BE ADMINISTERED IN THAT PERSON'S PRESENCE. IF THE PARTICIPANT SUFFERS FROM A SPEECH OR HEARING DEFICIT, THIS SECTION OF THE QUESTIONNAIRE MAY HAVE TO BE ADMINISTERED TO THE SPOUSE OR ANOTHER SPOKESMAN—SEE SECTION C.

First, I would like to ask some general questions about you/the participant.

1. Sex *(by observation)*: 1 Male 2 Female

2. Race *(by observation)*: 1 White 2 Black 3 American Indian 4 Asiatic 5 Spanish surname 6 Unknown 7 Other *(Specify)* ____

3. Household member number *(from A-1)*: ☐☐

4. What was your/the participant's age in years at last birthday?

☐☐ Years

5. What is your/the participant's birthdate?

(Month) ☐☐ – *(Day)* ☐☐ – *(Year)* ☐☐

6. What is your/the participant's approximate weight in pounds?

☐☐☐ lbs.

7. What is your/the participant's marital status?

1 Married 2 Never married 3 Widowed 4 Divorced 5 Separated 6 Other *(Specify)* ____

Next, I would like to ask some questions about your/the participant's education.

8. Are you/is the participant in school now? 1 Yes *(Continue)* 2 No *(Go to question 11)*

9. What type of school do you/does the participant attend?

1 Kindergarten, nursery, play, or day care school *(Continue)*

2 Elementary school
3 Junior high school
4 Senior high school
} *(Continue)*

5 Junior college
6 College
7 Graduate school
8 Technical school
} *(Go to question 11)*

9 Other *(Specify)* ____

10. What is the address of the school? ____ *(Street)* ____ *(City)*

Next, I would like to ask some questions about your/the participant's occupation and residence.

11. Are you/is the participant presently employed in any capacity? [1] Yes *(Go to question 13)* [2] No *(Continue)*

12. If not presently employed, which of the following best describes your/the participant's status?

[1] Housewife	*(Go to question 18)*	[4] Unemployed	*(Continue)*
[2] Student		[5] Retired	
[3] Child *(Go to question 21)*		[6] Disabled	

13. What is/was your/the participant's usual occupation? *(Specify)* ______

14. Are you/is the participant presently employed in this occupation? [1] Yes [2] No

15. If yes to above question, how many years have you/has the participant been employed in that occupation? [ ][ ] Years

    If no to above question, how many years were you/was the participant employed in that occupation? [ ][ ] Years

16. If you are/the participant is presently employed, what is the nature of the company for which you/the participant work(s)?

    (Specify) ______

17. How long have you/has the participant been employed by your/the participant's present employer? [ ][ ] Units [1] Months [2] Years

18. How many times have you/has the participant changed occupations during the past 5 years? [ ][ ]

19. Does your/the participant's occupation usually take you/the participant away from home? [1] Yes [2] No

20. Have you/has the participant worked at a smelter at any time during the past 12 months? [1] Yes (STOP!) [2] No *(Continue)*

21. Have you/has the participant ever worked at or lived for as long as 12 months within 2 miles of:

	Worked at		Lived near	
	Yes	No	Yes	No
a. Paper/wood industry	[1]	[2]	[1]	[2]
b. Smelting industries	[1]	[2]	[1]	[2]
c. Glass manufacturing plant	[1]	[2]	[1]	[2]
d. Pesticide manufacturing plant	[1]	[2]	[1]	[2]
e. Mining area	[1]	[2]	[1]	[2]

22. How many hours of the day, on the average, do you/does the participant normally spend more than 2 miles from home? [ ][ ] Hours

23. How many years have you/has the participant lived in this city or town? [ ][ ] Years *(If less than 1 year,* **STOP!***)*

24. *How long have you/has the participant lived at this address?* [ ][ ] Units [1] Days [2] Months [3] Years

25. How many times have you/has the participant changed living quarters during the last 5 years? [ ][ ]

Next, I would like to ask some questions regarding your/the participant's personal habits.

26. What is the natural color of your/the participant's scalp hair?

   [1] Brown [2] Black [3] Red [4] Blonde [5] Gray [6] Bald [7] Other *(Specify)* ________________

27. How many times per week, on the average, do you/does the participant shampoo your/the participant's hair? [ ][ ]

28. Which of the following hair care products do you/does the participant use? *(Check all that apply and specify the most frequently used brand.)*

	Brand		Brand
[1] Washing *(Shampoo or soap)*	________	[4] Artificial coloring	________
[2] Setting lotion	________	[5] Permanent	________
[3] Hair spray	________	Last application date *(Month)* [ ][ ] – *(Day)* [ ][ ] – *(Year)* [ ][ ]	

29. Have you/has the participant ever smoked as many as 5 packs of cigarettes—that is, as many as 100 cigarettes during your/the participant's entire life?

   [1] Yes *(Continue)* [2] No *(Go to question 34)*

30. Do you/does the participant now smoke cigarettes? [1] Yes [2] No

31. How old were you/was the participant when you/the participant first started smoking? [ ][ ] Years

32. If you/the participant no longer smoke(s), how old were you/was the participant when you/the participant last gave up smoking?

   [ ][ ] Years

33. On the average, how many cigarettes do (did) you/does (did) the participant smoke per day?

   [1] Less than ½ pack (1-4 cigarettes)
   [2] About ½ pack (5-14 cigarettes)
   [3] About 1 pack (15-24 cigarettes)
   [4] About 1½ packs (25-34 cigarettes)
   [5] About 2 packs (35-49 cigarettes)
   [6] More than 2 packs (50 or more cigarettes)

34. What is the average number of hours that you/the participant spend(s) out of doors each day? [ ][ ] Hours

35. Do you/does the participant ever eat non-food substances such as paint, clay, dirt, or plaster? [1] Yes [2] No

36. *(For children participants only)* Where does the participant play most frequently? *(Check one.)*

   [1] At home indoors
   [2] At home outdoors
   [3] On the same block indoors
   [4] On the same block outdoors
   [5] On a different block indoors
   [6] On a different block outdoors
   [7] Other *(Specify)* ________________________________

Next, I would like to ask some questions regarding your/the participant's health.

37. What do you consider the current status of your/the participant's health?

1 Excellent 2 Good 3 Fair 4 Poor

38. Are you/is the participant currently taking any prescription medication(s) on a regular daily basis? *(Check all that apply.)*

0 None
1 Tranquilizer
2 Sedative
3 Analgesic
4 Hormone
5 Oral contraceptive
6 Antibiotics *(Specify)* ______
7 Other *(Specify)* ______

39. Do you/does the participant currently have any of the following symptoms?

	Yes	No	*If yes, specify how long*		Yes	No	*If yes, specify how long*
a. Loss of appetite	1	2	______	h. Cough	1	2	______
b. Weight loss	1	2	______	i. Changes in skin pigmentation	1	2	______
c. Fatigue	1	2	______	j. White lines across fingernails	1	2	______
d. Nausea and/or vomiting	1	2	______	k. Pins and needles, numbness or pain of the limbs	1	2	______
e. Diarrhea	1	2	______	l. Weakness or withering of the muscles of the limbs	1	2	______
f. Abdominal pain	1	2	______	m. Pain or soreness of the mouth, nose, or eyes	1	2	______
g. Sore throat	1	2	______	n. Skin irritation	1	2	______

Next, I would like to ask some questions regarding your/the participant's diet.

40. Which meal(s) do you/does the participant usually eat at home? *(Check all that apply.)*

1 Breakfast 2 Lunch 3 Dinner

41. When you do not/the participant does not eat at home, where do you/does the participant eat? *(Check all that apply.)*

1 Meal prepared at home but eaten elsewhere 2 School 3 Work 4 Restaurant

5 Other *(Specify)* ______

42. Are you/is the participant presently following any of the following dietary regimens? *(Check all that apply.)*

1 Formula/prepared baby foods
2 Bland food ulcer diet
3 Diabetic diet
4 Reducing diet
5 Organic foods
6 Vegetarian
7 None of these
8 Other *(Specify)* ______

43. On the average, how often do you/does the participant eat the following foods? *(Check the appropriate box.)*

Foodstuff	More than once a week 1	About once a week 2	About once every 2 weeks 3	About once a month 4	Less than once a month 5	Never 6
a. Shellfish						
b. Fish						
c. Beef liver						
d. Roast beef						
e. Hamburger						
f. Chicken						
g. Frankfurters						
h. Bacon						
i. Eggs						
j. Whole milk						
k. Breakfast cereal						
l. White bread						
m. White rice						

Foodstuff	More than once a week 1	About once a week 2	About once every 2 weeks 3	About once a month 4	Less than once a month 5	Never 6
n. White potatoes						
o. CANNED FOODS:						
p. Pork and beans						
q. Peas						
r. Tomatoes						
s. Peaches						
t. Pineapple						
u. Corn						
v. Fish						
w. Applesauce						
x. Orange juice						
y. Diluted fruit drinks						
z. Vegetable soup						

C. RESPONDENT/INTERVIEWER INFORMATION

1. Site number: ☐ 2. Segment number: ☐☐ 3. Household number: ☐☐☐ 4. Participant number: ☐☐

5. Interviewer number: ☐☐☐ 6. Date of interview: *(Month)* ☐☐ – *(Day)* ☐☐ – *(Year)* ☐☐

7. Part A Respondent *(Check all that apply.)* Household member number: ☐☐

   1 Participant   2 Parent or guardian of participant   3 Head of household   4 Other household member

8. Part B Respondent *(Check one.)* Household member number: ☐☐

   1 Participant   2 Parent or guardian of participant

9. Does participant have transportation to central data collection facility? 1 Yes 2 No

   Appointment date: *(Month)* ☐☐ – *(Day)* ☐☐ – *(Year)* ☐☐

   And time: ☐☐ : ☐☐ a.m. p.m.

Comments: ____________________

COMMENTS

LABELS

S [redacted] S | [redacted] D D | [redacted] W W [redacted] W | [redacted] B B [redacted] | H [redacted] H | [redacted] U U

D. SAMPLE INFORMATION

For each sample collected for a given household or individual, attach the appropriate label to the appropriate container before collecting the sample. Complete section D below when appropriate.

1. Study number: ☐☐☐☐☐☐

2. Site number: ☐ 3. Segment number: ☐☐ 4. Household number: ☐☐☐ 5. Participant number: ☐☐

6. Paint lead measurements: I Exterior toward smelter ☐☐☐.☐ II Exterior away from smelter ☐☐☐.☐ III Interior dust - 1 ☐☐☐.☐ IV Interior dust - 2 ☐☐☐.☐ V Interior dust - 3 ☐☐☐.☐ VI Interior kitchen ☐☐☐.☐

Type of Sample	Original Sample: Collected		If Collected, Date			If Not Collected, Reason	Interviewer Number	Duplicate Sample: Selected		Collected		If Collected, Date			If Not Collected, Reason
	Yes	No	Month	Day	Year			Yes	No	Yes	No	Month	Day	Year	
2-97 7. Soil	1	2						1	2	1	2				
8. Tap Water *Source:* ____	1	2						1	2	1	2				
9. House Dust *Surface:* ____	1	2						1	2	1	2				
10. Scalp Hair	1	2						1	2	1	2				
11. Blood	1	2						1	2	1	2				
3-10-77 12. Urine	1	2						X	X	1	2				

13. Hematocrit: ☐☐ % 14. Urine protein: ☐ + 16. Date: ☐☐ *(Month)* – ☐☐ *(Day)* – ☐☐ *(Year)*

15. Specific gravity: ☐.☐☐☐ 17. Interviewer number: ☐☐☐

COMMENTS:

____

____

____

____

RESEARCH TRIANGLE INSTITUTE

STUDY OF HUMAN TISSUE HEAVY METAL BURDEN IN NON-FERROUS SMELTER COMMUNITIES

Chemical Analysis Report Form

Sample Number	Metal Symbol	Units			Sample Number	Metal Symbol	Units		
		Determination No. 1	Determination No. 2	Code			Determination No. 1	Determination No. 2	Co

2–98

3–10–77

Completed by *(RTI ID number)*: ☐☐☐☐

Date completed: ☐☐ – ☐☐ – ☐☐
(Month) *(Day)* *(Year)*

APPENDIX 2.4

PRETEST CONSIDERATIONS

PRETEST CONSIDERATIONS

In order to test and standardize the data collection instruments and procedures, RTI will conduct a Pretest of this Work Plan in a limited number of households at a non-ferrous smelter site not selected for the main study effort, most likely Corpus Christi, Texas, with the approval of the Project Officer. The Pretest will be conducted by the RTI project staff and consultants with on-site assistance by independent subcontractors. The Pretest will simulate the main study as closely as possible and will therefore follow the Work Plan as closely as possible, including sampling, field operations, and chemical analysis. If no major problems are encountered with the Work Plan such that modifications are minimal or unnecessary, then the data from the Pretest would provide at least some limited data on a seventh non-ferrous smelter community. If problems are encountered which require modifications of the data collection instruments or procedures before proceeding with the main data collection effort, some of the data collected in the Pretest may still be useful (other than as a justification for the modification), depending upon the nature of the problem and/or the required modification. The decision in favor of Corpus Christi (over Hayden, Arizona) has been based on a number of considerations related to the logistics of executing the study protocol at a site for the first time, in particular the availability and costs of, and problems and staff burden associated with, various ancillary and support services including:

1. Attitude of the smelter: Both of the smelter firms with operations at Hayden are involved in various litigations, although only the Asarco plant at Hayden is specifically involved in such litigation. In addition, there is information that the smelter

industry may undertake an epidemiological study at Hayden.

2. Attitude of federal, State, and local agencies: RTI would prefer a Pretest site where the appropriate federal, State and local agencies would be interested, perhaps experienced, and hopefully could be actively involved, in such a study. At a meeting at Phoenix, Arizona, on November 23, 1976, RTI was encouraged by support expressed by the Arizona Department of Health Services and the University of Arizona College of Medicine; however, the primary focus of that meeting was Ajo.

3. Availability of independent subcontractors: The Pretest will attempt to simulate the main study as closely as possible, except on a smaller scale, and will therefore follow the Work Plan as closely as possible, including involvement of independent subcontractors. Figures A-2.4.1 and A-2.4.2 present graphically the number of interviewers from the current RTI listings living in counties within a reasonable distance of the sites in Texas and Arizona respectively, which were under consideration for the Pretest. That is not to say, however, that all of those individuals would be available or suitable for this research effort. For example, RTI has two other major survey research efforts planned for the Phoenix area in early 1977 which would deplete the number of available interviewers in Maricopa county during that time. More important, however, is the distance which the interviewers must travel to reach the site and the cost and burden associated with that travel.

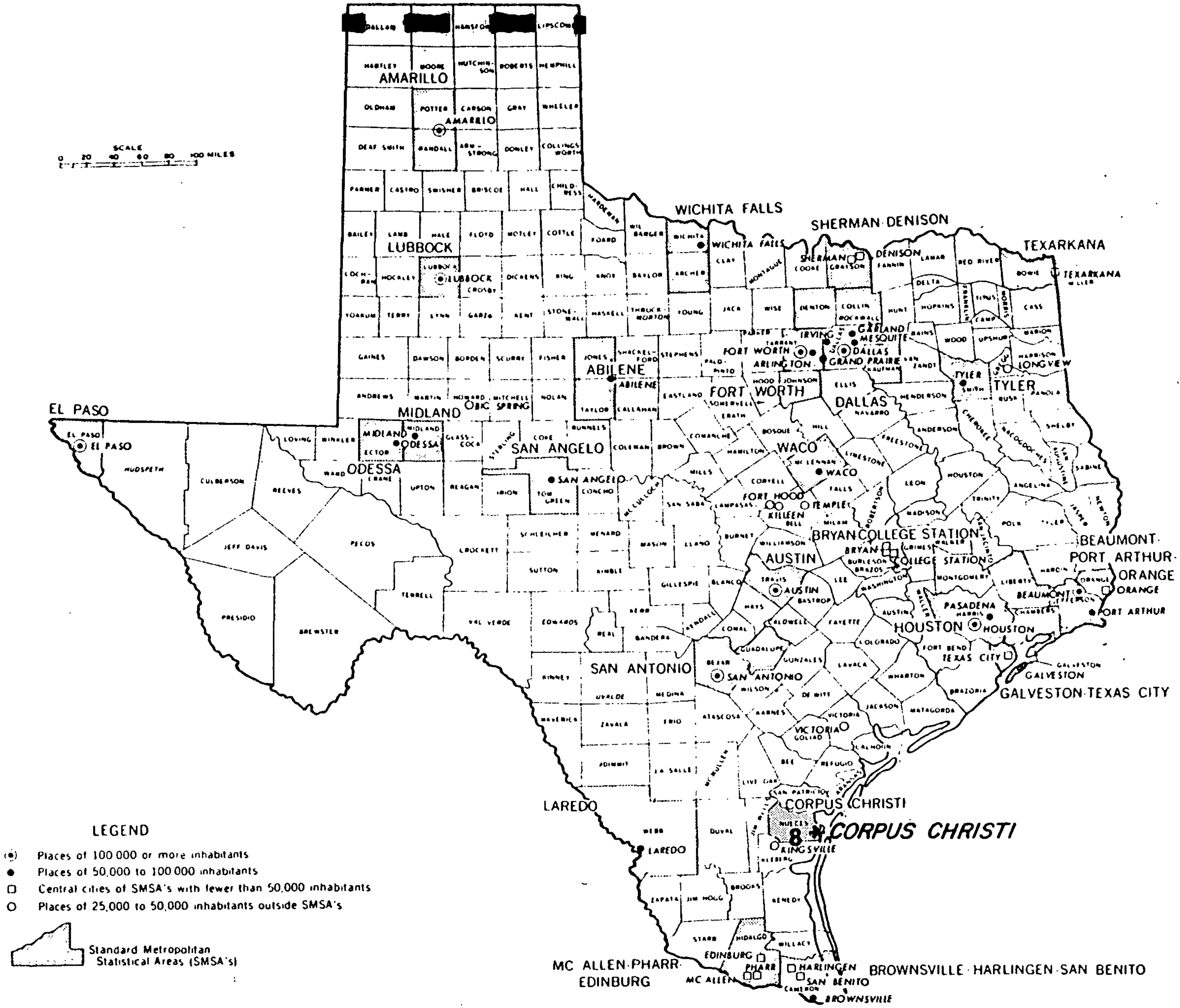


Fig. A-2.4.1. Location and number of interviewers from the current RTI listing living in counties within a reasonable distance of the Corpus Christi, Texas, potential Pretest site [Source: Ref. 2.3, p. 1013].

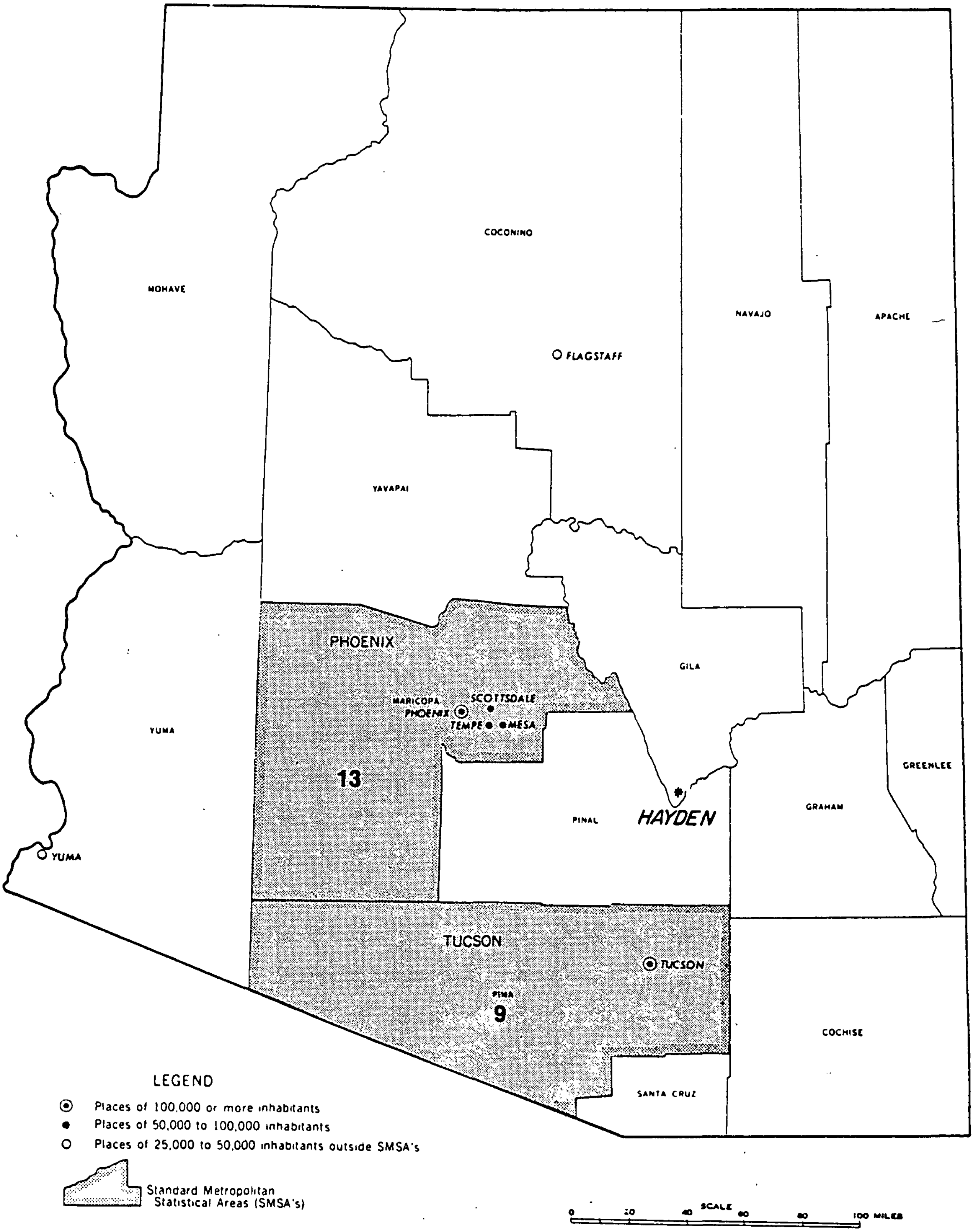


Fig. A-2.4.2. Location and number of interviewers from the current RTI listing living in counties within a reasonable distance of the Hayden, Arizona, potential Pretest site [Source: Ref. 2.3, p. 972].

4. Nature of the Site: RTI would prefer a community large enough to permit some flexibility in the event of a large number of nonparticipants, and so that the logistics of implementing the field operations for the first time would not be too involved. Both of the Pretest sites under consideration would present a bilingual population. However, Hayden and Winkelman, Arizona, which together make up the Hayden smelter community, have a combined population of less than 2,000, have extremely limited transportation and medical facilities, and are approximately two hours driving one way from the nearest transportation facilities and sources of supplies and support services.

5. Cost: Since the performance sites for the main study were not known when the proposal was written, one of the smelter communities in the St. Louis area was considered as a Pretest site for the purpose of estimating Pretest cost. Several of the considerations cited in preceding paragraphs will have some impact on cost, particularly the availability of qualified independent subcontractors within a reasonable distance of the site, the magnitude of the Pretest, and the site itself. For example, round trip tourist air fare Raleigh to Corpus Christi is $230, and Raleigh to Tucson is $308 (plus ground transportation to Hayden). The outcome of the Pretest may have some impact on RTI's time and cost projections.

Some of these same considerations entered into the choice of the three performance sites where elderly persons will be studied, in that RTI will need a larger population base and additional independent subcontractors.

APPENDIX 2.5

RELEVANT CORRESPONDENCE

State Board of Health

OTHO R. WHITENECK, D.D.S., PRESIDENT
ROBERT D. McCULLOUGH, D.O., VICE PRESIDENT
THOMAS DONICA, M.D., SECRETARY
GLEN L. BERKENBILE, M.D.
WALLACE BYRD, M.D.
ARNOLD HELVEY
EUGENE A. OWENS, M.D.
W. A. "TATE" TAYLOR
HAROLD A. TOAZ

Commissioner

R. LEROY CARPENTER, M.D., M.P.H.

Oklahoma

State Department of Health

Northeast 10th Street & Stonewall
Post Office Box 53551
Oklahoma City, Oklahoma 73105

September 17, 1976

Carl Hayes, Ph.D.
Air Pollution Control Division
Research Triangle Park,
North Carolina 27711

Dear Dr. Hayes:

I very much appreciate talking with you about the studies on the Heavy Metal Absorption conducted in Bartlesville in the Spring of 1975. I had previously discussed the findings with Dr. Phillip Landrigan at the Center for Disease Control.

I feel much more comfortable with your assurance that the final report when released to the public will be modified. I expressed to you our anxiety about some of the language in the preliminary report and I am pleased that you are planning to modify this language to indicate that the levels obtained in the children in the Bartlesville survey are not of sufficient magnitude to warrant immediate and concentrated reappraisal.

I am pleased that the EPA plans to conduct follow-up studies in some of the towns to further delineate the epidemiological significance of the levels found in the children. I would strongly urge that Bartlesville, Oklahoma be selected as one of the towns for further study. As we discussed on the telephone Bartlesville was the first town to be studied and you and I both realize that some of the technical aspects of the study were somewhat less than satisfactory especially in the areas of specimen collection and in the methodology of sampling. I would like to suggest that this is one very good reason for going back to Bartlesville with a follow-up study. In addition I would like to emphasize that some of the highest levels of cadmium and lead were found in children in Bartlesville and feel that this finding would be an important factor in selecting Bartlesville as one of the towns for further study.

Although I am unable at this time to commit the resources of the State Health Department's Epidemiology Program to assist in further follow-up studies I can assure you of our interest and we would be happy to evaluate the extent of the follow-up studies and the degree to which we could participate. Bartlesville is located in a county that does not have a local health department and for this reason the Epidemiology Program at the State Department of Health would assist in any further investigation of this problem.

At the present time we are not taking any action on the preliminary report which you forwarded some three weeks ago. I indicated to you that we felt that it would be important before the final report is released to the public that a meeting be arranged between the management of the National Zinc Company in Bartlesville and the local physicians in Bartlesville and representatives of the State Department of Health. We do not plan to ask for this meeting until such time as we receive the final draft copy of the report.

Sincerely yours,

Armond H. Start, M.D.
Director, Division of
Communicable Disease

AHS/mls

Acting Commissioner
WALTER D. ATKINS, D.D.S., M.P.H.

Oklahoma
State Department of Health

Northeast 10th Street & Stonewall
Post Office Box 53551
Oklahoma City, Oklahoma 73105

January 24, 1977

Warren Galke
Health Scientist
Population Studies Division
U.S. Environmental Protection Agency
Health Effects Research Laboratory
Research Triangle Park,
North Carolina 27711

EPA Contract No. 68-02-2442
RTI Project No. 31U-1372

Dear Mr. Galke:

I appreciate the opportunity to review the draft work plan. I am very impressed by the quality and the detailed methodology found in the plan. I have discussed the plan with members of the Epidemiology Program staff and we have no comment or suggestions for incorporation into the final product. We consider appropriate communication to be an essential element in working with a project involving people of a community. We commit ourselves to assist this project within the limits of our resources.

Sincerely yours,

Armond H. Start, M.D.
Director, Division of
Communicable Disease Control

AHS/mls

APPENDIX 2.6

SAMPLE COLLECTION METHODOLOGY

SAMPLE COLLECTION METHODOLOGY

A. General Considerations

The specific methods proposed by RTI for measuring environment-related factors differ somewhat among the various types of exposure. These differences reflect several considerations such as the extent to which surrogate variables reflect the factors of interest, the measurability of factors, the variability of factor measurements, the quality control of data collection, and the suitability of data collection techniques under actual survey conditions. The proposed methodology stresses random sampling techniques wherever possible to facilitate valid statistical analyses and to increase the degree of control over data collection; Field Interviewers (FI's) will follow explicit, nonjudgmental procedures throughout. These procedures will range, as described in subsequent sections, from obtaining small selective samples of relatively homogeneous items, such as tap water at a particular residence, to obtaining large stratified random samples for a highly variable item, such as air quality in a smelter community.

Sample collection will be divided among the various field staff. The collection of environmental samples will be divided between the Site Administrator (SA) and the FI. The SA will be responsible for collecting air, market basket, and general soil and water samples such as soil and water samples from each school where study children participants attend; the FI will be responsible for the collection of dust and tap water samples for each participating household and soil samples from the appropriate residential play area for each pre-school child participant, and the measurement of household paint lead levels. Responsibility for the collection of biological samples will be shared by the independent subcontractors. The FI will be responsible for the explanation of the procedure for collecting the urine sample, and arrangements for the participant to go to a central location for collection of the biological samples; at that central location, the urine and blood samples will be collected by the medical independent subcontractor, the hematocrit and urine protein and specific gravity will be determined by the medical independent subcontractor, and the scalp hair sample will be obtained, either by the medical independent subcontractor or an FI.

For each household containing a study participant, samples of housedust and tap water will be collected, and paint lead levels will be measured. For each study participant, RTI shall endeavor to obtain samples of blood, urine, and scalp hair; soil samples will be collected from the appropriate play area for each pre-school child participant and from each school yard where study children participants attend. In addition, air, soil, and market basket samples will be collected for the overall smelter community, and drinking water samples will be obtained from each school where study children participants attend.

B. Environmental Samples

1. Air

Twenty four hour air particulate samples will be collected by the SA using high-volume sampling units (Fisher Scientific, Cat. No. 1-037-40) on pre-washed Tape A 8" x 10" glass fiber filters (Fisher Scientific, Cat. No. 9-730-68).

The high-volume air samples will be obtained at random points, which are coincidental with a subsample of the random blocks (segments) containing sample individuals. This matching is not intended to provide matched observations between individuals and air samples, but rather to expedite the selection of a random point sample that is dispersed throughout the target population and that is representative of the area over time. These samples will be taken at random points in time concurrently with the other data collection activities at each performance site. At any point in time during the survey period, approximately five high-volume units will be operating at the site being investigated.

The SA will be provided with a list of sample days numbering from approximately 1 to 19. The randomization process will involve assigning, for example, three numbers from 1-19, selected at random and without replacement, and subject to the constraint that each day is assigned at most to three strata at each site. The constraint will facilitate maximum utilization of the high-volume air sampling equipment. The following partial table represents a hypothetical example of such a randomized list:

Stratum	Days on which a high-volume air sample is to be taken (day 1 = first day of survey at site)
S_1	8, 12, 17
S_2	2, 8, 15
.	
.	
.	
S_8	2, 3, 9, 10, 12, 14, 19

According to this schedule, two and three air samples (see table A-2.6.1) would be taken in strata S_2 and S_8, respectively, on the second day of the survey, and so on until approximately 87 operation sets are taken at that site (see figure A-2.6.1). Table A-2.6.2 presents the type of format which might be used to describe the survey and lab results for one of the study elements, such as lead.

The sampling units will be placed at locations prescribed by the stratum-day sampling scheme shown in figure A-2.6.1. Power drops will be used as required.

The initial air flow, approximately 1.7 m^3/min., and the final flow will be accurately read from the pressure gauge and related to total sample volume by the following expression [Ref.2.7]:

$$V = \frac{Qi\ Qt}{2} T$$

V = air volume samples (m^3)

Q_i = initial air flow (m^3/min)

Q_t = final air flow (m^3/min)

T = sampling time (min.)

Table A-2.6.1. Tentative sample allocation for air samples.*

Type of Observation	S_1	S_2	S_3	S_4	S_5	S_6	S_7	S_8
	Number of Observations in Each Stratum, Si							
Locations per day	2	2	2	2	2	2	3	3
Days	3	3	4	4	5	5	6	7
Ratio, days/locations	1.5	1.5	2.0	2.0	2.5	2.5	2.0	2.3

*Based on the following data from Djurić [Ref. 1.2]:

Day	Stratum 6; 2 locations (2.2 - 3.0 km)		Stratum 8; 3 locations (5.0 - 8.0 km)		
1	13.0	30.0	1.3	7.6	4.2
2	84.0	68.0	15.0	36.0	25.0
3	18.0	66.0	9.6	3.2	4.2
4	----	----	24.0	60.0	29.0

with approximate estimates of variance: $s_6^2 = \frac{1}{nm-1} (xij-\overline{x})^2 = 891$; and $s_8^2 = 697$

suggesting a total sample size, nm, needed for a 20 percent c.v.: $\hat{nm}_6 = (\frac{s6}{.2\ \overline{x}_6})^2 \doteq 9$

$\hat{nm}_8 \doteq 20$

a ratio; $\sqrt{\frac{s_6^2 \text{ days}}{s_6^2 \text{ locat.}}}$ suggests that sample size ratio days/locations should be approximately 2.2

where $s_6^2 = \frac{1}{n-1} \sum_i^n (\overline{x}_i-\overline{\overline{x}})^2$ and $(nm)_h$ is total sample size in stratum h.

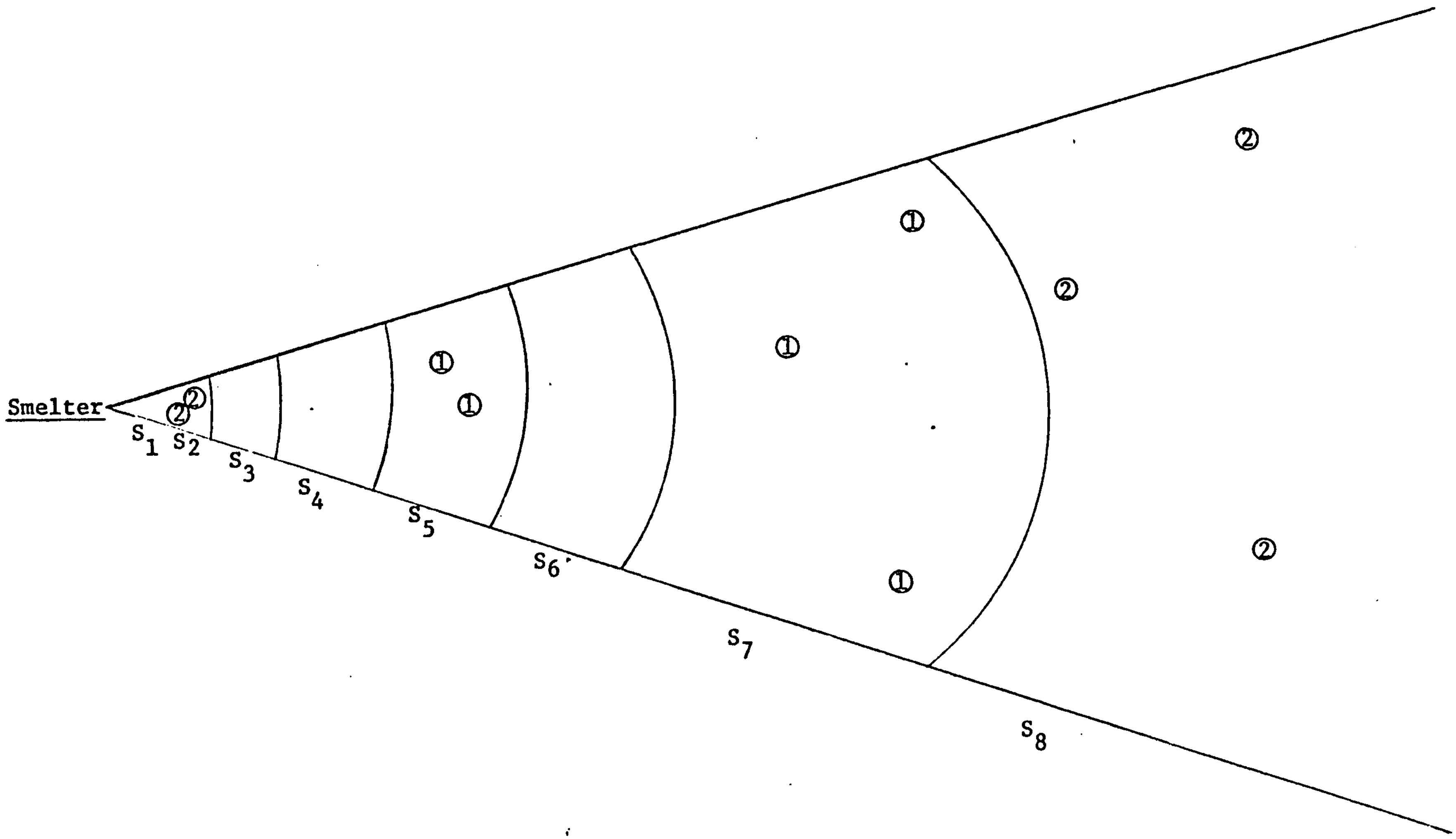


Fig. A-2.6.1. Geographic and temporal placement of high-volume air samples: a partial hypothetical example depicting only the first two days of the survey.

Table A-2.6.2. Exemplary format for presenting survey and laboratory results for study element: lead.

Observation number	Pb reading, mg. per cubic meter	Distance from source, km	Direction from source, degrees from transect	Wind velocity, km/hr	Wind direction, degrees from transect	Ground level temp., °C	Upper atmosphere temp., °C
1	4.2	2.5	0.4	35.1	-10.5	32.1	30.0
2	36.0	1.2	-5.2	20.4	-10.4	34.5	33.1
3	60.0	1.3	-10.1	2.4	-5.3	35.1	40.0
.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.
87	7.8	5.0	35.6	2.4	-2.1	38.1	34.0

Wind direction, wind speed and extent of precipitation will be noted for each sampling day.

Although each sampler will be calibrated at RTI, the air flow calibration data will be validated at the site with an EPA audit device.

After the collection period, the filter will be removed from the sampler, folded so that only surfaces with collected particulates are in contact and placed in a tightly secured plastic Zip-Loc bag for shipment to RTI.

2. Soil

The basic sampling protocol will call for the collection of samples of surface soil at air sampling sites, from the residential play areas of pre-school age study children participants, and from the school yard(s) where study children participants attend. Two soil samples will be obtained from the primary residential play area of each pre-school age child participant; if a given household contains more than one pre-school age study participant, these soil samples may represent more than one child. One soil sample will come from each air sampling location and one from each school yard where study children participants attend.

Variation in the soil content of study elements throughout the sample collection areas, both for different locations and time, is expected to be small relative to variation in the air samples. Nonetheless, two samples will be taken from each residential play area of pre-school age study participants in order to obtain some measure of variation in element exposure from soil in play areas. The boundaries of the most commonly used play area will be established and the two surface soil samples collected from random points in the play area using a random number table. Samples will be collected in appropriately labeled four ounce plastic bottles for shipment to RTI.

3. House Dust

A sample of settled dust will be collected for each household by the FI using a vacuuming technique after that of Solomon and Hartford [Ref. 2.8]. A single sample will be taken from the floor in the central area of the room which is the most frequent site of common family activity, away from the walls. The sampling area will be delineated and standardized using a 0.5 x 0.5 m template placed on the surface. In taking each dust sample, one pass will be made of the 0.25 m^2 area utilizing a portable vacuum source. The vacuumed dust will be trapped in a special chamber; the dust gathered will then be placed in appropriately labeled, tightly secured Zip-Loc bags for shipment to RTI. In the event that part of the floor of the selected room is carpeted and part bare, a section of carpeted floor will be selected for acquisition of the dust sample.

Random sampling at different locations and time is not proposed for this measure of exposure, because the sample should be relatively homogeneous within a household, and because what little improvement in data that might result from a suitable randomization does not seem to justify the accompanying increase in participant and interviewer burden.

4. Tap Water

At each household, the FI will collect two samples of *cold tap water* in four ounce plastic bottles, from the kitchen tap or other source commonly used for drinking and/or cooking. The first sample will be taken immediately upon turning on the water, without flushing; the second sample will be taken after the water has been allowed to run for three minutes. Time will be measured using a stop watch. Random sampling at different locations and time is not proposed for this measure of exposure, because the samples should be relatively homogeneous within a household, and because what little improvement in data that might result from a suitable randomization does not seem to justify the accompanying increase in participant and interviewer burden.

5. Paint Lead Measurement

At the time of household data collection, the FI will measure paint lead levels using a Princeton Gamma-Tech Portable Paint Lead Analyzer such as that shown in figure 2.10. Six paint lead measurements will be taken, one on an exterior wall considered to be closest to the smelter (I), one on an exterior wall considered to be farthest from the smelter (III), three at different points on one interior wall in the same room where the house dust sample is obtained (III-V), and one in the approximate center of an interior kitchen wall (VI). The readings will be recorded in Part D of the SQ (see appendix 2.3). Paint lead measurement is not part of the Scope of Work of this contract; impact on project cost projections will be assessed after the Pretest.

Portable Lead Paint Analyzer

PRELIMINARY INFORMATION

Model XK-3

Sensitivity - 0.5 mg/cm²
Penetration - 85% through 25 paint layers
Full Scale - 99.9 mg/cm²
Weight - 5½ pounds
Dimensions - 9.5" x 3.75" x 7"

PRINCETON GAMMA-TECH

Box 641 • Princeton, N.J. 08540 • Tel: 609 924-7310 • Cable PRINGAMTEC • Telex: 843486

Fig. 2.10.

C. Biological Samples

1. Urine

At the time that the participant is enlisted, arrangements will be made for the collection of a urine sample in a four ounce plastic bottle. A twenty-four hour urine sample would be considered ideal, but is considered impractical to collect from children, and adults who work away from home. The interviewer will leave the appropriately labeled specimen bottle with the participant, explaining that the participant is to collect a urine specimen from the first micturation on the morning that the participant is to have the blood sample drawn; the urine specimen will then have to be refrigerated by the participant until it is delivered to the central data collection facility. In the event that a participant arrives at the central data collection facility without a urine specimen, an attempt will be made to obtain one at that time, with appropriate labeling and notation; if the morning urine sample was collected but left at home, arrangements will be attempted to send an FI to the participant's home to retrieve the urine sample. Where RTI provides participant transportation to the central data collection facility, this last step may be avoided. In some instances, RTI may ultimately have two urine samples for some participants. The central data collection facility must have toilet facilities.

If children participants are not toilet-trained, special procedures may have to be implemented in order to obtain a urine specimen. RTI is considering testing commercial disposable absorbent diapers for this purpose in the Pretest. The mother would be provided two such commercial disposable absorbent diapers and an appropriately labeled Zip-Loc bag, with instructions to place the disposable diaper next soiled by urine only in the Zip-Loc bag for delivery to the central data collection facility with interim refrigeration as required. In the event that the disposable absorbent diapers are not workable, adhesive plastic bags will be considered.

At the central data collection facility, the medical independent subcontractor will determine urinary protein using reagent strips and specific gravity using a urinometer. Results will be entered in Part D of the SQ (see appendix 2.3). Measurement of urine protein and specific gravity are not part of the Scope of Work of this contract; impact on project cost projections will be assessed after the Pretest.

2. Scalp Hair

From each study participant from whom the collection of such a sample is feasible, a full-length sample of scalp hair of sufficient quantity for chemical analysis will be obtained using thinning shears. Although the amount of scalp hair available from the participant will ultimately determine the size of the scalp hair sample, a concerted effort will be made to collect as large a sample as possible from each participant up to the minimum amount needed for chemical analysis.

Scalp hair samples will be collected at the central data collection facility and placed in appropriately and individually labeled Zip-Loc plastic bags; the scalp hair sample will be completely enclosed within the plastic bag which will be locked carefully and returned to RTI for analysis.

3. Blood

An attempt will be made to collect a blood sample from each participant from a brachial vein by venipuncture using a heavy metal-free 10 ml. Vacutainer tube containing liquid EDTA as an anticoagulant. Prior to venipuncture, blood flow in the selected arm will be restricted using a tourniquet; the venipuncture site will be prepared by cleansing with an individually wrapped sterile alcohol swab. Venipuncture will be accomplished by a disposable 20 G x 1 1/2 inch Vacutainer needle contained in a reusable Vacutainer holder. After collection of the blood sample, the Vacutainer tube will be appropriately labeled and then inverted several times to insure mixture with the anticoagulant; the venipuncture site will again be cleansed with an individually wrapped sterile alcohol swab, pressure applied to retard hematoma formation, and a sterile adhesive bandage applied.

Where venipuncture by Vacutainer presents problems, as in the very young, obese, or elderly, alternatives may have to be employed at the discretion of the individual collecting the sample. In most instances, venipuncture may still be accomplished using a disposable needle and syringe with immediate transfer of the blood sample to a heavy metal-free 10 ml. Vacutainer tube containing liquid EDTA as an anticoagulant. The syringe would permit gradual and variable withdrawal of blood and be therefore less likely to collapse the vein. The preparation of the venipuncture site and the handling of the sample would be identical to that described in the preceding paragraph.

In the case of children participants, blood samples (0.5 ml.) may have to be drawn via finger (children over two years of age) or heel (children less than two years of age) stick using long point microlances and heparinized capillary tubes. The method of drawing blood samples by finger or heel involves several steps. After the child is secure or even before, his hand or foot must be cleansed of all noticeable dirt, grime and anything else, such as food stains, with a cotton swab. After that, the finger tip (usually the index finger) or heel to be stuck is selected, held, and wiped with an individually wrapped sterile alcohol swab. After this, the finger or heel is massaged by applying gentle pressure towards the puncture site, thereby pushing the blood up toward the puncture site. When the puncture site appears somewhat red and engorged with blood, the site is punctured with an individually packaged long point microlance. The first drop of blood thus elicited is wiped away with an individually wrapped dry sterile gauze pad. The free-flowing blood is then collected with a gentle *milking* motion into two or preferably three heparinized capillary blood collection tubes of approximately 280 microliters in volume to within one inch of their top end. During the blood collection procedure, care should be taken to see that the tip of the capillary tube is held right on the point of puncture and the blood collected there so that the blood does not run down the finger or heel and then into the tube, thereby opening possibilities of contamination. The tube fills itself through capillary action; when each tube is full, the blood collector places each tube on a clean level surface. When blood sample collection is completed for a particular child (see hematocrit section immediately following), the puncture site is wiped with a dry sterile gauze pad pressed to the puncture to stop the bleeding, and a sterile adhesive bandage is applied. The blood samples in the capillary tubes will then be transferred to an appropriately labeled vial for refrigeration and shipment to RTI for analysis.

4. Hematocrit Determination

Hematocrit will be determined at the performance site by the microhematocrit method using a microhematocrit centrifuge. Hematocrit values will be read with a reader and recorded in Part D of the SQ (see appendix 2.3).

In the case of Vacutainer blood samples, two microhematocrit tubes will be filled three-fourths full from the blood in the Vacutainer tube and one end of each hematocrit tube will be sealed with putty. The microhematocrit tubes will then be centrifuged, the percentage of packed red cells read on a hematocrit reader, and the value recorded on the SQ. The stopper will be replaced in the Vacutainer tube which will then be refrigerated for shipment to RTI for analysis.

In the case of the finger or heel stick, the procedure will be the same as that in the preceding paragraph except that only one microhematocrit tube will be filled per participant, directly from the puncture site.

D. Considerations of Dietary Heavy Metal Exposure

Diet is an important contributor of trace metal to an individual. Moreover, the amount of trace metal in various diets may vary by several orders of magnitude. Accordingly, it may be quite important to the success of the present study to obtain some measure of the amount of trace metals in the diets of the sample individuals. Procedures which have been suggested for obtaining diet trace metal levels include:

1. Feces samples,
2. Analyzing duplicate diets or meals from sample individuals,
3. Questions regarding diet in the Study Questionnaire, and
4. Analyzing area grocery store food samples (*Market Basket* procedure).

After review of the literature, discussions with consultants and other experts, and careful deliberation, RTI decided to employ questions regarding diet and the market basket approach together in order to obtain some measure of the amount of trace metals in the diets of the sample individuals. Those two procedures, while less precise than chemical analysis of feces samples and duplicate meals, are considerably less expensive, more suitable and practical under actual survey conditions, and less of a burden to the participant and interviewer.

1. Dietary History

RTI has included several questions regarding eating habits and diet in the SQ which will be completed for every participant by the FI during household data collection, including the frequency with which the participant eats certain foodstuffs known to contribute to trace metal exposure [Ref. 2.5]. RTI has planned that these questions would be part of the data collection process from the beginning; therefore, this method of collecting information on dietary trace metal exposure results in no additional significant cost.

2. Market Basket

In this approach, which is also relatively inexpensive, the RTI Site Administrator would purchase exemplary market baskets of food from grocery stores at the smelter sites. The food would then be returned to RTI for analysis for trace metal content. RTI is in communication with the Food and Drug Administration regarding the details of this procedure, including the specific foods which comprise the market basket sample.

The market basket procedure is not part of the Scope of Work of this contract; impact on project cost projections will be assessed after the Pretest.

E. Quality Control

Each sample will be properly labeled as it is collected. Each individual sample will be treated the same as all other samples of that particular type.

As a check on the quality or precision of the procedures and techniques for collecting certain of the biological and environmental samples, RTI plans to collect duplicate housedust, tap water, blood, and scalp hair samples (the last two from adult participants only) from ten percent of the sample sources, using the same technique and as nearly as possible the same site(s) as the original sample.

The duplicate housedust sample will be taken from a floor area immediately adjacent to the site of the original sample using the same collection procedures. The duplicate tap water sample will be taken from the same water source as the original after flushing sample using the same collection procedure. The duplicate scalp hair sample will be taken using the same collection procedure in an amount equal to the original sample (where possible). The duplicate blood sample will be taken from the same venipuncture using the same collection procedure as the original sample by changing Vacutainer tubes. The duplicate samples will be taken by the same person as the original sample and at the same approximate time.

APPENDIX 2.7

REFERENCES

REFERENCES

2.1. Landrigan, P. J., et al., *Epidemic lead absorption near an ore smelter: the role of particulate lead.* New England Journal of Medicine, Vol. 292, No. 3, pp. 123-129, January 1975.

2.2. Center for Disease Control, *Protocol: nationwide survey of children living near primary non-ferrous metal smelters.*

2.3. U. S. Department of Commerce, Social and Economic Statistics Administration, Bureau of the Census. County and City Data Book, 1972: Statistical Abstract Supplement. Washington, D. C.: U. S. Government Printing Office, 1973.

2.4. Hartwell, T. D., et al. Design, Data Collection and Analysis of a Field Test of Instruments and Procedures to Measure English Language Proficiency. Research Triangle Park, N.C.: Research Triangle Institute, April 1976.

2.5. Bureau of Foods, Compliance Program Evaluation, FY 1974 Heavy Metals in Foods Survey (7320.130, Chemical Contaminants Project), June 19, 1975.

2.6. Hall, W. G., and L. T. Slovic, U. S. Department of Commerce, National Bureau of Standards. Survey Manual for Estimating the Incidence of Lead Paint in Housing (NBS Technical Note 921). Washington, D.C.: U. S. Government Printing Office, 1976.

2.7. Federal Register, Vol. 36, p. 8192, 1971.

2.8. Solomon, R. L., and J. W. Hartford, *Lead and cadmium in dust and soils in a small urban community.* Environmental Science and Technology, Vol. 10, No. 8, pp. 773-777, August 1976.

3.0 Physical Methods of Analysis

This section describes the sample preparation procedures which will be carried out on the blood, urine, scalp hair, tap water, dust, air particulate, soil, and market basket samples collected at the smelter sites. These materials will be analyzed for As, Cd, Cu, Mn, Pb and Zn by atomic absorption spectrophotometry.

A spark source semiquantitative scan will be obtained on two biological samples from each age-sex group by Commercial Testing and Engineering Company, Golden, Colorado. This corresponds to a total of 252 samples from the six smelter sites which will be analyzed in this manner.

Free erythrocyte protoporphyrin (FEP) content will be determined in each blood sample to establish the extent of chronic exposure to lead. A microspectrofluorometric procedure will be employed.

Quality control will play a prominent role in all routine analytical operations. Both internal and external reference materials will be used to insure continuing analytical accuracy.

3.1 Atomic Absorption Analysis

All atomic absorption analysis will be carried out on a Perkin-Elmer Model 403 Atomic Absorption Spectrophotometer using an HGA-2000 Graphite Furnace with deuterium arc background correction. Absorption peaks will be recorded with a Perkin-Elmer Recorder Model 056. Homogeneity of the final sample will be insured by treatment in an ultrasonic bath prior to analysis. Sample injection will be accomplished with an Eppendorf pipet.

All glassware used in sample preparation will be soaked overnight in 1% HNO_3, rinsed well with deionized water and dried. Precleaned volumetric pipets will be used for reagent and sample deliveries. All

HNO_3 solutions will be prepared from analytical reagent grade material and deionized water.

Sample preparation procedures are described below for each matrix. Special workup conditions will be used for sample solutions slated for arsenic analysis (see Section 3.1.4).

3.1.1 Biological Samples

Samples in this category include blood, urine and scalp hair specimens collected from the study participants.

3.1.1.1 Blood

Blood samples will be diluted with 0.5% (v/v) HNO_3 and analyzed directly for the metals of interest. Results will be reported as weight of metal/100 ml blood.

3.1.1.2 Urine

Urine samples will be diluted with 1.0% (v/v) HNO_3 and analyzed directly for the metals of interest. Results will be reported as weight of metal/100 ml urine.

3.1.1.3 Scalp Hair

Scalp hair samples will be cut into approximately 1 cm sections with stainless steel scissors and rinsed with a 1:1 methanol:ether mixture. The hair material will be washed twice with a 10% Prell (liquid) solution, rinsed well with deionized water and dried at 105°C. A 250 mg (approximately) portion of the washed hair collection will be weighed and digested at 85°C with a 1:1 HNO_3 mixture. The concentrate will be diluted with deionized water and analyzed directly for the metals of interest. Results will be reported as weight of metal/gm hair.

3.1.2 Environmental Samples

Samples in this category include dust collected at the homes of the study participants, air particulate samples collected according to the sample design described in section 1.6.2; tap water samples taken from the homes of study participants and schools of school-age subjects; and soil samples taken at the air sampling locations, from the play area of pre-schoolers, and the school yard of school-age subjects.

3.1.2.1 Tap Water

Each tap water sample, already acidified with HNO_3 at the collection site, will be analyzed directly for the metals of interest. Results will be reported as weight of metal/liter tap water.

3.1.2.2 Dust [Ref. 3.1]

Dust samples will be weighed and digested at 85°C with 1:1 HNO_3. Deionized water will be added to a reference volume, the suspension will be filtered, and the filtrate analyzed directly for the metals of interest. Results will be reported as weight of metal/gm dust.

3.1.2.3 Air Particulates

Air particulate samples will be eluted from a 2.0 x 20.3 cm strip of the glass fiber filtering media with 1% (v/v) HNO_3 in a 50° - 60°C water bath. The filter strip will be quartered, placed in a covered beaker and warmed with dilute HNO_3 for 30 minutes. The supernatant will be drawn off and the filter sections treated for an additional 30 minutes with a fresh portion of 1% (v/v) HNO_3. The solution will be decanted, combined with the original supernatant, diluted to a reference volume with deionized water, filtered and analyzed directly for the metals of interest. Results will be reported as weight of metal/m^3 air (see appendix 2.6, B.1 for calculation of air sample volume).

3.1.2.4 Soil [Ref. 3.2]

The soil sample will be screened on a 20 mesh ASTM sieve and dried at 105°C. A weighed soil sample will be slurried in a minimum volume of deionized water and digested with concentrated HNO_3 at approximately 100°C. To the cooled mixture will be added 30% H_2O_2 and the heating continued with intermittent swirling. The cooled digestate will be filtered, diluted to a reference volume with deionized water, and analyzed directly for the metals of interest.

3.1.3 Arsenic Analysis

The analysis of arsenic by a graphite furnace procedure presents certain problems unique to this relatively volatile and interference-prone element. To overcome losses of arsenic from the furnace prior to atomization, tap water, hair, dust, and air particulate sample solutions will be "stabilized" with 1000 ppm nickel and will contain 1% (v/v) HNO_3 to minimize the effect of small differences in acid strength on signal intensity.

Blood, urine, and soil extracts will be subjected to an extraction workup to remove matrix interferences. This procedure is based on literature methods [Ref. 3.3, 3.4] and is outlined below:

- Overnight treatment with conc. HCl at room temperature.
- Reduction of arsenic species with $SnCl_2$/KI and extraction of these products into benzene.
- Back-extraction of total arsenic into dilute dichromate containing 1% (v/v) HNO_3.
- Addition of 1/10 volume of 10,000 ppm nickel.

3.1.4 Market Basket Samples

The food items collected at site grocery stores will be analyzed for all six elements. Each sample will be subjected to acid hydrolysis conditions and metal concentrations determined by standard additions.

Since this work area is not part of the originally proposed study, an estimate of additional cost will be made after the Pretest.

3.2 Spark Source Mass Spectrometric Analysis

Two samples of each biological type from every age-sex group and smelter site (total 252) will be submitted for spark source mass spectrometric analysis. A semiquantitative scan will be obtained by the Instrumental Analysis Division of Commercial Testing and Engineering Company, Golden, Colorado. The analysis will be run on an Associated Electrical Industries (AEI) Model MS7 instrument.

3.3 Free Erythrocyte Protoporphyrin (FEP) Analysis

A fluorometric method based on the procedure reported by S. Piomelli [Ref. 3.5] will be used to determine FEP. The method requires only 20 microliters of whole blood. The ethyl acetate-acetic acid extraction and the free porphyrin separation with aqueous HCl will be carried out and the fluorescence of the lower porphyrin layer measured directly. The excitation monochromator will be set at 400 nm and a scan obtained with the emission monochromator at 500–700 nm (fluorescence emission maxima occur at 608 and 658 nm with a relative intensity ratio of 2.08). Standard solutions of coporphyrin will be used for calibration purposes.

This assay will detect FEP levels as low as 4.5 μg/100 ml whole blood.

A Hitachi Perkin-Elmer Model MPF-2A Fluorescence Spectrophotometer will be used for the FEP analysis.

3.4 Quality Control and Analytical Protocol

3.4.1 Instrumentation

At the start of each analytical run, the atomic absorption spectrophotometer will be calibrated for the element to be analyzed for, using standard solutions containing known quantities of metal in the appropriate control matrix material. Pooled collections of blood, urine, scalp hair, tap water, dust and soil, shown to have minimal or nonelevated metal concentrations, will serve as baseline matrix material. In each case the actual metal concentration will be determined by the method of standard additions. Potential control soil samples will be obtained at a distant upwind location from the smelter in an attempt to simulate soil type.

Air particulate calibration solutions will be prepared by spiking glass fiber filter sections with known amounts of the metals of interest.

In the case of scalp hair, dust, soil and air particulate calibrations, the standard additions will be done prior to sample workup.

These calibration solutions will serve as internal reference materials as described below.

The calibration data will be fitted to the exponential equation, $y = ae^{bx} + k$, where

x = peak response, mV,

y = weight of metal, ng, and

a,b,k = constants.

The values assigned to the constants will be determined by a linear regression program on a Monroe Model 1800 programmable calculator. Sample metal concentrations will be calculated from this exponential expression on a Texas Instruments Model 51-II calculator.

3.4.2 Limits of Detection

Detection limit (DL) will be defined as that amount of metal which will give a net signal two standard deviation units greater than the mean matrix signal. This corresponds to that amount measurable at a precision level of 50% Regular Standard Deviation (RSD). An analysis giving a net signal less than two blank standard deviation units will be reported as not detected (ND).

3.4.3 Routine Analytical Protocol

After the instrument has been calibrated for a specific metal in a particular collection matrix, an analytical run (60-80 samples) will be initiated by a team of two analysts. Duplicate sample injections will be made on all samples, provided the intensity of the two signals satisfies the following criterion:

First Signal, % of Full Scale	Maximum Permissible Variation	Permissible Range of Second Signal, % of Full Scale
90	±10%	81-99
80	±10%	72-88
70	±10%	63-77
60	±10%	54-66
50	±10%	45-55
40	±15%	34-46
30	±17%	25-35
20	±20%	16-24
10	±25%	6-14
5	±40%	3-7
2	±50%	1-3

Depending on the total furnace program time, 20 to 30 samples will be processed per hour. The analysts will alternate between sample injection and data calculation; the metal concentration of each sample will be determined immediately after analysis. Matrices which vary widely in metal levels (air particulates, soil, dust) may exhibit concentrations outside of the linear working range. These samples will be set aside, suitably diluted and analyzed as a group against appropriate calibration standards.

Sample weights/volume, dilution factors, calibration and raw analytical data will be recorded on the Analytical Data Sheets, examples of which are shown in appendix 3.1.

3.4.4 Analytical Priorities

First priority will be given to the biological samples (urine, blood and scalp hair). Included in this category is the blood FEP assay. Tap water samples will be analyzed next. Dust, soil and air particulate analysis will be performed as soon as the others have been completed.

3.4.5 Quality Control Procedures

The quality control measures incorporated in the routine analytical protocol will serve two major functions: to maintain constant instrument performance and determine analytical precision and accuracy.

3.4.5.1 Instrument Performance

Instrument performance will be monitored by determining the signal response of a reference material after every 10-15 samples. These evaluations will be carried out with an original calibration solution (internal reference) or, when available, an external reference material with a metal concentration known to the analyst. These procedures are not intended to assess precision or absolute accuracy but to establish the validity of the original calibration data. If the reference sample signal has changed by more than ±10-15% or ±2 standard deviation units, appropriate measures will be taken before continuing the analytical run (e.g., changing the graphite tube, balancing the D_2 arc-light source intensities, recalibrating).

3.4.5.2 Accuracy and Precision

Accuracy will be assessed by analysis of external reference materials approximately every 20 samples. This procedure will be carried out blind. The reference materials will be coded and processed in the same manner as field samples. External reference materials available for this purpose are listed below:

- Blood (CDC) - Pb and FEP;
- Tap water (EPA/Cincinnati) - all metals;
- Air particulates (EPA/RTP) - As and Pb, others as they become available.

Precision will be assessed by analysis of duplicate samples (see Section 2.2.6.4). These materials will be coded at the smelter site; their identity as a duplicate will be unknown to the analyst. Samples which will be evaluated in this manner are listed below:

- Blood (10%) adult participants only,
- Scalp hair (10%) adult participants only,
- Tap water (10%) second sample after flushing,
- Dust (10%), and
- Soil (10%) from air sampling sites and school yards.

Evaluation of the tap water duplicates will serve two functions. The two consecutively drawn samples will be analyzed and the results used to estimate variability in water quality with time. Equal aliquots from the duplicates will be combined, the blend split in two portions and each analyzed to determine analytical reproducibility.

3.4.5.3 Interlaboratory Comparison

An interlaboratory comparison study will be initiated. Samples to be identified by the EPA Project Officer will be split for independent analysis.

3.4.6 Calibration of High Volume Air Samplers

All high volume air samplers will be calibrated against a top loading Orifice Calibration Unit Model 330 (Sierra Instruments, Inc., St. Paul, Minnesota). This device has been standardized against a primary standard, positive displacement Rwots Meter by the Environmental Protection Agency, Research Triangle Park, North Carolina (EPA/RTP). The calibration data are presented in figure 3.1.

Each high volume sampler will be equipped with a pressure gauge for monitoring air flow across the 20.3 cm x 25.4 cm glass fiber filter. To calibrate the pressure gauge readout in terms of air flow, one, two, and three, etc., glass fiber filters will be placed on the sampler to simulate resistance to air flow. As the resistance to air flow changes, measurements of the pressure drop across the orifice will be made with a water manometer and related to the corresponding pressure gauge reading. With this calibration data, the gauge on each sampler may be directly converted to standard cubic meters air flow per minute across the filter medium.

Sampler calibration will be checked at the site with an EPA audit device.

After use at a smelter site, brushes on the air samplers will be changed and the unit recalibrated.

3.5 Determination of Total Particulate Solids in Air

Subsequent to filter prewashing with 5% HNO_3, each filter will be tared, inspected for imperfections, and handled in a manner consistent

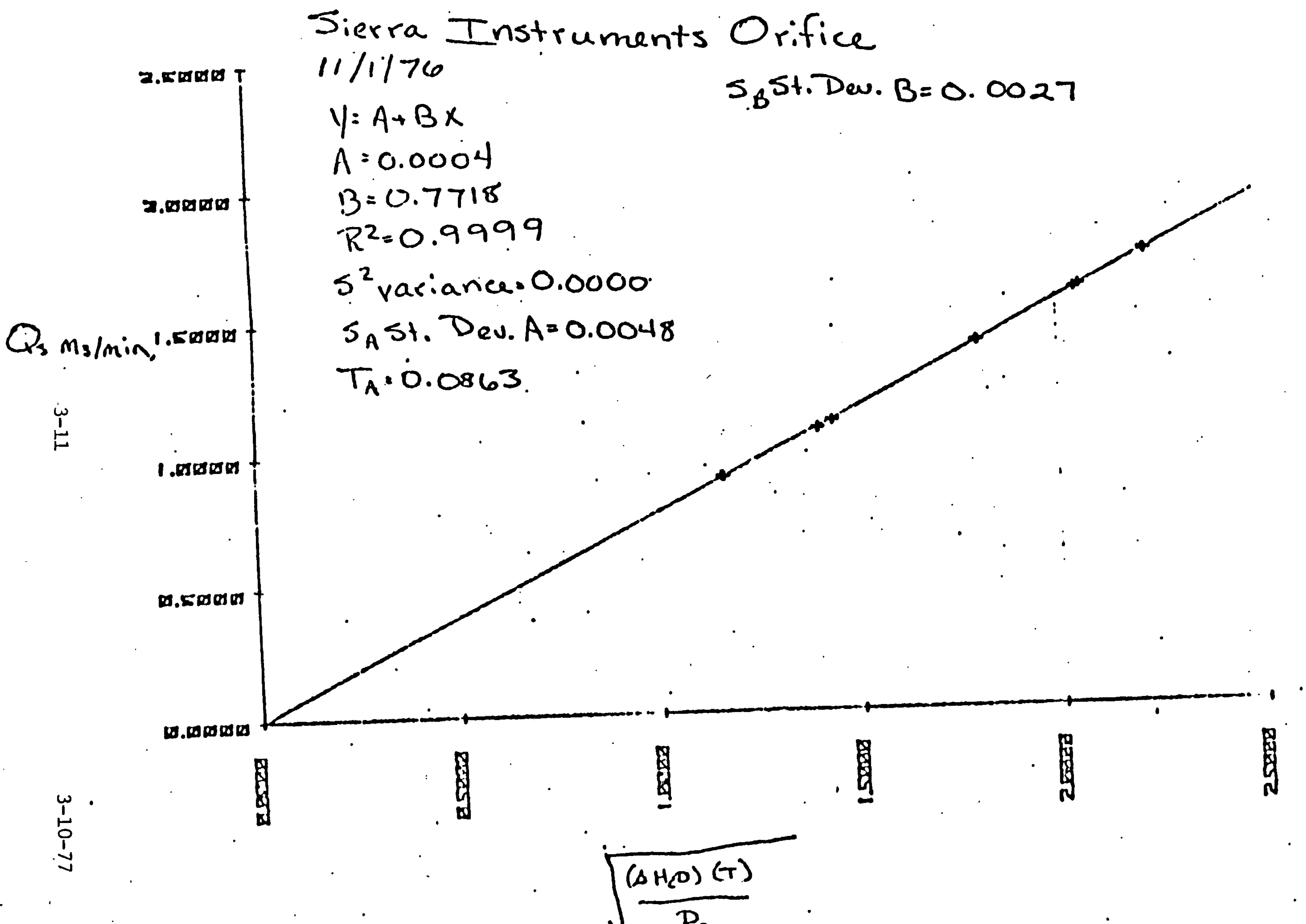


Fig. 3.1. Calibration of Sierra Instrument Orifice, Model 330.

with the procedures described in the Federal Register [Ref. 3.5]. Each filter will be stamped with an identification number and placed in a Zip-Loc bag for transport to the site. On return to RTI, the filters will be weighed as described [Ref. 3.6] and the net weight reported as weight of total particulates/m^3 air.

3.6 Personnel

All chemical analysis will be carried out at RTI under the direction of Dr. Robert W. Handy, Senior Chemist in the Chemistry and Life Sciences Group (CLSG). Dr. Monroe E. Wall, CLSG Director and RTI Vice President, will provide overall coordination for all phases of this program.

Assisting Dr. Handy will be chemical professionals Gail T. Hess, David F. Natchske, Karen Robbins and technician Carolyn Foust. Mrs. Hess will direct and evaluate the routine quality control measures during daily analytical runs.

Resumes of these individuals will be found in appendix 3.1.

3.7 References

3.1. Solomon, R. L., and J. W. Hartford, Environmental Science and Technology, Vol. 10, p. 777, 1976.

3.2. Krishnamurty, K. V., E. Shpirt, and M. M. Reddy, Atomic Absorption Newsletter, Vol. 15, p. 68, 1976.

3.3. Fitchett, A. W., et al., Analytic Chimica Acta, Vol. 79, p. 93, 1975.

3.4 Forehand, T. J., et al., Analytical Chemistry, Vol. 48, p. 999, 1976.

3.5 Piomelli, S., Journal of Laboratory and Clinical Medicine, Vol. 81, No. 6, p. 932, 1973.

3.6 Federal Register, Vol. 36, p. 8192, 1971.

APPENDIX 3.1

ANALYTICAL DATA SHEETS

ANALYTICAL DATA SHEETS - AA ANALYSIS

INSTRUCTIONS

There is a separate form for reporting the analytical results of each matrix. The individual forms have several features in common and some which are unique for the matrix material being analyzed. The following information will be supplied in the appropriate space:

a) The chemical symbol of the element being analyzed.

b) The bound notebook reference will be cited for each analytical run. This notebook will be used to record all operating conditions and any observations or remarks concerning the analysis. The notebook reference will also be noted on the strip chart recording.

c) The date and the operator(s) initials will be shown.

d) All calibration standards will be injected in duplicate and the corresponding peak height recorded.

e) A least squares regression analysis will be carried out on four standard solutions run in duplicate and the equation representing the best fit will be noted.

All samples analyzed during a run will be injected in duplicate. The following data will be recorded for each matrix type:

a) Column 1.

Each sample will be identified by the same code numbers used to label the sample container at the smelter site.

b) Column 2.

Instrument response during atomization is measured as peak height, expressed in units of millivolts (mv).

c) Column 3.

The weight of metal injected is calculated from a calibration equation of the form $y = ae^{bx} + k$, where

y = weight of metal injected

x = peak height

a, b, k = constants.

d) Column 4.

F is a function of the volume of analytical solution injected into the graphite furnace.

Volume injected	F
10 µl	100
25 µl	40
50 µl	20

e) Column 5.

The weight of metal contained in each ml of the solution injected into the furnace is calculated by multiplying the number in Column 3 by F.

The remaining columns on the Data Sheet are treated differently for each matrix.

a) Drinking Water -

To convert weight of metal/ml water to weight of metal/liter water simply change the units of weight as follows:

Units wt/ml	Equiv. units wt/l
pg	ng (ppt)
ng	pg (ppb)
µg	mg (ppm)

b) Urine -

The constant D (Column 6) is defined as the volume (ml) to which one ml of urine sample is diluted prior to injection in the graphite furnace. For example, if a 1:1 dilution is performed, D = 2; if a 1:49 dilution is necessary, D = 50.

The weight of metal/100 ml urine (Column 7) is determined by multiplying the value in column 5 by 100D.

c) Blood -

As with urine, the constant D (Column 6) is defined as the volume (ml) to which one ml of urine sample is diluted prior to injection in the graphite furnace. For example, if a 1:9 dilution is carried out, D = 10.

The weight of metal/100 ml blood (Column 7) is determined by multiplying the value in Column 5 by 100D.

d) Hair -

D (Column 6) = $V_i \left(\frac{V_f}{A}\right)$.

where, V_i = volume (ml to which sample digest is diluted.

V_f = final volume (ml) of diluted aliquot.

A = volume (ml) of aliquot withdrawn from initial sample volume (V_i) for further dilution to V_f.

NOTE - If no aliquoting of V_i is performed, the term $V_f/A = 1$.

$$D = V_i$$

The weight of metal/gm hair (Column 8) is found by multiplying Column 5 by D and dividing this product by the sample weight, W (gm)(Column 7).

Wt. metal/gm hair = Column 5 $\left(\frac{D}{W}\right)$

Example: A 250 mg hair sample was digested and diluted to 5 ml. Two ml of this solution was diluted to 10 ml prior to furnace injection.

$V_i = 5$; $V_f = 10$; $A = 2$; $W = .25$

$D = 5\ (\frac{10}{2}) = 25$; $\frac{D}{W} = 100$

Wt. metal/gm hair = Column 5 (100).

e) Air Particulates

In the case of air particulate analysis, D is defined as follows:

$$D(\text{Column } 6) = V_i(\frac{V_f}{A})\ \frac{F_t}{F_a}.$$

where, V_i = volume (ml) to which the extract of the entire filter strip is diluted.

V_t = final volume (ml) of diluted aliquot.

A = volume (ml) of aliquot withdrawn from initial sample volume (V_i) for further dilution to V_f.

F_t = total filter area.

F_a = area of filter used in analysis.

NOTE - If no aliquoting of V_i is performed, the term $V_f/A = 1$, and

$$D = V_i\ (\frac{F_t}{F_a}).$$

The weight of metal on the entire filter (Column 7) is determined by multiplying Column 5 by D. Column 7 is divided by air volume (m^3) (Column 8) to give weight of metal/m^3 air (Column 9). The calculation of air volume is shown on the air collection log sheet.

Wt. metal/m^3 air = Column 5 (D/air volume)

Example: A 40.6 cm^2 section of a 20.3 x 25.4 cm filter was treated with acid and diluted to 100 ml. Two ml of this solution was diluted to 5 ml prior to furnace injection. Air volume = 2500 m^3.

$V_i = 100$; $V_f = 5$; $A = 2$; $F_t = 515.6$; $F_a = 40.6$

$$D = 100(\frac{5}{2})\ \frac{515.6}{40.6} = 250\ (12.7) = 3175$$

$$\text{Wt metal/m}^3 \text{ air} = \text{Column 5 } (3175)/2500$$
$$= \text{Column 5 } (1.27)$$

f) Housedust

$$D(\text{Column 6}) = V_i(\frac{V_f}{A}).$$

where, V_i = volume (ml) to which sample digest is diluted.

V_t = final volume (ml) of diluted aliquot.

A = volume (ml) of aliquot withdrawn from initial sample volume (V_i) for further dilution to V_f.

NOTE - If no aliquoting of V_i is performed, the term $V_f/A = 1$, and

$$D = V_i$$

The weight of metal/gm dust (Column 8) is found by multiplying Column 5 by D and dividing this product by the sample weight, W(gm) (Column 7).

$$\text{Wt. metal/gm dust} = \text{Column 5 } (\frac{D}{W}).$$

Example: A 250 mg dust sample was digested and diluted to 25 ml. Two ml of this solution was diluted to 25 ml prior to furnace injection.

$$V_i = 25;\ V_f = 25;\ A = 2;\ W = .25$$
$$D = 25\ (\frac{25}{2}) = 312.5;\ \frac{D}{W} = 1250$$
$$\text{Wt. metal/gm dust} = \text{Column 5 } (1250).$$

The total weight of metal in a .25 cm^2 collection is found by either multiplying Column 8 by the weight of sample collected over this area or multiplying Column 5 by D.

g) Soil

$$D(\text{Column 6}) = V_i(\frac{V_f}{A}).$$

where, V_i = volume (ml) to which sample digest is diluted.

V_t = final volume (ml) of digested aliquot.

A = volume (ml) of aliquot withdrawn from initial sample volume (V_i) for further dilution to V_f.

NOTE - If no aliquoting of V_i is performed, the term $V_f/A = 1$, and

$$D = V_i$$

The weight of metal/gm soil (Column 8) is founding by multiplying Column 5 by D and dividing this product by the sample weight, W(gm) (Column 7).

$$\text{Wt. metal/gm soil} = \text{Column 5 } (\frac{D}{W}).$$

Example: A 1.0 gm soil sample was digested and diluted to 250 ml. One ml of this solution was diluted to 100 ml prior to furnace injection.

$$V_i = 250;\ V_f = 100;\ A = 1;\ W = 1$$

$$D = 250\ (\frac{100}{1}) = 25{,}000;\ \frac{D}{W} = 25{,}000$$

$$\text{Wt. metal/gm soil} = \text{Column 5 } (25{,}000).$$

ANALYTICAL DATA SHEET - AA ANALYSIS

Matrix - Housedust

Standard (wt/vol.) Peak Height (mv)

________________ ________, ________

________________ ________, ________

________________ ________, ________

________________ ________, ________

Element - ____________

Notebook No. _________

Date _______________

Operator(s) ____________________

Calibration Equ. _______________

1. Sample Code	2. Peak height (mv)	3. Wt. metal injected	4. F	5. Wt. metal/ ml anal. soln.	6. D	7. Sample weight	8. Wt. metal/ gm dust	9. Wt. metal .25 cm^2 area	10. Comment

ANALYTICAL DATA SHEET - AA ANALYSIS

Matrix - Air Particulates

Element - ____________

Standard (wt/vol.)	Peak Height (mv)	
________________	_______,	_______
________________	_______,	_______
________________	_______,	_______
________________	_______,	_______

Notebook No. ________

Date ________________

Operator(s) ____________________

Calibration Equ. ______________

1. Sample Code	2. Peak height (mv)	3. Wt. metal injected	4. F	5. Wt. metal/ ml anal. soln.	6. D	7. Wt. metal on filter	8. Air volume (m^3)	9. Wt. metal/ m^3	10. Comment

ANALYTICAL DATA SHEET - AA ANALYSIS

Matrix - Blood

Element - ____________

Notebook No. ________

Date ________________

Operator(s) ____________________

Calibration Equ. ______________

Standard (wt/vol.)	Peak Height (mv)	
________________	_______,	_______
________________	_______,	_______
________________	_______,	_______
________________	_______,	_______

1. Sample code	2. Peak height (mv)	3. Wt. metal injected	4. F	5. Wt. metal/ ml anal. soln.	6. D	7. Wt. metal/ 100 ml blood	8. Comment

ANALYTICAL DATA SHEET - AA ANALYSIS

Matrix - Urine

Element - ____________

Standard (wt/vol.) | Peak Height (mv)

Notebook No. ________

_________________ ________, ________

Date _________________

_________________ ________, ________

Operator(s) ____________________

_________________ ________, ________

Calibration Equ. _______________

_________________ ________, ________

1. [redacted]ample code	2. Peak height (mv)	3. Wt. metal injected	4. F	5. Wt. metal/ ml anal. soln.	6. D	7. Wt. metal/ 100 ml urine	8. Comment

ANALYTICAL DATA SHEET - AA ANALYSIS

Matrix - Drinking Water

Element - ____________

Standard (wt/vol.) Peak Height (mv)

Notebook No. ________

Date ________________

Operator(s) ____________________

Calibration Equ. _______________

Standard (wt/vol.)	Peak Height (mv)	
________________	_______,	_______
________________	_______,	_______
________________	_______,	_______
________________	_______,	_______

1. Sample code	2. Peak height (mv)	3. Wt. metal injected	4. F	5. Wt. metal/ ml anal. soln.	6. Wt. metal/ l. water	7. Comment

ANALYTICAL DATA SHEET - AA ANALYSIS

Matrix - Soil

Element - ____________

Notebook No. ________

Date ________________

Operator(s) ____________________

Calibration Equ. _______________

Standard (wt/vol.)	Peak Height (mv)
________________	_______, _______
________________	_______, _______
________________	_______, _______
________________	_______, _______

1. Sample Code	2. Peak height (mv)	3. Wt. metal injected	4. F	5. Wt. metal/ ml anal. soln	6. D	7. Sample weight	8. Wt. metal/ gm soil	9. Comment

ANALYTICAL DATA SHEET - AA ANALYSIS

Matrix - Hair

Element - ____________

Notebook No. __________

Date ________________

Operator(s) ____________________

Calibration Equ. ______________

Standard (wt/vol.)	Peak Height (mv)	
____________	________,	________
____________	________,	________
____________	________,	________
____________	________,	________

1. Sample code	2. Peak height (mv)	3. Wt. metal injected	4. F	5. Wt. metal/ ml anal. soln.	6. D	7. Sample weight	8. Wt. metal/ gm hair	9. Comment

3-10-77

APPENDIX 3.2

RESUMES OF RTI PROJECT STAFF

ROBERT W. HANDY, Senior Chemist

Professional Experience

1975 to date. Senior Chemist, Chemistry and Life Sciences Division, Research Triangle Institute, Research Triangle Park, North Carolina. Development of trace metal analysis techniques by atomic absorption spectrometry and general analytical methodology. Monitoring gas and aerosol levels in environmental chamber studies using instrumental and wet chemical methods. Analysis of environmental and biological materials for trace metals by atomic absorption spectrometry. Isolation, identification and quantitation of drug metabolites from various biological fluids using radiochemical tracers, gas and liquid chromatographic techniques.

1965 to 1975. Chemist, Chemistry and Life Sciences Division, Research Triangle Institute, Research Triangle Park, North Carolina. Synthesis of substituted cinnamylidene malononitriles; research in modified steroid synthesis and drug metabolism.

1954 to 1964. Research Chemist, Kay-Fries Chemicals Co., Inc., West Haverstraw, New York. Synthesis and bench-scale process development of fine organic intermediates; orthoesters, pyrimidines and miscellaneous polyfunctional compounds.

Education

B.S., Chemistry, Brown University, Providence, Rhode Island, 1954.
M.S., Organic Chemistry, Stevens Institute of Technology, Hoboken, New Jersey, 1964.
Ph.D., Medicinal Chemistry, University of North Carolina, Chapel Hill, North Carolina, 1971.

Professional Societies

American Chemical Society

Selected Publications

"Reactions of some 4-Piperidones with Olefin-forming Phosphorus Reagents," M.S. Thesis (1964).

"The Synthesis of Some 1-(β-Diethylaminoethyl)-2-(p-ethoxybenzyl)-5-substituted Benzimadazoles," F. I. Carroll, R. W. Handy, J. A. Kepler and Joan A. Gratz, J. Heterocyclic Chem., 4, 262 (1967).

"Metabolism of Antifertility Steroid IV - The Synthesis of 6-Chloro-17-hydroxypregna-4,6-diene-3,20-dione-4-^{14}C-acetate (Chlormadinone Acetate)," K. H. Palmer, R. W. Handy and M. E. Wall, J. Labelled Compounds, 7, 16 (1971).

"The Total Synthesis of 7 (8 → 11α) Aboestrogens. Delination of the Role of Steric Effects in the Biochemistry of Steroids," C. G. Pitt and R. W. Handy, Tetrahedron, 27, 527 (1971).

"An in vitro and Correlated in vivo Study of the Metabolism of Chlormadinone Acetate," Ph.D. Dissertation (1971).

"Metabolism of Antifertility Steroid VII - Chlormadinone Acetate," R. W. Handy, K. H. Palmer and M. E. Wall, The Pharmacologist, 13 (2) 221 (1971).

"Comparative Metabolism of Chlormadinone Acetate," R. W. Handy, T. R. Hess and M. E. Wall, The Pharmacologist, 15 (2) 228 (1973).

"The Metabolism of Antifertility Steroids: The In Vitro Metabolism of Chlormadinone Acetate," R. W. Handy, K. H. Palmer, M. E. Wall and C. Piantadosi, Drug Metabolism and Disposition, 2 (3), 214 (1974).

"Metabolism of Norethynodrel in Thrombophlebitic - Thromboembolic Subjects," R. W. Handy, Dawn Dominquez, Marsha Poirer, M. E. Wall, C. E. Cook, C. D. Christian and R. Bressler, Experientia, 31, 446 (1975).

"Quantitative Determination of Codeine in Plasma by Gas Chromatography," Ruth A. Zweidinger, F. M. Weinberg and R. W. Handy, J. Pharm. Sci., 65, 427 (1976).

"Estimation of Permissible Concentrations of Pollutants for Continuous Exposure," Robert Handy and Anton Schindler, EPA-600/2-76-155 (1976).

"Analysis of Aluminum Chlorohydroxide by Selective Ion Electrode Potentiometry," paper accepted for presentation at 1977 Pittsburgh Conference.

Patents

U.S. Patent 3,121,751, "Production of Purified Orthoformic Esters," 1964.

U.S. Patent 3,223,713, "Cyclic Malonaldehyde Diacetals," 1965.

U.S. Patent 3,258,496, "Purified Orthoformic Esters," 1966.

U.S. Patent 3,323,925, "Wax Polishes," 1967.

U.S. Patent 3,415,846, "2,6,7-Trioxabicyclo (2.2.2) octanes," 1968.

November 1976

TERESA ROBERTS HESS, Junior Chemist

Professional Experience

1972 to date. Junior Chemist, Chemistry and Life Sciences, Division, Research Triangle Institute, Research Triangle Park, North Carolina. Research on metabolites of chlormadinone acetate in rat liver, rhesus monkeys and humans. Investigation into the deposition of estradiol benzoate, testosterone propionate, progesterone, and their metabolites, in bovine tissue. Metabolic studies of trichlorocarbanilide in rats, rabbits, monkeys and humans. Analysis of rat blood, brain and femur for lead. Identification of components related to energy wastes and effluents.

October 1970 to August 1971. Lab Technician under Dr. Kenneth Vick, U.S. Department of Agriculture, Entomology Research Division, Gainesville, Florida. Research centered around the determination of the structure of the sex pheromones of Black Carpet beetle, T. Inclusum and T. Galabrum, and the biological aspects of the pheromones, for example, limits of detection of the insects for the pheromones.

June 1970 to September 1970. Summer Lab Technician with St. Regis Paper Company, Jacksonville, Florida.

Education

B.S., Chemistry, University of Florida, 1971.

June 1976

DAVID F. NATSCHKE, Junior Chemist

Professional Experience

September 1976 to date. Research Triangle Institute, Research Triangle Park, North Carolina 27709. Junior Chemist, Chemistry and Life Sciences Division. Analyze biological and environmental samples by atomic absorption. Methods development.

June 1974 - July 1975. Phelps-Dodge Corp., Morenci, Arizona. Assistant Chemist. Analysis of a variety of samples by classical methods. Some programming.

September 1972 - May 1973. New Mexico Bureau of Mines, Socorro, New Mexico. Student Analyst. Analyzed samples by atomic absorption and classical methods.

Education

Military Electronics School, 1966-1967.

B.S., Chemistry, New Mexico Institute of Mining & Technology, Socorro, New Mexico, 1974.

Graduate School in Chemistry, University of North Carolina, Chapel Hill, N.C., 1975-1976.

Professional Activities

American Chemical Society, member.
ACS Undergraduate Award in Analytical Chemistry, 1974.

October 1976

KAREN W. ROBBINS, Junior Chemist

Education

B.A., Chemistry, University of North Carolina, Chapel Hill, North Carolina, 1974.
Computer Science, Durham Technical Institute, 1975.

Experience

1976 to present. Research Triangle Institute, Research Triangle Park, N. C. Junior Chemist. Materials experience in preparation of piezoelectric films and optical coatings. Analysis of basic oxide furnace materials and processes.

1973 to 1974. Pathology Laboratory, University of North Carolina at Chapel Hill. Research assistant on various pathology problems.

4.0 Statistical Methods of Analysis

4.1 Confidentiality of Data Files

In carrying out its statistical analyses, RTI will utilize machine-readable data files maintained at the Triangle Universities Computation Center (TUCC) located in the Research Triangle Park. To maintain the confidentiality of these data files, RTI will use an encrypting of data procedure.

The encrypting procedure involves the use of a routine which scrambles data passed to the routine so that they are meaningless to anyone unless they are decrypted. The routine draws random numbers and adds a different number to each character of the data. The starter for the random number generator, referred to as the key, is passed to the routine in the calling sequence. Thus with the same starter to the random number generator, the data can be decrypted when required for processing. An encrypting procedure has the advantage of not splitting the primary data base and not having to depend on computer center personnel (non-RTI personnel) to maintain the confidentiality of a link file.

In addition to the encrypting procedure, TUCC has developed an extensive security system which RTI programmers use to protect computer account codes and data from other users. This is accomplished through a password protection system for account codes, data sets, and data storage volumes. These facilities are different from and replace the similar features provided by IBM. This system is described in TUCC publication GI-066-0, TUCC Security Features [Ref. 4.1]. Copies of this publication are available on request.

4.2 Data Analysis

RTI will use the TUCC IBM 370/165 computer facility for its data analysis. The data will be stored on 9-track tapes written at 1000 bpi with an OS standard label.

In its analysis, RTI will examine the following relationships:

(a) the relationship between environmental levels of the trace metals of interest (i.e., levels of metals in air, water, soil and dust samples), the distance from the smelter, wind speed, and wind direction; and

(b) the relationship between tissue levels of the trace metals (i.e., levels in hair, blood and urine), environmental levels, and sociodemographic variables (e.g., age, sex).

As is now envisioned, the principal statistical techniques that will be used to examine these relationships are the analysis of variance, multiple regression and stepwise regression. In addition, it may also be worthwhile to examine some multivariate techniques (i.e., techniques which consider the above relationships for more than one trace metal at a time).

4.2.1 Analysis of Environmental Levels

In particular, for the relationships in (a) above, the following type of model will be analyzed for each trace metal being studied:

$$Y_{ijk}(M) = u + D_i + S_j + W_k + e_{ijk} \qquad (1)$$

where

$Y_{ijk}(M)$ = concentration of metal M in either air, water, soil, or dust samples for the i^{th} distance, j^{th} wind speed, and k^{th} wind direction,

u = mean metal M level,

$D_i = i^{th}$ distance effect

$S_j = j^{th}$ wind speed effect,

$W_k = k^{th}$ wind direction effect, and

e_{ijk} = random error.

In the above model, the independent variables (distance from smelter, wind speed, wind direction) have been categorized and indexed by i, j, and k, respectively. This allows for a general type of relationship between the levels of the metals and the independent variables rather than imposing a functional relationship as does regression. With this model, one may use the technique of analysis of variance to test for the effects of different distances from the smelter, differences in wind speed, and also differences in wind direction. These correspond to tests of equality of the D_i, the S_j, and the W_k, respectively.

As required by the subject Request for Proposal (RFP), the analyses of the environmental levels, whether they be air, water, dust, or soil, will be done separately for each site. If differences between sites are also of interest, this may be investigated by including a site variable, L_h, in model (1) to produce

$$Y_{hijk}(M) = u + L_h + D_i + S_j + W_k + e_{hijk} . \quad (2)$$

Site differences may then be tested by testing the equality of the L_h and the differences may be exhibited by displaying the adjusted site means from model (2).

4.2.2 Analysis of Tissue Levels

For the relationships in (b) above, the analysis will again be done by site and in this case will also be done by broad age categories, since soil samples are taken only for school and preschool children. In particular, the following type of model will be analyzed for each trace metal:

$$Y_{ijk}(M) = u + A_i + S_j + B_1X_{1k} + B_2X_{2k} + B_3X_{3k} + B_4X_{4k} + B_5X_{5k} + e_{ijk} \quad (3)$$

where

$Y_{ijk}(M)$ = concentration of metal M in either blood, hair or urine samples for the k^{th} individual in the i^{th} age group and j^{th} sex group;

u = mean metal M level;

A_i = age effect for the i^{th} age group;

S_j = sex effect for the j^{th} sex group;

$B_1,\ldots,B_5$ = regression coefficients to be estimated;

$X_{1k},\ldots,X_{5k}$ = corresponding concentration of metal M in the air, water, soil, and dust samples, respectively, for the k^{th} individual; and

e_{ijk} = random error.

The above model will permit the examination of the effect of age and sex as well as environmental levels on metal M tissue levels. A similar model may also be used to examine the effects of distance and wind direction on metal M tissue levels. In model (3), testing for age and sex effects corresponds to testing the equality of the A_i and S_j while testing for the relationship between tissue levels and environmental levels corresponds to testing the nullness of $B_1,\ldots,B_5$. When the parameters in model (3) have been estimated, the resulting fitted equation may serve as a predictive model for the reference population.

In order to help determine the form of model (3) for the various metals, it may be worthwhile to employ the technique of stepwise regression.

This technique can be used to give insight into the relative strengths of the various demographic, environmental and meteorological variables in predicting tissue levels in humans. In essence, this technique selects those variables (in a stepwise manner) which best predict the dependent variable of interest (i.e., tissue levels).

In addition to using the various statistical models given above, other techniques which will be employed to examine the relationships of interest include: computing correlations between pairs of variables; examining scatter plots of tissue levels versus the demographic, environmental, and meteorological variables; and computing means of the demographic, environmental, and meteorological variables for various categories of tissue levels and then plotting these means.

4.3 Potential Problems

4.3.1 Missing Observations

Because of the nature of the data being collected for the present study, there undoubtedly will be a large number of missing observations. These missing observations may consist of all or only selected observations from a sample individual (e.g., the individual refuses to give any data at all or he gives all the data desired except a urine sample). In order to carry out the analyses described in section 4.2, it will be necessary to determine how these missing observations are to be handled, keeping in mind that the easiest solution of only analyzing individuals with complete observations is probably unsatisfactory because too many individuals with partial observations would have to be discarded.

The specific techniques to be used for handling missing observations will be determined during the analysis, and will depend upon several considerations. Some of the pertinent considerations include the following:

- The reason for the missing observation,
- The type of measurement (e.g., tissue level) for which the observation is missing,
- The type of analysis or estimate for which the missing observation is needed,
- The number of missing observations for that measurement,
- The minimum measurable level if the observation is missing because it is less than that level, and
- The information available from that and other individuals that may facilitate the estimation of the missing observation.

The methodology decided upon will be made available for Project Officer review and will be fully documented in the final report. The following methodologies will be among those considered.

If relatively few observations are approximately "randomly" missing for a particular measurement, cohort means will probably be substituted for the value and the degrees of freedom will be appropriately modified.

If relatively few observations are missing because they are below a measurable minimum, the range midpoint of this observation, $\frac{x_i'}{2}$, may be substituted for the missing value, particularly if the range is small (i.e., if $[0,x_i']$ is small where x_i' is the smallest measurable value for X_i). However, if the number or range of unmeasurable observations is large, a more refined technique may be used. Under this condition, methodology for the estimation of distributional location and scale parameters under the situation of singly censored samples, would be appropriate for the initial analysis. In Sarhan and Greenberg [Ref. 4.2], order statistics are used to obtain unbiased best linear estimates of location and scale parameters from samples of size 20 or smaller and unbiased "nearly best" linear estimates from larger samples in which single censoring occurs. Once the distributional parameters are estimated, it will then be possible to substitute values for the unmeasurable observations based upon the estimated distribution.

In running the regression analyses described in section 4.2, one may encounter either missing dependent (Y) or missing independent (X) variables. To handle this problem, one might use a model in which an indicator variable reflects the missing independent variables and "two-stage" estimation models [Ref. 4.3] are used to predict missing dependent variables. The two-stage method is used in SAS [Ref. 4.4], one of the software systems utilized by RTI. The method uses a least squares solution to obtain parameter estimates from the available observations, and then uses estimates of missing values from this preliminary model in place of the missing values--the analysis can then be conducted as if the data were complete except for changes in degrees of freedom. However, if information is known about the range of the dependent variable, i.e., that $0 \leq y_{ij} \leq y_i'$ where y_i' is the minimum detectable level for Y_i, then the two-stage estimation alone would ignore this useful bit of information. Therefore, the two-stage estimation (estimating missing data on the basis of complete observation vectors) would be used to set values when they fall below the minimum measurable level, but only if these estimated values were within the known range $[0, y_i']$. Thus, the following imputed value would be used for a missing y_{ij}:

$$y^*_{ij} = \begin{cases} \hat{y}_{ij}, \text{ if } 0 \leq \hat{y}_{ij} \leq y_i' \\ 0, \text{ if } \hat{y}_i \leq 0 \\ y_i' \text{ otherwise} \end{cases}$$

where

y^*_{ij} is the imputed value for the missing y_{ij} value,

$\hat{y}_{ij}$ is the first-stage estimate of the missing y_{ij}, and

y'_i is the minimum detectable level of Y_i.

The indicator variable model suggested above for accommodating missing X variables in regression analysis might be of the following type:

$$y_j = I_j[\beta_0 + \beta_1 X_j] + (1-I_j)\beta_2 + \varepsilon_j \qquad (4)$$

where

y_j is an observed dependent variable for individual j,

I_j is an indicator variable (0,1) according to whether the X observation is present or missing because it is below measurability,

β_k are parameters to be estimated, and

ε_j is a stochastic error term.

4.3.2 Trace Metal Intake Due to Diet

At the present time, it is anticipated that environmental levels of air, water, soil, and dust will be sampled to determine human exposure to the trace metals of interest. However, it is well known that diet is also an important contributor of trace metal to an individual. For example, EPA personnel have indicated that the proportion due to diet of the total lead absorbed by individuals may be as high as .66. In addition, the amount of lead in various diets may vary by several orders of magnitude. Accordingly, it may be quite important to the success of the present study to obtain some measure of the amount of trace metals in the diets of the sample individuals. Procedures which have been suggested for obtaining diet trace metal levels include:

- Feces samples
- Analyzing duplicate diets from sample individuals,
- Adding questions about diet to the individual's questionnaire, and
- Analyzing area grocery store food samples.

EPA and RTI personnel have investigated these procedures to determine if one or more of them should be incorporated into the present study. At the present time, RTI plans to ask questions about diet in the study questionnaire and to collect and analyze area grocery store food samples. Hopefully, these two procedures will provide some estimates of the relative levels of trace metal intake due to diet.

4.4 Personnel

The analysis of the data for the current project will be under the direction of Senior Statistician Dr. W. Kenneth Poole who is the Director of RTI's Statistical Methodology and Analysis Center (SMAC). Working with Dr. Poole in analyzing the data will be Senior Statistician Dr. Tyler Hartwell who is also a member of SMAC. In addition, Programmer Ms. Lois Bressler from the Computer Applications Center (CAC) will assist Drs. Poole and Hartwell with the data processing. Résumés of these individuals will be found in appendix 4.1.

APPENDIX 4.1

RESUMES OF RTI PROJECT STAFF

W. KENNETH POOLE, Head, Statistical Methodology Department

Professional Experience

1967 to date. Research Triangle Institute, Research Triangle Park, North Carolina, 27709. Statistician, Statistics Research Division. Consults in matters relating to the theory and application of stochastic processes. Does applied research in reliability, regression analysis and estimation.

Education

B.S., Mathematics, Austin Peay State University, Clarksville, Tennessee, 1961.
M.P.H., Biostatistics, University of North Carolina, Chapel Hill, North Carolina, 1963.
Ph.D., Statistics, University of North Carolina, Chapel Hill, North Carolina, 1968.
Held a one-year traineeship at Vanderbilt University during 1961-1962.
Attended a six-week summer session on Biostatistics at Stanford University, 1962.

Professional Activities

American Statistical Association, member.
Institute of Mathematical Statistics, member.

Selected Publications

"Particle Size Distribution and Hopper Flow Rates," with E. D. Sumner, Journal of the Pharmaceutical Sciences, Vol. 55, No. 12, December 1966.

"Water Absorptive Properties of Selected Solids in a Lipophilic Base I," with E. D. Sumner, D. N. Entrekin, and A. F. Ike, Journal of the Pharmaceutical Sciences, Vol. 58, No. 1, January 1969.

"Some Aspects of Linear Prediction in Stationary Time Series," Institute of Statistics Mimeo Series, No. 566, University of North Carolina, Chapel Hill, North Carolina, 1968.

"An Investigation of Certain Physical and Mechanical Properties of Wood-Plastic Combination," with Eric Ellwood, Robert Gilmore, and James A. Merrill. ORO-638, Isotopes-Industrial Technology, Division of Technical Information, United States Atomic Energy Commission.

"Fertility Measures Based on Birth Interval Data." Theoretical Population Biology, Vol. 4, No. 3, pp. 357-387, September 1973.

"Some Methodological Issues in Cohort Analysis of Archival Data," with K. O. Mason, H. H. Winsborough, and William M. Mason, American Sociological Review, Vol. 38, pp. 242-258, April 1973.

"Estimating the Effect of Unwanted Fertility of a Post-Partum Recruitment Strategy," with J. R. Udry. American Journal of Public Health, Vol. 64, No. 7, pp. 696-699, July 1974.

"The Estimation of Examiner Error and the True Transition Probabilities for Teeth or Surfaces in Dental Clinical Trials," with B. V. Shah and A. C. Clayton. Archives of Oral Biology, Vol. 18, pp. 1291-1302, 1973.

"Estimation of the Distribution Function of A Continuous Type Random Variable Through Randomized Response," Journal of the American Statistical Association, Vol. 69, No. 348, December 1974.

"An Index of The Economic Welfare of Rural Families," Frances M. Magrabi, Jean L. Pennock, W. Kenneth Poole and J. Valley Rachal. Journal of Consumer Research, Vol. 2, #3, pp. 178-187, December 1975.

"Diphenylhydantoin and Phenobarbital Concentration In Saliva and Plasma of Man Measured by Radioimmunoassay," C. E. Cook, Ellen Amerson, W. Kenneth Poole, Philip Lesserr and Lorcan O'Tauma. Clinical Pharmacology and Therapeutics, Vol. 18, #6, pp. 742-747, December 1975.

"A Computer Program for Multiple Decrement Life Table Analyses" with P. C. Cooley, to appear in Computer Programs in Biomedicine.

9/76

TYLER D. HARTWELL, Senior Statistician

Professional Experience

1964 to date. Research Triangle Institute, Research Triangle Park, North Carolina, 27709. Statistician, Statistical Methodology and Analysis Center. The work has involved the application of statistical methods to a wide variety of research areas. Considerable experience in using statistical computer packages to analyze laboratory and survey data. Research areas have included: analysis of the impact on environmental variables of nuclear power plants, estimation of the incidence and prevalence of head and spinal cord injuries, analysis of survey instruments and procedures designed to measure English language proficiency, use of ridge regression in copper smelter gas blending for control of sulfur dioxide, investigation of the role of leadership in preventing drug abuse in the army, evaluation of training methods designed to help army leaders reduce social problems in their units, investigation of the relationships between drugs and crime, projecting the supply of nursing manpower, evaluating sampling techniques as related to a national assessment of education, simulating hospital utilization, projecting U. S. manpower requirements for short-term general hospitals, method comparison of NO_2 air-monitoring instruments, investigation of the relationships between atmospheric oxidant and various pollutant and meteorological variables; time series analysis of non-stationary rocket vibration data, design of chemical experiments, and estimating tolerance limits from censored samples.

1962 to 1964. North Carolina State University, Raleigh, North Carolina. Graduate work in the Department of Experimental Statistics.

1961 to 1962. Autonetics, a Division of North American Aviation, Downey, California, Mathematical Analysis Group. The work included systems reliability, data analysis and developing computer programs.

Education

B.S., Mathematics, University of Michigan, Ann Arbor, Michigan, 1961.
M.E.S., Statistics, North Carolina State University, Raleigh, North Carolina, 1964.
P.h.D., Statistics, North Carolina State Universtiy, Raleigh, North Caroina, 1971.

Professional Activities

American Statistical Association, member.
Biometric Society, member.
Phi Eta Sigma
Phi Kappa Phi

Selected Publications

"Expected Mean Squares for Nested Classifications," with D. W. Gaylor, Biometrics, Vol. 25, pp. 427-430, 1969.

"Simulation of Hospital Utilization," with D. G. Horvitz and J. R. Batts, Proceedings of the American Statistical Association, Social Statistics Section, pp. 129-138, 1970.

"Estimating Variance Components for Two-Way Disproportionate Data with Missing Cells by the Method of Unweighted Means," with D. W. Gaylor, Journal of the American Statistical Association, Vol. 68, pp. 379-383, 1973.

"Compariability of Nine Methods for Moitoring NO_2 in Ambient Air," with C. A. Clayton, Environmental Monitoring Series, EPA-650/4-74-012, 1974.

"Head and Spinal Cord Injury: A Pilot Study of Morbidity Survey Procedures," with W. D. Kalsbeek, submitted to American Journal of Public Health, 1976.

"Estimating Morbidity Trends by Means of a Source Panel Design," with W. D. Kalsbeek. Paper presented at 104th Annual Meeting of the American Public Health Association, Miami Beach, Florida, October, 1976.

"Investigation of the Role of Multihearth Roaster Operations in Copper Smelter Gas Blended Schemes for Control of SO_2," with B. H. Carpenter and K. J. C. Smith, submitted to Environmental Science and Technology, 1976.

"Preliminary Analysis of Nonradiological Environmental Data at the Zion Nuclear Power Plant," Research Triangle Institute, Research Triangle Park, North Carolina, 1976.

"Design, Data Collection and Analysis of a Field Test of Instruments and Procedures to Measure English Language Proficiency," Research Triangle Institute, Research Triangle Park, North Carolina, 1976.

"Examining the Properties of Qualified Observer Opacity Readings Averaged Over Intervals of Less Than Six Minutes," Research Triangle Institute, Research Triangle Park, North Carolina, 1976.

"An Experimental Evaluation of Three Training Methods Designed to Help Company Level Army Leaders Reduce the Incidence of Social Problems in Their Units," Research Triangle Institute, Research Triangle Park, North Carolina, 1975.

"The Role of Company Level Leadership in Preventing Drug Abuse in the Army," Research Triangle Institute, Research Triangle Park, North Carolina, 1974.

"Review of Methods of Estimating Number of Narcotic Addicts," Research Triangle Institute, Research Triangle Park, North Carolina 1975.

"Trends in Registered Nurse Supply," Research Triangle Institute, Research Triangle Park, North Carolina, 1975.

"Relationship of Criminal Behavior and Drug Abuse: Phase I: The Identification, Evaluation, and Possible Utilization of Available Data Sets," Research Triangle Institute, Research Triangle Park, North Carolina, 1975.

"Examination of the Relationships Between Atmospheric Oxidant and Various Pollutant and Meteorological Variables," Research Triangle Institute, Research Triangle Park, North Carolina, 1975.

"Investigation of Motion Control and Fiber Lab Instrument Performance in Determining the Characteristics of Cotton Samples," Research Triangle Institute, Research Triangle Park, North Carolina, 1972.

"Evaluation of Sampling Plans which Determine the Characteristics of a Bale of Cotton," Research Triangle Institute, Research Triangle Park, North Carolina, 1972.

"Effects of Nitrogen Oxide Levels on Health Characterisitcs of Persons in Chattanooga, Tennessee," Research Triangle Institute, Research Triangle Park, North Carolina, 1973.

"Ten Year Projections of U.S. Manpower Requirements for Short-Term General Hospitals in Five Personnel Categories, Research Triangle Institute, Research Triangle Park, North Carolina, 1973.

"Estimation of Annual Ingestion of Strontium-90 from Two Diets in Selected Segments of the U.S. Population," Research Triangle Institute, Research Triangle Park, North Carolina, 1966.

"Advanced Studies of Stochastic Processes: Power Spectral Analysis in Non-Stationary Models," Research Triangle Institute, Research Triangle Park, North Carolina, 1967.

"Methodology for Assessing the Harzards of Electromagnetic Radiation to Ordinance: Statistical Tolerance Limit Calculations With and Without Censoring of the Data," Research Triangle Institute, Research Triangle Park, North Carolina, 1968.

LOIS D. BRESSLER, Programmer

Professional Experience

1969 to date. Research Triangle Institute, Research Triangle Park, North Carolina 27709. Programmer, Computer Applications Center. IBM 370/165 OS, FORTRAN, and statistical package programs.

1967-1969. General Telephone Company of the Southeast, Durham North Carolina. Programmer and systems programmer. IBM 360/30 and 40 DOS, PL/I and Assembler Language, billing applications and systems programming.

Education

B.A., Mathematics, University of North Carolina, Asheville, North Carolina, 1966.

Graduate work in linguistics and computer science, University of North Carolina, Chapel Hill, North Carolina, 1970-1972.

Selected Publications

Improved Exposure Measurements. S. B. White, C. A. Clayton and L. D. Bressler. Prepared for U.S. Department of Transportation, National Highway Traffic Safety Administration, Washington, D.C., September 1975.

North Carolina Educational Policy Plans for the 1970's. Alvin M. Cruze, Stephen A. Johnston and Lois A. Bressler. Prepared for North Carolina Department of Administration, Raleigh, N.C., April 1974.

January 1976

APPENDIX 4.2

REFERENCES

REFERENCES

4.1. Triangle Universities Computation Center (TUCC), *Memorandum: TUCC Security Features* (General Information Series Document No. GI-066-1). Research Triangle Park, North Carolina: TUCC, February 1976.

4.2. Sarhan and Greenberg, Contributions to Order Statistics. New York: John Wiley & Sons, Inc., 1962.

4.3. Cochran, W. G. and G. M. Cox, Experimental Designs. New York: John Wiley & Sons, Inc., 1962.

4.4. Service, J., A User's Guide to the Statistical Analysis System (SAS). Raleigh: North Carolina State University, 1972.

5.0 Cost and Labor Projections

Cumulative projected costs (exclusive of fee) and monthly direct labor charges for this study have been estimated and are shown graphically in Figures 5.1 through 5.6.

Figure 5.1 shows cost and labor projections for the sampling design phase of this work. Figure 5.2 shows the same information for field operations and is identical to Figure 2.9 on page 2-47. Figure 5.3 gives cost and labor estimates for the field supervision activities at the smelter sites. Included in these projections are costs for sample shipment to RTI. These estimates assume the pretest study will take place during March 1977 and that the final smelter will be sampled during November 1977. Figure 5.4 shows the projections for chemical analysis. An essentially constant monthly level of effort is projected for this work area. Figures 5.6 gives the monthly statistical analysis projections and shows an increased effort during the data evaluation phase of the study. Figure 5.6 shows the comparative monthly costs (exclusive of fee) for each of the 5 work areas. The projected costs are based on the same estimates used in constructing Figures 5.1 through Figures 5.5.

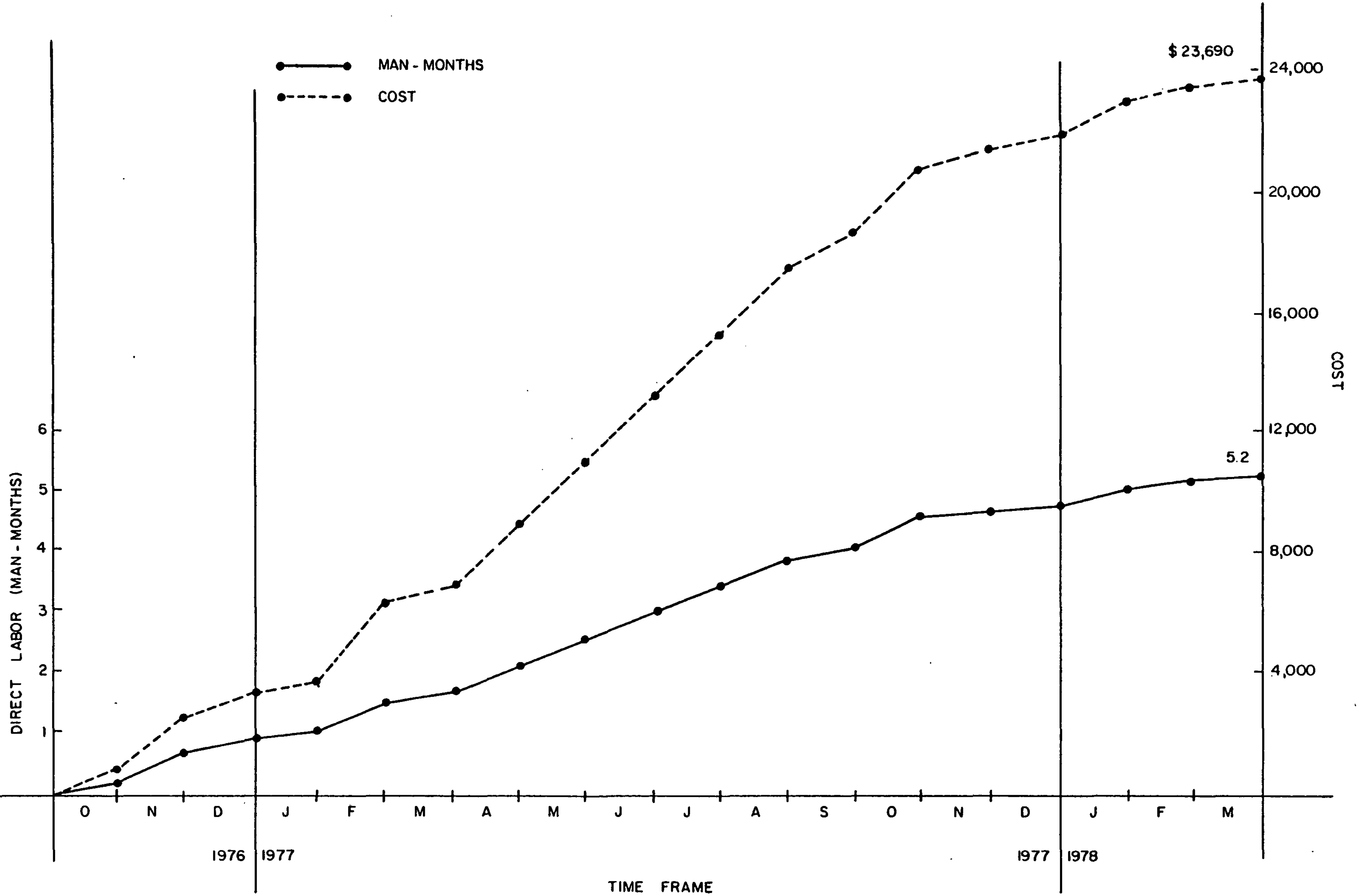


Fig. 5.1. Sampling design cost and labor-hour projections.

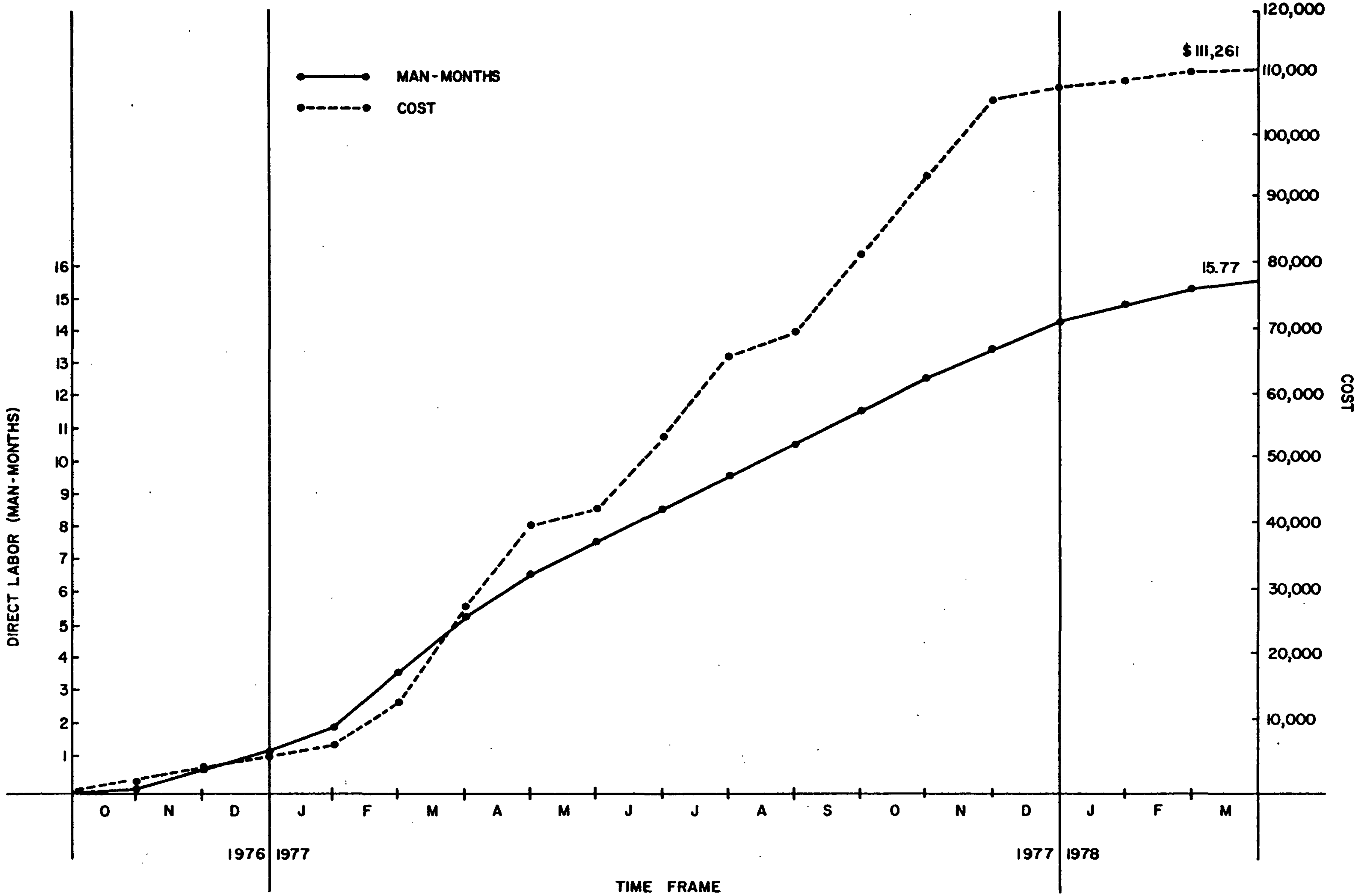


Fig. 5. 2. Field operations cost and labor-hour projections.

3-10-77

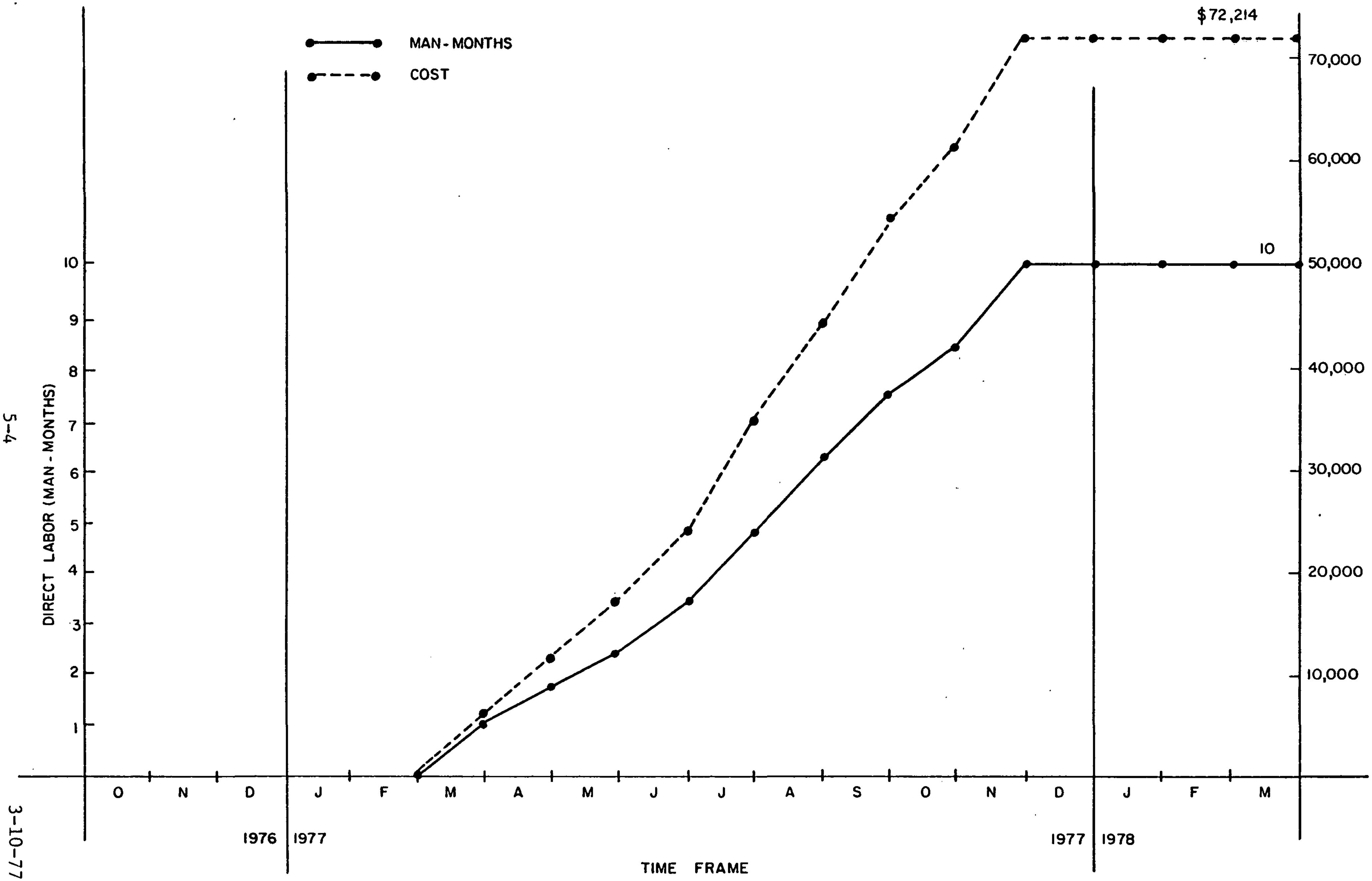


Fig. 5.3 Field supervision and shipping costs and labor-hour projections

3-10-77

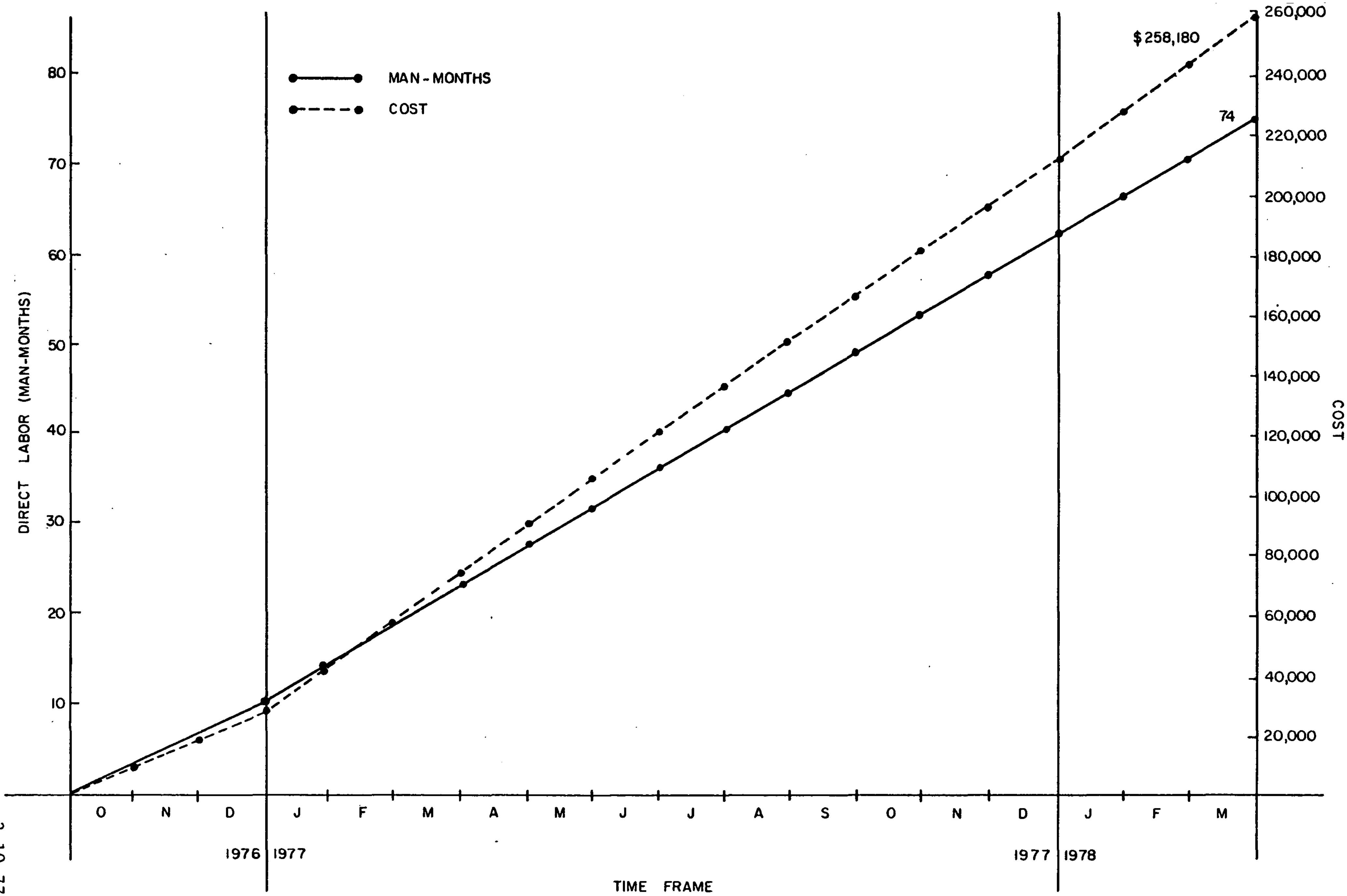


Fig. 5-4. Chemical analysis cost and labor-hour projections.

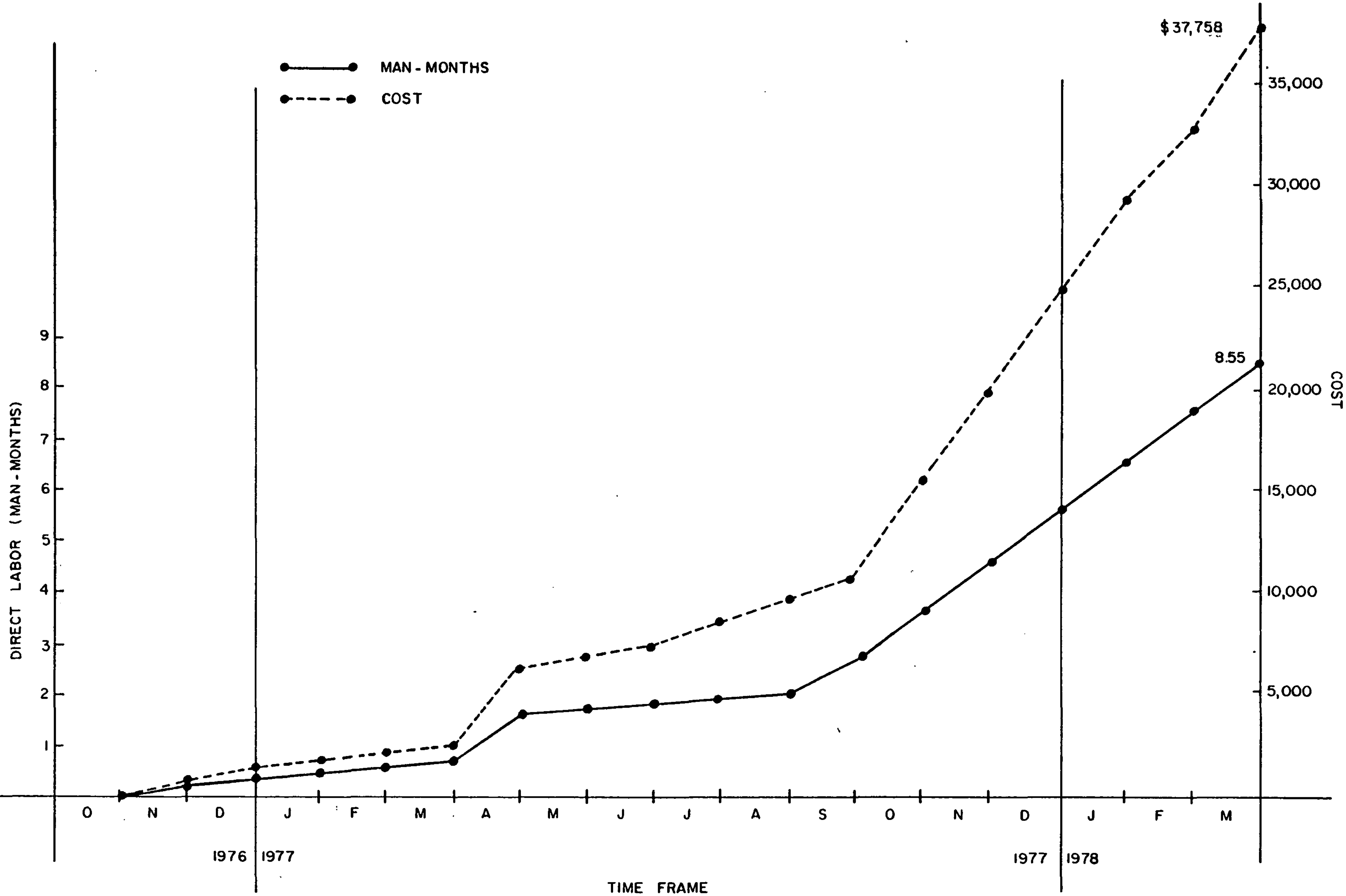


Fig. 5.5. Statistical analysis cost and labor-hour projections.

3-10-77

5-7

3-10-77

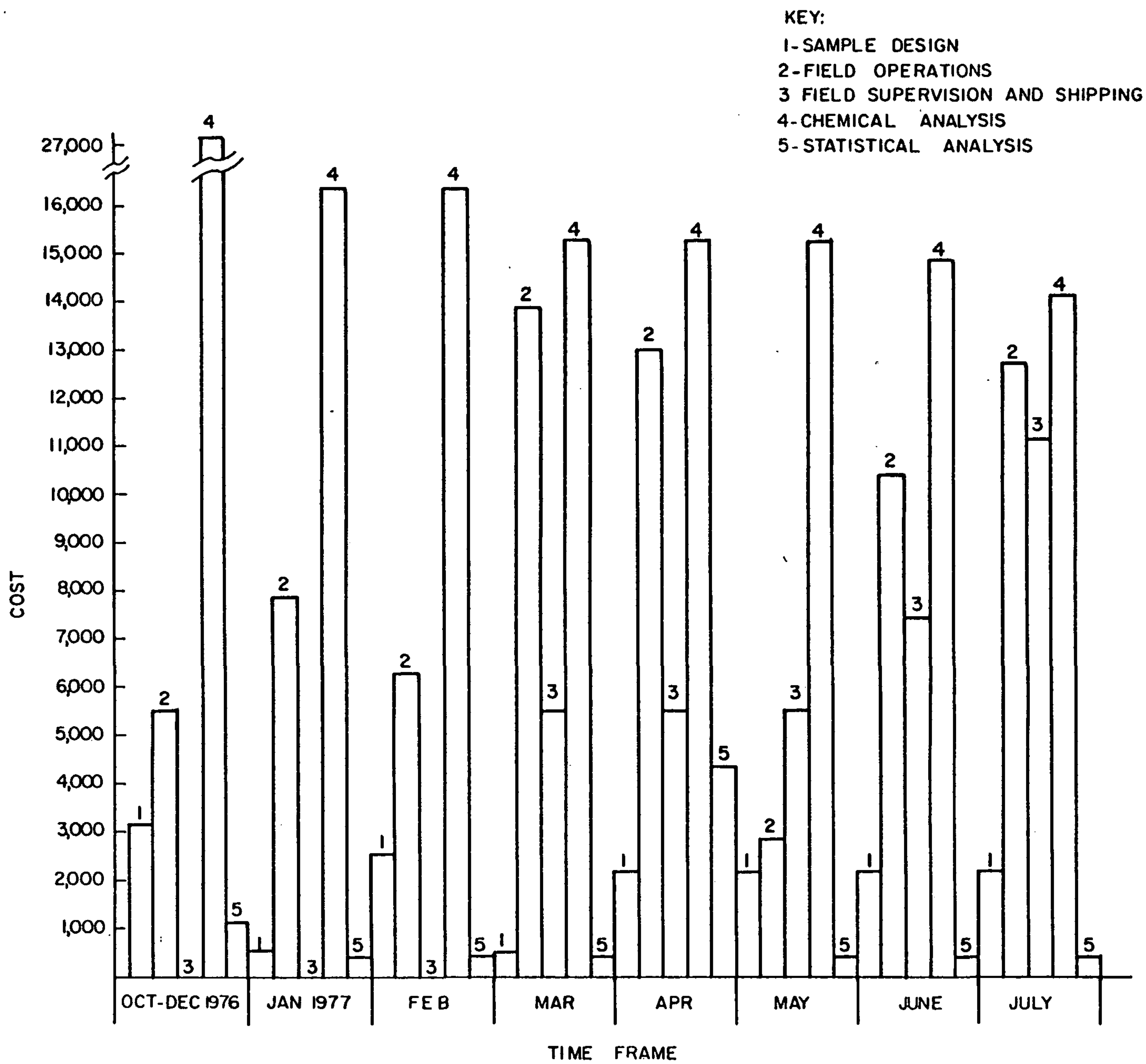


Fig. 5. 6. Projected monthly costs by activity.

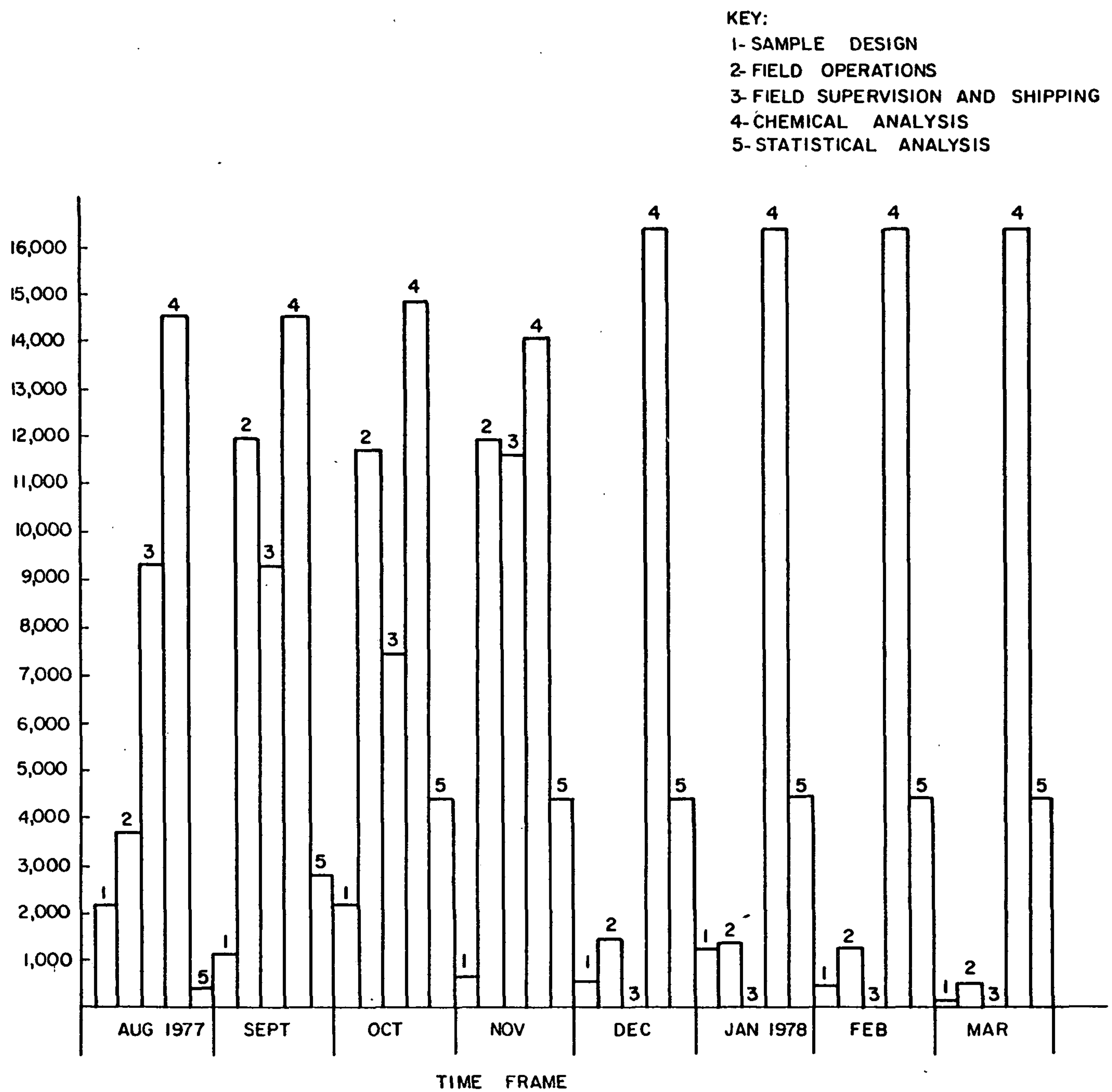


Fig. 5-6. (Cont'd). Projected monthly costs by activity