Public Comment Release

Testing for Beryllium Sensitization,

A Community Service in Elmore, OH

March 31, 2006

Agency for Toxic Substances and Disease Registry
U.S. Department of Health and Human Services
Atlanta, Georgia 30333

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APPENDICES

1.0 PLAN OVERVIEW

1.1 Summary

The purpose of this community service is to provide an opportunity for individuals who want to be tested for immune sensitivity to beryllium (Be). This opportunity will be limited to concerned individuals who live within 1 ¼ miles from the Brush-Wellman facility in Elmore, Ohio (the facility), household contacts of workers at this facility, employees of local machine shops that contract to machine beryllium alloys and their household contacts, and individuals diagnosed with sarcoidosis. Up to 200 people who express interest and volunteer will be offered this opportunity for testing.

The processing facility in Elmore was built in 1953 to produce beryllium metal and beryllium alloys. During the 1990's, this facility released up to 1100 pounds of beryllium per year to the ambient air.[1] After beryllium metal extraction ended in 2000, the amount released annually declined significantly. While current releases to the ambient air are not considered hazardous, little is known about the fate of beryllium that was:

a) released to the air and deposited since 1953;

b) incidentally taken home by the facility's beryllium workers; or,

c) incidentally taken home by workers at machine shops contracting with the facility to machine beryllium alloys.

Beryllium exposure in the workplace is known to be a human health hazard. Inhaled beryllium is deposited in the lungs and can lead to immunologic sensitization (BeS) among susceptible individuals. Some people who are sensitized can progress to chronic beryllium disease (CBD). Physicians may diagnose individuals without known occupational exposure to beryllium as "sarcoidosis," a granulomatous disease process that resembles CBD. Using the beryllium lymphocyte proliferation test (BeLPT),[2] CBD can be distinguished from "sarcoidosis."

1.2 Definitions

In this plan, the term *facility* refers to the Brush Wellman facility in Elmore, OH. The terms *beryllium exposure, exposure*, and *exposure potential* are used interchangeably. For efficiency in characterizing exposure potential, the present tense terms *live, work*, and *share* are equivalent to and include the past tense forms *lived, worked*, or *shared.* The term *sensitized* always implies immunologic sensitization to beryllium, whether the final diagnosis is BeS or CBD.

A number of descriptive phrases are used to simplify the plan presented here. Some are general definitions and some apply only to this testing plan.

Please refer to these definitions as needed throughout the text.

BeLPT –the beryllium lymphocyte proliferation test;

beryllium-related health effects – changes in health status that may occur after exposure to beryllium, including --

a) beryllium sensitivity *(BeS),* and,

b) chronic beryllium disease *(CBD);*

Elmore area - the area less than 15 miles from site boundary (Appendix J.2);

false negative BeLPT – a normal test result for a person who is *sensitized*;

false positive BeLP – an abnormal test result for a person who is *not sensitized*;

household contacts - individuals who live with a *beryllium worker;*

local machinists – in this plan, refers to current or former employees of the local machine shops that contract to machine beryllium alloys;

near the site – the area 1.25 mi from site boundary, or less (Appendix J.1);

The processing facility has an established health and safety program to protect their workers. As part of this program, current employees are tested periodically for sensitivity to beryllium. Past employees of the facility may qualify for the ongoing NIOSH study of current and former facility workers.[3]

The household contacts of the facility's workers are eligible, as are the household contacts of workers at the local machine shops that contract to machine beryllium alloys.

1.3 Personnel

The table below lists the primary project personnel.

Table 1. Personnel and Affiliations

Name	ATSDR Division* / Role
Dan Middleton, MD, MPH	DHS / Plan Leader
Peter Kowalski, MPH, CIH	DHAC / Plan Co-Leader
Loretta Bush, BS	DHAC / Communications
Jennifer Fink, MPH	DHS / Telephone Interviews
Robin Lee, MPH	DHS / Informed Consent
Carolyn Harris	DHS / Project Officer
Steve Inserra, MPH	DHS / Mapping and Eligibility
Alden Henderson, PhD, MPH	DHS / Implementation

* DHS is the ATSDR Division of Health Studies.
* DHAC is the ATSDR Division of Health Assessment and Consultation.

Contractor: the *Michigan Public Health Institute (MPHI)* will assist with certain aspects of this project (see timeline).

2.0 INTRODUCTION

2.1 Background Science

2.1.1 Mechanical Properties of Beryllium

Beryllium is lighter than aluminum, stiffer than steel, and dimensionally stable over a wide range of temperatures. These characteristics make it an important structural material in space technology,[4] finding applications in the windshield frames of space vehicles, brakes on the shuttle aircraft, satellite mirrors, space telescopes, and inertial guidance systems. Beryllium metal is also used as a reflector in nuclear reactors and to make certain components of nuclear weapons.

Beryllium is alloyed with copper, nickel, aluminum, and magnesium. The useful attributes of beryllium alloys are related to strength, hardness, fatigue and corrosion resistance, and electrical and thermal conductivity. For example, beryllium is alloyed with copper to make electrical contacts, non-sparking tools, springs, switches, golf clubs, bicycle frames, and dental prostheses.

Beryllium oxide (BeO) is used to make ceramics.[4] BeO is an excellent heat conductor and a good electrical insulator, making it useful in closely packed electronic devices. Because it is transparent to microwaves, it can also be used in microwave ovens.

Beryllium also forms water-soluble salts with flouride, chloride, and sulfate ions. These salts are useful catalysts in certain chemical reactions and have a role in glass manufacture.[4] Enthusiasm for this important metal is tempered by an appreciation of the association between exposure to its respirable forms (particles, dusts, fumes) and a potentially fatal lung disease (CBD).[5]

2.1.1 Granulomatous Lung Diseases (GLD)

Granulomatous lung diseases result from infectious etiologies (e.g., bacterial, fungal, viral, or helminthes), and from non-infectious etiologies (e.g., exposure to beryllium, coal dust, or silica). For some granulomatous diseases, the etiology has not yet been established (e.g., sarcoidosis, amyloidosis).

CBD and sarcoidosis are clinically similar. Indeed, sarcoidosis may be a group of disease processes with similar clinical presentations, but different etiologies and prognoses. As a diagnosis of exclusion, the term sarcoidosis does little to help establish etiology, select appropriate interventions, or determine prognosis.

If sarcoidosis is diagnosed without excluding CBD, then CBD remains a potential etiology.[6] Making the diagnosis of CBD identifies the exposure and helps to guide appropriate medical and exposure interventions for the patient. It may also protect others by calling attention to the outcome as a *sentinel health event.*

2.1.2 History of CBD in the United States

The symptoms of CBD include arthralgias, chest pain, cough, or dyspnea with relatively mild exertion. Physical examination may reveal hepatosplenomegaly, inspiratory rales, and lymphadenopathy. These findings are not very specific and CBD cannot be reliably distinguished from sarcoidosis by clinical findings alone.[6]

The first CBD cases at a fluorescent lamp manufacturer in Salem, MA (1930's) were initially misdiagnosed as sarcoidosis, creating what was thought at the time to be an "epidemic of sarcoidosis." *Berylliosis* (now called CBD) was recognized as a disease in the United States in the mid-1940's.[7]

The U.S. Beryllium Case Registry was established in 1952.[8] Because modern tests were not available, admission to the Beryllium Case Registry required documentation of *exposure,* plus at least three of four specified *clinicopathologic criteria* (see the table that follows).

Clinicopathologic Criteria for the U.S. Beryllium Case Registry *

1. Clinical symptoms of a lower respiratory tract disorder
2. Reticulonodular infiltrates on chest radiography
3. Restrictive or obstructive impairment of pulmonary function or a depressed diffusing capacity for carbon monoxide
4. Histologic demonstration of noncaseating granulomas and/or mononuclear cell interstitial infiltrates on lung biopsy specimens

** These criteria were used from 1952 to 1970. The Beryllium Case Registry is closed.*

The Beryllium Case Registry grew to include approximately 900 cases. Newman et al. reviewed the registry cases and concluded that the clinical presentation and rate of disease progression varied, the benefit of interrupting the exposure pathway had not been demonstrated, and the effects of potential risk factors were unknown.[5]

Sixty-five of the cases in the Beryllium Case Registry were associated with environmental exposures: 23 people were exposed in their residence to contaminated work clothes brought home by beryllium workers and 42 people were exposed to off-site air pollution.[6] These environmental cases were reported prior to 1960.

CBD was thought to have disappeared with improvements in industrial hygiene practices, but modern immunologic testing with the BeLPT demonstrated that exposed workers are still at risk for CBD. BeLPT testing has only rarely been extended to the communities nearby.

2.2 Modern Diagnostic Tests

Granulomatous lung disease is most clearly demonstrated when a biopsy specimen collected during bronchoscopy reveals granuloma formation, or (minimally) a mononuclear cell infiltration.[9] Lavage fluid collected during the bronchoscopy typically reveals a lymphocytosis.

The beryllium lymphocyte proliferation test (BeLPT) was developed to identify individuals who were *sensitized to beryllium.* In general terms, the BeLPT is performed by culturing T-lymphocytes from peripheral blood or bronchoalveolar (lung) fluid with and without beryllium salts. The proliferative response of lymphocytes stimulated by beryllium is compared to that of unstimulated lymphocytes, based on their uptake of tritiated thymidine.

The ratio of the response of stimulated lymphocytes to that of unstimulated lymphocytes is called the stimulation index (SI). Two elevated indices out of six are reported as an *"abnormal"* BeLPT test result; if only one of the six indices is elevated, the result is reported as a "borderline" BeLPT test result. A second abnormal BeLPT test result provides confirmation of sensitization *(BeS).* [10] Current medical practice also accepts one "abnormal" and one "borderline" as sufficient confirmation of sensitization. [11]

Researchers have assessed the value of various clinical tests used to identify beryllium disease.[12, 13] The predictive value of the BeLPT was higher than the chest radiograph, spirometry results, symptom reports, and clinical examination results. There was some evidence that abnormalities in gas exchange during exercise occur early in CBD, but the tests were more intrusive and less acceptable for screening. The thin-section CT was found to be more sensitive than plain chest radiographs, but delivered more radiation and missed approximately 25% of CBD cases.

The BeLPT has changed the diagnostic criteria for CBD. Documented exposure to beryllium is less important; the diagnosis of CBD currently depends on demonstrating both a g*ranulomatous lung disease* and *immunologic sensitization to beryllium*. [13, 14] In a study of exposed workers, a confirmed positive BeLPT had a positive predictive value for CBD of almost 50%.[15]

Beryllium sensitization can be established by testing lymphocytes from the peripheral blood or fluid from bronchoalveolar lavage. A negative blood test does not exclude the possibility of beryllium sensitization – false negative test results are not uncommon. While bronchoalveolar lymphocytes provide greater sensitivity,[12,13] they must be collected during a bronchoscopy, which is not part of this community service.

2.3 Justification

The 2002 ATSDR Health Consultation concluded that current releases from the facility did not threaten public health. Because ATSDR could not fully determine whether past beryllium releases presented a threat to public health, some community members may continue to be concerned about beryllium exposure.

2.3.1 Exposure

Testing for beryllium sensitization will be offered to up to 200 people who wish to be screened. Because resources are limited testing will be offered to those individuals most likely to benefit based on potential exposure scenarios.

Individuals could have been exposed to beryllium that left the facility over a period of decades in the following ways:

a) as airborne releases,

b) as beryllium alloys sent to be machined locally, or

c) incidentally, on the clothes of beryllium workers.

There are a number of factors that may influence the risk of sensitization, including exposure levels, particle size, time since first exposure, and individual susceptibility. During the 1940s, ten environmental (non-occupational) cases of chronic beryllium disease were identified and attributed to ambient air pollution from a local beryllium plant in Lorain, Ohio.[16] The furthest case detected by chest radiograph lived 0.75 mile from the beryllium plant.

While current exposures are lower, our ability to detect sensitization and early disease is much better. When the BeLPT was offered in modern occupational settings with less potential for exposure, investigators were surprised to find cases of beryllium sensitivity and CBD.

2.3.2 Current Medical Practice

When a primary care physician encounters a patient with a granulomatous lung disease, a pulmonary physician is typically consulted to search for the etiology. If no etiology is found and the clinical picture fits, the diagnosis of "sarcoidosis" is usually made. Because there is no specific test for sarcoidosis, the diagnosis depends on adequately excluding the other possible explanations.[16] In the absence of known occupational exposure, CBD is typically not considered in the differential diagnosis. The first CBD cases in the United States were initially thought to be sarcoidosis, creating what was believed to be an "epidemic of sarcoidosis." There is evidence in the peer reviewed literature that clinicians have continued to miss cases of CBD, typically mislabeling them as sarcoidosis.[17]

2.3.3 Identifying Beryllium Sensitization and Disease

A reliable test (*the BeLPT*) is now available to identify individuals who have become *sensitized to beryllium (BeS*). The predictive value of a positive (abnormal) result (PPV) is an important parameter for any test. Stange et al. [2004] recently reviewed screening data for a large cohort of current and former Department of Energy (DOE) workers. They concluded that "...the BeLPT is efficacious in the surveillance of beryllium exposed individuals. The PPV of the BeLPT is comparable to other widely accepted tests." [18] This is especially true of confirmed abnormal results.[19]

As is current medical practice, abnormal tests will be confirmed by additional testing before identifying the participant as sensitized to beryllium. Immunologic sensitization is not equivalent to lung disease, which requires both *immunologic sensitization to beryllium* and the presence of *granulomatous lung disease*. [12, 13]

2.3.4 Benefits of Participation

This screening plan provides testing to individuals who are concerned that past exposures may have caused them to become sensitized to beryllium. This testing should provide some reassurance to participants with normal test results. Individuals with confirmed abnormal results test will be asked to see their physicians for follow-up.

While sarcoidosis is considered a medical diagnosis, it is more accurately described as a family of similar granulomatous lung diseases. The BeLPT has enabled us to reliably diagnose CBD, which is a more specific and more informative diagnosis than sarcoidosis.[13] For example, the diagnosis of CBD tells the physician that:

a) exposure to beryllium caused the disease,

b) the disease is progressive [20],

c) the disease is unlikely to spontaneously resolve (sarcoidosis often does), and,

d) a need for oral steroids probably implies lifetime therapy.

A specific diagnosis (CBD) also reinforces the need for long term medical follow-up. As with other serious lung diseases, patients can get preferential treatment for vaccinations against influenza and pneumonia and can be identified for early and aggressive interventions during respiratory infections. Knowing the etiology makes it possible to review potential exposure pathways and consider ways to separate the individual from exposure to beryllium. BeS and CBD result from immunologic hypersensitivity, which makes interruption of the exposure pathway an especially important public health intervention. The hypersensitivity mechanism is so variable among individuals that is also difficult to establish a "safe" exposure level for susceptible persons.

2.4 Design and Location

This community service activity will provide testing for up to 200 people who are concerned that their past exposures may have resulted in sensitization to Be. Facility employees are regularly tested for beryllium sensitivity and will not be included. However, household contacts of facility workers who are concerned about beryllium "take home" can be tested.

Because the machine shops that contract for beryllium work do not screen their workers for sensitivity to beryllium, these local machine shop employees and their household contacts are eligible to be tested. Sarcoidosis patients who are concerned about beryllium sensitivity and live in the Elmore area will also be offered testing.

2. 5 Activities

The goal of this activity is to provide an opportunity for up to 200 community members who are concerned about past exposures to be tested for Be sensitization. Those thought to benefit most from testing are listed on page 18 in Table 1.

2.5.1 Activity 1. Inform community members previously diagnosed with sarcoidosis about the availability of testing. The following actions support "Activity 1."

a) Obtain a list of local and referral physicians and ask them to inform their sarcoidosis patients of the opportunity for testing (see Appendix A).

b) Inform area sarcoidosis patients of this opportunity for testing through media outreach (radio "spots" and newspaper ads).

2.5.2 Activity 2. Inform household contacts of facility workers, contract machine shop workers and their household contacts, and those living within 1 ¼ mile of the plant about the availability of testing. The following *actions* support "Activity 2."

a) direct mailings to nearby residents with factsheets enclosed;

b) a media outreach program, and,

c) factsheets distributed at local machine shops.

2.5.3 Activity 3. Identify the first 200 volunteers who wish to be tested and fall into at least one of the four categories of interest. The following *actions* support "Activity 3."

a) conduct a brief telephone interview with interested individuals, and,

b) determine their eligibility to be tested.

These tasks will be performed by ATSDR staff.

2.5.4 Activity 4. Test eligible volunteers for beryllium sensitivity and interpret the test results. The following *actions* support "Activity 4."

a) Obtain informed consent and signed physician notification forms for the persons to be tested (Appendices D, E).

b) Collect and test blood specimens from eligible participants identified during Activities 1 and 2.

c) Notify participants and their physicians (as authorized) of test results.

Those with normal results on the first BeLPT will receive their final results.

We will arrange a second round of BeLPT testing for patients who need additional (confirmatory) testing. The outcomes for those who need confirmatory testing will be either:

1) *not confirmed sensitized* to Be (includes an abnormal or borderline);

2) *confirmed sensitized* to Be (an abnormal ***plus*** another abnormal or borderline test result).

We will recommend that those confirmed as sensitized to beryllium should consult their personal physician to find out if they have *BeS* or *CBD.* Medical diagnoses can only be made by the individual's personal physician.

2.6 Purpose

This public health activity will provide testing to individuals who are concerned about their exposure to beryllium. It may also provide useful information to the community.

3.0 METHODS

This is a *voluntary testing program.* Outreach efforts will provide opportunities for self-identification. A brief questionnaire will determine eligibility.

Current plans are to obtain informed consent and draw blood specimens at the testing center and (in rare cases) at the participant's home. If the machine shops permit and adequate space is available, we may be able to draw blood samples from the machinists at their workplace.

The tasks performed by the contractor will include scheduling, drawing and labeling blood samples, and shipping blood samples overnight to the testing laboratory or laboratories.

3.1. Biomedical Screening

ATSDR personnel have met with the community and proposed an environmental investigation. Environmental sampling for Be is not currently planned. Instead, ATSDR will offer testing to people who are concerned about past exposures to beryllium.

ATSDR will conduct an availability session in Elmore, Ohio during the 30-day period that this protocol is available for review. The availability session will provide community members an opportunity to ask questions about the proposed testing.

3.1.1 Outreach

We are planning an availability session with the community during April. This toll free line will be open during the time periods for public comment, volunteering, testing, notification of results -- and for one month afterwards.

Outreach will also include:

a) sending letters and factsheets to local doctors, asking them to inform sarcoidosis patients about this opportunity to be tested;

b) sending letters and factsheets to people who live near the facility;

c) visiting local machine shops that contract to machine beryllium alloys to inform owners and workers about the testing; and,

d) media outreach, including placing ads in local newspapers and radio “spots” to inform the public about the testing.

We will answer questions and complete eligibility questionnaires for callers. Most callers will be informed of their eligibility status after completing the telephone interview.

Eligible persons who wish to be tested will be contacted by telephone to schedule a time to sign consent forms (Appendix D) and physician notification forms (Appendix E), as well as to provide blood specimens.

3.1.2 Collecting, Handling, and Shipping Specimens

During the first round of testing, blood specimens (30 cc) will be collected and promptly shipped by overnight carrier to the National Jewish Hospital's Immunology Laboratory (see Appendix H).

A second laboratory that performs the BeLPT will be selected. For participants who need confirmatory testing, a second blood specimen (60 cc) will be collected, split into two samples, and promptly shipped to the two testing laboratories in accordance with their specified procedures.

3.1.3 Interpreting Test Results

Researchers at the National Jewish Hospital in Denver, CO, did not find a single confirmed false positive among over 1000 unexposed individuals. They have stated in the public record that confirmed false positives occur *"rarely, if ever."* [21]

These results are consistent with the recent study by Stange et al. who found no *confirmed* abnormal results among 458 *unexposed* employees and new hires.[18] Further analysis of the information published by Stange et al. confirmed the low risk for false positive confirmation.[19] These results provide ample evidence of the specificity of a confirmed abnormal BeLPT.

A flow chart for interpreting BeLPT results is in Appendix K. A confirmed abnormal BeLPT will be considered sufficient evidence of beryllium sensitization to support encouraging the participant to seek medical evaluation by a pulmonologist experienced in diagnosing and treating beryllium disease. Clinical disease diagnoses will *not* be made or altered by the ATSDR project personnel.

For participants who agree and complete the authorization forms, the individual BeLPT test results will be shared with their personal physicians. We will recommend that participants with confirmed abnormal results seek evaluation by a pulmonologist experienced in caring for patients with beryllium-related health effects.

The participant's doctor is responsible for planning the individual's clinical evaluation, making any appropriate diagnoses, and recommending clinical follow-up and treatment as needed. ATSDR will not pay for any follow-up medical evaluations.

3.2 CURRENT TIMELINE -- CALENDAR YEAR

1st Quarter 2006

- ► Brief the Senator's office/DHHS/County Commissioners (March 24)
- ► Release the Protocol for Public Comment (March 31)
- ► Hold Press conference and availability meeting (April 25)
- ► Mail letters to physicians and residents (April)

2nd Quarter

- ► Begin Media outreach and open toll free call line for volunteers in May
- ► Computerize the information on volunteers (May)
- ► Finalize the protocol based on public comments (May)
- ► Brief Senator and Ottawa County Commissioners (May/June)
- ► Notify and schedule eligible participants – **Contractor** (May/June)
- ► Begin actual testing and collect blood samples - **Contractor** (June)

3rd Quarter

- ► Provide results and cover letters to those tested and their doctors (July)
- ► Collect additional samples to confirm sensitization – **Contractor** (July)
- ► Provide BeLPT results to participants that required retesting (August)
- ► Provide BeLPT retest results to doctors as requested (August)

4th Quarter

- ► Write the community report (Aug)
- ► Obtain ATSDR clearance for community report (September)
- ► Meet with the community (September)

4.0 POPULATION

4.1 Eligibility Criteria

Please refer to *1.1.1 (Definitions),* and Appendices I and J.

The individuals to be tested will come from the population of people who lived or worked in the Elmore, Ohio area but are not current or former employees of the beryllium processing facility. Participants must be adults (18 years of age or more), as normal values are not available for children.

The criteria for testing are based on either a clear potential for exposure to beryllium, or the presence of a granulomatous disease that is clinically similar to CBD. That is, eligibility for testing depends on the following:

1. ***Exposure-based Criteria*** – the individual has *(for at least 1 year)* ...

   a) lived or worked near the facility;

OR,

   b) worked at one of the local shops that machine beryllium alloys;

OR,

   c) shared a household with a beryllium worker *(a worker at the facility, or from a local machine shop contracting to work on beryllium alloys).*

2. ***Disease-based Criteria*** --a physician has diagnosed granulomatous lung disease without a clear etiology (sarcoidosis) AND prior to diagnosis:

   a) the individual met one of the Exposure-based Criteria ("1" above),

OR,

   b) lived or worked in the Elmore area *for at least 1 year.*

4.2 Estimated Number of Participants

ATSDR resources are available to test up to 200 people.

There are almost 70,000 adults (age 18 years or more) living within 15 miles of Elmore, Ohio (Appendix I). Using a prevalence estimate of 30 sarcoidosis diagnoses per 100,000 people, about 20 individuals with "sarcoidosis" are expected to live within 15 miles of the facility.

The machine shop located in Elmore, a shop that has worked extensively with beryllium alloys, has about 10 employees. We will offer testing there and at another machine shop in the area with similar exposure potential. Adult household contacts of workers from these machine shops or the facility are also eligible to be tested.

"*Nearby*" residents are adults who a) are 18 years or older; and, b) live within 1.25 miles of the facility. There are 130 adults living within 1 mile, and we estimate that about 200 live within 1.25 miles. The background data needed to interpret BeLPT test results are not available for children.

Table 1

Category	Estimated Numbers (Adults) *(n)*
Sarcoidosis Cases	20
Machine Shop Employees	20
Adult Household Contacts of...	
Local Machinists	40
Facility Workers	*Unknown*
Nearby Adult Residents	~200

ATSDR does not know how many people will be interested in being tested but is able to test up to 200. As a community service project, the first 200 people from these categories who express interest in being tested and are eligible will be tested.

5.0 HUMAN SUBJECTS

Volunteers will come from the adult population, regardless of gender, race, or ethnicity. The BeLPT has been used primarily for adult workers and there is no reason to believe that it will function differently among adult community members who are eligible to be tested.

People with cognitive difficulties can also participate if their "legally authorized

representative" (typically a spouse or parent) consents and can provide screening information for the participant.

5.1 Description of Risks and Benefits

We expect the risks for participation to be low. Blood collection (30 cc) could result in a small bruise. If follow-up testing is necessary, the follow-up blood collection will be 60 cc. It is also possible that people could faint, but this is uncommon and the nurse or phlebotomist will have an established response plan for such situations.

The questions on the survey are not expected to cause the participants emotional discomfort. Participants may refuse to answer questions they do not want to answer.

All participants who provide a blood sample will receive a letter providing the results of their BeLPT blood test. If the initial BeLPT result is an abnormal or a borderline abnormal result, the participant will be notified by *phone* and by *registered letter*. A second round of testing will be offered (Appendix K). For uninterpretable results, the participant will be offered the opportunity to repeat the testing.

This is a voluntary testing program. No money is available for testing beyond that described above. All participants with a confirmed positive BeLPT will be advised to contact their personal physician and to arrange follow-up with a pulmonary physician familiar with beryllium-related disease.

Individuals will be responsible for the cost of their own follow-up medical care. No money is available for any follow-up medical care that is recommended.

5.2 Procedures for Informed Consent

This testing is offered as a clinical service to the community. It involves no more than minimal risk to participants. A written consent form is not needed to participate in the telephone interview. Informed consent will be obtained for blood collection and BeLPT testing.

ATSDR personnel will be available during the testing period to answer any questions about what to expect, the risk, and the potential benefits to the best of their ability. After those who wish to be tested sign the consent form, ATSDR will collect the form and the contractor will collect the blood specimen for testing.

An unsigned consent form will be given to the person tested. In some circumstances, the informed consent procedure, the interview, and the blood collection may occur at the participant's home or another location. This will occur if the participant is unable to come to the collection site or prefers to provide the blood specimen at another location.

Given the various expectations of this blood screening the investigators would like to confirm that participants have the same expectations as the investigators. To ensure persons who consented to have their blood tested are aware of the objectives of the program each person will be asked if they are willing to answer a few questions on the blood screening and material written in the consent form. The questions they will be asked are included in Appendix L. If there are elements not understood the personnel administering the consent form will go over the item(s) with the subject to confirm comprehension and expectations of the blood screening.

5.3 Protection of Confidentiality

5.3.1 Protections

Each participant will receive a unique identifying number. The survey and consent materials include names, addresses, and telephone numbers; these documents will be kept in a locked file cabinet by ATSDR. Responses to the survey will be entered into an electronic database.

Blood samples that are sent to the laboratory will be labeled with an identification number, but not with personal identifiers. Results from the laboratory will also be entered into the electronic database. Access to any electronic file containing identifying data will be password protected and restricted to personnel affiliated with the testing program.

The results may be published in a written report, or published in a scientific journal. Individual cases may be described, but no personal identifiers will be included and care will be taken to protect the identity of participants.

5.3.2 Exceptions

Other federal, state, and local public health personnel may be allowed to see the information, if necessary to protect the participant's health, or to ensure the public's health. If a judge orders us to turn the information over to a court of law, we will comply.

6.0 DATA HANDLING AND ANALYSIS

6.1 Training

ATSDR project personnel will receive the phone calls and administer the survey to callers who wish to participate. Before beginning, the project leaders and other project personnel will meet to review and finalize the "on call" schedule and ensure consistency in administering the eligibility questionnaire (not included) and storing the information in a computer database.

The project leaders will meet with the personnel selected to administer the screening questionnaire, obtain informed consent, and ask for medical releases. A training session will take place to ensure that project administration has been understood and then practiced.

All components of specimen collection, handling, and shipping will be coordinated with the two laboratories selected. One laboratory is to be the national reference laboratory, currently the Beryllium Program at National Jewish Medical and Research Center in Denver, CO. National Jewish Beryllium Program personnel are available at (303) 398-1722, or by email at beryllium@njc.org (Appendix H).

6.2 Data Handling

Participants will receive unique identifying numbers when they complete the screening questionnaire. As they are collected, hard copies of this questionnaire, the consent forms, and the medical release forms will be kept in a locked file cabinet at ATSDR. Only the ATSDR project personnel and the contractor will have access to the personal identifiers of participants. Paper copies of survey instruments will be maintained in locked file cabinet under the control of the ATSDR Project Leader. The results obtained will be entered into the computer on a timely basis.

The database will be compared to hard copies for quality assurance. When data quality has been assured, paper copies of the survey instruments will be destroyed. Paper copies of consent and medical release documents will be maintained for a minimum of three years.

Blood samples that are sent for BeLPT testing will not be labeled with personal identifiers. Samples will be labeled with a unique identification number that is linked to the participant's personal identifiers and questionnaire data. The ability to electronically link personal identifiers with survey information and test results will be maintained until ATSDR has completed work at this site. This is necessary initially to ensure proper notification of the participants and to ensure our ability to discuss the results with individuals and their physicians (as authorized).

Access to any electronic file containing identifying data will be password protected and restricted to project personnel. If necessary, we will share information with state or local public health personnel who need access to protect public health.

6.3 Interpreting Results

6.3.1 Participants

To be eligible to participate, the individual must provide eligibility information and meet one of two sets of eligibility criteria. These criteria focus on either *exposure potential* or *disease diagnosis (sarcoidosis).*

6.3.2 Tentative Outcomes

The primary outcome of interest is the BeLPT test result. A confirmed positive BeLPT can be used, along with the survey information collected, to categorize participants as

a) probably *not sensitized* to beryllium;

b) *sensitized* to beryllium, either as...

1) *BeS* (confirmed sensitization to beryllium) ; OR,

2) *CBD* (sensitized to beryllium **AND** has granulomatous lung disease)

Medical diagnoses can only be made by the individual's personal physician.

7.0 DISSEMINATION, NOTIFICATION AND REPORTING OF RESULTS

Participants will be informed of the results of their blood tests.
The scripts and draft letters that will be used are included in Appendicies F and G.

A community report will be provided by ATSDR. A public meeting will be held to discuss the results and answer questions. Results may be published in the peer-reviewed literature.

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Appendix A. Letter to physicians Flesch-Kincaid Grade Level = 12.6

Dear Dr. _____

The Agency for Toxic Substances and Disease Registry (ATSDR), an agency of the US Public Health Service, plans to offer the BeLPT blood test to people in the Elmore, Ohio, area. We can test up to 200 people who want to find out if their immune systems have been sensitized to beryllium. We would appreciate your assistance in notifying your sarcoidosis patients about this opportunity for testing.

Because sarcoidosis and chronic beryllium disease (CBD) are similar clinically, some patients diagnosed with "sarcoidosis" may actually have chronic beryllium disease (CBD). For example, sarcoidosis was the original diagnosis given to a local beryllium worker's wife: "*Nonoccupational beryllium disease masquerading as sarcoidosis: identification by blood lymphocyte proliferative response to beryllium. Am Rev Respir Dis. 1992 May; 145(5): 1212-4."*

There will be no cost to your patient for these blood tests. People tested will receive copies of their test results. If your patient gives us permission, we will also send a copy to you.

We have enclosed copies of a factsheet that you can give to your sarcoidosis patients. If you have any questions, you can call the ATSDR toll free line (1-888-422-8737) and ask for me. Or, if you prefer, my direct line is 1-404-498-0565.

During May 2006, your sarcoidosis patients can call 1-866-577-4258 to request the test. This toll free line will be answered between the hours of 8 am - 8 pm (EST), Monday through Friday from May 1, 2006 through May 31, 2006.

Thank you,

Dan Middleton, MD, MPH

Enclosure: factsheet

Appendix B. Letter to Nearby Residents

Flesch-Kincaid Grade Level = 8.8

Dear _____

The Agency for Toxic Substances and Disease Registry (ATSDR), an agency of the US Public Health Service, is offering to test people in your area for beryllium sensitivity. We can test up to 200 people who are concerned about their potential exposure to beryllium. A factsheet is enclosed with more information.

If you are interested, you can call us. We will ask you a few questions about where you live, your job, your age, and your health. You may choose not to answer any questions that you wish. These questions will take about 15 minutes.

If your information confirms that you are eligible, we will contact you to make an appointment. We will take about 2 tablespoons of blood from a vein in your arm. It usually takes less than 10 minutes to take this sample. Your blood will be tested to see if your immune system has been sensitized to beryllium. We will send your results to you. If you give us permission, we will also send a copy of your test results to your doctor.

During May 2006, you can call 1-866-577-4258 to volunteer for the test and find out if you are eligible. This line will be answered between the hours of 8 am - 8 pm (EST), Monday through Friday from May 1, 2006 through May 31, 2006.

Thank you,

Dan Middleton, MD, MPH

Enclosures: 1

Appendix C. Facts about Testing for Beryllium Sensitization

Purpose

This fact sheet describes a blood testing program being offered by the Agency for Toxic Substances and Disease Registry (ATSDR). This blood test is to determine if you have sensitivity to beryllium. ATSDR plans to offer this test to up to 200 people in the Elmore, Ohio area.

Beryllium Lymphocyte Proliferation Test (BeLPT)

The name of the test being offered by ATSDR is the beryllium lymphocyte proliferation test (BeLPT). The BeLPT can identify people whose immune system is sensitive to beryllium, a kind of allergic response to beryllium from past exposure.

Who Will Be Offered the Test?

The BeLPT will be offered to people who are concerned about past exposure to beryllium if they are household contacts of Brush Wellman workers, workers at machine shops that work with beryllium metals from Brush Wellman or their household contacts, live within 1 ¼ mile of the Brush Wellman facility, or have received a diagnosis of sarcoidosis. Sarcoidois (a lung disease) and beryllium exposure cause similar changes in the lungs.

How Has the BeLPT Been Used in the Past?

The BeLPT is used at Brush Wellman (Elmore) and other workplaces that process or machine beryllium. The test is used to find out whether workers have been sensitized to beryllium. In this situation, the testing is usually repeated every year or two.

The BeLPT has been used in community settings only a few times. ATSDR was recently involved in testing former workers, household contacts, and residents at another site where beryllium was used. The accuracy under these conditions may be slightly different than in the workplace.

Doctors use this test to find out if persons who appear to have sarcoidosis may actually have chronic beryllium disease (CBD).

About Beryllium Sensitivity (BeS)

BeS is an immune system response to beryllium exposure. A person can develop beryllium sensitivity soon after exposure or years later. People who are sensitized may, or may not, develop a beryllium related disease. Most doctors who treat patients with BeS advise those patients to avoid more exposure to beryllium.

(Appendix C continued)

Chronic Beryllium Disease (CBD)	CBD develops in some sensitized people who breathe air with low levels of beryllium. CBD may be present when beryllium sensitivity is found or may develop years later. People who have CBD have damage to their lungs. Some symptoms of CBD are cough, shortness of breath, fatigue, fever, night sweats, appetite loss, and weight loss.
What Will the BeLPT Results Show?	The test should indicate whether or not you are sensitized to beryllium. It does not indicate if you have disease. If you are sensitized to beryllium you may, or may not, develop lung disease. If you are sensitized to beryllium, you should see a doctor who specializes in lung disease. If you see a doctor for further tests, you or your insurer will have to pay for all costs. The test has well known limitations. It does not always identify everyone who is sensitized and occasionally may identify as sensitized someone who is not.
Advantages of the Test	If the test indicates you are not sensitized you may be reassured that your risk of developing CBD is very low. If you have BeS, you can take steps that may reduce your risk for CBD.
BeS, CBD, and Sarcoidosis	BeS means that beryllium sensitivity is present, but the lungs are not damaged. CBD means that beryllium sensitivity *and* lung damage (scars) are present. The symptoms and progression of the disease (CBD) can be managed, but there is no cure for CBD at this time. Sarcoidosis is very similar to CBD, but beryllium sensitivity is not present. If your current diagnosis is *sarcoidosis, an abnormal blood test may* help your doctor to diagnose CBD. Your doctor can plan your treatment better with a more accurate diagnosis.
For More Information	If you would like to speak to someone regarding this testing program, or if you would like to request a test, please call 1-866-577-4258 between the hours of 8 am - 8 pm (EST), Monday through Friday from May 1, 2006 through May 31, 2006. ATSDR has resources to test up to 200 people that may benefit from the testing.

Appendix D.1 Informed consent with Sarcoidosis

Flesch-Kincaid Grade Level = 7.8

TESTING FOR IMMUNE SENSITIVITY TO BERYLLIUM

1. Project Description

You have asked to be tested for beryllium sensitization. This testing is sponsored by the Agency for Toxic Substances and Disease Registry.

When people are exposed to beryllium, some can develop a disease called chronic beryllium disease (CBD). You are eligible to be tested because a doctor has told you that you have **sarcoidosis,** an illness that is similar to beryllium disease. Also, you live in an area where beryllium is processed and machined.

2. Procedures

We will take about 2 tablespoons of blood from the vein in your arm. We will need less than 10 minutes to take the blood sample. We will send your blood to a lab. The lab will test your blood for sensitivity to beryllium. If your test result is abnormal, we will ask for another blood sample to test.

We will send you a letter telling you your test results. If your test shows that you are sensitized to beryllium, we will contact you to discuss your exposure and your illness. You do not have to speak with us.

3. Discomfort and Risks

We expect the risks to you to be very low. You may feel a slight sting or “pinch” in your arm when the blood is drawn. You may also get a small bruise where the needle went in. Some people faint, but this is rare.

It is possible that the results from these tests might cause your doctor to want you to have more tests. If this happens you (or your insurer, Medicare, or Medicaid) will be responsible for the costs of any other tests. Before you agree to have other tests, you should discuss the risks, benefits, and alternatives with your physician.

4. Benefits

The results of the test for Beryllium sensitivity will allow you and your doctor to better understand your health condition. The results of the test may help you and your doctor to make better decisions about your medical treatment.

If you want we will also tell your doctor what we find. We can not make or change any diagnoses, but the results might lead your doctor to make or change a diagnosis.

5. Confidentiality

Your answers and test results will be kept private to the extent allowed by law. To protect your privacy, we will keep the records under a code number rather than by name. We will keep the records in locked files and only study staff will be allowed to look at them.

6. Costs

There are no costs to you for this testing.

Based on your blood test, we might recommend that you see your doctor. If you see your doctor to discuss the results of the tests, you, your insurer, Medicare, or Medicaid will need to pay your doctor.

7. Persons to Contact

If you have any questions about the testing, or if you think that you have been harmed by the testing, contact Dr. Dan Middleton. He is at the Agency for Toxic Substances and Disease Registry in Atlanta, GA. He can be reached by calling 1-888-422-8737 and asking for Dr. Middleton.

8. Consent for Adult Participants

☐ Adult Consent

I give consent for my blood sample to be collected and tested as described in this consent form.

Please check “YES” or “NO” ☐ YES ☐ NO

I give consent for the project personnel to contact me in the future.

Please check “YES” or “NO” ☐ YES ☐ NO

Signature:_____Date:_____

Print name:_____

Appendix D.2 Informed Consent w/o Sarcoidsosis

Flesch-Kincaid Grade Level = 7.4

TESTING FOR IMMUNE SENSITIVITY TO BERYLLIUM

1. Project Description

You have asked to be tested for beryllium sensitization. This testing is sponsored by the Agency for Toxic Substances and Disease Registry.

When people are exposed to beryllium, some will develop immune sensitivity to it. Some people with beryllium sensitivity can develop a disease called chronic beryllium disease (CBD).

You are eligible to be tested because you have ...

☐..... worked at a local machine shop that machined Be alloys**;**

☐ .... lived with someone who worked at a local machine shop that machined Be alloys,

☐ .... lived with someone who worked at the Brush Wellman facility in Elmore, OH.

☐ .....lived close to the Brush Wellman facility in Elmore, OH.

2. Procedures

We will take about 2 tablespoons of blood from the vein in your arm. We will need less than 10 minutes to take the blood sample. We will send your blood to a laboratory. The lab will test your blood for sensitivity to beryllium. If your test result is abnormal, we will ask for another blood sample to test.

We will send you a letter telling you your test results. If your test shows that you are sensitized to beryllium, we will contact you to discuss your exposure and your illness.

3. Discomfort and Risks

We expect the risks to you to be very low. You may feel a slight sting or “pinch” in your arm when the blood is drawn. You may also get a small bruise where the needle went in. Some people faint, but this is rare.

4. Benefits

Finding out if you are sensitive to beryllium may help to explain a current or future health problem. You will receive a letter with the results of your blood test. If you have any questions, you may speak with Dr. Dan Middleton, who leads this study. The letter will tell you if you need to see your doctor.

We will also tell your doctor what we find if you give us permission. We cannot make or change any diagnoses, but the results might lead your doctor to make or change a diagnosis.

5. Confidentiality

Your answers and test results will be kept private to the extent allowed by law. To protect your privacy, we will keep the records under a code number rather than by name. We will keep the records in locked files and only study staff will be allowed to look at them.

6. Costs

There are no costs to you for this testing. If you see your doctor to discuss the results of the test, you, your insurer, Medicare, or Medicaid will need to pay your doctor.

7. Persons to Contact

If you have any questions about how the testing works or if you think that you have been harmed by the testing, contact Dr. Dan Middleton. He is at the Agency for Toxic Substances and Disease Registry in Atlanta, GA. He can be reached by calling 1-888-422-8737 and asking for Dr. Middleton.

8. Consent for Adult Participants

☐ **Adult Consent (18 years of age and older)**

I give consent for my blood sample to be collected and tested as described in this consent form.

Please check "YES" or "NO" ☐ YES ☐ NO

I give consent for the project personnel to contact me in the future.

Please check "YES" or "NO" ☐ YES ☐ NO

Signature:_____Date:_____

Print name:_____

Appendix E. Release of Results to Personal Physician

Release of information to your private doctor
If you would like us to send your results to your doctor, please fill in the name and address of your doctor and sign below.

I would like my test results sent to the doctor whose name and address are shown below:

Doctor *(Please print Doctor's name)*

Name: _____

Phone: _____(_____)_____

Mailing Address: _____

_____

_____

_____

Signatures: Sign below

Adult Participant (sign):_____ Date: _____

Print name:_____

Appendix F.1 Letter to Participants with Normal Result

Flesch-Kincaid Grade Level = 6.9

Date

Heading

Dear:

Thank you for taking part in testing by the Agency for Toxic Substances and Disease Registry (ATSDR). Your blood test did not show sensitivity to beryllium.

This test is not perfect. If your doctor suspects a beryllium condition, you may need to be tested again. Also, this does not mean than you cannot become sensitive to beryllium in the future.

If you have questions for me, you can call 1-888-422-8737 toll free and ask for Dr. Middleton. My direct number is 1-404-498-0565. Your doctor can also call me.

Sincerely,

Dan Middleton, MD, MPH
Medical Officer

Appendix F.2 Telephone Script to report an Abnormal or Borderline Test Result

Flesch-Kincaid Grade Level = 7.2

You recently provided a blood specimen for testing to the Agency for Toxic Substances and Disease Registry (ATSDR). Your blood was tested for sensitivity to beryllium. Your test result

was borderline / was abnormal.

We would like to repeat your blood test. You will receive a letter with your results. If you agree, we will contact you to schedule your second round of testing. Do you have any questions for me?

Appendix F.3 Letter to Report an Abnormal or Borderline Result

Flesch-Kincaid Grade Level = 5.6

Date

Heading

Dear:

Thank you for taking part in testing by the Agency for Toxic Substances and Disease Registry (ATSDR). As we discussed on the phone, your test result

was borderline / was abnormal.

We would like to test your blood again. You will also receive a letter with these results. If you agree, we will contact you to schedule your second round of testing. We will need to take about 4 tablespoons of blood for this. Your blood will be tested at two laboratories.

Do you have any questions for me? If you do, you can call 1-888-422-8737 and ask for Dr. Middleton. My direct number is 1-404-498-0565. Your doctor can also call me.

Sincerely,

Dan Middleton, MD, MPH
Medical Officer

Appendix G.1 Letter to Report an Unconfirmed Result

Flesch-Kincaid Grade Level = 6.9

Date

Heading

Dear:

Thank you for taking part in testing by the Agency for Toxic Substances and Disease Registry (ATSDR). Your original blood test was interpreted as ***abnormal / borderline.*** We have repeated the test on a second blood specimen. Your blood was tested at two laboratories. These two test results on your most recent blood specimen were _____ and _____.

We interpret these results as an unconfirmed result. That is, your first result was not normal, but we cannot say that your are sensitive to beryllium. This test is not perfect. If your doctor suspects a beryllium condition, you may need to be tested again. Also, this does not mean than you cannot become sensitive to beryllium in the future.

If you have questions for me, you can call 1-888-422-8737 and ask for Dr. Middleton. My direct number is 1-404-498-0565. Your doctor can also call me.

Sincerely,

Dan Middleton, MD, MPH
Medical Officer

Appendix G.2 Script to Report Confirmed Abnormal Results

Flesch-Kincaid Grade Level = 8.0

Hello I am _____ . I am calling from to the Agency for Toxic Substances and Disease Registry (ATSDR). You recently provided a blood specimen to ATSDR for testing. Your blood was sent to two laboratories. These two test results on your most recent blood specimen were _____ and _____.

Overall, you have had three blood tests.

Those results included:

two abnormal results / an abnormal result and a borderline result.

We will send you a letter with your results. I am calling to tell you that we consider this a "positive screen." That is, we believe that you have been sensitized to beryllium. We recommend that you see a physician who knows about beryllium.

Do you have any questions for me?

Appendix G.3 Letter to Report Confirmed Abnormal Results

Flesch-Kincaid Grade Level = 7.5

Date

Heading

Dear:

You recently provided a blood specimen for testing to the Agency for Toxic Substances and Disease Registry (ATSDR). Your blood was sent to two laboratories. As we discussed on the phone, these latest two test results were _____ and _____.

Overall, you have had three blood tests.

Those results included:

two abnormal results / an abnormal result and a borderline result.

We consider this to be a "positive screen." That is, we believe that you have been sensitized to beryllium. We cannot tell you what (if any) effects beryllium has had on your health or make a diagnosis. We recommend that you see a medical doctor who knows about beryllium.

Do you have any questions for me?

If you have questions for me, you can call 1-888-422-8737 and ask for Dr. Middleton. My direct line is 1-404-498-0565.
Your doctor can also call me.

Sincerely,
Dan Middleton, MD, MPH
Medical Officer

Appendix H. Blood Collection and Shipping for the BeLPT National Jewish Clinical Reference Laboratories

Adapted from Website: http://www.njc.org/lab/beryllium_blood.html

Below are collection and shipping instructions for the BeLPT.

All specimens sent to the laboratory should conform to all Federal and IATA shipping regulations.

Sample:

1. *Call the Clinical Immunology Lab at 303-398-1184 to schedule the test, preferably 24 hours in advance. Alternatively, you may send a fax to (303) 270-2175. Please include the number of specimens you anticipate sending. We accept samples Monday through Saturday - there are no limits on the number of samples you may collect and ship each day.*

2. *Draw 30 ml of blood into sterile, green-top heparinized vacutainers. Blood collection kits (3 10-ml green-top vacutainers and one safety mailer) are available from National Jewish for an additional $5 per test.*

3. *Label tubes with patient's name, date of blood draw and "LPT-Beryllium".*

4. *For each sample sent, please enclose a requisition with the name of the patient.*

5. *Pack the vacutainers in a Styrofoam container. Do not refrigerate. Keep at room temperature. Do not pack on ice. Avoid temperature extremes.*

6. *Label package "Human Blood - Deliver Immediately. Do Not Freeze. Perishable".*

7. *The blood must be shipped via priority overnight courier (i.e. FedEx, UPS, Airborne Express) to reach National Jewish the morning after it is drawn. National Jewish does not pay for overnight shipping charges.*

Address package to:

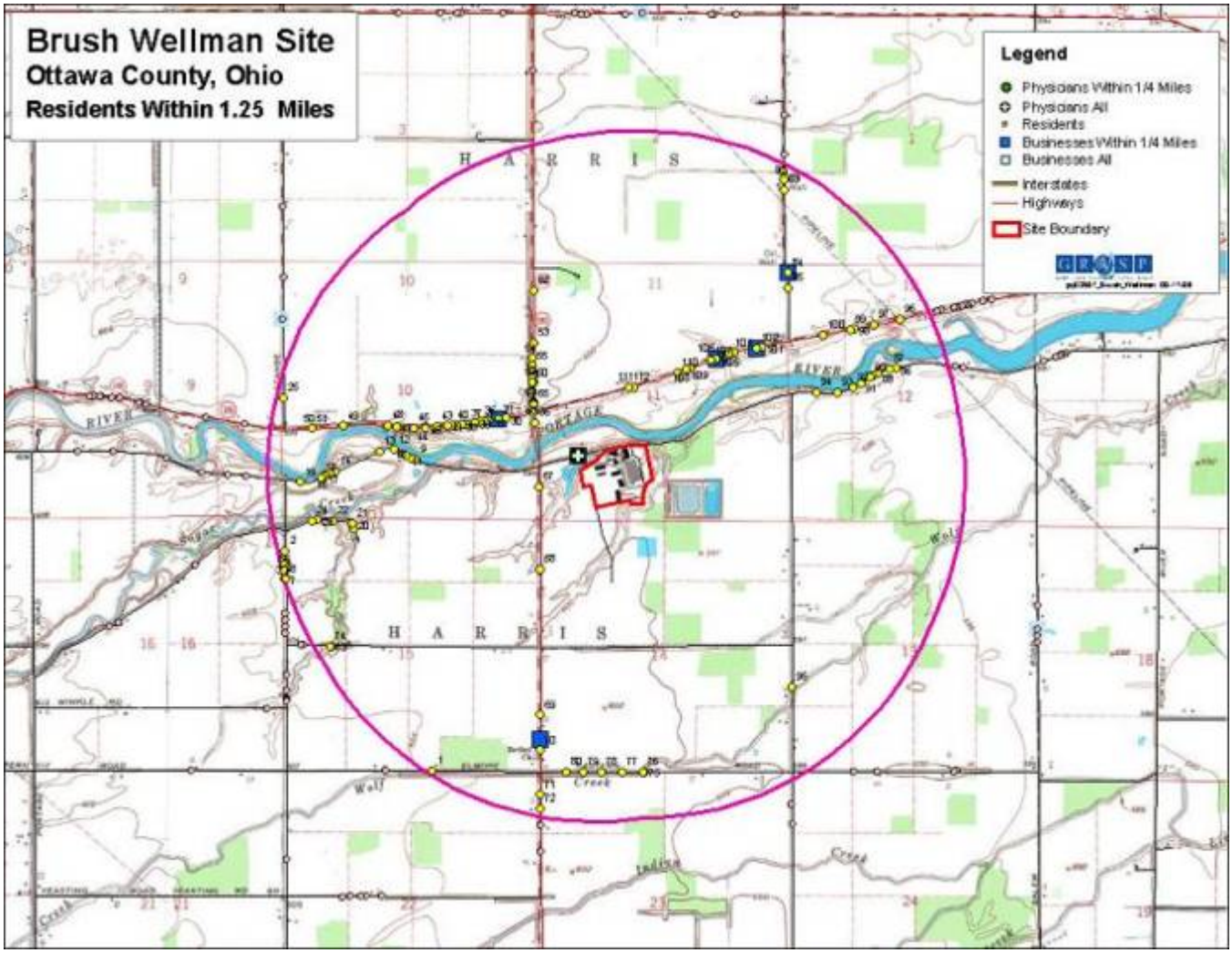
National Jewish Medical and Research Center
Beryllium Lab, Room M017
1400 Jackson St
Denver CO 80206
Phone: (303) 398-1288

Appendix I. Area Information

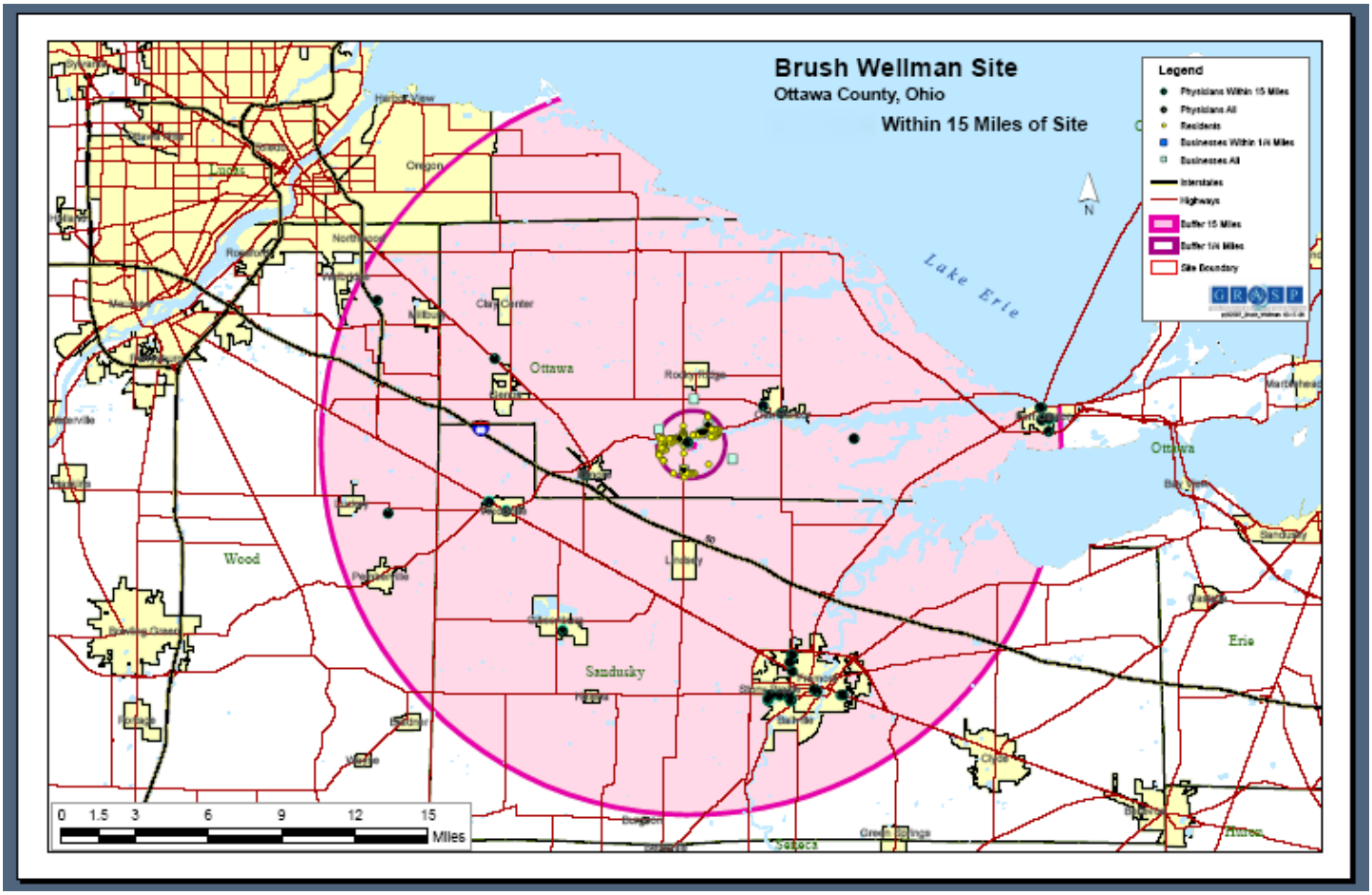
Table I.1 Demographics of the study area, by age group			
Age Groups	**Distance from facility**		
	1 Mile		**15 Miles**
Age 65 and Older	30		13,075
Age 18 to 64	100		53,737
Age 18 and Under	40		23,450
Total Population	170		90,262

Table I.2 Machine shops that contract (or have contracted) to machine beryllium alloys		
Company	**Address**	**Status**
Elmore Manufacturing Co, LLC	343 Clinton Elmore, OH	Current Contractor
Royal Tool & Machine Co	5740 Woodville Rd. Northwood, OH	Former Contractor

Appendix J.1 Topographic Map of 1.25 mile area



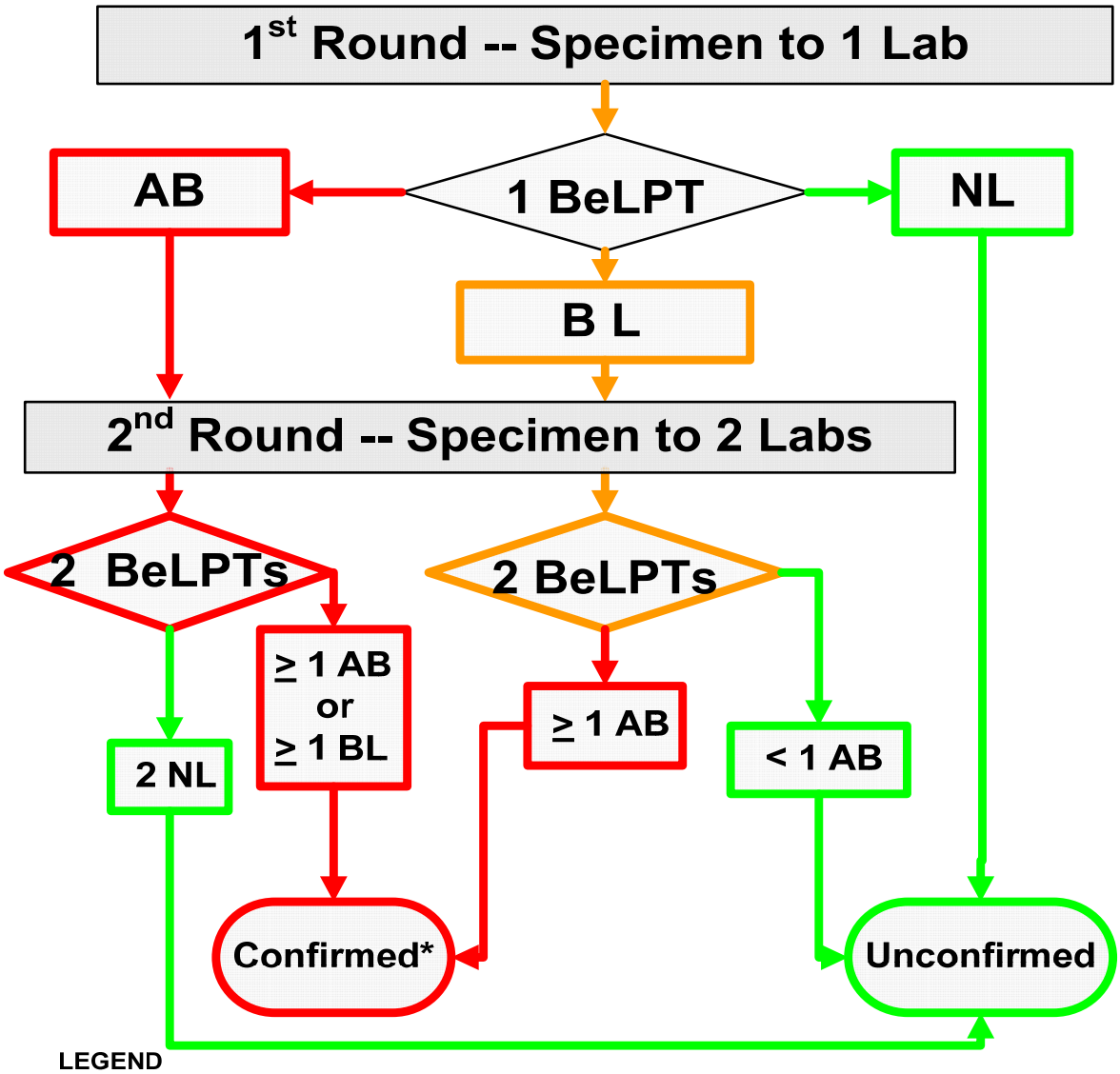
Appendix J.2 Topographical Map of Fifteen Mile Area



Appendix K. Flow Diagram for BeLPT Testing

Figure 1. Basic BeLPT Testing Paradigm

(Normals, Abnormals, and Borderlines)



LEGEND

NL = NORMAL TEST BL = BORDERLINE TEST AB = ABNORMAL TEST

CONFIRMED = Classical definition includes two abnormal BeLPT results. As used here (abnormals and borderlines), implies that the results met the criteria for referral to a medical specialist. Evaluation outcomes may include *BeS, CBD*, and *"BeS/CBD unproven."*

UNCONFIRMED = Did not meet the test criteria to require referral to a medical specialist; needs information, counseling, and (in some cases) repeat testing in the future.

REFERENCE

Welch L, Ringen K, Bingham E, Dement J, Takaro T, McGowan W, Chen A, Quinn P. Screening for beryllium disease among construction trade workers at Department of Energy Nuclear Sites. American Journal of Industrial Medicine 46:207-218 (2004).

Appendix L. Consent Comprehension

Dear Participant,

Thank you for agreeing to have your blood tested. Before we take your blood we want to make sure you understand this program. Please take a few minutes to answer questions about this screening. When you are done, give the sheet to the interviewer. The interviewer will look at your answers and give you more information if needed.

Select either "No", "Yes", or "Don't know"

1. I am joining this study because…

A. I felt pressured to join this study. __No __Yes __Don't know

B. I choose freely to join in this study. __No __Yes __Don't know

2. By signing the consent form…

A. I agreed to join other studies in the future. __No __Yes __Don't know

B. I may choose to stop participating at any time. __No __Yes __Don't know

3. I was given the name and telephone number of a person I can call if I have questions about this study?

__No __Yes __Don't know

4. I was asked to take part in this project because

A. I live in an area of the country where beryllium is processed. __No __Yes __Don't know

B. Everyone in Ohio is being asked to be tested. __No __Yes __Don't know

5. In 1-2 short sentences, describe how knowing whether you are sensitized to beryllium can help you.

_____

_____

_____

6. Are these statements about the study true?

A. Someone will take blood from my arm. __No __Yes __Don't know

B. ATSDR is providing this service. __No __Yes __Don't know

C. Someone from this project may call me later. __No __Yes __Don't know

D. My blood will be tested for beryllium sensitivity. __No __Yes __Don't know

E. My blood will be tested for chemicals unrelated to beryllium. __No __Yes __Don't know

7. As a participant in this study, I am aware there may be some risks.

I was told that	*Select either "No", "Yes", or "Don't Know"*
A. A small number of people who give blood may faint	__No __Yes __Don't know
B. I may get a small bruise where the needle was inserted	__No __Yes __Don't know
C. My doctor may ask me to have more medical tests based on the results of this test	__No __Yes __Don't know
D. If my doctor recommends medical tests, my insurance or I would be responsible for the cost.	__No __Yes __Don't know
E. Your answers and test results will be kept private to the extent allowed by law. This means a judge could order all study information including who took part in this study be handed over to a court of law.	__No __Yes __Don't know

8. To identify which tube has my blood in it, the researchers will write my name on the tube. __No __Yes __Don't know

9. My name or other identifying information <u>will be used</u> when presenting the study results to the public. __No __Yes __Don't know

Please hand this sheet back to the interviewer.