Health Consultation

Exposure Investigation Protocol

Brush Wellman Elmore Plant

Elmore, Ottawa County, Ohio

EPA FACILITY ID: OHD004212999

July 22, 2004

U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Agency for Toxic Substances and Disease Registry
Division of Health Assessment and Consultation
Atlanta, Georgia 30333

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INTRODUCTION

The health effects associated with exposure to beryllium at work are well documented (1) but few investigations have considered the potential for significant environmental exposure in residential areas nearby (2, 3). In the present investigation, the pathways of interest include the past deposition of beryllium air emissions to the environment from the Brush Wellman facility in Elmore, Ohio, and, beryllium dust unintentionally brought home on beryllium workers' clothes and shoes.

In the Public Comment protocol released in July 2003, ATSDR proposed collecting environmental samples from homes and motor vehicles of a) beryllium workers, b) residents who live near the facility; and, c) residents of a comparison community. The stated purpose of the sampling was to further clarify the current beryllium exposure situation in the community.

ATSDR received over 100 public comments on the draft exposure investigation work plan. This document contains the revised exposure investigation based on the public comments received. A summary of the public comments and ATSDR's responses to the comments are contained in Appendix 5

BACKGROUND

The Brush Wellman plant is located northeast of Elmore, between the villages of Elmore and Oak Harbor. There are more than 600 current and former workers in the greater Elmore area, and approximately 4,000 persons live within 5 miles of the Brush Wellman Plant. This plant began operations in 1953 and is the primary supplier of beryllium metal, beryllium alloys, and beryllium oxide in the United States. From 1990 through 1999, Brush Wellman released between 720 and 1,105 pounds of beryllium per year into the ambient air (4). When beryllium metal extraction operations ended in 2000, the air emissions dropped to less than 200 pounds per year (4).

In 2001, ATSDR was asked by U.S. Senator Mike DeWine (R-OH) to determine whether beryllium from the Brush Wellman plant in Elmore was creating a health hazard for local residents. ATSDR released a health consultation in August of 2002, concluding that a) long-term air emissions (30-day averages) from the plant were not a health hazard and, b) there was insufficient environmental data to determine whether worker-take-home was a significant source of community exposure (6).

The Brush Wellman-Elmore Plant contains extensive hygiene and housekeeping controls to prevent beryllium from tracked from the plant on workers clothing and shoes. There are other beryllium-exposed workers in "downstream" facilities that machine beryllium alloys, including one facility, Elmore Manufacturing Company that may contract directly with Brush Wellman. Community members have reported that the hygiene and housekeeping practices at the contract machine shops are not comparable to those at Brush-Wellman. Therefore, ATSDR will offer

sampling to workers from the two local contract machine shops in this exposure investigation (EI) as well as homes within a 1-kilometer radius from the Brush Wellman facility.

Literature Review

When exposed to beryllium, some individuals develop an immune sensitization to the metal. The prevalence of beryllium sensitization among occupationally exposed groups typically lies between 2 and 8 percent (1). Some sensitized individuals go on to develop chronic beryllium disease (CBD), a noncaseating granulomatous lung disease. Granulomas (scars) form in the lungs and eventually can impair lung functions. CBD can progress to severe respiratory impairment and can also be fatal (1). The early symptoms that cause a patient to seek medical evaluation frequently include cough and shortness of breath with relatively mild exertion (1).

CBD is clinically similar to sarcoidosis, a granulomatous disease of unknown etiology. An unknown number of patients with CBD have been mistakenly told that they had sarcoidosis (1). This error can be avoided by a careful exposure history and testing appropriate patients for immunologic sensitization to beryllium.

Preventing additional exposure is an important intervention, but has not been proven to arrest the disease process (8). Following exposure, beryllium-containing particles may become deposited in the lung where they can be retained for months or even years (8). Thus, primary prevention (i.e., minimizing exposure) is considered to be the most prudent approach.

During the 1940s, ten environmental (non-occupational) cases of chronic beryllium disease were attributed to ambient air pollution from a local beryllium plant in Lorain, Ohio (2). The furthest case lived 0.75 mile from the beryllium plant. More than 50 cases of chronic beryllium disease have occurred among household contacts of beryllium workers; these cases apparently resulted from contact with beryllium carried home on contaminated work clothing (7). CBD has occurred in both occupational and environmental settings where exposure was not expected (8).

Sources of Beryllium in the Environment

Beryllium is a naturally occurring element found in soil, air, and water. The general population is exposed to trace amounts of beryllium by inhalation of air and ingestion of drinking water and food (1). Coal-fired electricity-generating plants are the largest man-made source of beryllium air emissions in the United States (1). The EPA estimated that coal-fired power plants in the United States released 7.1 tons of beryllium in 1990 (9). Toledo Edison's Bay Shore power plant is located approximately 20 miles west of Elmore in Lucas County and is the only coal-fired power plant in Northwest Ohio. EPA estimated that in 1996 61 pounds of beryllium were released via air emissions in Lucas County from the Bay Shore Plant and 821 pounds of beryllium were released via air emissions in Elmore's Ottawa County from the Brush Wellman Plant (10).

Coal ash may contain trace levels of beryllium, and coal was also a common fuel for home

heating in this area prior during the early 1900s. Trace levels of beryllium have been measured in lawn and garden fertilizers (11).

PURPOSE

The purpose of this effort is to measure the airborne levels of beryllium in the homes of local machine shop workers and residents near the Brush Wellman facility . Results will be used to determine whether persons are exposed to beryllium above a public health-based screening value during routine activities in their residences.

STUDY OBJECTIVES

1. Identify the occupational and community member participants for environmental sampling (Table 1).

2. Explain the EI, obtain informed consent, and administer a brief exposure questionnaire (Appendices 1-3).

3. Conduct the air sampling.

4. Computerize and manage the data collected.

5. Analyze and interpret the data, grouping information by potential exposure categories.

6. Identify appropriate follow-up activities.

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7. Report the results and any planned follow-up activities to participants, the community, and other interested groups

Table 1 - Proposed Exposure Group Classification for Environmental Sampling

Exposure Group	Homes (n)	Population	Selection Criteria	Rationale for sampling
1	10	Workers in contract machine shops	Currently work in either of two local machine shops that contract with Brush Wellman	Determine whether homes of beryllium machine shop worker contain levels of beryllium in air above health-based guidance values
2	50	Local residents – live within 1 km of the plant	Live 1 km or less from the Brush Wellman plant	Determine whether the homes near the Brush Wellman plant contain levels of beryllium in air above health-based guidance values

ATSDR is not actively seeking to sample in the homes of current or former Brush Wellman workers but will we will attempt to accommodate those have expressed interest in taking part in the sampling.

ATSDR will solicit participants by door-to-door surveys, telephone calls and/or letters using the outreach and education information described in Appendix 1.

METHODS

All participants will be asked about their employment history to determine whether they work (or have worked) with beryllium-containing products. The questionnaire will verify eligibility for the various study groups and may identify other occupational sources of beryllium.

Public health interventions could be necessary in this community if it determined that exposures exceed of EPA screening values. In addition to the possibility that follow-up environmental sampling could be needed, the categories of appropriate preventative actions could include health education and one or more of the following:

- primary prevention -- activities to limit or eliminate exposure pathways;
- secondary prevention -- biological monitoring to identify sensitized individuals*;*
- tertiary prevention -- ensuring that sensitized individuals are referred for further evaluation and (if appropriate) medical intervention**.**

Activities beyond primary prevention would require the development and approval of a separate protocol.

Community Involvement

ATSDR released the protocol for 30-day public comment in July 2003 and held a public meeting in Elmore Ohio to answer questions about the protocol (12). ATSDR received over 100 public comments. This protocol was extensively revised to address the public comments. ATSDR will inform the community of the final protocol in a newsletter and hold a public availability session to answer questions about the final protocol.

Newsletters, fact sheets, and press releases will be used as tools to keep the community informed of EI activities. EI participants will be provided with ATSDR will provide a fact sheet (Appendix 1) that outlines the purpose of the investigation, the methods to be used, the kinds of results that can be expected, the investigation time-line, and when to expect their results.

Consent Forms

Residents must give their consent for environmental sampling prior to participation. The consent form (Appendix 2) specifically authorizes the U.S. Environmental Protection Agency (EPA) and the Ohio EPA to access the information collected. Written consent for access, sampling, and interviewing will be obtained prior to participation prior to requesting consent and collecting environmental samples.

At least one consenting adult will be interviewed at each residence. Children (those less than 18 years of age) will not be interviewed. ATSDR investigators will ask about the work history of adults in the household and the years lived at the residence. The specific questions are in Appendix 3. If more than one adult is interviewed in the home, each adult will be asked to sign a separate consent form. Within the limits of state and federal regulations, ATSDR will make every effort to protect participants' confidentiality. Even so, there are some circumstances that would require us to release information; for example, if a judge ordered us to turn the records over. The information presented in the Exposure Investigation Report will not include personal identifiers.

Roles

ATSDR has overall responsibility for planning and carrying out this exposure investigation. Study personnel will identify the participants, obtain consent, schedule the sampling visits, administer the questionnaire, analyze and interpret the data collected, inform participants of their results, and prepare the exposure investigation report. Prior to finalizing the report, a draft ("public comment") version will be shared with the public and other stakeholders.

Environmental Sample Collection

Two indoor area air samples will be collected simultaneously at each residence for a 24-hour period. Normal activities, including routine cleaning, will be encouraged at each residence. For this investigation "routine" includes cleaning and is defined as occurring on one to two-week basis. The samples will be collected in high uses living areas.

Air sampling pumps will be operated at a minimum flow rate of 11 liter per minute, for a minimum total sample volume of 15 cubic meters. Samples will be collected 0.8 micrometer pore-size, 37 millimeter diameter Mixed Cellulose Ester filters. Air sampling pumps will be stationed outside the residences to limit indoor pump-noise.

Follow-up Sampling

Follow-up air sampling will be scheduled and conducted at residences where one or more of the initial air samples exceeded 0.002 $\mu g/m^3$, which is 10 percent of the Environmental Protection Agency's Reference Concentration for beryllium. This sampling will be performed for seven consecutive 24-hour periods. One sampler will be employed at each residence. The sampler will be configured identical to the initial sampling. Participants will be asked about cleaning and occupancy during the previous 24-hour sample period.

Rationale for the Types of Environmental Sampling

The goal of the environmental sampling is to determine whether the residents may be exposed to beryllium above the EPA Reference Concentration (R_fC) of $0.02\mu/M^3$ during routine daily activities (13). Environmental Protection Agency defines the Reference Concentration (R_fC) an estimate of a continuous inhalation exposure to the human population, including sensitive subgroups, that is likely to be without an appreciable risk of harmful effects during a lifetime of exposure (13).

Personal samplers, rather than area air samplers, are preferred for assessing of human exposure to airborne dust (14). This is because dust re-suspension is largely a function of human activity (14). However, personal samplers are not practical for to wear for extended periods and they cannot collect sufficient sample volume to measure low levels of beryllium required. Therefore, ATSDR will perform area sampling in the residences.

Indoor particulate exposure is mostly likely to occur during activities such as cleaning. Consequently, ATSDR will ask the participants to provide basic information about these activities during the sampling periods. ATSDR will ask participants to perform routing cleaning during the initial sampling. For this investigation, ATSDR defines "routine cleaning" as cleaning that would regularly occur during every one to four weeks.

Quality Assurance/Quality Control (QA/QC)

Field blank samples will be collected for 10 percent of the air samples. Standard QA/QC comparisons for these environmental samples will monitor the reproducibility of laboratory results.

Sample Handling and Storage

Samples will be stored in clean containers at room temperature. Samples will be submitted to the laboratory with chain of custody forms.

Laboratory Analysis of Samples

Samples will be analyzed for beryllium by a laboratory accredited by the American Industrial Hygiene Association (AIHA), in accordance with National Institute for Occupational Safety and Health (NIOSH) methods. The limit of quantitation for each sample will be no greater than 0.02 micrograms per filter. Based on a minimum sample volume of 15 cubic meters, than Limit of Quantitation (LOQ) will be less than 0.0014 micrograms per cubic for the investigation. (*This is approximately seven percent of the Environmental Protection Agency's Reference Concentration* (R_fC).

Data Management

Results will be received from the laboratory in an electronic format. Questionnaire data will be collected on paper forms and entered manually into a standard computer database. Twenty percent of the entered results will be audited for accuracy. Data entry errors will be corrected. The entire database will audited and corrected if a pattern of errors are detected in the initial audit.

Data Analyses

The data will be analyzed as follows:

(1) simple descriptive statistics will be developed for initial air sampling results for the exposure groups
(2) simple descriptive statistics will be developed for airborne beryllium levels for each residence where follow-up sampling was conducted, and
(3) a single 24 hour result that exceeds the Environmental Protection Agency's Reference Concentration for beryllium (0.02 µg/m3) will identify the residence as an exposure location, and prompt additional testing.

A reference concentration is an estimate of a continuous inhalation exposure that is likely to be without appreciable risk of non-cancer effects during a lifetime of exposure (13)**.** Some effects associated with beryllium are strongly associated with individual characteristics of the person exposed (8). That is, it produces immunologic hypersensitivity in some exposed individuals (but not others) (8). From a public health viewpoint, it is advisable to limit exposure to any substance that operates through immunologic hypersensitivity.

The questionnaire results will be used to verify the participant exposure groupings and to identify other potential occupational sources of beryllium exposure (e.g., working in a foundry, or a dental laboratory). Summary statistics will be reported for each exposure group. Sample results from individual residences (and potential beryllium sources) may be reported and discussed, but only after ensuring that individual participants are not identifiable.

Limitations of this Investigation

Directly measuring personal exposure levels is not feasible in this investigation. Identification of an "exposure location" requires that one of two 24-hour area screening results exceed 10% of the EPA RfC and that one of seven 24-hour follow-up results exceed the EPA RfC. The area sampling employed is only an approximation of individual exposure to beryllium dust indoors.

The results of the investigation represent current conditions in participating residences and do not accurately reflect prior exposures. The results may be influenced by the activities at the time of the sampling. If the levels of beryllium in the residences are elevated it may or may not be possible to clearly identify the source (or sources) of the excess beryllium.

Follow-up sampling will be applied selectively, so ATSDR will use caution in generalizing the results obtained.

Presentation of Results

Each participating household will be provided with its individual results prior to releasing the summary report. ATSDR will also hold a public availability meeting with the community following the release of the summary report. The report will be completed and made available to the community for public comment without names and addresses or other information that is traceable to individual participants.

Follow-Up Activities

If ATSDR determines that the levels of beryllium in indoor air, exceed or are likely to exceed the EPA reference concentration for beryllium, or total beryllium,

Letters will be sent to participants that explains their individual results and describe actions they can take to immediately reduce exposure.

Appropriate health-related follow-up activities, such as health education for the community and for healthcare providers, will be identified and outlined in a final report.

ATSDR may recommend that the Ohio EPA conduct environmental sampling to identify the potential sources of beryllium.

INVESTIGATORS AND ACKNOWLEDGMENTS

INVESTIGATORS

Peter Kowalski, CIH, Division of Health Assessment and Consultation (DHAC), is the principal investigator; Dan Middleton, MD, and Lynn Wilder, CIH, Division of Health Studies, are the co-investigators.

ATSDR ADVISORS AND TEAM MEMBERS

The following ATSDR employees reviewed and commented on the draft and provided thoughtful input: Dr. Susan Metcalf, and Susan Moore, Dr. Ken Orloff, James Durant CIH, Dr. Robert Johnson, the ATSDR Brush Wellman Team (Loretta Bush, Sarah Stuart Cox, Clayton Koher, Peter Kowalski, Dan Middleton MD, and Lynn Wilder)

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Appendix – 1 – Brush Wellman Exposure Investigation Outreach Information

ATSDR is would like sample the air in homes near the Brush Wellman Plant for beryllium. The purpose of the sampling is to see if beryllium levels in homes' air are below the Environmental Protection Agency's (EPA) guidance value for human health.

ATSDR will run two air samplers in each home for a 24-hour period. The samplers will be placed in such as living room and or family room. If the results are show more than 10 percent of the EPA guidance value, ATSDR will ask to come back to do follow-up sampling. The follow-up sampling will take over seven consecutive days. The results will determine us whether residents are exposed to beryllium during normal activities.

If you are interested in taking part this effort ATSDR will provide additional information to you. This is a completely voluntary effort and you can change you mind later.

ATSDR is federal public health agency responsible assessing the public health risk of hazardous chemicals in the environment. United States Senator Mike DeWine asked ATSDR to look at beryllium concerns in Ottawa County Ohio.

Last year, ATSDR proposed an exposure investigation to collect a variety of samples. The proposed sampling included soil, indoor wipe and vacuum samples, vacuum samples in vehicles, and air samples.

The protocol was sent out for comment comments. Many persons were concerned about to how determine the meaning of surface samples. ATSDR has focused the investigation to air sampling in response to the public comments. The EPA has clearly established guidance values for beryllium in air.

Appendix 2 – *Adult* Consent Form

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

Interview and Indoor Air Testing for Beryllium
Brush Wellman (Elmore) Exposure Investigation
(Flesch-Kincaid Scale = 8.6)

Sponsors

We are offering to test homes that may contain beryllium in Elmore, Ohio. The homes of machine shop workers and homes located near the Elmore facility are the focus of this study.

Purpose

The purpose is to compare beryllium levels in your home's air to safe levels set by the Environmental Protection Agency (EPA).

Procedures

We have checked a box below to show why you were invited to take part in this study.

- o You are a machine shop worker, or you share a residence with someone who is.
- o Your home is near the Brush Wellman facility.
- o Other e.g., your are a current or former Brush Wellman or other beryllium worker.

You can decide to take part in this study, or not to take part. If you do take part, you will be asked about current and past homes and jobs. You may be asked similar questions about other adults in the home. Answers to these questions will help us explain the meaning of the results. Our questions should take less than 20 minutes to answer.

Sampling Methods

We will place two air samplers inside your home. The samplers are about twice the size of shoe-box. They will be placed in frequently-used areas such as living and or family rooms. The samplers will run for 24-hours. It will take about 15 minutes to set-up and take down the samplers before and after the sampling. The air samplers run on electricity and make a low level of noise.

We are asking persons who take part in the sampling to clean their homes in a routine manner during the air sampling. For this effort, we are defining this "routine cleaning" as cleaning that you would normally do every one week to two weeks. After the sampling will ask you some

more questions about your activity during the time the sample ran.

If the results of the sampling show more than 10 percent of the EPA guidance value for beryllium in air, ATSDR will ask to come back to do follow-up sampling for a seven day period. During the seven days we check and change the air sampling filter. This will take about 15 minutes each day.

Benefits

You will help us find out whether persons near a beryllium plant, or family members of machine shop workers, may be exposed to beryllium in their homes.

Risks

Taking part in the sampling will require some inconvenience of having air samplers in your home.

If beryllium is measured above the EPA guidance value, you might have to tell prospective buyers if you sell your home. These are same as the disclosure requirements for testing lead-based paint, asbestos, or radon gas. Please see the attached Ohio Residential Property Disclosure Form for more information about the State of Ohio disclosure requirements.

Follow-up

Depending on what we find in your home's air we may recommend additional testing by the Ohio EPA. More information will be provided before any additional sampling is started.

Participation

Taking part in this project is voluntary. If you do not wish to take part, there is no penalty. You will not lose any benefits that you are entitled to receive.

If you sign the consent form and then change your mind, you can stop at any time. If you stop, there is no penalty. You will not lose any benefits that you are entitled to receive.

Results

ATSDR will send a letter to explain your test results. After these results have been mailed to you, ATSDR will come back to Elmore to explain the findings. We will answer any questions and discuss any concerns you have. You can call Peter Kowalski of ATSDR at any time. His number is 1- 888-422-8737 (toll free), or 1-404-498-0492.

Confidentiality

After this study is over, ATSDR will write a report about the findings. The report will be available to the public, but it will not identify you or anyone else. We will not include your name, address, or phone number. Your privacy will be protected to extent allowed by federal and state laws. ATSDR cannot completely guarantee the privacy of the individual results. Your name, address, answers to questions, and individual environmental results will be stored in a password-protected computer or in a locked file cabinet at ATSDR.

Federal, state, or local agencies may ask us for access to your results. If you agree to let us share your results with them, they will also be required to protect your confidentiality.

Contact

If you have any questions, or if you feel you have been harmed by this investigation, you may contact: Peter Kowalski of ATSDR at 888-422-8737 (toll free) or 404-498-0492.

Participant Consent

I have read the description of this exposure study. My questions have been satisfactorily answered. I know that I can ask more questions at any time. I know that I can stop being part of this project at any time, even if I sign this consent form. If I drop out, there will be no penalty.

Please check one:

☐ *I give my consent to allow ATSDR to test: air inside my home, and also I give my consent to answer questions about my work history and the place I live.*

☐ ***I DO NOT** give my consent to allow ATSDR to test, air inside my home, and answer questions about my work history and the place I live.*

***Please Check One*:**

☐ *I give my consent to allow ATSDR to share my test results with the United States EPA and the Ohio EPA.*

☐ ***I DO NOT** give my consent to allow ATSDR to share my test results with the United States EPA and the Ohio EPA.*

Signature _____ Date _____

Witness _____

Name (print) _____
First **M.I.** **Last**

Address _____
Street

_____
City **State** **Zip code**

Telephone number _____ - _____
(Area Code)

Appendix 3 - Brush Wellman Exposure Investigation Questionnaire

Date _____

Hello, my name is _____, I am an environmental health scientist with the Agency for Toxic Substance and Disease Registry (ATSDR). ATSDR, with help from the Environmental Protection Agency (EPA), is doing an exposure investigation (EI) in the Elmore area. We would like you to answer these questions to provide us with more information about possible exposure sources to beryllium. First, I will ask you how many adults live at this home. Then, I will also ask you about the work history of each adult in your house. Your answers to these questions will help us decide how to interpret the results. Thank you for your help.

Demographic Information

1. What is your name?_____
First Middle Last

a. How many persons 18 or older live in this house [ ]

b. What are their names? .

Name$_{(i)}$

Name 1. _____
First Middle Last

Name 2. _____
First Middle Last

Name 3. _____
First Middle Last

Name 4. _____
First Middle Last

2. What is your current (this) address?

Current Street Address _____

City _____ State _____ Zip code _____

Occupational History (one for each adult resident)

Note: < > are used in indicate where interviewer would identify the person for whom the questions are about. If the participant is answering questions about themselves use appropriate personal pronouns ("you" or "your"), otherwise refer to the household member by their name: labeled NAME(i), where i = 1 to "n" adults in the household. Use additional sheets as needed.

Questions	***Fill in blank spaces and check boxes [ ].***
LENGTH OF RESIDENCE	
3. Name of Adult resident (subject of interview): Note: **NAME(i)** , "i" goes from "1" to "n" adults. *4 How long have <you / NAMEi >lived at this (current) address?*	_____ First Middle Last _____ years _____ months
SELECTING PERSON TO INTERVIEW *If questions refer to person interviewed, GO TO Q7. If not, CONTINUE.*	
5. Is < NAME(i) >available to answer some work-related questions?	Yes [ ] No [ ] *If yes, GO TO Q8.* . *If no, CONTINUE.*
6. If < NAME(i) > is not available, can I ask you some questions about < NAME(i) > 's work? 7. What is the name of the person responding for the subject?	Yes [ ] No [ ] *If yes, go to Q7.* *If no, STOP.* _____ First Middle Last
CURRENT EMPLOYMENT *If the participant is answering questions about themselves use appropriate personal pronouns (e.g., "you" or "your"), otherwise refer to the household member by their name (NAME(i))*	
8. Which best describes < YOUR/NAME(i) > current employment status?	Work outside the home: [ ] CONTINUE. Work at home: [ ] GO TO Q12 Unemployed: [ ] GO TO Q12 Retired: [ ] GO TO Q12
9. What is the name of < YOUR/NAME(i) > <u>current employer</u>?	
10. When did < YOU/NAME(i) > start work for your <u>current employer?</u>	Year began:
9. Is beryllium in any form processed or machined at the facility where < YOU/NAME(i) > currently work?	Yes[ ] No [ ] Don't Know [ ]
10. What is < YOUR/NAME(i) > current job title ?	
11. Before leaving work.... a ..do < YOU/NAME(i) >shower? b. do < YOU/NAME(i) > change from work clothes? c. ....do < YOU/NAME(i) > remove work shoes?	always [ ] sometimes [ ] never [ ] always [ ] sometimes [ ] never [ ] always [ ] sometimes [ ] never [ ]

PAST EMPLOYER(S) (j) Note: j = "1" to "m" past employers that processed or machined beryllium.	
12. Have < YOU/NAME$_{(i)}$ > worked in any (other) facilities in the past that processed or machined beryllium?	Yes [ ] No [ ] Don't Know [ ] If Yes, continue. If "No" or "Don't Know", GO TO STOP.
13. What was the name of the most recent (previous) beryllium-related company? < PAST EMPLOYER $_{(j)}$ >	
14.What was < YOUR/NAME$_{(i)}$ > job title at < PAST EMPLOYER $_{(j)}$ >:	
15. What were < YOUR/NAME$_{(i)}$ > dates of employment < PAST EMPLOYER $_{(j)}$ >:	Year began: _____ Year left: _____
16. At < EMPLOYER (j) >, before leaving work.... a .....did < YOU/NAME$_{(i)}$ > shower? b. ....did < YOU/NAME$_{(i)}$ > change from work clothes ? c. ....did < YOU/NAME$_{(i)}$ > remove work shoes?	always [ ] sometimes [ ] never [ ] always [ ] sometimes [ ] never [ ] always [ ] sometimes [ ] never [ ]
Go back to 12.	

STOP

Thank you for your helping with this survey. Your responses are an important part of our investigation.

Post Sampling Questions

Please answer the following questions. Your answers will help understand of the results.

1. How many persons lived in your home during past 24 hours? _____

2. Did you or others do cleaning in the house during the past 24 hours?

Yes □ - continue
No □ - go to question 3

a. About how long did the cleaning last?

Less than one hour □
One to two hours □
More than two hours □

B What type of cleaning was it? *(check all that apply)*

Sweeping □
Vacuuming □
Moping □
Dusting □
Other – specify □ _____

Thank you for your taking part in this survey. Your responses are an important part of our investigation.

Appendix 4 - AIR SAMPLING PROCEDURE

1.0 Scope

The purpose of this procedure is to describe sample collection technique for the Brush Wellman exposure investigation. The mention of trade names or commercial products does not constitute ATSDR endorsement or recommendation for use.

2.0 Method Summary

This air sampling procedure relies on passing a known quantity of air across a mixed cellulose ester (MCE) filter. The particulate phase of the air, with a nominal size of greater than or equal to 0.8 microns (μm) is trapped in the filter. This method requires air sampling utilizing 37 millimeter (mm), 3-stage cassettes loaded with 0.8 um MCE filters and support pads.

3.0 Sample Preservation, Containers, Handling, and Storage

No preservatives or special storage conditions are required. The samples will be transported and handled in a manner to prevent impact and vibrations which would dislodge particulates from the filters.

4.0 Interference and Potential Problems

A potential problem with the sampling method is over-loading of the filter. This can produce falsely low analytical results by reducing the flow. However, this is condition is not anticipated in this investigation.

5.0 Equipment

The following equipment is required for the air sampling:

- medium volume air pumps (SKC AirChek HV30 or similar medium volume pump)
- 1/4"' Tygon tubing
- 0.8 μm MCE filters with support pads
- 37 mm 3-stage cassettes
- Hose-barb filter adapters (Luers)
- Air flow calibration standard (a precision rotameter calibrated to a primary standard within one month of the sampling)
- Screw driver set
- Air Sampling Worksheets and sample labels
- Chain of Custody records
- Whirl bags
- Bubble wrap
- Shipping containers
- Permanent marking pens
- Quartz watch

6.0 Procedure

1. Identify participants.

2. Prepare scheduling and coordinate with staff and participants.

3. Arrange for sample analysis and sample media with DataChem Laboratory, Salt Lake City, Utah.

4. Obtain and organize the necessary sampling and monitoring equipment.

5. Pre-clean equipment, and ensure that it is in working order, and pre-calibrate sampling pumps to 12 liters per minute.

6. Review the purpose of the sampling and information contained in the consent form with participants.

7. Identify two sampling "high use" locations within each residence. Such locations may be living room, TV room, family room or den.

8. Deploy the air samplers and assemble sampling trains.

6.2 Calibration

A - Rotometer calibration

Calibrate the required number of sampling pumps in the following manner:

1. Assemble the calibration train using a representative 37 mm, 3-stage filter cassette loaded with a 0.8 µm MCE filter and support pad (outlet plug removed), tygon tubing, a hose -barb filter adapter, a calibrated rotameter, and an air sampling pump. Position the filter cassette in a downward manner.

2. Plug-in pump to AC outlet. Turn on the pump and adjust the flow using the flow adjust mechanism until the float ball on the rotameter is aligned with the rotameter's precalibrated flow rate value (12 liters per minute). (A sticker on the rotameter will indicate this value.)

6.3 Sampling

1. Verify the pump calibration by removing the inlet plug from the cassette, attaching a rotameter with Tygon tubing and turning on the sampling pump. Ensure that all connections are tight. Position the filter cassette in a downward manner using a closed face cassette. Record the actual flow rate and start time on the Air Sampling Worksheet. Allow the sample to run for a minimum of a 24-hours.

6.4 Post Sampling

1. Verify the pump calibration by attaching a rotameter with Tygon tubing to the sampling pump. Record the actual flow rate on the Air Sampling Worksheet. Turn of pump and record sample stop time. Insert plug.

2. Remove the sampling cassette from the sampling train and insert the outlet plug.

3. Complete the Air Sampling Worksheet and calculate the sample volume.

4. Label the sample and place it in a whirl bag for transport to the laboratory for analysis.

5. Prepare the samples (including QC samples) for transport by packing them in a shipping Results of the QA/QC samples will be evaluated for container with bubble wrap or styrofoam contamination. This information will be utilized to pieces. Complete a Chain of Custody record qualify the environmental sample results accordingly in accordance with applicable Chain of with the project's data quality objectives.

7. Administer post-sampling portion of the questionnaire to the participants.

7.0 Calculations

The total volume of a sample is calculated by multiplying the total sample time by the average flow rate. The total volume for each sample must be indicated on the Chain of Custody Record.

8.0 Quality Assurance/Quality Control

All data will be documented on Air Sampling Worksheets or within site logbooks.

All instrumentation will be operated in accordance with operating instructions as supplied by the manufacturer unless otherwise specified.

Equipment checkout and calibration activities will be documented prior to sampling/operation and they must be documented.

All deviations from this procedure shall be documented by the field personnel.

The following specific QC activities apply:

1. A minimum of one field blank will be collected per ten samples. The field blank will be handled in the same manner as the sampling cassette (remove/replace cap and plug, and transport) except that no air is drawn through it.

2. A minimum of two lot blanks per manufacturer's lot of sampling cassettes will be utilized per sampling event.

9.0 Data Validation

Results will be considered valid for if conditions are met:

- Field blank samples are free of beryllium contamination
- No more than a 10 percent difference exists between starting and ending flow rates.
- Sample trains are remain in operation throughout during sampling period (a minimum of 24 hours).

10.0 Health and Safety

No special personal protective equipment will be worn by the field personnel because time weight beryllium exposure are anticipated to be less than the OSHA's Permissible Exposure Limit for beryllium.

11.0

12.0 References

NIOSH Manual of Analytical Methods, NIOSH (1) Method 7300, Elements (ICP) (Issued 02/15/84).

Appendix 5 – Summary of Public Comments and ATSDR Responses
General Comments

Comment

The exposure investigation will negatively impact the property value of the participants and others in Ottawa County.

ATSDR Response

Property values may be affected by a number of economic and societal factors including perceived or actual environmental contamination. Property values are a common concern voiced by persons living near hazardous waste sites. ATSDR cannot predict the effect, if any, of the investigation will have on the local property values. The prospective participants, as individual households, should determine whether the benefits of sampling out weigh the perceived drawbacks.

Comment

Participants will have to disclose the beryllium sampling results during property transactions.

ATSDR Response

The State of Ohio Residential Property Disclosure Form requires disclosing the knowledge of the presence of common household hazards including asbestos, urea-formaldehyde insulation, lead, and radon. This form also requires disclosure about the presence of "other toxic or hazardous substances".

Environmental sampling for beryllium on residential properties in Ottawa County has occurred for sometime. For example, Brush Wellman has monitored airborne beryllium levels on private property near the plant for years. Brush Wellman and Ohio EPA have tested private wells adjacent to the Elmore Plant for the presence of beryllium.

Comment

The exposure investigation will result in needless worry.

ATSDR Response

The potential participants should decide whether they want to take part investigation. ATSDR has revised the exposure investigation to focus on air sampling and the inhalation pathway. ATSDR will compare results to health-based screening values that are established by the United States Environmental Protection Agency.

Comment

The exposure investigation will not result in any benefit to Ottawa County.

ATSDR Response

Individuals and households should formulate their own opinions about the merit of the investigation.

Comment

The exposure investigation will damage the company's image and undermine integrity of ATSDR.

ATSDR Response

ATSDR' primary objective is to determine whether selected community members are exposed to beryllium at levels of health concern. The revised protocol will receive internal and external review to determine its scientific validity prior conducting the sampling.

Comment

The exposure inexpensive and will be ineffective and costly.

ATSDR Response

ATSDR has refined the scope of the investigation to focus on data which directly related to inhalation pathway. The revised protocol will go through internal and external review to determine whether it can be effective in achieving it goals.

Comment

ATSDR should develop a comprehensive communications program for the investigation.

ATSDR Response

ATSDR has developed a communication plan for the site. This plan will available to stakeholders prior the start of the investigation.

Comment

ATSDR should not do the testing if it cannot guarantee confidentiality.

ATSDR Response

ATSDR will make every reasonable effort to maintain the confidentiality of the individual homeowners sampling results. The limitations on our ability to ensure confidentiality will be explained to prospective participants during the disclosure process.

Comment

ATSDR's investigation will create news media frenzy.

ATSDR Response

We will make reasonable efforts to educate the media on the purpose, methods and results of the investigation.

Comment

ATSDR has allowed the scope of this study to creep well beyond its congressionally mandated objective.

ATSDR Response

ATSDR is charged with assessing health hazards at specific hazardous waste sites, helping to prevent or reduce exposure and the illnesses that result, and increasing knowledge and understanding of the health effects that may result from exposure to hazardous substances. ATSDR actions in Ottawa County Ohio are consistent with its mandate.

Comment

The ATSDR plans to identify appropriate health education for the community and health care providers. Since this cannot be accomplished without fully understanding Brush Wellman's efforts and practices with regard to health education, we look forward to meeting with those ATSDR representatives who are working to evaluate the need.

ATSDR Response

ATSDR recognizes Brush Wellman for its effort to protect and educate its workers. ATSDR is also aware of its recent efforts to educate the community about beryllium levels in the environment. ATSDR will work its stakeholders on determining appropriate health education activities.

Comment

The stated purpose for the study plan does not fulfill the request made by Senator DeWine in

2001 nor does it meet the purpose as set forth by the ATSDR in its 2002 Health Consultation report for the Brush Wellman Elmore plant. The ATSDR 2002 report stated the following reason for performing this investigation.

> "Ohio Senator Mike DeWine asked the Agency for Toxic Substance and Disease Registry (ATSDR) to investigate the potential for beryllium exposures from the Brush Wellman plant in Elmore, Ohio. Specifically, Senator DeWine asked whether beryllium air emissions from the plant and the possible off-site transport of beryllium dust on workers' clothing constitutes a health hazard to area residents."

ATSDR Response

ATSDR prepared the health consultation in response to Senator DeWine's request.
One of the recommendations of the health consultation was to conduct an exposure investigation to evaluate the potential for on-going exposure through a) worker take home, and, b) past deposition of beryllium.

Comments

The ATSDR states that it considers this investigation to be primarily a public health service to the community." Brush Wellman does not understand how the ATSDR can consider this study plan a public health service when the plan fails to address Senator DeWine's request to determine if a public health risk exists and only serves to raise more unanswerable questions.

ATSDR Response

The individuals eligible to participate should determine whether the investigation provides any benefits for them and for their community.

Comments - Methodology

Comment

The investigation will result in un-interpretable data for soil and surface sampling.

ATSDR Response

Changes in the protocol will make soil and surface sampling unnecessary, though we believe such information can be interpreted.

Comment

The investigation non-randomly selects the participants.

ATSDR Response

Random selection is important for doing a study that can be generalized to a larger community. The revised exposure investigation will provide information about airborne beryllium levels for the investigation participants.

Comment

The protocol arbitrary establishes "elevated levels".

ATSDR Response

The 95th and 99th percentiles are common measures for determining elevated exposure levels in humans. The revised protocol calls for comparing sample results to the EPA Reference conference (RfC) for beryllium rather than a percentile value.

Comment

The public comment protocol guarantees that five percent of the tests will be elevated.

ATSDR Response

The intent of public comment protocol was to compare the results beryllium sampling in the individual homes and vehicles of interest to the summary levels measured in the reference community. This does not mean that 5 percent of the target groups would be elevated. In the revised protocol, ATSDR will compare air sampling results to the EPA guidance values.

Comment

There is no point of testing when ATSDR cannot determine the source of the beryllium.

ATSDR Response

The investigation will focus on airborne concentrations of beryllium. Source characterization is beyond the scope of the investigation and beyond the scope of ATSDR's congressional mandate.

Comment

How did ATSDR calculate the sample size?

ATSDR Response

The sample size was calculated based on the estimated variance of the proposed surface sampling, In the revised protocol, ATSDR will compare individual air sampling results to the EPA reference value for beryllium in air. There is no comparison group; therefore, the sample

sizes of the exposure groups are not relevant.

Comment

Why limit group one to 4 kilometers from plant. ATSDR should do more sampling downstream toward Oak Harbor.

ATSDR Response

Exposure and deposition are most likely to occur immediately adjacent to the plant.

Comment

ATSDR should not use the Environmental Media Exposure Guide (EMEG) for beryllium for ingestion in the exposure investigation.

ATSDR Response

The revised protocol does not specify comparison to the ATSDR EMEG.

Comment

ATSDR should not use the Environmental Protection Agency Reference Concentration for beryllium in the exposure investigation

ATSDR Response

The National Emission Standards for Hazardous Air Pollutant (NESHAP) Standard for beryllium was developed during the early 1970s and has not been substantially revised. The purpose of the standard is to control plant *emissions*.

The EPA Reference Concentrations are health-based screening values which are periodically reviewed and updated as necessary. They incorporate and reflect recent scientific literature.

Comment

The use of Ottawa (Putman County) is not appropriate comparison community because of a nearby power plant.

ATSDR Response

The revised investigation no longer calls for the use of a comparison community.

Comment

The U.S. EPA health-based standard is the only standard that exists for beryllium air emissions in a community. The standard is based on a 30-day sample taken monthly (more than 700 hours of continuous sampling). Brush Wellman is concerned with ATSDR's plan to take air samples for less than 3 hours at each residence – less than one half of one percent of the time specified by the EPA. The ATSDR's 3-hour air sample results will not be comparable to the EPA's 30-day health based standard, and thus are meaningless and not actionable from a public health standpoint.

ATSDR Response

The National Emission Standards for Hazardous Air Pollutant (NESHAP) Standard for beryllium was developed during the early 1970s and has not been substantially revised. The purpose of the standard is to control plant *emissions*.

ATSDR has revised the protocol to conduct sampling for 24-hour periods. If initial sampling results are greater than 10 per cent of the EPA RfC, additional sampling will be conducted for seven consecutive 24-hour periods. (Brush Wellman continuously monitors ambient air near the plant by sampling for 7-day periods and averaging four consecutive 7-day periods.) ATSDR believes that participants' added burden and inconvenience of additional three weeks of sampling would not result in any measurable benefit.

Comment

The inclusion of Toxic Release Inventory (TRI) data in protocol provides the public no interpretable data as it relates to public health or an understanding of health risk. To provide the public meaningful information, which relates to public health risk, the ATSDR should remove the TRI information in its entirety and refer only to the statement found in paragraph 3 of this same section which states:

"ATSDR released a health consultation in August of 2002, concluding that long-term air emissions (30-day averages) from the plant were not a health hazard"

ATSDR Comment

TRI data are provided in beginning of the protocol as pertinent background information, but ATSDR did not rely on the TRI data to make public health determination.

Comment

The inclusion of the Sanderson study data is both inappropriate and misleading to the public. The Sanderson data is also not interpretable from a public health standpoint. There are no health standards comparable to the Sanderson data. Additionally, the sampling methods used by Sanderson are not standardized or approved.

The fourth paragraph mostly describes practices at Brush Wellman's Elmore facility. The paragraph should be revised to better describe the long time, well-established work practices utilized at Brush Wellman to minimize the drag-out of beryllium from the plant site into the community.

ATSDR Response

The specific reference to Sanderson article has been removed from the protocol. However, the lack of "approved method" does not prevent the use of surface sampling to measure environmental beryllium levels provided that the methods are consistently applied. For example Brush Wellman uses wipe surface sampling to evaluate the surface levels of beryllium within its plants by consistently applying the same technique.

ATSDR has revised this section of the protocol as follows:

> The Brush Wellman-Elmore Plant contains extensive hygiene and housekeeping controls to prevent beryllium from tracked from the plant on workers clothing and shoes. There are other beryllium-exposed workers in "downstream" facilities that machine beryllium alloys, including one facility, Elmore Manufacturing Company that may contract directly with Brush Wellman. Community members have reported that the hygiene and housekeeping practices at the contract machine shops are not comparable to those at Brush-Wellman. Therefore, ATSDR will offer sampling to workers from the two local contract machine shops in this exposure investigation (EI) as well as homes within a 1-kilometer radius from the Brush Wellman facility

Comment

The first paragraph of the literature review includes the words *"and can also be fatal"*. It would be more accurate to replace the wording with "and is sometimes fatal".

ATSDR Response

We believe that the phrase "...and can also be fatal" and the phrase "...and is sometimes fatal" are essentially the same.

Comment

We recommend the word *"etiology"* be replaced with "origin" for improved comprehension by the public. We believe the public is better served by rewriting the second sentence to reflect what is known versus what is unknown. The last sentence is inaccurate and misleading, i.e. testing for sensitization cannot diagnose CBD.

> CBD is clinically similar to sarcoidosis, a granulomatous disease of unknown <u>origin</u> ~~etiology~~. ~~An unknown number of patients with CBD have been mistakenly told that they~~

~~had~~ Cases of CBD have been misdiagnosed as sarcoidosis (1). ~~This error can be avoided by~~ Proper diagnosis of CBD includes a careful exposure history and appropriate medical testing ~~appropriate patients for immunologic sensitization to beryllium~~.

ATSDR Response

The words "etiology" and "origin" are not interchangeable. That is, they do not mean the same thing. This protocol describes methods for air sampling for beryllium. However, one component of establishing CBD is the test for sensitization.

The discussion relationship between beryllium sensitization and beryllium disease will be fully discussed in a companion protocol.

Comment

We believe the following paragraph to be confusing and too cryptic for the general public.

> "Preventing additional exposure is an important intervention, but has not been proven to arrest the disease process (8). Following exposure, beryllium-containing particles may become deposited in the lung where they can be retained for months or even years (8). Thus, primary prevention (i.e., minimizing exposure) is considered to be the most prudent approach.

The first sentence contradicts itself and appears to pertain to persons with CBD. The second and third sentences appear to pertain to beryllium workers. This paragraph needs to be clarified to improve reader comprehension.

ATSDR Response

We believe the paragraph is clear and understandable.

Comment

We recommend the following sentence be added after about the Lorain study to improve the public's understanding of the data presented.

> During this study, community exposure to airborne beryllium was determined to be 10 to 1000 times higher than the current U.S. EPA community exposure standard.

ATSDR Response

The Lorain study is important historically, but this protocol does not seek to present details of the study's strengths, weakness, or findings.

Comment

In addition, the sentence referencing more than 50 cases of CBD "apparently" due to take-home exposures should be qualified as to the veracity of the data. It would be very instructive for the public to learn that the vast majority of these cases resulted from exposures in the 1940s and early 1950s. The last sentence in this paragraph is presumptive as stated. We recommend it be modified by replacing the word *"expected"* with "not believed to be significant based on knowledge at the time."

ATSDR Response

We believe the paragraph is accurate and appropriate as written.

Comment

The protocol inadequately describes sources of beryllium, and the study design inadequately accounts for those sources. Beryllium is found in soils in amounts that vary over a wide range. According to the U. S. EPA[1], the largest source of emission to the atmosphere is wind blown dust. The second largest source is coal and fuel-oil fired electricity generating plants. The third largest source of beryllium emissions are commercial, industrial, and institutional boilers fueled by coal, wood, or oil. The location of all such significant sources needs to be accounted for in the design of the proposed study protocol.

ATSDR Response

For Ottawa County residents who live near the Brush Wellman Elmore Plant, the main source of beryllium is the emissions from the facility. ATSDR will be comparing the results of the air sampling to EPA guidance values rather than to beryllium levels in a comparison community.

Comment

The statement: *"Any contribution the coal-fired power plant made to beryllium depositions in Elmore's Ottawa County would be minor when compared to the depositions from Brush Wellman's air emissions."* This statement is presumptive on the part of ATSDR and is not scientifically supported by the agency. Depending on wind direction, areas around the Elmore plant may well have received more beryllium deposition from coal-fired power plants than from emissions from the Elmore plant.
The ATSDR should qualify or remove this sentence.

ATSDR Response

This statement is supported by EPA Toxic Release Inventory data and the EPA Report entitled

1 U.S. EPA, 1990 Emissions Inventory of Forty Section 112(k) Pollutant (1997).

"Study of hazardous air pollutant emissions from electric utility steam generating units – final report to congress" (EPA-453/R-98-004a). It was removed for the sake of brevity.

Comment

It is premature to dismiss emissions from the Bayshore plant as insignificant. The study protocol permits the selection of residences of current and former beryllium workers who may live at a distance from the Elmore plant and close to the Bayshore plant.

ATSDR Response

The revised protocol calls for sampling homes of those residents living near the plant or local beryllium machine shop workers.

Comments

The use of *"trace levels"* in the second paragraph in this section is colloquial and inconsistent with available scientific data. In fact, the ATSDR's own document published in 2002[2] demonstrates levels of beryllium in coal and coal ash at levels much higher than levels found in typical soil. In addition, the same document identified that beryllium levels measured in fertilizers can be significantly higher than that found in typical soils. In addition, wood typically contains small amounts of beryllium and would have been used as a fuel for heating homes in the Ottawa County area. In fact, even today, it is quite common for home heating to include the use of coal or wood, especially in rural areas of Ottawa County.

ATSDR Comment

The comments provided above may be relevant to source characterization studies.

Comment

Though the repairing of golf clubs made with beryllium-containing alloys is possible, it is a non-representative example of a hobby scenario. Such golf clubs are uncommon because they are very expensive costing about $1000 for a set of irons. Since beryllium can be found naturally at low levels even in steel, hobbies involving the working of metals offer a more likely potential for exposure than owning and repairing golf clubs made with alloys containing beryllium. On the other hand, gardening exposes persons to naturally occurring beryllium in soil worldwide.

ATSDR Response

The statement about hobbies has been removed from the protocol.

2 Agency for Toxic Substances and Disease Registry. Toxicological Profile for Beryllium. ATSDR. Atlanta (2002).

Comment

The protocol does not determine the source(s) of beryllium; hence, it cannot be used scientifically to determine if air emissions or off-site transport from the Elmore plant are a source. Nevertheless, by its very nature, the protocol implies that any "elevated" levels of beryllium are attributable to the Elmore plant. Such implications are inappropriate.

ATSDR Response

The protocol states "If the levels of beryllium in the residences are elevated it may or may not be possible to clearly identify the source (or sources) of the excess beryllium."

Comment

The proposed testing protocol, as stated by the ATSDR is to determine if *"higher-than-background exposures to beryllium occurring due to worker take-home or from past air emission deposition"*, departs from Senator DeWine's request.

ATSDR Response

ATSDR revised the purpose of the protocol to determine whether persons are exposed to beryllium above a public health-based screening value during routine activities in their residences.

Comment

Study objectives 6 & 7 refer to identifying appropriate follow-up activities and communicating any planned follow-up activities to the public. It appears from these stated objectives that the ATSDR has already assumed that follow-up activities are imperative.

ATSDR Response

ATSDR is obligated to convey of the results of the investigation to the participants and the community in an understandable method. ATSDR considers this to be one type of follow-up action that may be needed.

Comment

The ATSDR's objective to identify follow-up activities detours beyond the request made by Senator DeWine. The ATSDR should only complete its study in a manner that fulfills the Senator's request.

ATSDR Comment

Please see the ATSDR's previous response.

Comment

Local government officials and Senator DeWine have the responsibility to decide if further evaluation or activities are in the best interests of the citizenry of Ottawa and Putnam Counties. The ATSDR is not knowledgeable in these matters and needs to limit its scope to stating its findings as they relate to a known health-based standard. The ATSDR should not put itself in the position to create seemingly endless work for itself beyond the scope of the specific mandate requested.

ATSDR

The decision to participate (or not) should be made by individuals and household units.

Comment

The second sentence of the methods paragraph refers to the questionnaire possibly identifying other occupational sources of beryllium. Brush Wellman believes that any questionnaire used should also seek to identify non-occupational sources of beryllium.

ATSDR Response

The primary goal of this investigation is to determine whether beryllium exposure is occurring at levels above health based guidance values. Identifying additional sources may be useful if beryllium levels are elevated, but is not purpose of investigation.

Comment

The protocol states:

> *"If significant beryllium contamination is identified, public health interventions could be necessary in this community."*

This reference to "*significant beryllium contamination"* is the first attempt by the ATSDR to establish that any measure of beryllium on surfaces beyond an arbitrarily established cut-point, based on a comparison to a control population, constitutes *"significant beryllium contamination"*.

ATSDR Response

The term *"significant beryllium contamination"* is not in the revised protocol. ATSDR will be based on the levels of beryllium in air samples.

Comment

The ATSDR's logic is seriously flawed in several respects. From an operational standpoint, ATSDR's July 2002 Health Consultation report recognized Brush Wellman's extensive efforts to prevent the "drag out" of beryllium particulate by workers since the 1950s. The Brush Wellman facility provides workers with work clothing and safety shoes, which are not allowed to be removed from the plant site. Since 1957, Brush Wellman has required workers to change into company-issued work clothing before entering production areas of the plant. At the end of their shifts, workers are required to remove work clothes and shoes, shower, and dress back into their personal clothing prior to leaving the plant. Brush Wellman is confident that these advanced practices are effective in preventing its workers from carrying a significant amount of beryllium into the community. Brush has provided these protections voluntarily and proactively, without a requirement from the government to do so.

ATSDR Response

Based on ATSDR tour of the Brush Wellman Plant in 2003, ATSDR agrees that Brush Wellman Elmore Plant currently contains extensive measures to prevent to beryllium from leaving the plant on workers' person.

Comment

From a community health standpoint, Brush Wellman's primary objection with the ATSDR's proposed use of surface sampling is that no correlation exists between area surface sample results and health risk. The ATSDR concedes this on page 12 of its draft document.

> *"The results of the soil and vacuum samples (concentration and loading) cannot be used to make a health determination for beryllium hypersensitivity or for chronic beryllium disease; there are no surface standards for this purpose."*

The reason the ATSDR and numerous other researchers have found that a health determination cannot be made is because an area surface sample result is not predictive of an air sample result. Simply stated, surface sampling results cannot be used as a defining line between safe and unsafe conditions.

ATSDR Response

ATSDR will sample media (air) for which the results will be directly compared to health- based guidance values.

Comment

To show a statistically valid comparison, the ATSDR would need to increase the number of homes to be sampled within each exposure group from 15-25 homes to hundreds of homes.

ATSDR Response

The revised protocol does not use a comparison population; air sampling results will be compared to an EPA health-based guidance value.

Comment

A single sample per household approach fails to recognize the large potential discrepancy between single samples test results and the actual range of values expected within each household.

ATSDR Response

In the revised protocol; seven follow-up samples will be conducted if one or more of the initial results exceed 10 percent of the EPA guidance value.

Comment

The NESPAP 30-day standard of 0.01 μg/m3 is only marginally above the detection limit of 0.007 μg /m3 for air samples. It is possible that a single sample result at the 95^{th} percentile of the comparison group may be statistically indistinguishable from the detection limit

ATSDR

For air samples, the detection limit is base on the sample volume and the analytical method used. ATSDR will employ an analytical method that has a limit of quantitation of no greater than 0.02 micrograms per filter. The limit of quantitation for a 15 cubic meter air sample is 0.00133 micrograms per cubic meter. ATSDR no longer plans on comparing the air sampling results to a comparison group.

Comment

What value will be assigned to non-detectable concentrations in the environmental samples?

ATSDR Response

ATSDR is will be comparing individual air sampling results to the EPA health-based guidance value. There is no need to assign values to non-detectable samples results. ATSDR has specified a minimum sample volume of 15 cubic meters of air and a limit of quantitation of 0.0014 micrograms per cubic meter. This is less than 10 percent of the guidance values.

Comment

Based on ATSDR's proposed interpretation of sample result, the 95th percentile of the comparative group becomes a de facto beryllium standard for "elevated" levels.

ATSDR Response

The goal of the investigation has been refocused to determine whether individual air sampling results exceed the EPA's health-based comparison value.

Comment

From a quality control standpoint, the surface sampling methods for beryllium are not standardized, are highly variable, not quantifiable, and not repeatable in addition to having no direct relationship to health risk or airborne levels of beryllium.

ATSDR

Brush Wellman performs surface sampling to track the surface levels of beryllium within its plants without having a standardized method. By surface sampling in consistent manner Brush Wellman makes inferences about the levels of beryllium within its plants. This logic is also applicable in the community.

Public Comment

The ATSDR's use of the term *"significant beryllium contamination"* is arbitrary and not supportable by the science or any health regulation. Significant beryllium contamination should only be determined by measuring the potential exposure of the community to airborne beryllium and comparing it to the only established community health metric for beryllium which is the U.S. EPA 30-day ambient air standard for beryllium.

ATSDR Response

The term significant beryllium contamination has been removed from the protocol. There are at least two community health metrics for beryllium: a) the EPA reference concentration, and b) the National Emission Standard for Hazardous Air Pollutant's 30-day standard**.**

Comment

With regard to primary prevention and Brush Wellman work practices, it is not apparent to Brush Wellman what more can reasonably be done to interrupt the potential drag-out of beryllium into the community. The ATSDR recognized Brush Wellman's efforts in its 2002 Health Consultation and did not suggest any changes to Brush Wellman's practices after their extensive plant tour last year.

ATSDR Comment

ATSDR acknowledges that the Brush Wellman Elmore Plant currently takes precautions to prevent the beryllium from leaving the plant on workers' clothing and shoes.

Comment

The protocol states: "*Attempting to evaluate the contribution of these behavioral factors to beryllium contamination in the residences is beyond the scope of this investigation."* These behavioral factors are critical variables because of the presence of beryllium in soils and vegetation. Hence, the amount of beryllium in a residence can be expected to be much higher if footwear is not removed before entering, especially in a rural area. Such potentially significant variables cannot be discounted. If the ATSDR views the critical behavioral factors (variables) in this study as beyond the scope of the investigation, then there is no need for the ATSDR to develop or implement a study protocol, because it is only the control of those variables which may produce useful scientific information. Indeed, the protocol induces some uncontrolled behavioral variables, such as directing residents to clean floors and dust during a 3-hour sampling period.

ATSDR Response

The purpose of comparison community was to control these variables. Routine house cleaning is the only behavior that ATSDR will ascertain the investigation.

Comments

The providing of sampling data to individual households or as a summary to the public without an ability to interpret the health risk constitutes intentional fear mongering at its worst. The ATSDR needs to either write a major modification to this protocol or abandon it so as not to create unsubstantiated fears among the residents of Ottawa and Putnam Counties.

ATSDR Response

ATSDR will provide participants their individual sample results along with an interpretation of their health implications.

Comment

In columns 3 and 4, the distance from the plant requirement should be consolidated into either column 3 or 4 to avoid confusion and repetition.

ATSDR Response

Table 1 has been completely revised.

Comment

The use of the term "elevated" in column 5 and as defined beneath the table is absolutely inappropriate because it is arbitrary and misleading to the public. The ATSDR has provided no basis to support the use of the term "elevated" as it does not meet the specific requirement of Senator DeWine's request "*to determine whether beryllium air emissions from the Brush Wellman plant and the possible off-site transport of beryllium dust on workers' clothing present a health hazard to the community."*

ATSDR Response

The text in the table has been revised to determine whether the homes of interest contain levels of beryllium in air above health-based guidance values.

Comment

Brush Wellman expressed its concerns in the above methods section regarding the sampling methods and uncontrolled study variables. Brush Wellman is further concerned that the selection of a single comparison area is insufficient to determine if a statistically valid difference can be determined based on the low number of homes to be tested as compared to the number of variables that can influence the study outcome. In addition, ATSDR's intention to use a mathematical difference between the comparison area and the Elmore area to define "elevated" or "significant beryllium contamination" is wrong due to the ATSDR's own conclusion that:

> "The results of the soil and vacuum samples (concentration and loading) cannot be used to make a health determination for beryllium hypersensitivity or for chronic beryllium disease; there are no surface standards for this purpose."

ATSDR Response

The goal of the investigation is to determine whether individual air sampling results exceed the EPA's health-based comparison value. A comparison group is no longer required for the interpreting the results.

Comment

ATSDR's selection of the comparison community of the Village of Ottawa, Ohio has great potential to cause confusion amongst the public simply because the Elmore plant is in Ottawa County. Brush Wellman believes the selection of any comparison community should not pose the real potential to confuse the public.

ATSDR Response

ATSDR not use a comparison community in the revised protocol.

Comment

Brush Wellman recommends the confidentiality section of the consent form be modified by ATSDR to emphasize that a participant's identity and confidentiality cannot be completely protected from disclosure by the ATSDR. This point is made in this section but not on the consent form.

ATSDR Response

ATSDR has revised the consent form as requested.

Comment

For reasons previously stated, the *"benefits"* section of the form makes statements which cannot be substantiated by the ATSDR based on the current sampling protocol. The ATSDR has not defined *"typical levels found in the environment"*, nor can it associate any health risk. Therefore, the reference *to "elevated levels"* is arbitrary and the offer of instructions on how to reduce beryllium levels in the home lacks a foundation based on public health risk.

ATSDR Response

The consent form has been modified to reflect changes in the protocol.

Comment

Brush Wellman is concerned that use of the U.S. EPA Environmental Response Team will cause unnecessary panic and concern among residents simply due to the team's name. The name implies that the U.S. EPA is responding to a problem. In addition, there is the potential for the team's vehicles to be marked with the U.S. EPA name. Brush Wellman is concerned that the team, as a matter of normal protocol, will dress in white chemical suits to collect samples. Again, this sends a message of fear which will likely be exacerbated by live press coverage. The ATSDR needs to take steps to ensure its sampling protocols are not misconstrued by the public and the press.

ATSDR Response

The revised protocol calls for ATSDR personnel to conduct air sampling. We will wear normal street clothing during the air sampling.

Comment

We question whether the hose used to vacuum samples can be adequately cleaned of all soil and debris between samples. It has been Brush Wellman's experience that cleaning of sampling hoses and tubes is extremely difficult when the goal is to prevent drag-out from sample-to-sample. The ATSDR needs to demonstrate their capability to adequately decontaminate its equipment between samples by sampling the insides of hoses after cleaning.

ATSDR Response

ATSDR not longer plans on collecting vacuum samples.

Comment

The proposed environmental sampling rationale does not address Senator DeWine's request that ATSDR evaluate potential beryllium exposures in the community as it may relate to public health risk. The environmental sampling plan as currently proposed is un-interpretable for evaluating public health risk.

ATSDR Response

In the revised protocol, the air sampling results will be compared to EPA health-based guidance values.

Comment

ATSDR makes the statement that measures of surface loading indicate the amount of dust potentially available for re-suspension. This statement is misleading and inaccurate because the potential for re-suspension of dust into the air is highly dependent on particle size. For example, if a beryllium metal alloy chip falls off of someone's shoe in his or her home, it would not be available for re-suspension because it is too heavy to become airborne. However, the chip would be picked up in a wipe sample based on the ATSDR sample plan. Without a multivariate analysis of all factors that can affect the sampling results, the proposed sampling protocol contains a great risk of being misinterpreted due to the small number of samples and the large number of sampling variables.

ATSDR Response

These comments are no longer relevant since surface sampling will not be performed by ATSDR.

Comment

The ATSDR should justify its use of a 100-mesh screen used to screen vacuum samples. Brush Wellman questions whether dust which will contain fibrous material can be adequately screened with a 100-mesh screen without manually abrading the collected material. The manual manipulation of the sample may cause parts of it to break-up into smaller particles. It would be more accurate to use a particle size selective sampler to fractionate the sample by particle size.

ATSDR Response

ATSDR will not collect vacuum samples in the revised protocol.

Comments – Biological Testing and Case Finding

Comment

There are no known cases of non-occupational CBD in the community so why do the testing.

ATSDR Response

Since the best for sensitization is only done for beryllium workers, it is unclear whether cases of beryllium disease exist in the community with another name (e.g., sarcoidosis).

Comment

"...the BeBLPT does not at this time meet the criteria as a screening test for CBD. Screening refers to the early detection of pre-clinical disease in persons without signs or symptoms suggestive of the disease with the requirement that this detection be of medical benefit. In a recent affidavit (see Attachment 4), Stephen H. Woolf, M.D., an expert on public health screening who has served as science advisor to the U.S. Department of Health and Human Services' Preventive Services Task Force, has stated, *"Under contemporary scientific principles of accepted medical practice, screening for CBD is not medically reasonable or necessary for workers regularly exposed to airborne beryllium…"* Dr. Woolf further states, *"Testing for CBD is appropriate clinical practice only for diagnostic purposes, based on the symptomology of individual patients, or in the context of experimental studies."* In other words, he is saying the test should only be used for persons with clinical symptoms which may be a result of beryllium exposure or in the context of well-defined research.

ATSDR Response

While these comments are consistent with the strictest definition of screening, this view does not represent accepted occupational medical practice and is not the approach used for employees at the BW facility we are evaluating. The peer reviewed literature supports a role for the BeLPT testing of an exposed population, though the semantic debate ("screening" vs surveillance) may continue.

Comment

The ATSDR must consider all potential physiological, psychological and financial implications of its study plan to the community surrounding the Elmore plant. Brush Wellman recommends that the secondary and tertiary preventions be removed because they are not preventative and they extend well beyond the scope of Senator DeWine's request.

ATSDR Response

We do believe that careful thought should precede environmental and biological investigations. As a public health agency, we routinely consider the potential for secondary and tertiary prevention of adverse health effects.

Comment

ATSDR states: *"Finally, some effects associated with beryllium are strongly associated with individual characteristics of the person exposed (8). That is, it produces immunologic hypersensitivity in some exposed individuals (but not others) (18). From a public health viewpoint, a potential outcome such as hypersensitivity makes it advisable to limit exposures that substantially exceed background levels."* As was previously stated, hypersensitivity (sensitivity) to beryllium is not an illness or disability (see the extensive comments provided on this topic in the methods section). In the end, the ATSDR was explicitly asked to determine if a public health risk exists. Senator DeWine did not ask the ATSDR for a potential public health viewpoint. This paragraph should be omitted from the protocol.

ATSDR Response

A confirmed positive BeLPT is clearly a change in health risk, providing evidence of both exposure and immunologic sensitivity to beryllium. The positive predictive value for the BeLPT has been shown to be "high3." [Deubner 2001].

Comment

ATSDR poses the possibility of ATSDR recommending biomedical testing in the community. In these and earlier comments Brush Wellman provided input on ATSDR's consideration of the use of biological testing. Biological testing is fraught with problems of reliability and cannot diagnose any beryllium related health effect. Moreover, there is no baseline for interpreting the results of biological testing of persons without occupational exposure to beryllium. Before any such testing can be considered, the ATSDR would need to perform a statistically valid study in the general population to determine the naturally occurring rate of sensitization in the general population. Brush Wellman has explored having such a study performed and has received rough estimates ranging from $500,000 to $1,000,000. In addition, based solely on the current known rate of detection of positive BeLPT's in the unexposed general population, one could expect a sensitization rate of 20 to 40 people within the 2000 people living within three miles of the Elmore plant, even if the Elmore plant never existed. Finally, before undertaking any such study, one must ask what is the medical benefit to the community. As stated earlier in these comments, the only independent scientific organization to evaluate the use of biological monitoring is the ACGIH. The ACGIH concluded:

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3 Deubner DC, Goodman M, Iannuzzi J. Variability, predictive value, and Uses of the beryllium blood lymphocyte proliferation test (BeLPT): Preliminary analysis of the ongoing workforce survey. Applied Occupational and Environmental Hygiene 16(5): 521-526

> "BLPT has good positive predictive value in population expressing clinical CBD and is established as a diagnostic criterion and a useful medical surveillance tool. However, criteria for use in screening have not been met at present. The BEI Committee does not recommend BLPT as an effective indicator."

Brush Wellman does not understand the ATSDR's continuing consideration of possibly using a biological monitoring method in a community when the scientific data clearly shows its use to be contraindicated. The ATSDR should scientifically justify its position for suggesting that biological screening could be used in a community or withdraw the above statement in light of recent findings from the ACGIH.

ATSDR Response

The purpose of this protocol is to describe the rationale and methods for environmental sampling for beryllium.

Comment

A comprehensive pathway analysis should only be conducted after concluding that health risk is likely to be present**.** A well crafted study surveying the pulmonary health of the community surrounding the plant in comparison to a similar control population can answer the question and help place the subsequent environmental reading in context.

ATSDR Response

This exposure investigation protocol has been refocused to determine whether air borne beryllium levels in residences exceed EPA guidance values. The merits of an epidemiological investigation are outlined in separate protocol.

Comment

Prior to using the beryllium lymphocyte proliferation testing, ATSDR must consider the benefits and risks of the testing, and the ethical implications of the testing. Such testing must reviewed by a human subjects review board.

ATSDR

Any biological testing proposed by ATSDR will be outlined and discussed in a separate protocol.

Comment

An alternative to the current study design is to for ATSDR to look at sarcoidosis cases in the Elmore area and offer those cases the BeLPT.

ATSDR Response

A separate protocol will address ATSDR's plans for beryllium disease case finding.