Brush Wellman Exposure Investigation
Peer-Review Comments and ATSDR Response

(ATSDR's responses are italicized).

Comments of Lee Newman, MD

Are the purpose and objectives of the investigation clearly defined; and do they merit this investigation?

Yes (x) No ( ) Unsure ( )

Need for exposure data. There is a definite need for environmental data to assess potential take-home exposure by workers in beryllium facilities and to assess airborne exposures in homes that are in close proximity to the Brush Wellman plant. Although the investigators deleted reference to this paper in their response to public comment, the publication by Sanderson (Sanderson W et al. Beryllium Contamination inside vehicles of machine shop workers. Appl Occ and Environ Hyg 1999; 14:223-230) nonetheless remains part of the scientific rationale for this investigation: the well-established, published fact that take-out exposures can occur when beryllium machinists leave the workplace. There is also well-established, published data that community cases of CBD can occur (as illustrated both in both Reading, PA and Lorain OH) in proximity to beryllium-using facilities. Furthermore, in direct contradiction of one of the public comment statements in Appendix 5 ("There are no known cases of non-occupational CBD in the community so why do the testing?"), there has been at least one non-occupational case of the wife of a Brush Wellman Elmore facility employee. She contracted CBD, from take-home exposure, and later died of this disease. (Reference: Newman L and Kreiss K. Non-occupational chronic beryllium disease masquerading as sarcoidosis: Identification by blood lymphocyte proliferative response to beryllium. Am Rev Respir Dis, 1992; 145:1212-1214). Thus, further investigation of exposure levels in the homes described in this protocol are warranted.

Potential benefit to the community and to science. The exposure data obtained in this study has the potential to provide important information for the residents of the community and to public health professionals regarding the distribution of beryllium in the community, at levels that may produce health consequences for those exposed. The work will extend the understanding of airborne health hazards in the community surrounding the Brush Wellman plant, thus addressing the concern voiced by U.S. Senator DeWine.

Can the environmental sampling methods meet the objectives of the investigation?
Yes (x) No ( ) Unsure ( )

The proposed methods are adequate. Analytical method is state of the art with acceptable limit of detection relative to levels that the investigators seek to measure. The sample size, method and duration of sampling should prove adequate to determine if there is detectable air borne beryllium contamination.

3. Can the sampling results provide meaningful information that can be interpreted from a health standpoint?
Yes (x) No( ) Unsure ( )

The levels of exposure that the investigators have targeted for this study are levels that have been shown to be sufficient to cause beryllium sensitization and CBD.

4. Are there other sampling strategies that you would employ to achieve the goals of the investigation?
Yes (x) No ( ) Unsure ( )

Questionnaire. The occupational questionnaire is efficient and well done but some additional information about current beryllium work exposure may prove helpful. Specifically, on a given day of home sampling, the airborne levels of beryllium in the home of a beryllium-machine shop worker might be influenced by whether or not he/she did any beryllium-dust related activities on the job that day or previous day. It is common for beryllium machinists in such shops to work on beryllium on an irregular schedule. An airborne plume of beryllium carried home might be missed if the worker was not using beryllium on the day of home sampling.

ATSDR has revised the protocol so that the work history questionnaire will be given to only those persons at residences where beryllium levels exceeded 10 percent of the EPA RfC (0.002 μg/m^3). ATSDR decided not to include an additional question on beryllium work on the day of the sampling because the questionnaire already asks about current beryllium work and hygiene practices.

Also with regard to the questionnaire, it would probably be helpful to determine the age of the residence. I would suspect that settled beryllium dust that has the potential to be re-entrained in the air might be greater in the older homes within 1 km of the Brush Wellman plant.

ATSDR agrees with comment. The questionnaire has been revised as suggested.

Surface sampling. Through my reading of the Appendix and the response to public comment, I understand why the investigators may have elected to not perform surface sampling. Although what they now propose is valid, justifiable, and meritorious, I think that the study would be stronger with collection of pilot data: surface sampling of infrequently cleaned (settled dust) areas of the home. While such measurements could not be directly linked to either air borne exposure or to health risk, these data can provide an indirect indication of cumulative beryllium accumulation and could be analyzed by correlational methods for homes within the 1 km radius. They would be in keeping with the Senator's request to investigate the health hazard, because while sampling the air for beryllium on any given day in someone's home might yield a non-detectable result, sampling on a day when major cleaning occurs (along exposed beams, in attics and crawl spaces, on top of appliances, relocating of furniture etc.) has been shown to increase airborne beryllium levels by re-entraining settled dust.

ATSDR has decided not to perform surface sampling during the initial sampling because of the difficulty interpreting these surface sampling results. ATSDR may recommend additional sampling, including surface sampling, if the beryllium levels approach or exceed the EPA reference concentration.

The study acknowledges that it will not directly determine the source of the beryllium that may be found in the homes. However, at the time of follow-up sampling, it would be reasonable to consider performing more specific particle analysis in those homes that are found to have elevated levels of beryllium. i.e. instead of simply repeating the sampling, it may be possible to obtain some of the subsequent samples and characterize whether the beryllium particles are beryllium alloy or not. If particles of beryllium-aluminum, beryllium-copper, or beryllium-nickel were detected, for example, this would certainly suggest a point source of exposure (such as a machine shop). The study is valid and meritorious even without investigating the sources of exposure, but it would be strengthened by this additional information.

ATSDR may recommend additional testing to determine appropriate follow-up actions if the beryllium levels in air present a health hazard, is possible.

Correlating location with exposure levels. As another approach to the question of beryllium source, I would suggest that the investigators add a fourth form of data analysis: Correlate location (i.e. distance from the Brush Wellman plant) with beryllium level in the home for the 50 local residents.

ATSDR will evaluate the relationship between the beryllium levels and the distance and direction from the Brush Wellman Plant.

Parallel outdoor sampling at time of follow-up sampling. Will there be air sampling conducted outdoors? It would seem reasonable to include simultaneous air sampling both indoors and outdoors as part of the Follow-up sampling protocol, especially if elevated beryllium levels are found in the homes of workers in the contract machine shops.

ATSDR will consider follow-up air ambient sampling if warranted. However, a number of studies have shown no or a poor correlation between the ambient outdoor and indoor particulate levels [15].

5. Are there any other comments about the investigation that you would like to make?

I found the protocol clear, concise, and well written. It is likely to provide important information and I commend the investigation team.

6. Select the appropriate category below:

(List recommended changes or reasons for not recommending)

A. Recommend (x)

B. Recommend with Required Changes ( )

C. Not Recommended ( )

Comments of Wayne Sanderson, PhD CIH

1. Are the purpose and objectives of the investigation clearly defined; and do they merit this investigation?
Yes (X) No ( ) Unsure ( )

Yes, it is clearly stated on page 5, that the purpose of this investigation is to measure the airborne levels of beryllium inside the homes of local machine shop workers and residents near the Brush Wellman facility in Elmore, Ohio. This work was specifically requested by concerned citizens through their U.S. Senator, Mike DeWine. Because overt respiratory disease—chronic beryllium disease (CBD)—has not been documented historically among residents near the Brush Wellman facility, I believe it is unlikely that people living near this plant have significantly increased risk for developing this disease. But this question has never been adequately studied and it remains unknown if individuals have developed sensitivity to beryllium due to living near the beryllium plant or living with workers machining beryllium products. There is a level of public concern which should be addressed.

CBD was documented in the 1940s among residents living near beryllium plants in Lorain, Ohio and Reading, Pennsylvania. And, household members of beryllium workers have been shown to develop CBD. However, in recent years Brush Wellman has developed excellent procedures for reducing the migration of beryllium from inside the plant into the community and homes of its workers. It has also reduced environmental air emissions from its production plant in Elmore. However, it remains unknown what beryllium exposure levels residents near this plant may experience inside their homes from current air emissions and residual levels in the environment. It is also not known whether workers at machine shops—not operated by Brush Wellman--in the Elmore area have been afforded the same level of protection to prevent migration of beryllium from their worksites into their homes.

I have high praise for investigators at ATSDR for their efforts addressing this concern. It is a difficult task and they have developed a reasonable approach to evaluating the problem.

2. Can the environmental sampling methods meet the objectives of the investigation?
Yes ( ) No ( ) Unsure (x)

Why?

I believe that the current plans to collect two 24-hour air samples at 12 liters/minute at two locations inside the homes of volunteers will measure the general beryllium air levels inside these homes on the particular day which the samples are collected. I suspect that most of these samples will either be very low or below the analytical limit of detection. Unless they are collected on a day when the residents vacuum their floors, implement relatively vigorous cleaning, or are taken nearby while machine shop workers remove potentially contaminated clothing, they may not represent times of greatest exposure potential. This one time sample has limited ability to estimate the average beryllium exposure levels inside the homes. One way to address this would be to increase the sample duration or the number of one-day samples collected inside each home.

These air samples will not be able to determine whether surfaces inside the homes have been contaminated with beryllium, and may not adequately address whether the beryllium may become airborne.

Residents will be asked to perform routine cleaning and occupy their home for a minimum of 12 hours while two 24 hour air samples are collected. This sampling will be repeated on two occasions if one or both of the two samples initial samples exceeded 10 percent of the EPA Reference Concentration.

3. Can the sampling results provide meaningful information that can be interpreted from a health standpoint?
Yes (x) No ( ) Unsure ( )

The sampling results from this study can be directly compared to the Environmental Protection Agency's Reference Concentration for beryllium in air (0.02 $\mu g/m^3$). This standard is based on evaluation of toxicological and epidemiological data and is meant to protect the general public from risk of developing chronic lung disease. If air measurements are found to exceed this level, data is being collected which will allow evaluation of risk factors which might be associated with increase air exposure, such as location of the home, occupations of the inhabitants, and cleaning practices.

4. Are there other sampling strategies that you would employ to achieve the goals of the investigation?
Yes (x) No ( ) Unsure ( )

It is disappointing that evaluation of beryllium concentrations on surfaces, such as floors, inside the homes is not going to be conducted as originally planned. It is true that no standards or accepted criteria for safe levels of beryllium on surfaces have been established. The U.S. Department of Energy has proposed limits of beryllium on work surfaces and equipment, but these limits are not based on health effects. However, this effort provides an excellent opportunity to evaluate the beryllium surface concentrations inside the homes of residents living near a large beryllium plant and the potential migration of beryllium inside the homes of machinists who manufacture beryllium products. These measurements would have to be compared to concentrations inside the homes of a control population who did not live near a beryllium plant or work with beryllium products. Background levels of beryllium on residential surfaces are not well documented. It would have to be clearly noted in the protocol that these measurements were for research purposes and could not be compared to prevailing health criteria. However, these measurements would help evaluate the long-term chronic risk of beryllium exposure inside study participants' homes, beyond the current plan to collect a few samples over only a few days.

ATSDR has decided not to perform surface sampling during the initial sampling because of the difficulty interpreting the health implications of surface sampling data. ATSDR has not ruled recommending additional sampling, including surface sampling, if the beryllium levels exceed the EPA reference concentration.

Budget and logistic considerations may prevent the possibility of collecting more air samples, but single, 24-hour air samples *(two samples will be completed – ATSDR)* inside the homes of study participants is very limited for estimating risk. It would be good to increase the number of samples collected, the sampling duration or both. Perhaps at least a winter and summer sampling campaign could be employed.

ATSDR will recommend follow-up sampling if the initial sampling indicate the presence of a health hazard.

5. Are there any other comments about the investigation that you would like to make?

In Table 1, column 3, it states that Local residents living within 1 km of the plant will be sampled. Why is one km chosen instead of 1 mile, which would be consistent with the health study?

ATSDR has revised to protocol include those living within 1 mile of the plant.

In the methods section, no control group is chosen because it appears the air samples are simply to be compared to the USEPA ambient air standard. However, it would be useful to have samples collected inside a group of comparison homes at a greater distance from the plant.

ATSDR will not use comparison population because of the limited nature of the sampling investigation.

It is not stated in the Methods Section—Environmental Sample Collection—where the samples will be collected. Although homes vary considerably, an effort should be made to collect the samples in consistent locations across the homes, such as family gathering areas—kitchens, family rooms, or children's play areas. It is stated in the Appendix, but might also be stated in the Methods Section.

ATSDR agrees with this comment and has revised the protocol as suggested.

The selected air flow rate of 11 liters per minute is a considerable air flow through a relatively small 37 mm MCE filter. Has this method been employed before and are the selected sampling pumps been able to maintain a consistent flow rate with a high expected static pressure? Also, in the Appendix the airflow rate is reported to be 11 and 12 liters per minute (page 24).

ATSDR will test sample train well in advance of the field sampling.

In Section 6.2, it is noted that a calibrated rotometer will be used to check the flow rate of the sampling pumps. The sampling pumps should first be calibrated against a primary standard and then the flow rate simply checked in the field using the rotometer. I don't think it is good accepted practice to use a rotometer to calibrate airflow pumps.

ATSDR agrees with the comment and has specified a primary standard for calibration rather than a rotometer.

On page 24, third line from the bottom the sentence reads "Turn of pump..." This should read "Turn off pump..."

The protocol has been revised as noted.

On page 26, item 3 under 11.0 Rotometer Calibration, it will be difficult to use even a 1 liter bubble burette to calibrate the rotometer at 12 liters per minute (bubble start to stop = 5 seconds). I recommend using either a high-volume Gilibrator, SKC Dri Cal, or a larger bubble burette to calibrate the pumps and the rotometer.

ATSDR agrees with comment and has specified an electronic primary standard for calibration e.g. Dri-Cal or Gilibrator.

On page 27 the comment is made that exposure investigation will negatively impact property values. This seems like an unacceptable reason to not evaluate potential public health problems. If in fact residents are at risk of developing a serious lung disease, the long-term medical costs may outweigh a potential drop in their property values. On the other hand, if beryllium levels are found to be low and no sensitivity or lung disease is found, the potential fear that residents have will be alleviated.

ATSDR agrees with this comment.

On page 28, the spacing seems to be a bit off. It is a bit errant elsewhere in the comment and response section.

ATSDR has modified the spacing.

Also, on page 28 it is stated that the study will not benefit Ottawa County. Lack of identified disease or exposure will certainly lessen residents concern about risk for chronic beryllium disease, but if sensitivity, beryllium lung disease, and high exposures are found, then public health measures may be implemented to reduce peoples' health risk. I found many of the criticisms of the ATSDR protocol in Appendix 5 to be obstructionistic and ridiculous.

On page 31, third paragraph from the bottom the word 'of' was omitted from the first sentence. Also, The word Comment near the bottom of page 34 should be bolded rather than italicized.

These format and grammar errors have been corrected.

On page 49, second paragraph, it would be helpful if the criticizer could provide a reference for the statement "...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." I struggle frequently with an estimate of the false positive rate for the beryllium lymphocyte proliferation test. I do not believe an accurate estimate of false positives for this test exists and I do not believe this statement can be backed up.

The companion case finding protocol contains a detailed discussion of beryllium lymphocyte proliferation test.

6. Select the appropriate category below:

(List recommended changes or reasons for not recommending)

D. Recommend (x)

E. Recommend with Required Changes ( )

F. Not Recommended ( )

Aside from addressing the minor comments I have noted above and my disappointment that no surface sampling will be conducted, I recommend this protocol for implementation.

Comments from Milton Rossman, MD

1. Are the purpose and objectives of the investigation clearly defined; and do they merit this investigation?

   Yes (x) No ( ) Unsure ( )

   Are there any other comments?

   No

2. Are there other sampling strategies that you would employ to achieve the goals of the investigation?

   Yes ( ) No ( ) Unsure (x)

   The purpose of this study is to measure the airborne levels of beryllium in the home of local machine shop workers and in the home of individuals who live within 1 km of the Brush Wellman plant in Elmore. The levels determined will be compared to EPAs reference concentration for beryllium. However, the real purpose of this investigation is to determine whether contamination has occurred in the past. Thus, while the residents may be reassured that at the time of the sampling, there were not elevated levels of beryllium in their houses, the study will do little to reassure the residents that contamination did not occur in the past or that it could not occur in the future.

   ATSDR will clearly communicate the limitations of the sampling to the prospective participants. They will determine whether the benefit of the investigation outweighs its limitations.

3. Can the sampling results provide meaningful information that can be interpreted from a health standpoint? Yes

   The environmental sampling will meet the purposes of the investigators since direct measurements of air samples will be done.

4. Can the sampling results provide meaningful information that can be interpreted from a health standpoint?

   While air sampling will give results that will reflect the airborne levels of beryllium in the homes at the time of investigation, it may not mean the contamination has not occurred in the past. It does not rule out that significant exposure may have occurred in the past but now has been either cleaned up or diluted by time. Thus, negative results will probably do little to reassure the community that contamination has not occurred in the past. However, positive results will show that contamination has occurred.

   As noted above, ATSDR will clearly communicate the limitations of the sampling to the prospective participations. They will determine whether the benefit of the investigation outweigh its limitations.

5. Are there any other comments about the investigation that you would like to make?

   Yes (x) No ( ) Unsure ()

   Consideration should have been done to sample for 1 week rather than just one day. Because the strategy relies on re-suspension of beryllium in the contaminated house, a longer sampling strategy might lead to more activities in the house the might lead to the detection of abnormal levels. Examples of this might be washing clothes, taking off work clothes, and vacuuming and cleaning at the end of a week or on a normal cleaning day rather then on a day when it might have been done a day or two before. In addition, depending on whether the sampling was done on a week day or a weekend, members of the household may or may not be in the home on the day of the sampling.

   Residents will be asked to perform routine cleaning and occupy their home for a minimum of 12 hours while two 24-hour air samples are collected. This sampling will be repeated on two separate occasions if one of the two samples initial samples exceeded 10 percent of the EPA Reference Concentration.

6. Select the appropriate category below:

   (List recommended changes or reasons for not recommending)

   Recommend ( )

   Recommend with Required Changes ( )

   Not Recommended (x)

Clearly this proposal is in conjunction with the case finding proposal. Combining the immunologic surveillance and the detection of abnormal air levels will be most useful, however I would suspect that the immunologic surveillance would be a more sensitive technique to determine if exposure has occurred.

This protocol will have similar participation criteria to the case finding protocol. ATSDR will attempt compare results to the extent possible. ATSDR also supports exposure-based environmental sampling because substantial past air emission from the Brush Wellman – Elmore Plant and of the possibly of worker-take-home from machine shop workers.

In the consent form, under risks it should be noted that a negative air sample does not rule the possibility of past or future exposure.

ATSDR agrees with comment. The consent form has been revised as noted.