

**BRUSH WELLMAN INC.**  
**STATEMENT OF CURRENT KNOWLEDGE**  
**JANUARY 2008**

This communication summarizes current information regarding beryllium health research, Brush Wellman's programs for promoting the safe handling of beryllium, the status of occupational standards and testing procedures. We have structured this communication to address the questions we commonly receive from the beryllium user community. For important health, safety and environmental information on the use of specific beryllium-containing materials, please see the product-specific material safety data sheets (MSDS), research studies and other relevant information available at [www.brushwellman.com](http://www.brushwellman.com).

**What is Brush Wellman's model for protecting workers?**

Brush Wellman's Beryllium Worker Protection Model<sup>1</sup> is a comprehensive and multifaceted approach for reducing occupational exposure to beryllium particles. The model focuses on keeping beryllium work areas clean and keeping particles and solutions containing beryllium out of the lungs, off the skin, off of clothing, in the work process, in the work area and on the plant site. Worker and management education and motivation are important components. A combination of engineering, work practice and personal protection approaches are used, as needed, to attain the reduction in potential occupational exposure. The goal of the Beryllium Worker Protection Model is to prevent sensitization<sup>2</sup> to beryllium (BeS), subclinical chronic beryllium disease (CBD)<sup>3</sup> and clinical CBD<sup>4</sup>.

The Beryllium Worker Protection Model is based on our knowledge, experience and understanding gained from the most recent joint studies with the National Institute for Occupational Safety and Health (NIOSH) which includes the potential exposure risks posed by the various chemical forms of beryllium and disease prevention methods tailored to specific material processing operations, engineering, work practice control, and personal protective measures that have been demonstrated to be effective in preventing sensitization and CBD at Brush Wellman facilities. The model includes the use of a recommended exposure guideline of 0.2 micrograms of beryllium per cubic meter of air ( $\mu\text{g}/\text{m}^3$ ) which is ten times below the current OSHA permissible exposure limit (PEL) of 2  $\mu\text{g}/\text{m}^3$ .

The recommended exposure guideline is, in part, supported by a 2007 study by Cummings<sup>5</sup> which demonstrates that the Beryllium Worker Protection Model, in use since 2000, has been effective in reducing the detection of beryllium sensitization from over 8% to 1%, a rate that is similar to the background rate found in the non-occupationally exposed population<sup>6</sup>. The Beryllium Worker Protection Model is very similar to the successful exposure control model used at the United Kingdom Atomic Weapons Establishment facility in Cardiff, Wales as described in the 2001 paper by Johnson<sup>7</sup>.

Users of beryllium-containing materials are reminded to perform workplace exposure characterization, including air monitoring, to determine if conditions or situations exist which dictate the need for additional industrial hygiene controls and improved work practices.

**How can I learn more about the Beryllium Worker Protection Model?**

An innovative tool called the *Interactive Guide to Working Safely with Beryllium and Beryllium-containing Materials* (Interactive Guide) has been developed to provide employers and employees with specific information on the elements of the Beryllium Worker Protection Model. The Interactive Guide is available on CD and operates from most personal computers. The Interactive Guide provides an important foundation for the safe handling of beryllium and beryllium-containing materials in the workplace. It is made up of eight elements that describe beryllium health and safety practices in an easy-to-understand format. Simply place the disk in your CD drive and it will start automatically, leading you through the entire Interactive Guide.

Upon completion of the Interactive Guide, users are provided with a printable action plan and information to address most types of operations and tasks performed on beryllium-containing materials in an industrial environment. A copy of the Interactive Guide has been included with this Statement of Current Knowledge for your information and use. Additional copies are available by contacting your sales representative or by making a request through our website.

### **Does Brush Wellman have a recommended exposure guideline for airborne beryllium?**

Yes. As part of the Beryllium Worker Protection Model to prevent CBD, Brush Wellman has adopted a recommended exposure guideline for airborne beryllium of  $0.2 \mu\text{g}/\text{m}^3$  as an 8-hour time-weighted average. Research findings<sup>7</sup> suggest that a high level of compliance with the current Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL) of  $2 \mu\text{g}/\text{m}^3$  can prevent clinical CBD (with symptoms)<sup>8,9</sup>. Recent research findings<sup>10,11</sup> indicate that individuals at operations with exposures that rarely exceed  $0.2 \mu\text{g}/\text{m}^3$  did not experience sensitization<sup>12,13</sup> or subclinical (no symptoms) CBD<sup>14</sup>.

The studies by Madl (2007) and Schuler (2005) provide the best evidence to demonstrate that CBD (predominantly subclinical CBD) can occur in workers exposed at levels below the current OSHA PEL. The Madl study, using over 3,000 personal air samples, is the first study to actually perform a complete dose reconstruction of persons defined as beryllium sensitized or diagnosed with subclinical CBD or clinical CBD. The Madl study concluded,

*“Results showed that exposure metrics based on shorter averaging times (i.e., year versus complete work history) better identified the upper bound worker exposures which could have contributed to the development of BeS or CBD. It was observed that all beryllium sensitized and CBD workers were likely exposed to beryllium concentrations greater than  $0.2 \mu\text{g}/\text{m}^3$  (95<sup>th</sup> percentile) and 90% were exposed to concentrations greater than  $0.4 \mu\text{g}/\text{m}^3$  (95<sup>th</sup> percentile) within a given year of their work history. Based on this analysis, it would appear that BeS and CBD generally occurred as a result of exposures greater than  $0.4 \mu\text{g}/\text{m}^3$  and that maintaining exposures below  $0.2 \mu\text{g}/\text{m}^3$  95% of the time may prevent BeS and CBD in the workplace.”*

The Schuler study performed a cross-sectional survey to examine prevalence of BeS and CBD, and relationships between BeS and CBD and work areas/processes at a copper beryllium alloy strip and wire finishing facility. The study concluded:

*“Sensitization and CBD were associated with an area in which beryllium air levels exceeded  $0.2 \mu\text{g}/\text{m}^3$ , and not with areas where this level was rarely exceeded.*

The 2001 study by Johnson<sup>7</sup> remains highly relevant to determining a safe level of exposure to prevent clinical CBD. There is no beryllium facility study to have a larger air sampling data set or has been able to claim the success of clinical CBD prevention as that accomplished at the United Kingdom Atomic Weapons Establishment in Cardiff, Wales. In fact, we know of no other air sampling data set for any substance that more thoroughly characterizes the exposures of a worker population. The Johnson study includes over 217,000 personal samples using an exposure assessment strategy that monitored every worker on every day for 36 years. The Johnson study demonstrated that the Cardiff beryllium control model achieved compliance with the United Kingdom  $2 \mu\text{g}/\text{m}^3$  8-hour Maximum Exposure Limit (MEL) over 98 percent of the time and prevented clinical CBD.

Although the Cardiff study suggests that a high level of compliance with the  $2 \mu\text{g}/\text{m}^3$  standard can prevent clinical CBD, the results from the Schuler and Madl studies, along with uncertainties of particle size<sup>15,16</sup>, chemical form<sup>17</sup> and process related risks<sup>18</sup>, support taking a more conservative approach. Accordingly, Brush Wellman has adopted a recommended exposure guideline for airborne beryllium of  $0.2 \mu\text{g}/\text{m}^3$  as an 8-hour time-weighted average.

## **What is the status of OSHA's review evaluating the need for a beryllium rule and a revised PEL?**

OSHA first stated that it was considering a beryllium rule in 1998. In November 2002, OSHA issued a beryllium Request For Information (RFI) in the Federal Register, posing about 50 questions for public comment. Since that time, OSHA has been collecting additional information from beryllium using industries to aid its evaluation of the need for a rule. OSHA began the Small Business Regulatory Enforcement Fairness Act (SBREFA) process in September 2007. SBREFA was designed to give small businesses assistance in understanding and complying with regulations and a greater voice in the development of new regulations. Small Entity Representatives (SERs), from a group of affected small businesses, were provided a draft proposed standard for beryllium as well as various supporting analysis and reports. The draft standard did not propose an 8-hour PEL, but did indicate that a range of PELs from 0.1  $\mu\text{g}/\text{m}^3$  to 2.0  $\mu\text{g}/\text{m}^3$  (the current PEL) was being considered. During conference call meetings in December 2007, SERs were provided the opportunity to present their comments, ideas and concerns to a panel consisting of representatives from OSHA, the Small Business Administration (SBA) and the Office of Management and Budget (OMB). The panel will review the comments from the SERs and issue a written report to OSHA in early 2008. OSHA will then decide if it is going to issue a proposed rule. In the past, it has taken OSHA as little as six months and up to four years to issue a proposed rule following the completion of the SBREFA process. The most recent OSHA regulatory agenda does not define a 2008 timeframe for issuing a proposed rule. If OSHA decides to issue a proposed rule, public hearings will be scheduled to provide an opportunity for comments and suggestions. Issuance of a final rule generally takes two years following the issuance of a proposed rule.

## **I have heard that the PEL for beryllium changed in California. Is this true?**

Yes. In April 2006, the California Occupational Safety and Health Standards Board approved revisions to the PEL listed in Section 5155, Air Contaminants, of the General Industry Safety Orders for 18 substances, including beryllium and beryllium compounds. In the case of beryllium and beryllium compounds, the Board approved the proposed ten-fold reduction of the PEL from 2  $\mu\text{g}/\text{m}^3$  to 0.2  $\mu\text{g}/\text{m}^3$  and the elimination of the 5  $\mu\text{g}/\text{m}^3$  Short-Term Exposure Limit (STEL). The PEL for beryllium and beryllium compounds was lowered to prevent sensitization and CBD. A copy of the approved revisions to Section 5155, Air Contaminants can be found at [www.dir.ca.gov/oshsb/airbornecontaminantsappvdreg.pdf](http://www.dir.ca.gov/oshsb/airbornecontaminantsappvdreg.pdf). The revision to the PEL for beryllium and beryllium compounds listed in Section 5155 of the California Air Contaminant regulations only apply to facilities operating in the State of California. The revised PEL for beryllium and beryllium compounds became effective July 6, 2006.

## **What is REACH and how does it affect me as a customer of Brush Wellman?**

Registration, Evaluation and Authorization of Chemicals, or REACH, is legislation approved by the European Union (EU) that is designed to provide safety, health, environmental and use information about chemical substances to the REACH Agency. REACH requires producers and importers to register chemical substances produced in or imported to the EU market in excess of 1 metric ton per year through a phased approach. After registration, chemicals may be evaluated, subjected to authorization or restricted by the agency in concert with member states. The ultimate goal of the REACH legislation is to ensure that useful safety information gets to the end users.

REACH does not ban the use of beryllium metal, beryllia ceramics, or beryllium-containing alloys. Under the guidance provided in the REACH Implementation Project 3.8 (Guidance on Substance in Alloys), the products Brush Wellman ships into the EU are considered articles. Substances in articles are not subject to Registration or Authorization. Regardless, Brush Wellman will register beryllium metal and beryllium oxide as we are committed to making our customer's transition into REACH as simple and straight forward as possible for the products you purchase from Brush Wellman. When appropriate, Brush Wellman will develop and provide to you Safety Data Sheets (SDS) that will be in accordance with REACH and the Global Harmonized System (GHS) requirements. You can choose to pass the relevant REACH information to your customers using the Brush Wellman SDS or a data sheet that you create.

In all respects, Brush Wellman will continue to supply all of its products to customers who either reside in the EU or export their products to the EU. Beryllium is a strategic substance that also provides unequalled performance characteristics to alloys. The properties beryllium imparts to these alloys cannot be substituted by any other metal. Brush Wellman is committed to making compliance with REACH simple and easy so manufacturers, importers and all downstream customers can continue to take advantage of the beneficial properties and high performance they have come to expect from beryllium-containing alloys.

### **Is beryllium a carcinogen?**

Recent studies by Levy<sup>19,20</sup>, Brown<sup>21</sup> and Deubner<sup>22</sup> provide new evidence that exposure to beryllium does not represent a significant risk of cancer to humans. The 2001 study by Sanderson<sup>23</sup> has been used to try to demonstrate a beryllium exposure response relationship for lung cancer. Levy (2007) and Deubner (2007) identified a significant methodological error in the Sanderson study which negates the use of Sanderson as a dose/response cancer link for beryllium. Levy also provides a reanalysis of the Sanderson study which demonstrates that when the error is corrected, the conclusion is that the lung cancer in this population was not associated at all with beryllium exposure, whether defined as time worked, or cumulative, average or maximum exposure. Deubner confirms the methodological error identified by Levy using repeated data simulations.

These beryllium studies deal with sizeable cohorts exposed to very high levels of beryllium. Failure to find convincing evidence that these highly exposed workers have excess rates, combined with clear evidence that lung cancer is not related to degree of exposure in beryllium workers, strongly refutes the premise that beryllium is a carcinogen and supports a reclassification of beryllium as non-carcinogenic in humans.

### **How is CBD currently diagnosed?**

Before the late 1980s, workers were diagnosed with CBD only when they exhibited clinical (observable) symptoms of CBD and changes in their chest x-ray or lung function test. During the late 1980s and early 1990s, the criteria by which CBD was diagnosed changed to include workers without clinical symptoms or measurable impairment. These workers are often described as having subclinical CBD, which is diagnosed based on demonstration of sensitization to beryllium plus the presence, upon surgical biopsy, of microscopic biological lung formations called granulomas.

Workers with subclinical CBD may never develop clinical CBD or may develop clinical CBD over time<sup>12</sup>. The natural history of subclinical CBD is not yet known, yet it is very evident from studies conducted by Brush Wellman, NIOSH and others that the rate of subclinical CBD is much higher than the historical rate of clinical CBD. It is, therefore, logical to conclude that most persons with subclinical CBD do not progress to clinical CBD. If most subclinical cases of CBD progressed to a clinical state, historical studies would have shown much higher rates of clinical CBD.

### **Can I get CBD from skin contact with beryllium or beryllium-containing materials?**

No. Handling beryllium and beryllium-containing materials in solid form cannot cause CBD. CBD requires an inhalation exposure to particulate containing beryllium.

### **What is beryllium sensitization (BeS)?**

Prior to the 1980s, the term “beryllium sensitization” referred to the inflammatory response in the lungs (a health effect) associated with the early physical symptoms of clinical CBD. Today, beryllium sensitization does not refer to an inflammatory response, but refers to a laboratory test result which may indicate that a person’s immune system can recognize and respond to the presence of beryllium. Although different tests are used to detect immune system beryllium sensitization, the test most frequently used today is the beryllium blood lymphocyte proliferation test (BeBLPT).

The BeBLPT is a laboratory test used to indicate whether a person is sensitive to beryllium by measuring if a response occurs when a water-soluble beryllium compound is added to immune cells isolated from a blood sample. Sensitization to beryllium is not an illness or disability and, as such, is not considered a health effect. The BeBLPT, in and of itself, does not detect subclinical or clinical CBD. Diagnosing subclinical CBD requires a biopsy to obtain samples of lung tissue using a medically invasive procedure called a bronchoscopy, which has associated health risks, such as a collapsed lung, bleeding or infection and a possibility of death.

### **Is medical screening for beryllium sensitization recommended?**

Use of the BeBLPT for medical screening for persons with no clinical symptoms is not recommended by independent scientific bodies and government authorities, such as the ACGIH Biological Exposure Indices (BEI) Committee, the U.S. Army, U.S. Navy and U.S. Air Force. In position papers published on this matter, these authorities recommend the use of the BeBLPT only for diagnostic purposes when persons have clinical symptoms which may be due to CBD or as part of a well defined research project<sup>24,25,26,27</sup>.

In a 2006 paper, Dr. Jonathan Borak<sup>28</sup> reviewed the appropriateness of using the BeBLPT as a screening tool using criteria established by the World Health Organization (WHO). Borak focused on five elements essential to judging effectiveness of a screening test: 1) burden of suffering, 2) accuracy and reliability of screening tests, 3) effectiveness of early detection, 4) harms of screening, and 5) benefits outweighing harms. He identified that the prevalence of beryllium sensitization and CBD in asymptomatic (without symptoms) individuals is unknown and that there are important gaps and deficiencies in the available evidence. He found the accuracy and reliability of the BeLPT to be uncertain and that the clinical benefits of early intervention have not been confirmed or quantified in persons without symptoms. Borak concluded: *“There is currently insufficient scientific evidence to support the use of BeLPT for routine screening of asymptomatic individuals”*. The Borak paper is important when determining the value of medical monitoring, medical surveillance and medical screening as those terms are used and applied in common practice.

In general, screening tests for diseases are recommended only when an individual can benefit from early detection or treatment that prevents or delays the onset of clinical disease. Testing people for sensitization to beryllium has many disadvantages and no proven medical benefit to the individual worker. Additional disadvantages of screening include perceived decreased health and reduction in work/employment options with potentially adverse social and economic consequences. Therefore, the use of the BeBLPT as a screening tool cannot be justified in terms of expected individual benefit. In fact, we are not aware of any beryllium primary care physician who recommends pre-symptomatic treatment of beryllium sensitization or subclinical CBD. Brush Wellman uses the BeBLPT as a diagnostic tool to evaluate persons with symptoms compatible with CBD and also as a research tool to target work areas and specific jobs for improved exposure controls and to evaluate the effectiveness of exposure controls in the work place. Brush Wellman does not use or recommend the BeBLPT as a screening test for CBD because there is no documented health benefit to the individual worker.

### **Does the BeBLPT produce consistent and reliable results?**

No. The BeBLPT is highly variable<sup>29,30,31</sup> and unreliable. Substantial disagreement in test results has been found when test data are compared within and between the laboratories that conduct the BeBLPT<sup>32,33</sup>. Of the four commercial labs offering the BeBLPT, periods of instability in laboratory performance have been observed by Brush Wellman in three of the four laboratories. This lack of stability makes consistent scientific and clinical work very difficult. Additionally, some individuals who test consistently positive at one point in time can test consistently negative at a later point in time. In a survey at Brush Wellman’s Elmore, Ohio facility, 18 persons who were confirmed BeBLPT positive (2 positive tests) in the early 1990s and who continued to work in beryllium operations were retested in 1999. The retest found 10 of the 18 (55%) tested negative based on testing a blood sample at two different laboratories<sup>29</sup>. This reversion from positive to negative was confirmed in a 2007 study by Donovan<sup>6</sup>. In addition, the Donovan study and studies by others have found that 1-2% of individuals not occupationally exposed to beryllium test positive for sensitivity to

beryllium<sup>34,35</sup>. It is not known why persons not occupationally exposed to beryllium can test positive, but exposure to naturally occurring materials containing beryllium, such as all soil, as well as cigarette smoke, have been suggested<sup>18</sup>.

### **Is the use of beryllium or materials containing beryllium banned or restricted?**

No. The use of beryllium and beryllium-containing materials is not banned, restricted or otherwise limited by any current or proposed international, federal, state or local regulations. This includes directives and regulations on restrictions of certain hazardous substances in electrical and electronic devices (RoHS) in the European Union (EU), China, California and all other jurisdictions. Equipment manufacturers, designers and users can remain confident that the performance enhancing properties of beryllium and beryllium-containing materials will be available now, and in the future.

### **Can beryllium-containing materials be safely recycled?**

Yes. Beryllium-containing materials can be safely recycled and have been for many years. Certain processes, such as melting, utilized in the recycling of metals and materials require additional engineering and work practice controls to reduce potential exposure to the many hazardous materials encountered during recycling.

### **Who can I contact for beryllium health and safety assistance?**

If you have any questions regarding the information provided herein, would like a copy of any of the documents described in this statement or wish to provide feedback, please contact your sales representative or call the Product Safety Hotline at **(800) 862-4118**.

To better serve our customers and those interested in understanding more about beryllium-containing products, Brush Wellman provides access to health, safety and environmental information for beryllium-containing products on our websites. Items available on the website include Material Safety Data Sheets, Safety Facts, the Beryllium Consultant Network, Frequently Asked Questions, past beryllium health and safety updates and recent research papers. You can access the information on our websites at [www.brushwellman.com](http://www.brushwellman.com), [www.berylliumproducts.com](http://www.berylliumproducts.com), [www.electrofusionproducts.com](http://www.electrofusionproducts.com) and [www.brushceramics.com](http://www.brushceramics.com).

The Beryllium Consultant Network consists of professional industrial hygienists who have either attended an industrial hygiene training seminar on beryllium or have previous experience in controlling occupational exposure to beryllium. These consultants provide services independent of Brush Wellman. Brush Wellman assists the network consultants by providing them periodic updates through refresher courses and written correspondence. A listing of consultants in the Beryllium Consultant Network can be obtained from our website or by calling the Product Safety Hotline.

Beryllium health, safety and environmental information can also be obtained through other organizations such as OSHA, NIOSH, AIHA and ACGIH. You can obtain information from these organizations by accessing their websites at [www.osha.gov](http://www.osha.gov), [www.cdc.gov/niosh](http://www.cdc.gov/niosh), [www.aiha.org](http://www.aiha.org) and [www.acgih.org](http://www.acgih.org).

## Endnote References

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- <sup>2</sup> Beryllium sensitization is defined as confirmed beryllium positive blood lymphocyte proliferation test or beryllium positive broncho-alveolar lavage lymphocyte proliferation test without granuloma upon lung biopsy.
- <sup>3</sup> Subclinical CBD is defined as beryllium sensitization plus granuloma upon lung biopsy with normal chest X-ray and lung function test.
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- <sup>19</sup> Levy P., Roth H., Hwang P., Powers T. Beryllium and Lung Cancer: A Reanalysis of a NIOSH Cohort Mortality Study. *Inhalation Toxicology* 14:1003-1015 (2002).
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