



September 3, 2001

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Occupational Safety & Health Administration
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Dear Assistant Secretary Henshaw:

Public Citizen, a consumer group with 135,000 members and the Paper, Allied-Industrial, Chemical & Energy Workers International Union (PACE), a union with 302,000 members, hereby petition the Occupational Safety and Health Administration (OSHA), pursuant to section 6(c) of the Occupational Safety and Health Act, 29 U.S.C. Section 655(c), to issue an Emergency Temporary Standard (ETS) to lower the Permissible Exposure Limit (PEL) for beryllium and beryllium compounds from the current standard of 2.0 ug/m³ of air to 0.2 ug/m³ as an 8-hour time-weighted average. This urgent step is necessary because the chemical can cause an often fatal lung condition called chronic beryllium disease (CBD) and immune system sensitization to beryllium at air levels far below the current PEL and after as little as two months of exposure.^{1,2} We are also petitioning for annual blood lymphocyte proliferation testing (LPT), a measure of immune sensitization to beryllium. This test is often positive in beryllium-exposed workers before symptoms of actual lung disease develop. The LPT should be available to all workers in plants that process beryllium so that those with positive LPTs, and hence at risk for CBD, can be reassigned. In the event that an ETS is not granted, we request that you immediately initiate the usual rulemaking process as described in 29 USC 655(f).

Twenty-four years ago, OSHA formally proposed lowering the beryllium PEL, yet this led to no final action. In April 1998, OSHA added beryllium to its Unified Regulatory Agenda,³ a list of planned regulatory actions, and has repeated its commitment to do so semi-annually since. In a 1998 letter to the Department of Energy (DOE), Assistant

Secretary Jeffress even went so far as to criticize DOE for not lowering the PEL from the OSHA level of 2.0 ug/m³ (DOE opted instead to retain the PEL, but requires exposures to be reduced to an “action level” of 0.2 ug/m³), claiming that,

OSHA’s intention is to proceed with a full rulemaking on this substance which will, in part, presumably lower the PEL ... because we now believe that our 2 ug/m³ PEL does not adequately protect beryllium-exposed workers from developing chronic beryllium disease, and there are adequate exposure and health effects data to support this rulemaking.⁴

On September 17, 1999, Mr. Jeffress, reiterated that, “... our current permissible exposure limits for beryllium in the workplace now appear to be too high to prevent chronic beryllium disease.”⁵ The agency has even acknowledged that, under the current 2.0 ug/m³ OSHA standard, 2-10% of exposed workers have developed CBD.⁶ Nonetheless, the agency has made only vague claims of proposed regulatory action and concrete actions are nowhere in sight.

OSHA’s inaction on this issue has been rendered still more ludicrous by the DOE’s regulations, which took effect in January 2000 and required DOE and its contractors to establish programs to reduce beryllium exposure to 0.2 ug/m³ (the standard we are seeking in this petition), ten times lower than OSHA’s current PEL. Meanwhile, the agency whose primary charge is to protect U.S. workers from workplace hazards has taken no significant regulatory action.

Other organizations have joined the chorus of those proclaiming beryllium’s dangers. The International Agency for Research on Cancer (IARC) has since 1993 regarded beryllium as a known human carcinogen,⁷ a link that has been confirmed recently.⁸ The National Institute for Occupational Safety and Health (NIOSH), a research arm of the government and part of the Centers for Disease Control and Prevention (CDC), has also criticized the current PEL, stating in comments to DOE in 1999 that “the current PEL of 2 ug/m³ has not eliminated chronic beryllium disease and sensitization to beryllium, and that disease has occurred in workers exposed to levels lower than the detection limit.”⁹

Tragically for American workers, your agency’s inaction on beryllium mirrors its inaction on other occupational hazards: OSHA, in the eight years under the Clinton administration, failed to propose a single new chemical health standard. The preventable death and suffering wrought by beryllium offer you a chance to change that.

Background

It has been previously estimated that between 30,000 and 800,000 U.S. workers have been exposed to beryllium through industrial use, although the actual number may be closer to 30,000.¹⁰ The exact number at present is difficult to determine, although it is thought to be increasing due to growing use in the electronics industry. Exposure primarily occurs through the inhalation of fumes or dust from beryllium metal, alloys or ceramics during fabrication or processing. Patients with CBD gradually develop cough,

chest pain, progressive shortness of breath, weakness, and fatigue. Loss of appetite, weight loss, lung and right-heart failure may occur in people with advanced disease.¹¹ In the past, one-third of those with CBD died from related problems^{12,13} and another third endured crippling respiratory insufficiency and distress,¹⁴ often permanently bound to an oxygen tank. The DOE still uses an estimate that 30% of sensitized individuals die of CBD or its complications.¹⁵ This may have improved somewhat now that patients are treated with steroids, but there are no trials proving steroid efficacy for CBD.

The defense, electronic, aviation, dental and sporting goods industries use beryllium for its many unique and strategic properties. For example, beryllium's heat capacity is five times that of copper. An alloy of 2% beryllium and 98% copper is six times stronger than pure copper. Beryllium alloys are also very hard and light. Beryllium oxide is resistant to corrosion and high temperatures. Beryllium and its compounds are commonly used in ceramics, aircraft parts, dental prostheses, golf clubs, missile guidance systems, springs, wheels and precision instruments.¹⁰ Beryllium exposure occurs when, in the process of producing these items, beryllium is ground, sanded or cut, producing a fine dust or fume that can be inhaled. There is some evidence that machinists are at particularly high risk, perhaps because they are exposed to smaller particles that can reach the deepest recesses of the lung.¹⁶ All U.S. domestic supplies of beryllium come from a mine near Spor Mountain, UT and are produced by a single company, Brush Wellman of Elmore, OH, which is also a major manufacturer of beryllium alloys. NGK Metals Corporation of Reading, PA is the other major U.S. manufacturer of beryllium alloys. U.S. consumption of beryllium has increased from 198 metric tons in 1994 to 240 metric tons in 1998, approximately equal to the amount extracted from the Utah mine.¹⁷

The current OSHA standard of 2.0 ug/m³ was originally established in 1949, more than 50 years ago, by the Atomic Energy Commission (AEC) in an effort to combat Acute Beryllium Disease (ABD). In the 1940s, 7% of beryllium workers developed ABD, of whom 10% died acutely,¹⁰ and many of those surviving went on to develop CBD. While the 1949 AEC standard effectively eliminated ABD, a 1958 AEC report indicated that the AEC knew beryllium was toxic at lower levels, but considered the risk acceptable "because of the relatively small numbers of people involved."¹⁸

In fact, the AEC standard was barely grounded in science at all. In a memoir, Merrill Eisenbud, one of the pioneers in beryllium disease, described how the standard was developed:

One morning I was riding to [a new laboratory that would use beryllium] by taxi with Dr. Willard Machle. He was a medical consultant to the company that was building the laboratory ... We knew that when we arrived we would be expected to provide the laboratory designers with design criteria and decided that a tentative [standard] should be two micrograms per cubic meter. In view of the circumstances, this standard has been dubbed the "taxicab standard" in recognition of the seemingly flimsy basis on which it was established.¹⁹

The Occupational Safety and Health Act passed in 1970 and OSHA adopted the 2.0 ug/m³ AEC standard in 1971 when the agency began its operations.¹⁰

In 1977, NIOSH recommended that OSHA reduce the PEL for beryllium to 0.5 ug/m³ due to its carcinogenicity.²⁰ That year, OSHA itself proposed reducing the PEL to 1 ug/m³.²¹ DOE and Department of Defense (DOD) officials objected, claiming that stricter OSHA standards would threaten national security due to an interrupted beryllium supply. The Secretary of Energy stated in a letter to the Secretaries of Health, Education, and Welfare (now the Department of Health and Human Services) and Labor, “Clearly, cessation of beryllium metal and/or beryllium oxide production is unacceptable and would significantly degrade our national defense effort.”²² Twenty-four years after this proposal, OSHA has yet to publish a new standard, leaving the current standard at an out-of-date 2.0 ug/m³.

Beginning in the 1980s, the results of LPTs brought increasing attention to the inadequacy of the existing OSHA standard. More and more workers with limited exposures developed sensitization and, later, CBD. Reacting to the growing evidence of beryllium toxicity, the American Conference of Governmental Industrial Hygienists (ACGIH) proposed a Threshold Limit Value (analogous to a PEL) of 0.2 ug/m³ in 1998.²³

Ironically, two decades after having helped to thwart OSHA’s efforts to enact a safer standard, DOE (which in part replaced the AEC) found that 1.2% of its present and former nuclear weapons employees and contract workers who had been screened had been diagnosed with CBD and an additional 2.5% had been sensitized to beryllium.¹¹ DOE published a rule effective January 7, 2000 according to which DOE and its contractors must establish a program to reduce beryllium exposure to 0.2 ug/m³, a level already achieved at many DOE sites,¹¹ but not at numerous facilities beyond the reach of DOE. Indeed, the DOE rule only affects about 1600 workers, perhaps 5% of the beryllium-exposed workforce. Former DOE Secretary Bill Richardson has described the placing of nuclear workers at risk as “... one of the saddest chapters in [DOE’s] history.”²⁴

With the reduction in the size of the nuclear weapons industry, beryllium has increasingly found new uses in a broader segment of U.S. industry, especially in the form of alloys (e.g., dental laboratories). The result has been a redistribution of risk away from workers covered by the DOE to a broader segment of the U.S. workforce, where, in many cases, little research has been done.

Although workers outside DOE have no less a right to safety and health than those covered by DOE, OSHA’s response so far has been limited to issuing a Hazard Information Bulletin for beryllium two years ago.²⁵ This is obviously an inadequate and dangerous substitute for a mandatory standard. In a recent Federal Register Notice, OSHA indicated that it plans to issue a Notice of Proposed Rulemaking on Beryllium in December 2001.²⁶ Given the pace of previous agency action on this issue, it seems unlikely that this deadline will be met.

In this petition, Public Citizen's Health Research Group documents the following:

- 1. Beryllium sensitization generally precedes CBD and predicts CBD**
- 2. The current standard of 2 ug/m³ is inadequate for protecting workers from CBD**
- 3. A standard of 0.2 ug/m³ would drastically reduce the risk of CBD**
- 4. Engineering controls to dramatically reduce beryllium exposure are feasible**
- 5. Mandatory medical surveillance and removal of sensitized persons must be part of the OSHA standard**

1. Beryllium sensitization generally precedes CBD and predicts CBD

A. The definition of sensitization and CBD

Immune system sensitization occurs when white blood cells (lymphocytes) attack beryllium in the lung. In contrast to lymphocytes from unsensitized persons, those obtained from the blood or lungs of sensitized persons take up larger quantities of thymidine (a constituent of DNA), indicating higher lymphocytic activity, or sensitization, when cultured with beryllium and thymidine. Except where noted, we have defined a person as sensitized if he or she had two or more abnormal LPTs. If sensitization were defined as just a single positive test, a higher fraction of sensitized persons would be identified, but more persons who are not sensitized (false-positives) would be included.

There are several definitions of CBD that have been used over the past fifty years. In this petition, we use a definition proposed by Mroz, et al.²⁷ in which the diagnosis of CBD requires sensitization of either blood or lung lymphocytes, a history of exposure to beryllium and granulomas (nodules consisting of inflammatory cells) on lung biopsy, irrespective of symptoms.

B. Population-based studies of beryllium sensitization and rate of progression

1. Prevalence of sensitization and CBD

Prevalence is the percentage of an exposed population that has a specific characteristic. It will underestimate population disease burden for diseases that only occur long after exposure. Because CBD has a latency period of up to 40 years, the studies described here likely underestimate the true extent of CBD. Another factor that lowers the apparent prevalence is that persons sick with CBD are less likely to be working than healthy persons.

As shown in Table 1, studies in 14 populations addressed the prevalence of sensitization. This ranged from 1.8% among gemstone cutters²⁸ to 3.6%²⁹ in beryllium plants where many had low-level or no exposure to 16% in populations with significant exposure to beryllium.³⁰ CBD prevalence ranged from 0%²⁸ to 7.8%³¹ in eleven studies that measured it.

Excluding the gemstone cutter study, which had only one person with sensitization, between 20% and 80% of sensitized persons in the various studies described in Table 1 had CBD.

2. Incidence of sensitization and CBD among unsensitized persons

Incidence is the fraction of exposed at-risk people who develop a condition or disease per year. These incidence studies also likely underestimate cumulative incidence rates because they do not span a long enough period of time to detect all cases of a disease with a long latency period (the longest period of follow-up was four years and CBD can occur 40 years after exposure).

Table 2 shows that studies in three populations measured the incidence of sensitization at between 0.6%^{32,33} and 2.7%³⁰ per year. Two studies of CBD incidence among unsensitized individuals found that between 0.06%^{32,33} and 0.84%¹ develop CBD per year.

3. Incidence of CBD among sensitized individuals

Newman, et al. followed a cohort of 28 sensitized persons of whom 16 were fully evaluated. He found that 44% (7/16) developed the granulomas indicative of CBD over an average of 2.3 years, for an annual CBD incidence of 19%. Assuming, conservatively, that none of 12 in this cohort whose evaluation is either pending or missing developed disease in this period, the overall incidence would be approximately 10% per year (7/28/2.8 years).³⁴ Some experts in the field estimate that 50-90% of those sensitized will ultimately develop CBD.³⁵

C. Lymphocyte proliferation tests

The LPT has dramatically altered our understanding of CBD, underscoring that a larger population than previously recognized has been affected by exposure to beryllium. In this section, we do not attempt to evaluate the customary indices of test performance: sensitivity, specificity, negative predictive value and positive predictive value. This is because a positive LPT is typically one of the diagnostic criteria for CBD and bronchoscopies are typically conducted primarily on workers with positive LPTs. This lends a degree of circularity to the definitions of CBD and sensitization, precluding the assessment of the utility of the LPT using these four measures. Moreover, because there is a sometimes-long latent period between sensitization and CBD, the ability of a positive LPT to predict CBD is likely to increase over time. However, in studies evaluating the usefulness of the LPT, long prospective follow-up was generally not conducted.

Nonetheless, a recent review of the LPT concluded that, “The BeLPT has become an important diagnostic component for both [beryllium sensitization] and CBD.”³⁶ The test is widely used in research and is at the core of the DOE’s surveillance program. This has not prevented the industry from trying to raise questions about the test. For example, a recent industry study showed only “moderate” inter-laboratory agreement on the LPT,

using split samples.³⁷ However, this study looked at only the first LPT; confirmatory second LPTs were excluded from the analysis. Other investigators have reported concordance rates of 85%-96% for the two-test LPT sequence, with lower levels of concordance for positive tests,³² indicating better specificity (ability to not label normal workers as sensitized) than sensitivity (ability to correctly identify affected workers).

When screening for relatively low prevalence conditions, it is often important that the test produce few false-positives, as such results can lead to unnecessary anxiety and medical workups. Thus, a screening test need not identify all sensitized workers, particularly if the screening will be repeated annually, the workers remain accessible for testing and the disease has a long latency period; the worker may well test positive at the next screening. These characteristics make the blood LPT very suitable for screening beryllium-exposed workers.

2. The current standard of 2 ug/m³ is inadequate for protecting workers from CBD

The following section describes the studies that examine the relationship between beryllium exposure and adverse health effects.

A. Workers

1. The relationship between exposure and prevalence

Table 1 shows ten studies of populations that compared exposure to beryllium with sensitization and/or CBD rates. In all but three studies, sensitization and CBD occurred at median or mean exposures consistently less than the 2 ug/m³ OSHA PEL. In all studies, at least some exposures were less than the OSHA PEL.

A study of surface mine and process mill workers by Rom, et al. showed sensitization rates as high as 16% in 1979 when exposures were a mean of 7.2 ug/m³.³⁰ This decreased to 8% in 1982 when mean exposures were 1.0 ug/m³.

There were five (7.1%) employees with CBD in a study by Cullen, et al. at a precious metals plant.³⁸ Workers at the plant were exposed to average air concentrations of 1.2 ug/m³. In the furnace area, where four of the five cases occurred, exposures were consistently below 2 ug/m³.

Kreiss, et al. related exposure from 1981-1992 at a ceramics plant to sensitization and CBD prevalence in 1992.³⁹ All six persons with CBD and all eight beryllium-sensitized persons were hired after 1981 when the median air beryllium levels were 0.3 ug/m³. Despite beryllium levels far below OSHA standards, overall sensitization rates were 5.9%. Non-machinists were exposed to median levels of 0.3 ug/m³; 80% of measurements were less than 1 ug/m³. Nevertheless, 1.2% of non-machinists were sensitized. Machinists were exposed to median levels of 0.6 ug/m³, yet 14% (7/49) were sensitized. This study unequivocally demonstrates that exposures well below the current OSHA standard pose a significant threat to workers.

A study of production plant workers in metal, alloy, and ceramics processing had similar findings.⁴⁰ Kreiss, et al. found the median exposure during 1980-1993 to be 1.4 ug/m³. 9.4% (59/627) were sensitized and 3.8% (24/627) of workers had CBD. Five (2.6%) workers hired after 1984 had CBD and 18 (9.5%) were sensitized despite median daily weighted average exposures of 1.3 ug/m³. Furthermore, pebble plant workers hired after 1983 were exposed to median beryllium levels of 1.1 ug/m³, yet 6.4% had CBD.

From 1992-1995, Yoshida, et al. compared general area exposures in four different processes in two plants to sensitization.²⁹ (General area exposures are an alternative method of measuring beryllium and generally give lower measurements than those taken within a worker's breathing zone, the usual way beryllium exposure is measured.) They found that no worker was exposed to above 1.85 ug/m³ of beryllium (below the current OSHA standard) and no geometric mean exposure level was above 0.26 ug/m³, yet 3.6% of the workers were sensitized by the definition of sensitization used in this petition. Furthermore, persons who ever had an abnormal blood LPT were statistically more likely to have been exposed to average concentrations above 0.01 ug/m³. As with the two previously mentioned studies, exposure data were not reported for the period before the study.

Over 10,000 DOE employees, by far the largest number studied to date, have been screened for sensitization and CBD.¹¹ The first 8838 workers screened were exposed to beryllium at average levels approximately half the current OSHA standard, yet overall 3.4% were sensitized and 1.2% had CBD.¹¹ In the largest nuclear plant (Rocky Flats, CO) beryllium exposure in the buildings with the highest levels was 0.035-1.19 ug/m³; however, 3.5% of the workers (221/6,257) were sensitized and 1.3% (79/6,257) had CBD. Similarly, in Y-12 (Oak Ridge, TN), 1,949 employees were exposed to an average of 0.3-0.9 ug/m³ of beryllium. Four percent of the workers (77/1949) were sensitized and 1.3% (25/1949) had CBD.

Just this year, four new studies relating exposure to disease and sensitization have been published. In one, in which workers in a beryllium metal machinery facility were exposed to median exposures of 0.3 ug/m³, the prevalence of sensitization was 9.4% (22/235) and that of CBD was 5.5% (13/235).^{1,2} Four of the 22 sensitized workers had worked in the plant for less than three months, in one case for only 50 days. Every worker with sensitization or CBD had a lifetime weighted average beryllium exposure below the current OSHA PEL, with one case of CBD occurring in a worker with just three months of exposure at 0.024 ug/m³, about 100 times lower than the current OSHA PEL.

In a ceramics plant with median exposures of 0.3-0.4 ug/m³, the prevalence of sensitization was measured at 9.9% (15/151) and that of CBD at 5.3% (8/151).⁴¹ Two workers were sensitized at exposures of 0.05 ug/m³ and 0.06 ug/m³ after less than six years of exposure.

A study at a mining and extraction facility showed the often large discrepancy between personal breathing samples, which ranged up to 15.9 ug/m³, and general area samples,

which never exceeded 0.7 ug/m^3 .⁴² For the diseased workers, disease rates were not correlated with exposures.

Finally, sensitization and CBD rates of 10.1% (54/535) and 4.3% (23/535) respectively were obtained in a beryllium manufacturing facility in which median exposures were 0.9-5.7 ug/m^3 .⁴³ However, the exposure histories of the diseased workers were not provided.

In conclusion, the ten populations studied had high prevalences of CBD and sensitization with median or mean beryllium exposures generally much less than the OSHA PEL of 2 ug/m^3 .

2. The relationship between exposure and incidence

The incidence studies by Stange, et al. in Table 2 show that each year 0.6% (8/452/3 years) of current Rocky Flats employees exposed to average air beryllium levels of 1 ug/m^3 between 1970 and 1988 became sensitized and 0.07% of current employees contracted CBD (1/452/3 years).^{32,33} (Of course, any incidence estimate based on only one case is inherently imprecise.) One percent or fewer measurements exceeded 5 ug/m^3 , and only 15% were estimated to exceed 2 ug/m^3 .⁴⁴ The more recent study by Newman, et al. is even more concerning. Despite median exposure levels of 0.3 ug/m^3 , only 15% of OSHA's current PEL, the incidence of sensitization was 1.2% per year and that of CBD was 0.84% per year. These figures underestimate the incidence of disease because they exclude four of 60 new employees, screened within three months of initial employment, who already had positive LPTs and CBD despite no evidence of beryllium exposure prior to employment.^{1,2}

B. Non-exposed workers and non-employees

Additional studies confirm that the risk of sensitization and CBD extends beyond those working directly with the metal. Although workers directly exposed to beryllium are usually those who contract CBD, others in beryllium plants, including a secretary, a security guard, an inspector, an employee in accounting, and an employee in purchasing, have also contracted CBD.^{40,45} Cases have also occurred among people exposed to contaminated clothes,⁴⁶ and community members,¹³ who presumably have relatively lower exposure levels, have also contracted the disease. Specific cases of CBD include an 8-year-old girl,⁴⁷ a housewife who used bags from a beryllium plant as dishcloths,⁴⁷ and persons who lived near beryllium plants.^{13,48,49} In 1951, the prevalence of CBD among non-beryllium workers living within one quarter of a mile of the Lorain, OH beryllium plant was 1.0%. These individuals were exposed to average beryllium levels of approximately 1 ug/m^3 , half the current OSHA standard.⁵⁰ The Environmental Protection Agency's (EPA's) ambient air standard for beryllium is 0.01 ug/m^3 . Research has also demonstrated significant beryllium levels in the cars of workers exposed to beryllium.⁵¹

In conclusion, CBD and sensitization clearly occurs in persons exposed to beryllium at levels well under OSHA's PEL, including even those without direct occupational exposure to the metal.

3. A standard of 0.2 ug/m³ would drastically lower the risk of CBD

As demonstrated in section 2, high rates of sensitization and CBD have been found to occur at levels below 2 ug/m³, and some cases have occurred with presumably very low-level exposure. While an absolutely safe beryllium level remains unknown, when up to 16% of a workforce has sensitization³⁰ and up to 8% has CBD³¹ and workers develop sensitization and CBD within three months of employment at exposures as low as 0.3 ug/m³,^{1,2} it is clear that the present PEL does not adequately protect the workforce. Thus, the lowest possible standard that is technically feasible needs to be chosen. As seen in Tables 1 and 2, the great majority of cases of CBD occurred at levels above 0.2 ug/m³.

In addition, four studies suggest a dose-response relationship between exposure and disease and thus support the notion that lowering exposures will reduce disease. The first study showed that machinists were exposed to median beryllium levels of 0.6 ug/m³ while non-machinists were exposed to 0.3 ug/m³. Machinists had odds of sensitization 14 times higher than non-machinists (14% sensitized versus 1.2%) and 8.5 times higher odds of CBD (10% versus 1.2%).³⁹ These findings were strongly statistically significant. The second study showed that persons exposed to above 0.01 ug/m³ had statistically higher lymphocyte response levels to beryllium compared to persons exposed to less than 0.01 ug/m³.²⁹ In the third study, in multivariate analysis, intermediate and high exposures were generally associated with increased risks of sensitization or CBD compared to low exposures, although the findings did not reach statistical significance.² In the fourth study, multivariate analysis showed a strong relationship between various exposures and CBD.⁵² Cases with beryllium sensitization also had higher exposure measures, but this relationship did not reach statistical significance. While some studies have failed to demonstrate a dose-response relationship, this may be due to imprecise exposure monitoring (too few samples, general area vs. personal breathing zone measurements), genetic susceptibility and, perhaps, greater danger represented by small rather than large particles.⁴³

Other groups are already taking action. As mentioned above, in 1998, ACGIH suggested a level of 0.2 ug/m³ because studies suggested that exposures below this would maintain a sensitization rate below 3-4%.²³ DOE put in place an action level of 0.2 ug/m³ earlier this year.¹¹ Many DOE facilities were already approaching the level that the agency now recommends (see section 4).

We selected 0.2 ug/m³ based on the current state of knowledge that most cases will likely be eliminated at this level, but recognize that as more knowledge becomes available even this standard may turn out to be too high. For example, one recent study, based on the observation that the EPA's standard for beryllium in ambient air of 0.01 ug/m³ appears to prevent beryllium disease, then used mathematical modeling to recommend an occupational PEL of 0.1 ug/m³.⁵³ In conclusion, as the ACGIH and DOE concluded, strong evidence supports the notion that 0.2 ug/m³ is the highest PEL that should be in effect, and even that may be inadequately protective.

4. Engineering controls to dramatically reduce beryllium exposure are feasible

A number of reports have outlined methods for reducing worker beryllium exposure.^{11,25,54} First, the number of workers exposed to beryllium operations must be minimized. Improved engineering controls include enclosing work processes known to liberate beryllium, improving ventilation systems and using vacuum systems or wet machining processes whenever possible. Certain specific work practices can also be beneficial: avoiding compressed air to clean machinery, using high-efficiency particulate air (HEPA) vacuums instead of conventional vacuums and making sure not to leave a film of dust after cleaning floors with a wet mop. Other work practice measures include various hygienic practices (including changing rooms, showering and handwashing facilities), respirators and protective clothing. Administrative measures such as scheduling operations likely to liberate dust at times when few workers are present, improving training and providing information sheets to workers are also important.

Together, these measures can have a significant beneficial impact on exposure levels. DOE facilities in Rocky Flats and Oak Ridge have decreased exposure levels more than 30-fold to levels approaching 0.03 ug/m^3 ,¹¹ approximately one-seventh of the standard we are proposing. Modifications included remodeling of the ventilation system and the elimination of operations performed outside hoods. In Oak Ridge, 98% of samples were less than 2 ug/m^3 and the arithmetic mean exposure between 1990 and 1996 was 0.3 ug/m^3 . Similarly, the Rocky Flats machine shop reduced exposure levels to 0.035 ug/m^3 with 99.8% of exposures below 2 ug/m^3 . However, it is likely that substantial, but still feasible, improvements will be necessary before changes in disease prevalence are noted. At a ceramics plant, modest decreases in exposures (median exposures for workers hired prior to 1992 were 0.39 ug/m^3 , compared to 0.28 ug/m^3 for those hired after that date) had no detectable impact upon disease rates.⁴¹

5. Mandatory medical surveillance and removal of sensitized persons must be part of the OSHA standard

Under the new DOE regulations, employers must also provide medical evaluations (including annual LPTs for the most heavily exposed workers) and offer medical removal based on a positive blood LPT. Medical removal must include the opportunity to transfer to a job in the same company with comparable pay where exposure is less than the DOE action level of 0.2 ug/m^3 . DOE also requires medical removal benefits including compensation for lost wages due to illness. We call on OSHA to endorse DOE's approach to medical surveillance and removal.

Medical surveillance is particularly justified when one can demonstrate that screening picks up the disease earlier and when earlier treatment or removal from exposure can result in clinical benefit. There is evidence that both of these criteria have been met.

In 1993, Pappas and Newman compared 21 persons with CBD originally identified by blood LPT screening with 15 clinically or radiographically identified patients with CBD.⁵⁵ Of the 21 identified by screening, 7 (33%) had developed abnormalities on

pulmonary function tests, compared to 9 (60%) who presented with clinical or radiographic abnormalities. Similarly, none of the screened group had arterial blood gas abnormalities compared to 7 (47%) in the clinically identified group. Finally, exercise physiology tests were abnormal in 11 (52%) in the screened group, but in 13 (87%) in the clinical group. Therefore, persons with CBD identified by screening had less severe disease than those identified by clinical evaluation. Screening thus provides an opportunity for early intervention.

Two studies have suggested that lowering the exposure levels to which patients with CBD are exposed may reduce CBD progression rates or even reverse disease. First, Nishikawa, et al. found that radiographic abnormalities in three of ten persons with CBD reversed; however, the article does not state whether workers were removed from beryllium exposure or whether exposure levels were reduced during the study period.⁵⁶ In the second study, Sprince et al. demonstrated, based on medical surveys in 1971 and 1974, that radiographic abnormalities typical of CBD in 9 of 18 persons resolved completely during a period when engineering modifications drastically decreased peak beryllium levels. For example, in the two operations with the highest exposures, vacuum drying and material transfer, peak levels decreased from over 1200 ug/m³ to less than 2 ug/m³ and 15 ug/m³, respectively. Additionally, 13 workers who were hypoxic (low oxygen in the blood) in 1971, had marked increases in their blood oxygen levels in 1974 (from an average of 72 mm Hg to 91 mm Hg).⁵⁷

In its final rule, DOE maintains that “the responsible employer must establish and implement a medical surveillance program for beryllium-associated workers who voluntarily participate in the program.”¹¹ The screening gives exposed employees important health information so that they can decide whether to get further workup and treatment and to make personal and family decisions. The LPT also distinguishes diagnostically between CBD and a similar disease, sarcoidosis, in which the test is negative.⁵⁸ Medical surveillance also provides information on the effectiveness of any modified standard. A successful surveillance program has recently been described.¹

Summary

This petition has shown that the current OSHA PEL of 2.0 ug/m³ is grossly and dangerously inadequate, that a PEL of 0.2 ug/m³ would greatly reduce the burden of disease and that this level has been achieved at DOE sites and elsewhere. It has shown that medical surveillance is beneficial for employees. The inadequacy of the current PEL has been recognized by the DOE, the ACGIH, NIOSH and even OSHA itself. Yet your agency’s unjustifiable inaction continues. Given the current state of scientific knowledge, and the tens of thousands of exposed workers whose health is in the balance, OSHA must act immediately to issue a safer standard and accompanying medical surveillance. In his 1998 letter to DOE, then-OSHA head Charles Jeffress had it right: “I urge you not to rely on a PEL that was developed by the Atomic Energy Commission in 1949 and adopted by OSHA in 1971 ...”⁴ We agree.

Sincerely,

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Table 1. Prevalence of abnormal beryllium (Be) LPTs and CBD among Be-exposed workers *

Author, year	Population studied	Mean or median personal breathing zone Be-exposure, ug/m ³ , number of samples	Prevalence of abnormal blood Be LPT, % (n/N)	Prevalence of CBD, % (n/N)
Rom, 1983 ³⁰	Utah surface mine and process mill employees	1979: 7.2 ug/m ³ , 27 1982: 1.0 ug/m ³ , 13	1979: 15.9% (13/82) 1982: 8.2% (5/61)	
Nishikawa, 1980 ⁵⁶	Beryllium oxide workers in a ceramic factory			2.3% (10/435) [†]
Preuss, 1985 ⁵⁹	Beryllium workers		6.5% (36/553)	
Cullen, 1987 ³⁸	Workers in a precious metal refinery, 70	1.2 ug/m ³ , 114	7.1% (5/70)	5.7% (4/70)
Kreiss, 1989 ³¹	Aerospace applications plant employees exposed to beryllium oxide dust generated during machining, or beryllium metal fumes generated during casting		11.8% (6/51)	7.8% (4/51)
Kreiss, 1996 ³⁹	Current employees of a ceramics plant	0.3 ug/m ³ , 4133	5.9% (8/136)	4.4% (6/136)
Kreiss, 1997 ⁴⁰	Production plant workers exposed to beryllium metal, alloy, and oxide	1.4 ug/m ³ , 15,787	9.4% (59/627)	3.8% (24/627)
Yoshida, 1997 ²⁹	Two manufacturing factories in Japan	<0.01-0.26 ug/m ³ [‡]	Any abnormal test: 15% (12/83) Repeatedly abnormal: 3.6% (3/83)	
DOE, 1999 ¹¹	Current and former DOE employees screened	Rocky Flats: 0.035 -1.19 ug/m ³ , 378. Y-12 plant: 0.3 -0.9 ug/m ³ , 1596 [§]	3.4% (299/8838)	1.2% (104/8838)
Wegner, 2000 ²⁸	Gemstone cutters		1.8% (1/57)	0% (0/57)
Newman, 2001 ¹ Kelleher, 2001 ²	Beryllium metal machinery facility employees	0.3 ug/m ³ , 100	9.4% (22/235)	5.5% (13/235)
Henneberger, 2001 ⁴¹	Current employees of a ceramics plant	0.3-0.4 ug/m ³ , 18,903 ^{**}	9.9% (15/151)	5.3% (8/151)
Deubner, 2001 ⁶³	Beryllium mine and extraction facility	0.3-15.9 ug/m ³ , 34,307 ^{††}	4.0% (3/75)	1.3% (1/75) ^{‡‡}
Kent, 2001 ⁴³	Beryllium manufacturing facility	0.9-5.7 ug/m ³ , 108 ^{§§}	10.1% (54/535)	4.3% (23/535)

* Excludes studies of hospitalized patients.

† The definition of CBD in this study required radiographic changes, and therefore excludes some with earlier disease.

‡ Be levels were measured by general area sampling, number of samples not provided.

§ Medical workups also conducted at Mound, but no exposure data available

** General areas samples were used only when the worker was away from the production process.

†† Included general area, personal breathing and lapel samples, but exposure presented is for personal breathing zone.

‡‡ Two workers declined pulmonary work-up.

§§ Includes lapel and general area samples.

Table 2. Incidence of abnormal Be LPTs and CBD among Be-exposed workers

Author, year	Population studied	Exposure (personal breathing zone)	Incidence of abnormal blood Be LPT, (n/N/years)	Incidence of CBD, (n/N/years)
Rom, 1983 ³⁰	Utah surface mine and process mill employees, unsensitized in 1979 and retested in 1982	0.25 - 7.18 ug/m ³	2.7%/year (5/61/3 years)	
Stange, 1996 ^{32,33}	Rocky Flats Nuclear Facility employees retested in 1993	1.04 ug/m ³	Current: 0.6%/year (8/452/3 years) ^{***} Former: 1.0%/year (2/66/3 years) Total: 0.6%/year (10/518/3 years)	Current: 0.07%/year (1/452/3 years) Former: 0%/year (0/66/3 years) Total: 0.06%/year (1/518/3 years)
Newman, 2001 ¹ Kelleher, 2001 ²	Beryllium metal machinery facility employees	0.3 ug/m ³	1.2%/year ^{†††}	0.84%/year

^{***} Includes patients with radiographic evidence (as opposed to bronchoscopic evidence) of granulomatous disease in addition to a history of exposure and positive blood Be LPT.

^{†††} Excludes four cases of abnormal LPTs and CBD detected among 60 employees at “initial screening,” within three months of employment, but with no test at initial employment. Based on a weighted average of 235 employees followed for various lengths of time.

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