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May 6, 2016

William Perry, C.I.H.
Director, Directorate of Standards & Guidance
Occupational Safety & Health Administration
U.S. Department of Labor
200 Constitution Ave., NW
Washington, D.C. 20210

The Honorable David Michaels, Ph.D., M.P.H.
Assistant Secretary of Labor for Occupational Safety and Health
Occupational Safety & Health Administration
U.S. Department of Labor
200 Constitution Ave., NW
Washington, D.C. 20210

Re: Docket No. OSHA-H005C-2006-0870-1745 [Beryllium: Memorandum for Reopening of the Docket to Allow for Submissions of Post-Hearing Comments and Briefs]

Dear Mr. Perry and Dr. Michaels,

Public Citizen, a worker and consumer advocacy organization with more than 400,000 members and supporters nationwide, submits these comments related to the Occupational Safety and Health Administration's (OSHA's) proposed beryllium rule,[1] in response to OSHA's request[2] for additional comments following the agency's public hearing on March 21-22, 2016.[3] Please refer also to our original comments, submitted on November 5, 2015,[4] and our testimony, on March 22, 2016,[5] at OSHA's public hearing.

[1] 80 FR 47565. Docket No. OSHA-H005C-2006-0870. Proposed Rule; request for comments. Occupational Exposure to Beryllium and Beryllium Compounds. August 7, 2015. https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-17596.pdf. Accessed May 6, 2016. **[Hereafter referred to as "OSHA Proposed Rule"]**

[2] Occupational Safety and Health Administration. Memorandum for beryllium hearing participants: Reopening of the docket to allow for submissions of post- hearing comments and briefs. William Perry, Director, Directorate of Standards and Guidance. March 24, 2016. https://www.regulations.gov/#!documentDetail;D=OSHA-H005C-2006-0870-1745. Accessed May 6, 2016.

[3] 81 *Fed Regist* 7717. Occupational Exposure to Beryllium. February 16, 2016. https://www.federalregister.gov/articles/2016/02/16/2016-02782/occupational-exposure-to-beryllium. Accessed May 6, 2016.

[4] Public Citizen. Comments Urging OSHA to Finalize a More Protective Beryllium Rule. November 5, 2015. http://www.citizen.org/hrg2281. Accessed May 6, 2016.

[5] Public Citizen. Testimony at OSHA Hearing on the Agency's Proposed Beryllium Rule. March 21, 2016. http://www.citizen.org/hrg2309. Accessed May 6, 2016.

Our comments here concern: 1) adapting the proposed rule for outdoor workers, such as open-air abrasive blasters, including in the construction and shipyard industries; 2) a provision in the proposed rule regarding medical surveillance for chronic beryllium disease (CBD) with beryllium sensitization (BeS) screening; and 3) a provision regarding medical surveillance for lung cancer with biennial low-dose CT scans.

Before this, however, we wish to take this opportunity to – again – urge OSHA to do everything in its power to finalize its updated beryllium rule as soon as possible. It has been more than 14 long years since we petitioned OSHA for a more protective beryllium standard, with too many workers killed or permanently disabled from exposure to levels of beryllium that would have been banned had OSHA accepted our petition. Public Citizen also reiterates its call for OSHA to lower the proposed permissible exposure limit (PEL) to 0.1 $\mu g/m^3$ and short-term exposure limit (STEL) to 1.0 $\mu g/m^3$, levels that are feasible and that will adequately protect a larger proportion of workers from the devastating and irreversible effects of beryllium exposure.

I. Applying the proposed rule to outdoor settings, including in the construction and shipyard industries

Public Citizen urges OSHA to apply the PEL and the STEL, in addition to all ancillary provisions in the proposed rule, to the tens of thousands of construction and shipyard workers exposed to levels of airborne beryllium that can lead to lung cancer and CBD. Workers in these industries are often exposed to beryllium when performing abrasive blasting in outdoor settings.

OSHA does not need to create an entirely separate rule to expand coverage to the construction and shipyard industries since many of the rule's provisions could and should be easily applicable to outdoor abrasive blasting settings. We support the comments of the United Steelworkers panel during the March 22, 2016 informal public hearing that specifically addressed expanding the rule to cover outdoor workers in the maritime industry.[6]

Construction and shipyard companies employing abrasive blasters have several tools to adapt their worksites to outdoor settings. Devices such as temporary enclosures protect workers from hazardous contaminants like beryllium while they perform open-air blasting. In addition to temporary enclosures, an OSHA maritime guidance document outlines other control measures employers may use to mitigate the hazards of abrasive blasting, such as exclusion zones and blasting rooms, among numerous other safeguards.[7] Such measures should be applied to outdoor construction abrasive blasting operations as means of complying with the lower proposed PEL and STEL.

Public Citizen asserts that there is no justifiable reason to exclude from the proposed rule the estimated 23,000 construction and shipyard workers (40% of all workers) exposed to beryllium.

II. Medical surveillance: Medical examinations and screening for beryllium sensitization

The proposed rule's medical surveillance provisions would: 1) provide medical examinations, including screening for BeS, only to employees who are exposed to beryllium above the

[6] Docket No.: OSHA-H005C-2006-0870-1756, pages 294-298.
[7] Docket No.: OSHA-H005C-2006-0870-1632.

proposed PEL for 30 days or more per year, who are exposed to beryllium in an emergency, or who show signs or symptoms of CBD; and 2) provide low-dose computed tomography (CT) scans to employees exposed to beryllium above the proposed PEL for 30 days or more per year for 5 years or more.[8] This section addresses the first provision, relating primarily to screening for BeS, while the next section addresses the second provision dealing with screening for lung cancer with low-dose CT scans.

Public Citizen advises OSHA to revise the proposed standard to trigger medical examinations and screening for BeS with the beryllium lymphocyte proliferation test (BeLPT) at the proposed action level (0.1 $\mu g/m^3$), rather than at the proposed PEL (0.2 $\mu g/m^3$).

As written, the rule would leave far too many workers without proper screening for BeS. In our comments submitted on November 5, 2015,[9] Public Citizen cited peer-reviewed research demonstrating that workers become sensitized to beryllium even when exposed to extraordinarily low levels of exposure for short periods of time, including levels significantly below the proposed rule's PEL. One study in particular found that two of 20 short-term workers exposed to average airborne beryllium concentrations of less than 0.2 $\mu g/m^3$ became sensitized to beryllium, with one of the two sensitized workers exposed to an average concentration of just 0.05 $\mu g/m^3$.[10]

Making BeS screening available only to workers exposed to the PEL also contradicts OSHA's past practices for developing toxic chemical standards. An OSHA staff member indicated during the March 21-22 informal beryllium hearing that OSHA's toxic chemical standards normally make medical surveillance available at the action level in instances where there is risk for workers at the PEL.[11]

Some in the occupational health community recommend applying the medical surveillance provisions to all workers in workplaces with any detectable airborne beryllium – regardless of the level or duration of exposure – since, as indicated above, beryllium sensitization can occur even below the proposed action level of 0.1 $\mu g/m^3$.[12] We urge OSHA to conduct a feasibility analysis to determine whether such testing could be expanded to all beryllium-exposed workers. If OSHA determines that it would indeed be feasible to do so, then Public Citizen would urge OSHA to revise the standard accordingly in order to make all beryllium-exposed workers eligible for BeS screening.

In the meantime, Public Citizen recommends revising the proposed rule to at least trigger BeS screening with BeLPTs at the action level of 0.1 $\mu g/m^3$. Should OSHA adopt our recommendation to lower the PEL to 0.1 $\mu g/m^3$, we would urge the agency to lower the trigger for BeS screening to a new action level of 0.05 $\mu g/m^3$.

[8] OSHA Proposed Rule, p. 23.
[9] Public Citizen. Comments Urging OSHA to Finalize a More Protective Beryllium Rule. November 5, 2015. http://www.citizen.org/hrg2281. Accessed May 6, 2016. Also available at: Docket ID No.: OSHA-H005C-2006-0870-1670.
[10] Docket No.: OSHA-H005C-2006-0870-1313, pages 167-176.
[11] Docket No.: OSHA-H005C-2006-0870-1756, page 298. See e.g. Cadmium [29 CFR 1910.1027(l)(1)(i)(A)]; Lead [29 CFR 1910.1025(j)(1)(i)]; Inorganic arsenic [20 CFR 1910.1018(n)(1)(i)(A)].
[12] Docket No.: OSHA-H005C-2006-0870-1720, page 6.

III. Medical surveillance: Biennial low-dose CT scans to screen for lung cancer

As noted in our November 5, 2015 comments, beryllium is a recognized carcinogen[13] that, when inhaled, can cause lung cancer.[14]

OSHA's proposed rule includes the following provisions to screen certain beryllium-exposed workers for lung cancer:[15]

> The proposed requirements for medical surveillance include…low-dose helical tomography (low-dose computed tomography, hereafter referred to as "CT scans"), for employees who were exposed above the proposed PEL for more than 30 days in a 12-month period for 5 years or more. This type of CT scan is a method of detecting tumors, and is commonly used to diagnose lung cancer. The proposed standard would require periodic medical exams to be provided for employees in the medical surveillance program annually, while tests for beryllium sensitization and CT scans would be provided to eligible employees biennially…
>
> … The CT scan must be offered to employees who meet the criteria of paragraph (k)(1)(i)(D) for the first time beginning on the start-up date of this standard, or 15 years after the employee's first exposure to beryllium above 0.2 μg/m^3 for more than 30 days in a 12-month period, whichever is later.

While we praise the protective intent of this provision, we are concerned that the risks, for some workers, of periodic CT scans would outweigh the benefit of early detection of beryllium-induced lung cancer. **We stress that our concern is limited to workers with an insignificant or no smoking history for whom airborne beryllium is the only identifiable risk factor for lung cancer.** By contrast, beryllium-exposed smokers or former smokers who meet the criteria for low-dose CT lung cancer screening laid out by the U.S. Preventive Services Task Force (USPSTF)[16] should be screened – with annual, not biennial low-dose CT scans – regardless of their beryllium exposure history. (Significant beryllium exposures would, of course, increase their baseline, smoking-induced risk for lung cancer even more.)

A. Risks of radiation load and cancer risk from initial CT screening

The health effects of radiation at doses as low as those emitted by low-dose CT scans have long been debated, with some arguing that very low doses of radiation are not harmful to health. That

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[13] World Health Organization. International Agency for Research on Cancer. List of Classifications, Volumes 1-114. http://monographs.iarc.fr/ENG/Classification/latest_classif.php. Beryllium is classified as a Group 1 carcinogen, which means that "sufficient evidence of carcinogenicity in humans" exists. World Health Organization. International Agency for Research on Cancer. Preamble to the IARC monographs: Scientific review and evaluation. http://monographs.iarc.fr/ENG/Preamble/currentb6evalrationale0706.php. Both links accessed May 3, 2016.

[14] National Toxicology Program. Report on Carcinogens, Thirteenth Edition. Beryllium and Beryllium Compounds CAS No. 7440-41-7 (Beryllium). http://ntp.niehs.nih.gov/ntp/roc/content/profiles/beryllium.pdf. Accessed May 3, 2016.

[15] OSHA Proposed Rule, pp. 23 and 815.

[16] U.S. Preventive Services Task Force. Lung Cancer: Screening: Summary of Recommendation and Evidence, December 2013. http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/lung-cancer-screening. Accessed May 6, 2016.

position alleges that there exists a threshold (very low) radiation dose, below which health effects do not occur.[17] However, the National Academy of Sciences, in its most recent analysis of the health effects of low-dose radiation, the comprehensive Biologic Effects of Ionizing Radiation (BEIR) VII report, concluded that no such threshold exists and postulated that the risk of cancer displays a linear relationship with the dose of radiation, regardless of how low the dose may be.[18] This is known as the "linear, no-threshold" hypothesis of radiation-induced health effects. Consistent with this hypothesis, a recent study found a small, but significant, increased risk of leukemia in nuclear power plant workers at very low lifetime doses of ionizing radiation.[19]

The USPSTF estimated that low-dose CT scans expose patients to anywhere between 61 and 150 millirems (mrems) of ionizing radiation per scan.[20] In estimating the total radiation burden imposed by these low-dose CT scans, we assumed a number approximately in the middle of this range, 100 mrems.

We offer the following examples, which we believe represent reasonable upper- and lower-bound estimates of lifetime radiation exposure from low-dose screening CTs. We assumed that such screening would continue throughout a worker's life.

A worker first exposed to beryllium above the concentration- and duration-thresholds designated by the proposed rule at age 18 would begin undergoing biennial low-dose CTs at age 33 (15 years after first exposure). The age-adjusted life expectancy for a 33-year-old American is 78 for a male and 82 for a female.[21] Taking the middle number between these two (80), the worker would undergo biennial low-dose CT scans for 47 years, for a total of approximately 23 scans.

A worker first exposed at age 50 would commence screening at age 65. The age-adjusted life expectancy for a 65-year-old American is 83 for a male and 85 for a female.[22] Taking the middle number between these two (84), the worker would undergo approximately 9 scans.

The upper bound estimate, for the younger exposed worker, of cumulative radiation load from 23 low-dose screening CT scans, at 100 mrems per scan, would therefore come to 2,300 mrems, or 2.3 rems. The lower bound estimate, for the older exposed worker, from 9 scans would be 900 mrems.

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[17] Doss M. Linear No-Threshold Model VS. Radiation Hormesis. Dose Response. 2013;11:480-97.
[18] The National Research Council of the National Academies. BEIR VII, Phase 2. Health Risks from Exposure to Low Levels of Ionizing Radiation. Page 323. http://www.nap.edu/read/11340/chapter/15#323. Accessed May 6, 2016.
[19] Leuraud K, Richardson DB, Cardis E, et al. Ionising radiation and risk of death from leukaemia and lymphoma in radiation-monitored workers (INWORKS): an international cohort study. Lancet Haematol. 2015;2(7):e276-81.
[20] U.S. Preventive Services Task Force. Evidence Summary: Other Supporting Document for Lung Cancer: Screening, December 2013. http://www.uspreventiveservicestaskforce.org/Page/Document/evidence-summary4/lung-cancer-screening. Accessed May 6, 2016.
[21] Social Security Administration. Actuarial Life Table. 2011. https://www.ssa.gov/oact/STATS/table4c6.html. Accessed May 6, 2016.
[22] *Ibid.*

While estimates of the cancer risk from low levels of radiation are somewhat uncertain, the National Academies' BEIR VII report compiled sufficient data to provide approximate values. That report provided estimates of the lifetime attributable risk, from exposure to 10,000 mrems of radiation, of solid cancers and leukemia for men and women.[23] The table below extrapolates linearly from the BEIR VII values to present the estimated number of excess solid organ cancer and leukemia cases resulting from radiation exposure from low-dose CT screening exams.

Table. Estimated excess number of cancer cases resulting from biennial low-dose CT screening radiation exposure per 10,000 workers (based on BEIR VII report[24])*

	Solid organ cancer (cases)		Leukemia (cases)	
	Men	Women	Men	Women
2,300 mrems	18.4	29.9	2.3	1.6
900 mrems	7.2	11.7	0.9	0.6
	Solid organ cancer (deaths)		Leukemia (deaths)	
	Men	Women	Men	Women
2,300 mrems	9.4	14.0	1.6	1.1
900 mrems	3.7	5.5	0.6	0.5

*The number of cases in the table in the BEIR VII report were based on a dose of 10,000 mrems and used a denominator of 100,000 persons. The values from that table were therefore divided by a factor of approximately 43 for the 2,300 mrems category and by a factor of around 111 for the 900 mrems category. The 2,300 mrems exposure level is the estimated radiation burden incurred by a worker first exposed to beryllium at age 18 and beginning biennial low-dose CT scans at age 33. The 900 mrems exposure level applies to a worker first exposed to beryllium at age 50 and beginning biennial low-dose CT scans at age 65.

B. Risks of false-positive results: radiation load from follow-up CT scans

It is important to note that the estimates above do not account for radiation exposure from follow-up CT scans for false-positive results on initial screening CT. To get a sense of the number of workers who would experience false-positive CT results, we referred to the National Lung Screening Trial (NLST), published in 2011, which remains the largest randomized controlled trial evaluating the benefits and risks of periodic CT scans in the early detection of lung cancer.[25] The NLST enrolled 53,454 subjects 55 to 74 years of age who had a 30-pack-year or more smoking history and, if former smokers, had quit within the previous 15 years. Half were randomized to low-dose CT scans and the other half to chest X-rays, every year for three years.

There was an extremely high rate of false positives in the trial. A total of 39.1% of all subjects undergoing low-dose CT screening experienced at least one positive result, with 96.4% representing false positives.[26] Therefore, approximately[27] 37.7% of all NLST subjects

[23] BEIR VII. Report in Brief: Health Risks from Exposure to Low Levels of Ionizing Radiation. June 2005. http://dels.nas.edu/resources/static-assets/materials-based-on-reports/reports-in-brief/beir_vii_final.pdf. Accessed May 2, 2016.
[24] BEIR VII. Report in Brief: Health Risks from Exposure to Low Levels of Ionizing Radiation. June 2005. http://dels.nas.edu/resources/static-assets/materials-based-on-reports/reports-in-brief/beir_vii_final.pdf. Accessed May 2, 2016.
[25] National Lung Screening Trial Research Team. Reduced lung-cancer mortality with low-dose computed tomographic screening. N Engl J Med. 2011;365(5):395-409.
[26] *Ibid*.

experienced at least one false positive result after three annual CT scans. Of all (true- and false-) positive results on initial CT with sufficient data available for ascertainment of follow-up diagnostic information, half (49.8%) led to follow-up CT scans and 8.3% to follow-up PET or PET-CT scans.[28]

The number of follow-up CT scans for false-positive results would be expected to be higher in beryllium-exposed workers for two reasons. First, the subjects in the NLST all had a 30-pack-year or more smoking history and almost certainly a higher prevalence of lung cancer than beryllium-exposed workers, only some of whom will match or exceed this pack-year history. A lower prevalence of lung cancer in beryllium-exposed workers translates to a higher rate of false-positive results.

Second, under OSHA's proposed rule, workers will be given the option to undergo biennial CT scans for the rest of their lives and many workers will therefore undergo more than the three screening CT exams subjects received in the NLST. For such workers, the lifetime probability of a false positive screening result will consequently be higher than that seen in the NLST. However, this risk will likely not increase in a linear fashion, given that an increasing number of suspicious findings will be stable from prior scans and therefore will not qualify for additional follow-up tests. This is why the proportion of subjects with CT scans deemed positive decreased from the first (27.3%) to the last (16.8%) of the three annual scans.[29] Moreover, many of these follow-up scans will likely be performed with low-dose (not standard-dose) CT, as per the National Comprehensive Cancer Network's 2012 suggested algorithm for lung cancer screening.[30]

Given all of these factors, it is difficult to estimate: a) the number of workers who will undergo one or more follow-up CT scans for a false-positive screening result; and b) the aggregate radiation burden incurred from these follow-up tests. Nevertheless, it is reasonable to conclude that a substantial number of workers would be expected to incur additional radiation exposure from follow-up CT exams.

C. Risks of false-positive results: invasive procedures

Of the 17,702 positive screening results in the NLST for which complete follow-up data was obtained, 1.8% led to a biopsy or other procedure to obtain cellular material, 3.8% to a bronchoscopy, 4.0% to a surgical procedure, and 1.8% to other, unspecified procedures.[31] It is

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[27] Note that this is merely an approximation, as it combines two values with different denominators: the figure of 39.1% refers to the proportion of *subjects* with a false positive result, while 96.4% refers to the proportion of *tests* that were falsely positive.

[28] National Lung Screening Trial Research Team. Reduced lung-cancer mortality with low-dose computed tomographic screening. N Engl J Med. 2011;365(5):395-409. Note that these are not necessarily mutually exclusive categories, as it is possible (though unlikely) that a single positive test led to both a follow-up CT and a PET-CT.

[29] *Ibid*.

[30] National Comprehensive Cancer Network. NCCN Guidelines Version 1.2012: Lung cancer screening (LCS-2, Slide 5). http://www.lungcanceralliance.org/assets/docs/news/NCCN%20Screening%20Guidelines%2010_11.pdf. Accessed May 6, 2016.

[31] National Lung Screening Trial Research Team. Reduced lung-cancer mortality with low-dose computed tomographic screening. N Engl J Med. 2011;365(5):395-409.

highly likely that true positives (i.e. lung cancer cases) comprised a much larger proportion of these invasive follow-up procedures than of the overall sample with positive results, thereby justifying the risks of the invasive procedures for many. It is also reassuring that only 0.06% of the false-positive CT screening test results were associated with a major complication from a follow-up invasive procedure.[32] However, the risk of unnecessary invasive procedures in patients with false-positive CT screening results would increase should a lower-risk population than that screened in the NLST undergo periodic CT scans.

D. Benefit of early detection of beryllium-induced lung cancer

The sole purpose of the provision providing for biennial low-dose CT scans is to detect lung cancers potentially caused by beryllium at a stage early enough for effective treatment. As OSHA is aware, such scans confer no benefit in monitoring the progression of CBD.

For subjects with at least a 30 pack-year history of smoking, the NLST found a 20% relative risk reduction (95% CI: 6.8 – 26.7%; p=0.004) in lung cancer deaths in subjects screened with three annual low-dose CTs as compared with subjects screened with three annual chest X-rays.[33] The majority of lung cancers found on low-dose CT were early Stage IA or IB tumors. The absolute risk reduction for CT-screened subjects was 62 lung cancer deaths per 100,000 person-years; 320 high-risk subjects were required to be screened with three annual CT scans to prevent one death from lung cancer.

After conducting a systematic review of the evidence on lung cancer screening with low-dose CT, the USPSTF concluded in 2013 that the benefits of annual low-dose CT screening outweighed the harms only for patients 55-80 years of age with at least a 30 pack-year history of smoking and, if former smokers, had quit no more than 15 years previously.[34] Illustrating the fragility of this benefit:risk balance, the USPSTF pointed out in its systematic review that two smaller European trials of low-dose CT screening found no benefit from such screening, with both trials requiring only a 20 pack-year smoking history (the NLST required 30 pack-years) and one of the two trials enrolling younger patients than those enrolled in the NLST.[35]

It has long been difficult to precisely quantify the risk of lung cancer following varying levels and durations of beryllium exposure. Schubauer-Berigan et al. (of the National Institute for Occupational Safety and Health, or NIOSH) attempted to do so in a 2011 study of more than 5,000 male workers at three beryllium processing plants.[36]

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[32] *Ibid*.
[33] *Ibid*.
[34] U.S. Preventive Services Task Force. Final Recommendation Statement. Lung Cancer: Screening, December 2013. http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/lung-cancer-screening. Accessed May 4, 2016.
[35] Humphrey LL, Deffebach M, Pappas M, et al. Screening for lung cancer with low-dose computed tomography: a systematic review to update the US Preventive services task force recommendation. Ann Intern Med. 2013;159(6):411-20.
[36] Schubauer-Berigan MK, Deddens JA, Couch JR, Petersen MR. Risk of lung cancer associated with quantitative beryllium exposure metrics within an occupational cohort. Occup Environ Med. 2011;68(5):354-60.

In order to approximate the excess relative risk of lung cancer mortality at mean exposures above 0.2 μg/m^3, we referred to the paper's analysis of lung cancer mortality for workers exposed to a daily weighted average beryllium concentration of 0.5 μg/m^3 (the NIOSH recommended exposure limit). It should be noted that this exposure level is more than twice the proposed PEL of 0.2 μg/m^3, above which workers would be eligible for lung cancer screening under OSHA's proposed rule. Workers with this considerably higher level of exposure than OSHA's proposed threshold for lung cancer screening were estimated to have a 9 to 74% increased risk of lung cancer. By contrast, smokers have an approximately 2,400% increased risk of lung cancer than nonsmokers.[37]

In terms of absolute excess risk, OSHA concluded in its proposed rule that a daily weighted average exposure of 0.2 μg/m^3, incurred over a lifetime of work (45 years), was associated with 2.7 to 30 excess lung cancer deaths per 1,000 male workers over their lifetime.[38] Again, these estimates assume continuous exposure to these levels over 45 years of work whereas OSHA's proposed threshold for lung cancer screening is exposure to this level of airborne beryllium for just 1/12 of a year for five years (equivalent to a cumulative exposure of 5/12 of a year). This represents just 0.9% of the cumulative exposure (full year multiplied by 45 years) that formed the basis for OSHA's estimate of the number of excess lung cancer deaths above.

Although it is somewhat imprecise to extrapolate cancer risk from a higher to lower exposure in a linear fashion, if we do so here, OSHA's proposed threshold of exposure for lung cancer screening would therefore result in 0.02 to 0.27 excess lung cancer deaths per 1,000 workers over their lifetimes. By contrast, according to the National Cancer Institute, a 30-39 pack-year smoking history results in 2.0 to 4.1 excess deaths from lung cancer per 1,000 person-years in men by the ages of 60-69 and 70-79, respectively.[39]

Therefore, rates of excess lung cancer deaths in smokers with 30-39 pack-year histories exceed, by orders of magnitude between 10 to 100 times, those of non-smoking workers exposed to beryllium at OSHA's proposed PEL. It is highly probable that biennial CTs would be more harmful than helpful for beryllium-exposed workers with a lung cancer risk considerably less than that of the subjects in the NLST.

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[37] U.S. Surgeon General. The Health Consequences of Smoking—50 Years of Progress. Executive Summary. 2014. http://www.surgeongeneral.gov/library/reports/50-years-of-progress/exec-summary.pdf. Accessed May 4, 2016.

[38] OSHA Proposed Rule, p. 374. The Schubauer-Berigan (NIOSH) study found that a daily weighted average beryllium exposure of 0.033 μg/m^3 was associated with a 1 in 1,000 excess lifetime risk of lung cancer mortality.

[39] National Cancer Institute. Division of Cancer Control & Population Sciences. Tobacco Control Monograph Series, Monograph 8: Changes in Cigarette-Related Disease Risks and Their Implications for Prevention and Control. Chapter 5: Age and the Exposure-Response Relationships Between Cigarette Smoking and Premature Death in Cancer Prevention Study II. Appendix 8 (PDF p. 461). http://cancercontrol.cancer.gov/brp/tcrb/monographs/8/m8_complete.pdf. We assumed 20 cigarettes per pack, based on the American Cancer Society's Cigarette Calculator. http://www.cancer.org/healthy/toolsandcalculators/calculators/app/cigarette-calculator. Both links accessed May 4, 2016.

E. Conclusion and recommendations regarding biennial low-dose CT screening for lung cancer

Low-dose CT scans impart a low level of radiation per scan. However, the cumulative radiation burden from a lifetime of biennial scans would alone result in a not-insignificant number of solid organ cancers and leukemias. In addition, the rate of false-positive results from such scans would likely exceed even the extremely high proportion (96.4%) seen in the NLST, thereby leading to a large number of unnecessary follow-up CT scans with additional radiation exposure, invasive follow-up tests, additional medical expenses associated with these tests, and considerable anxiety for the workers involved.

The risk of lung cancer must be sufficient to justify these harms. We therefore recommend that OSHA restrict the scope of the provision on lung cancer screening to workers with a risk for lung cancer that meets or exceeds that of the subjects in the NLST and for whom the USPSTF recommends low-dose CT screening. This includes all workers 55 to 80 years of age with at least a 30 pack-year history of smoking and who are either current smokers or quit within the past 15 years. **However, for these workers, we note that the USPSTF recommends *annual*, not biennial screening with low-dose CT scans.** OSHA's proposed rule should reflect that more protective screening frequency.

For workers with less or no pack-year smoking history, the evidence is not as clear, but OSHA's proposed cutoff of exposure to the proposed PEL of 0.2 $\mu g/m^3$ for 30 days per year for five years is likely too low of a threshold to justify screening for lung cancer with low-dose CT scans.

While we do not have a precise estimate of the degree and duration of beryllium exposure that would confer a risk of lung cancer equivalent to that of a 30 pack-year smoking history, we recommend that OSHA assess whether such an analysis, which would result in a precise daily weighted average and cumulative beryllium exposure at which biennial CT scans would be more beneficial than harmful, is possible. Based on the evidence presented in these comments, we anticipate that this new threshold would be applicable, if at all, only to workers with the most extreme levels of beryllium exposure. Non-smoking beryllium-exposed workers have a very small risk of lung cancer. It would be a dangerous mistake to increase this low risk through a lifetime of CT scans that will not benefit the vast majority of these workers.

IV. Conclusion

To summarize, Public Citizen recommends that OSHA:

1. Expand the scope of the proposed beryllium rule to all beryllium-exposed workers, including those working in outdoor areas in, among others, the construction and shipyard industries, for whom the rule could be readily adapted;
2. Expand screening for BeS with the BeLPT to include all workers exposed to the proposed action level of 0.1 (or, if OSHA adopts our recommendation to lower the proposed PEL to 0.1, then to the new action level of 0.05); and
3. Change the provision on lung cancer screening with biennial CT scans as follows:
    a. For all workers with a smoking history who meet the USPSTF criteria for annual lung cancer screening, require annual, not biennial, screening with low-dose CTs.

b. For workers who do not have a smoking history that would qualify them for USPSTF-recommended annual lung cancer screening, undertake a rigorous analysis to determine a (likely far higher) threshold of daily weighted average and cumulative airborne beryllium exposure that would put those workers at an equivalent risk for lung cancer as smokers or former smokers meeting the USPSTF screening criteria.

We reiterate that these provisions, along with the rest of OSHA's proposed rule, should be finalized without delay.

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