TRANSCRIPT OF PROCEEDINGS

IN THE MATTER OF:)
)
RULEMAKING: NOTICE OF PROPOSED)
RULEMAKING FOR 10 CFR PART 850,)
CHRONIC BERYLLIUM DISEASE)
PREVENTION PROGRAM)

Pages: 1 through 89

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BEFORE THE U.S. DEPARTMENT OF ENERGY
OFFICE OF ENERGY EFFICIENCY & RENEWABLE ENERGY

IN THE MATTER OF:	)
	)
RULEMAKING: NOTICE OF PROPOSED	)
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CHRONIC BERYLLIUM DISEASE	)
PREVENTION PROGRAM	)

Room 1-E245
Forrestal Building
1000 Independence Avenue, S.W.
Washington, D.C.

Thursday,
August 11, 2016

The parties met, pursuant to the notice, at 9:00 a.m.

BEFORE:

JACQUELINE ROGERS, Industrial Hygienist

SPEAKERS:

LISA BARKER, National Jewish Health

MARC KOLANZ, Materion Brush Wellman, Inc.

JIM FREDERICK, United Steelworkers

STEVEN MARKOWITZ, M.D., Occupational Medicine Physician Representing Himself

MICHAEL BRISSON, Savannah River National Laboratory

KATHRYN CREEK, Beryllium Protection Program Leader

ASHLEY FITCH, United Steelworkers

DONNA HAND, Worker Advocate Representing Herself

SPEAKERS: (Cont'd.)

STEPHANIE CARROLL, Nuclear Workers Advocate
Representing Herself

P R O C E E D I N G S

(9:00 a.m.)

MS. ROGERS: Good morning. Good morning, and welcome. I am Jacqueline Rogers, an industrial hygienist within the Office of Environment, Health, Safety & Security. On behalf of the Department of Energy, I would like to thank you for taking the time to participate in this public hearing concerning the Notice of Proposed Rulemaking to Amend the Chronic Beryllium Disease Prevention Program, particularly those of you who have traveled to be here with us today.

The purpose of this hearing is to receive oral testimony from the public on the Department of Energy's notice for the Chronic Beryllium Disease Prevention Program, 10 CFR 850. Your comments are not only appreciated, they are essential in developing a final rule. The comments received here today and those submitted during the written comment period will assist the Department in the rulemaking process. All comments received -- all comments must be received by September 6, 2016, to ensure consideration by DOE.

The address to send in the comments is: Jacqueline D. Rogers, U.S. Department of Energy, Docket No. AU-RM-11-CBDPP, Mailstop AU11, 1000

Independence Avenue, Southwest, Washington, D.C., 20585. Also, comments can be filed electronically at http://www.regulations.gov or emailed to rulemaking.850@hq.doe.gov.

As the presiding official for this hearing, I would like to set forth the guidelines for conducting the hearing and provide other pertinent information.

This is not an evidentiary or a judicial hearing. It will be conducted in accordance with the Administrative Procedures Act and the DOE Organization Act to provide the Department with as much pertinent information and as many views as can reasonably be obtained and to enable interested persons to express their views. The hearings will be conducted in accordance with the following procedures.

Speakers will be called to testify in the order indicated on the agenda. Speakers have been allotted 10 minutes for their verbal statement. Anyone may make an unscheduled oral statement after all scheduled speakers have delivered their statements. To do so, please submit your name to the registration desk, and Meredith is working the registration desk, before the conclusion of the last scheduled speaker.

At the conclusion of all presentations, if time permits, scheduled speakers who request to do so will be given the opportunity to make a rebuttal or clarifying statement. If you would like this opportunity and if it's available, and it looks like it will be available today, please give your name to the person at the registration desk and indicate that you are making such a request.

Only members of the DOE panel, and today I am the only member of the DOE panel, conducting the hearing will be allowed to ask questions for the speaker.

In approximately 30 days, a transcript of this hearing will be available for inspection and copying on the website located at http://www.energy.gov/EHSS/Chronic-Beryllium-Disease-Prevention-Program-10-CFR-850. As mentioned earlier, the public comment period will close on September 6, 2016. All written comments will be made available for public inspection at the internet web address I just gave.

Three copies of your comments are requested. If you have questions concerning the submission of comments, please contact me, Jacqueline Rogers, on (202) 586-4714.

Today it is assumed that any information provided at this hearing is public and will be included in the record for the rulemaking. Any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit to the comment address I mentioned a total of four copies of the information, one complete copy with the confidential material included and three copies without the confidential information. The Department of Energy will make its own determination in accordance with applicable procedures as to whether the information will be exempt from public disclosure.

We appreciate the time and effort you have taken in preparing your statements and are pleased to receive your comments.

Now I will call the first speaker to the agenda. For the record, I ask each speaker to state his or her name, whom you represent before making your statement. Thank you. And the first speaker is Lisa Barker.

MS. BARKER: Well, good morning, everybody. My name's Lisa Barker and I work at National Jewish Health in Denver, Colorado. We have worked for a very long time with the beryllium industry, with the Department of Energy, the Department of Labor on

beryllium health effects.

So National Jewish physicians evaluate, diagnose, and treat and manage workers, DOE workers and contractors with exposure to beryllium and then beryllium, subsequent beryllium health effects. We do see patients at National Jewish, but we also work with physicians locally where the patient actually lives to make sure that they continue to have ongoing care and treatment.

Our advanced diagnostics lab at National Jewish in Denver performs the BeLPT and has been doing that for a long, long time, 20-plus years, and we do that test both for worker medical surveillance and then also for workers that are undergoing a clinical evaluation at National Jewish.

National Jewish supports the proposed beryllium action level that DOE is proposing. We believe it will provide a more comprehensive standard which will reduce beryllium exposure and provide additional health and safety protections for workers at the DOE facilities.

So, when we think about beryllium exposure, we think about an up-down, up-side -- everybody has probably heard this many times, any of you that have ever been to any of the sort of beryllium health and

safety meetings. We think about an upside down or an iceberg, but we think about the bottom of the iceberg as very, very large and you can't really see it, but it's the beryllium exposed population, and we think of those -- we think of that group as a very, very large population, and then a smaller population that is going to become sensitized and then an even smaller population that's going to become to have chronic beryllium disease, and we know that up to 15 percent of people that are exposed will go on to develop sensitization, and that's the immune response to beryllium. It doesn't have any symptoms, but it's the response and it's detectable by the BeLPT.

Of those identified with sensitization, most do have a clinical evaluation, and when those people have a clinical evaluation, CBD rates for that population range from 20 percent to 100 percent, and of those who develop CBD, we know that some have -- some or most actually go on to develop respiratory problems which affect their quality of life, and some individuals have a very severe course of disease. That's the reason for our support of the proposed changes.

So we looked through the proposal. We reviewed it very carefully and we picked a few places

to make public comment, but we also have submitted written comments as well.

And, Jackie, I just want a clarification. Do you want -- if there's anything here that gets a comment or a request for additional information, would you like those additionally sort of added on to our previously prepared, or would we --

MS. ROGERS: Only I can ask questions.

MS. BARKER: Oh, okay. Okay. All right. So we would -- National Jewish would recommend against excluding -- when we talk about revising the definition of beryllium, National Jewish would recommend against excluding the mineral forms from the definition, and it's a cause for the concern, particularly if results out of sight demonstrate beryllium breeding zone samples that are around or above the proposed action level.

So most of you know that OSHA is in this similar process and they recommended that workers exposed to beryllium and coal dust and copper slag receive full protections of their proposed beryllium rule, which, again, is somewhat similar and somewhat different.

There is a NIOSH report on beryllium exposure during field studies on abrasive blasting

that indicates that an eight-hour time-weighted average during blasting was 2.1 micrograms per meter cubed.

We also recommend that the soluble forms of beryllium be included in the rule even though it's not widely used around the facilities or not known to be widely used around the facilities. One of the reasons is that the BeLPT actually uses soluble salts and laboratory personnel in that setting are at risk of exposure.

In the past, soluble beryllium caused -- could cause skin sensitization as it's easily absorbed through the skin, and additionally, if soluble beryllium was to be used at a DOE site in the future, there would have to be an amendment to the rule if it's removed now.

So we agree with DOE's revised definition of beryllium worker, and we would suggest for the beryllium-associated worker definition that the phrase "a worker who exhibits signs or symptoms of beryllium exposure" should be removed from that definition.

So beryllium exposure -- exposure does not result in specific signs and symptoms, and in its place we were suggesting "a beryllium associated worker is a worker who enters areas where beryllium

operations of any type exist and have existed or have existed and has the potential for beryllium exposure". This would allow for the inclusion of employees such as administrative professionals, quality control inspectors, program reviewers, and visitors to be included in beryllium health surveillance operations, and this recommendation is based on well-established research from DOE and other sites that show these people in these job titles are at risk for developing BDS and CBD.

For the beryllium sensitization definition, National Jewish just recommends that we add -- that you add the three borderline abnormal BeLPTs to the definition, and that recommendation is based on work by both ATSCR and National Jewish that show that three borderline tests have a similar predictive value for CBD as the same -- a similar predictive value for CBD as two abnormal tests do, and I have those references for you.

So, when we talk about the definitions of chronic beryllium disease, we would suggest the following change in the definition: to include the evidence of beryllium-specific inflammation in the lung without the presence of an abnormal lung biopsy. The following -- I'm sorry. So the following --

sorry, let me just step back.

So the following conditions must be present for the diagnosis of CBD. So beryllium sensitization first as defined by the BeLPT and as defined in your section. And then at least one or more of the following: a lung biopsy that indicates the presence of non-caseating granulomas or interstitial mononuclear cell infiltrates and/or an abnormal bronchoalveolar lavage, BeLPT, and lymphocytic avelolitis greater than 15 percent lymphocytes, and/or a high resolution CT scan showing radiographic evidence of abnormality consistent with granulomatous lung disease.

National Jewish would recommend deleting the phrase "consistent with pulmonary granulomas". That's a radiologic finding and not a specific finding of any particular disease.

National Jewish supports the lowering of the proposed action level. Numerous studies with quantitative exposure data indicate that sensitization and CBD occur at lower levels than the DOE standard of two micrograms per cubic meter. Numerous studies have confirmed that sensitization and disease occur in susceptible populations due to genetic factors, and that's important to the immune response in beryllium.

Specifically, those with no E69 alleles have the lowest risk of CBD and those with two copies of that allele have the highest risk of developing disease.

Recent work by our group has shown that the prevalence of this genetic factor which we call E69 affects the risk of sensitization and disease, and in combination with exposure, this genetic factor differentially impacts disease risk and results in a highly susceptible at-risk population. I have those references as well for you.

Although reducing exposure reduces risks in all groups, medical surveillance provides the safety nets that we need to identify sensitization and disease in those most susceptible. So that work that I just spoke about about the E69 by Mike Van Dyke demonstrates that there's this highly susceptible population of workers and that increased exposure is associated with an increased risk of disease and that exposures at and below the current level can result in CBD.

For the proposed change to require mandatory medical and periodic evaluations for beryllium workers, National Jewish supports the proposed change requiring mandatory medical surveillance. These evaluations can provide information to the worker

about personal health but also to the workplace, both the medical staff and the workplace and the workplace as a whole to enable further investigation of work areas where an individual had exposure that resulted in a diagnosis of BDS or CBD.

In this context, an individual worker's diagnosis of BDS should spur the employer's industrial hygiene staff to investigate the exposure associated with both the job task performed and the work area involved to assess the possibility of increased beryllium exposure in that area that may put other workers in that same area at risk for developing beryllium health effects, and this is still in the complete understanding that beryllium exposure sometimes well predates beryllium sensitization. There still are cases where people are exposed and then become -- fairly quickly become sensitized, and that's the case where this would be -- this is useful.

So requiring medical evaluations for beryllium and beryllium-associated workers that show signs and symptoms of sensitization when -- or beryllium disease when the SOMD determines an evaluation is warranted. So sensitization, as I said before, is an immune response to beryllium and it's demonstrated by an abnormal blood LPT, but there's no

physical signs or symptoms of sensitization. People don't have any symptoms when they're sensitized. So it's a cell-mediated immune response.

National Jewish recommends the provision here be reworded to reflect the clinical medical evaluation at a diagnostic center be required for beryllium and beryllium-associated workers who are determined to be sensitized as defined in your definition on page 36717. So the beryllium sensitization definition.

In addition, workers without prior evidence of BDS who exhibit signs or symptoms of CBD should be provided medical evaluation, including an LPT outside the regular medical surveillance schedule, whether it's annual or every three years, depending on what classification they are.

For workers who are diagnosed with CBD, standards of practice dictate annual evaluations to assess where the disease has progressed and treatment is needed -- excuse me -- needs to be initiated or adjusted. The SOMDs need to collaborate with both the worker and their diagnosing physician regarding the most appropriate evaluation schedule for them.

The proposed change to require exit medical evaluations for beryllium workers and beryllium-

associated workers who voluntarily participated in medical surveillance, so exit evaluations for workers leaving the site provide workers a final on-site assessment of any beryllium health effects and they give the medical staff an opportunity to discuss the former worker programs that are available to them once they've moved off, moved out of the DOE purview. These provide separated workers with continuing medical surveillance at regular intervals.

This is a valuable resource for exiting workers, and we recommend that employees leaving employment be offered the opportunity to have their medical surveillance results that were collected during the current worker program to be moved over to the former worker program, understanding there's a lot of logistics involved with that, but the idea of continuing a worker's health record with them to provide continuity of surveillance after employment.

Regarding the proposed change of requiring mandatory medical removal for workers based on the site occupational medical director's opinion, National Jewish notes that workers who are diagnosed with sensitization should be removed from further exposure to minimize their risk of future exposure and then the development of CBD.

Once an individual is diagnosed with BDS or CBD, the focus is on maintaining their highest level of health possible, so no more exposure, and to ensure the best possible outcome for individuals with BDS, permanent removal from exposure is most prudent. So, as mentioned when we talked about this before, our group has shown that increasing exposure is associated with increasing risk of CBD, and this supports removal from additional exposure. We recognize this is a very complex topic, but as healthcare providers, our first focus is primary prevention, so recommending a permanent removal.

For the proposed change to ensure that workers are informed and understand that medical testing is mandatory, National Jewish agrees that workers must be informed and must demonstrate an understanding of the new rule and their part in it. When the changes proposed herein take effect, National Jewish recommends that all sites collaborate to create standardized materials across the complex with which to educate beryllium workers.

Healthcare safety and administrative staff on site as well as the beryllium and beryllium-associated workers should develop and optimize those educational materials. DOE headquarters should

participate to ensure the materials are comprehensive and all site appropriate.

For the proposed change to revise the consent form for beryllium, forms for beryllium and beryllium-associated workers, we appreciate that's a legal document and National Jewish doesn't have comments on the legality of the document, but we would recommend some changes.

For the chest X-ray or standard chest image, chest X-rays can be performed on a conditional employment medical evaluation and then no more than once every five years or if symptoms suggest the need. Spirometry should be performed on an initial medical evaluation and then when needed for respirator fit testing. Spirometry doesn't provide useful data for the diagnosis of beryllium sensitization or CBD and it doesn't need to be obtained more regularly for the purposes of beryllium medical surveillance.

Regarding the suggestion of two split BeLPTs on peripheral blood, based on current BDS rates, National Jewish recommends that splits not be performed as part of routine beryllium medical surveillance, but we recommend that a split is performed on exit but not in a routine setting.

With regard to additional studies that

National Jewish thinks that the DOE should consider, the four references that I've already talked about: the Middleton paper about borderlines; Dr. Mayer's paper about borderlines; and then the two Van Dyke papers that talk about genetic susceptibility and risk of disease would be papers we would recommend, and we're happy to provide those PDFs for you. Recent work by the group has shown this prevalence of this genetic factor, and we think that would be an important point to consider.

And I think I have one more comment. Oh, so my final comment is actually from -- I can't read the page number on that, it's so small. From page 36736 where DOE is proposing to delete from the final rule the section that requires employers to establish routine and systematic evaluation or analysis of medical job and exposure data altogether on site. The purpose of this is to collect and analyze information so the prevalence of disease can be accurately described and conclusions reached on causes or risk factors for disease. So the Department is intending to delete this requirement and rely on the data collected from the registry.

National Jewish strongly recommends against deleting this requirement. Specifically, we recommend

that each site continue to perform their regular systematic analysis of medical, job, and exposure data specific to the site. We feel like it's only by reviewing data at the site level in a timely fashion that individual site risks can be identified and managed. Aggregate data from the registry is helpful for ascertaining risk over the entire complex, but relying on data from the registry will hamper timely and place-specific identification of works -- excuse me -- of risks and implementation of site-specific control measures that can protect workers on that site from exposures there.

The fundamental purpose of medical surveillance is to identify and eliminate hazards with the ultimate goal of preventing disease. It should remain delineated in the rule that medical surveillance should include data analysis where the employer routinely and systematically analyzes these sets of data together, with the aim of identifying individuals or groups of individuals potentially at risk for CBD and the working conditions that contribute to CBD -- BDS and CBD, which is what I think the registry is ultimately set up to do or hope that the plan would be, and then use these results to identify exposure controls to reduce risk.

And that's it for me. Thanks for letting me speak. It might have been more than 10 minutes.

MS. ROGERS: Okay. It's not like we have 25 speakers today. Thank you.

The next speaker is Marc. For the record, could you state your name and who you're representing?

MR. KOLANZ: I will.

MS. ROGERS: Thank you.

MR. KOLANZ: Good morning. My name is Mark Kolanz. I'm the Vice President of Environmental Health and Safety from Materion Brush, Incorporated. Materion Brush is the world's largest fully integrated producer of beryllium products. I appreciate the opportunity provided by the DOE today to offer comments on DOE's proposed amendments to its CBDPP beryllium rule.

Materion Brush will be providing to DOE its detailed written comments and recommendations on its proposed rule by the end of this month. Today I wish to share four general comments with regard to DOE's proposed rule.

First, in February 2012, a unique collaboration between United Steelworkers and Materion Brush resulted in a joint submission to the Occupational Safety and Health Administration of a

model beryllium standard to better protect workers. In our cover letter to OSHA, Materion and the USW stated, "We believe the current OSHA permissible exposure limit for beryllium of two micrograms per cubic meter is too high" and that we believed that our "enclosed draft standard is both necessary and sufficient to protect beryllium workers and that it meets all the criteria established by Congress for rules promulgated under the OSHA Act."

Materion believes the DOE should review and consider this model standard in the context of developing its final rule, and DOE should adopt the industry and labor proposed PEL of 0.2 micrograms per cubic meter to better protect its workers.

Second, we found the language and descriptors used by DOE to define or describe beryllium sensitization to be inconsistent throughout the rule. DOE often combined descriptions of beryllium sensitization and CBD together, potentially making them appear equivalent to the reader. In various places, either separately or linked to CBD, the DOE refers to beryllium sensitization as a health effect, health risk effect, critical effect, beryllium-induced medical condition, or a negative health effect as a few examples.

We believe such inconsistency in language does not fairly inform workers who are trying to understand the health risk differences between a finding of beryllium sensitization and CBD. At one point in its preamble to its proposed rule DOE provides a clearer picture of what beryllium sensitization is and is not. Early on the preamble states, "Beryllium sensitization alone does not cause physical symptoms." It also states, "As mentioned earlier, individuals sensitized to beryllium are asymptomatic and are not physically impaired."

DOE should review its descriptions, terminology, and references to beryllium sensitization throughout its rule to ensure it is providing a consistent and accurate representation of beryllium sensitization to workers.

In addition, DOE should specifically separate the term beryllium sensitization from CBD within sentence structures where the definition of beryllium sensitization may be confused with that of CBD.

Materion and United Steelworkers provided OSHA with an agreed upon definition of beryllium sensitization that would be understandable and meaningful to workers. This definition might be of

value to the DOE. We define beryllium sensitization as a test result for beryllium sensitization indicating a person has been identified as having an immunological sensitivity to beryllium. With a determination of beryllium sensitization alone, there are no clinical symptoms, no measurable or material impairment of health, no identifiable health effects, and no illness or disability.

We wanted to make clear to workers that sensitization did not mean illness, impairment, or death. We took this approach based on the fact that experts and leading government agencies have agreed that beryllium sensitization has no physical symptoms or impairment.

Third, DOE is proposing surface limits and an action level in the absence of any evident scientific health-based analysis by DOE to support its selected values. Though we understand this DOE rule only applies to DOE sites, DOE needs to understand and consider that its actions can have impacts beyond the stated scope of this rule.

For example, agencies and governments may interpret DOE's actions to mean that DOE has completed a comprehensive review of the science surrounding surface limits and action levels for beryllium when in

fact there's no evidence in its proposed rule to support a health-based analysis of scientific evidence underlying the DOE's selected values.

To avoid misinterpretations of DOE's actions outside of its own operations, we ask that the DOE clarify and acknowledge that its proposed action level and surface limits are not health-based determinations but are administrative determinations by DOE. The DOE should make clear that its proposed levels are based on what it believe is achievable solely within the funding and resources provided by DOE to its operational sites.

Lastly, the DOE proposed rule requires workers to be trained on the potential health risks of exposure to beryllium and the DOE supports its use of mandatory testing and worker removal based on potential benefits of early detection and/or early treatment of CBD amongst other stated beliefs.

Under the proposed medical removal criteria, a determination of beryllium sensitization in a worker will be the most likely cause of a medical removal determination. For full transparency to workers, we believe DOE needs to include in its worker training information on the health and socioeconomic risk to workers so they have -- or I'm sorry -- include in its

worker training information on health and socioeconomic risk to workers so they have a complete picture of both the risks and benefits of the DOE rule as it relates to their acceptance of a job within a DOE facility.

Workers deserve to know and understand that in a worker beryllium sensitization determination the use of the BeLPT is not always a definitive or reliable test, that its results can be variable over time, it does not predict an individual's future health impacts, and that beryllium sensitization has been detected in the general non-occupationally exposed population at a rate of about 1 percent.

In other words, workers deserve to clearly understand how the requirements of this rule can affect their livelihood before they make a decision to pursue a job in a beryllium work area.

Again, on behalf of Materion Brush, our sincere thanks to DOE for allowing us this opportunity to comment on its proposed rule. Thank you.

MS. ROGERS: Thank you. Jim.

MR. FREDERICK: There's three of us from the Steelworkers. Is it possible for each other to go out of order, or do we need to go by what's on the agenda?

MS. ROGERS: Uh-uh. Who wants to go first?

MR. FREDERICK: I'm going to do it first and then we can actually let Steve.

MS. ROGERS: Okay.

MR. FREDERICK: Okay. Thank you.

Good morning. My name is Jim Frederick. I'm the Assistant Director of Health, Safety, Environment at the United Steelworkers International Union, the USW. The formal name of the USW is the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial, and Service Workers International Union. As the name of the union indicates, our organization represents workers in many sectors of the economy. The USW represents 850,000 men and women in North America employed in a variety of industries, including metals, mining, atomic, pulp and paper, rubber, chemicals, glass, auto supply, and the energy-producing industries, along with a growing number of workers in public sector and service occupations.

We appreciate the opportunity to provide comments to the U.S. Department of Energy on the proposed rule for Chronic Beryllium Disease Prevention Program, 10 CFR 850. The USW has been actively engaged in protecting our members and workers generally from exposure to beryllium. For example,

the USW, via our predecessor unions, provided comments and testimony in the 1977 OSHA beryllium proposed rulemaking process. In addition, we were engaged with the DOE in the 1998 rulemaking leading to the 1999 existing DOE beryllium rule.

The USW represents thousands of workers at U.S. Department of Energy facilities. This includes current and former workers at Hanford, Washington; Idaho Falls, Idaho; Brookhaven, New York; Portsmouth, Ohio; Carlsbad, New Mexico; Paducah, Kentucky; and Oak Ridge, Tennessee. We also formerly represented workers at Rocky Flats, Colorado and Mound, Ohio.

Our members perform many different jobs at these facilities, primarily in the production, operation, and maintenance roles. Our members work in many different areas of these facilities. A significant number of our members have been, are currently, or may be exposed to beryllium materials at some points in their work. As we know in part from our experience with the DOE's former worker program, many workers have experienced beryllium exposure and have tested positive to beryllium sensitivity. We are also aware that many DOE workers have developed occupational illnesses, such as chronic beryllium disease or lung cancer.

As previously stated, the USW and Materion Brush have been working collectively for a number of years with the goal of increasing health and safety protection of workers exposed to beryllium materials. Part of that process resulted in the Materion Brush/ USW February 8, 2012, submission of a model beryllium draft standard to the U.S. Department of Labor, Occupational Safety and Health Administration.

In our cover letter to OSHA, Materion and the USW stated, "We believe the current OSHA permissible exposure limit for beryllium of two micrograms per cubic meter is too high and that we believe our draft standard is both necessary and sufficient to protect beryllium workers." The USW extends this reasoning to the DOE's PEL of two micrograms per cubic meter that has been in place since 1949 at the Atomic Energy Commission sites.

This, of course, is too high as well. Reduced exposure limits for workers exposed to beryllium materials is needed and necessary. The Materion and USW process was not a negotiated rulemaking or any other formal or sponsored process by OSHA. Rather, it was a process of stakeholders working together toward a common goal and presenting a path to OSHA for the agency to better protect worker

health and safety for those who are exposed to beryllium materials at work.

The parties did not and still do not agree on everything associated with worker beryllium exposure. This effort has received support from the business community, occupational health and safety professionals, organized labor, as well as elected and career government officials.

The USW/Materion recommendation to OSHA will be submitted to the record for this rulemaking, and there's no need to reproduce it in these comments. However, the following is a short summary of its major provisions:

Reduce the current permissible exposure limit of two micrograms per cubic meter to a new level of 0.2 micrograms per cubic meter for an eight-hour time-weighted average; add a short-term exposure limit of two micrograms per cubic meter; add an action level of 0.1 micrograms per cubic meter; require feasible engineering controls for any operation with the potential for generating airborne beryllium; limit the scope of the standard to materials containing 0.1 beryllium or situations where the PEL is exceeded; require exposure monitoring, but address the concerns of small businesses by limiting it to the shift with

the highest exposure instead of all shifts; require appropriate medical surveillance, including the current test for beryllium sensitization, a low dose CT scanning for workers with long-term beryllium exposure; and require medical removal protection to protect the pay and benefits of sensitized workers.

In its independent analysis, OSHA came to many of the same conclusions as we did and included many of our recommendations in its own proposal, but in several ways they diverged from our recommendations. Two of those decisions by OSHA could significantly compromise worker protection.

First, the limitation of the standard's scope to material exceeding 0.1 beryllium even where exposures exceed the PEL or cell and the lack of a requirement to use feasible engineering controls for any operation capable of generating airborne beryllium.

The USW and Materion have continued to work collectively, most recently through the OSHA rulemaking earlier this year where we collaborated and presented joint comments to OSHA -- to the OSHA record at the OSHA hearing. This collaboration has provided an opportunity for the USW and Materion to develop an effective working relationship, and we hope to

continue the relationship as final standards are promulgated at both OSHA and the DOE. This collaboration among stakeholders will be very helpful as the new and revised requirements are implemented in workplaces both inside and outside of the DOE complex.

The DOE states, I believe, that the medical surveillance -- that medical surveillance can only be effective in detecting and preventing disease if workers, one, seek medical attention if they feel ill, and, two, retain -- refrain from efforts to conceal their true health status, and, three, fully cooperate with examining physicians to facilitate accurate medical diagnosis and effective treatment.

The USW believes that all workers must be afforded proper medical treatment when symptoms of exposure of health effects occur. We believe that workers should cooperate with medical professionals in all aspects of occupational health. However, there are many reasons that workers do not seek medical attention if they feel ill or do not reveal their true health status. Failure to recognize this factor by the DOE in this rulemaking is very disappointing and concerning to workers in the DOE complex. These issues revolve around retaliation for their actions and fear of losing their jobs.

Unfortunately, DOE does not adequately address these barriers to worker participation in this order. We believe that the DOE should address these barriers in the final rule. We urge the DOE to work with stakeholders and other regulatory agencies to address these barriers in the final rule.

The OSHA docket associated with the recent revision to recordkeeping requirements contains significant amount of information pertaining to the policies, programs, and practices associated with the barriers for full worker involvement. The DOE should review these records and other pertinent relevant resources on this subject and incorporate better provisions to address these concerns in their final rule.

In addition, we believe that it is important to state that the USW hopes that reduction in worker exposure to beryllium through the new lower permissible exposure limit will limit the frequency of needed medical removal and benefits. However, we know that it will not likely eliminate the need in total.

The DOE states that without medical removal employees with beryllium sensitization or chronic beryllium disease may remain undiagnosed and continue to be exposed to beryllium at or above the action

level which would not sufficiently protect their health. The USW concurs with this concern of the DOE.

The DOE states that only the SOMD may recommend temporary or permanent removal of a beryllium worker from exposure to beryllium at or above the action level. The DOE proposes revising the wording used in this section to clarify that the SOMD would make the final medical determination even when a multiple physician review or alternative physician determination is used.

On face value this makes sense. However, we believe there are some issues which may affect the efficacy of this program. The USW urges the DOE to ensure the adequate multiple physician review process is utilized. Additionally, prescriptive language should be included in the final rule to ensure that all sites and all contractors properly implement this requirement of the final rule when promulgated. This should include the ability of workers to select a properly qualified physician at their employer's expense.

In addition, we are aware of some instances of the site occupational medical director's position being vacant for periods of time. In this instance, the provisions of the proposed rule could not be

fulfilled.

The DOE states that they've received several comments pertaining to the mandatory medical removal of workers and provide enhanced medical removal benefits. One item that needs to be addressed by the DOE regarding this issue is the effect medical removal has on future employment of affected workers beyond the time of permanent removal benefits. The DOE should perform additional review of the effect that this rule has on workers when they leave their employment at DOE.

Rather than relying on several comments, the DOE must invest the appropriate resources to determine what negative impact on future employment exists for this group of workers. A work-related illness is no fault of the worker and should not negatively affect them if they're not able to return to their job.

USW former workers at the Rocky Flats facility reported that it's extremely difficult to find comparable work in the area after the facility closed. They further reported that it was next to impossible to find work if a worker was known to have any illness from their work, including beryllium-related diseases. A failure to address this concern will continue the inadequate medical removal that

exists currently in the DOE complex and will result in the DOE not reaching their objectives of Section 850.36.

We believe that the recent OSHA proposed rule provides some useful framework for medical removal protection. This includes when a worker is exposed at or above the action level and has been clinically diagnosed with CBD or has tested positive for beryllium sensitization working at or above the action level than he or she is eligible for medical removal. If an employee chooses medical removal, the employer must train and relocate him or her within one month. If comparable work is unavailable, then the employee must be awarded paid leave.

Additionally, OSHA proposed that if an employee is eligible for medical removal protection, the employee must choose, one, removal as described above, or, two, remain at their current job provided that the employee wears a respirator in accordance with the respiratory protection standard. While this is a lower level of hazard control, it does control the hazard to the worker.

Conditionally hired employees must be included in the definition -- as a definition in the final rule. The DOE provides the following

description in the preamble to the rule as "An individual conditionally hired for beryllium work would be an individual who has been offered a job as a beryllium worker, either a new hire or current worker being transferred into a new job as a beryllium worker, but such offer would be subject to the outcome of the medical evaluation."

This definition does not appear in the definitions of the proposed rule and certainly should be included there.

The hiring of workers who have previously worked at another DOE site is a benefit to the DOE and their contractors. If it were not, it would not be a prevalent practice. The DOE states, "Newly hired beryllium workers may have previously been exposed to beryllium at a different DOE site and may have already developed beryllium sensitivity or chronic beryllium disease. It is also possible or even probable that newly hired beryllium workers were previously exposed to beryllium while working for other employers."

The DOE also states that "The Department does not believe that it is reasonable to place new hired individuals in such conditions -- with such conditions into jobs where the airborne concentration of beryllium is at or above the action level if they

too would be subject to removal or restricted once hired."

And the DOE states, "An individual conditionally hired for beryllium work would be an individual who has been offered a job as a beryllium worker, either a new hire or current worker being transferred to a new job as a beryllium worker, but such offer would be subject to the outcome of a medical exam."

And the DOE states, "The way the medical screening indicates individual conditionally hired for beryllium work has CBD, beryllium sensitivity, or another medical condition for which exposure to airborne concentrations of beryllium at or above the action level would be contradicted, the employer determines that no reasonable accommodation is available to enable the conditionally hired individual to work in an area where the airborne concentration of beryllium is at or above the action level, the employer would not be permitted to retain the individual as a beryllium worker."

Finally, the DOE states, "Such conditionally hired individuals would not be eligible for medical removal benefits under 10 CFR 850.36."

While the employer may have the right to

medically screen newly hired employees, the DOE should retain the obligation to account for beryllium illness that is a result of their workplace exposure when exposure occurred at the same or another DOE facility. It is good to see that the DOE recognizes the right of labor organizations to bargain over these mandatory subject items as part of the implementation.

It is well known that DOE workers have to work for more than one contractor and sometimes at more than one site during the course of their working career at DOE. DOE must recognize this fact in any final rule that is promulgated. It is in the best interest of the DOE to encourage long-term employment of workers to ensure the continuity in all facets of work across the complex.

The DOE has a history of concerns with workforce retention and fitness for duty programs. This issue and relevant concerns have been assessed by the DOE in the past. Recently, this concern was addressed by the DOE's Office of Health, Safety and Security, the predecessor of Environmental Health Safety and Security AU. The intention of this undertaking was to make it easier for workers to retain employment within the DOE complex, not make it more difficult or to remove reckless protections for

workers. The final rule should take into account the work done by others in the same office of the DOE.

There are instances where a worker may work for a site and a contractor one day but report to work the following day and find that they now work for a new contractor. Sometimes these changes are only for workers in some areas, some departments, some buildings or part of some buildings. While there are many labor relations issues related with this situation, one should not be the fact that the new employment relationship may exclude a worker from the regulatory protections of medical removal protection as a now conditionally hired individual.

In addition, if a conditionally hired individual reports to work at a new site and they test positive for a health effect related to beryllium exposure that they experienced at a former DOE site, the DOE should retain the obligation to provide medical removal protections to that worker. This assists the DOE in achieving the objectives outlined in Section 850.36, medical removal benefits. Failure to do so leaves the worker holding the bag for his or her exposure from their work at the DOE site.

Thank you for the opportunity to share this information with the DOE and interested parties today.

We will provide additional information in our written comments.

MS. ROGERS: Thank you. Ashley.

MS. FITCH: Good morning. Ashley Fitch, F-I-T-C-H, from United Steelworkers. I'm not going to go through the big long name of the United Steelworkers and all the industries it represents, but I think it is important to point out that in each of those industries we do run council meetings and council members. So each of our worker -- atomic energy worker sites do have a council at which they operate on.

We have been talking to them very closely about the proposed rule and they have been fully engaged with us. And coming from the council, we support the necessity of the DOE's proposed revisions to the Chronic Beryllium Disease Prevention Program. The revision of the standard significantly reduces workers' exposure and prevents the development of chronic beryllium disease or sensitization.

The USW commends the efforts of DOE and involved stakeholders for the development and the release of the proposal and the recognized need for these protections. Given the substantial need for these protections, it is concerning that the DOE would

release a comprehensive standard that is harmful to the rights of workers at DOE facilities and creates a burden on workers who have contracted this disease while working at DOE facilities.

Multiple components of the proposed revision inflict on the livelihood of these DOE workers and create a health and safety program with little protections for the workers exposed at DOE and involvement of workers.

The DOE is considering a reduction in the surface sampling action level in the final rule. The background for this level is not based on any quantitative data or studies that determine a threshold surface contamination as related to worker exposure to beryllium. Rather, it is based upon the occupational experience of the DOE.

Although the intentions of creating such a threshold are respectable, it is not based on scientific or health studies. To create requirements mandating compliance to a rather arbitrary level based upon experience, we feel, exceeds the intent of this rule. The USW agrees that there are protective measures and necessary to do wipe sampling and do not necessarily oppose surface sampling. However, feel that this number should be reviewed by the DOE and

based upon scientific and health data.

The DOE also seeks comments on the establishment of beryllium restricted areas where levels of beryllium are at or above the surface action level. The USW fully supports the intent of using restricted and regulated areas to ensure that workers are aware of the potential for concentrations of this hazard. Limiting access to these areas can significantly reduce the number of workers potentially exposed at or above the levels cited by DOE to beryllium. However, the criteria is also cited on -- also cited due to DOE's operational experience and not health and scientific data.

The USW believes that reducing the bystander exposure is necessary for beryllium. However, would recommend that the DOE look for scientific and health data to support this.

In addition to these changes, the DOE is proposing to make significant changes to the medical removal protections that are currently utilized by DOE. Workers with the clinical form of chronic beryllium disease or have been confirmed with beryllium sensitization would have the opportunity or -- sorry -- or mandatorily have to utilize MRP or medical surveillance. When these provisions become

mandatory, workers lose the choice to activate their rights and the proposal allows this decision to be based upon the medical appointment of the SOMD.

The USW strongly urges DOE to focus on the revisions of the program -- on proactive elements to decrease worker exposure instead of implementing a provision that could inflict on workers' rights and to utilize MRP and take into consideration the exposures that have happened in the past five to 20 years at DOE facilities. Thanks.

DR. MARKOWITZ: Good morning. My name is Stephen Markowitz. I'm an occupational medicine physician and epidemiologist at City University of New York where I'm professor and direct the Barry Commoner Center for Health in the Environment. Actually, I had a PowerPoint today, but we're not really equipped to show PowerPoints, so I'm going to try to describe to you some of the pictures that I planned to show. We'll see how that goes.

I need to disclose conflicts of interest. The City University of New York, our unit is funded by the Department of Energy Former Workers Screening Program to conduct medical surveillance for former workers and some current workers and have been funded since 1998. That's in association with United

Steelworkers, the Atomic Trade Labor Council, and others. I should also disclose that I'm an unpaid advisor to the United Steelworkers on medical issues.

I want to talk mainly about something I think that's missing from the proposed changes, which is a lost opportunity to detect beryllium-related disease of critical importance, and that is lung cancer.

Beryllium is -- so I recognize that the rule is named and under the proposed changes is still named the Chronic Beryllium Disease Prevention Program. If you simply change the name and say the Beryllium Associated Disease Prevention Program, you could capture lung cancer as well as BES sensitivity and CBD, chronic beryllium disease.

Beryllium is a recognized human lung carcinogen. It has been so for at least two decades. The World Health Organization under its International Agency for Research on Cancer declared it a lung carcinogen in 1993 and confirmed that just a couple years ago in a review, and in fact even in the preamble of the proposed rule changes DOE recognizes that beryllium is a lung carcinogen. I know actually, I think, in some of the required posting under the proposed rules that DOE says that beryllium is a

cancer hazard that has to be identified for workers.

When I looked at the goals or purpose of the CBD prevention program, what I found was, and I want to quote this, that the proposed rule and changes "focuses on beryllium sensitivity and chronic beryllium disease because they represent the critical effects for beryllium and beryllium-associated workers at DOE sites." And I would suggest that lung cancer should be added to that because, in fact, lung cancer is more lethal certainly than sensitivity and more lethal than chronic beryllium disease.

At most, as bad as chronic disease is, chronic beryllium disease can be, at most it's got a 30 percent mortality rate and that, frankly, is from decades ago when conditions were far worse than they are today. The lung cancer mortality rate in general approaches 80 or 90 percent. So this lung cancer is a critical effect in relation to beryllium exposure and should be addressed by the Department of Energy.

I want to describe actually what I'm talking about in terms of addressing it because we now have a method for early lung cancer detection which I think more and more people have heard about in the last few years for a number of reasons. And if you can imagine a picture of a CT scan, a low-dose CT scan, which I

intended to show, as complicated as CT technology is, actually, it produces images that -- slices of lung that can be seen -- where small lung cancers can be readily seen. They're certainly readily seen to the chest radiologists and readily seen to others as well. We can now detect very small, a centimeter or less, lung cancers which can be removed surgically.

When the person leaves the hospital -- with limited surgery the person leaves the hospital a couple days later, no chemotherapy, no radiation therapy, with a normal life expectancy. That's what's possible now with the early detection of lung cancer and, in fact, it's now part of routine medical practice, which I'll discuss in a moment.

Now why should DOE include lung cancer screening as part of its medical surveillance program? Well, you could look to the example of the consensus proposal of Materion and United Steelworkers developed and submitted to OSHA several years ago in which both parties endorsed the provision -- the inclusion of low-dose CT in the OSHA standard. You can look at the OSHA proposed beryllium rule itself which included low-dose CT, recognizing that beryllium was a lung cancer -- lung cancer was an important effect of beryllium.

And, in fact, you can actually look within DOE because DOE's Former Workers Medical Screening Program runs early lung cancer detection through the use of low-dose CT. In fact, Department of Energy has operated, continues to operate the largest occupational lung cancer screening program in the country, perhaps the world, through the former worker program, through screening DOE workers, mostly former workers but some current workers as well, for those who are at increased risk for lung cancer, including those exposed to beryllium and other exposures as well. It's not strictly focused on beryllium. It's broader than that.

But right now DOE -- in fact, DOE started this work in the year 2000 as a pilot in the former worker screening program. It was under our former worker program with the steelworkers. We've now screened over 13,000 workers, and I'll just mention some of the data in a minute, but that pilot has now been broadened by Department of Energy to include the entire Former Worker Medical Screening Program and it's part of the national medical protocol of DOE's Former Worker Medical Screening Program, to include low-dose CT for the purposes of early lung cancer detection.

So here we have the organization endorsing, and to its great credit actually, has provided leadership for the last 15 years and now endorsing use of low-dose CT for its workers at increased risk for lung cancer. DOE deserves a lot of credit for that work.

We're going to miss the pictures of our CT scanners, but some of you have seen CT scanners in the past, I'm sorry to say. Actually, this technology is readily available anywhere there's a CT scanner. You just ask the radiology technician to dial back on the dose, so you use a lower dose, and the radiologist can get perfectly good images for the detection of early lung cancers.

In our program, the former worker program funded by DOE, we've screened over 13,000 workers for lung cancer since the year 2000. We have now detected 145 lung cancers. That's 145 lung cancers out of 13,400 people screened. That is one out of every 93 workers that we've screened we've detected lung cancer in, and more important than detecting lung cancers is the stage at which they've been detected, and 60 percent of the cancers we detected have been at Stage I, the earliest stage of lung cancer, and that's really the stage where lung cancer is readily

resectable by the surgeon without the need for follow-up chemotherapy or radiation therapy.

An additional 12 percent of the lung cancers we detected were Stage II, which is still considered early stage disease. So, if you add 60 and 12 percent, that's 72 percent. About one-quarter of the lung cancers that we detected have been at the most advanced stages where, frankly, treatment is more difficult. But we have successfully detected a large number of lung cancers and most of them, the majority of them have been early stage and proven to be beneficial for DOE workers.

Now I just want to -- I'm all in favor of BeLPT and the early detection of sensitization and also early detection of CBD, but I do want to point out a contrast. For lung cancer, we have scientific evidence that you can detect lung cancer early for people with high risk for lung cancer and intervene in a way that matters to them, that is to say it saves lives.

We do not really have that scientific evidence for beryllium, and to some extent the preamble recognizes this, acknowledges this in that we do not have solid scientific support such that the early detection of sensitivity and thereafter the

cessation of exposure changes the natural history, the natural course of that individual in terms of where if they develop chronic beryllium disease.

Likewise, if a person has developed CBD, we don't really know whether further exposure to beryllium affects the course of that illness. So there is not scientific, strong scientific evidence in favor of cessation of exposure either for sensitivity or disease in terms of changing the course of that illness for that person. And that's not just my opinion. You can look at the American Thoracic Society statement in 2008 and others that acknowledge that.

Now that does not mean that I don't recommend to individual workers that if they're sensitive that they stop exposure. I do recommend that. That does not mean that I don't recommend that people have BeLPT if they're exposed to beryllium. I do recommend that to them. Likewise, if they have CBD, I would advise them not to continue further exposure.

But in terms of actual scientific support for that, we need to acknowledge that it's very slim, and that's in contrast to really for low-dose CT, which has now through the highest kind of level of

evidence, which is a randomized controlled trial, the National Cancer Institute demonstrated to reduce lung cancer mortality through the use of low-dose CT.

Actually, when we started in the year 2000 to introduce low-dose CT, we did it because we knew it had been established you could detect nodules at an early stage -- lung cancers at an early stage, but it hadn't yet been proven that you could reduce lung cancer mortality. That was proven in a 2011 study of the National Cancer Institute and very rapidly adopted in medicine.

The United States Preventive Services Task Force reviewed that study and others and endorsed low-dose CT for people exposed -- for high risk for lung cancer in 2013, and once the U.S. Preventive Services Task Force did that, then it meant that under ObamaCare private insurers and Medicare had to begin to offer low-dose CT for people at high risk for lung cancer. So that is now the policy both of the federal government in Medicare/Medicaid, as well as what private insurers have to offer, which is for people at high risk for lung cancer that they're offered low-dose CT.

Now there are a number of risk factors for lung cancer and I want to be forthright, that under

the National Cancer Institute study they looked at only two risk factors, which was age and smoking, because those are the most -- certainly smoking is the most important risk factor for lung cancer. But the idea has been since broadened to include other risk factors in identifying who should be eligible for low-dose CT.

So, if you look at the organization of the most prestigious cancer centers in the U.S., which is called the National Comprehensive Care Network, they recommend for screening for lung cancer people age 50 and over who have some limited smoking history but also who may have a history of, family history of lung cancer, chronic obstructive pulmonary disease, or occupational exposure to asbestos, beryllium, they named beryllium, silica, and others.

So there are recommendations by authoritative organizations saying that, yes, occupational exposure to carcinogens, including beryllium, should be included in looking at the risk factors to decide whether people are eligible for low-dose CT.

So, to add to the reasons I mentioned before as to why DOE should include lung cancer screening, I would add the fact that there is strong scientific

evidence that low-dose CT can prevent premature unnecessary lung cancer mortality among people at high risk for chronic beryllium disease -- excuse me -- who have beryllium exposure.

So I have one, just one additional much shorter comment to make which is about the move to make testing and removal mandatory for beryllium-exposed workers. I think that the idea of mandatory testing, to move from voluntary, strongly recommended to compulsory testing and compulsory removal of workers violates a critical ethical principle in medicine, and that ethical principle is called autonomy, and it's a shorthand way of saying that people, whether they're workers or patients or us, have the first say and have primacy in deciding on their medical care, deciding on their health status, deciding on their health information, and deciding all matters in relation to their health, and that value core principle of autonomy, there are only a few that really apply, not just to research, but apply to clinical practice of medicine is a preeminent value.

It wasn't always that way. I can tell you that when I went to medical school, my medical school, when I entered in 1976, we would go in the front door of the hospital and etched in stone it said, "From of

most High cometh healing". It was a Presbyterian hospital built in the late 1800s, so when they etched in stone "From of most High cometh healing" we understood what they meant at that time, but I can tell you that by 1976, when I was in medical school, what we understood that to mean was that healing came from us, that the doctors were in charge and we were the ones who were going to provide that healing.

And I think really the attitude in medicine and in society has changed since that time. Health status, healthcare, health is clearly understood to be a shared concern, that yes, healthcare providers have a critical role, but that people themselves have a critical role in determining their health and in determining their healthcare and determining what happens to their health information.

I think actually DOE recognizes this. If you look at its privacy concerns, its privacy rules, regulations, they understand the importance of the individual in health decisionmaking, both about information but also about what happens. So I think, frankly, to make testing mandatory, to say to a worker as a condition of this job you have to have this test is to violate and overstep that autonomy.

Now is that principal inviolate? I mean,

are there conditions under which we can -- are there sometimes goals more important than autonomy? And the answer is yes. Public safety, for example, we require, and I agree, we require truck drivers to have drug testing. We should because if they have a problem with drugs they're a threat to the public, and there are many other job categories with those concerns.

That's not true really of beryllium-exposed workers. That particular issue of public safety is not -- can't be really cited as a reason to violate autonomy, and I really can't think -- I was trying to think, well, can there -- can we create a rational, a real rational whereby we can forego the worker's autonomy, and I don't, I just don't see it. The information value for not just the worker but for co-workers in the workplace and the employer of early detection of sensitivity, in part because it's an immunologic disease, so who gets it is idiosyncratic at any given low level. It does not necessarily broadly reflect what the co-workers have in terms of risk. So I don't think actually that is a compelling reason.

I'm also concerned -- I can't think of a precedent here, and OSHA does not mandate testing. In

other words, they mandate employers to provide testing, but they don't require as a condition of work that workers undergo medical testing, and so I'm concerned here not just about DOE and beryllium but more broadly crossing that boundary in occupational medicine because I think it's not for the right boundary.

By contrast, I think the way to approach it is the way DOE has approached it, which is that workers are educated, they're advised. The contract with the employer has to offer those programs. The workers are given every opportunity to understand the need for testing, the desirability of testing. If they're sensitive, they have CBD, the advisability of them no longer being exposed, but I don't think it should be mandatory. I think it should be voluntary with full information and education.

And I think that if you change that aspect, the mandatory aspect that you'll be on much stronger ground both ethically in terms of mainstream medical ethics, but also I think you'll be on solid ground scientifically because the scientific support for that mandatory removal just really isn't there. Thank you very much.

MS. ROGERS: Thank you. Mike.

MR. BRISSON: Good morning, everyone. My name is Michael Brisson. I am professionally a technical advisor at the Savannah River National Laboratory, which is a Department of Energy site in South Carolina. I am not here today speaking on behalf of SRNL or my employer. The comments that I would like to share today are primarily my own, but they do also represent a consensus of the Sampling Analysis Subcommittee of the Beryllium Health and Safety Committee.

And so my comments today are going to be different from most of the others that have been presented or will be presented in that I am narrowly limiting my comments to analytical chemistry issues because there are concerns with the technical feasibility of being able to meet the sensitivity limits that are required for the proposed action level of 0.05 micrograms per cubic meter in air, and so my comments today are limited to that sphere, but I will be providing additional written comments prior to the close of the public comment period.

So, again, regarding the technical feasibility of the proposed action level, from my laboratory perspective, I would like to share a little bit of laboratory background.

The permissible exposure limit and the action levels, whatever values they may be for air or for surface contamination, are based on mass per volume of air or mass per square centimeter for surface wipes. But laboratory detection is based on mass only. Whatever actually shows up on the air filter or on the surface wipe, that is what the laboratory measures and then it has to be converted to mass per unit volume based on how much air is drawn through the filter or mass per square centimeter depending upon how many square centimeters might have been wiped.

The laboratory also needs to be able to detect one-tenth of an action level to ensure quantitative determination. This is primarily a typical laboratory practice internationally, but it is also based on consensus standards, one of which is EN 482, which is a European standard, and ISO has drafted a similar international standard, ISO 20581, which is in final balloting now, both of which specify this 10 percent criterion that I'm describing.

Now being able to meet the above criteria is therefore a function both of the amount of air drawn through the filter or the amount of surface wiped and the sensitivity of the analytical method, and I'll

describe for the audience the three methods that are most commonly used for detection of beryllium.

The first of them is inductively coupled plasma atomic emission spectroscopy, which has a sensitivity of .03 micrograms per sample as stated in ASTM Standard D7035. This one is most -- the one that is most commonly used in industrial hygiene laboratories. It is also the least sensitive of the three that I am going to describe.

The second is ICP mass spectrometry, inductively coupled plasma mass spectrometry, which has a sensitivity of 0.004 micrograms per sample as stated in ASTM Standard D7439. This particular method is becoming more common in industrial hygiene laboratories but is more expensive and requires greater oversight than atomic emission spectroscopy does.

The third method is molecular fluorescence, which is described in ASTM Standard D7202 and also in NIOSH Standard 7704. Now 7704 is for air samples and there is a separate NIOSH method 9110 for surface wipes. This particular method has recently been improved to provide a sensitivity of .0001 micrograms per sample, and there is a journal article that has been submitted to apply spectroscopy that will

describe this particular -- the improvements that have been made to achieve this enhanced sensitivity, and I won't read off the authors or the title, but I will have them in the written document that I provide with these comments.

This particular method, however, is less commonly used. Even though it is the most sensitive and it is also field deployable, it is only used at a handful of locations presently.

Now it is important to note that the values that I cited should be considered optimal sensitivities. Some of the samples may require various pre-treatment, such as dilutions, depending upon their nature, the nature of those samples and what is required to get them fully into solution that would reduce the sensitivity for those particular samples.

And before I can continue along this line I would like to mention as an aside that I would like to encourage DOE to consider listing appropriate analytical standard methods from ASTM International, NIOSH, and OSHA in the preamble to the final rule because I believe that that would be valuable guidance for the regulated community.

Regarding the ability to meet the proposed

action level of 0.05 micrograms per cubic meter, the fluorescence method has sufficient sensitivity for an air sample at the proposed action level collected at 2 liters per minute for 15 minutes. So its sensitivity is very good.

For a sample at the proposed action level, ICP mass spectrometry would require 0.08 cubic meters, and that's without considering the 10 percent sensitivity criterion that I mentioned from EN 482, and so that would be 40 minutes of sampling at 2 liters per minute. You need that much to be able to detect at that level. For the same sample, ICP atomic emission spectroscopy would require even more air, 0.6 cubic meters.

So DOE should note that only a handful of analytical laboratories presently utilize the fluorescence method. More labs will need this capability if the proposed rulemaking is made final because they will need the sensitivity that that method provides.

The biggest issue here, I mean, there is obviously a cost issue associated with that, although the fluorescence method is not particularly expensive, but the bigger issue is the time required for the laboratory to purchase the equipment, implement the

analytical method, and obtain accreditation for that method since accreditation is currently a requirement and a proposed requirement.

Typical experience suggests a timeline of up to 18 months for a laboratory to do all of those things. It's a little bit more complicated than just making the purchase and plugging the device in.

So, if more air is collected, for example, by using higher volume air pumps, one or both of the other methods that I mentioned may also be sufficient, and I think that's a key consideration going forward is both analytical sensitivity and the amount of air that you collect. Higher volume air pumps may also be beneficial.

So the proposed rule, and now I'm migrating into analysis quality assurance as proposed in 850.24, subparagraph (e). The proposed rule specifically calls for analytical methods to be accredited, and while this is consistent with 10 CFR 851, it may have the unintended effect of deterring the use of field deployable instrumentation, such as the fluorescence method or other such methods that may be available in the future. Encouraging such instrumentation is desirable to save time and money.

The American Industrial Hygiene Association

has proposed a field analyst registry program similar to the asbestos analyst registry that would be more cost-effective. The analyst would need an affiliation with an accredited laboratory to ensure that the analyst is following a suitable analysis quality system, but that laboratory does not necessarily need to be at the same site, and so DOE should consider allowing this alternative in the final rule as well.

And as I said before, I will provide additional written comments prior to the close of the public comment period, but I would like to thank DOE for the opportunity to participate and present these comments today.

MS. ROGERS: Thank you. Kathy.

MS. CREEK: Good morning. My name is Kathryn Creek. I am the Beryllium Protection Program leader for Los Alamos National Laboratory. I don't represent my organization today. However, I am the subcommittee chair for the Research Needs Subcommittee for the Beryllium Health and Safety Committee, and this is our collective comments on the notice of proposed rule.

So the Beryllium Health and Safety Committee, Research Needs Subcommittee, recommends that the Department of Energy and the Department of

Labor engage in immediate discussions regarding the establishment of targeted research and development funds for: (1) improving the sampling and analytical methods or instrumentations used for measuring the beryllium content of industrial hygiene air and surface samples; (2) using data collected as part of the current DOE registry and the Energy Employees Occupational Analyst Compensation Program Act, or EEOICPA, to provide feedback to the specific DOE sites on beryllium sensitization and chronic beryllium disease cases; and (3) for identifying and validating an improved means for the identification of beryllium sensitization and CBD diagnosis.

The establishment of the targeted research funding would provide the DOE and the DOL with the ability to improve the health and safety environment of DOE sites and the private sector and potentially reduce the rate of beryllium-related compensational claims submitted to EEOICPA.

In specific, we provide recommendations for further research and development for the following:

Item No. 1: Development of a real-time beryllium monitor or detector.

Sample collection and analysis is timely and lab-based. Rather large resources have gone into the

development of real-time detection instrumentation for radionuclides, yet limited funding for the development of a beryllium monitor.

In regards to contamination potential, sites experience having limited information about legacy locations, requiring extensive sampling plans that is costly and time-consuming. Real-time instrumentation would allow for sites to pinpoint contamination locations, thereby reducing the number of times to conduct compliance sampling and decontamination to achieve the desired action limits.

Reduction in the amount of sampling would be realized since real-time instrumentation will provide the user the information needed to perform focused, targeted, specific sampling.

For our workforce protection, currently we may overprotect with respiratory protection even though the majority of our breathing zone samples are below the analytical reporting detection limit. Real-time instruments could give assurances of the need for or level of respiratory protection. By evaluating exposure as it happens, the exposure risk can more effectively be controlled. On occasion, we have high results where we would benefit from reducing the time or the number of days which employees are exposed.

For radionuclides, we currently have continuous air monitors, yet there is no beryllium cam.

As an added benefit, instrumentation developed for beryllium could probably be used for other contaminants as well, thus increasing the effectiveness in general of our IH programs. Given the many benefits of real-time instrumentation, we recommend that beryllium real-time instrumentation be developed and tested in order to improve our inventory, improve our workplace health programs, and worker confidence in our data.

Item No. 2: An alternative to the beryllium registry.

From 2002 to present, DOE sites have provided -- have been reporting employee exposure beryllium data to the Beryllium Associated Worker Registry, or BAWR. The goal was to collect health and exposure information for individuals potentially at risk for chronic beryllium disease at their work locations. However, the data does not presently allow for useful determinations for the level of risk and does not provide useful information in specific to the DOE sites.

The Department of Labor's EEOICPA collects data on our former workers and also some of our

present workers. Beryllium sensitization and chronic beryllium disease cases are identified. We have attempted to obtain general yet reliable data on where the individuals were exposed and what they were doing at the time of that beryllium exposure. It is our perception that the data is in a format that may not be easily retrievable.

From word of mouth from local EEOICPA office personnel, reportedly landscaping personnels, firefighters and secretaries are sensitized or have CBD. Yet we cannot conduct any exposure assessment nor have prior knowledge of some of these tasks being evaluated as hazards, so this anecdotal information suggests the presence of unevaluated beryllium risks. We would benefit from this information, but without hard data we find it difficult to act on.

We recommend that DOE fund a Ph.D. study to evaluate the beryllium sensitization and CBD using the Department of Labor EEOICPA data. We also recommend the study be provided to DOE and the individual sites in order to improve our inventory and reduce our workplace risks.

An alternative means of improving the BAWR would be to provide DOE with data through a centralized database for exposure and health

surveillance records. DOE sites would collectively use the database systems that would be easily retrievable by individual sites and DOE.

This central database would eliminate the need for sites to provide data to DOE in batches and would always be available for DOE to review. DOE could then conduct reviews, provide study results to the specific sites, and collectively provide the information to all the DOE sites. This central system would reduce any risk of contract changes causing loss of data and also reduce the cost of each location developing and maintaining their own database.

Item No. 3: An alternative to the beryllium LPT and improved or noninvasive tests for CBD diagnosis.

The lymphocyte proliferation test, or LPT, is used to determine if a worker is sensitized. The LPT is a method prone to false positives and false negatives, which reduce confidence in the diagnosis of beryllium sensitization and at times chronic beryllium disease. Additional or new tests are needed to improve the confidence and diagnosis of sensitization. As an example, recent work by National Jewish Hospital and other highly skilled organizations who conduct the tests show there is promise of using the

ELISPOT method in tandem to the LPT.

The ELISPOT test gives additional information to workers' immune system activity in general and can be an aid to determining if the LPT result is more likely to be a false positive. However, this test cannot be used with the LPT for diagnosis if a study has not been conducted to prove the ELISPOT is a truly vetted procedure for that purpose. The ELISPOT is one example of a test that can be used in conjunction with the LPT.

Also, the tests to diagnose CBD are invasive. A less invasive test would be very beneficial. We are aware of a number of former workers who have refused to take the test due to the risk of the associated bronchial lavage. They are informed also that their own insurance would have to cover any risks of this test being conducted.

Further, one of our organization's program has conducted a study using beryllium urinalysis for monitoring beryllium worker exposure. Preliminary results show that this method may be useful at monitoring and thereby correcting exposure for those workers that have elevated beryllium urine results.

Therefore, we support the further development of new or current tests that can be used

to diagnose beryllium sensitization, development of noninvasive tests for CBD, and the monitoring of beryllium exposure through BEIs. It is our collective opinion that DOE and DOL should work closely to fund research and development to improve the testing of our current and former workforce.

Item No. 4: Improvement of Instrument Detection Capabilities.

Lowering the action level to 0.05 micrograms per cubic meter eight-hour TWA stretches the limits on current sampling and analysis detection limits, as further commented by Mike Brisson, the Beryllium Health and Safety Committee sampling and analysis subcommittee.

The sample detection limit is a result of the combination of the volume of the sample collected and the beryllium analysis detection limit. The two parameters, volume and beryllium level, each play a part in determining the detection limit for that sample. Therefore, increasing the sample volume and/or decreasing the analysis detection limits will improve the sample detection limit.

We recommend that DOE pursue the improvement of instrument detection capabilities and/or a higher flow rate personal air sampling pump to increase the

air volume collected per amount of time. Also, the evaluation of a lower pressure differential sampling media to reduce the load on the pump could improve pump efficiency. Research and development for the improvement of analytical detection limits and increase in sampling volume should be funded by DOE.

Item No. 5: Real-time instrumentation validation methods.

Real-time instruments are now capable of detecting beryllium on a metal surface to determine if the material contains beryllium. This is in the percent category, not in part per million or what we use for detecting workplace exposure risk. It's for the metal, and it's used commonly in scrap metal industry.

Yet there is no assessment of the instruments to determine the detection limit or methods to show reliability, such as an ASTM method. This type of instrument would be very useful in determining beryllium content and low percent beryllium alloys, such as copper and aluminum beryllium alloys.

Many of our facilities have a fixed material such as fingerstock on doors for faraday cages and electrical connections in cranes that have copper

beryllium materials. Risk of disturbances of low percent beryllium-containing alloys is a concern since we have seen airborne levels for removal of copper beryllium above the proposed action level.

Further assessment of these materials is needed and use of swipe samples is cumbersome for determining if the material contains beryllium. Therefore, we recommend that the evaluation of hand-held surface samplers for beryllium be conducted and an ASTM method be developed. We would have confidence in our results that the metal either did or did not have beryllium as a constituent, and this could also expound the definition of a beryllium article.

And in closing, I want to thank Jackie Rogers and David Weitzman, Bill McArthur from the Department of Energy, and the Chief Industrial Hygienist, Dan Field with NNSA, for their hard work and steadfastness on developing the changes on the rule, and this concludes my comments.

Are there any questions? Thank you.

MS. ROGERS: Okay. I have to wait for --

(Whereupon, a short recess was taken.)

MS. ROGERS: Excuse me. We have another speaker. The next speaker is Donna, and for the record, I would ask that you state your full name and

who you're representing, please.

MS. HAND: My name is Donna Hand. I am a worker advocate, and I'm representing myself.

Some of the issues in the new preamble and some of the questions that DOE was asking was their soluble or insoluble compounds. Well, according to the beryllium -- the Annual Association of Lab Managers Conferences, that there are soluble compounds and these compounds are used in the nuclear weapons industry.

Another thing was that the elemental definition and metallic forms include pellets, rod, wire, and granulars for evaporation sources and material purposes. Beryllium oxide is an insoluble source and it's available in the powder and the dense pellets, optical coating and thin film applications. Beryllium fluoride is in the oxygen and metallurgically chemical, physical vapors, but beryllium soluble forms include chlorides, nitrates, and acetates.

Again, if you print out beryllium, you have ammonia beryllium chloride, you have beryllium aluminate, bromate and a whole list of different beryllium compounds.

So the regulations or the rules should take

into effect the health effects of having a soluble and insoluble exposure, so in your medical surveillance, that is going to be -- needs to be looked at because they are treated differently.

From my understanding is that when it's insoluble it may stay in the lung longer and then go into the other organs. Then you'll have your liver, your skeleton, your spleen. Soluble is also easier to be into the skin, so you have more dermatitis. You have vapors in fumes that you'll have eye diseases and eye issues, problems. We now know there's nanoparticles, so the particles are even smaller, and the eye situation is either from the particles or from the vapors and fumes and it's also the nano size.

There has been studies, and it was another thing that the DOE request studies in current, there was more current studies now since 2010 to present regarding beryllium, and there is a sensitization and disease from exposure to soluble and insoluble beryllium at manufacturing facilities that was done in 2012. So there are current studies that have not been looked at, and there's a list of studies.

Also, the National Academy Council made a book about health effects of beryllium exposure, and then the DOE has a facilitator manual in 2002 that

went out to all the facilities for the training. So that part there to be looked at because in that part it admits that it does go to the liver, the spleen, and the skeleton, that there's other organs.

As far as testing, we have studies saying that beryllium LPT is very variable. We now know that there is skin patch testing and that skin patch testing has been done by the Mayo Clinic, Johns Hopkins whenever they're replacing hip replacements to detect the metal part and see if a person is allergic to it. They have found out that that is more responsive than the old allergic prick test. And then you also have the sputum test. You know, again, these are two noninvasive tests that are being thrown up as being very reliable, and these should be looked at as beryllium can be used in one of those tests, so then it's not so invasive for the workers. And that's basically it. Thank you.

MS. ROGERS: Thank you. Anybody else got a narrative?

(No response.)

(Whereupon, a short recess was taken.)

MS. CARROLL: Hello. My name is Stephanie Carroll. I am a nuclear worker advocate. I specialize in establishing chronic beryllium disease

under the Energy Employees Occupational Illness Compensation Program, and I have reviewed over 100 data sets related to CBD. I have access to workers' site clinical records, exposure records, IH documentation, CBD prevention program records, former workers program records, and current treating notes and study results.

In the preamble, I would like the language changed in the definition of beryllium sensitization. The word "sensitivity" does not describe the condition, and I feel the place is blamed on the worker calling them sensitive rather than describing it as a sentinel event that characterizes the safety of working conditions at the site. I feel like it's a way to get to genetic evaluations of workers.

When you say you are sensitive, you're implying that they have a physical problem that is causing them to become sensitized, and the problem isn't their physical issue. It is the issue at the sites. It's the fact that the sites are not safe enough for them to work in. So the worker was made sensitized by the working conditions and lack of protections.

It is a cell-mediated immune response to exposure to beryllium and is an important marker of

beryllium exposure. Most current studies use the term "sensitization". I don't think there will be any confusion if that gets changed.

Beryllium sensitization is an impairment, and history has been arguing the protective limits on exposure since the 1970s by challenging the science of the lower permissible limits. I am concerned about the language used in the definition of chronic beryllium disease. The definitions provided in the proposed rule and add as a new term to ensure consistency within the Department in how CBD is diagnosed. This is in the preamble.

BDS is defined in a lung biopsy showing non-caseating granulomas or lymphocytic process consistent with CBD or radiographic, including CT, and pulmonary function testing results consistent with pulmonary granulomas. I think there was a problem when this was written. It should read "pulmonary granulomas are not found by PFTs". I believe that the intention was to read that the radiographic science should be consistent with pulmonary granulomas and the fourth criteria was meant to read "pulmonary function testing results consistent with CBD". So I would like to see that changed and pulmonary function testing results consistent with CBD added.

To be consistent with the accepted diagnostic criteria of the Department of Labor's EEOICPA program, I suggest that you require a choice of one of three criteria to meet for diagnosis of CBD. The preferred language would be roll BES together with lung pathology consistent with CBD, including one of these three: lung biopsy showing non-caseating granulomas or lymphocytic process consistent with CBD; a CT scan I added or other radiographic signs showing changes consistent with CBD. I would still like to see pneumoconiosis to be used as radiographic signs consistent or pulmonary function or exercise testing showing pulmonary deficits consistent with CBD.

DLCO deficits and gas exchange on exercise are the first signs of CBD besides some of the clinical symptoms that I've seen in records for years and years from workers on site.

My argument is under 42 U.S.C. 7384, SCBES monitoring under DOL's EEOICPA, the treatment suite V81.4 used every day by the leading occupational clinics to confirm and monitor beryllium sensitization incudes the following diagnostic testing to determine whether a worker has established chronic beryllium disease.

The testing that is used every day to

determine if workers have progressed to CBD from beryllium sensitization are a physical exam; chest X-ray, chest X-ray is used; a CT scan; a pulmonary function test spirometry using SEC, SEV1, those are included on a daily basis to determine progression to CBD, which include diffusing capacity studies, exercise tolerance testing. CBCs are used to determine if there's multiple blood chemistry. This is the protocol that's been established, and I have the documentation of it -- multiple blood chemistries; bronchoscopy; Berlin Skin Patch testing is still in the protocol; LPT or LTT, so that's just a lymphocyte transformation test or it's not a BeLPT, but you can also use other lymphocytes to determine if there's a response to beryllium; and biopsies are covered.

So the DOL's beryllium biobank has included spirometry in medical evaluation results and tests requested for the repository. CBBR PFT Form F09, including FEC, FEV1, RBTLC, FRC, so they want the full range of pulmonary function testing, but the beryllium biobank supported by the Department of Energy did want FEC and FEV1 in their data sets to review for chronic beryllium disease.

The BE registry used PFTs up until 2005. In 2007, PFTs were removed from the requirements of the

sites to document changes on the pulmonary function testing. So the reason I was given by the person who was putting this together was there was too much documentation to add to the computer system, or maybe it was just too much information to ask from the sites because they were unable to even complete the forms properly in the first place.

I know that Rocky Flats had a very difficult time filling out the documentation for the beryllium registry. They would just leave a lot of the information blank and send it in.

So, under 850.34, DOE continues to believe that medical surveillance is important for -- I'm just noting this -- making possible the early treatment of beryllium-induced medical conditions. I agree with that. 850.34(a)(2), page 36731, procedures required to diagnose CBD will be performed or validated by a specialist in pulmonary medicine or occupational medicine. I agree with that.

I disagree and request that the following language be removed, "or by another physician familiar with the specialized equipment and examination protocols required to definitively differentiate between CBD and other lung diseases. DOE believes that this is necessary due to the unusual nature of

CBD and the fact that not all physicians are familiar with the evaluation of patients exposed to BED in their workplace."

I believe that workers should have the opportunity to choose their own physician, that being a pulmonologist. All pulmonologists are able to diagnose granulomatous lung disease.

Now, if a worker is beryllium-sensitized, I think the SOMD can get an evaluation by a worker's choice physician, hopefully their treating physician who has been evaluating them for years, and then make the decision on if the person qualifies for chronic beryllium disease. The testing protocols have already been put together by the Department of Energy. They have a website for the worker. They have a little card that they give them to bring to their own physicians asking them to do -- giving them a protocol to evaluate for chronic beryllium disease.

It is not a difficult disease. It's a granulomatous lung disease. It's like sarcoidosis, but it's a known etiology of beryllium exposure. It's not something special where all patients need to be sent to a specialized center. That is not true. A pulmonologist does have the expertise to diagnose CBD, as I said earlier.

850.3 definitions, beryllium-induced medical conditions refers to BES and CBD, I agree with that, but I would like to see removed other diseases, for example, CBD, that are not attributable to beryllium. That's not true. As Dr. Markowitz stated, lung cancer is a beryllium-attributed disease. Also, cardiac disease, liver disease, lymphatic kidney, dermal, and eye diseases can be attributable to beryllium and are in the protocols used by leading clinics in their evaluation of beryllium sensitization to chronic beryllium disease. So, if they are daily doing tests for these illnesses, that would suggest that they agree that these illnesses could be related.

On the BDS definition, I would suggest adding as just an option the beryllium patch testing which is still used by top research clinicians and that the borderline BeLPTs, I agree with the Middleton paper. It was very comprehensive in that recommendation. And ELISPOT has been around for a long time, but it has not been used clinically, and I believe that that should be looked into.

So there should be an option for other testing that's not so invasive to determine beryllium sensitization for workers, and we don't know what science is going to find. So I think that option

should be left open in the rule.

Now I just want to tell you what it's like to be a beryllium worker and the workers that I see, just a short representation of actually the first person I ever saw with beryllium disease and what this person had to go through.

So his experience was he was a liberal worker, wait, okay, okay, so I'm just going to read this. I would like to describe the experience of a typical liberal worker that I see and ultimately get diagnosed with CBD under the criteria established by EEOICPA. I have the unique perspective on the life of these workers and their families.

This Rocky Flats worker was a chemical operator process specialist from 1982 to 2003. Within a few years of hire he began experiencing upper respiratory inflammation, shortness of breath with exertion, night sweats, joint pain, and chronic dry cough. Every year they get evaluated on periodic health reviews. All workers at Rocky Flats did. It's great data because you get to see all the symptoms they've been suffering for the last year. Usually these guys aren't just -- they want to keep their jobs. They are reporting symptoms. They're very believable. Let's put it that way.

In 2002, he became beryllium-sensitized. He was still working there, and he was approved for DOL monitoring benefits. He went on to receive five abnormal BeLPTs. I don't know why more than two BeLPTs were done once it was clinically established he had beryllium sensitization, but he did continue to get these blood tests at the expense of Department of Labor. He was referred for clinical follow-up every two years.

During his clinical follow-up he signed up for studies, concentrating on genetic susceptibility, but he was told during his few minutes that he had in a room with somebody when he was requested to be a study subject that he would be helping other workers. And I don't know if workers would believe that they were helping other workers if they knew that they were contributing to studies to determine if they were genetically susceptible to beryllium disease.

He suffered restriction and was treated with corticosteroids, not restriction from work but restriction on his PFTs or spirometry. He had gas exchange abnormalities on his C-pad. He had two positive B reads. He had a CT scan with pulmonary nodules. He had two lavages and biopsies. In the studies that I have seen from the top clinical

evaluators, it actually says you don't do a lavage and biopsy on a worker who doesn't have signs consistent with CBD, clinical science consistent.

I have never seen in the over 100 sets of records and evaluation of beryllium sensitization any reference to a CT scan with multiple nodules as being consistent with CBD and therefore requiring a lavage and biopsy. I didn't see everybody get lavages and biopsies if they will agree to them.

The lavage actually showed two, two separate times that he had them, he was positive on the BALLPT. He had negative stains, and he had diffuse inflammation in his lungs. He never received a diagnosis of chronic beryllium disease, and to this day he still does not have chronic beryllium disease according to the top clinical evaluators of chronic beryllium disease.

In 2011, I fought -- well, I fought from 2010 to almost 2012 the Department of Labor to get him approved for chronic beryllium disease. All he needed to meet from the Department of Labor was beryllium sensitized, a PFT showing obstruction, or a C-pad with exercise tolerance testing with deficits consistent with CBD; CT scan consistent with CBD; and, of course, lavage or biopsy or lymphocytic process consistent

with CBD. He couldn't get his doctor to write that for anything. He tried over and over again to get the doctor to say, oh, yeah, your CT scan is consistent with CBD. That's why we did a lavage and biopsy. Therefore, you qualify for CBD.

What would have happened had he been diagnosed with CBD? He may not have ever gone back to a research institute and signed up for any studies. That's the only reason I can see for him not getting diagnosed with CBD but continually being brought in every two years to go under the knife for a lavage and biopsy.

This is my greatest concern, that with a low rate of progression -- or this is the problem. So, with a lack of diagnosis of CBD, all the data that we see on Middleton's report, which was great, all of the data that comes out of research that already has determined that there's a very low rate of progression to CBD based on the fact people just aren't getting diagnosed, I believe that data is skewed. Let's look at the basic data. If people are not getting diagnosed with CBD in modern times, then it looks like there's no problem with beryllium.

So, with a low rate of progression of CBD, the public agencies and workers do not understand the

dangers of beryllium exposure.

So thank you for allowing me to comment on behalf of workers sensitized and suffering with CBD, along with their families that dearly miss them now that they're gone. Thank you so much.

MS. ROGERS: Okay. Any additional speakers?

(No response.)

(Whereupon, at 11:10 a.m., the hearing in the above-entitled matter concluded.)

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REPORTER'S CERTIFICATE

DOCKET NO.: N/A

CASE TITLE: Notice of Proposed Rulemaking

HEARING DATE: August 11, 2016

LOCATION: Washington, D.C.

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the U.S. Department of Energy, Office of Energy Efficiency & Renewable Energy.

Date: August 11, 2016

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