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February 14, 2011

Ms. Jacqueline D. Rogers
U. S. Department of Energy
Office of Health, Safety and Security
Office of Worker Safety and Health Policy
1000 Independence Avenue, SW
Washington, DC 20585

Dear Ms. Rogers:

Department of Energy Request for Information – Chronic Beryllium Disease Prevention Program

Enclosed are Babcock and Wilcox Technical Services Y-12, LLC's (B&W Y-12) responses to the Department of Energy's request for information and comments on issues related to its current chronic beryllium disease prevention program (73 Fed. Reg. 80734, December 23, 2010). As the management and operating contractor for the Department of Energy National Nuclear Security Administration Y-12 Site Office, B&W Y-12 manages the Y-12 National Security Complex in Oak Ridge, Tennessee.

Y-12 Site Office management officials have reviewed and concurred with the contents of our submission.

Sincerely yours,

William R. Klemm
Senior Vice President and Deputy General Manager

WRK:mwt

Enclosure: As stated

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Internal Distribution for February 14, 2011, William R. Klemm to Jacqueline D. Rogers letter "Department of Energy Request for Information – Chronic Beryllium Disease Prevention Program"

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Enclosure
Letter, Klemm to Rogers
Dated: February 14, 2011

Letter Title

Department of Energy Request for Information – Chronic Beryllium Disease Prevention Program

Response to the Department of Energy (DOE) Request for Information regarding 10 CFR Part 850, *Chronic Beryllium Disease Prevention Program.*

Following are Babcock and Wilcox Technical Services Y-12, LLC's (B&W Y-12) responses to the Department of Energy's (DOE) request for information and comments on issues related to its current chronic beryllium disease prevention program (73 Fed. Reg. 80734, December 23, 2010). As the management and operating contractor for the DOE National Nuclear Security Administration Y-12 Site Office B&W Y-12 manages the Y-12 National Security Complex (Y-12) in Oak Ridge, Tennessee.

For ease of review, we copied in italics the language taken directly from DOE's request, and have followed that with B&W Y-12's response.

I. Background

DOE has a long history of beryllium use because of the element's broad application to many nuclear operations and processes. Beryllium metal and ceramics are used in nuclear weapons as nuclear reactor moderators or reflectors and as nuclear reactor fuel element cladding. At DOE, beryllium operations have historically included foundry (melting and molding), grinding, and machine tooling of parts.

Inhalation of beryllium particles may cause chronic beryllium disease (CBD) and beryllium sensitization. CBD is a chronic, often debilitating, and sometimes fatal lung condition. Beryllium sensitization is a condition in which a person's immune system becomes highly responsive (allergic) to the presence of beryllium in the body. There has long been scientific consensus that exposure to airborne beryllium is the only cause of CBD.

On December 3, 1998, DOE published a notice of proposed rulemaking (NOPR) to establish a Chronic Beryllium Disease Prevention Program (CBDPP) (63 FR 66940). After considering the comments received, DOE published its final rule establishing CBDPP on December 8, 1999 (64 FR 68854). At that time, DOE sought to reduce the number of workers exposed to beryllium in the course of their work at DOE facilities managed by DOE or its contractors; to minimize the levels of, and potential for, exposure to beryllium; and to establish medical surveillance requirements to ensure early detection of the disease. DOE now has nearly 10 years of job, exposure, and health data, as well as experience implementing the rule, since CBDPP was fully implemented in January 2002. In addition, new research related to CBD has been published in the years since 1999.

Currently, the Department is considering establishing new requirements in several sections of the CBDPP rule (10 CFR part 850). DOE is gathering data, views, and other relevant information to develop a revised standard for CBDPP at its facilities. The Department urges those individuals interested in this issue to provide responses to the questions provided in this document.

Background Statement: B&W Y-12 Comments

In the background section it is stated that "there has long been scientific consensus that exposure to airborne beryllium is the only cause of CBD." However, it is not clear if the goal of revising 10 CFR Part 850 is to prevent CBD or beryllium sensitivity (BeS). As such, the answers to many of the subsequent questions could vary significantly based upon a goal of preventing CBD versus a goal of preventing BeS.

II. Questions for Comment

DOE would like to have more data and information to decide whether its current CBDPP can be improved, and if so, how it can be improved. When answering specific numbered questions below, key your response to the number of the question and, if possible, include the mission and cost impacts implied by the question and by your answer.

1. *DOE currently defers to the Occupational Safety and Health Administration (OSHA) for establishing the permissible exposure limits (PEL) and uses an action level as the administrative level to assure that controls are implemented to prevent exposures from exceeding the permissible exposure limits. Should the Department continue to use the OSHA PEL? Please explain your answer and provide evidence to support your answer.*

Question 1: B&W Y-12 Comments
A number of studies have shown that the current OSHA PEL does not provide the level of protection necessary to prevent BeS or CBD. However, the action level established in 10 CFR Part 850 requires exposure controls at one-tenth of the PEL, effectively eliminating the impact of the PEL on the exposures experienced by beryllium associated workers. Implementation of the CBDPP at Y-12 further dilutes the impact of the PEL by requiring hazard assessment, engineering, administrative, and personal protective equipment (including respiratory protection when there is a potential for airborne beryllium) anytime work with beryllium is performed. As is recognized in the documentation of the current TLV® for beryllium, Madl et al.[J Occup Environ Hyg 4(6):448-466(2007)] concluded that BeS and CBD may be preventable if exposures are maintained below 0.2 $\mu g/m^3$ 95% of the time. Adoption of the current action level of 0.2 $\mu g/m^3$ total fraction as the Occupational Exposure Limit (OEL) might be appropriate and is technically and economically feasible if the goal of the changes to 10 CFR Part 850 is to prevent both BeS and CBD.

2. *Should the Department use the 2010 ACGIH threshold limit value (TLV) of 0.05 $\mu g/m^3$ (8-hour time-weighted average of 0.05 microgram of beryllium, in inhalable particulate matter, per cubic meter of air), for its allowable exposure limit? Please explain your answer and provide evidence to support your answer.*

Question 2: B&W Y-12 Comments
For a number of reasons, it is not appropriate to adopt the 2010 ACGIH®TLV®. These reasons include the following:

- The ACGIH® acknowledges that the TLV® is not a consensus standard and does not address issues such as technical or economic feasibility.
- The current TLV® is based upon lifetime weighted (LTW) average exposures resulting in the development of BeS. OELs are used as upper limits of single shift exposures and it would be inappropriate to establish an enforceable limit based upon LTWs. [Madl et al. J Occup Environ Hyg 4(10):D103-104(2007); Hewett Appl Occup Env Hyg 16(2):251-256(2001); Kelleher et al. J Occup. Env Med 43:238-239 (2001)]
- The adoption of the inhalable fraction for the 2010 beryllium TLV® is not based upon the review of data used to establish the 0.05 $\mu g/m^3$ limit but on the presumption that BeS could result from beryllium interaction in the upper respiratory tract, conducting airways, pulmonary region, and the GI tract. Again this raises the question of the intent of the standard i.e., protecting against CBD or BeS and CBD.
- Cost would be prohibitive for the questionable additional level of protection afforded. B&W Y-12 estimates initial cost of implementing inhalable sampling in excess of $1M with ongoing annual additional cost approaching $1M. This would require additional funding or significantly reducing the number of samples taken annually. A reduction in exposure monitoring would impact the ability to evaluate the effectiveness of controls and might be perceived as less protective by beryllium workers.
- The additional dilution volume associated with collecting wall deposits from the filter cassette will likely raise the analytical reporting limit.
- There is no validated and approved National Institute of Occupational Safety and Health (NIOSH) or OSHA sampling and analysis method for the inhalable fraction of beryllium.

- At Y-12, most beryllium air sampling is of short duration tasks (<4 hours). It would be difficult with the currently available personal sampling equipment and analytical reporting limit to collect a sufficient volume of air to compare against the 0.05 $\mu g/m^3$ limit.

3. *Should an airborne action level that is different from the 2010 ACGIH TLV for beryllium (8-hour time-weighted average of 0.05 microgram of beryllium, in inhalable particulate matter, per cubic meter of air) be established? If so, what should be the level? Please explain each of your answers and provide evidence to support your answers.*

Question 3: B&W Y-12 Comments
For the reasons stated in response to Question 2, the ACGIH® TLV® is not appropriate for an enforceable regulatory limit. The current DOE action level of 0.2 $\mu g/m^3$ total fraction, as mentioned in response to Question 1, acts as the *de facto* exposure limit and is supported technically by the Madl et al. (2007) study previously cited. If an OEL lower than the current PEL is adopted then, if technically and economically feasible, an action level of one-half that limit may be appropriate. Wambach and Tuggle (Appl Occup Env Hyg 15(7): 581-587) suggest that an 8-hour Time Weighted Average of 0.1 $\mu g/m^3$ total fraction beryllium should provide lifetime exposure means that would be protective against BeS and CBD. This level might be appropriate for an action level that would require hazard assessment, medical monitoring, engineering and administrative controls and respiratory protection. Experience at Y-12 demonstrates that this is feasible.

4. *In the past DOE encouraged, but did not require, the use of wet wipes rather than dry wipes for surface monitoring. DOE's experience with wipe testing leads the Department to consider requiring the use of wet wipes, unless the employer demonstrates that using wet wipes may cause an undesirable alteration of the surface, in order to achieve greater comparability of results across the DOE complex and in response to studies demonstrating that wet wipes capture more of the surface contamination than do dry wipes. Should the Department require the use of wet wipes? Please explain your answer and provide evidence to support your answer.*

Question 4: B&W Y-12 Comments
There is currently no basis for endorsing any specific protocol for evaluating surface dust loading. The decision on what sampling methodology is to be used is best left to the individual sites. If a specific protocol is included in the rule, it should be limited to a specified purpose (such as release to another DOE facility or the public) and not prohibit individual sites from determining what protocol is appropriate for their internal application.

- Experience at Y-12 has shown that while wet wipe sampling tends to collect more beryllium contamination, this is not a consistent outcome. From July 14, 2009, through July 27, 2009, the B&W Y-12 Industrial Hygiene Department conducted a series of side-by-side swipe samples on surfaces with legacy beryllium contamination to compare the results of wet swipes versus dry swipes. A total of 64 samples were taken (32 wet and 32 dry) excluding blanks. The samples were taken in six separate locations across Y-12 on a variety of horizontal surfaces including concrete, tile and linoleum flooring, and other smooth non-porous surfaces such as stainless steel. After comparing the methods and the data sets, it could not be conclusively determined in all data sets that one method was more effective than the other in measuring beryllium surface contamination. For example, the dry swipes were up to seven times more effective on surfaces with residual oil and wet swipes were up to ten times more effective on the cleaner, less-porous surfaces. In summary, in 27% of the side-by-side samples, the dry samples were more efficient in collecting beryllium surface contamination than the wet samples. The wet samples were more efficient in 73% of the samples.

- Wipe sampling does not show the degree of precision that is normally required in industrial hygiene practice. Lichtenwalner Am Ind Hyg assoc 53(10):657-659 (1992) The results of any method of swipe sampling should be viewed as a qualitative assessment due to the high environmental and sampling errors such as non-uniform distribution of contamination and variability resulting from differing sampling pressures. Sanderson et al. J Occup Environ Hyg 5(7):475-481 (2008)
- Experience at Y-12 has shown, with certain sample media, negative analytical factors related to increased time for solubilizing wet samples, increased cost, and increased volume of diluent potentially raising the reporting limit.
- At Y-12, not mandating a change from dry to wet wiping has the advantage of making current sample results consistent with historical ones allowing comparison and trending possible.
- Y-12 facility characterization is based upon dry wipe sampling. The cost of validating the current characterization against a new sampling protocol would be prohibitive. Based on an analysis of Y-12 data, the estimated cost to re-characterize the facility using wet wipes is in excess of $2M with little or no benefit for protecting against airborne beryllium. If a requirement is established to switch to wet wipes, B&W Y-12 would propose to characterize on a forward only basis and not perform a complete re-sampling.
- The appropriate use of beryllium surface sampling should be to verify housekeeping controls to prevent the migration and re-suspension of beryllium contamination. There is no advantage between wet and dry protocols in demonstrating good housekeeping practices.
- As discussed in the current ACGIH® TLV® documentation there is some evidence that humans may become BeS from skin exposure. To mitigate that potential hazard, all work with beryllium at Y-12, regardless of airborne levels, is conducted under a beryllium work plan and requires the use of skin protection; thus, any perceived additional precision in surface sampling is unnecessary.

5. *Since the use of wipe sampling is not a common occupational safety and health requirement, how do current wipe sampling protocols aid exposure assessments and the protection of beryllium workers? How reliable and accurate are current sampling and analytical methods for beryllium wipe samples? Please explain your answers and provide evidence to support your answers.*

Question 5: B&W Y-12 Comments
It is generally accepted that variables involved in wipe sampling are poorly understood and significant. Wipe sampling results cannot be accurately correlated with airborne exposures. In an internal Y-12 study, no correlation was found between breathing zone sampling results and surface contamination levels. DOE should consider funding studies to evaluate the re-suspension of surface contamination to airborne levels. Relative to exposure assessment, the wipe sampling methodology used for housekeeping practices by B&W Y-12 are protective of workers against airborne beryllium at the action levels.

Technical references regarding the applicability and reliability of beryllium surface sampling are as follows:

- "There is no general quantitative relationship between surface contamination and air concentration that is adequate for estimating inhalation dose with sufficient accuracy for use in Industrial Hygiene. If inhalation dose is of concern, appropriate air sampling should be conducted." "For Industrial Hygiene purposes, there is no usable quantitative correlation between air and wipe samples." "As will be apparent from the conclusions of this report, wipe sample results have not even an approximate quantitative relationship to concentrations of respirable dust in the workplace." Caplan Am Ind Hyg Assoc J 54(2)70-75 (1993)

- "Unfortunately, surface sampling has limited reliability for exposure assessment." "With the wide range of surface sampling collection methods in use it is obvious why professional industrial hygienists seldom use wipe sampling to assess potential exposures." McArthur App Oc Env Hyg 8(9) (1993)

- "This shows that the wipe sampling procedure does not have the degree of precision generally accepted in industrial hygiene practice." Lichtenwalner Am Ind Hyg assoc 53(10):657-659(1992)

- "The method was never intended to be used as a means to determine a level of air contamination. There is no correlation between surface and air-borne beryllium concentrations." Mitchell and Hyatt American Industrial Hygiene Association Quarterly, Volume 18, page 207 (1953)

- "The only possible value that numerical expressions of beryllium surface contamination might have would be merely for qualitative indication of total presence or absence of contaminant." "They concluded that surface contamination is not itself a good criterion for judging the existence of hazardous conditions and that it is probably unsound to establish acceptable levels because of the many variables involved." Cohen and Kusian, The Significance of Beryllium Surface Contamination to Health. Surface Contamination, Proceedings of a Symposium held at Gatlinburg, Tennessee (June 1964)

- "Surface sampling should not be used to measure worker exposure or demonstrate regulatory compliance. It is not highly reproducible, not completely efficient in removing material, and shows variable recovery from different surfaces." USDOE Defense Programs Beryllium Good Practices Guide (1997)

- "DOE views wipe sampling as a useful and accepted method for providing qualitative information on chemical contamination of work surfaces, and agrees with the following statement from the OSHA Technical Manual (Section II: Chapter2, Sampling for Surface Contamination): "Wipe sampling is an important tool for work site analysis for both identifying hazardous conditions, and in evaluating the effectiveness of housekeeping and decontamination programs." Accordingly, this requirement is intended only as a housekeeping performance measure, and should not be viewed as a mechanism for measuring or predicting airborne concentrations of beryllium." USDOE, 10 CFR Part 850, Chronic Beryllium Disease Prevention Program; Final Rule (1999)

6. *What is the best method for sampling and analyzing inhalable beryllium? Please explain your answers and provide evidence to support your answers.*

Question 6: B&W Y-12 Comment
The B&W Y-12 Industrial Hygiene Department does not have experience with inhalable fraction sampling and, therefore, does not have an opinion relative to the preferred method for sampling and analyzing inhalable beryllium.

7. *How should total fraction exposure data be compared to inhalable fraction exposure measurements? Please explain your answer and provide evidence to support your answer.*

Question 7: B&W Y-12 Comments
There are many variables that influence the collection efficiency when sampling either for the inhalable fraction or for the total fraction using the industry standard 37 mm closed face cassette (CFCs), thus making it impractical to apply a correction factor across tasks with differing physical characteristics (e.g., Mass Mean Aerodynamic Diameter, particle charge, air velocity, particle momentum, etc.). For relatively static operations it might be possible to develop a correction factor through side-by-side sampling. It is

generally accepted that sampling by the inhalable convention collects more efficiently, especially in the upper end of the inhalable particle range. Spear et al. [58(12): 893-899 (1997)] reported ratios of IOM/37mm for lead from 1.39 to 2.14 and for cadmium from 1.29 to 2.12 with the factor tending to be greater for areas where aerosols were coarser. A published study Lidén et al. [Appl Occ Env Hyg 15(3): 263-276, (2000)] proposed a factor of 0.5 for converting inhalable total fraction OELs to inhalable fraction OELs. However, they went on to add that, for some types of dust, sampling for the inhalable fraction might produce lower results than sampling with the 37 mm CFC. Wilsey et al. [Am Ind Hyg Assoc J 57(12): 1149-1153 (1996)] reported a ratio of 2.96 for coarse aerosols. Demange et al. [Appl Occ Env Hyg 17(3): 200-208 (2002)] in a field comparison of 37 mm CFCs to IOM samplers determined that when material on the cassette walls was recovered the results tended to be equivalent. However, NIOSH analytical methods do not call for recovery of wall deposits and Martine et al. determined from their study and previously reported results that there is too much variability to determine an appropriate correction factor when only the filter has been analyzed. There is some consensus that collecting wall deposits using CFCs may be comparable to inhalable fraction sampling at a much lower initial and ongoing cost.

8. *Should surface area action levels be established, or should DOE consider controlling the health risk of surface levels by establishing a low airborne action level that precludes beryllium settling out on surfaces, and administrative controls that prevent the buildup of beryllium on surfaces? If surface area action levels are established, what should be the DOE surface area action levels? If a low airborne action level should be established in lieu of the surface area action level, what should that airborne action level be? What, if any, additional administrative controls to prevent the buildup on surfaces should be established? Please explain each of your answers and provide evidence to support your answers.*

Question 8: B&W Y-12 Comments
As cited in responses to Questions 4 and 5, due to the sampling error/variability, lack of correlation between surface and airborne levels, and the absence of a technical basis, it is not appropriate to establish a surface contamination limit that is enforceable by Federal Regulation.

As a best management practice, B&W Y-12 has adopted a beryllium surface contamination level of 0.2 μg/100cm^2 as a housekeeping limit for beryllium contamination outside of beryllium operational areas. Levels above that require immediate cleaning or the implementation of hazard assessment, engineering and administrative controls, and the demarcation of the area as a beryllium operational area. However, this policy was not based a correlation between airborne and surface levels. It is more appropriately used as a measure of the effectiveness of housekeeping measures to ensure that beryllium does not spread outside of beryllium operational areas. Adoption of a low airborne level to control surface levels is impractical because it does not take into consideration surface contamination as a result of object to object contamination or legacy contamination. B&W Y-12 believes that no additional administrative controls are necessary in the rule. The decisions on how to best minimize surface contamination is more appropriately left to the discretion of the individual sites where an understanding of the source and the impact of specific activity can result in a CBDPP that is tailored to risk. In order to preclude significant re-characterization costs associated with a lower limit, B&W Y-12 recommends that any established surface contamination limit not be lower than the 0.2 ug/100 cm^2 level widely used throughout DOE.

9. *Should warning labels be required for the transfer, to either another DOE entity or to an entity to whom this rule does not apply, of items with surface areas that are free of removable surface levels of beryllium but which may contain surface contamination that is inaccessible or has been sealed with hard-to-remove substances, e.g., paint? Please explain your answer and provide evidence to support your answer.*

Question 9: B&W Y-12 Comments
In most instances B&W Y-12 will not release to entities not covered by the rule equipment or

material that has detectable beryllium or has the potential to have beryllium contamination that is inaccessible. In some instances, with specific contractual disclosures on the presence of beryllium and the need to take precautions during handling and disposition of the material, B&W Y-12 will release material that has been coated to cover beryllium contamination or has suspected inaccessible beryllium.

It is B&W Y-12's position that if material is transferred with known or suspected beryllium, it should be labeled. However, for transfer to an entity to whom the rule does not apply, in addition to the labeling, communication and agreement on future handling and disposition should be formalized. Material that has been determined to have no detectable beryllium through sampling or process knowledge can be released without labeling.

10. *Should the Department establish both surface level and aggressive air sampling criteria (modeled after the U.S. Environmental Protection Agency's aggressive air sampling criteria to clear an area after asbestos abatement) for releasing areas in a facility, or should the Department consider establishing only the aggressive air sampling criteria? Please explain your answers and provide evidence to support your answers.*

Question 10: B&W Y-12 Comments
Aggressive air sampling should not be the only criteria for releasing areas in a facility. B&W Y-12 believes that surface sampling is the best available criteria for releasing areas and facilities. The use of surface levels for determining the release of an area or facility should be the primary method adopted in the rule. Surface levels can be readily determined without concern for disturbing or aerosolizing either the beryllium or another contaminant and samples can be collected according to an easily generated statistical sampling plan. However, in the rare instances when surface level measurements could not be used, aggressive air sampling might be considered as a part of an overall sampling strategy that could be determined to have some statistical validity. Prior cleaning and/or encapsulation would need to be accomplished in all levels of the area or facility (e.g., elevated beams). The presence of other hazards (e.g., radiologic) would need to be considered. If the area was not a discretely enclosed structure, an artificial enclosure would be necessary. It has been B&W Y-12's experience that aerosolization of sufficient material within an enclosed area results in elevated beryllium air samples due to naturally occurring beryllium. Additionally, the physical characteristics of the surfaces would have to be such that any beryllium contamination would be aerosolized. Oily or tacky surfaces, for example, would not be conducive to use of aggressive air sampling.

11. *Currently, after the site occupational medicine director has determined that a beryllium worker should be medically removed from exposure to beryllium, the worker must consent to the removal. Should the Department continue to require the worker's consent for medical removal, or require mandatory medical removal? Please explain your answers.*

Question 11: B&W Y-12 Comments
The department should require mandatory medical removal. Essentially all recommendations made by a medical provider regarding a worker's exposure to hazardous agents (other than beryllium) require strict adherence to the stated work restrictions. Employees are not offered an opportunity to elect whether or not the recommendation is accepted. The employer has the responsibility of ensuring that the restrictions are adhered to and that the worker is offered maximal protection per the medical provider's advice and/or federal regulations. These measures are important in an effort to prevent the development of disease or to slow the progression of an existing medical condition.