

February 10, 2014

Ms. Anne Soiza
Assistant Director
DOSH
Washington State
Department of Labor & Industries
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cc: Alan Lundeen, Jeff Rochon

Re: Petition to Modify WAC 296-62-500 Part R Hazardous Drugs

Dear Assistant Director Soiza:

As we have stated in previous letters, we want to thank LNI, Pam, and the team of Industrial Hygienists for their work with the Hazardous Drug rule. In a letter that was submitted to LNI in July, 2013 in regards to the model programs we addressed concerns and asked for clarification on several aspects of the rule. We were asked if we wanted to make the letter a petition for a rule change and we said that we did not. We hoped that in responding to our questions that updates to the rule would take place. In a recent Hazardous Drug Advisory meeting we were told that LNI does not have any plans to modify the rule at this time. Washington has been a leader in the nation but, as the first, we did not fully understand the implications of various aspects of the rule. We now have a better understanding and it makes sense to start the fine tuning process. As a result we would like to formally petition LNI to modify the rule to address the following concerns.

1. Our first request is a new one. California recently adopted legislation requiring the creation of a hazardous drug rule there. Their legislation copied Washington's almost word for word except they made it apply to only Chemotherapy drugs, not every rule on this list. Testimony supporting the limitation mentioned the trails and tribulations that WA has had with implanting the rule for the non-chemotherapy drugs. They learned from our problems, why shouldn't we? We would like to propose that the rule be modified to only address chemotherapy agents. Other drugs should be addressed using standard hazard assessment practices rather than the more prescriptive Hazardous Drug Rule. Please note that this is a request of employers only. Karen Bowman and other labor reviewers do not agree with this request.

If request #1 is granted, some of the following requests will be moot since they will not longer be an issue.

2. In the definition of hazardous drugs, there is a class of drugs that mimic existing hazardous drugs in structure and toxicity. We propose that this be removed unless a

definition of “mimic” is defined. At this point, there is no guidance to suggest when mimic applies and when it does not.

3. Chemotherapy drugs – please define for the rule. Does the rule’s reference to them only cover cytotoxic chemo or all chemo? Some targeted chemo drugs do not pose a high risk to the worker and should not be treated the same.
4. The WAC is tied to a list that was created to be a worst case list with some drugs with minimal hazard being on it because of a warning that a manufacturer made or the toxicity of it in the bulk form, not the final product. Tying a rule that is supposed to be a minimum standard to a worst case list goes against LNI mandates. In a letter written by Thomas H. Connor, Ph.D., Barbara A. MacKenzie, B.S., and D. Gayle DeBord, Ph.D., B.S. Pharm. in the November 15, 2012 edition of the American Journal of Health-System Pharmacy, they clarify that not all drugs on the list should be treated the same regardless of dosage formulation. They mention that the guideline requirements may not apply to some formulations or activities. The list is to be used as a guide when developing hazardous drug programs, not a determination of when a hazardous drug program is needed. We propose that the list be used as a reference point for the hazard assessment.
5. MSDS are referenced in the definition section. This should be SDS now.
6. WAC 296-62-50025 Handling non-chemo – Please define when engineering controls are actually needed? What are appropriate engineering controls?
7. WAC 296-62-50025 (2) (a) (i) allows preparation of hazardous drugs outside of chemical cabinets if cleaning procedures are followed. Please define what “clean” means with regards to HD. There are no PELs established for many HD’s so healthcare agencies cannot determine when they have met this requirement. In addition, there is still confusion as to which cleaning agents actually neutralize hazardous drugs
8. WAC 296-62-50025 (2)(a)(ii) allows for chemotherapy drugs that are non-routine or handled infrequently to be prepared outside of a ventilated cabinet. What is the exact expectation of when this exclusion can be used?
9. Please see comment numbers 1, 1B and 3 about ventilated cabinets. (Note: The comments were part of the comments submitted about the model programs in July, 2013.) WAC 296-62-50025 (2) (a)’s requirements need clarification and modification to address the concerns. The rule was modified quickly just before publishing and had not been properly vetted by ventilation experts to explain impacts of wording. In addition, in WAC 296-62-50025 (2), please define when external exhaust is actually needed. An exclusion was added to the rule at the last minute that has caused confusion. Also, the wording indicates that some cabinets will not be allowed which would work. It also could exclude future innovations because they are not listed.

10. WAC 296-62-50025 (g)(viii) says to decontaminate and bag equipment parts prior to removing from a ventilated cabinet for repair or replacement. If they are decontaminated, why would they then need to be bagged? We suggest that this become an "or" statement. If they are not decontaminated, they will need to be bagged for disposal or later decontamination.
11. WAC 296-62-50030 (2)(c) – Please clarify significant risk and remove the changing gloves (d) section. The hazard assessment should determine the changing frequency.
12. WAC 296-62-50030 (4)(a) - Please define splash or spill. Would a small dose cup of a low hazard HD require a gown? What about a spill of pills? They pose a very low risk of staff exposure so a gown should not be needed. When is an injection a spill potential? Under a general rule, injections of 5 ml or less are normally considered to not have a splash potential. What are the minimum requirements for a Depo-Provera shot by a 50 year old female nurse?
13. WAC 296-62-50035 (4)(b) says to wash hands before and after wearing gloves. Washing before should be removed. It can be a recommendation but should not be a requirement.

Employers believe that washing afterward should be determined by the hazard assessment and depend on the toxicity and contamination potential of the drug. In some cases, gloves are not needed because the hazardous drug is coated, encapsulated or in a sealed container. This section may need to be reworded to clarify the intent. Labor representatives would like to keep the requirement to wash after removing gloves to remain unchanged.

14. WAC 296-62-50045 – Spill Control – this section should just reference the WAC for spill control. Restating the requirements can lead to confusion and contradicting regulations.
15. WAC 296-62-50050 – Training – Regularly scheduled basis after the initial training should be reworded to more clearly specify when it is needed. The wording in the Hazcom rule could be used.
16. Please see Comment number 2.

Thank you for reviewing our concerns and petition for changes to the rule. Please contact us if you want additional information or supporting documentation for our requests.

Respectfully Submitted,

Karen R. Bowman, MN, RN, COHN-S – Labor Chair for the Hazardous Drug Advisory Committee

K. Bowman, MN, RN, COHN-S

Alex Truchot, MM, HEM -- Employer Chair for the Hazardous Drug Advisory Committee

Alex T. [Signature] 2-10-17

Comments from emails send by stakeholders. Names are not included:

Comment #1:

Anyway, regarding the lack of "Engineering Controls" definitions in the templates I had asked why there were none listed in the three templates as we have already had calls asking about what they should use and how what they have now can or cannot be used for certain tasks?

In listening to some of the others discuss the L&I definitions on Engineering Controls to us as Nuaire Representatives they definitely read this way in our opinion:

- 1) For Chemo work you must use a Class B2, 100% Biocabinet. Other wording precludes the use of Thimble Ducted / Transition Ducted A2 (30 % exhaust) even though 100% of the exhaust in a properly working Thimble Ducted A2 will be exhausted. We have many users using Thimble Ducted A2 Cabinets for Chemo work and they are all wondering how they are going to afford the much higher cost associated with having to buy a B2 100% exhaust (hard ducted, IE closed exhaust system) biocab to meet the new L&I rules? As a general rule of thumb the B2 Cabinets will cost about 3-5K more than the same sized A2 cabinets plus the cost of actually implementing the much higher exhaust demands of the B2 usually doubles the cost of the actual cabinet! So explaining this in a different way lets say a Pharmacy client already has a Thimble Ducted A2 Cabinet they use for Chemo and they paid 8-9K for that BSC. If they are required to buy a B2 BSC as it appears to read in the L&I rules the new cabinet of equal size will cost them 12-15K and they may spend as many need to another 10-15 K outfitting their exhaust system to meet the much higher flow and vacuum needs of the B2 vs. A2 cabinets! Plus the loss of conditioned air being exhausted is about 2-3 times that of the A2. This all adds up to a very large additional cost for anyone needing to upgrade to a B2 BSC!
- 2) If L&I says all chemo prep facilities will need to use and purchase B2, 100 percent exhaust units that have no internal recirculation then neither Nuaire or Cascade Scientific are going to suggest otherwise other than to say that a properly functioning A2, 30% exhaust Biocab with a properly functioning Thimble Exhaust should expel 100% of the expelled exhaust into the exhaust system of the facility. If the A2 with 70% of the circulating air is not acceptable even though 100% of the 30% of the exhausted air is expelled then so be it. Nuaire advises me that there are a number of States that are suggesting B2 use in chemo prep applications but are continuing to allow Thimble Ducted A2 BSCs to be used. I believe I was told California appears to be one of these States. All we are saying is that there are quite a few pharmacies using A2 BSCs with Thimble Ducting and they will now be required to use/purchase new B2 units and probably need to upgrade their exhaust systems to handle the much large exhaust requirements. Larger cost expenditures are commented on below of course. No matter what the wording in any of the new laws or documents neither Nuaire nor Cascade Scientific can or will comment on the safety of any particular setup or products being used. This must be defined by the facilities safety committee or Pharmacy Management based on current local laws.

- 3) There were also some comments made from the group that inferred that HEPA Filtered BSCs will capture all potential particulates that may occur in chemo work. Yes, they should if they are 0.3 microns or larger and even if smaller they may be captured as well. BUT, there is something missing in this observation. As far as our understanding is regarding these chemo drugs, about 20-25% of them are volatile and HEPA Filters do not stop volatilized compounds in any way! This is very important to realize in the scheme of things and how engineering controls are looked at. Expanding further on how these BSCs work within minutes any circulating particulates should be caught up in the HEPA Filters while any volatiles from the chemo drugs will probably expel through the HEPA filters into the exhaust system.
- 4) Finally, Nuaire and a number of other companies have designed Barrier Isolators that have given the small and mid-sized facilities answers to doing both chemo and sterility work at a reasonable price and have met any and all USP797 definitions over the last 5-6 years. This includes the Nuaire NTE797-400 and -600 for chemo work. Unfortunately the other huge concern we have again goes back to the new L&I rules that state these Barrier Isolators must be certified to "International Glove Box standards". These extremely stringent standards are for "glove boxes" that are designed for the Nuclear Industry and not for the Medical Industry as currently defined and met by a number of manufacturers using USP797 guidelines. Based on L&I's current rules as we read them they will preclude pretty much any manufacturer currently meeting USP797 rules due to this wording alone! In challenging this wording we have not been able to find anyone with a viable response to this huge concern as we currently have quite a number of Barrier Isolators being used for chemo work in our NW territory and all around the USA.

The main request / suggestion here is to hold any and all Barrier Isolators not to the standard setup for the Nuclear Industry but to the currently accepted CETA Standard and accepted by USP 797 that has been widely used for many years. If this is not changed then there will be few if any Barrier Isolators designed currently for Pharmacy work that would ever pass the American Glove Box testing standard mentioned and defined for the Nuclear Industry! Note Nuaire has been a leader in Barrier Isolator design and sales of these Barrier Isolators since USP 797 guidelines were first proposed and have made sure all Nuaire Isolators meet or exceed any past and current USP797 and CETA Testing Guidelines. Please see the attached comments from Mr. Bill Peters (Head of Engineering at Nuaire). I have also attached the CETA Testing Std and two white papers regarding Nuaire Barrier Isolators Performance with regard to USP 797 for your review as well.

Sorry for the length of this note but we have NW clients calling us every other week asking us to help them define what they need to do? All we can tell them is how we read the current L&I Rules and it appears to us they read they need to upgrade to a B2 at large additional cost and they cannot use currently designed Barrier Isolators that meet USP797 containment levels but will never pass the Nuclear Industry containment levels required by the International Glove Box Standards.

Comment #1 B

I reviewed the Washington State Guidelines as requested and made some brief comments on the attachment. If you have any trouble reading them or need further clarification, please let me know. They really should reference the CETA CAG 002 document when testing compounding isolators. They also really should reference isolators when defining for use in compounding as compounding aseptic isolators and compounding aseptic containment isolators. As you know, there are so many types of isolators used for many different disciplines; they really should be specific which follows the USP 797 for definitions.

Comment #2:

1. Regarding your comments/concern for page 7, Step 2: ONS has already issued specific guidelines by task for handling hazardous drugs. Would the committee/rules allow for reference to the ONS guidelines so that the subcommittee does not have to reproduce recommendations – which could also cause significant confusion for the nurses if L&I Model guidelines are difference than ONS?

*Safe Handling of Hazardous Drugs (Second Edition) Martha Polovich, by
Publisher: Oncology Nursing Society, Publication date: 2/1/2011*

2. Engineering Control Definitions: NIOSH defines engineering controls as follows: “Devices designed to eliminate or reduce worker exposures to chemical, biological, radiological, ergonomic, or physical hazards. Examples include laboratory fume hoods, glove bags, retracting syringe needles, sound-dampening materials to reduce noise levels, safety interlocks, and radiation shielding.”

Specific to “closed-systems” there are 2 distinct types of closed-systems for which the terminology currently causes a great deal of confusion in facilities today.

- NIOSH defines a “Closed system”: *as a device that does not exchange unfiltered air or contaminants with the adjacent environment.* (Examples: Glove box, barrier isolator).
- Note: Both the rule and Page 8, Step 4 Engineering Controls of the draft references “closed-system transfer devices”. NIOSH defines this as *closed system drug-transfer device (CSTD): A drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system.* (Examples: PhaSeal, EquaShield).

Recommendation: There should be clear definition of a closed system transfer device (CSTD), which is recommended by NIOSH to be used in conjunction with BSC and PPE when preparing parenteral hazardous drugs, and use in combination with PPE when administering hazardous drugs.

In my role with BD I have the opportunity to interface globally with organizations/governments there are, like the state of Washington, enacting legislation regarding safe handling of

hazardous drugs. One such organization is the SA Health Services – see attached. They have recently published their draft guidelines / model procedures that may provide additional best practices or ideas for your draft refinement.

Lastly, as a manufacturer of healthcare worker safety products (i.e. CSTDs and the Sharps container mentioned by Seth Eisenberg), BD welcomes the opportunity to provide whatever educational material/tools the committee is considering providing for impacted facilities. Thank you again for the consideration and open collaboration.

Comment 3:

Here are renditions of two points that I made in today's Hazardous Drug Advisory Committee meeting:

1. Biological Safety Cabinets - Under WAC 296-62-50025 Engineering Controls, the rule appears to require "where feasible, exhaust one hundred percent of the filtered air to the outside unless the employer can provide an evidence-based justification to do otherwise" for chemotherapy drug preparation. The concern of one hospital is that their existing BSC, although HEPA filtered, exhausts only 30% of the filtered air and they have been told by the manufacturer that the BSC they own cannot be re-configured to exhaust 100% of the filtered air. The clause "evidence-based justification" does not imply that financial limitations are a legitimate reason to grandfather such a BSC for use in chemotherapy preparation. Because of the term for capital budget approval in their system (Providence), they feel that they must submit a request to replace their existing BSC this year to have a 100% exhausted air system for chemotherapy preparation installed by January 1, 2016.
2. Training Standard for Chemotherapy Spill Response - In a conversation that I had with Pamela Edwards in 2012, L&I is leaning towards accepting that chemotherapy drug spills constitute an "incidental spill" under the *Emergency Response Standard* (WAC 296-824) and that the Oncology Nursing Society chemotherapy spill response training standard is sufficient for responding staff. I.e., chemotherapy drug spills do not constitute "uncontrolled releases" and should not require a Code Orange response. Further, L&I appears to accept NIOSH's recommendation for PPE to be used by responders at a chemotherapy drug spill: N-95 mask, chemo gloves, gown and goggles.

Comment #5:

For spills, it would be useful to have a listing of the drugs that have been show to vaporize at room temperature in order to determine what respiratory protection is needed (and possibly come up with a cartridge recommendation as well).

Comment #6

I believe that the structure of the L&I template is commendable and gives practices a format to follow. However, the specifics of their examples cast an overly broad net over all of oncology.

Their examples do not take into account the specifics of the individual drugs, the dose and volume of drug administered, the frequency with which a practice might use each drug, the route of administration, and combined effect of the PPEs and closed systems used when administering such drugs. Giving 5mg of methotrexate is very different from administering 5,000 mg.

Given that the practices are responsible for doing their own hazardous drug assessments and creating their own policies and procedures based on their unique patient and disease mix and drug utilization, we believe that practices should be able to individualize their approach rather than having to use "universal precautions" (section C, page 16) or "gloves, gown, eyewear, face shield " for injecting liquids as indicated in their example B on page 13.