Washington State Department of Labor & Industries

Notes from the April 15th Conference call with Tom Connor

Q: Would be curious to know if there is any work in progress (including work by any HD manufacturers) on evaluating current practices or developing new practices for managing HD releases/spills including:

- deactivation of HD;
- rapid field monitoring (air or wipe); and
- containment including the effectiveness of products currently in use (e.g. Green Z) on volatile agents?

A: We have looked at this there are so many different classes. You would never find an agent that would be able to do this. You could find and develop an universal cleaning agent and there are a couple of agents on the market, for cleaning agents. If there is a spill this could be for a hand full of drugs
I do not know what Green Z is.

Q: Will Oncology offices, who mix or compound their own Chemotherapy drugs, be required to have a Clean room? If so, which class must it be? (A biological safety cabinet will be used for all mixing).
A: These are the USP 787 standards. I am on a panel that is reviewing this USP and we plan to complete the USP 787 sterile compounding in 2015.

Q: If a clean room is required, will a buffer or anteroom be required? Will there be new rules or regulations on storage of antineoplastic agents?
A: I do not know and I can't answer that.

Q: Why doesn't NIOSH provide a document with the rationale for adding each med to the list (e.g., clonazepam?)
A: If there are specific questions on specific drugs we could provide if they ask us. Please send questions to veda.mccall@lni.wa.gov and they will be forwarded to NIOSH. We try to keep this as simple as possible. It would be too messy if we did this. We will do a better job in the future.

Q: Why doesn't NIOSH provide recommendations on PPE/handling precautions based on risk level (e.g., do you expect us to handle oral carbamazepine in the same fashion as oral cyclophosphamide?)?
A: This is addressed in the 2012 update, it will be in the 2014 update and it will be expanded in the future.

Q: Please explain this statement from the 2012 NIOSH Hazardous Drugs List: "In addition to using the list of hazardous drugs presented here, each organization should create its own list of drugs considered to be hazardous." Does this mean:
a. At a minimum, organizations should include all "NIOSH List" meds on their hazardous drugs list (if the meds are on formulary). – OR –
b. Just because a formulary med is on the NIOSH list does not mean it has to be on the facility's hazardous drug list. If the facility decides the risk from a med is low (e.g., clonazepam is rarely split/crushed and the manufacturer does not consider it hazardous), they can exclude it from their list.

A: NIOSH can only recommend facilities create their own list of drugs. If a facility adds a drug to their own list, they would have to address it.

Q: OSHA's HCS rule says: "The HCS only applies to pharmaceuticals that the drug manufacturer has determined to be hazardous and that are known to be present in the workplace in such a manner that employees are exposed under normal conditions of use or in a foreseeable emergency [OSHA Interpretation Letter, (1994, March 3)]." Why doesn't NIOSH agree?
Q: "There are exemptions to the standard such as: Drugs that are in solid, final form for direct administration to the patient, e.g., tablets, or pills [29 CFR 1910.1200(b)(6)(vii)]." Does NIOSH agree?
A: There is a way that the manufacture could. There is a lot more information on drugs now. Drugs in solid form do not usually provide a hazard. OSHA has probably changed their view.

Q: "Final form exemption would also apply to tablets or pills that are occasionally crushed, if the pill or tablet is not designed to be dissolved or crushed prior to administration. Consumer products that are subjected to the labeling requirements of the terms as defined in the Consumer Product Safety Act and the Federal Hazardous Substances Act [29 CFR 1910.1200(b)(5)(v)]." What is the definition of "exposure" as used in OSHA's Record Retention rule? Does routine compounding of chemo constitute "exposure" or does this only apply to cases where there has been spill/obvious exposure?
Q: OSHA: "Any workplace exposure record created in connection with HD handling shall be kept, transferred, and made available for at least 30 years and medical records shall be kept for the duration of employment plus 30 years in accordance with the Access to Employee Exposure and Medical Records Standard (29 CFR 1910.1020).108"
A: I have been under the impression that it has been done.

Q: On page 10 of NIOSH alert of 2004, the recommendations start with hazard assessment it then goes into other recommendations:

- Disposable gloving
- Transfers in hoods
- Etc.

Was the intent that the recommendation be implemented as needed (determined by the hazard assessment.)
Q: Would you have to use full PPE if a drug is coated? Does the drug list all formulations of each type considered hazardous? Many pose almost no hazard if in capsule or bubble packs or coated.
A: The 2012 update on page 3 addresses this is one area. We need to expand on this information and provide more guidance.

Q: I understand that NIOSH is publishing a new haz drugs list in 2014. Can you share any information about the proposed changes?
A: We are trying to go through the FDA warnings every two years. Public comments start with 250 drugs and we then whittle that down. We will be posting a group of drugs in May and the public can then comment before it goes on the register. The original list in 2004 was a borrowed list. Most of the drugs were intravenous drugs and antiviral drugs. A few drugs may come off of that list.

For the public's safety the FDA has now developed a series of codes in order to make a distinction between "fluid transfer devices" and truly "closed system transfer devices".

Q: Is NIOSH going to circulate information regarding the new (ONB) code assigned by the FDA to Closed System Transfer Devices? (FDA document attached)

- The new "ONB" FDA clearance was based on three criteria:
- No escape of hazardous drug or vapor concentration
- No transfer of environmental contaminants
- Prevention of microbial ingress.
- Please reference the attached document.

A: I am not sure what to make of this ONB code. We do not know how this got through and I do not know how to respond to this right now. We will update in the next year or two.

Q: What about the drug list are all drugs
A: We actually look at the generic compound. When we do the analysis we just look at the compound, basic characteristics. We make our list based on a hazard analysis and not the form of the drug. Any drug that has a safe handling warning automatically goes in the list

Q: Could you let us know what your current research initiatives have a project looking at exposures in operating rooms.
A: We are looking at updating 2014 Hazardous drug list.

Q: Would NIOSH ever look at making Closed System Transfer Device usage mandatory, as an adjunct to wearing PPE?
A: That is a difficult question. We would consider it but the most we could do is recommend it.

Q: Just to clarify, I accessed the information for my earlier question about the discrepancy with the oral, solid medication exemption on OSHA's HCS (Hazard Communication Standard) and NIOSH recently from this OSHA website:
http://www.osha.gov/SLTC/etools/hospital/pharmacy/pharmacy.html
From what I heard, it appears that info may be outdated??
A: I believe there is more current information on the OSHA website.

Q: If we have questions about individual drugs (e.g., why is oral carbamezpine on the list), who should we send them to?
A: Please send questions to veda.mccall@LNI.wa.gov and they will be forwarded to NIOSH.