NIOSH, USP <800>, and EPA: Update on All Things Hazardous

Session 285- Post Session Question Review

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Question: Do you have to record Lot and expiration for components of a compounded IV?

Answer: This appears to be a question relating to USP 795 or 797, relating to compounding not handling of hazardous drugs. The currently official version of Chapter <797> does not require recording of lot and expiration dates for sterile preparation components. However, state board of pharmacy regulations vary and may include this requirement.

Question: When will the 2020 NIOSH draft hazardous drug list be released/published?

Answer: At this time NIOSH cannot provide and estimation for finalization of the DRAFT NIOSH List.

Question: Are you aware if there is a database that references hazardous designation by NDC look up?

Answer: Yes, the PharmEcology Waste Wizard has this information.

Question: Have spill protocols been expanded to include drugs on the Table 2 Group 2?

Answer: NIOSH cannot say what is appropriate for any given facility. Their needs will differ based on the hazards, formulations, and handling processes in each facility.

Question: For the manufacturer special handling information (MSHI), is this a highly scrutinized section by FDA for the PI? More recent PI's list 'Handling per facility procedures' as a default. How reliable is the MSHI for our assessment?

Answer: MSHI is not hightly scrutinized by FDA. Most manufacturers do choose to identify genotoxic/cytotoxic hazardous drugs for special hanlding to protect the workers who must handle them.

Question: The current NIOSH list says they removed TVEC because it is a CBER med, but will NIOSH consider making a separate hazard list for hazardous viral vector meds and other hazardous meds from CBER?

Answer: At this time NIOSH does not have plans to make a separate list for CBER drugs. Facilities should evaluate the potenial hazards of the treatments they handle, including those approved by CBER which may have other hazards than the ones NIOSH identifies.

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Question: How should rx NIOSH drug waste not on the P List or D codes be disposed of?

Answer: We recommend that classical antineoplastics, such as methotrexate, be managed as hazardous waste as a best management practice. Drugs which are not antineoplastics can be managed as non-hazardous pharmaceutical waste. All should be incinerated.

Question: In NIOSH's opinion and expertise; should we consider table 2 antineoplastics as the same as Table 1 as it relates to containment requirements outlined by USP 800? USP 800 only states Table 1.

Answer: The NIOSH list is not intended to rank hazards. The hazards of the drugs in Table 1 will relate to carcinogenicity or some other identified hazard by the manufacturer, usually genotoxicity/cytotoxicity. The strategies used to manage the risk should match the hazard.

Question: How does NIOSH plan bring the HD list up to date with drugs approved since 2016?

Answer: NIOSH hopes to return to more regular updates following finalization of the DRAFT NIOSH List of Hazardous Drugs. However NIOSH has always had some delay in time between new drugs and the list finalization. It is important that facilities evaluate the hazards of the drugs in their formularies.

Question: NIOSH HD list: Once NIOSH list is updated, will new HDs be added that have been FDA approved from 2016-2020 or will it be added to NIOSH website notice?

Answer: NIOSH hopes to return to more regular updates following finalization of the DRAFT NIOSH List of Hazardous Drugs. However NIOSH has always had some delay in time between new drugs and the list finalization. It is important that facilities evaluate the hazards of the drugs in their formularies. NIOSH will begin the next review period after the final date of the last review period.

Question: Can you speak to why NIOSH decided not to evaluate drugs from CBER?

Answer: NIOSH does not review CBER drugs partially due to their approval process and partially due to their different hazards that do not fall under NIOSH's evaluation criteria. Some may be infectious hazards or have other types of hazards NIOSH does not evaluate.

Question: Can you speak to the issue of concentration on surfaces and how that relates to the hazard identification step. Currently, USP 800 states: If any measurable contamination is found, the designated person must identify, document, and contain the cause of

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Answer: I am not sure I know what the actual question is here but I'll try to answer what I think it is. Determination of the amount of surface contamination helps understand the risk. It identifies a potential likelihood of exposure. The hazard is based on the potential effects of the drug. The surface concentrations help determine the risk. Facilities should determine the risk and risk management strategies based on the risk related to the potential exposures in their facilities. This may be based on the sensitivity of their specific methods.

Question: table 2 administration whole tablet what type gloves & how many?

Answer: NIOSH table 5 suggest that for administering an intact tablet a single chemo glove is likely sufficient.

Question: How are regulatory agencies working with the major wholesalers in terms of how they send hazardous medications to the Pharmacies. Are they considering unique packaging/tote coloring?

Answer: To our knowledge, major wholesalers are reacting more to client requests than regulatory communications.

Question: What are your thoughts on using CSTD rather than full PPE for preparation or administration of table 2 (2020) or non table-1 (2016) medications?

Answer: This could also be dependent on where the work is being performed. Is the CSTD handling also happening in a PEC? Additionally there may be concerns about contamination related to the outside surfaces of and containers and handling devices, which can be cross contaminated In the event of a mishap during the use of the CSTD, the employee is not "protected"

Question: How would you address compounding in the pharmacy in the AOR for the examples of Oxytocin IV? IE we have all PPE and cleaning before and after etc.

Answer: If you are preparing the dose(s) in Pharmacy using all containment strategies, then you are managing the HD at the highest level.

Question: What about nitroglycerin IV bottles and tubing?

Answer: Weak medicinal nitroglycerin such as that found in healthcare facilities was excluded from federal hazardous waste regulations in 2001 under t 40 CFR 261.3(g). Most, but not all, states have

adopted this change. For the majority of states, nitroglycerin bottles and tubing are solid waste and can be disposed in the trash or in a container for glass, if preferred for safety. Please check with your state.

Question: If OTC nicotine is used in an inpatient pharmacy where nothing is practically considered "over the counter" (all meds require an order), is this still exempt from the P listing requirements?

Answer: Yes, in states that have adopted the nicotine exclusion, OTC nicotine gum, lozenges, and patches are out of regulation as a hazardous waste under 261.33 regardless of whether or not they are "prescribed" or purchased over-the-counter. Prescription nicotine products and vaping products are still regulated as hazardous waste P075 federally and in all states.

Question: How are reproductive risk drugs identified? Some drugs have MOAs that cause fetal death but are not on the NIOSH list (neither current group 3 or future table 2). If NIOSH groups/tables are NOT a ranking of hazardous drug risk, then why does USP let you

Answer: Reproductive hazards are reviewed through the same process as all the other hazards. Reproductive hazards are identified based on information often available in the package insert. Again NIOSH may not have reviewed all treatments, some treatments that weren't added in 2004 that have never had relevant safety related updates may be overlooked.

Question: We've been having trouble identifying an EPA medication list. Do you know if this is planning to be developed?

Answer: A list of EPA hazardous waste pharmaceuticals has been developed and is maintained by a variety of hazardous waste consultantsincluding PharmEcology.

Question: Any recommendations for cutting/crushing HD's (especially table 2 and 3). Huge operational challenge to have to do this in pharmacy

Answer: Use of plastic baggies, with ziplock, prepared in a designated area, with absorbent pad, cleaned before and after. PPE to prevent inhalation and absorption via skin.

Question: Charollotte, just to clarify no sewering of pharmaceuticals vs. hazardous drugs? Is 'hazardous' just those drugs listed on RCRA's list?

Answer: Yes, the EPA sewer prohibition refers to only those drugs, including controlled substances, that designate as hazardous waste. It does not apply to the definition of NIOSH hazardous drugs, although there is overlap with respect to actual products.

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Question: where can we find a list of hazardous controlled substances?

Answer: EPA has listed some in their regulation, although not all actually designate as hazardous waste. PharmEcology maintains a list of hazardous waste controlled substances.

Question: Does your facility address D list items?

Answer: The PharmEcology database identifies all characteristics hazardous wastes, including those which have D codes for ignitability, toxicity, corrosivity, or reactivity.

Question: Is NIOSH planning to provide more timely review of new drugs and drugs approved since 2015?

Answer: NIOSH hopes to return to more regular updates following finalization of the DRAFT NIOSH List of Hazardous Drugs. However NIOSH has always had some delay in time between new drugs and the list finalization. It is important that facilities evaluate the hazards of the drugs in their formularies. NIOSH will begin the next review period after the final date of the last review period.

Question: I may have missed it, but are Chloraseptic (phenol spray) and Selsun Blue (selenium sulfide) also considered to be EPA hazardous under the updates? Thanks in advance!

Answer: Chloraseptic spray that contains phenol and Selsun Blue designate as hazardous wastes under the EPA's Resource Conservation and Recovery Act which was enacted in 1976 with regulations published in 1980. This is not an update, however, as they have designated as such since that time or since they entered the marketplace. This designation is not related to the updated NIOSH list nor to EPA's new hazardous waste pharmaceuticals rule which did not change the definitions of hazardous waste, but rather exempted them from counting towards generator status.

Question: Great Job! Expired Warfarin kept in stock bottle/box can still be sent to reverse distributor?

Answer: Yes, as long as the warfarin is in the original manufacturer's container, is within one year of expiration, and has not been dispensed to a patient, it can be sent to a reverse distributor for potential credit. The pharmacy does not need to document if credit was actually received.

Question: If we are a retail pharmacy that only dispenses solid final dosage forms of HD. Is using IPA sufficient to clean the counting trays and work area?

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Answer: Counting trays and work areas where HDs are handled can become contaminated with powders and other materials. Proper HD cleaning procedure, which includes deactivation, decontamination, and cleaned, should be followed on those surfaces. EPA-registered oxidizing agents should be used for deactivation; isopropyl alcohol is not a deactivating agent.

Question: Will arsenic trioxide waste still be required to be weighed if a partial bag is returned to the pharmacy?

Answer: No, once your state has adopted Subpart P, the weight of the arsenic trioxide does not have to be documented. However, EPA is now requiring that the waste arsenic trioxide be segregated and managed separately by your hazardous waste vendor due to the high percentage of a heavy metal.

Question: Did you say drugs on the 2020 NIOSH list will only be current through 2016?

Answer: Yes, the evaluation cycle for the current draft document was through 2016.