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Secundum Artem

Current & Practical Compounding Information for the Pharmacist.

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COMPOUNDING WITH HAZARDOUS DRUGS

GOALS AND OBJECTIVES

Goal: To provide information on the proper handling procedures associated with compounding with hazardous drugs.

Objectives: After reading and studying the article, the reader will be able to:

1. Discuss issues related to compounding with hazardous drugs.
2. Develop a facility list of hazardous drugs.
3. Develop appropriate standard operating procedures for handling hazardous drugs.
4. Properly receive, store, compound with, dispense, transport and dispose of hazardous drugs.
5. Handle spills associated with hazardous drugs.

I. INTRODUCTION

Compounding with hazardous drugs requires careful attention to all aspects of handling these substances for personnel protection. Undoubtedly, this area of compounding pharmacy will continue to increase in importance as the number and types of hazardous drugs continues to increase. USP Chapter <797> specifically addresses hazardous drugs when compounded as sterile preparations.

Workplace exposure to hazardous drugs, according to the National Institute of Occupational Safety and Health (NIOSH) Alert, has resulted in health effects such as skin rashes and adverse reproductive outcomes (including infertility, spontaneous abortions, and congenital malformations) and possibly leukemia and other cancers. The purpose of the National Institute of Occupational Safety and Health (NIOSH) Alert released in 2004 is to increase awareness among health care workers and others about health risks posed when working with hazardous drugs and to provide measures for protecting their health. This includes health care workers who prepare or administer hazardous drugs, who work in areas where these drugs are used, and who may be exposed to these agents (1) in the air, (2) on work surfaces, (3) wearing contaminated clothing, (4) medical equipment, (5) patient fluids / excreta, and (6) other surfaces.

The NIOSH Working Group on Hazardous Drugs considers a drug as hazardous if it exhibits one or more of the following six characteristics in humans or animals:

1. Carcinogenicity (in animal models or the patient population, or both).
2. Teratogenicity or other developmental toxicity (or fertility impairment in animal studies or in treated patients).
3. Reproductive toxicity
4. Organ toxicity at low doses (evidence of serious organ or other toxicity at low doses in animal models or treated patients).
5. Genotoxicity (i.e., mutagenicity and clastogenicity in short-term test systems).
6. Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria.

Generally, the safety program used in a compounding pharmacy to protect pharmacists and technicians handling hazardous drugs would include those activities whose efficacy and cost-effectiveness have been documented. The safety program is not necessarily easy to design in a compounding pharmacy but initially involves developing a list of hazardous drugs specific to the pharmacy, and use of the appropriate isolators to protect personnel. Compounding personnel of reproductive capability should confirm in writing the fact that they understand the risks of handling hazardous drugs.

II. GENERATING THE LIST OF HAZARDOUS DRUGS

One must develop a list of all drugs that are considered to be hazardous that are used in the workplace. Lists will vary from pharmacy to pharmacy, so it is difficult to simply take a list from another pharmacy and utilize it as some modifications may be required. Hazardous drug evaluation is a continual process as new drugs may be added and some drugs no longer used may be removed.

The inclusion of a drug in a list of hazardous drugs could include the following factors:

Loyd V. Allen, Jr., Ph.D., R.Ph.
- Professor Emeritus, University of Oklahoma College of Pharmacy
- Editor in Chief, International Journal of Pharmaceutical Compounding
- Dr. Allen is not affiliated with Paddock Laboratories Inc.

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1. drugs known or suspected to cause adverse health effects from exposures in the workplace
2. drugs used in cancer chemotherapy
3. antiviral drugs
4. hormones
5. some bioengineered drugs
6. miscellaneous drugs

In some cases, drugs that may otherwise be listed as hazardous may not actually be hazardous because the risk of direct exposure is minimal. An example would be if the tablets or capsules are coated and the worker will not be directly exposed. However, if the coated dosage form is modified as by crushing the tablets or emptying the capsules for making solutions or suspensions, then they may be considered for the list.

A number of resources can be used to obtain information related to drug toxicity. These include material safety data sheets (MSDSs), package inserts, special health warnings from drug manufacturers, the FDA and other professional groups and organizations, published reports and case studies, and evidence-based recommendations from other facilities that have successfully defined hazardous drugs and have a prepared list.

III. CONTAMINATION SOURCES AND EXPOSURE

There is the potential for being exposed to hazardous materials when working in any pharmacy or healthcare facility. There is the apparent exposure that one may be consciously aware of, and then there is the inadvertent exposure, of which one may not be aware. Pharmacists, pharmacy technicians and other healthcare workers can be exposed to hazardous drugs when manipulations create aerosols, generate dust, contact contaminated surfaces and clean up spills, etc. Exposure to an individual may occur through inhalation, skin contact, ingestion or injection.

Routes of exposure.

Hazardous drugs can enter the body through inhalation, accidental injection, ingestion of contaminated foodstuffs or mouth contact with contaminated hands, and dermal absorption. Unintentional ingestion may result from hand to mouth contact and accidental injection by a needle-stick or “sharps” injury.

Surface contamination studies do, however, suggest that dermal contact and absorption may be a primary route of exposure. While some hazardous drugs are dermally absorbed, there may be no detectable skin absorption of doxorubicin, daunorubicin, vincristine, vinblastine, or melphalan. An alternative to dermal absorption is that surface contamination transferred to hands may be ingested via the hand-to-mouth route. One or more of these routes might be responsible for workers’ exposure.

It becomes apparent that the likelihood that a worker will experience adverse effects from exposure to hazardous drugs increases with the amount and frequency of exposure and the lack of proper standard operating procedures / practices.

Methods of Exposure

Specific sources of exposure of pharmacy personnel to hazardous drugs in a pharmacy working environment include receipt of materials, such as commercial products (bottles, vials, bags, and packages received from drug manufacturers or wholesalers), bulk powder packages received from pharmaceutical compounding suppliers, and compressed gas tanks.

Exposure can also occur when involved with dispensing prescriptions, including counting individual, uncoated oral doses and tablets, packaging uncoated tablets in unit-dosing packages or blister-packages, working with broken tablets or broken or separated capsules in commercial bottles, reconstitution of containers of oral powders into liquid and especially injectable hazardous drugs that may cause back-spray, drops, aerosol formation, etc., when handling hazardous drugs the same as less hazardous substances, counting tray and machine build up of tablet and capsule residue, and during accidental spillage of oral liquids when pouring in to smaller bottles.

Additional exposure can result from activities involved with compounding prescriptions, including container surfaces, working in an uncontrolled environment with hazardous drugs, handling equipment used with hazardous drugs, washing equipment used with hazardous drugs, packaging and labeling hazardous drugs, crushing tablets and emptying capsules, compounding capsules, troches, oral liquids, ointments, creams, gels, suppositories, injectables, etc., generating aerosols during reconstitution of commercial vials, expelling air from syringes that have contained hazardous drugs, obtaining hazardous drugs from vials or ampoules during the compounding of an intravenous admixture or other sterile or nonsterile dosage form, touch contamination of drugs present on drug vials, work surfaces, floors and final drug preparations (vials, bottles, bags, cassettes, syringes, tubes, etc.), and priming an intravenous administration set or pump device.

IV. TRAINING

All staff who will be compounding hazardous drugs must be trained in the proper techniques necessary for working with hazardous drugs. Once trained, staff must demonstrate competence by an objective method, and competency must be reassessed on a regular basis.

All personnel who work with or around hazardous drugs must be trained to appropriately perform their jobs following standard operating procedures and using the established precautions and required personal protective equipment. Training must include appropriate procedures for personal protection and prevention of contamination. Hazardous drugs should be compounded in a controlled area where access is limited to authorized personnel trained in handling requirements. Due to the hazardous nature of these preparations, a contained environment where air pressure is negative to the surrounding areas or that is protected by an airlock or anteroom is preferred; pass-through windows are desired.

Also included should be the ability to recognize potential sources of exposure to hazardous drugs, including receiving, unpacking, cleaning, manipulating, compounding, packaging, labeling, packing and shipping procedures, as well potential exposure in the patient-care settings is critical.

Training shall include, among other items, safe manipulations, use of MSDSs. negative pressure techniques, correct use of closed system transfer devices (CSTDs), containment, cleanup, spills, and disposal procedures for breakages and spills and treatment of personnel contact and inhalation exposure.

V. FACILITY AND GENERAL WORK PROCEDURES

Proper air handling engineering controls designed to eliminate or reduce worker exposure to chemical, biological, radiological, ergonomic, and physical hazards are critical. Ventilated cabinets and engineering controls must be designed for the purpose of worker protection.

Hazardous drugs should be compounded in an area restricted to only authorized personnel. The work areas should be cleaned and decontaminated before and after each compounding activity, as well as at the end of each shift.

Distinctive labels should be used to indicate drug packages, bins, shelves, and storage areas for hazardous drugs as those requiring special handling precautions. Hazardous drugs should be protected from potential breakage during storage in bins that have high fronts and on shelves that have guards to prevent accidental falling. Segregation of hazardous drug inventory improves control and reduces the number of staff potentially exposed to the danger. Staff members must wear double gloves when stocking and inventorying these drugs and selecting hazardous drug packages for further handling. Transport of hazardous drug packages must be done in a manner to reduce environmental contamination in the event of accidental dropping.

Carts or other transport devices must have guards to protect against containers falling and breaking. Handling final preparations and transport bags with gloves contaminated with hazardous drugs will result in the transfer of the contamination to other workers. Don fresh gloves whenever there is a doubt as to the cleanliness of the inner or outer gloves.

Develop and implement policies and procedures to prevent spills and to govern cleanup of hazardous drug spills. Written procedures must specify who is responsible for spill management and must address the size and scope of the spill. Spills must be contained and cleaned up immediately by trained workers.

VI. PERSONNEL PROTECTION

Gloves

- Wash hands before donning and after removing gloves.
- Wear powder-free, high-quality gloves made of latex, nitrile, polyurethane, neoprene, or other materials that meet the American Society for Testing Materials (ASTM) standard for chemotherapy gloves.
- Double glove for all activities involving hazardous drugs.
- Prior and after donning, inspect gloves for visible defects.
- Sanitize gloves with sterile 70% alcohol or other appropriate disinfectant before performing any aseptic compounding activity.
- Change gloves every 30 minutes during compounding or immediately when damaged or contaminated.
- Remove outer gloves after wiping down final preparation but before labeling or removing the preparation from the isolator.
- Outer gloves must be placed in a containment bag while in the isolator.
- In an isolator, a second glove must be worn inside the fixed-glove assembly.
- In an isolator, fixed gloves or gauntlets must be surface cleaned after compounding is completed to avoid spreading hazardous drug contamination to other surfaces.
- Clean gloves (e.g., the clean inner gloves) should be used to surface decontaminate the final preparation, place the label onto the final preparation, and place it into the pass-through.
- Don fresh gloves to complete the final check, place preparation into a clean transport bag, and remove the bag from the pass-through.
- Remove gloves with care to avoid contamination. Establish and follow detailed procedures for removal.
- Dispose of contaminated gloves as contaminated waste.

Gowns

- Select disposable gowns of material tested to be protective against the hazardous drugs to be used (low-permeability).
- Gowns should be worn during compounding, during administration, when handling waste from patients recently treated with hazardous drugs, and when cleaning up spills of hazardous drugs.
- Coated gowns must be worn no longer than three hours during compounding and changed immediately when damaged or contaminated.
- Avoid skin contact by using a disposable nonlinting-nonabsorbent gown made of polyethylene-coated polypropylene material. The gown should have a closed front, long sleeves, and elastic or knit closed cuffs. Gowns should not be reused.
- Remove gowns with care to avoid spreading contamination. Specific procedures for removal must be established and followed.
- Dispose of gowns immediately upon removal.
- Contain and dispose of contaminated gowns as contaminated waste.
- Wash hands after removing and disposing of gowns.

Also, shoe and hair coverings should be worn during the sterile compounding process to minimize particulate contamination of the critical work zone and the preparation.

Eye and Face Protection

Eye and face protection should be used whenever there is a possibility of exposure from splashing or uncontrolled aerosolization of hazardous drugs (e.g., when containing a spill or handling a damaged shipping carton). In these instances, a face shield, rather than safety glasses or goggles, is recommended.

Circumstances may warrant the use of a respirator. All workers who may use a respirator must be fit-tested and trained to use the appropriate respirator according to the Occupational Safety and Health Administration (OSHA) Respiratory Protection Standard. A respirator of correct size and appropriate to the aerosol size, physical state (i.e., particulate or vapor), and concentration of the airborne drug must be available at all times. Surgical masks do not provide respiratory protection.

VII. NONSTERILE COMPOUNDING WITH HAZARDOUS DRUGS

Although nonsterile dosage forms of hazardous drugs contain varying proportions of drug to nondrug (nonhazardous) components, there is the potential for personnel exposure to and environmental contamination with the hazardous components if hazardous drugs are handled (e.g., packaged) by pharmacy staff. Although most hazardous drugs are not available in liquid formulations, such formulations are often prescribed for small children and adults with feeding tubes. Formulas for extemporaneously compounded oral liquids may start with the injection, or they may require that tablets be crushed or capsules opened. Tablet trituration has been shown to cause fine dust formation and local environmental contamination.

Follow careful, prescribed procedures, using dedicated equipment, for counting and pouring of hazardous drugs. After use, the contaminated equipment should be cleaned with water, then detergent, then rinsed with water. Both water and gauze (if used), need to be disposed of as contaminated waste.

Recommendations for compounding and handling noninjectable hazardous drug dosage forms

- Compounding should occur in a ventilated cabinet or a large plastic "glove-bag" may be appropriate to use in some instances.
- Hazardous drugs should be labeled or otherwise identified as such to prevent improper handling.
- Bulk containers of liquid hazardous drugs, as well as specially packaged commercial hazardous drugs, must be handled carefully to avoid spills. These containers should be dispensed and maintained in sealable plastic bags to contain any inadvertent contamination.
- During routine handling of noninjectable hazardous drugs and contaminated equipment, workers should wear two pairs of gloves that meet the ASTM standard for chemotherapy gloves.
- Counting and pouring of hazardous drugs should be done carefully, and clean equipment should be dedicated for use with these drugs.
- Tablet and capsule forms of hazardous drugs should not be placed in automated counting machines, which subject them to stress and may introduce powdered contaminants into the work area.
- Contaminated equipment should be cleaned initially with gauze saturated with sterile water; further cleaned with detergent, sodium hypochlorite solution, and neutralizer; and then rinsed. The gauze and rinse should be contained and disposed of as contaminated waste.
- Crushing tablets or opening capsules should be avoided, if possible; liquid formulations should be used whenever possible.
- During the compounding of hazardous drugs (e.g., crushing, dissolving, or preparing a solution or an ointment), workers should wear nonpermeable gowns and double gloves.
- Hazardous drugs should be dispensed in the final dose and form whenever possible.
- Disposal of unused or unusable noninjectable dosage forms of hazardous drugs should be performed in the same manner as for hazardous injectable dosage forms and waste.

VIII. STERILE COMPOUNDING WITH HAZARDOUS DRUGS

Working with Compounding Aseptic Containment Isolators

An "isolator" is a device that is sealed or is supplied with air through a microbial retentive filtration system (HEPA minimum) and may be reproducibly decontaminated. When closed, an isolator uses only decontaminated interfaces (when necessary) or transfer ports for materials movement. When open, it allows for the ingress and / or egress of materials through defined openings that have been designed and validated to preclude the transfer of contaminants or unfiltered air to adjacent environments. An isolator can be used for aseptic processing, for containment of potent compounds, or for simultaneous asepsis and containment. Some isolator designs allow operations within the isolator to be conducted through attached rubber gloves without compromising asepsis and / or containment.

Compounding aseptic containment isolator (CACI) is designed to provide for worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exiting a CACI is first passed through a microbial retentive filter (HEPA

minimum) capable of containing airborne concentration of the physical size and state of the drug being compounded. If volatile, the hazardous drugs are removed in the exhaust air from the isolator by properly designed building ventilation.

- The use of a CACI must be accompanied by a stringent program of work practices, including operator training and demonstrated competence, contamination reduction, and decontamination.
- Gather all needed supplies before beginning compounding.
- Avoid exiting and re-entering the work area of the isolator.
- Do not place unnecessary items in the work area of the cabinet or isolator where hazardous drug contamination from compounding may settle on them or overcrowd the isolator.
- Appropriate handling of the preparation in the pass-through of the isolator, including spraying or wiping with sterile 70% alcohol or another appropriate disinfectant, is necessary for aseptic compounding.
- Reduce the hazardous drug contamination burden in the isolator by wiping down hazardous drug vials before placing them in the isolator.
- Do not place transport bags in the isolator work chamber during compounding to avoid inadvertent contamination of the outside surface of the bag.
- Wipe down the outside of the isolator opening and the floor in front with detergent, sodium hypochlorite solution, and neutralizer at least daily.
- Decontaminate the work surface of the isolator before and after compounding and at the end of the shift / day per the manufacturer's recommendations or with detergent, sodium hypochlorite solution, and neutralizer.
- Decontaminate final preparations within the isolator and place into the transport bags in the isolator pass-through, taking care not to contaminate the outside of the transport bag.
- Seal and then decontaminate surfaces of waste and sharps containers before removing from the isolator.
- Decontamination is required after any spill in the isolator during compounding.
- Seal all contaminated materials (e.g., gauze, wipes, towels, wash or rinse water) in bags or plastic containers and discard as contaminated waste.
- Decontaminate the isolator prior to replacing gloves or gauntlets.

IX. TECHNIQUE/WORKING PROCEDURES

Only supplies and drugs essential to compounding the dose or batch should be placed in the work area of the main chamber of the isolator. Luer-Lok syringes and connections must be used whenever possible for manipulating hazardous drugs, as they are less likely to separate during compounding. Spiking an intravenous set into a solution containing hazardous drugs or priming an intravenous set with hazardous drug solution in an uncontrolled environment must be avoided.

In reconstituting hazardous drugs in vials, it is critical to avoid pressurizing the contents of the vial as pressurization may cause the drug to spray out around the needle or through a needle hole or a loose seal, aerosolizing the drug into the work zone. Pressurization can be avoided by creating a slight negative pressure in the vial. Too much negative pressure, however, can cause leakage from the needle when it is withdrawn from the vial. Small amounts of diluent should be transferred slowly as equal volumes of air are removed. The needle should be kept in the vial, and the contents should be swirled carefully until dissolved. With the vial inverted, the proper amount of drug solution should be gradually withdrawn while equal volumes of air are exchanged for solution. The exact volume needed must be measured while the needle is in the vial; any excess drug should remain in the vial. With the vial in the upright position, the plunger should be withdrawn past the original starting point to again induce a slight negative pressure before removing the needle. The needle hub should be clear before the needle is removed. If a hazardous drug is transferred to an intravenous bag, care must be taken to puncture only the septum of the injection port and avoid puncturing the sides of the port or bag. After the drug solution is injected into the intravenous bag, the intravenous port, container, and set (if attached by the pharmacy in the isolator) should be surface decontaminated. The final preparation should be labeled, including an auxiliary warning, and the injection port covered with a protective shield.

To withdraw hazardous drugs from an ampoule, the neck or top portion should be gently tapped. After the neck is wiped with alcohol, a 5- µm filter needle or straw should be attached to a syringe that is large enough that it will be not more than three-fourths full when holding the drug. The fluid should then be drawn through the filter needle or straw and cleared from the needle and hub. After this, the needle or straw is exchanged for a needle of similar gauge and length; any air and excess drug should be ejected into a sterile vial (leaving the desired volume in the syringe); aerosolization should be avoided. The drug may then be transferred to an IV bag or bottle. If the dose is to be dispensed in the syringe, the plunger should be drawn back to clear fluid from the needle and hub. The needle should be replaced with a locking cap, and the syringe should be surface decontaminated and labeled.

- Use double gloving procedures, as appropriate; the inner gloves should be placed under the gown cuff and the outer gloves should cover the gown cuff. Use non-powdered gloves.
- Use closed-system drug-transfer devices, glove bags, and needleless systems during compounding, if available and appropriate.
- Keep hazardous waste-trash separate from other wastes.
- Use venting devices containing 0.2-µm filters or 5-µm filter needles, as appropriate.
- Minimize exposure to the patient and / or caregiver by presenting the final preparation in a ready-to-use form, if possible.
- Return excess drug to the drug vial or discard into a closed container (empty sterile vial), as appropriate.

X. DECONTAMINATION, DEACTIVATION AND CLEANING

Contaminated equipment includes administration devices that have been used for administering hazardous drugs, contaminated wastes resulting from any step in the dispensing, compounding or administration process and unused hazardous drugs remaining in vials, bags, cassettes or that are outdated.

Decontamination may be defined as cleaning or deactivating. Deactivating a hazardous substance is preferred, but no single process has been found to deactivate all currently available hazardous drugs. The use of alcohol for disinfecting the isolator will not deactivate any hazardous drugs and may result in the spread of contamination rather than any actual cleaning. Surface decontamination may be accomplished by the transfer of hazardous drug contamination from the surface of a nondisposable item to disposable ones (e.g., wipes, gauze, towels).

Decontamination of isolators should be conducted per manufacturer recommendations. The MSDSs for many hazardous drugs recommend sodium hypochlorite solution as an appropriate deactivating agent. Cabinets used for aseptic compounding must be disinfected at the beginning of the workday, at the beginning of each subsequent shift (if compounding takes place over an extended period of time), and routinely during compounding.

XI. HAZARDOUS DRUG SPILL KIT

Spill kits, containment bags, and disposal containers must be available in all areas where hazardous drugs are handled. Spill kits should contain materials needed to clean up spills of hazardous drugs. These kits should be readily available in all areas where hazardous drugs are routinely handled. A spill kit should accompany delivery of injectable hazardous drugs to patient care areas even though they are transported in a sealable plastic bag or container. If hazardous drugs are being prepared or administered in a nonroutine area (e.g., home setting, unusual patient care area), a spill kit and respirator should be available. Signs should be present to indicate restricted access to the spill area.

The circumstances and handling of spills should be documented. Staff and nonemployees exposed to a hazardous drug spill should also complete an incident or exposure report and notify the designated

emergency service for initial evaluation. All spill materials must be disposed of as hazardous waste.

Clean up spills immediately, using proper safety precautions and personal protective equipment. If large spills occur, notify the pharmacist-in-charge immediately.

Spill cleanup procedure

- Assess spill (size and scope).
- Spills that cannot be contained by two spill kits may require additional assistance.
- Post signs to limit access to spill area.
- Don personal protective equipment, including inner and outer gloves and respirator.
- Once fully and properly garbed, contain spill using spill kit.
- Carefully remove any broken glass fragments and place them in a puncture resistant container.
- Absorb liquids with spill pads.
- Absorb powder with damp disposable pads or soft toweling.
- Spill cleanup should proceed progressively from areas of lesser to greater contamination.
- Completely remove and place all contaminated material in the disposal bags.
- Rinse the area with water and then clean with detergent, sodium hypochlorite solution, and neutralizer.
- Rinse the area several times and place all materials used for containment and cleanup in disposal bags. Seal bags and place them in the appropriate final container for disposal as hazardous waste.
- Carefully remove all personal protective equipment using the inner gloves. Place all disposable personal protective equipment into disposal bags. Seal bags and place them into the appropriate final container.
- Remove inner gloves; contain in a small, sealable bag; and then place into the appropriate final container for disposal as hazardous waste.
- Wash hands thoroughly with soap and water.
- Once a spill has been initially cleaned, have the area re-cleaned by housekeeping, janitorial staff, or environmental services.

Isolator Spills

- Spills occurring in an isolator should be cleaned up immediately.
- Obtain a spill kit if the volume of the spill exceeds 30 mL or the contents of one drug vial or ampoule.
- Utility gloves (from spill kit) should be worn to remove broken glass in an isolator. Care must be taken not to damage the fixed-glove assembly in the isolator.
- Place glass fragments in the puncture resistant hazardous drug waste container located in the isolator or discard into the appropriate waste receptacle of the isolator.
- Thoroughly clean and decontaminate the isolator.
- If the spill results in liquid being introduced onto the HEPA filter or if powdered aerosol contaminates the “clean side” of the HEPA filter, use of the isolator should be suspended until the equipment has been decontaminated and the HEPA filter replaced.

Only trained workers with appropriate personal protective equipment (PPE) and respirators should attempt to manage a hazardous drug spill. All workers who may be required to clean up a spill of hazardous drugs must receive proper training in spill management and in the use of PPE and NIOSH-certified respirators.

XII. CLOSED SYSTEM TRANSFER DEVICES

Closed-system drug-transfer devices mechanically prevent the transfer of contaminants into the system and the escape of drug or vapor out of the system.

Closed-system transfer devices shall be used within a ISO Class 5 environment of an isolator. ADD-Vantage and Duplex devices are closed-system drug-transfer devices currently available for injectable antibiotics. A similar system that may offer increased environmental protection for hazardous drugs is a proprietary, closed-system drug transfer device known as PhaSeal.

Several studies have shown a reduction in environmental contamination with marker hazardous drugs during both compounding and administration when comparing standard techniques for handling hazardous drugs with the use of PhaSeal. It should be noted, however, that PhaSeal components cannot be used to compound all hazardous drugs. The venting device does not lock onto the vial, which allows it to be transferred from one vial to another. This practice creates an opportunity for both environmental and product contamination.

XIII. HAZARDOUS WASTE

Hazardous drug waste materials include packaging materials, disposable equipment, used syringes, absorbent/cleaning materials (paper towels, gauze pads, wipes), wash and rinse water, partially filled vials, undispensed preparations, unused intravenous admixtures, needles and syringes, gloves, gowns, under pads, soiled materials from spill cleanups, containers containing trace amounts of hazardous drugs, weigh boats and papers, disposable spatulas, and shoe covers.

Waste vendors should ensure acceptance of all possible hazardous waste, including mixed infectious waste, if needed. Once hazardous waste has been identified, it must be collected and stored according to specific EPA and Department of Transportation requirements. Properly labeled, leak-proof, and spill-proof containers of nonreactive plastic are required for areas where hazardous waste is generated. Hazardous drug waste may be initially contained in thick, sealable plastic bags before being placed in approved accumulation containers.

Place all contaminated materials in leakproof, puncture-resistant containers while in the contained environment. Then, place these containers in larger containers outside the contained environment for disposal.

Glass fragments should be contained in small, puncture-resistant containers to be placed into larger containers approved for temporary storage. Waste contaminated with blood or other body fluids must not be mixed with hazardous waste. Transport of waste containers from accumulation areas to storage sites must be done by trained individuals.

Hazardous waste must be properly recorded and transported by properly licensed hazardous waste transporter to a licensed hazardous waste storage, treatment, or disposal facility. A licensed contractor may be hired to manage the hazardous waste program. Investigation of a contractor, including verification of possession and type of license, should be completed and documented before a contractor is engaged.

XIV. TREATMENT FOR EXPOSURE TO HAZARDOUS DRUGS

Procedures must be in place to address worker contamination and protocols for medical attention must be developed before the occurrence of an incident. Emergency kits containing isotonic eyewash supplies (or emergency eyewashes, if available) and soap must be immediately available in areas where hazardous drugs are handled. Workers who are contaminated during the spill or spill cleanup or who have direct skin or eye contact with hazardous drugs require immediate treatment.

A general procedure for immediate, emergency treatment may include the following steps:

1. Call for help, if needed.
2. Immediately remove contaminated clothing.
3. Flood affected eye with water or isotonic eyewash for at least 15 minutes.
4. Clean affected skin with soap and water; rinse thoroughly.
5. Obtain medical attention.
6. Supplies for emergency treatment (e.g., soap, eyewash, sterile saline for irrigation) should be immediately located in any area where hazardous drugs are compounded or administered.
7. Document exposure in employee’s medical record and medical surveillance log.

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Please circle the most appropriate answer for each of the following questions. There is only ONE correct answer per question.

1. Hazardous drug substances may be present;:
   I. in the air
   II. on work surfaces
   III. on commercial drug containers
   A. I only
   B. III only
   C. I and II only
   D. II and III only
   E. I, II and III

2. Which of the following characteristics may place a drug in the "hazardous" category?
   A. carcinogenicity
   B. teratogenicity
   C. reproductive toxicity
   D. genotoxicity
   E. all the above

3. Which of the following is considered the primary route of exposure for hazardous drugs?
   A. inhalation
   B. eating
   C. injection
   D. through the skin
   E. through the eyes

4. Which of the following activities involving hazardous drugs should NOT be hazardous to personnel?
   A. counting uncoated tablets
   B. reconstitution of powders into oral liquids
   C. reconstitution of vials for injection of dry powders
   D. emptying capsules into a mortar for compounding
   E. counting enteric coated tablets

5. Which of the following statements is FALSE regarding the facility?
   A. Proper air handling controls are required.
   B. The compounding area should be restricted to authorized personnel.
   C. Moving stock items does not require gloving.
   D. Storage bins, shelves should carry distinctive labeling.
   E. Worker protection is the basis for the facility design.

6. Which of the following are NOT required or even allowed when working with hazardous drugs?
   A. makeup
   B. gloves
   C. mask
   D. hair cover
   E . gown

7. Which of the following, related to gloves, is required?
   A. a second glove when working within a fixed-glove unit.
   B. nonsterile, but sanitized, gloves for aseptic compounding
   C. powdered gloves
   D. disposal into regular trash after use
   E. all the above are required

8. After a compounding activity, the contaminated equipment should be:
   A. washed with water, then detergent, then rinsed with water
   B. rinsed with alcohol, washed with water, then detergent, then rinsed with water.
   C. washed with water, then detergent, then rinsed with alcohol
   D. washed with bleach solution, then rinsed with water
   E. washed with water, then detergent, then bleach solution, then rinsed with water

9. Which of the following statements is FALSE?
   A. Avoid pressurizing a vial when reconstituting.
   B. Excessive negative pressure in a vial can be a problem.
   C. Since a vial contains sterile drug, it is not necessary to wipe the vial down prior to placing in the work area.
   D. Needle penetrations should be minimized in a vial during reconstitution and withdrawal procedures.
   E. Filter needles should be used when obtaining drug from an ampoule.

10. Which of the following is the most recommended "deactivating" agent?
    A. hydrogen peroxide
    B. sodium hypochlorite
    C. ethyl alcohol
    D. isopropyl alcohol
    E. purified water

11. My practice setting is:
    A. Community-based
    B. Managed care-based
    C. Hospital-based
    D. Consultant and other

12. The quality of the information presented in this article was:
    A. Excellent B. Good C. Fair D. Poor

13. The test questions correspond well with the information presented.
    A. Yes B. No

14. Approximately how long did it take you to read the Secundum Artem article AND respond to the test questions?

    _____

15. What topics would you like to see in future issues of Secundum Artem?

    _____
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