



Supplemental Information

USP 800

What is USP 800?

The U.S. Pharmacopeial Convention (USP) has drafted a new chapter which provides guidance on the handling of hazardous drugs in healthcare settings, and includes requirements for receipt, storage, mixing, preparing, compounding, dispensing, and administration of hazardous drugs to protect the patient, healthcare personnel and the environment. It covers all healthcare entities that store, prepare, transport or administer hazardous drugs, including pharmacies and veterinary clinics; and it applies to all healthcare personnel who handle hazardous drugs, including veterinarians and veterinarian technicians.

What are hazardous drugs?

According to the National Institute for Occupational Safety and Health (NIOSH), a drug is hazardous or potentially hazardous if it has any of the following effects:

- Carcinogenicity
- Teratogenicity or developmental toxicity
- Reproductive toxicity in humans
- Organ toxicity at low doses in humans or animals
- Genotoxicity

Drugs that mimic existing hazardous drugs in structure or toxicity also are considered hazardous. For example, all anti-neoplastic drugs (used in chemotherapy to kill cancer cells) used in practice qualify as hazardous drugs. Apomorphine, cyclosporine and fluconazole are other commonly used drug that are also on the NIOSH list of hazardous drugs which can be found at <https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf?id=10.26616/NIOSH PUB2016161> and are approved for use in humans. Although veterinary-only drugs aren't included in the list, some of them meet the NIOSH criteria and should be considered hazardous and handled appropriately.

What is safe handling of hazardous drugs?

Safe handling standards that apply to all healthcare personnel who receive, prepare, administer, transport or otherwise come in contact with hazardous drugs and all the environments in which they are handled. Practices must have a written Standard Operating Procedure (SOP) and train employees before handling hazardous drugs. This includes a list of hazardous drugs, exposure, designated personnel, signs, handling, PPE, written hazard communication plan, SDS and labeling, training and competency assessment, administration, disposal, cleaning spills and more.

CTP training meets USP 800 requirements for veterinary practices.

WORKPLACE SOLUTIONS

From the National Institute for Occupational Safety and Health

Safe Handling of Hazardous Drugs for Veterinary Healthcare Workers

Summary

Veterinary healthcare employees working where hazardous drugs are handled may face health risks. Many of these workers treat small companion animals (primarily cats and dogs), but also larger animals such as horses, with antineoplastic and other drugs that may be hazardous to humans. NIOSH recommends establishing a program to provide appropriate protective measures for veterinary healthcare workers exposed to hazardous drugs.

Description of Exposure

Hazardous drugs are defined as having specific health effects (such as skin rashes, cancer, and reproductive effects) and high toxicity at low doses [NIOSH 2004]. Most hazardous drugs in veterinary medicine are used to treat animal illnesses such as cancer [Mair and Couto 2006]. The risk of exposure for veterinary health care workers is similar to that for human healthcare settings.

In the United States, an estimated 500,000 veterinary healthcare workers are potentially exposed to hazardous drugs or drug waste at their work-sites [BLS 2007]. Many are women of reproductive age. These workers include veterinarians, technicians, kennel workers, cleaning and maintenance workers, and office staff.

Veterinary workers may be exposed to hazardous drugs when they handle drug vials; compound, administer, or dispose of hazardous drugs; clean up spills; touch surfaces that are contaminated with these drugs; or clean bedding, cages, kennels, or waste of treated animals [Meijster et al. 2006]. Skin absorption, inhalation, and ingestion are the most likely ways these workers may be exposed. Needlestick or sharps injuries pose a risk of exposure in veterinary health care settings [NIOSH 2007a].

Administration of medications to animals presents additional exposure opportunities for workers not encountered with human patients. Many hazardous drugs and their metabolites can be excreted in urine and feces for up to 72 hours or more [Cass and Musgrave 1992]. In addition, oral medications may be present in vomitus for several hours [Mader et al. 1996].

Controls

Recommendations on handling hazardous drugs and waste are summarized below [OSHA 1999; NIOSH 2004; ASHP 2006; USP 2008; Polovich 2009]. Specific recommendations for the safe handling of antineoplastic drugs in veterinary medicine are available [Lucroy 2001; Takada 2003; Fielding and Lacroix 2009].

Policies and Procedures

- Ensure that hazardous drugs are prepared or administered only by trained personnel in designated areas that are limited to authorized personnel.
- Post a sign to warn employees that they are working in an environment where hazardous drugs are handled.
- Warn employees who are pregnant, breastfeeding, or of reproductive age of the potential health effects, especially during the first trimester when a woman may not know she is pregnant.
- Document and retain evidence that workers have been trained in and understand these procedures.

Training Requirements

- Train workers to recognize and understand the risks of working with hazardous drugs, and the risks of working in an environment where these drugs are handled.
- Train workers how to care for and use personal protective equipment (PPE) [NIOSH 2009].

Receiving and Storage

- Begin exposure control when hazardous drugs enter the facility.
- Ensure that all personnel are able to identify hazardous inventory upon arrival. Handle all hazardous inventory with gloves. Label clearly with a hazardous designation.
- Store hazardous drugs separately from other inventory, and separate from food/drink.
- Keep a spill kit available in case inventory arrives damaged [ASHP 2006].

Drug Preparation

- Prohibit eating, drinking, chewing gum, applying cosmetics, or storing food or drinks within the hazardous drug preparation area.
- Use PPE, including chemotherapy gloves [ASTM 2005], non-permeable gowns, respiratory protection, underpads, eye and/or splash protection, shoe covers and spill kit [NIOSH 2009].
- Use a proper containment device: preferably a 100% vented biological safety cabinet or compounding aseptic containment isolator. A horizontal laminar flow hood (clean bench) only protects the drug and not the worker. [OSHA 1999; NIOSH 2004; ASHP 2006; USP 2008].
- Use a proper closed-system drug transfer device (CSTD) in low-volume facilities (e.g. 2 or less drug preparations per week) without a clean room [NIOSH 2004; USP 2008].
- Properly clean all equipment, counters, and other surfaces. No universal cleaner exists for all chemotherapy drugs. Bleach solution can be used to disinfect and a strong detergent and water rinse may remove most drug residues. Repeating the cleaning steps should provide additional drug removal.
- Wash hands with soap and water after drug compounding.

Drug Transportation

- When drug preparation is complete, seal the final product in a plastic bag or other sealable container before taking it out of the ventilated cabinet.

- Seal and wipe all waste containers inside the ventilated cabinet before removing them from the cabinet.
- Store and transport hazardous drugs in closed containers that minimize the risk of breakage.

Drug Administration

- Use dedicated cages, kennels or stalls with dedicated drains for animals undergoing treatment with hazardous drugs.
- Use proper PPE and technique during administration.
- Attach drug administration sets to the IV bag, and prime them before adding the drug to the bag. Prime tubing in the containment device or with non-toxic solution whenever possible.
- Remove the IV bag and tubing intact, dispose of items directly in a chemotherapy waste container, and close the lid.
- Remove outer gloves and gowns, and bag them for disposal in the chemotherapy waste container at the location where drug administration was performed.
- Wash hands with soap and water after administering the drug.

Waste Cleaning and Disposal

- PPE should be worn during waste cleanup and disposal procedures, and footwear should not be worn outside the facility.
- Dispose of all hazardous drug waste according to Federal, State, and local regulations (separately from regular waste).
- Double-bag all chemotherapy waste including partially filled vials, undispensed products, unused IVs, needles and syringes, gloves, gowns, mats, and contaminated materials from spill cleanups or animal bodily fluids/waste.
- Place materials with trace wastes (those that contain less than 3% by weight of the original quantity of hazardous drugs)—such as needles, empty vials and syringes, gloves, gowns, and tubing—in chemotherapy waste containers. Assure that such containers protect from sharps injuries. Do not use red sharps containers for drug disposal.
- Dispose of P-listed arsenic trioxide and its containers and any bulk amounts of U-listed drugs [40 CFR* 261.33] in hazardous waste containers at an EPA/Resource Conservation and Recovery ACT (RCRA)-permitted incinerator [EPA 2001].
- Consider disposing of other bulk hazardous drugs (expired or unused vials, ampoules, syringes, bags, and

*Code of Federal Regulations. See CFR in references.

bottles of hazardous drugs or solutions of any other items with more than trace contamination) in a manner similar to that required for RCRA-defined hazardous wastes.

- Avoid using sprayers or pressure washers to clean the cages, kennels or stalls of treated animals to minimize the aerosolization of hazardous wastes.
- Clean the cages and kennels of treated animals with disposable towels if possible and use disposable towels to clean bodily waste from treated animals.

Spill Control

- Manage hazardous drug spills according to the established, written policies and procedures for each workplace [NIOSH 2004; ASHP 2006].
- Ensure that the written policies and procedures address PPE required for various spill sizes, the possible spreading of material, restricted access to hazardous drug spills, and signs to be posted.
- Ensure that cleanup of a large spill is handled by workers who are trained in handling hazardous materials [29 CFR 1910.120].
- As required by OSHA, follow a complete respiratory protection program, including fit-testing, if you wear respirators such as those contained in some spill kits [29 CFR 1910.134]. Use NIOSH-certified respirators [42 CFR 84]. Surgical masks do not provide adequate protection.
- Dispose of all spill cleanup materials in a hazardous chemical waste container, in accordance with EPA/RCRA regulations regarding hazardous waste—not in a chemotherapy waste or biohazard container.

Medical Surveillance Program

- Conduct reproductive and general health questionnaires at the time of hire and periodically thereafter [NIOSH 2007b].
- Conduct physical examination at the time of hire and then as needed for any worker whose health questionnaire or blood work indicates an abnormal finding.
- Conduct followup for those workers who have shown health changes or have had a significant exposure (substantial skin contact, cleaning a large spill a broken bag, leaking IV line etc.).

Guidance for Compounding of Hazardous Drugs (HDs)

Revisions include the following requirements:

1. Compounding of HDs must be performed:
 - In containment of primary engineering control (C-PEC) devices with external ventilation situated in walled-off room that function as containment secondary engineering controls.
 - Under negative pressure that ranges from 0.01 to 0.03 inches of water column (inch WC) relative to all adjacent areas.
 - With at least 12 air changes per hour.
 - With venting directly to the outside.
2. HD storage areas, including rooms in which HDs are stored in refrigerators, are subject to the same negative air pressure requirements as compounding areas.
3. HDs must be stored and prepared in areas separated from areas where non-HDs are similarly handled, and unless certain conditions are met, the compounding of sterile and non-sterile HDs must be done in separate rooms. An exception permitted under USP <797> that allowed small volumes of HDs to be compounded in the same areas as non-HDs has been eliminated.
4. Personal Protective Equipment (PPE)—gowns, head, hair and shoe covers; and two pairs of chemotherapy gloves—is required for compounding both sterile and non-sterile HDs, and two pairs of such gloves are required for administering antineoplastic HDs. Facilities also need to develop standard operating procedures regarding appropriate PPE for any workers who otherwise handle HDs.
5. Closed-system transfer devices (CSTDs) are mandated to minimize the exposure to those who administer HDs.

Active Shooter Supplemental Information

There are several things a healthcare facility can do to ensure safety for their employees. Practices will want to ensure the following:

1. Organizational Preparedness

a. Emergency Action Plan

Preparing an emergency action plan helps employees know and understand proper procedures. A successful plan should include:

- How to report emergencies to authorities
- Evacuation polices and escape procedures
- Contact information for area hospitals and individual who perform specific tasks during emergencies

b. Training Exercises

- Develop training exercises that simulate active shooter situations
- Contact local law enforcement and emergency response agencies for their assistance
- Training includes the following
 - Recognizing the sound of gunfire
 - When to dial 911
 - What to do when law enforcement arrives
 - Understanding a “survival mindset”
*see training exercise

c. Preventative Measures

- Cultivate a respectful environment in the workplace
- Watch for signs of workplace violence and take necessary corrective actions

d. Organizational Responsibilities

- Perform background checks for all new employees
- Implement a workplace violence reporting system
- Provide resources

e. Warning Signs

- Before an incident, active shooters usually exhibit traits of potentially violent behavior over an extended period of time
- Know the warning signs and train employees
- Report signs of potentially violent behavior to a manager

- Common traits that may be indicative of potentially violent behavior:
 - Resistance to policy or procedural changes
 - Increased mood swings
 - Unprovoked outbursts of rage or anger
 - Increased talk of personal, financial or domestic issues
 - Increased absences
 - Talk of suicide or preparing for death
- Shooter Statistics
 - Usually associated with the location of the incident
 - May be current employees or friends or relations of employees

2. Active Shooter Response

a. What to Expect

- Active shooter incidents are rarely prolonged
 - Many are over in a matter of minutes
 - Often end before law enforcement can arrive
 - End when the active shooter stops shooting and flee or take their own lives

b. Evacuation

- First plan is to evacuate
- Have an escape route in mind
- Evacuate regardless of whether others agree to follow
- Leave your belongings behind
- If possible, help others to escape
- Prevent individuals from entering an area where the shooter might be
- Keep your hands visible
- Do not move wounded individuals
- Call 911 when you are safe

c. Hiding

- If you are not able to evacuate, find a safe place to hide
- A safe hiding place should:
 - Be out of view from the shooter
 - Provide protection if shots are fired in your direction
 - Allow safe access to possible evacuation routes
- If the shooter approaches your hiding place
 - Lock and barricade the door, if possible
 - Set any mobile devices to silent and turn off any other sources of noise
 - Hide behind a large item
 - Stay quiet

d. If Unable to Evacuate or Hide

- Keep call
- Dial 911 to notify police of the shooter's location

e. The Last Resort

- Attempting to incapacitate an active shooter is strictly a last resort. Never attempt to confront a shooter unless your life is in immediate danger and there are not safe evacuation routes or hiding places
- Strategies recommended:
 - Acting as aggressively as possible against him/her
 - Throwing items and improvising weapons
 - Yelling
 - Committing to your actions

f. When Law Enforcement Arrives

- Police officers may be outfitted with tactical equipment and high-powered firearms
- Officers will proceed directly to the shooter's last known location and will not stop to tend to wounded individuals
- If you encounter police officers:
 - Officers may shout or push individuals to make sure they are out of harm's way.
 - Keep calm and obey orders
 - Put down any items you may be carrying and raise your hands and spread your fingers
 - Do not make any sudden or quick movements in the direction of the officers
 - Avoid screaming, yelling or pointing
 - Continue in the direction from which the officers are coming from and do not ask them for help

3. Post-Incident Actions

a. Immediate Response

- Take a count of personnel to determine if anyone is missing and/or wounded.
- Contact families of those involved
- Implement plans to provide counseling or psychological care for employees

b. Analyzing the Incident

- Thoroughly document the incident
- Document response activities
- Identify successful actions and procedures that took place
- Identify areas where stronger preventative measures or more training is required
- Evaluate the existing emergency action plan's effectiveness. Make recommendations for improvement as needed

Active Shooter and Workplace Violence Training Exercises

The scenario below looks at the incident from the perspective of first responders and the private sector owner/operators. As the scenario develops, the reader should identify actions relevant to their company and position within the company. The scenarios only look at the incident and do not take into consideration recovery, business continuity planning, or after-event considerations.

Dental Office

Date: Friday, February 19

Time: 11:00am EST

A member of your dental team, who has been with your company for eight years, has just had his employment terminated. As he is escorted out of the building by security, he tells them they will regret treating him like this.

- Who should be informed of this behavior?
- What concerns might you have?
- What actions would you consider taking, if any, at this stage?

Date: Monday, April 5 Time: 9:15 am EST A popping sound is heard within the building. An employee runs into your office shouting that there is a man firing a gun in the waiting area.

- What actions should you take?
- How are you communicating with employees? Who is communicating?
- Who is in charge of the situation?

Update:

You decide to shelter in place in an office and secure the immediate area.

The popping noises seems to be close. There is yelling and screaming outside your door.

- What actions are taken to secure the area?
- Who is responsible for contacting law enforcement?
 - o What information do you relay to them?
- What are you telling your employees?

Update: A woman knocks frantically on your door pleading to be let in.

- What action will you take to ensure your office remains secure?
 - o What will you do about the woman outside your door?
- What additional concerns do you have at this time?

Update: You hear someone attempting to open the door, then several loud shots. After a few minutes of silence, it appears that the shooter may have moved on.

- What are your immediate concerns at this time?
- What do you tell coworkers sheltering in place with you?

Update: For nearly an hour there is no sound from outside your door. Employees are receiving calls from family members who have learned of the active shooter in your building. Emergency personnel can be seen outside. Several employees express interest in leaving.

- Who is responsible for deciding when it is safe to leave the secure area?
- How will family members be contacted?

Update: Law enforcement personnel arrive outside your office door and direct you to evacuate the building.

- How do you prepare your employees for the disturbing scenes they may encounter as they evacuate?
- Who is responsible for communicating with law enforcement?
- What concerns do you have leaving your office unsecured?

Update: Upon evacuation, your employees are cornered by news reporters asking about the experience. Some employees do not have their car or house keys and are concerned about getting home.

- Who is responsible for communicating with news media?
 - o What information will you give them?
 - o Can you control who else the media approaches? If not, what can you do?
- How will your employees get home?
 - o Will you request access back into the building? Who would go in?

Update: The building is designated a crime scene and is closed for a week.

- Who initiates business continuity plans?
- What else needs to be considered?
- How is information disseminated to employees?

Update: Date: Monday, April 12 You can get back into the building and resume normal business operations. Several employees ask for more time to emotionally recover from the event.

- Are you able to continue normal business operations using fewer staff?
- How will you accommodate individuals who have been emotionally traumatized by the event?
- What resources will you make available to all staff?
- How will you communicate your company's resilience to concerned clients? Additional considerations:
- Upon arriving on scene, law enforcement officials will remove the threat before treating victims and evacuating survivors. It is important to be patient and stay in the secure area until you are instructed to evacuate
- Because some employees may not feel comfortable returning to work right away, be prepared to work with a dispersed or smaller work force following an active shooter event.
- Ensure mental health professionals are available for employees.

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TRAINING

- Are employees provided training on all applicable OSHA regulations?
- Are new employees provided training before performing duties?
- Are training records kept for a minimum of 3 years?
- Are all safety practices and procedures updated annually?
- Have employees using radiographic equipment been properly trained?
- Have you appointed someone in the hospital to be in charge of OSHA compliance?

HAZARD COMMUNICATION

- Is a written hazard communication program customized, reviewed and updated annually?
- Are SDS sheets on file?
- Has a chemical inventory list containing all hazardous materials been created?
- Are all hazardous products labeled properly?
- Do all employees understand emergency spill procedures?
- Is there a spill kit available?
- Do all employees know how to use the eyewash station?
- Is the eyewash station labeled and functioning properly?

ZOONOTIC DISEASE PREVENTION

- Are waste containers in treatment areas labeled with the biohazard label?
- Does a written exposure control plan exist and is it accessible to all employees?
- Is the plan reviewed and updated at least annually?
- Is handwashing performed before and after treating patients?

CYTOTOXIC DRUGS/CHEMOTHERAPY

- Is a biological safety cabinet (BSC) used for drug preparation?
- Is proper PPE available including, double chemo gloves, disposable chemo gown and safety eyewear?
- Is a chemo spill kit available?
- Do only authorized/trained staff treat chemo patients?
- Are patients isolated and a special cage card used?
- Are excretions from cytotoxic drug patients disposed of properly?
- Is chemo waste disposed of using yellow colored chemo specific containers and picked up by an approved hauler?

GENERAL HOUSEKEEPING, STORAGE, WALKING SURFACES, MEANS OF EGRESS

- Are all areas of the office clean, uncluttered, and sanitary?
- Are all passageways and aisles free from obstruction?
- Are lighted or glow in the dark exit signs in place?
- Are there at least 2 means of egress (exits)?
- Are employees' food and beverages kept in a designated refrigerator, separate from clinical supplies?
- Does the office have proper ventilation and air quality control (HVAC fan on during working hours, filters changed regularly)?
- Are electrical and medical gas closets free from any stored items?

ELECTRICAL

- Are all the electrical devices properly grounded (3 prong plug)?
- Are all electrical outlets that are near water (e.g. bathrooms, kitchens) on a Ground Fault Interrupter (GFI) circuit?
- Have you checked that extension cords are not in use?
- Are all cords and plugs free of visible wear?

COMPRESSED GASES

- Are the gas cylinders properly secured to prevent tipping?
- Are gas cylinders properly labeled?
- Are employees trained on compressed gas safety?

MEDICAL EMERGENCIES, SAFETY & FIRST AID

- Do all staff members know the proper post exposure procedures?
- Is there an accident report file established and maintained?
- Are monthly inspections of the facility being conducted, including the first aid kit and fire extinguisher?
- Is there an eyewash station within 25 feet or 10 seconds of hazardous chemicals?
- Is the eyewash station being inspected and tested weekly?
- Is a fire extinguisher available?
- Have employees been trained on proper use of the fire extinguisher?
- Do stairs have a handrail with adequate headroom and lighting?

EMPLOYEE FILES / RECORD KEEPING

- Do employee files contain medical reports of workplace accidents and injuries?
- If vaccination is required, has a copy been placed in the employee medical record?
- If an accident occurred in the workplace, has OSHA form 301 been completed and a copy placed in the employee record?
- If an accident occurred and form 301 was filled out, was this information transferred to OSHA form 300?

PERSONAL PROTECTIVE EQUIPMENT (PPE)

- Is proper personal protective equipment provided and maintained by the employer?
- Are employees trained to put on and remove PPE?
- Do employees understand the limitations of PPE?
- Is protective eyewear worn during all procedures and when handling chemicals?
- Are long sleeve lab coats and/or gowns worn and changed when visibly soiled and at the end of the day?
- Are nitrile or synthetic gloves provided to those who have sensitivity to latex?
- If lasers are used, is laser protective eyewear worn?
- Is hearing protection provided in high noise areas where levels exceed 85 decibels over an 8-hour time weighted average?

POSTERS, FORMS AND SIGNS PROPERLY DISPLAYED

- Is the Federal Minimum Wage poster displayed?
- Is the OSHA 3165 poster displayed?
- Is the OSHA form 300A available?
- Is the Equal Opportunity Employer poster displayed?
- Is the Family Medical Leave Act poster displayed (50 or more employees)?
- Is the Employee Polygraph Protection Act poster displayed?
- Is the Uniformed Service Employment and Reemployment Rights Act poster displayed?
- Are state specific posters displayed where required?
- Is there an emergency evacuation plan in place?
- Is a housekeeping schedule posted?
- If lasers are used, is a warning sign posted?
- If X-Rays are used, is a warning sign posted?

LAUNDRY

- Is protective clothing soiled by a human disease causing pathogens, placed in a bag labeled with the biohazard symbol and either laundered in-house or by a professional service?

SHARPS

- Is there a sharps log available for documenting exposure incidents?
- Are sharps containers readily accessible in the area of use?
- Are filled containers transported by a licensed regulated biohazardous waste hauler?
- Are filled sharps containers picked up at the time interval mandated by your state?
- Are employees using a single-handed needle recapping technique or are engineering controls (mechanical devices) being used to assist them in recapping?
- Are scalpel blade removers or disposable one piece scalpel blade/handles being used?

NON-SHARP REGULATED WASTE

Are carcasses, body parts, bedding, and related waste from infected animals or animals that were in isolation disposed of according to state regulations?

MONITORING

Are exposed employees wearing radiation dosimeters?

If the office is using ethylene oxide, formaldehyde/formalin or halogenated anesthetic gases, is air monitoring being conducted as required?