

Respiratory Protection Guidance for Hazardous Drug Handling in Healthcare

Quick Links

- [3M Quick Reference Guide - Disposable Respirators](#)
- [USP General Chapter 800 “Hazardous Drugs – Handling in Healthcare Settings” \(USP-800\)](#)
- [OSHA and NIOSH - Hospital Respiratory Protection Program Toolkit](#)
- [NIOSH Workplace Solutions – Personal Protective Equipment for Health Care Workers Who Work with Hazardous Drugs](#)
- [NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016](#)

Purpose

The intent of this technical bulletin is to summarize and clarify the respiratory protection guidance from both USP and NIOSH for workers who handle hazardous drugs in the healthcare environment.

Background

In the United States, an estimated 8 million healthcare workers are potentially exposed to hazardous drugs or drug waste at their worksites (does not include drug manufacturing). These workers include pharmacy personnel, nurses, physicians, operating room personnel, veterinary personnel, shipping and receiving personnel, janitorial/environmental services personnel, laundry personnel, waste handlers and maintenance personnel.(1)

Every day in healthcare settings, workers are exposed to hundreds of powerful drugs used for cancer chemotherapy, antiviral treatments, hormone regimens and other therapies. While these drugs are used to relieve and heal patients, many of them present serious hazards to the health and safety of workers. Some of these drugs have been known to cause cancer, reproductive and developmental problems, allergic reactions, and other adverse effects that can be irreversible even after low-level exposures.(2) Collectively these drugs are known as “Hazardous Drugs” and their use and handling within the healthcare environment have been a focus of OSHA, NIOSH, The Joint Commission, the US Pharmacopeial (USP) Convention, among others.

NIOSH has identified and published the “NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings” since 2004. The current list is from 2016 and contains 217 drugs – 116 antineoplastic (cytotoxic); 52 that are non-antineoplastic but meet one or more of the NIOSH criteria for hazardous drugs; and 49 that are non-antineoplastic but have adverse reproductive effects. (3) There are currently 44 additional drugs under review for inclusion on the next version of this list.(4)

With the issuance of the USP General Chapter 800 “Hazardous Drugs – Handling in Healthcare Settings” (USP-800), the US Pharmacopeial Convention provides standards on the handling of hazardous drugs by healthcare personnel; the implementation date will be December 2019. The chapter can be downloaded with registration directly from www.usp.org.







i IMPORTANT NOTE

Personal protective equipment, such as NIOSH-certified respirators and protective clothing, must be used to reduce exposure to hazardous drugs when engineering controls and administrative controls are not adequate or possible. Healthcare organizations are responsible for their own risk assessments.

Respiratory Protective Equipment Program Basic Elements

- Select specific respirators and protective clothing based on an assessment of your workplace, the hazardous drugs being used and the potential for exposure to these drugs.
- The employer is responsible for reviewing all drug safety information and ensuring that employees are aware of the hazards and trained on the procedures being implemented to reduce exposures.
- Surgical masks DO NOT provide respiratory protection from hazardous drug exposures.
- Understand the proper use and limitations of any selected respirator to ensure that it functions properly, works with other PPE, while still allowing the employee to perform their necessary tasks.
- Use care in donning and removing all items to prevent contamination or damage to PPE. All procedures should meet your organization's protocol and follow manufacturer guidance.
- Ensure that all PPE fits correctly – multiple styles, or models will likely be needed to meet your population's needs.
- Fit test tight fitting respirators, including surgical N95 respirators.
- Follow all requirements in the Occupational Safety and Health Administration (OSHA) Respiratory Protection Standard (29 CFR 1910.134) and any local requirements. OSHA and NIOSH - *Hospital Respiratory Protection Program Toolkit* can be a valuable resource for Respirator Program Administrators – DHHS (NIOSH) Publication Number 2015-117 <https://www.cdc.gov/niosh/docs/2015-117/default.html>

3M Healthcare N95 Respirator and Surgical Masks

| | | | | | | | |
|---------------------|--|--|--|--|---|--|---|
| |  |  |  |  |  |  |  |
| Product | 3M™ Health Care Particulate Respirator and Surgical Mask 1860 | 3M™ Health Care Particulate Respirator and Surgical Mask 1860S (small) | 3M™ Aura™ Health Care Particulate Respirator and Surgical Mask 1870+ | 3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask 1805 | 3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask 1805S (small) | 3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask 1804 | 3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask 1804S (small) |
| APF | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| Class/ Feature | N95 | N95 | N95 | N95 | N95 | N95 | N95 |
| Valve | Unvalved | Unvalved | Unvalved | Unvalved | Unvalved | Unvalved | Unvalved |
| Headband Attachment | Stapled | Stapled | Stapled | Stapled | Stapled | Stapled | Stapled |
| Country of Origin | Made in the USA with globally sourced materials | Made in the USA with globally sourced materials | Made in the UK | Made in the USA with globally sourced materials | Made in the USA with globally sourced materials | Made in the USA with globally sourced materials | Made in the USA with globally sourced materials |
| Shelf Life | 5 years from date of manufacture | 5 years from date of manufacture | 5 years from date of manufacture | see 3M Stockpile Shelf Life Memo | see 3M Stockpile Shelf Life Memo | 5 years from date of manufacture | 5 years from date of manufacture |

Unique considerations related to respiratory protection selection for hazardous drugs

- There are a lot of different formulations of drugs that are considered hazardous, most without exposure limits or specific respiratory protection recommendations.
- The primary airborne exposure concerns are particulates and aerosols, for which NIOSH approved particulate respirators can help reduce exposures to hazardous drugs.
- There are studies that show that some hazardous drugs can vaporize. Although not all hazardous drugs have been evaluated, Carmustine, Cisplatin, Cyclophosphamide, Etoposide and 5-Fluorouracil can all exhibit vapor concentrations at room temperature.(5) NIOSH and USP recommend combination particulate and multi-gas/chemical cartridges for certain exposure situations due to this concern.(3), (6)

- Consideration should also be given to the chemicals used to “neutralize” hazardous drug residue or spills. These should be evaluated both for effectiveness in neutralizing the particular hazardous drugs being used in the facility and for their own health hazard potential. Two of the more commonly referenced neutralizing agents are bleach and peracetic acid/peroxide-based cleaners. (3M recommends the OV/AG/Particulate cartridges, which are capable of filtering certain hazardous drugs and both of these neutralizing agents).

Common Tasks and PPE Options to Consider for Respiratory and Eye/Face Protection

Pharmacy Receiving Personnel

Unpacking, inspection and initial handling of hazardous drugs from suppliers.

| | Tablet/Capsules/Powder | Liquid |
|---|------------------------|--------|
| 3M Surgical N95 respirator models along with Goggle Gear 500 safety goggles | X | |
| 3M reusable full-face models with 7093 Particulate (P100) Filters or 60923 Particulate (P100)/Organic Vapor/Acid Gas or 60926 Particulate (P100)/Multi-Gas Cartridges | X | |
| 3M TR-600 Powered Air Purifying Respirator System with TR-6710N Particulate (HEPA) Filter or TR-6530N Particulate (HEPA)/Organic Vapor/Acid Gas Cartridge | X | |
| 3M reusable full-face models with 60923 Particulate (P100)/Organic Vapor/Acid Gas or 60926 Particulate (P100)/Multi-Gas Cartridges | | X |
| 3M TR-600 Powered Air Purifying Respirator System with TR-6530N Particulate (HEPA)/Organic Vapor/Acid Gas Cartridge | | X |

Pharmacy Personnel

Compounding of all hazardous drug formulations should be conducted in ventilated engineering controls. When this is not possible, PPE such as, respiratory protection and eye/face protection would be recommended. Some options to consider would include:

- 3M reusable full-face models with 60923 Particulate/Organic Vapor/Acid Gas or 60926 Particulate/Multi-Gas Cartridges
- 3M TR-600 Powered Air Purifying Respirator System with TR-6530N Particulate/Organic Vapor/Acid Gas Cartridge

Cutting, crushing, or manipulating tablets or capsules should be conducted in ventilated engineering controls. When this is not possible, respiratory protection and eye/face protection would be recommended. Some options to consider would include:

- 3M Surgical N95 respirator models along with Goggle Gear 500 safety goggles
- 3M reusable full-face models with 7093 Particulate (P100) Filters or 60923 Particulate (P100)/Organic Vapor/Acid Gas or 60926 Particulate (P100)/Multi-Gas Cartridges
- 3M TR-600 Powered Air Purifying Respirator System with TR-6710N Particulate (HEPA) Filter or TR-6530N Particulate (HEPA)/Organic Vapor/Acid Gas Cartridge

Administering Hazardous Drugs to Patients (Physicians/Nursing Personnel)

Below are various types of PPE that would be recommended. Some options to consider would include:

| | Intact tablet or capsule | Oral liquid drug or feeding tube | Topical Drug | Injection from a vial (if not using a closed system drug transfer device (CSTD)) | Prepared intravenous or intramuscular solution (if not using a closed system drug transfer device (CSTD)) | Irrigation (bladder, heated intraperitoneal chemotherapy (HIPEC), limb perfusion, etc.) | Aerosol Treatment |
|---|--------------------------|----------------------------------|--------------|--|---|---|-------------------|
| No respiratory protection; splash protection if potential for patient to spit up or vomit | X | X | | | | | |
| 3M Surgical N95 respirator models along with Goggle Gear 500 safety goggles | | | X | X | X | | |
| 3M reusable full-face models with 7093 Particulate (P100) Filters or 60923 Particulate (P100)/Organic Vapor/Acid Gas or 60926 Particulate (P100)/Multi-Gas Cartridges | | | X | X | X | | |
| 3M TR-600 Powered Air Purifying Respirator System with TR-6710N Particulate (HEPA) Filter or TR-6530N Particulate (HEPA)/Organic Vapor/Acid Gas Cartridge | | | X | X | X | | |
| 3M reusable full-face models with 60923 Particulate (P100)/Organic Vapor/Acid Gas or 60926 Particulate (P100)/Multi-Gas Cartridges | | | | | | X | X |
| 3M TR-600 Powered Air Purifying Respirator System with TR-6530N Particulate (HEPA)/Organic Vapor/Acid Gas Cartridge | | | | | | X | X |

Spills or Leaks of Hazardous Drugs

Below are various types of PPE that would be recommended. Some options to consider would include:

- 3M reusable full-face models with 60923 Particulate/Organic Vapor/Acid Gas or 60926 Particulate/Multi-Gas Cartridges
- 3M TR-600 Powered Air Purifying Respirator System with TR-6530N Particulate/Organic Vapor/Acid Gas Cartridge

Handling Patient Body Fluids with Hazardous Drugs or Metabolites (Nursing/Janitorial/Environmental Services/Laboratory Personnel)

Below are various types of PPE that would be recommended. Some options to consider would include:

- 3M Surgical N95 respirator models along with Goggle Gear 500 safety goggles
- 3M reusable full-face models with 7093 Particulate (P100) Filters or 60923 Particulate (P100)/Organic Vapor/Acid Gas or 60926 Particulate (P100)/Multi-Gas Cartridges
- 3M TR-600 Powered Air Purifying Respirator System with TR-6710N Particulate (HEPA) Filter or TR-6530N Particulate (HEPA)/Organic Vapor/Acid Gas Cartridge

Cleaning Patient Rooms and Bathrooms/Handling Contaminated Laundry (Janitorial/Environmental Services/Laundry Personnel)

Below are various types of PPE that would be recommended. Some options to consider would include:

- 3M Surgical N95 respirator models along with Goggle Gear 500 safety goggles
- 3M reusable full-face models with 7093 Particulate (P100) Filters or 60923 Particulate (P100)/Organic Vapor/Acid Gas or 60926 Particulate (P100)/Multi-Gas Cartridges
- 3M TR-600 Powered Air Purifying Respirator System with TR-6710N Particulate (HEPA) Filter or TR-6530N Particulate (HEPA)/Organic Vapor/Acid Gas Cartridge

Handling Drug Contaminated Wastes (Janitorial/Environmental Services Personnel)

Below are various types of PPE that would be recommended. Some options to consider would include:

- 3M Surgical N95 respirator models along with Goggle Gear 500 safety goggles
- 3M reusable full-face models with 7093 Particulate (P100) Filters or 60923 Particulate (P100)/Organic Vapor/Acid Gas or 60926 Particulate (P100)/Multi-Gas Cartridges
- 3M TR-600 Powered Air Purifying Respirator System with TR-6710N Particulate (HEPA) Filter or TR-6530N Particulate (HEPA)/Organic Vapor/Acid Gas Cartridge

Deactivating, Decontaminating, and Cleaning Inside and Underneath the Work Surface of Engineering Controls/Cabinets (Pharmacy/Maintenance/Janitorial/Environmental Services Personnel)

Below are various types of PPE that would be recommended. Some options to consider would include:

- 3M reusable full-face models with 60923 Particulate/Organic Vapor/Acid Gas or 60926 Particulate/Multi-Gas Cartridges
- 3M TR-600 Powered Air Purifying Respirator System with TR-6530N Particulate/Organic Vapor/Acid Gas Cartridge

IMPORTANT NOTE

For most activities that require respiratory protection - double chemotherapy gloves and protective gowns would also be recommended – follow your organizational protocols.

Additional Respiratory Protection Guidance

Particulate filter change out guidance

For disposable respirators or reusable respirator filters, if not superseded by hospital policy, 3M guidance is to change out when they are damaged, dirty or difficult to breathe through. For PAPR filters – if not superseded by hospital policy, change out when damaged or the TR-600 filter loading indicator shows a red light or is alarming. See User Instructions for more details on any specific product.

Cartridge change out guidance

This is a challenge due to very low or no exposure limits for hazardous drugs and very little knowledge of actual airborne levels of hazardous drugs. Suggest changing out based on the task/exposure situation, the time worn, or basing the change out on the neutralization chemical exposure levels if known. See User Instructions for more details on any specific product.

Neutralization chemicals

Sodium Hypochlorite (bleach) and Peracetic acid/peroxide-based cleaners are both strong oxidizers and are listed as appropriate deactivating agents for some hazardous drugs (always check the Safety Data Sheet for the particular hazardous drugs being used in your facility). 3M testing has shown that a particulate respirator will reduce bleach exposures (odor may still come through – if that is a concern then use a combination particulate cartridge with an Acid Gas adsorbing carbon). For peracetic acid/peroxide based cleaners a combination particulate cartridge with Organic Vapor capabilities can be used to help reduce exposures. (3M recommends the OV/AG/Particulate cartridges, which will help reduce respiratory exposures to the hazardous drugs and both of these neutralizing agents).

PAPR Headcover Decision Guidance

- OSHA Assigned Protection Factor (APF) provides the factor by which a properly fitted and properly used respirator will reduce your exposure. The higher the APF the greater the potential reduction in exposure. Headtops have an APF of 25; hoods have an APF of 1000.
- Incidental splash protection – both headtops and hoods will help protect the mucous membranes and the eyes, hoods will also provide splash protection for the full head and neck area.
- The S-Series hoods are classified as loose fitting so fit testing is not required.
- The following S-series hood models can accommodate surgical masks and most full beards:

| Model Number and Description | Replacement Hood Model Number |
|--|-------------------------------|
| S-655 Hood assembly with inner neck collar and premium head suspension | S-605 |
| S-657 Hood assembly with inner shroud and premium head suspension | S-607 |
| S-855 Hood assembly with sealed seams, inner neck collar and premium head suspension | S-805 |
| S-857 Hood assembly with sealed seams, inner shroud and premium head suspension | S-807 |

References

- (1) NIOSH [2009]. NIOSH Workplace Solutions – Personal Protective Equipment for Health Care Workers Who Work with Hazardous Drugs. DHHS (NIOSH) Publication No. 2009-106.
- (2) OSHA, Joint Commission, NIOSH [2011] Letter to US Hospitals highlighting work precautions for handling hazardous drugs, April 4, 2011.
- (3) NIOSH [2016]. NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016. DHHS (NIOSH) Publication No. 2016-161.
- (4) <https://www.cdc.gov/niosh/review/peer/isi/hazdrug2018-pr.html> - viewed October 16, 2018.
- (5) Kiffmeyer TK, Kube C, Opiolka S, Schmidt KG, Schoppe G, Sessink PJM [2002]. Vapour pressures, evaporation behavior and airborne concentrations of hazardous drugs: implications for occupational safety. Pharmceut J 268:331-7.
- (6) US Pharmacopeial (USP) Convention [2017] USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings. Downloaded with registration directly from www.usp.org on October 16, 2018.