



Preventing Occupational Exposure to Hazardous Drugs

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2016 MHCSA Quarterly Meetings

Friday, March 11, 2016

Thursday, June 16, 2016

Friday, September 16, 2016

Friday, November 4, 2016 - Conference

\$25 Annual Membership

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The mission of the **Michigan Health Care Safety Association (MHCSA)** is to promote and maintain safety as a primary function in the delivery of quality health care services. As a statewide organization of professionals, MHCSA will provide resources, leadership and educational opportunities to its membership and the health care industry.



www.mhcsa.org

PREVENTING OCCUPATIONAL EXPOSURE TO HAZARDOUS DRUGS

Module 1

Consultation Education & Training Division
Michigan Occupational Safety & Health Administration
www.michigan.gov/miosha
517-284-7720

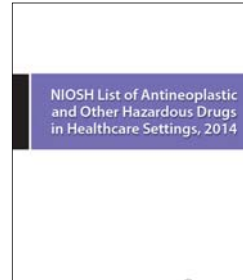


MODULE 1 TRAINING OVERVIEW

- Hazardous drug categories
- Specific hazards of drugs
- Employees at risk
- Applicable MIOSHA standards
- Resources



LIST OF HAZARDOUS DRUGS



www.cdc.gov/niosh/docs/2014-138

- Carcinogenicity
- Teratogenicity or other developmental toxicity
- Reproductive toxicity
- Organ toxicity at low doses
- Genotoxicity
- Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria
- Proposed 2016 revision



HAZARDOUS DRUGS

- Anti-neoplastic medications
- Anti-viral drugs
- Hormones
- Bioengineered drugs



NIOSH LIST OF HAZARDOUS DRUG

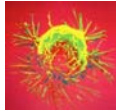
- **Table 1:** Antineoplastic drugs
- **Table 2:** Non-antineoplastic that meet one or more of the NIOSH criteria for a hazardous drug
- **Table 3:** Drugs that primarily pose a reproductive risk to men and women who are actively trying to conceive and women who are pregnant or breastfeeding



WHAT ARE THE HAZARDS OF EXPOSURE?

Hazardous drugs may cause the following:

- Cancer
- Developmental or reproductive toxicity
- Genotoxicity: Chromosome 5 or 7 changes
- Harm to organs:
 - Liver
 - Kidney
- Nausea
- Rashes
- Hair loss
- Hearing loss



WHO IS AT RISK?

- Pharmacy staff
- Nursing staff
- Physicians
- Medical assistants
- Operating room staff
- Veterinary care workers
- Research staff in laboratories
- Environmental service workers
- Shipping and receiving personnel
- Others



HAZARDOUS DRUGS THAT ARE CARCINOGENS

<u>Known Carcinogens</u>	<u>Probable Carcinogens</u>	<u>Possible Carcinogens</u>
Arsenic trioxide	Tamoxifen	Azacitidine
Azothiaprine	Thiotepa	Carmustine
Busulfan	Treosulfan	Cisplatin
Chlorambucil	MOPP*	Doxorubicin
Cyclophosphamide	ECB*	Lomustine
Etoposide		Nitrogen Mustard
Melphalan		Procarbazine
Semustine		Teniposide

*Combination regimens

International Agency for Research on Cancer (IARC) <http://www.iarc.fr/>



POTENTIAL ROUTES OF EXPOSURE

- Dermal absorption:
 - Direct drug contact
 - Contact with contaminated surfaces*
 - Contact contaminated body fluids
- Injection:
 - Sharps
 - Breakage
- Ingestion via contaminated:
 - Food, gum
 - Hand-to-mouth transfer
- Inhalation:
 - Aerosols
 - Vapors

ASHP, 2006; NIOSH, 2014; Polovich, et. al. (ONS), 2014; Polovich, 2011



EXPOSURE OPPORTUNITIES: DRUG PREPARATION

- Unpacking / stocking hazardous drugs
- Handling drug vials
- Breaking open ampoules
- Reconstituting / mixing drugs
- Pressure build-up in vials
- Transferring drugs from one container to another
- Needle sticks
- Crushing oral forms



EXPOSURE OPPORTUNITIES: DRUG DISPOSAL

- Handling contaminated materials
 - Used IV equipment
 - Residual drug
 - Used personal protective equipment
- Carrying drug waste from administration site to disposal site
- Reaching into waste containers
- Using wrong containers
- Over-full containers



EXPOSURE OPPORTUNITIES: DRUG ADMINISTRATION

- Injected drugs
 - Aerosols from purging air
 - Needle-sticks
- Intravenous infusions
 - Spiking into a drug-filled bag
 - Leaks from prime tubing
 - Loose connections
 - Needle-sticks
 - "Un-spiking"
- Intracavitary drugs
 - Poor fitting connections
 - Splashing
- Oral drugs
 - Broken tablets / capsules
 - Crushing tablets / opening capsules
 - Spilling liquid forms



EXPOSURE OPPORTUNITIES: CONTAMINATED EXCRETIONS

- Variable HD excretion: hours to days (48 hours average)
- Handling body fluids of patients who have received HDs
 - Urinals / urine
 - Bedpans / stool
 - Emesis basins / emesis
 - Sweat (?)
 - Flushing toilets
 - Linen contaminated with bodily fluids



APPLICABLE MIOSHA REGULATIONS

- Hazard Communication - MIOSHA Part 92/430
- Personal Protective Equipment - MIOSHA Part 33/433
- Respiratory Protection - MIOSHA Part 451
- Bloodborne Infectious Diseases - MIOSHA Part 554
- Housekeeping – MIOSHA Part 1
- Sanitation – MIOSHA Part 474
- Recordkeeping – MIOSHA Part 11



SAFETY DATA SHEETS (SDSs)

Maintain SDSs for all hazardous chemicals

- Examples:
 - Hazardous drugs (liquid or powdered)
 - Disinfectants
 - Oxygen
- Consumer products exemptions:
 - Personal use items (i.e. hairspray, aspirin)
 - Other household products used for purpose and quantity intended in the home.
- Contact manufacturer/distributor/supplier when required SDS not received



MIOSHA PART 92/430

HAZARD COMMUNICATION (HAZ COM)

Requires manufactures and employers to provide chemical safety and health information to employees:

- Written Program
 - Chemical Inventory (list of chemicals)*
 - Multi-employer worksites
 - Non-routine Tasks
- Labeling
- Safety Data Sheets (SDSs)
- Training*



* List of Hazardous Drugs reviewed annually and annual documented effective training competency is required by U.S. Pharmacopeial Convention (USP) <800>



SAFETY DATA SHEETS (SDSs)

NEW 16-SECTION STANDARDIZED SDS FORMAT REQUIRED (ANSI Z400.1)

- | | |
|--|---|
| Section 1 – Identification | Section 10 – Stability and Reactivity |
| Section 2 – Hazard(s) identification | Section 11 – Toxicological Information |
| Section 3 – Composition/Ingredients | Section 12 – Ecological Information* |
| Section 4 – First-aid Measures | Section 13 – Disposal Consideration* |
| Section 5 – Fire-fighting Measures | Section 14 – Transport Information* |
| Section 6 – Accidental Release Measures | Section 15 – Regulatory Information* |
| Section 7 – Handling and Storage | Section 16 – Other information including date of preparation of last revision |
| Section 8 – Exposure Controls / PPE | |
| Section 9 – Physical and Chemical Properties | |

*Sections outside of MIOSHA jurisdiction but inclusion of these sections is necessary for a GHS compliant SDS



EXAMPLE OF ASSESSMENT FORM

Personal Protective Equipment Hazard Assessment Certification

Area Or Job Being Assessed _____ Date _____

Assessed By _____ Position Or Title Of Assessors _____

Refer to The "Selection Chart" on page 8 of the General Industry Safety Standard part 33 on Personal Protective Equipment, and all applicable Occupational Health Standards, for additional hazards and applications.

 <p>EYE HAZARDS _flying particles _dust & dirt _chemical splash _molten metal _sparks _weld flash _electrical other _____</p>	 <p>HAND HAZARDS _skin absorption _punctures _severe cut or laceration hazard _chemical or thermal burns other _____</p>
 <p>HEAD HAZARDS _falling objects _flying objects _electrical _hair entanglement _hot surfaces _chemicals other _____</p>	 <p>FOOT HAZARDS _falling objects _rolling objects _powered lawn equipment _wet process areas _logging areas other _____</p>
 <p>FACE HAZARDS _impact hazards _chemical _heat _torch cutting _welding _casting _high temperature exposures other _____</p>	 <p>BODY HAZARDS _wet process areas _chemical _buffing _sand blasting _polishing _hot liquids (water,grease,acids,etc.) other _____</p>
 <p>HEARING HAZARDS _loud process and/or equipment _air and electrical impact tools _forging _hogging _tree trimming other _____</p>	 <p>BREATHING HAZARDS _spray finishing _fumes _vapors _dust _welding _foundries _sewers required confined spaces other _____</p>



MIOSHA PART 451 RESPIRATORY PROTECTION



PPE TRAINING REQUIREMENTS

Employer shall provide training to each employee who is required use PPE:

- When PPE is necessary
- What PPE is necessary
- How to
 - Put it on (don)
 - Take it off (doff)
 - Adjust, and wear PPE



MIOSHA PART 451 RESPIRATORY PROTECTION

Employer must evaluate exposure and determine:

- If respiratory protection is required
 - Examples:
 - Aerosolization of hazardous drugs – ribavirin, pentamidine, others
 - Preparing outside a biological safety cabinet- fluorouracil, cyclophosphamide, crushing tablets/dust
- If required, the type of respirator to be used:
 - Air purifying respirator high-efficiency particulate air (HEPA) filter
 - Powered air purifying respirator



MIOSHA PART 451 RESPIRATORY PROTECTION EMPLOYER RESPONSIBILITIES

For required use of a respirator, the employer must:

- Supply required respirators at no cost to the employees
- Maintain a written program by a program administrator
- Provide training:
 - Use
 - Limitations
 - Proper care, maintenance and disposal
- Medical Evaluation
- Fit testing – complete initial then annually



EVALUATION OF RESPIRATORY PROTECTION

Is this a respirator?
Is this proper use?



2.



TYPES OF RESPIRATORS



Air purifying w/HEPA filter



Powered air purifying respirator



MIOSHA PART 554 BLOODBORNE INFECTIOUS DISEASES



MIOSHA PART 554 BLOODBORNE INFECTIOUS DISEASES

- Applies where reasonable anticipation of occupational exposure to blood or other potentially infectious materials
- Needle stick with needle contaminated only with hazardous drugs are not covered by Bloodborne Standard
- Bloodborne Standard engineering and work practices controls could be implemented to reduce exposure to hazardous drugs



WASTE DISPOSAL

Containers or bags that are:

- Closable
- Leak-proof
- Color-coded or labeled

For contaminated sharps all the above plus puncture-resistant



(Image used with permission)



BLOODBORNE EXPOSURE CONTROL PLAN RELATED PROVISIONS

- Exposure Determination
- Summary of the training program.
- Procedures for evaluating exposure incidents
- Task-Specific SOP's to include:
 - Employee recognition of exposure
 - Personal Protective Equipment (PPE) selection, use, maintenance, and disposal
 - Contingency Plans
- Task-specific SOPs for management of inadvertent exposures such as needlesticks



MIOSHA PART 1 GENERAL PROVISIONS AND PART 474 SANITATION

General Provisions – Housekeeping:

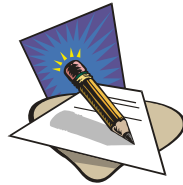
- Materials shall be placed in a container in a manner that does not create a hazard to an employee
- All places of employment, aisles, passageways, storerooms, and service rooms shall be kept clean and orderly

Sanitation - Food and beverages:

- No employee shall be allowed to consume food or beverages in any area exposed to a toxic material
- Food or beverages shall not be stored in an area exposed to a toxic material



MIOSHA Part 11 Recording and Reporting Occupational Injuries and Illnesses



PARTIALLY EXEMPT HEALTHCARE INDUSTRIAL CODES

- 6211 Offices of Physicians
- 6212 Offices of Dentists
- 6213 Offices of Other Health Practitioners
- 6214 Outpatient Care Centers
- 6215 Medical and Diagnostic Laboratories



WHO MUST KEEP MIOSHA RECORDS?

- Employers with more than 10 employees during the previous calendar year.
- Employers selected to participate in the mandatory Bureau of Labor Statistics (BLS) annual survey.
- Partially Exempt employers:
 - Employer with ≤ 10 employees during the previous calendar year.
 - Employers in designated North American Industry Classification System (NAICS) codes.



“PARTIALLY EXEMPT” MUST REPORT WHEN:

- When requested to record/report by the Bureau of Labor Statistics (BLS)
- Any workplace incident that results in:
 - fatality
 - in-patient hospitalization
 - amputation
 - loss of an eye



EXPANDED REPORTING REQUIREMENTS

Began **September 1, 2015**, all covered employers **must report** the following:

- Within 8 hours: any work-related fatality (No change from previous requirement)
- Within 24 hours:
 - work-related in-patient hospitalizations of one or more employees
 - work-related amputations
 - work-related losses of an eye



MIOSHA RESOURCES: STANDARDS AND COMPLIANCE

- Compliance Instruction (coming soon)
- [Part 92 and 430 Hazard Communication](#)
- [Part 431 Hazardous Work in Laboratories](#)
- [Part 33 and Part 433 Personal Protective Equipment](#)
- [Part 451 Respiratory Protection](#)
- [Part 474 Sanitation](#)
- [Part 554 Bloodborne Infectious Diseases](#)
- [Recording & Reporting of Occupational Injuries & Illnesses](#)



OCCUPATIONAL DISEASE REPORTING

- Employee information
- Employer information
- Illness and comments information
- Report submitted to the State (see MIOSHA website)

Michigan Department of Licensing and Regulatory Affairs Management and Technical Services Division
Known or Suspected Occupational Disease Report
(Information will be held confidential as prescribed in Act)

EMPLOYEE AFFECTED						
Name (Last, First, Middle)	Age	Sex M F	Race: White Other	Black	Hispanic	
Street	City		State	Zip		
Home Phone Number	Last Four Digits of Social Security Number (Optional)					
CURRENT EMPLOYER						
Current Employer Name			Worksite County			
Worksite Address		City	State	Zip		



MIOSHA RESOURCES: CONSULTATION AND TRAINING

- [Preventing Exposure to Hazardous Drugs Training Module 1 – Overview](#)
- Preventing Exposure to Hazardous Drugs Training Module 2 – Staff (coming soon)
- [Fact Sheet: Preventing Exposure to Hazardous Drugs](#) (doc)
- [Hazard Communication Sample Plan](#) (doc)
- [Personal Protective Equipment Guide](#) (doc)
- [Respiratory Protection Program](#) (doc)
- [Bloodborne Sample Exposure Control Plan](#) (doc)



FEDERAL RESOURCES

Centers for Disease Control and Prevention:

[NIOSH Hazardous Drugs webpage](#)

OSHA:

- [Hazardous Drugs Website](#)
- [Hazardous Drugs eTool](#)
- Technical Manual Section VI: Chapter 2:
[Controlling Occupational Exposure To Hazardous Drugs](#)



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