NIOSH 2024 Updates & USP 800

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Disclosure

JP Ghuman, BS, PhT *does not have relevant financial relationships with ineligible companies and has* no actual or potential conflict of interest in relation to this program/presentation.

- None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.

Disclosure

I will not discuss off label use and/or investigational use in my presentation.

Objectives

At the completion of this program, the participant will be able to: For Pharmacists and Pharmacy Technicians

- Understand the key updates in the NIOSH 2024 Hazardous Drug List and their implications for pharmacy practice.
- Implement best practices for minimizing exposure to hazardous drugs in various healthcare settings.
- Evaluate the roles and responsibilities of pharmacy personnel in maintaining a safe environment when handling hazardous drugs.
- Develop strategies for effective communication and training within the pharmacy team to ensure adherence to the standards.

Pre-learning Questions

Approximately how many drugs remain unevaluated by NIOSH

A. Over 100

B. Over 400

C. over 1000

D. None of the above

Pre-learning Questions

How many new drug additions & removals were made to the NIOSH 2024 list Table 1

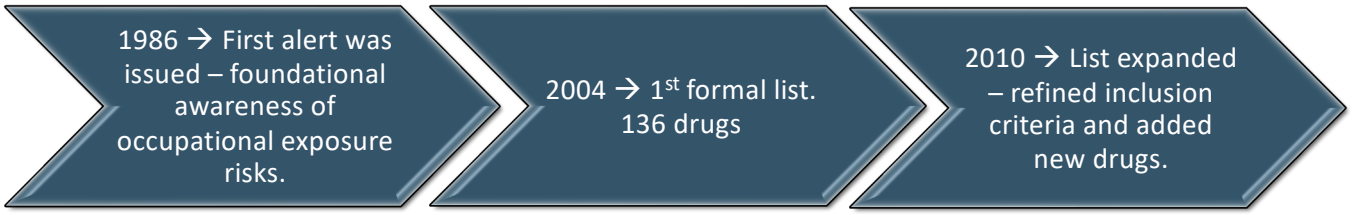
A. 25 new additions and 7 removals

B. 50 new additions and 20 removals

C. 7 new additions and 25 removals

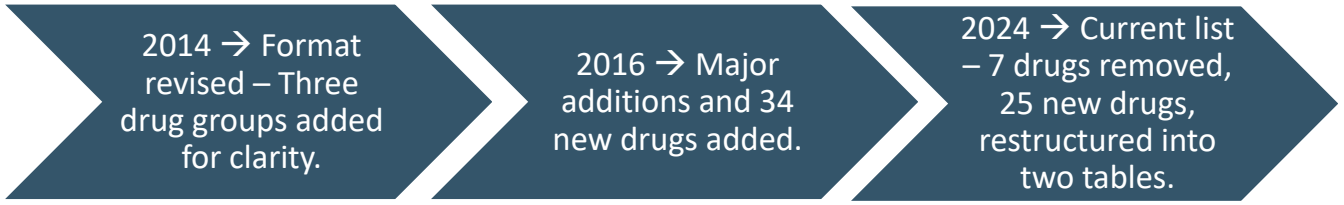
D. 20 new additions and 50 removals

Hazardous Drug List – Historical Overview



SOURCE: HTTPS:WWW.CDC.GOV/NIOSH/DOCS/2016-161/DEFAULT.HTML

Hazardous Drug List – Historical Overview



SOURCE: HTTPS:WWW.CDC.GOV/NIOSH/DOCS/2016-161/DEFAULT.HTML

Hazardous Drug List – Tables & Groups

The 2016 List

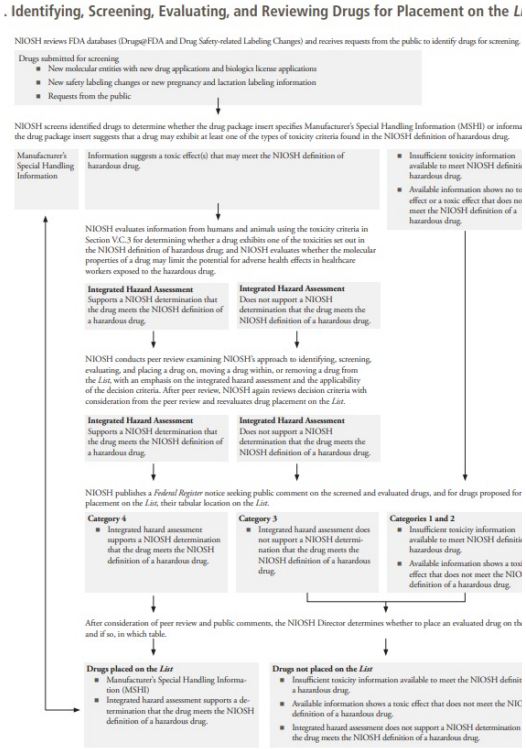
Table 1 Group 1: Antineoplastic

Table 2 Group 2 Non-Antineoplastic

Table 3 Group 3 Reproductive Risk

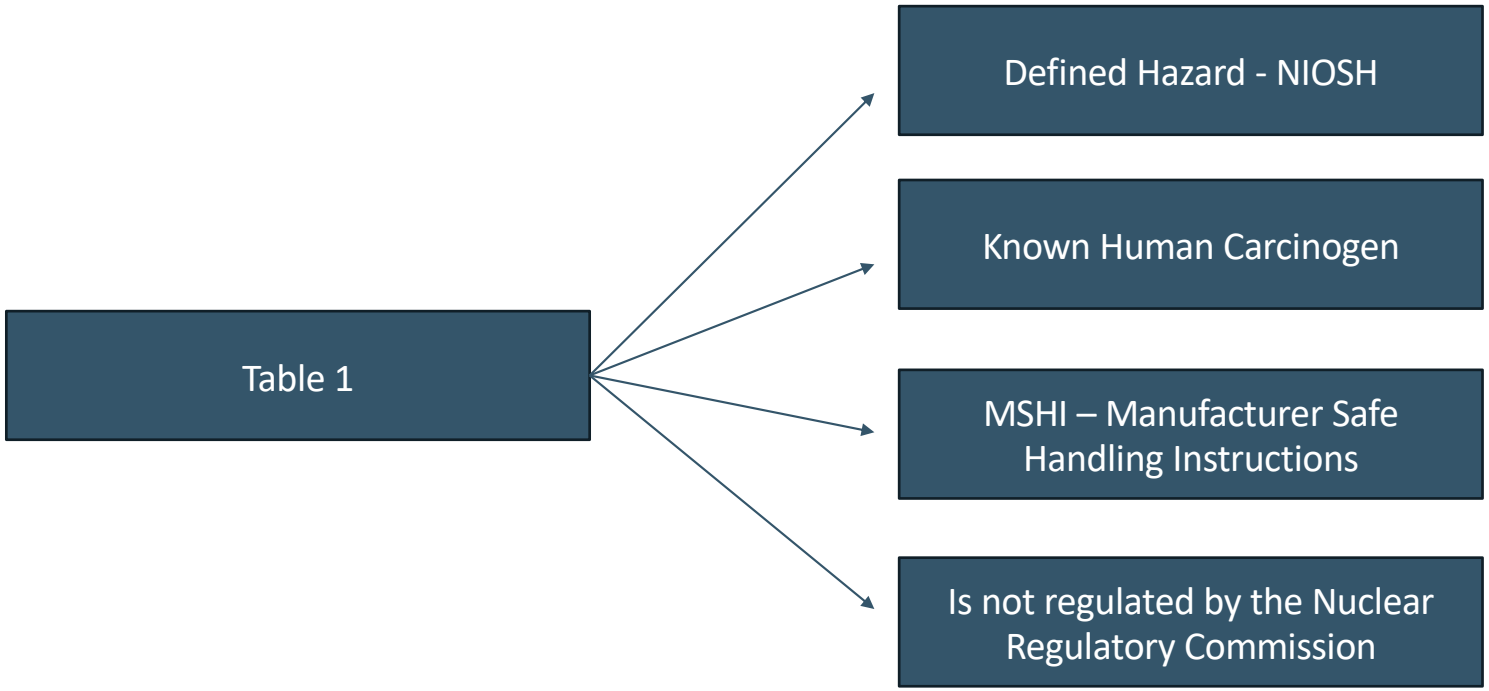
SOURCE: HTTPS://WWW.CDC.GOV/NIOSH/TOPICS/HAZDRUG/PUBS.HTML

How is the NIOSH list developed?



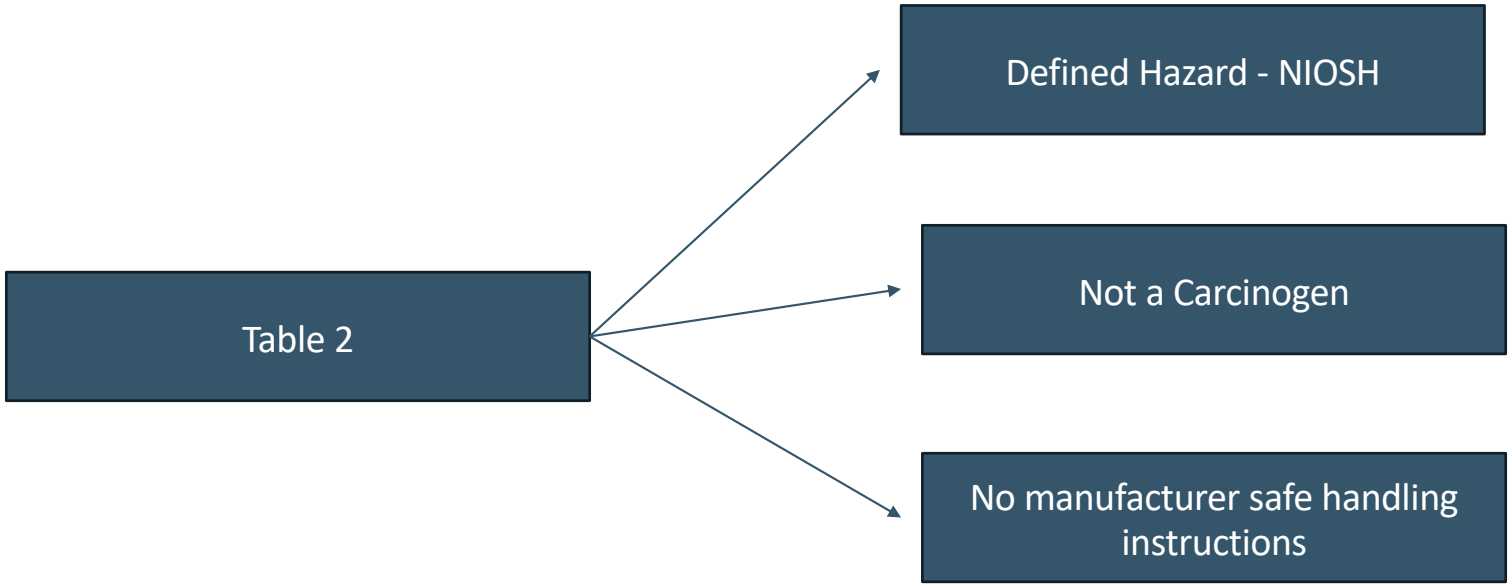
SOURCE: NIOSH [2023]. HTTPS://DOI.ORG/10.26616/NIOSHPUB2023129.

NIOSH 2024 – Table 1



SOURCE: HTTPS://WWW.CDC.GOV/NIOSH/DOCS/2025-103/PDFS/2025-103.PDF?ID=10.26616/NIOSHPUB2025103

NIOSH 2024 – Table 2



SOURCE: HTTPS://WWW.CDC.GOV/NIOSH/DOCS/2025-103/PDFS/2025-103.PDF?ID=10.26616/NIOSHPUB2025103

Removals from the 2016 list

Bacillus Calmette Guerin (BCG): Refer to *Specific Handling Instructions*

ergonovine

liraglutide

paliperidone

pertuzumab

risperidone

telavancin

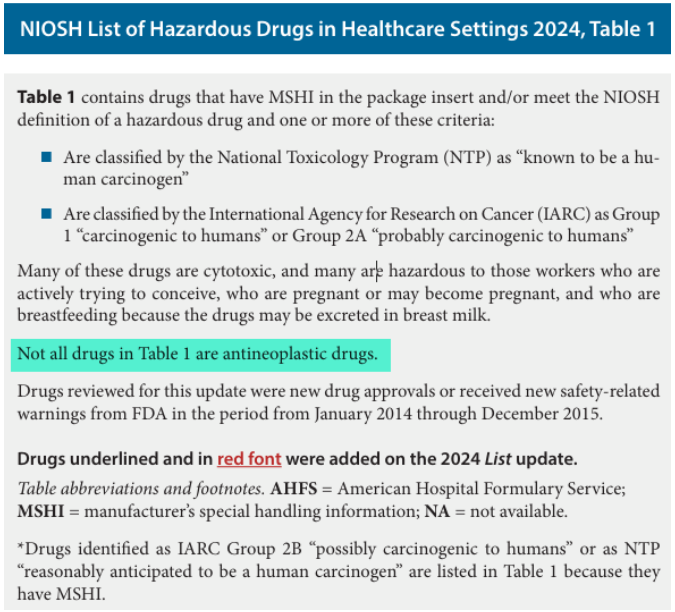
SOURCE: HTTPS://WWW.CDC.GOV/NIOSH/DOCS/2025-103/PDFS/2025-103.PDF?ID=10.26616/NIOSHPUB2025103

Updates to the 2024 list

Addition of 25 drugs (12 with special handling instructions) and removal of 7 drugs.

Reorganization into two tables.

Updates to drug classifications and nomenclature.



NIOSH List of Hazardous Drugs in Healthcare Settings 2024, Table 1

Table 1 contains drugs that have MSHI in the package insert and/or meet the NIOSH definition of a hazardous drug and one or more of these criteria:

- Are classified by the National Toxicology Program (NTP) as "known to be a human carcinogen"
- Are classified by the International Agency for Research on Cancer (IARC) as Group 1 "carcinogenic to humans" or Group 2A "probably carcinogenic to humans"

Many of these drugs are cytotoxic, and many are hazardous to those workers who are actively trying to conceive, who are pregnant or may become pregnant, and who are breastfeeding because the drugs may be excreted in breast milk.

Not all drugs in Table 1 are antineoplastic drugs.

Drugs reviewed for this update were new drug approvals or received new safety-related warnings from FDA in the period from January 2014 through December 2015.

Drugs underlined and in red font were added on the 2024 *List* update.

Table abbreviations and footnotes. **AHFS** = American Hospital Formulary Service; **MSHI** = manufacturer's special handling information; **NA** = not available.

*Drugs identified as IARC Group 2B "possibly carcinogenic to humans" or as NTP "reasonably anticipated to be a human carcinogen" are listed in Table 1 because they have MSHI.

SOURCE: HTTPS://WWW.CDC.GOV/NIOSH/DOCS/2025-103/PDFS/2025-103.PDF?ID=10.26616/NIOSHPUB2025103

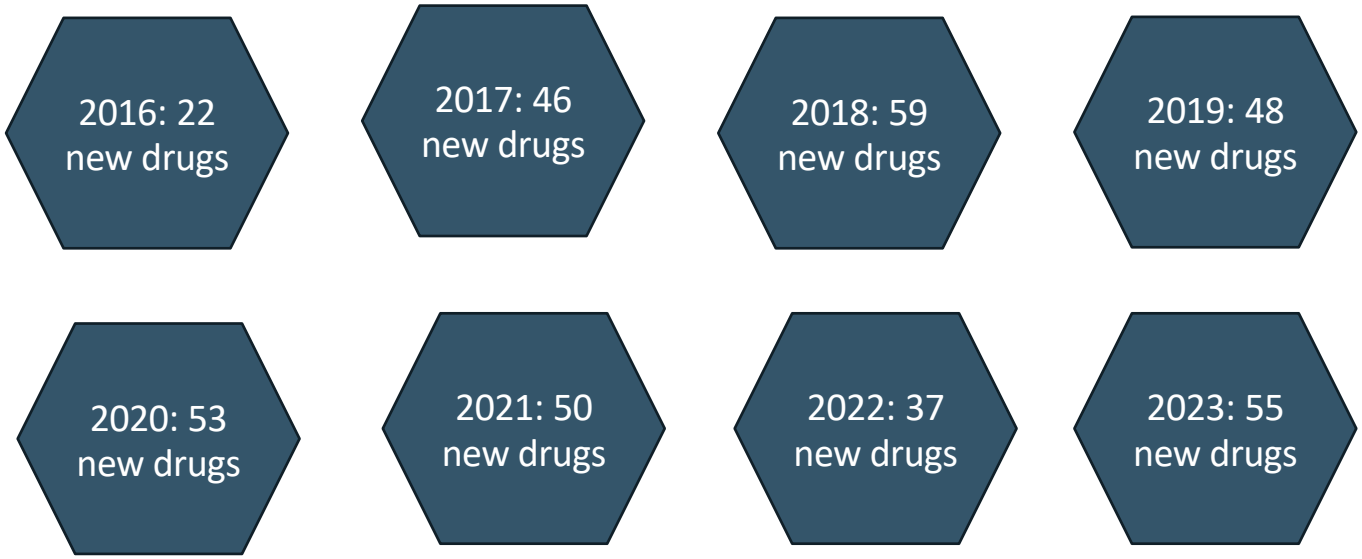
NIOSH 2024 Hazardous Drug List

CAUTION: Drugs purchased and used by a facility may have entered the marketplace after the list below was assembled. Therefore, this list may not be all-inclusive, and employers should consider creating a facility-specific hazardous drug list.

What's MISSING

- Drugs approved by CBER are not reviewed by NIOSH
- Investigational drugs
- Drugs with emergency use authorization
- Supplemental Information column
- Drugs approved since 2016

NIOSH 2024 – What about 2016 to now?



SOUCE: MULLARD A; 2023 FDA APPROVALS; NATURE REVIEW DRUG DISCOVERY, VOL 23, JANUARY 2024

What about mAbs?

Currently, 10 mAbs are on the 2024 NIOSH HD list.

- Table 1
  - ado-trastuzumab emansine
  - Belantamab mafodotin
  - Fam-trastuzumab Vedotin
  - Gemtuzumab ozogamicin
  - Inotuzumab ozogamicin
  - Loncastuximab tesirine
  - Mirvetuximab soravtasine
  - Polatuzumab vedotin
  - Sacituzumab govitecan

- Table 2
  - blinatumomab

SOURCE: HTTPS://WWW.CDC.GOV/NIOSH/DOCS/2025-103/PDFS/2025-103.PDF?ID=10.26616/NIOSHPUB2025103

What should be assessed?

Organizational Formulary

- NIOSH Table 1
- NIOSH Table 2

Other considerations:

- Patient Own Medication (PTOMs)
- Non-Formulary Medications
- Research/Investigational Drugs
- Compounded Preparations
- Biological agents

What is USP <800>?

Set of enforceable standards for the safe handling of Hazardous Drugs in healthcare settings.

Aims to protect healthcare personnel, patients, and the environment from exposure to HDs.

<800> complements the NIOSH list by providing practical implementation standards.

SOURCE: HTTPS://WWW.USP.ORG/COMPOUNDING/GENERAL-CHAPTER-HAZARDOUS-DRUGS-HANDLING-HEALTHCARE

Scope of USP <800>?

Applies to all healthcare personnel who receive, prepare, administer, transport, or dispose of HDs.

Covers all environments where HDs are handled, including pharmacies, clinics, and hospitals.

Includes non-traditional settings like outpatient clinics and home care.

Key Requirements of USP <800>?

Responsibilities of personnel handling HDs.

Facility and Engineering Controls.

Deactivation, decontamination, cleaning, and spill management.

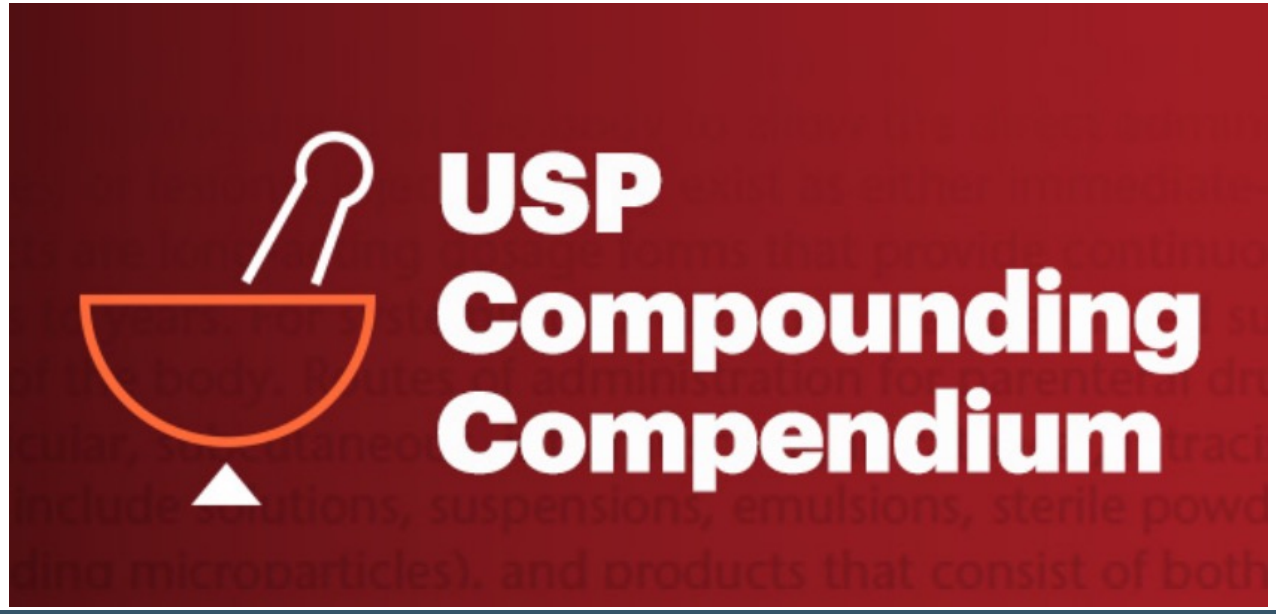
Documentation and training.

SOURCE: HTTPS://WWW.USP.ORG/COMPOUNDING/GENERAL-CHAPTER-HAZARDOUS-DRUGS-HANDLING-HEALTHCARE

NIOSH list and USP <800>?

<800> uses the NIOSH list to define which drugs are considered hazardous.

Facilities must review the NIOSH list regularly and update their HD inventory accordingly.



SOURCE: HTTPS://WWW.USP.ORG/COMPOUNDING/GENERAL-CHAPTER-HAZARDOUS-DRUGS-HANDLING-HEALTHCARE

USP – Clarifies Antineoplastic

Revision Bulletin for USP<800> posted 6/26/2020

Became Official 7/1/2020

- *"For the purposes of this chapter, the term antineoplastic only refers to antineoplastic drugs included in Table 1 of the most current NIOSH list"*

SOURCE: HTTPS://WWW.USP.ORG/COMPOUNDING/GENERAL-CHAPTER-HAZARDOUS-DRUGS-HANDLING-HEALTHCARE

Performing an Assessment of Risk (AoR)

Minimum criteria for an Assessment of Risk

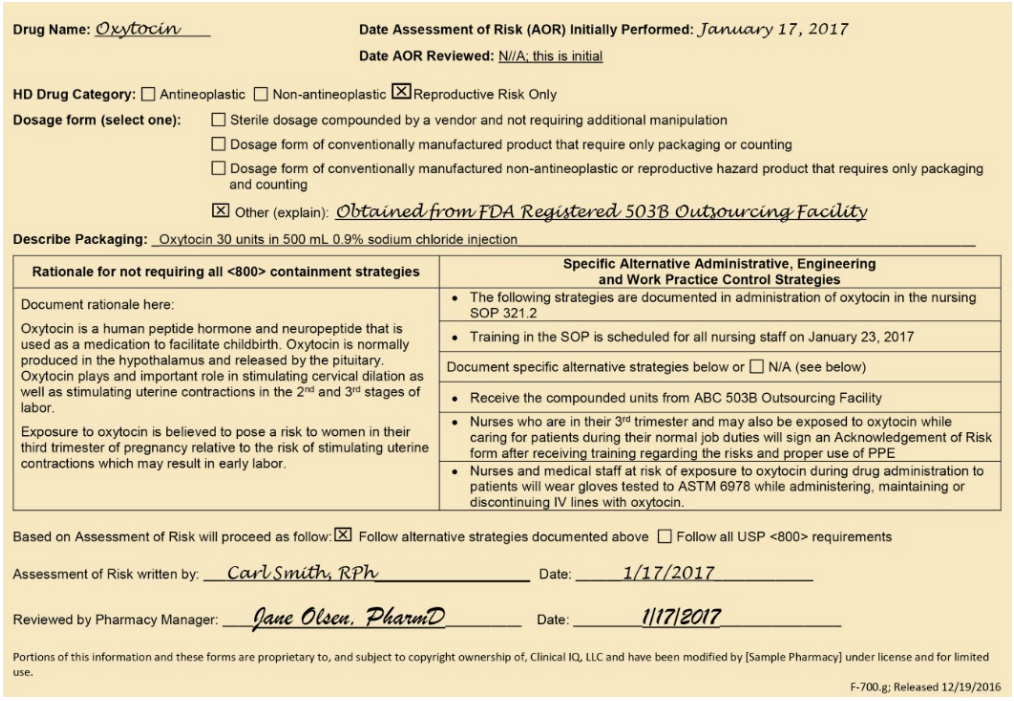
- Type of HD
- Dosage From
- Risk of Exposure
- Packaging
- Manipulation

SOURCE: HTTPS://WWW.USP.ORG/COMPOUNDING/GENERAL-CHAPTER-HAZARDOUS-DRUGS-HANDLING-HEALTHCARE

Assessment of Risk (AoR) Tools

SOURCE: NIOSH [2023]. MANAGING HAZARDOUS DRUG EXPOSURES: INFORMATION FOR HEALTHCARE SETTINGS. BY HODSON L, OVESEN J, COUCH J, HIRST D, LAWSON C, LENTZ TJ, MACKENZIE B, MEAD K. CINCINNATI, OH: U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTERS FOR DISEASE CONTROL AND PREVENTION, NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH, DHHS (NIOSH) PUBLICATION NO. 2023-130, HTTPS://DOI.ORG/10.26616/NIOSHPUB2023130

Assessment of Risk (AoR)



Drug Name: Oxytocin

Date Assessment of Risk (AOR) Initially Performed: January 17, 2017

Date AOR Reviewed: N//A; this is initial

HD Drug Category: ☐ Antineoplastic ☐ Non-antineoplastic ☒ Reproductive Risk Only

Dosage form (select one):

☐ Sterile dosage compounded by a vendor and not requiring additional manipulation

☐ Dosage form of conventionally manufactured product that require only packaging or counting

☐ Dosage form of conventionally manufactured non-antineoplastic or reproductive hazard product that requires only packaging and counting

☒ Other (explain): Obtained from FDA Registered 503B Outsourcing Facility

Describe Packaging: Oxytocin 30 units in 500 mL 0.9% sodium chloride injection

Rationale for not requiring all <800> containment strategies	Specific Alternative Administrative, Engineering and Work Practice Control Strategies
Document rationale here: Oxytocin is a human peptide hormone and neuropeptide that is used as a medication to facilitate childbirth. Oxytocin is normally produced in the hypothalamus and released by the pituitary. Oxytocin plays and important role in stimulating cervical dilation as well as stimulating uterine contractions in the 2nd and 3rd stages of labor. Exposure to oxytocin is believed to pose a risk to women in their third trimester of pregnancy relative to the risk of stimulating uterine contractions which may result in early labor.	• The following strategies are documented in administration of oxytocin in the nursing SOP 321.2 • Training in the SOP is scheduled for all nursing staff on January 23, 2017 Document specific alternative strategies below or ☐ N/A (see below) • Receive the compounded units from ABC 503B Outsourcing Facility • Nurses who are in their 3rd trimester and may also be exposed to oxytocin while caring for patients during their normal job duties will sign an Acknowledgement of Risk form after receiving training regarding the risks and proper use of PPE • Nurses and medical staff at risk of exposure to oxytocin during drug administration to patients will wear gloves tested to ASTM 6978 while administering, maintaining or discontinuing IV lines with oxytocin.

Based on Assessment of Risk will proceed as follow: ☒ Follow alternative strategies documented above ☐ Follow all USP <800> requirements

Assessment of Risk written by: Carl Smith, RPh Date: 1/17/2017

Reviewed by Pharmacy Manager: Jane Olsen, PharmD Date: 1/17/2017

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F-700.g; Released 12/19/2016

SOURCE: HTTPS://PPPMAG.COM/ARTICLE/2012

Resources

- Drug Package Insert
- Safety Data Sheets
- Peer reviewed literature
- NIOSH 2024 list
- Home - National Toxicology Program
- IARC – INTERNATIONAL AGENCY FOR RESEARCH ON CANCER
- Joint USP & NIOSH Webinar – January 2025

SOURCES: HTTPS://NTP.NIEHS.NIH.GOV/ ; HTTPS://WWW.IARC.WHO.INT/

Additional Resources

Novel Drug Approvals for 2024 | FDA

Drug Safety-related Labeling Changes (SrLC)

SOURCES: HTTPS://WWW.FDA.GOV/DRUGS/NOVEL-DRUG-APPROVALS-FDA/NOVEL-DRUG-APPROVALS-2024, HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/SAFETYLABELINGCHANGES/INDEX.CFM

Next Steps

- Access the NIOSH 2024 List
- Updating the organizational HD list
- Evaluate what was removed and reclassifications
- Make AoR part of the formulary review process
- Staff Education/Training
- Go Live!

Post-learning Questions

Approximately how many drugs remain unevaluated by NIOSH

A. Over 100

B. Over 400

C. over 1000

D. None of the above

Post-learning Questions

How many new drug additions & removals were made to the NIOSH 2024 list Table 1

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Questions

References