- Comm[illegible]ker HDs that can be ass[illegible]ved in[illegible]ude cyclophosphamide, ifos[illegible]ide, methotrexate, fluorouracil, and plat[illegible]um-containing drugs. Many [illegible] are being developed. Research suppliers to ensure appropriate [illegible]sidue will be detected if present.
- [illegible]y measurable contamination is found, the designate[illegible]on must identify, document, and contain the cause of contamination. This may include:
  - Performing thorough deactivation, decontamination and cleaning
  - Reevaluating work practices
  - Re-training personnel
  - Improving engineering controls.
  - Repeating the wipe sampling to validate that the deactivation/decontamination and cleaning steps have b[illegible]n effective.

11.0 Disposal

a. T[illegible]harmacy has contracted with a hazardous waste disposal [illegible]pany.
b. T[illegible]ompany has provided color-coded bins in which to put h[illegible]ous waste a[illegible] contaminated materials. Black for contamin[illegible]ted or l[illegible] HD waste, yellow for trace contaminated materials, and red for b[illegible]onaza[illegible]us or sharps.
c. HD waste bins are located in all areas where HDs a[illegible] ha[illegible]d.
d. All personnel a[illegible] trained in the appropriate proced[illegible]res identify and handle HD waste, and in cl[illegible]ning o[illegible]reas that may be co[illegible]ed with HD residue. This includes all house[illegible]ping [illegible]ustodial per[illegible]nnel that perform cleaning or waste removal from [illegible]harma[illegible]
e. Appropriate disposal of HD waste is handled by the contracted HD waste disposal company.
f. If the pharmacy does not contract with a company, the pharmacy must comply to all local, state, and federal (including EPA) regulations for the segregation, handling, [illegible] disposal of [illegible] waste.

[illegible]0 S[illegible]control

Spill kits [illegible]of the appropr[illegible]e size an[illegible]mposition to contain [illegible] clean [illegible]ill of HD[illegible]andled by the [illegible]cility.
b. [illegible]spill kit[illegible]t be availabl[illegible] areas w[illegible] HDs are received[illegible] [illegible]mpound[illegible] and with d[illegible]ry drivers.
[illegible]ll employe[illegible] trai[illegible] handling s[illegible]ling emp[illegible]es that are delive[illegible] drivers, initially [illegible]ually.
d. A "spill" of an HD includes dropping solid dosage forms, spilling of liquid HDs, damaged or leaking containers of HDs received, HD packaging damaged when handling, etc.

e. Procedure
   1. A spill is identified

ii. Si posted or other means used to alert staff to the spill and restrict access to the spill area until clean-up is complete.
iii. The appropriate personnel (or spill team, if you have one) dons PPE and retrieves the spill kit. PPE includes a cartridge respirator or, if the capacity of the spill kit is exceeded or there is potential exposure to vapors or gases, a full-facepiece, chemical cartridge-type respirator is used.
iv. The materials in the spill kit are used to contain and soak up any HDs, and to collect any solids, packaging and broken glass for disposal.
v. The spill area is then thoroughly cleaned by deactivating the HD, decontaminating the area, cleaning and sanitizing.
vi. All spill and clean-up materials are placed in the bag(s) supplied with the spill kit, sealed, and disposed of as contaminated or bulk hazardous waste (black bin).
vii. The spill and actions taken afterward are documented.

f. Personnel and others who are exposed during the spill or clean-up or who have direct skin or eye contact with HDs require immediate evaluation.
i. Provide a copy of the HD SDS to medical personnel performing the evaluation for reference to the specific HD the person was exposed to.
ii. Document the exposure
iii. Monitor for exposure-related health changes (see 5.40 Medical surveillance)

g. All spills and any related incidents of exposure are evaluated as part of the pharmacy quality assurance program. This may include evaluation of:
i. Administrative controls
ii. Engineering controls
iii. PPE and spill kits available
iv. SOPs
v. Training

5.40 Medical surveillance (optional)

[redacted] a "should" [redacted] – not required. May not be necessary if the pharmacy does [redacted] compounding or manipulation of HDs. May be used for acute spills and exposures of certain [redacted]. The pharmacy should determine if the amounts and types of HDs handled in compounding [redacted] large amounts of antineoplastic HDs or hormones) would warrant this type of [redacted]

a. Pharmacy personnel who handle HDs as a regular part of their job assignment should be enrolled in a medical surveillance program. It is part of a comprehensive exposure control program along with engineering controls, safe work processes, and use of PPE. It is a secondary prevention tool that may provide early detection if health problems develop.

b. Medical s[illegible]ce programs involve ass[illegible]sme[illegible] and documentation of sympto[illegible]om[illegible]aints, physical findings, and [illegible]abora[illegible]ory values (such as a blood coun[illegible] to de[illegible]rmine whether there is a deviation fr[illegible]m the expected norms.
c. Th[illegible]ata-g[illegible]hering elements of a medical surveil[illegible]a[illegible]e program are used to e[illegible]a[illegible]lish a baseline of workers' health and then to monitor t[illegible]ture health for changes that may result from exposure to HDs.
d. [illegible]dical surveillance programs also look for trends in popula[illegible] of workers. [illegible]mining grouped data compared with data from unexposed [illegible]rke[illegible]s may reveal a small alteration or increase in the frequency of a he[illegible]h [illegible]ec that would be obscured if individual workers' results alone were consi[illegible]ed.

Procedure:

i. Identify personnel who are potentially exposed to HDs as p[illegible] of their regular job duties.
ii. Contract with a health service to perform the tests while pro[illegible]ting the employee medical information.

Have a baseline assessment performed.

1. Medical and reproductive history
2. Physical examination including lab tests linke[illegible] get organs based on the types of HDs handled
3. Exposure history (HDs handled, dosa[illegible] form[illegible] quantities, estimated time handling HDs weekly or mo[illegible]y, etc.)
4. Blood or urine levels of a specific H[illegible] on[illegible]th acute spills and e[illegible]osure to the s[illegible]ecific HD.
5. Mo[illegible]oring a[illegible] documentation[illegible]ained according to OSHA.
6. Pros[illegible] pen[illegible] performed and monitoring for changes.
7. Develop follow-up plan for changes suggesting toxicity or for those with acute exposure. The occurrence of exposure-related health changes should prompt immediate re-evaluation of primary preventive [illegible]sures (i[illegible]ding administrative and eng[illegible]ering controls, PP[illegible] etc.).

Completion [illegible]an exit e[illegible]ination when an employe[illegible]s employmen[illegible] the pha[illegible]cy to document the infor[illegible]ion on the employee's [illegible]dical, re[illegible]uctive, and exposure h[illegible]ries.

Refer[illegible]es

USP Chapter [illegible]ardous Drugs

- NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings https://www.cdc.gov/niosh/topics/antineoplastic/pdf/hazardous-drugs-list_2016-161.pdf [Note that current edition is 2016, the 2018 revision is anticipated to be released in early 2019]

Respirators: https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource1.html

- Respirato ting: https://www.osha.gov/video/respiratory_protection_fittesting_transcript.html
- Med Surv illance: https://www.cdc.gov/niosh/docs/wp-solutions/2013-10 dfs/2013-103.pdf

[NO should the respirator and medical surveillance referen es be incorporated di y into the specific sections or stay here with the references.

VII. Atta ments

Hazardous Drug Handling and Exposure Acknowledgement

Hazar s Drug Handling and Exposure Acknowled ent

Employee Print Name: _____

I understand that this pha les and ares hazardous drugs.

Hazardous drugs are those drugs that have one or more of the following characteristics: carcinogenicity, teratogenicity, reproductive toxicity, organ t at low dose or genotoxi .

ve b provid training tha ncludes view of the pharma standar operating rocedures OPs) a agree to comply w th

ve tak and p ed the ass sment estions for haza us drug ning, a succe ully demo ated c petency in the ardou ugs.

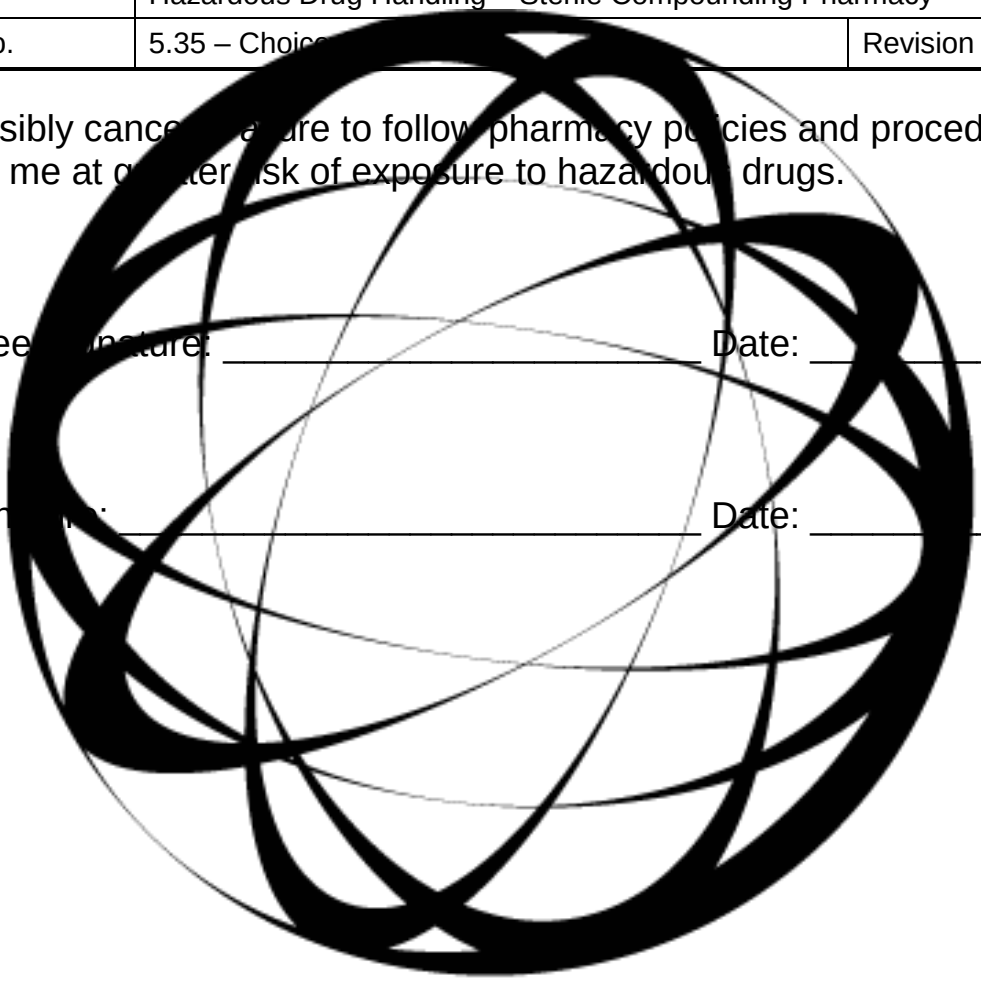
I am familiar with SDS and the assessment of risk for the hazardous drugs handled at this pharmacy.

I acknowledge that exposure to hazardous drugs may cause acute and chronic effects including skin rashes, infertility, miscarriage, birth defects

and possibly cance[illegible]ure to follow pharmacy policies and procedures may put me at g[illegible]ter risk of exposure to hazardou[illegible] drugs.

Employee [illegible]nature: _____ Date: _____

PIC Sign[illegible]: _____ Date: _____



BULA INTELLIGENCE