

USP <800>: The Devil's in the Details....

We've Got You Covered!

1. Identification of facility's hazardous drugs
 - A. Customized list of hazardous drugs
 2. Evaluation of Organization's Compliance with NIOSH Recommendations
 - A. Hazardous Drug Assessment of Risk: Are the facility's current practices aligned with Table 5? Compare to NIOSH Recommended PPE per Drug/Dosage Form.
 - B. If not, utilize the Assessment of Risk Algorithm to determine appropriate PPE (not pictured).
 - C. Documented Assessment of Risk process resulting in appropriate PPE for pharmacy AND nursing
- 1.A. Customized List of HDs: NIOSH Report in Inventory Analysis

pharm ^e ecology [®]		NIOSH Hazardous Drug Review				Sample Facility	
PharmE® Inventory Analysis		Reviewed on June 7, 2017					
Drug	Product	Form	Size	Strength	CHLOROFORM METHYL SILICO NITR O	CLASSIFICATION REASON	Original NDC Report NDC
Arsenic Trioxide	TRISENOX SOL 10MG/10M	SOLN	10 ML	10 MG/10ML	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	P012 ARSENIC TRIOXIDE	60553011110
Busulfan	MYLERAN TAB 2MG	TABS	25 EA	2 MG	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	Chemotherapy Agent	173071325
Chlorambucil	LEUKERAN TAB 2MG	TABS	50 EA	2 MG	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	U035 CHLORAMBUCIL	173069335
Chlorambucil Sodium Succinate	CHLORAMBIPHEN INJ 1GM	SOLR	1 EA	1 GM	<input type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	Non-hazardous NIOSH 2016	83323001115
Cyclophosphamide	CYTOXAN TAB 25MG	TABS	100 EA	25 MG	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	U058 CYCLOPHOSPHAMIDE	15050401
	CYTOXAN TAB 50MG	TABS	100 EA	50 MG	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	U058 CYCLOPHOSPHAMIDE	15050301
Daunorubicin Citrate Liposome	DAUNOXOME INJ 2MG/ML	INJ	25 ML	2 MG/ML	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	U059 DAUNOMYCIN	61958030101
Estrogens, Conjugated	PREMARIN INJ 25MG	SOLR	1 EA	25 MG	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Non-hazardous NIOSH 2016	46074905
	PREMARIN TAB 0.3MG	TABS	100 EA	0.3 MG	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Non-hazardous NIOSH 2016	46089881
Ganirelix Acetate	GANIRELIX AC INJ	SOLN	5 ML	250 MCG/0.5ML	<input type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	Non-hazardous NIOSH 2016	52030151
Lefunomide	ARAVA TAB 20MG	TABS	30 EA	20 MG	<input type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	Non-hazardous NIOSH 2016	86216130
Medroxyprogesterone Acetate (Contraceptive)	DEPO-PROVERA INJ 150MG/ML	SUSP	1 ML	150 MG/ML	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Non-hazardous NIOSH 2016	9074630
Melphalan	ALKERAN TAB 2MG	TABS	50 EA	2 MG	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	U150 MELPHALAN	56672030250
Methylglanovine Maleate	METHERGINE INJ 0.2MG/ML	SOLN	1 ML	0.2 MG/ML	<input type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	Non-hazardous NIOSH 2016	78005303
Phenxybenzamine HCl	DIBENZYLINE CAP 10MG	CAPS	30 EA	10 MG	<input type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	Non-hazardous NIOSH 2016	51655018724
Phenytol Sodium	PHENYTOIN INJ 50MG/ML	SOLN	2 ML	50 MG/ML	<input type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	Non-hazardous NIOSH 2016	74131701
Propylthiouracil	PROPYLTHIOUR TAB 50MG	TABS	100 EA	50 MG	<input type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	Non-hazardous NIOSH 2016	143148001
* Sirolimus	RAPAMUNE SOL 1MG/ML	SOLN	60 ML	1 MG/ML	<input type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	Non-hazardous NIOSH 2016	8010304 8103004
Testosterone	ANDROGEL GEL 1% (25MG)	GEL	2.5 GM	25 MG/2.5GM	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	D001 Alcohol greater than or equal to 24%	51842501

2.A. Hazardous Drug Assessment of Risk (PPE for Pharmacy & Nursing)

Drug name or active pharmaceutical ingredient	** NIOSH Table	* Type of HD (antineoplastic (A), non-antineoplastic (N), reproductive risk (R))	Strength	* Dosage forms (tablets (T), capsules (C), solution (S), injectable (INJ), inhalation (INH))	Unit dose, Unit of use, Single dose or Multi-dose	** Preparation Activity and PPE Code	Glove 2	Gown	Eye/Face	Resp	Vent	** Administration Activity and PPE Code	Glove 2	Gown	Eye/Face	Resp	Vent	Y except tabs or caps that are film coated or directly from UD package	Y except tabs or caps that are film coated or directly from	Y if vomiting potential exists or liquid could splash	Y if inhalation is possible	CSTD if dosage form allows	
																							Y Always
abiraterone acetate	Table 1	A	250 mg uncoated	T	M	2	Y Always	Y Always	N	Y	Y	3	N	N	Y	Y	N	N	Y	Y	N	NA	
arsenic trioxide	Table 1	A	1mg/ml, 2 mg/ml, 10 mg and 12 mg vials	INJ	S	10	Y	Y	N	N	N	11	Y	Y	Y	Y	N	NA	Y	Y	Y	Y	NA, CSTD required if dosage form allows
bezarotene	Table 1	A	1% gel	TOP	MD	NA	NA	NA	NA	NA	NA	7	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	NA
apomorphine	Table 2	N	30 mg/3 ml cartridge pen	INJ	MD pen	NA	NA	NA	NA	NA	NA	9	Y	Y	Y	Y	N	NA	Y	Y	Y	Y	NA
carbamazepine	Table 2	N	40 mg/ml	Suspension, per institution	MD	4	Y	Y	Y	Y	Y	5	Y	Y	Y	Y	N	NA	Y	Y	Y	Y	NA
ribavirin	Table 3	R	6 gm solution vial	Inhalation	MD	14	Y	Y	Y	Y	Y	15	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	NA
testosterone	Table 3	R	2 mg, 2.5 mg, 4 mg and 5 mg	Patch	UD	NA	NA	NA	NA	NA	NA	7	Y	Y	NA	NA	NA	NA	Y	Y	NA	NA	NA

3. Integrate Assessment of Risk decisions into drug management operations

A. Functional Risk Minimization

PERSONNEL	PHASE OF HD CYCLE	RECEIVE	STORE	PREPARE	TRANSPORT	ADMIN	WASTE	SPILL CLEAN UP	SYSTEM COMPONENT
Pharmacist		X	X	X			X	X	
Pharmacy Technician		X	X	X	X		X	X	
Nurse				?		X	X	X	
Other HC Practitioner (i.e. Surgeon, RN)						X	X	X	
EVS Staff		?					X	X	
Other (i.e. RT)						X	X	X	
ACTION	CONTAINMENT STRATEGY (CS), WORK PRACTICE (WP), ADMINISTRATIVE RULE (AR)								RESOURCES, CQI, STAFF, PEOPLE, P&P, TRAIN, TOOLS, ENVIRONMENT, REGULATIONS
Prohibiting food, chewing gum or tobacco, applying cosmetics, and storing food in areas where HDs are used	WP	X	X	X	X	X	X	X	P&P, Train

B. Comprehensive Compliance Management Document

USP <800> COMPLIANCE MANAGEMENT DOCUMENT										
	Leadership	Pharmacy	Nursing	Other Dept	Fully Completed	Partially Completed	Not Completed	Documentation of existing requirement, OR description of plan to meet requirement	Person(s) Responsible	Timeline
CULTURE										
Regulatory compliance	x	x	x	x						
Federal regulations (EPA, DEA, OSHA)										
State regulations (including Board of Pharmacy)										
Designated Person (prevent harm to patients, minimize/eliminate exposure to personnel and the environment)	x	x								
Qualifications										
Training for this position										
Develop and implement appropriate procedures										
Oversee compliance with laws, regulations and standards										
Understand rationale for risk prevention policies, risks to staff and patients/visitors										
Monitor program: monitor, report, implement resolutions										
Resources	x	x	x	x						
Safety Data Sheets per Hazardous Drug (GHS classification and labeling of chemicals)										
Personnel										
Continuous Quality Improvement (CQI), including competency assessment and documentation	x									
Documentation of continuous operation of C-PEC										

**For more information, please contact us at
info@pharmecology.com or 1-877-247-7430.**