


Name of Policy: <u>Use of list I and II chemicals in research-Drug Enforcement Agency guidelines</u>		 <p>Original effective date: May 25, 2010</p>
Policy Number: 3364-70-17		
Approving Officer: President		
Responsible Agent: Senior Director for Research Administration		
Scope: All University of Toledo Campuses		
X	New policy proposal	Minor/technical revision of existing policy
	Major revision of existing policy	Reaffirmation of existing policy

(A) Policy statement

The University of Toledo supports the efforts of the Drug Enforcement Administration of the U.S. Department of Justice (DEA) Chemical Control Program to prevent the diversion of chemicals that may be used in the illicit production of controlled substances (drugs of abuse).

(B) Purpose of policy

The purpose of this policy is to provide guidance on the process for obtaining, maintaining, and disposing of DEA restricted list I and List II chemicals.

(C) Procedure

(1) Authorized purchasers

An authorized purchaser is a university designee who has knowledge of the proper use of the list I chemical or list II chemical or is the legally authorized user of the chemical. According to 21 CFR 1310.07, “Each regulated person who engages in a regulated transaction must identify the other party to the transaction. For a domestic transaction, this shall be accomplished by having the other party present documents which would verify the identity or registration status of a registrant, of the other party to the regulated person at the time the order is placed.”

For purposes of research the Drug Enforcement Agency recommended that the department chairs (or designee) be the authorized signer for purchasing of list I and list II chemicals for their area(s) of responsibility.

A Drug Enforcement Agency (DEA) licensure (registration) is not required but is recommended for those authorized to purchase list I and list II chemicals. In lieu of a DEA licensure a chemical substance license can be obtained but again is not specifically required. A department chair (or designee) having a license referred to in this paragraph that is in good standing will be recognized as meeting the intent of this policy. A department chair (or designee) not having a license will be required to get institutional authorization before they may become an authorized purchaser/signer of these listed chemicals.

Each individual researcher does not have to register according to 21 CFR 1309.24 that states: "The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his or her business or employment."

(2) Redistribution

Employees of The University of Toledo are prohibited from redistribution of any list I or list II chemical. The Controlled Substances Act (CSA) requirements for a manufacturer, distributor, importer or exporter may apply and the regulations become far more burdensome.

(3) Record keeping

"Endusers" defined as physicians, professors, students, employees engaged in authorized research should maintain accurate records of the intake (amount received), use and purpose of the list I and list II chemicals. For example, iodine used to disinfect, each use would be difficult to measure, however recording the amount received, purpose and the number of estimated users, such as five students on a daily basis would be sufficient documentation. The signed and dated packing slip or a tamper evident log are examples of acceptable documentation. These records must be maintained for at least three years and be readily producible upon proper request.

(4) Disposal of list I and list II Chemicals

List I and list II chemicals will be disposed of in accordance with federal, state and university policy. Contact the department of health and safety at 419-383-5069 for the Health Science Campus and 419-530-3600 for the Main Campus for disposal of all chemicals. A record of this disposal including the date, the amount, and the signature of the department chair (or designee) is required and will also be maintained for three years in the same fashion as the intake records.

(5) Definitions

List I chemical is a chemical that, in addition to legitimate users, is used in manufacturing a controlled substance in violation of the CSA and is designated a list I chemical by the DEA administrator or congress. Chemicals in list I generally are precursors and have been determined by DEA to require a greater level of control than other listed chemicals. Anthranilic acid, ergotamine, piperidine, and drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine are examples of list I chemicals.

List II chemical is a chemical other than a list I chemical, that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the CSA and is designated a list II chemical by the DEA administrator or congress. Chemicals in list II are generally reagents and solvents.

- (6) Addendum A is the list I chemicals and addendum B is the list II chemicals.

<p>Approved by:</p> <p><u>/s/</u> Lloyd A. Jacobs, M.D. President</p> <p><u>May 25, 2010</u> Date</p> <p><i>Review/Revision Completed by: Senior Director of Research Administration, Compliance Officer</i></p>	<p>Policies Superseded by This Policy: <i>none</i></p> <p>Original effective date: May 25, 2010 Review/Revision Date: Next review date: May 25, 2013</p>
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APPENDIX A

List of Federal DEA List I Chemicals (per 21 CFR 1310.02(a))

Congress passed the Chemical Diversion and Trafficking Act (CDTA) in 1988 and subsequent amendments in 1993, placing under control 34 chemicals. These laws provide a system of regulatory controls and criminal sanctions to address both domestic and international diversion of important chemicals without interrupting access to chemicals destined for legitimate commerce. The CDTA created two categories for the controlled chemicals: List I & List II.

- (1) Anthranilic acid, its esters, and its salts**
- (2) Benzyl cyanide**
- (3) Ephedrine, its salts, optical isomers, and salts of optical isomers**
- (4) Ergonovine and its salts**
- (5) Ergotamine and its salts**
- (6) N-Acetylanthranilic acid, its esters, and its salts**
- (7) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers**
- (8) Phenylacetic acid, its esters, and its salts**
- (9) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers**
- (10) Piperidine and its salts**
- (11) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers**
- (12) 3,4-Methylenedioxyphenyl-2-propanone**
- (13) Methylamine and its salts**
- (14) Ethylamine and its salts**
- (15) Propionic anhydride**
- (16) Isosafrole**
- (17) Safrole**
- (18) Piperonal**
- (19) N-Methylephedrine, its salts, optical isomers, and salts of optical isomers (N-Methylephedrine)**
- (20) N-Methylpseudoephedrine, its salts, optical somers, and salts**

of optical isomers

(21) Hydriodic Acid

(22) Benzaldehyde

(23) Nitroethane

(24) Gamma-Butyrolactone (Other names include: GBL; Dihydro-2 (3H)-furanone; 1,2-Butanolide; 1,4-Butanolide; 4-Hydroxybutanoic acid lactone; gamma-hydroxybutyric acid lactone)

(25) Red Phosphorus

(26) White phosphorus (Other names: Yellow Phosphorus)

(27) Hypophosphorous acid and its salts (including ammonium hypophosphite, calcium hypophosphite, iron hypophosphite, potassium hypophosphite, manganese hypophosphite, magnesium hypophosphite, and sodium hypophosphite)

APPENDIX B

List of Federal DEA List II Chemicals
(per 21 CFR 1310.02(b))

Congress passed the Chemical Diversion and Trafficking Act (CDTA) in 1988 and subsequent amendments in 1993, placing under control 34 chemicals. These laws provide a system of regulatory controls and criminal sanctions to address both domestic and international diversion of important chemicals without interrupting access to chemicals destined for legitimate commerce. The CDTA created two categories for the controlled chemicals: List I & List II.

- 1) Acetic anhydride**
- (2) Acetone**
- (3) Benzyl chloride**
- (4) Ethyl ether**
- (5) Potassium permanganate**
- (6) 2-Butanone (or Methyl Ethyl Ketone or MEK)**

- (7) Toluene**
- (8) Hydrochloric acid (including anhydrous hydrogen chloride)**
- (9) Sulfuric acid**
- (10) Methyl Isobutyl Ketone (MIBK)**
- (11) Iodine**