



Document # CHE026-Controlled Substances Waste Management	Distribution: External
Section: Chemical Safety-Chemical Waste Management Program	Effective Date: 4/2023
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1. DESCRIPTION:

The purpose of this document is to provide guidance on the proper waste management of controlled substances at Temple University (TU). Proper use and disposal of DEA controlled substances is the responsibility of the individual (registrant) holding the DEA registration used to obtain them.

Damaged, expired, unwanted, unusable, or unreturnable controlled substances must be accounted for, stored, and disposed of in accordance with applicable state and federal regulations. The Drug Enforcement Agency's (DEA) Office of Diversion Control regulates the disposal of DEA controlled substances. Disposal of a controlled substance must render it "non-retrievable."

Controlled substances are materials containing any quantity of a substance with a stimulant, depressant, or hallucinogenic effect on the higher functions of the central nervous system and have the tendency to promote abuse or physiological or psychological dependence, as designated in state and federal controlled substances schedules.

This information applies to researchers with an active DEA research registration. Researchers who "orphan" controlled substances by abandoning or losing control of them are in violation of federal law.

EHRS is not authorized by the DEA to remove, dispose of or manage scheduled controlled substances.

Contact EHRS via ehrschem@temple.edu for questions on controlled substances waste management at the university.

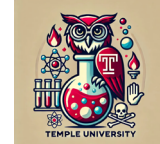
2. WASTE MINIMIZATION

The University encourages the following to minimize waste:

- Limit purchases of DEA scheduled controlled substances.

3. GENERAL REQUIRMENTS

The following must be completed prior to the disposal of any controlled substance:



- 3.1. Clearly label the substance for disposal as “Expired”
- 3.2. Segregate the substance labeled for disposal from the remainder of inventory within the secure storage location.
- 3.3. The registrant and a witness must be present to observe the waste disposal and to document the waste (initials) on any applicable forms or logs. Valid witnesses include:
 - 3.3.1. Authorized worker under DEA registrant.
 - 3.3.2. Department faculty or staff familiar with research
 - 3.3.3. Temple University Public Safety
- 3.4. Registrant Records of Controlled Substances Destroyed ([DEA Form 41](#)) must be completed prior to disposing of any controlled substance and a copy must be retained by the registrant.
- 3.5. Record the disposal on all applicable logs, and zero out the remaining balance.

Note: All DEA controlled substances must be accumulated and stored under lock and key according to the requirements of the DEA registration.

4. UNIVERSITY APPROVED DISPOSAL OPTIONS

Disposal of a controlled substance must render it “non-retrievable.” The DEA states that “‘non-retrievable’ shall permanently alter the substance’s physical or chemical condition or state through irreversible means and thereby render the substance unavailable and unusable for all practical purposes.”

There are three (3) university approved disposal options for controlled substances.

4.1. Reverse Distribution

For large quantities/volumes or schedule I controlled substances, contact a reverse distributor. This option transfers ownership of the controlled substance to a DEA-approved pharmaceutical returns processor for re-use, re-sale, or destruction at a hazardous waste incinerator. This process may involve the completion of DEA Form 222 or DEA Form 41 depending on the reverse distributor and the substances involved.

All reverse distributors have their own slightly different methods and requirements. The process typically involves most if not all the following:

- 4.1.1. Contact a DEA registered Reverse Distribution Vendor
- 4.1.2. Complete the vendors’ application for approval to ship the materials-in either paper form or sent by mail/fax in electronic form (both require DEA registration).
- 4.1.3. Additional forms-Completing a DEA form if necessary (for schedule I and II controlled substances)
- 4.1.4. Payment-payment or payment information is required with application.
- 4.1.5. Shipping-once authorized, items are packaged and shipped by the registrant via an approved

shipper (Fed-Ex or UPS usually).

4.1.6. Always request documentation of return/disposal/destruction.

4.1.7. Copies of all documents must be kept in file by the registrant and be available for review.

Reverse Distributor Vendor List

The following is a list of DEAs registered reverse distributors licensed to provide return/disposal services in the State of Pennsylvania:

- Chesapeake Waste Solutions – (717) 653-8882
- Clean Earth– (215) 822-8995 ext. 111
- Complete RX Returns DBA CRX – (570) 706-9589
- Pharmareturns – (215) 653-7400 ext. 114
- Republic Environmental Systems (Pennsylvania), LLC -
- Specialty Disposal Services Inc. SDS – (973) 402-9246

Contact the DEA local Field Division at 215-238-5160 for the most recent list of DEAs registered Reverse Distributors in PA.

4.2. On-Site Disposal Via Rx Destroyer

RX destroyer is the only approved method for the on-site disposal of controlled substances at the university. EHRS has reviewed this product and has found this product to be compliant with the DEAs controlled substance destruction requirements in accordance with Title 21 CFP Parts 1330.

4.2.1. Review DEA Form 41.

4.2.2. Render expired controlled substances non-retrievable (destroyed)

4.2.2.1. Read and follow the Rx Destroyer instructions.

4.2.2.2. Label the Rx Destroyer Container with a TU Hazardous Waste Tag and include accumulation start date.

4.2.2.3. Place the expired controlled substance(s) into the Rx Container with a witness present.

4.2.2.4. Triple rinse empty container and dispose of in Rx Destroyer.

4.2.3. Complete DEA Form 41 with a witness present

4.2.3.1. Must be completed for each date that expired controlled substance(s) is/are destroyed.

4.2.4. Submit the Rx destroyer for disposal via EHRS. Once the Rx destroyer container is full or all controlled substance marked for disposal are processed,

Note: [Rx Destroyer](#) is available for purchase through Fisher Scientific. Additional distributors can be provided by contacting RX Destroyer directly at (888)-608-5160.

4.3. Return to Original Supplier



Some suppliers will take back unopened controlled substances or dangerous drugs for credit. This process may involve the completion of manufacturer-specific return or recall transaction records or DEA Form 222 depending on the supplier and the substances involved.

Contact the local DEA Diversion Field Office to request assistance to dispose of the controlled substances.

5. EMPTY CONTAINER VIALS/SYRINGES

Residual amounts of **non-recoverable** waste may remain in the used (empty) syringes or vials after the administration or use of a controlled substance. If this waste cannot be drawn out with a syringe (i.e., is non-recoverable), you may deface and discard the empty-controlled substance container in a red biohazard sharps container. There is no need to record the disposal of the non-recoverable waste separately on the usage log if the container balance is zeroed out on the usage log upon disposal of that container.

6. LEAKAGE/SPILLAGE

If **recoverable** waste remains from container spillage (e.g., puddle on the bench top)

- 6.1. Place cleanup refuse (e.g., paper towels) from a spilled container into a biohazard bag for solid materials or a red biohazard sharps container for sharps.
- 6.2. Record spillage amount on the usage log **and** [DEA Form 41 \(link is external\)](#).

7. ORPHANED CONTROLLED SUBSTANCES

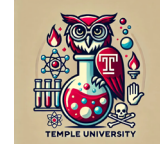
Maintaining accurate and current records of usage and maintaining a current DEA registration are critical for compliance with DEA regulations. Registrants who “orphan” controlled substances by abandoning or losing control of them are in violation of federal law.

In situations where “orphaned” or abandoned DEA substances are discovered, the department must make a concentrated effort to determine how these substances were originally obtained. Contact EHRS at 215-707-2520 if the original DEA registrant or department is unknown or not available.

8. TRAINING REQUIREMENTS

All university personnel who manage or generate this waste stream must complete the following training:

Course Name	Frequency	University personnel who generate:
Controlled Substance Training	Initial	Controlled Substance Waste



Chemical Waste Management for Laboratories	Initial and Annual	Regulated chemical waste in labs or research
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Refer to the [EHRS Training Webpage](#) to access training information and to determine any additional training requirements.

9. RECORDERKEEPING

Registrants must maintain all relevant disposal records with the following information:

- The registrant's DEA number, name, and address, if applicable
- If a reverse distribution is done, the reverse distributor's DEA number, name, and address.
- The number of units (in finished forms and/or commercial containers) disposed of in any manner, including the manner of disposal.
- The date when the products were sent for destruction and left the registrant's inventory.
- Any additional documentation recording the exchange of custody.

These records must be available for review upon request.

10. REFERENCES

The following resources served as substantive references to this document:

- Temple University Chemical Waste Management Program
- RX Destroyer (<https://www.rxdestroyer.com/>)
- [US Drug Enforcement Administration-Diversion Control Division](#)
- National Research Council. Prudent Practices in the Laboratory: Handling and Management of Chemical Hazards, Updated Edition (2011). National Academies Press, Washington, DC