

Michigan Technological University

Controlled Substance Guidelines

INTRODUCTION

The purpose of this program is to assist campus personnel in obtaining their controlled substance licenses, and to help them understand the requirements of managing their controlled substance inventory. Forms and advice will be provided both in this document and on a case-by-case basis.

Due to their potential for abuse, items identified by the United States Department of Justice, Drug Enforcement Administration (DEA), and the Michigan Department of Licensing and Regulatory Affairs (LARA), Board of Pharmacy as controlled substances are subject to extensive licensing, registration, storage, security, use, disposal, and inventorying requirements.

CONTROLLED SUBSTANCE DEFINITIONS

Controlled substances are drugs or other chemicals that have the potential to be addictive or habit forming. The Drug Enforcement Administration has divided controlled substances into 5 schedules based on their potential to be habit forming and usefulness in medicine as a drug, with I being the most severe and V being the most mild. For a more comprehensive listing, see the Drug Enforcement Agency (DEA) [Office of Diversion Control website](#).

A. Schedule I

These drugs, or other substances, have a high potential for abuse, no currently accepted medical use in the United States, and have an accepted lack of safety under medical supervision. They require a separate license from Schedules II-V.

B. Schedule II

These drugs or other substances have a high potential for abuse; currently have an accepted medical use in treatment in the United States, or a currently accepted medical use with severe restrictions. An example of a Schedule II drug that could potentially be used at Michigan Tech is pentobarbital.

C. Schedule III

These drugs or other substances have a potential for abuse less than Schedule I or II, with currently accepted medical use in treatment in the United States. Schedule III drugs may lead to moderate or low physical and high psychological dependence. Examples of Schedule III drugs that are in use at Michigan Tech include buprenorphine and ketamine.

D. Schedule IV

These drugs or other substances have a low potential for abuse relative to those listed in Schedule III. These drugs have currently accepted medical use in the United States, and abuse of them may lead to limited physical or psychological dependence relative to those in Schedule III.

E. Schedule V

These drugs or other substances have a low potential for abuse relative to Schedule IV. These drugs have currently accepted medical use in the United States, and abuse of them may lead to limited physical or psychological dependence relative to those in Schedule IV.

Violations of Controlled Substances laws, even when unintended, can lead to substantial civil and criminal liability.

CONTROLLED SUBSTANCES REGISTRATION

Controlled substance use requires registration with:

- A. The Federal Drug Enforcement Administration
- B. Michigan Department of Licensing and Regulatory Affairs
- C. Michigan Technological University

Specific, step by step instructions for applying with both the DEA and the State of Michigan can be found in Appendix A.

A. Federal Drug Enforcement Administration

Every person that engages in research with controlled substances must be registered with the Drug Enforcement Administration (DEA). There are different activities that require different registration types. Further, one registration type may not cover two different activities, such as research with controlled substances and dispensing of controlled substances.

B. The State Board of Pharmacy

In addition to the federal DEA paperwork, applicants in the State of Michigan must fill out and submit the Michigan Department of Licensing and Regulatory Affairs (LARA) Board of Pharmacy Application for Controlled Substance Research License. The State of Michigan requires this form to be filled out for every person who manufactures, distributes, prescribes, dispenses or conducts research with controlled substances.

C. Michigan Technological University

In order to maintain supervision of the Michigan Technological University Controlled Substances Program, each person that registers with the DEA and State of Michigan must also fill out a Michigan Technological University Notification of Controlled Substance Registration (Appendix B).

REGULATIONS

The regulations governing controlled substances include the following: United States Department of Justice, Drug Enforcement Administration, Controlled Substances Act, 21 C.F.R. Sections 1300 et. seq.; and the Michigan Public Act 368 of 1978 Part 73 et. seq.

The regulations are designed to ensure a system of security and accountability in the acquisition, use and disposal of controlled substances. They require license holders to document the receipt of controlled substances and their use until they are used to completion or properly disposed of. License holders are also required to maintain a list of individuals who are authorized to access the substances and the locations where controlled substances are stored.

In order to comply with the regulations, researchers must include the following in their policies for the use of controlled substances in their research.

1. The type of activity conducted. This includes buying, possessing, preparing dosage forms,

conducting research, etc.

2. The type and form of controlled substances handled. Examples: bulk liquids, usable powders, pills, etc.
3. The quantity of controlled substances handled.
4. The location where controlled substances are kept.
5. The type of vault, safe, or other storage system and the closures on such storage systems.
6. The extent of unsupervised public access to the facility. Prohibiting public access is recommended.
7. Supervision of employees having access to storage areas.
8. The procedures for handling visitors, maintenance personnel, and non-employee service personnel.
9. A system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances. This system must be demonstrated with actual forms.

RESPONSIBILITIES

A. Research Integrity

1. Provide guidance to campus personnel for registering with state and federal agencies.
2. Provide advice on storage of controlled substances.
3. Facilitate disposal of controlled substances.
4. Conduct yearly meetings with controlled substance license holders to ensure compliance.

B. Registered Controlled Substance User

1. Ensure compliance with Federal and State Laws.
2. Maintain proper record keeping for controlled substances.
3. Ensure controlled substances are stored in a way that will not lead to theft or misuse.
4. Report any theft or loss of controlled substances.
5. Properly dispose of controlled substances.
6. Properly document and supervise authorized users. See below.

AUTHORIZED USERS

The **registrant is responsible** for managing the controlled substances in accordance with the requirements of the regulations including inventory, record keeping and security provisions.

The registrant is required to screen potential authorized users and have them fill out a questionnaire prior to authorization of work with controlled substances.

Fill out one questionnaire (Appendix C) for each person who is authorized by the Principal Investigator (PI) to handle DEA controlled substances under that PI's supervision. Make copies of the form as needed

for each person who will be working with these substances. It is prudent to keep the number of authorized users as low as possible. The registrant is ultimately responsible for any mistakes that authorized users may make with regard to controlled substances.

Keep these questionnaires on file in the lab. All questionnaires should be kept for a minimum of two (2) years past the date the controlled substance is used up or disposed of. If controlled substances are in continuous use, then the questionnaire should be kept until two (2) years after the person is no longer actively involved in the laboratory.

POSSESSION OF CONTROLLED SUBSTANCES

ORDERING

A. Schedule II

Any person registered to conduct research with Controlled Substances in Schedule II must send, in triplicate, DEA order form # 222. This form is available only through the DEA.

[Instructions for requesting DEA Form #222](#)

Fax a copy of DEA Form #222 to the controlled substance distributor when placing your order.

B. Schedule I

Special permission is required from the Research Integrity office to use Schedule I drugs.

C. Schedule III-IV

Obtaining Schedule III-V Controlled Substances may be handled by invoicing normal records as stated in section VII of this document. **All controlled substances should be ordered through the ACF Director.**

CONTINUING RECORDS: INVENTORY PROCEDURES

Each person registered to handle Controlled Substances must maintain an inventory.

The inventory must be:

- Kept current
- Available for 2 years after the substance is completely used up or is disposed of
- Repeated annually

The inventory must have the following information:

A. For a controlled substance in finished form

An exact count of the dosage units must be made. Schedule II substances must be separated on the inventory from other substances. The inventory must include the following:

1. Name, address, and DEA registration number
2. Date the inventory was taken and whether it was at the beginning or end of the day
3. Name of substance
4. Size and strength of the substance
5. The number of units or volume of each commercial container

6. Signature and date

B. For each substance not listed above (i.e. damaged, defective or impure substances)

An exact count of the dosage units must be made, or the container must be graduated to reflect its content. Inventory shall include the following:

1. Name, address, and DEA registration number
2. Date the inventory was taken and whether it was at the beginning or end of the day
3. Name of substance
4. Total volume of substance
5. Reason for the substance being maintained by the researcher
6. Signature and date

SECURITY

Researchers are generally permitted to keep Controlled Substances in a securely locked, sturdy cabinet or safe.

DEA regulations state that:

- Schedules III-V, the Controlled Substance must be in a locked cabinet or safe.
- Schedules I and II, the Controlled Substance must in a locked cabinet, with the cabinet secured to a wall or otherwise not removable.

However, it is Michigan Tech policy that **all** controlled substances that do not require refrigeration are kept in a securely locked, sturdy cabinet or safe that is mounted to the wall.

If there is a theft or loss of a controlled substance contact Michigan Tech's Department of Public Safety and Police Services immediately (dial 911). In addition a [DEA form 106](#) must be submitted to the DEA and the State Administrator must be notified within 10 days of the discovery of the theft or loss.

DISPOSAL

When a registrant has controlled substances that are expired or unwanted one of the following protocols must be followed.

A. Use to completion/manufacture return

The preferred method of disposal of controlled substances is complete use of the substance such that there is none left to dispose. If there is excess material at the completion of research, contact the manufacturer to see if it is possible to send the controlled substances back. If the controlled substance is expired and you are using it in animal research, this method cannot be used.

B. Disposal through

Research Integrity

Required Information

To dispose of controlled substances, the registrant must contact Environmental Health and Safety (EHS) and provide the following information.

1. Name of contact person and phone number where they can be reached
2. Name of person under whom substances are registered with the DEA
3. DEA registration number
4. Location of controlled substances
5. Inventory of drugs to be destroyed including:
 - a. Name of drug with strength
 - b. Quantity of drug
 - c. Technical name of controlled substance

DEA Notification

DEA notification is no longer required. Instead, [DEA Form 41](#) should be filled out. This form is not required to be submitted to the DEA. However, the form must be available for **at least two years** from the date of destruction. Form 41 asks for the following:

1. Name, address and DEA registration number
2. Inventory of controlled substances to be destroyed
3. Exact place and date destruction is to take place
4. Method of destruction
5. Name of persons who will witness the destruction. Persons are required to be an employee of the institution.

Method of Destruction

- **Controlled substances that are not hazardous waste:**
 - Contact Environmental Health and Safety for assistance in determining the best disposal method.
- **Controlled substances that are hazardous wastes:**
 - All controlled substances that are considered hazardous waste will be disposed of through Environmental Health and Safety. **Do not** use the kitty litter method of disposal, or any other method of disposal, without first calling 7-2118. EHS will determine the best method of disposal and assist in the disposal of the substance.
 - Examples of controlled substance hazardous waste includes phenobarbital, and chloral hydrate.

Witnessing the Destruction

All efforts should be made to ensure that the registrant is on hand for the destruction. Besides the registrant, two witnesses are required. Both witnesses should be permanent employees of Michigan Technological University. One person must be a permanent employee from EHS. If possible, the second witness should be a public safety officer. Both persons should be present to witness the destruction and will be required to sign a statement of witness.

Appendix A: Instructions for Applying for a Controlled Substance License

How do I get both my DEA and State of Michigan controlled substance license/registration? Obtaining a license to use controlled substances is a relatively easy process, but it does take some time. You will need to get both a State of Michigan Controlled Substance Research License and a Drug Enforcement Administration (DEA) Controlled Substance Researcher Registration. You will need your State of Michigan Controlled Substance Research License number in order to get final approval from the DEA, so submit it first to get the process started. You do not have to wait until you receive the State of Michigan license number to submit the application for your federal DEA registration.

Procedures for Obtaining Both SOM License and DEA Registration

1. Obtain a State of Michigan license

- a. Applying for a State of Michigan Controlled Substance Research license is a two part process:
 - i. Follow the guidance provided at the [Michigan Controlled Substance Individual Licensing Guide](#) to complete the online [application form](#) at Michigan's Department of Licensing and Regulatory Affairs (LARA) Please note that you will have to register to create an account your first time:
 - ii. You will need the following supplemental information:
 1. Credentials to conduct the proposed research
 2. Protocol of the proposed research
 3. List of controlled substances & doses to be used
 4. Procedures for storage & security of drugs
 5. List of other staff/people involved, including students
 - iii. There is a fee.
 - iv. Criminal background check
 1. A criminal background check is part of this process. The State of Michigan will contact you with procedures for completing the fingerprinting and background check.

2. Obtain a DEA Registration

- a. You will need your State of Michigan Controlled Substance License Number to complete the DEA application. However, you should still fill out the application and submit it prior to receiving your State of Michigan Controlled Substance License Number.
- b. Drug Enforcement Administration Controlled Substance Registration Application
 - i. Complete the form for a [New Registration](#)
 - ii. Complete Form 225 for Researchers.
 - iii. There is a fee however, employees of the university qualify for the fee exemption. Your department chair can serve as the certifying official.

Please note: In all cases, a separate application must be filed with BOTH the DEA and the State of Michigan if you wish to work with Schedule I controlled substances.

Appendix B: Michigan Technological University Notification of Controlled Substance Registration

Please fill out this form when registering or renewing a DEA and State of Michigan Controlled Substance License.

Send to Kathy Halvorsen, Associate Vice President for Research Development, kehalvor@mtu.edu, 1-906-487-3098

Registrant Name:

Department:

Controlled Substance Registration Type (circle or indicate one):

Research Dispenser Analysis Instructional

If renewing:

Provide copies of your new license.

DEA License Number:

Expiration date:

Are there any changes in the controlled substances you will be using?

If yes, indicate:

Are there any changes in your Authorized Users?

If yes, indicate:

If registering:

Provide copies of both your DEA license and your State of Michigan License.

List the controlled substances you will be using:

Explain where and how the controlled substances will be stored and secured.

Provide forms that you will be using for inventory. Indicating that you will be using the forms provided in Michigan Tech's controlled substances guidelines is fine.

How many authorized users will you have? Do you have questionnaires filed for all of them?

Appendix C: Employee Questionnaire for Users Who Will Have Access to Controlled Substances

The Drug Enforcement Agency requires that any person who will have access to controlled substances as a result of employment at Michigan Technological University answer the following questions. Any false information or omission of information may jeopardize your position with respect to employment. Information furnished in this questionnaire or recovered as a result of any inquiry will not necessarily preclude employment but will be considered as part of an overall evaluation of your employment qualifications. The responses to this questionnaire will be held in the strictest of confidence.

- 1. Within the past five years, have you been convicted of a felony, or, within the past two years, any misdemeanor, or, are you presently charged with committing a criminal offense? Do not include traffic violations, juvenile offenses or military convictions, except by general court martial.

Yes _____ No _____

If yes, furnish the details of conviction, offense, location, date and sentence.

- 2. In the past 3 years, have you knowingly used narcotics, amphetamines, or barbiturates other than those prescribed to you by a physician?

Yes _____ No _____

If yes, furnish details.

I authorize Michigan Technological University to make inquiries of courts and law enforcement agencies for possible pending charges or convictions. I understand that Michigan State University will maintain fair employment practices, will protect my right of privacy, and will assure that the results of such inquiries will be treated in confidence. In addition, I acknowledge that I am aware of the rules and the restrictions associated with the use of controlled substances as outlined in both State of Michigan (Michigan Act 368 of 1978 Public Health Code: Article Seven Controlled Substances; Michigan Board of Pharmacy Administrative Rules: Controlled Substances) and federal regulations (Title 21 Code of Federal Regulations, Part 1300-1399; Title 21 United States Code (USC) Controlled Substances Act).

Employee Signature

Licensee/Registrant Signature

Employee Name (print)

Licensee/Registrant Name (print)

Date

Appendix D: Michigan Technological University Controlled Substance Usage Log

- Usage is tracked on a per dose (use) basis and the log balance must match the physical balance at all times.
- Complete one log sheet for each container.
- Record total quantity to the nearest metric unit weight or the total number of units finished form.
- Keep log in the controlled substance drawer.
- Send copy of log sheet to EH&S when the controlled substance has been used up. Deface the label and discard in trash.
- Retain for 3 years from the date of transfer to EH&S for disposal or the date of complete use.
- Breakage must be initialed by the individual responsible and co-signed by the PI.
- Report log discrepancies, suspected misuse, or theft to EHS immediately.
- Contact EHS for instructions if the controlled substance remaining is no longer needed.

<u>Principal Investigator:</u>		<u>Department:</u>
Product:	Purchase Order:	Container ID:
Substance:	Container Type:	Finished Form:
Schedule:	DEA Reg #:	Strength:
Storage Location:		Initial Amount:

Date	Amount Dispensed	Remaining Balance	Person Dispensing Substance (Print)	Reason for Use/Animal Protocol/Species