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Office of Indiana State Chemist  
 175 S. University St.  
 West Lafayette, IN 47907

Code:	SOP 0295-FD Rev. 01
Supersedes:	SOP 0295-FD Rev. 00
Issued Date:	12/05/2019
Effective Date:	01/14/2020



## STANDARD OPERATING PROCEDURE

### Controlled Drug Substances

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#### A. PURPOSE

The Drug Enforcement Administration (DEA) defines a controlled drug substance as any compound categorized in Title 21 of the Code of Federal Regulations, Part 1308 as a Schedule I, II, III, IV or V substance. The purpose of this Standard Operating Procedure (SOP) outlines the procedures used for the storage, accountability and disposal of controlled drug substances as well as record maintenance at the Office of Indiana State Chemist (OISC).

#### B. SCOPE

This procedure shall apply to all individuals involved in the sampling, handling, analysis or disposal of schedule I controlled drug substances. Refer to SOP 0282-FD [1] for the storage, handling, accountability and disposal of hemp.

#### C. PROCEDURE

##### 1. Definitions

- a. Hemp: Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol (THC) concentration of not more than 0.3 percent on a dry weight basis.
- b. Controlled Substance: a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V. The term does not include distilled spirits, wine, malt beverages, or tobacco.

##### 2. Storage and Security

- a. Controlled drug substances, upon receipt, must be placed into locked storage within OISC under the control of the Quality Assurance Director or Feed Chromatography Laboratory Supervisor.
- b. The hemp laboratory is a locked laboratory with access only by those who directly analyze, or audit the samples or records.
- c. All samples above 0.3% THC will be stored inside a combination locked freezer, or at ambient inside a key-locked safe. A lock-box may be used if separation of expired and non-expired controlled drug substances is required.
- d. Because the controlled drug substances received are in milligram or gram quantities, the safes, freezers, and lock boxes do not need alarms.
- e. Locked storage locations can be found in table 1.
- f. Combination locks will be changed upon termination of any employee with access to the combinations.
- g. Any copies of combinations or keys to locked storage boxes or safes will be stored in a push button combination key box in the hemp laboratory.

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### Controlled Drug Substances

- h. Prior to the analysis of hemp, samples will be stored in a locked air dryer. Key to the dryer is maintained by the Feed Chromatography Laboratory Supervisor, or an analyst assigned to the analysis of the samples [1].
- i. All controlled drug substance samples must be returned to a locked storage location the same day they were removed. Controlled drug substance samples must not be kept in any other location overnight.

**Table 1**

Locked Storage	Location	Lock Type
Refrigerator	OISC Hemp Laboratory	Combination
Freezer	OISC Hemp Laboratory	Combination
Safe	OISC Hemp Laboratory	Key
Cash Box	OISC Hemp Laboratory	Key
Locked Cabinet for Records	OISC Hemp Laboratory	Key

### 3. Authorized Users

- a. Anyone who has access to the handling of controlled substances, the locked box, or any key or combination to where controlled substances are stored is considered an authorized user.
- b. Prior to personnel becoming an authorized user for the handling of controlled substances, REMCS Form 6, Controlled Substance Program Security Release, must be completed.
- c. A background check for felony or misdemeanor drug violations must be performed and passed as negative findings for all personnel identified as authorized users.
- d. A list of authorized users must be documented on Authorized User List, REMCS Form 5.
- e. REMCS Form 5, Authorized User List must be updated when changes in personnel happen that affect the list.
- f. A copy of updated forms REMCS Form 5, Authorized User List will be sent to the REM Biosafety Officer.

### 4. Use of DEA Form 222 and Purchasing Controlled Substances

- a. OISC is registered with the DEA as an analytical laboratory. As a registered analytical laboratory, OISC receives pre-numbered DEA 222 carbon-copy forms. OISC is responsible for the disposition of every DEA 222 form received.
- b. DEA Form 222 is required for ordering schedule I or II controlled substances. OISC is authorized to handle Schedule I controlled drug substances.
- c. An inventory of all pre-numbered DEA 222 forms are kept on REMCS Form 4, Purdue University Record of DEA Form 222 Use.
- d. If there is a request for work or collaboration with OISC laboratories involving schedule I controlled substances, OISC, as the purchaser, must transmit a Form 222 to the individual requesting the work.



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## STANDARD OPERATING PROCEDURE

### Controlled Drug Substances

- e. No more than ten (10) items may be entered on each line of the DEA form 222. The total number of items must be indicated by marking out unused lines if less than ten.
- f. OISC, as the purchaser, fills-out the number of packages, size of the package and name of item. The purchaser must also record name and address of the supplier on the form.
- g. No alterations will be made on the form. If errors are made void and retain all copies of the partially used form, and use another DEA 222 form to provide the correct information.
- h. Only the DEA Registration License Holder is authorized to sign a DEA Form 222, unless a DEA prescribed power of attorney has been executed.
- i. The DEA license holder for OISC is the Quality Assurance Director.
- j. Copy 1 and copy 2 of the form must be submitted to the supplier, must not be separated, nor the carbon removed. OISC retains copy 3.
- k. Controlled substance samples must be received by an authorized user within 60 days of transmittal of the form.
- l. The Quality Assurance Director, or designee, must record on copy 3 the number of containers furnished for each item and the date each is received.
- m. Purchasing records must be kept and recorded on REMCS Form 2, Record of Controlled Substance Purchases. Records include, and must contain:
  - i. Copy 3 of DEA form 222
  - ii. Copy of invoice
  - iii. Copy of the shipping document
  - iv. Copy of the packing slip
  - v. Name, address and DEA registration number of company from which the controlled substance was purchased
  - vi. Name of controlled substance purchased
  - vii. Size and strength of the controlled substance purchased
  - viii. Amount purchased (which should match the amount received)
- n. The purchasing record(s) must be annotated with the handwritten date of receipt and initials of person receiving the controlled substance. The date written on this document(s) must match the date entered in the "Date Received" column of REMCS Form 2, Record of Controlled Substance Purchases.
- o. These records must be maintained per section C.8 Maintenance of Records even if a business office or purchasing department keeps all purchasing records.

#### 5. Inventory of Controlled Substances

- a. An inventory log is maintained on REMCS Form 1, Controlled Substances Physical Inventory found on the REM website.
- b. After initially receiving DEA registration, or if all controlled substances have been disposed, prior to receiving any new controlled substances, "Zero Inventory" must be documented on the REMCS Form 1, Controlled Substances Physical Inventory.

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## STANDARD OPERATING PROCEDURE

### Controlled Drug Substances

- c. DEA Requires inventory every two (2) years, however, REM requires annual inventory in addition to the requirements in the steps below.
- d. Every time a new controlled substances is brought in to the laboratory that is different from any controlled substance currently inventoried, an inventory must be completed. For example, Controlled Substance "A" is documented on the physical inventory form with the amount that was initially received. A month later Controlled Substance "B" is received which is different from Controlled Substance A. A complete inventory will be done upon receipt of Controlled Substance B, to record how much of Controlled Substance A is left, and the amount of the Controlled Substance B received.
- e. If any controlled substance amount is zero (0) it will be recorded as zero on the physical inventory form.
- f. All expired controlled substances will be included on the inventory, clearly marked as "expired" and kept in a separate locked box from useable controlled substances.
- g. A weigh-in and weigh-out procedure will be done every time a controlled substance is removed and replaced into locked storage. Follow weigh-in, weight-out procedures outlined in SOP 0282-FD, *Storage, Handling Accountability, and Disposal of Hemp at the Office of Indiana State Chemist* [1].

#### 6. Disposal

- a. Any hemp sample, once tested, found to be above 0.3% THC [2, 3] may be given to the individual holding the DEA registration for the Indiana State Police Laboratory. These samples will remain in locked storage until pick-up or shipment can be coordinated with the Indiana State Police Laboratory.
- b. It will be documented on form 47, Relinquishment of Controlled Substance Samples that these samples were given to the Indiana State Police Laboratory in addition to the DEA 222 form.
- c. For those samples, once tested, found to be above 0.3% THC that the Indiana State Police Laboratory do not want, disposal will be done through REM.
- d. It will be documented on Form 47, Relinquishment of Controlled Substance Samples that these samples were given to REM.
- e. REM will take custody of the samples and forward DEA Form 41 to DEA with a projected two-week disposal date.
- f. REM will contact a police witness to be onsite during the disposal.
- g. Never dump controlled substances down a drain or dispose without police witness.
- h. Form 47, Relinquishment of Controlled Substance Samples will include the sample number, percent THC level of the sample, and final gross weight of the sample.
- i. Weight of samples must be taken at room temperature. Samples will be moved from sub-ambient storage to the safe in order for them to equilibrate to room temperature prior to weighing.
- j. Form 47, Relinquishment of Controlled Substance Samples is considered a critical controlled paper form [4]



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### Controlled Drug Substances

#### 7. Theft or Significant Loss

- If controlled substances samples are found missing, both REM and DEA will be notified upon discovery of the missing samples. Notification should occur immediately upon discovery and without delay. A CAPA will be issued to investigate the circumstances of the missing sample(s).
- DEA form 106, Report of Theft or Loss of Controlled Substances, should be used to detail the circumstances of the theft or significant loss in conjunction with the CAPA.
- If significant loss occurs, both REM and DEA will be notified. It will be decided whether the loss should be documented on a DEA form 106 or on a REM form. Notification should occur immediately upon discovery and without delay and a CAPA issued.
- Notification of local law enforcement may also occur.
- If a sample is spilled where significant loss occurs, the sample will be weighed after the loss and documented, with an explanation of the loss, on REM form 1, Controlled Substances Physical Inventory.

#### 8. Maintenance of Records

- Forms, and any records pertaining to controlled substances, will be maintained via Table 2.

**Table 2**

Document	Storage Location	Retention	Maintained By
REMCS Form 1, Controlled Substances Physical Inventory	OISC Hemp Laboratory	5 years	Authorized Users
REMCS Form 2, Record of Controlled Substance Purchases	OISC Hemp Laboratory	5 years	Authorized Users
REMCS Form 4, Purdue University Record of DEA Form 222 Use	OISC Hemp Laboratory	5 years after last record is used	Authorized Users
REMCS Form 5, Authorized User List	OISC Hemp Laboratory	5 years	After 5 years moved to individual training files, indefinitely by the QA Unit
REMCS Form 6, Controlled Substance Program Security Release	OISC Hemp Laboratory	5 years	After 5 years moved to individual training files, indefinitely by the QA Unit
Additional Records, including purchasing records	OISC Hemp Laboratory	5 years	Authorized Users
DEA Form 41	OISC Hemp Laboratory	5 years	QA Director
DEA Form 222	OISC Hemp Laboratory	5 years	QA Director



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### Controlled Drug Substances

#### D. REFERENCES

1. SOP 0282-FD, *Storage, Handling, Accountability and Disposal of Hemp at the Office of Indiana State Chemist*, OISC
2. MTD 0500-FD *Analysis of Delta-9-Tetrahydrocannabinol in Hemp by Gas Chromatography*, OISC
3. MTD 0502-FD *Analysis of Delta-9-Tetrahydrocannabinol in Hemp by Liquid Chromatography*, OISC
4. SOP 0275-GN, *Paper Form Control*, OISC

#### D. FORMS

1. REMCS Form 1, Controlled Substances Physical Inventory, REM
2. REMCS Form 2, Record of Controlled Substance Purchases, REM
3. REMCS Form 4 Purdue University Record of DEA Form 222 Use, REM
4. REMCS Form 5, Authorized User List, REM
5. REMCS Form 6, Controlled Substance Program Security Release, REM
6. Form 47 Relinquishment of Controlled Substance Samples, OISC
7. DEA Form 222
8. DEA Form 41
9. DEA Form 106

#### E. REVISION

1. Revision 00 on 10/07/2019: Initial Issuance.
2. Revision 01 on 01/14/2020

Change	Justification
a. Removed reference to room numbers of hemp laboratory	For security purposes
b. Made editorial changes	NA

