

Knoxville Campus Policy: SALS030-K - Controlled Substances	
Version 1	Effective Date: 07/16/2018

Environmental Health & Safety

Controlled Substances

UTK Environmental Health & Safety Program LS-030

The purpose of this document is to ensure that researchers planning work with controlled substances are aware of and understand their responsibility for complying with the relevant state and federal statutes and regulations governing the use of these substances.

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Purpose

The acquisition, use and disposal of controlled substances in the state of Tennessee are strictly regulated by the Tennessee State Board of Pharmacy and the United States Department of Justice Drug Enforcement Administration (US DEA). These regulations are intended to prevent diversion of controlled substances. The purpose of this document is to ensure that researchers planning work with controlled substances are aware of and understand their responsibility for complying with the relevant state and federal statutes and regulations governing the use of these substances.

Scope and Applicability

This document applies to the use of controlled substances in research conducted under the auspices of the University of Tennessee Knoxville campus (the "University"), including all in vivo research under IACUC-approved protocols and in vitro research.

Any individual who uses or synthesizes controlled substances for research under the auspices of the University must be: (a) licensed with the Tennessee State Board of Pharmacy and registered with the US DEA (a "Licensed Individual") to conduct such research; or (b) authorized under the license of a Licensed Individual with respect to such research.

The University does not hold an "institutional license" for use of controlled substances in research. Even if an individual already has a practitioner's (clinical) license and DEA registration for treatment of patients with controlled substances, if he or she will also be conducting laboratory or non-therapeutic research involving controlled substances, a separate research license from the Tennessee State Board of

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Pharmacy is required. In addition, for research with Schedule I a drug, a separate registration with the DEA is required.

Abbreviations and Definitions

Abbreviations

DEA: U.S. Drug Enforcement Administration

PI: Principal Investigator

Definitions

Controlled Substance: Controlled substances are drugs that are regulated by state and federal laws that aim to control the danger of addiction, abuse, physical and mental harm, the trafficking by illegal means, and the dangers from actions of those who have used the substances. Such drugs may be declared illegal for sale or use, but may be dispensed under a physician's prescription.

The Controlled Substances Act (CSA), Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, is the legal foundation of the federal government's fight against the abuse of drugs and other substances. This law is a consolidation of numerous laws regulating the manufacture and distribution of narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals used in the illicit production of controlled substances.

Licensed Individual: the person ultimately responsible for controlled substance research compliance. Typically, the Licensed Individual is the Principal Investigator of a research protocol.

Other Authorized Individual: – a member of the Licensed Individual's staff authorized to work with controlled substances under the Licensed Individual's license/registration

Roles and Responsibilities

Licensed Individual

The responsibility for controlled substance research compliance rests with the Licensed Individual. Typically, the Licensed Individual is the Principal Investigator of a research protocol. The Licensed Individual is responsible for obtaining and renewing both the DEA registration and the TN State Board of Pharmacy license and for assuring that all acquisition, storage, security, inventory, disposal and record-keeping requirements are met.

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Other Authorized Individual

The Licensed Individual may authorize members of his or her staff to work with controlled substances under the Licensed Individual's license/registration ("Other Authorized Individuals"). However, the Licensed Individual retains overall responsibility for meeting all regulatory requirements. Other Authorized Individuals must be listed on the Licensed Individual's controlled substance protocol submitted with the license application, as set forth in section D(1)(b)(ii) above. Licensed Individuals may not name as Other Authorized Individuals any person who: (i) has been convicted of a felony offense relating to controlled substances; or (ii) at any time, has had an application for registration with the DEA denied, a DEA registration revoked or has surrendered a DEA registration for cause.

The Office of Research

The Office of Research staff will be responsible to aid all researchers and PIs maintain compliance with the program through training sessions, guidelines, consultations and inspections. The Office of Research staff will also escort the DEA inspectors during their inspections of labs and act as a liaison between the inspectors and the PI or lab staff.

Procedures

Drug Schedules

Drugs, substances, and certain chemicals used to make drugs are classified by the DEA into five (5) distinct categories or schedules depending upon the drug's acceptable medical use and the drug's abuse or dependency potential. The abuse rate is a determinate factor in the scheduling of the drug; for example, Schedule I drugs are considered the most dangerous class of drugs with a high potential for abuse and potentially severe psychological and/or physical dependence. As the drug schedule changes—Schedule II, Schedule III, etc., so does the abuse potential—Schedule V drugs represents the least potential for abuse. A Listing of drugs and their schedule are located at Controlled Substance Act (CSA) Scheduling or CSA Scheduling by Alphabetical Order. These lists describes the basic or parent chemical and do not necessarily describe the salts, isomers and salts of isomers, esters, ethers and derivatives which may also be classified as controlled substances. These lists are intended as general references and are not comprehensive listings of all controlled substances.

Please note that a substance need not be listed as a controlled substance to be treated as a Schedule I substance for criminal prosecution. A controlled substance analogue is a substance which is intended for human consumption and is structurally or pharmacologically substantially similar to or is represented as being similar to a Schedule I or Schedule II substance and is not an approved medication in the United

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States. (See 21 U.S.C. §802(32)(A) for the definition of a controlled substance analogue and 21 U.S.C. §813 for the schedule.)

Schedule I

Schedule I drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse. Schedule I drugs are the most dangerous drugs of all the drug schedules with potentially severe psychological or physical dependence. Some examples of Schedule I drugs are:

heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), 3,4-methylenedioxymethamphetamine (ecstasy), methaqualone, and peyote

Schedule II

Schedule II drugs, substances, or chemicals are defined as drugs with a high potential for abuse, less abuse potential than Schedule I drugs, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous. Some examples of Schedule II drugs are:

cocaine, methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), fentanyl, Dexedrine, Adderall, and Ritalin

Schedule III

Schedule III drugs, substances, or chemicals are defined as drugs with a moderate to low potential for physical and psychological dependence. Schedule III drugs abuse potential is less than Schedule I and Schedule II drugs but more than Schedule IV. Some examples of Schedule III drugs are:

Combination products with less than 15 milligrams of hydrocodone per dosage unit (Vicodin), Products containing less than 90 milligrams of codeine per dosage unit (Tylenol with codeine), ketamine, anabolic steroids, testosterone

Schedule IV

Schedule IV drugs, substances, or chemicals are defined as drugs with a low potential for abuse and low risk of dependence. Some examples of Schedule IV drugs are:

Xanax, Soma, Darvon, Darvocet, Valium, Ativan, Talwin, Ambien

Schedule V

Schedule V drugs, substances, or chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes. Some examples of Schedule V drugs are:

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cough preparations with less than 200 milligrams of codeine or per 100 milliliters (Robitussin AC), Lomotil, Motofen, Lyrica, Parepectolin

Some of the controlled substances used in research and their schedule numbers and DEA codes are:

Substance	Schedule	Narcotic?	DEA Code
Ketamine	III	N	7285
Pentobarbital (e.g., Nembutal)	II	N	2270
Buprenorphine	III	Y	9064
Fentanyl	II	Y	9801
Diazepam	IV	N	2765
Pentobarbital & non-controlled active ingredients (e.g., B-Euthanasia)	III	N	2271

A complete list of DEA controlled substances is found at:

http://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf

Researcher Licensing and Registration

Authorization for acquisition of controlled substances for research is a two-step process: (a) licensing with the Tennessee State Board of Pharmacy; and (b) registration with the US DEA.

Controlled Substances Licensure

Authorizations are required prior to the use of controlled substances in animals. To obtain and use controlled substances such as certain common analgesics or anesthetics (e.g., buprenorphine, ketamine, pentobarbital) it is necessary to have appropriate federal Drug Enforcement Agency (DEA) registration, which in turn requires prior licensure by the Tennessee State Board of Pharmacy.

To initiate the process, download and complete the state form (available at https://www.tn.gov/content/dam/tn/health/documents/Researcher_Application.01-2017.pdf). This will require a concise description of the planned research use of the drug, a plan for secure storage, as well as payment of a fee. Once a state license number has been obtained the federal registration can be initiated (http://www.deadiversion.usdoj.gov/drugreg/reg_apps/index.html).

In the Tennessee Legend Drug and Controlled Substance Research Act of 1984 (See 53-14-104 License/Required/Application/Fees) it states:(a) No person shall manufacture, obtain, possess,

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administer or dispense a legend drug or controlled substance for the purpose of scientific research, chemical analysis, instruction or training of detection animals without having first secured a license to do so from the director. This means that even if a physician investigator maintains appropriate licensure for controlled substances used in his/her medical practice, (s)he must obtain research licensure from the Tennessee State Board of Pharmacy to use these substances in research involving animals and/or must modify his/her state license to include the use of controlled substances in the research setting.

Clinical Researchers Obtaining Controlled Substance for Use in Research

Some clinicians may be using their practice license to secure controlled substances for research purposes. All personnel responsible for procuring control substances for research purposes must obtain researcher licensure from the State Board of Pharmacy. Non-clinical research personnel are already required to obtain State licensure before obtaining controlled substances for use in research. The URL for information is: https://www.tn.gov/content/dam/tn/health/documents/Researcher_Application.01-2017.pdf

TN State Board of Pharmacy 53-14-104. License Required Application Fees.

- No person shall manufacture, obtain, possess, administer or dispense a legend drug or controlled substance for the purpose of scientific research, chemical analysis, instruction or training of detection animals without having first secured a license to do so from the director.
- An application for the license shall be submitted on the prescribed form, and shall be accompanied by:
 - A nonrefundable fee of thirty dollars (\$30.00), or in an amount set by the board;
 - Copies of all papers and materials filed with any state or federal governmental agency in connection with the applicant's proposed project; and
 - A detailed protocol, in triplicate, setting forth:
 - The nature of the proposed project;
 - The qualifications of the applicant to engage in the project;
 - The proposed quantity of each drug involved;
 - The measures proposed to provide for security and proper record-keeping of the drugs;
 - Specific provisions for the safe administration or dispensing of drugs to humans, if contemplated, and the proposed method for selecting the humans; and

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- Other information the commissioner may require.
 - [Acts 1984, ch. 717, § 4; 1990, ch. 1026, § 14.]
 - 53-14-102. Exemption from chapter. –
- This chapter shall not apply to:
 - A licensed physician, dentist or veterinarian lawfully administering, dispensing or prescribing a legend drug or controlled substance in the course of the individual's professional practice to an ultimate user for a recognized medical purpose; or
 - A manufacturer or distributor whose research protocol has been approved by the federal food and drug administration under that agency's auspices, or otherwise subject to jurisdiction of the federal food and drug administration and if lawful under that jurisdiction. [Acts 1984, ch. 717, § 2.]

US DEA registration

1. The US DEA registration requires inclusion of the licensee's state license number and identification of the controlled substances used. Note that for work with Schedule I substances, applicants must attach three copies of a more detailed Schedule I Controlled Substance Protocol. A Schedule I Controlled Substance Protocol template is attached as Appendix B.
2. The registration application, DEA Form 225, is available at https://www.deadiversion.usdoj.gov/drugreg/reg_apps/225/225_form.pdf . Registration procedures, including detailed instructions on form submission, are available here: <http://www.deadiversion.usdoj.gov/drugreg/process.htm>. Persons who are already registered with DEA as a medical practitioner are not required to obtain an additional DEA registration for research involving any drug in Schedules II-V if this clinical registration is being actively used to prescribe drugs to patients.
3. For any research involving Schedule I drugs, a researcher's registration (DEA Form225) is required for all researchers, including medical practitioners who are already registered with DEA. Upon receipt of a registration application, the DEA may schedule a telephone interview or an on-site inspection.
4. New registrants must complete their initial inventory of controlled substances immediately upon receipt of their DEA registration, on the first day of business after registration. See Section H(4). In most cases, this initial inventory will show zero quantities.
5. DEA registration must be renewed annually, except for the practitioner's (clinical) registration described in paragraph (b) above, which must be renewed every three years.

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Procurement of Controlled Substances

Purchasing may require additional information from the registrant in the case of initial orders and amendments to initial orders for use of controlled substances in research (see 21 CFR 1301.18 and 1301.32). For Schedule I and II drugs, the request will include a completed DEA form 222.

Registrants may only order/purchase controlled substances within a given class specified on their registration. For example, if the registrant is approved for the use/purchase of schedule II non-narcotic drugs (e.g. Nembutal) that does mean that he/she can also purchase a schedule II narcotic drug (e.g. Fentanyl) not specified on the DEA application. The registrant would need to go through the DEA and the TN State Board of Pharmacy first to get this approved. Registrant must verify the accuracy of a shipment of Controlled Substances from a supplier immediately upon receipt. Discrepancies must be reported to the DEA, UT Police, the Office of Research, and the supplier upon discovery.

Payment of Fees

It is the responsibility of the registrant to pay any required registration and licensure fees. Current information on the fee for annual renewal of the DEA registration is found at <http://www.deadiversion.usdoj.gov/drugreg/categories.htm>

In addition, the registrant will be responsible for paying any disposal fees associated with discarding controlled substances.

Storage and Security:

Controlled substances shall at all times be properly safeguarded and securely kept at the address on file with the DEA and which corresponds with the information indicated in the ordering of the controlled substances. Adequate security and storage must be provided and access to such storage must be limited to Licensed and/or Other Authorized Individuals. Security requirements vary depending on: (1) whether the storage is for working stocks or reserve or main stocks; and (2) the schedule of controlled substance.

- Working Stocks – appropriate for most individually licensed Principal Investigators.
 - Schedule I-IV controlled substances shall be kept in stationary (typically built in a wall), locked double cabinets. Both cabinets must have key-locked doors with separate keys; spring locks or combination locks are not acceptable.
 - Schedule V controlled substances shall be stored in a stationary, securely locked cabinet of substantial construction.
- Reserve or main stocks – generally restricted to activities carried out under institutional licenses or when more than one Principal Investigator will ultimately receive the material.

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- Schedule I and II controlled substances shall be stored in a GSA class 5 rated steel cabinet or equivalent safe approved by the DEA. Any cabinet or safe weighing less than 750 pounds shall be bolted or cemented to the floor or wall in such a way that it cannot be removed. The door of the cabinet or safe shall contain a multiple position combination lock, a relocking device or the equivalent, and steel plate having a thickness of at least one-half inch.
- Schedule III, IV and V controlled substances shall be stored in a securely locked cabinet of substantial construction.

Reporting Loss, Theft, or Unauthorized Use

Each incident or alleged incident of possible theft, loss or diversion of a controlled substance must be immediately reported to the Licensed Individual and to UT Police. Thereafter, the Licensed Individual must promptly report the incident to the TN State Board of Pharmacy. Finally, the Licensed Individual must report to DEA the theft or significant loss of any controlled substances within one business day of discovery.

Each agency has its own form that must be used for this reporting. Links to the forms are available at https://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html

Authorizing Other Users

The registrant may request that additional UT employees who are supervised by the registrant (within the same department and registered physical location) be authorized to use the substances for approved activities. The registrant must first screen these employees prior to authorization, as described at 21 CFR 1301.90. The registrant should maintain a log book of who has access to controlled substances in their lab, and the substances and amounts used.

Spills

Breakage, spills, or other witnessed controlled substance losses do not need to be reported as lost. This type of loss must be documented by the registrant and witness on the inventory record. Controlled substances that can be recovered after a spill, but cannot be used because of contamination (tablets), must be placed in the disposal/destruction waste stream (Completion of DEA Form 41 required). If the spilled controlled substance is not recoverable (liquids); the registrant must document the circumstances in their inventory records and the witnesses must sign.

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Training and Information

The University requires all Licensed Individuals and Other Authorized Individuals to complete an initial Controlled Substances Acquisition, Use and Disposal training. The training must be renewed triennially. The Office of Research will oversee the training development and delivery of this program.

Record Keeping

The controlled substances regulations require significant record keeping at every point, including initial receipt, use, and disposal.

The licensed individual is responsible for maintaining this documentation with respect to controlled substances used for his or her research. The records must be easily produced in the event of an inspection by the TN State Board of Pharmacy, or the DEA. All signatures in the Inventory and records must be legible and dated.

Initial receipt documentation

An initial inventory shall include:

- Whether the inventory was taken at the beginning or close of business;
- The name of the substance;
- Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);
- The number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and
- The number of commercial containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter vials).

Damaged, defective, expired, or impure substances awaiting disposal must also be inventoried including name, total quantity, and the reason why the substance is being maintained.

In determining the number of units of a controlled substance in a commercial container that has been opened, the registrant shall, if the substance is listed in Schedule I or II, make an exact count or measure of the contents. If the substance is listed in Schedule III, IV or V, the registrant may make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he/she must make an exact count of the contents.

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After the initial inventory, a new inventory must be taken by the registrant at least every two years. The biennial inventory date must be within two years of the last inventory.

Initial and biennial inventories must be maintained by each registrant and kept at the location where the substances are stored. Initial and biennial inventories must be kept for two years from the date the inventory was conducted.

It is the registrant's responsibility to ensure that databases are up to date. As far as the DEA is concerned, **the registrant, not the institution, is solely responsible for ensuring that any rules and regulation pertaining to the use of controlled substances are implemented.**

Use Documentation

Use documentation must include the name of the Licensed Individual, the date, type and quantity of drug and signature of the Licensed Individual or Other Authorized Individual using the controlled substance.

In addition, such records shall include the following information for each controlled substance:

1. Name of substance.
2. Each finished form (such as 10 mg. tablet, or 10 mg. concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container.
3. The number of commercial containers of such finished form received from other persons, including the date of and number of containers in each receipt, and the name, address, and registration number of the person from whom the containers were received.
4. The amount of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, and the written or typewritten name or initials of the individual who dispensed or administered the substance.
5. The number of units or volume of the finished form and/or commercial containers disposed of in any other manner by the researcher, including the date and manner of disposal.

Biennial Inventory Documentation

An inventory of the stock of controlled substances at all locations where controlled substances are present must be recorded on the day after the DEA registration is received, when research with/possession of controlled substances begins and then biennially thereafter. The inventory must specify whether it was taken at the open or close of business on that day.

1. A separate entry must be made with respect to each kind of substance or preparation, and each kind or size of package.

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2. Each entry shall show the name, quantity and content of controlled substance and the size of the individual package, the number of packages and the total content of all packages covered by the entry on hand as of the date of the inventory.
3. This biennial inventory must be retained on file with other controlled substances records.

Record Retention

All controlled substance records shall be readily available and maintained at the premises where the licensed activity is conducted. Inventories and records of controlled substances listed in Schedules I and II, including DEA Form 222, shall be maintained separately from other controlled substance records of the Licensed Individual.

All records must be maintained by Licensed Individuals for a period of at least **five years** from the date of the last recorded purchase, transfer, use, or other transaction involving the controlled substance.

Disposal and Transfer of Controlled Substances Inventories

Licensed individuals are responsible for documenting the disposal of controlled substances. Registrants leaving UT must notify the Office of Research 30 days prior to their termination of employment so that records can be reconciled and unused controlled substances can be disposed of properly or transferred in a timely manner to the inventory of another licensed individual at UT. If one licensed individual transfers Controlled Substances to another licensed individual, the transfer must be documented to the Office of Research and all inventory records and other records pertaining to the inventory must be transferred to the next licensed individual responsible for the controlled substances.

In the event of death or extended absence of a licensed individual, the licensed individual supervisor must notify the Office of Research, which will either arrange for disposal of them, or work with the Registrant's school to arrange for another Registrant to assume responsibility for them.

Diversions, Theft or Loss of Controlled Substances

Anyone having knowledge or reasonable suspicion of inventory irregularities or diversion, theft or loss of controlled substances from a registered location or other site has an obligation to report such information to UT Police, the Office Research, and the licensed individual (if the licensed individual is not the person reporting). The licensed individual shall notify the DEA Field Division Office of any theft or significant diversion or loss of any controlled substances upon discovery of the theft, loss, or diversion.

Oversight

The Office of Research will review each licensed individual's management of controlled substances and compliance with this policy at least once every 12 months. More frequent reviews are at the Office of Research discretion. More frequent reviews may be initiated due to concerns about compliance with

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this policy and the law, and also may be requested by a licensed individual, or a licensed individual's supervisor, department head or dean, if there are concerns about compliance with this policy.

Disposal

Licensed Individuals should make every effort to limit the amount of controlled substances requiring disposal by monitoring expiration dates and ensuring use of controlled substances within the appropriate timeframe, as well as limiting purchase/storage of controlled substances to appropriate quantities (e.g., sufficient to support the equivalent of 3-months of research). Disposal and/or surrender of controlled substances must be in accordance with applicable laws and regulations

- If controlled substances expire or otherwise require disposal, the Licensed Individual should contact a Reverse Distributor and arrange for the documented return of the controlled substances through a reverse distribution process.
- When controlled substances cannot be surrendered to a Reverse Distributor, the Licensed Individual must seek permission from the DEA to destroy on-site.
 - In addition, in accordance with 21 C.F.R. § 1307.21, DEA Form 41 must be filed. DEA
- Form 41 is an on-line form that may be completed at
- http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/index.html.
 - Controlled substances may be destroyed on-site or surrendered only with the permission of DEA and in accordance with their respective regulations.
- All controlled substances must remain securely stored in accordance with the "Storage" section of this Policy while awaiting DEA approval for disposal.
- If controlled substances are discovered for which registration cannot be ascertained, please contact the Office of Research for guidance.
- Any person disposing of a controlled substance must maintain written records containing:
 - Date of return or destruction;
 - Name, form, quantity of the substance returned or destroyed;
 - Name, address, registry number of the person making the return;
 - Name, address, registry number of the supplier or manufacturer to whom the substances are returned or the name and license number of the persons performing and witnessing the destruction.

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Abandonment

Under no circumstances are controlled substances to be abandoned by a registrant. However, occasionally, licensed individuals will leave without appropriately disposing or transferring all controlled substances from their lab or other location. Under these circumstances, the department or unit head responsible for that location will, in lieu of the registrant, need to follow the procedure outlined under “Disposal” above.

References

Title 21, Part 1306 of the Code of Federal Regulations (CFR): Controlled Substances Act

Disclaimer

The information provided in these guidelines is designed for educational use only and is not a substitute for specific training or experience.

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Appendices

[LS-030 Controlled Substances \(full document download pdf\)](#)

[Appendix A: Controlled Substances Purchase Request](#)

[Appendix B: DEA Biennial Controlled Substance Inventory Form](#)

[Appendix C: Initial Controlled Substance Inventory Form](#)