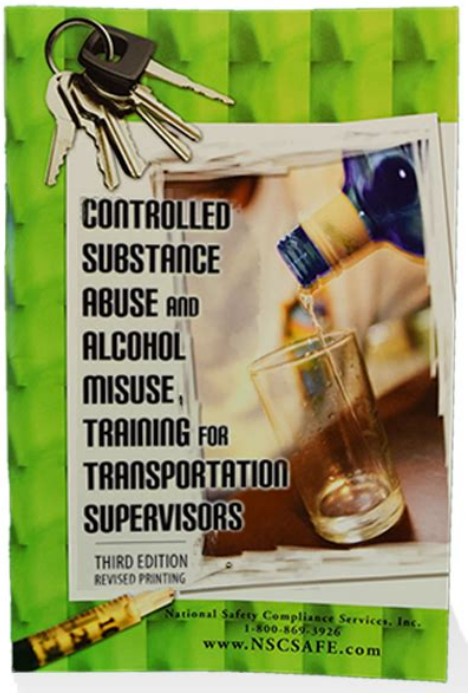
Controlled Substances Training Manual



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Book Descriptions:

Controlled Substances Training Manual

Controlled substances may be present in substrates that include powders, solid materials, liquids, plant material, mushrooms, blotter paper, and food items. In addition, the section examines pharmaceutical preparations in the form of tablets, capsules, injectables and transdermal patches. Controlled Substances examiners will also analyze evidence that is related to the suspected clandestine manufacture of controlled substances. Except as noted below under “Exceptions,” the DVR Pharmacy is the only organization authorized to acquire controlled substances and Drug Enforcement Agency DEA regulated chemicals for nonhuman use for the NIH Institutes and Centers ICs. All controlled substances, including vendor samples and those supplied by other ICs, shall come through the DVR Pharmacy. All Intramural NIH personnel and organizations involved in the nonhuman use of controlled substances and DEA regulated chemicals are subject to the provisions of this policy. The above organizations shall develop internal policies and procedures governing controlled substances which are consistent with the policies and procedures contained herein. The alternate performs the duties of the NIH CSO in the absence of the NIH CSO. There may be no more than two alternates in each IC. The assigned number will be affixed to the inside of the controlled substance lock box or safe. Examples a three ring binder, a file folder, a Ziploc bag, a plastic page protector, a pocket page or folder paper or plastic. Do not put more than two folds in a record page. Do not attach them by rubber band to the controlled substance. Instead, place both in the same Ziploc bag or page protector. The database will contain a record for each substance dispensed. The record will include the name of the substance, quantity dispensed, lock box number, and CS Custodian responsible. The database will also contain the inventory of substances in the DVR Pharmacy; and will include a record for each item received.http://www.s-energokomplekt.ru/userfiles/how-to-perform-performance-testing-manually.xml

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The NIH CSO checks that training has been completed prior to the appointment of a new CS Custodian. At the time of the annual inventory the list of CS Custodians is checked against the data base maintained in the pharmacy. The IC CSPC reviews the request and justification of need to ensure its validity.Assisting the NIH CSO in conducting the inventory sooner, if there is an issue. In high volume areas more frequent physical inventories may be necessary. CS Custodians shall review the completed form for accuracy and obtain funding and approval signatures prior to submitting the form to the IC CSPC. Note If the items under procurement are not stocked by the DVR Pharmacy, possible sources must be included in the appropriate areas of the form. Only these individuals will be authorized to place and approve such orders and contracts. Officials who order controlled substances may not receive delivery of those controlled substances. The DVR Pharmacy will issue a corresponding Form NIH 27652 “Controlled Substance Record for Nonhuman Use”, with each controlled substance. The forms must be accessible for review and recording at all times. When recording the use of a controlled substance, a line entry is made on the form, using one line per procedure or animal treated. Entries on the NIH Form 27652 “Controlled Substance Record for Nonhuman Use” shall be made by the individual withdrawing the drug from the lock box or safe at the time the item is withdrawn. Units of measure must remain constant on an individual CS Record and accurately reflect the amount of controlled substance in stock example mg, ml, tablet count, or

gm. When a group of animals of the same species without individual charts or identification numbers are treated at the same time, with the same dose, for the same purpose, a oneline entry can be made for the entire group, and; 3 when no animal is involved, describe the in vitro use of the substance.http://andaautoparts.com/upload/how-to-perform-stress-testing-manually.xml

Each line entry shall include the date, description of the circumstances, the signatures of two individuals witnessing the destruction of the substance, the quantity involved and the current balance. When a dose is withdrawn from the lock box and recorded on the NIH Form 27652 “Controlled Substance Record for Nonhuman Use” and only partially administered to an animal, any remaining excess should be destroyed and logged as such, in either the animal’s permanent medical record, See Section H. Records Retention and Disposal, or on the NIH Form 27652 “Controlled Substance Record for Nonhuman Use”. The entry should be witnessed and signed by both parties. Draw up the balance of solution and spray it in a sharps container MPW box, burn box. Then on the corresponding record page, record what happened and have two people who witnessed the destruction sign the notation. Send the record page to the pharmacy when the balance is zero. Powdered controlled substances need to be returned to the DVR Pharmacy along with the corresponding record page. In general, these substances are provided in jars with removable and replaceable lids. On the first line of the NIH Form 27652 “Controlled Substance Record for Nonhuman Use”, make an entry that states 1 the date; 2 the total weight of jar, lid and contents in mg; 3 the signature of person making the entry; and 4 in the balance column, record the weight of the controlled substance contained in the full jar as stated on the manufacturer’s label. All items transferred must be accompanied by the item’s original NIH Form 27652 “Controlled Substance Record for Nonhuman Use”. Transfers between ICs are not permitted without the authorization of the NIH CSO. Items listed as DEA Schedule 1 cannot be transferred. Upon completion of each NIH Form 27652 “Controlled Substance Record for Nonhuman Use”, the balance of the controlled substance remaining should be zero.

Copies shall be filed by drug and are required to be kept for a period of two years by the CS Custodian. If at any time all entry lines are filled in on a given NIH Form 27652 “Controlled Substance Record for Nonhuman Use” and there is still a quantity of the drug remaining, the CS Custodian shall use a copy of a blank back page of NIH Form 27652 “Controlled Substance Record for Nonhuman Use” available on the NIH Electronic Forms website. The CS Custodian can also contact the DVR Pharmacy for a continuation page. Staple the first page and the continuation page together. Logging each use and keeping balances are not required for these items. Therefore, no Controlled Substance Records will be issued to the CS Custodian when they sign for and receive DEA regulated chemicals. Acquiring or procuring DEA regulated chemicals requires completion of the Form NIH 27651 “Request for Controlled Substances for Nonhuman Use”. To meet this biennial inventory requirement, NIH will conduct a physical inventory annually in the month of May. The NIH CSO will notify, in writing, each IC CSPC when the annual inventory is to be conducted. Attached to the memo will be reports entitled “Outstanding Sheets by Lock Box” listing the outstanding NIH Form 27652 “Controlled Substance Record for Nonhuman Use” for each CS Custodian in the IC. The report will contain the Control number of each record and the corresponding controlled substance issued to each CS Custodian that has not been returned to the DVR Pharmacy. A physical inventory will be taken by comparing the report with the contents of the controlled substances lock box and the balance on each NIH Form 27652 “Controlled Substance Record for Nonhuman Use” in the CS Custodian’s Controlled Substance Record File. Record the current balance on the same line as the corresponding control number and the controlled substance description on the “Outstanding Sheets by Lock Box” report.

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The controlled substances physical inventory list contained on the “Outstanding Sheets by Lock Box”

form will reflect all controlled substances in stock at the time the inventory is taken. If there are items in stock that are not on the report, the IC CSPC should add them to the list. The CS Custodian and the IC CSPC or designee will sign and date the bottom of the report.Contact the DVR Pharmacy to arrange the transfer of the controlled substance and the corresponding NIH Form 27652 “Controlled Substance Record for Nonhuman Use”. The NIH CSO is responsible for arranging the disposal of controlled substances that are expired or no longer required. The DVR Pharmacy uses a reverse distributor to dispose of controlled substances. Quantities of DEA regulated chemicals below the threshold levels See CFR 21 part 1310.04f 1 can be disposed of through NIH’s chemical waste contractor. For onsite disposal, see section G. 4. a. 3 b. DVR will conduct annual physical inventories and random unannounced checks of the ICcontrolled lock boxes by the NIH CSO or designee, and other issues or trends that may arise that require monitoring. Issues of special concern will be brought to the immediate attention of the Director, ORS; and the Deputy Director for Intramural Research DDIR as requested. He audits companies to assess DEA compliance and consults for companies regarding the proper handling and disposal of controlled and List I substances, and on documentation compliance. John provides DEA training to JPC clients throughout the US, and is a subject matter expert for Regulatory DEA compliance. He held top level security clearance and was instrumental in counterintelligence drug operations in Mexico and Panama. He also served as the National Security Agency’s European Liaison Officer. He is the Lannett Company representative for DEA inspections and DEA correspondence.He reports noncompliance and takes appropriate corrective action.

He performs annual inventory of CII, CIII and CIV substances i.e. Oxycodone, Hydrocodone, Amphetamine, etc. and compiles data for Year End Report submission. He coordinates and implements the destruction of controlled substances. He monitors controlled material movements as related to receipts, production, shipments and destruction, acquires all necessary data and submits for the DEA procurement quota encompasses all controlled substance usage. In addition to coteaching our course Mike also trains personnel within Lannett regarding DEA regulations. Please click here to see our course refund page and to see our policies regarding course cancellation. He will walk you through the questions you can expect, documents you will be asked to produce, and will give you tips on how to prepare your employees for an unexpected DEA inspection. The online manual contains chapters covered in the ZCBs Animal Control Officer Basic Training course, including such topics as animal identification, capture and restraint, transportation, impoundment, disposition, health, safety, sanitation, records, controlled substances, animal cruelty investigations, and communication skills. There are also copies of the laws pertinent to animal control. Additionally, the manual is an excellent reference tool for animal control agencies.The manual was fully revised in 2014; however, updates have been incorporated to the Table of Contentsand the section on Texas laws. The current dates are noted by the individual file names; those using the manual should check to ensure that they have the most recent versions The Department of State Health Services no longer conducts ACO Advanced Training courses and no longer updates these chapters. Are you using controlled substances in research, teaching, or veterinary care at UAB. If yes to either of these questions, you are required to complete this training course. If any regulations change, the training is required to be repeated.

A copy of the completed training certificate must be maintained in the laboratory files and presented to the proper authorities upon request. Registration If you are a UAB Campus Employee, go to the Campus Learning System to complete this training course. If you are an Academic Student, UAB Hospital, or UAB Medicine, follow these registration instructions. To access transcripts, log into Learning Locker. Course Objectives. At the conclusion, participants should be able to After

completing the course, feel free to return here and print any of the material you find useful. The abuse rate is a determinate factor when assigning a drug to a specific schedule. As the drug schedule number decreases, Schedule II, Schedule III, etc., so does the abuse potential. The schedules and examples are listed below source Schedule I drugs are the most dangerous drugs of all the drug schedules with potentially severe psychological or physical dependence. Examples of Schedule I drugs are heroin, lysergic acid diethylamide LSD, marijuana cannabis, 3,4methylenedioxymethamphetamine ecstasy, methaqualone, and peyote. These drugs are also considered dangerous. Examples of Schedule II drugs are combination products with less than 15 milligrams of hydrocodone per dosage unit Vicodin, cocaine, methamphetamine, methadone, hydromorphone Dilaudid, meperidine Demerol, oxycodone OxyContin, fentanyl, Dexedrine, Adderall, and Ritalin. Examples of Schedule III drugs are products containing less than 90 milligrams of codeine per dosage unit Tylenol with codeine, ketamine, anabolic steroids, testosterone. Examples of Schedule IV drugs are Xanax, Soma, Darvon, Darvocet, Valium, Ativan, Talwin, Ambien, Tramadol. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes. Examples of Schedule V drugs are cough preparations with less than 200 milligrams of codeine or per 100 milliliters Robitussin AC, Lomotil, Motofen, Lyrica, Parepectolin.

To begin this approval process, a Controlled Substance Licensee Designation Form must be completed and approved by EHS. Designate a double locked, secure area storage location for the Controlled Substances. NOTE This procedure must be done with oversight by EHS. EHS will coordinate the renewal process with Licensees.Laboratory personal must complete training before working with Controlled Substances. Contact EHS X3420 for more information or to be enrolled in the Controlled Substance Training Program. It is the responsibility of the Licensee to provide effective controls to guard against theft of Controlled Substances. Developing a key accountability standard operating procedure is recommended. Authorized users names must be documented on the Authorized Users Signature Log. Schedules I and II must be maintained separately from all other records of the Licensee, and Schedule III, IV, and V must be maintained either separately from all other records of the Licensee or in such form that the information required is readily retrievable from the ordinary business records of the Licensee. All records required shall be maintained for at least two years from the date of such inventory or records, for inspection and copying by authorized employees of the DEA. Keep records spanning the past five years easily accessible in case of civil actions. Forward a copy to EHS. Forward a copy to EHS. NOTE when individuals leave the lab and are no longer considered Authorized Users, the date they left MUST be entered into the Signature Log.Uptodate inventory maintenance is the key to the loss detection, theft, and the diversion of controlled substances. The current University approved vendor is Pharma Logistics . This type of loss must be documented by the Licensee and a witness on the appropriate Controlled Substance Usage Log. Controlled Substances that can be recovered after a spill, but cannot be used because of contamination, must be collected for disposal by a reverse distributor.

If the spilled Controlled Substance is not recoverable liquids, the Licensee must document the circumstances in the appropriate Controlled Substance Usage Log and the witness must sign. Also, law enforcement agencies can find contact information for our 3 laboratories across Canada. Each year we receive over 120,000 drug samples from law enforcement agencies. These samples are submitted for analysis without information about where they came from or the cases they were involved in. For example, in a powder sample, an analysis would let us see how much of the powder is cocaine purity. These can be used by police in investigations and as evidence in Canadian courts. We also share statistics and trends based on the drug samples submitted for analysis. We also provide information and training on We work with partners around the world to develop proper, scientific drug analysis procedures that other countries may use. We provide a Certificate of Analyst to the submitting officer within 60 business days. Sometimes, more time may be needed if These services include providing Contact your nearest DAS laboratory to receive a copy. It includes DAS

contact information, operating hours and our service standards. It also includes information on Based on their needs, we can teach law enforcement agencies how to Orillia, Ontario L3V 7V3 London, Ontario N6A 5R2 For enquiries, contact us. 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.

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 nontherapeutic research involving controlled substances, a separate research license from the Tennessee State Board of Pharmacy is required. In addition, for research with Schedule I a drug, a separate registration with the DEA is required. Such drugs may be declared illegal for sale or use, but may be dispensed under a physician's prescription. 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. Typically, the Licensed Individual is the Principal Investigator of a research protocol. 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 recordkeeping requirements are met. 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 D1bii 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 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.

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. 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 These drugs are also considered dangerous. Some examples of Schedule II drugs are 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 Some examples of Schedule IV drugs are Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes. Some examples of Schedule V drugs are 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. Once a state license number has been obtained the federal registration can be initiated . All personnel responsible for procuring control substances for research purposes must obtain researcher licensure from the State Board of Pharmacy. Nonclinical research personnel are already required to obtain State licensure before obtaining controlled substances for use in research. The URL for information is License Required Application Fees. 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.

Registration procedures, including detailed instructions on form submission, are available here 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 IIV if this clinical registration is being actively used to prescribe drugs to patients. Upon receipt of a registration application, the DEA may schedule a telephone interview or an onsite inspection. See Section H4. In most cases, this initial inventory will show zero quantities. 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. Current information on the fee for annual renewal of the DEA registration is found at 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. Both cabinets must have keylocked doors with separate keys; spring locks or combination locks are not acceptable. 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 onehalf inch. 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. Links to the forms are available at 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. This type of loss must be documented by the registrant and witness on the inventory record. If the spilled controlled substance is not recoverable liquids; the registrant must document the circumstances in their inventory records and the witnesses must sign. The training must be renewed triennially. The Office of Research will oversee the training development and delivery of this program. 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. The biennial inventory date must be within two years of the last inventory. Initial and biennial inventories must be kept for two years from the date the inventory was conducted. 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. The inventory must specify whether it was taken at the open or close of business on that day. 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. 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.

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. More frequent reviews are at the Office of Research discretion. More frequent reviews may be initiated due to concerns about compliance with 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. 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. The material contained in these guidelines may not be the most current. However, if included in publications, written or electronic, attributions must be made to the author. Commercial use of this material is prohibited without express written permission from the author. These controlled substances are grouped into schedules I through V depending on their potential for abuse see “definitions” at the end of this document for more information; a list is available on the DEA website. The Principal Investigator PI or supervisor is responsible for registering controlled substances. This document provides links and information for the registration process and the use of controlled substances. DEA Listed chemicals are not the same as controlled substances Schedules IV. Additional information about Listed chemicals is below. Registration Current federal protocols require that institutions or individuals acquire a state controlled substance license before applying for a federal registration.

Submit form IDFPR 097 other controlled substances licensees for activities related to research, chemical analysis, instruction, and teaching. Federal Drug Enforcement Administration Every person that uses controlled substances in research must register with the Drug Enforcement Administration. Different activities have different registration requirements. Forms and detailed instructions are available on the DEA website. For activities related to research and chemical analysis, submit form 225. Use Form 225A to renew an existing registration. For instructional activities and for dispensing controlled substances as a practitioner physicians, dentists, veterinarians, nurse practitioners, hospitals, and pharmacies, submit form 224. These activities are authorized only for schedules II through V. Use form 224A to renew the registration. The application should also include a letter from a department head verifying University of Illinois affiliation or employment. Note The use of a government designation during the application process will allow for a fee exemption. Authorized Use The registrant is responsible for managing the controlled substances according to the regulatory requirements covering inventory, record keeping, and security provisions. Agents designated employees of the registrant may engage in approved activities under the registrant’s direction. The registrant is required to screen employees before authorizing them to work with controlled substances. Employee Questionnaire Appendix A The employee questionnaire Appendix A should be included as part of the screening process 21 CFR, 1301.90. Fill out one questionnaire for each employee who is authorized by the PI to handle DEAcontrolled substances under that PIs supervision. Make copies of the form for each employee who will be working with these substances. Keep these questionnaires on file at the registered location.