



UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES



SUBJECT: Management of Controlled Substances, Regulated Chemicals and Alcohol

Instruction 6404

(PHM)

JUN 4 2013

ABSTRACT

This instruction provides policy and guidance regarding the Management of Controlled Substances, Regulated Chemicals and Alcohol at the Uniformed Services University of the Health Sciences (USUHS). This instruction includes definitions, responsibilities, and time-sensitive procedures.

A. Reissuance and Purpose.

The purpose of this instruction is to equip Pharmacy Supply personnel, Controlled Substances Custodians (CSC), Department Chairpersons and Principal Investigators (PI) with important guidelines needed to comply with the Drug Enforcement Administration (DEA), Alcohol, Tobacco, and Firearms (ATF), Centers for Disease Control (CDC), Environmental Protection Agency (EPA), Occupational Safety and Health Administration (OSHA), and local regulations and requirements. The processes included in this instruction are critical to the proper management of highly regulated and potentially dangerous materials. Additionally, USUHS personnel will be aware of how to best interface with the Pharmacy Supply Center to meet their needs.

B. References. *See Enclosure 1.*

C. Glossary. *See Enclosure 2.*

D. Applicability.

The provisions of this instruction are applicable to all USUHS personnel to include Henry M. Jackson Foundation and contractor personnel planning on, or engaging in, work involving controlled substances, regulated chemicals or alcohol.

E. Policy.

It is USUHS policy that controlled substances, regulated chemicals and alcohol will be:

1. Safeguarded against theft, pilferage, and misuse.
2. Accounted for in accordance with this instruction.
3. Safeguarded against unauthorized chemical production.
4. Safeguarded against trafficking or unauthorized distribution or improper use.
5. Purchased or obtained only through the USUHS Pharmacy Supply Center to ensure tracking and control is established upon receipt and distribution at USUHS.

F. Chain of Command. See *Enclosure 3*.

G. Responsibilities.

1. President, USUHS, is responsible for setting policy for the internal control, management, and accountability for controlled substances for all affiliated programs and activities. He will appoint the members of the Controlled Substances and Alcohol Inventory Board (CSAIB).

2. Controlled Substances and Alcohol Inventory Board:

a. The CSAIB is composed of the Chair, and at least two other faculty appointed by the President, USUHS. Other members will be chosen among faculty and staff with experience working in a research environment with controlled substances. No member will audit within his/her own department.

b. The CSAIB will:

(1) Inventory all departments utilizing controlled substances. An annual, announced inventory of controlled substances will be conducted as determined by the Chair, CSAIB. Random, unannounced spot-checks will be accomplished as needed.

(2) Document the inventory using the CSAIB Inventory Audit Checklist (*Enclosure 4*).

(3) During inventories, review controlled substances forms, quantities of controlled substances on hand, CSC appointment letters, CSC and PI training and storage of controlled substances.

(4) During inventory of the pharmacy, in addition, review alcohol forms, quantities of alcohol on hand, and alcohol storage.

(5) The Chair, CSAIB, will provide a written report to the President, USUHS, through the Director, Environmental Health & Occupational Safety (EHS), to include the results of all inventories accomplished, highlighting any discrepancies noted. Reports of the annual completed inventories will include a statement regarding the adequacy of the control and security of the controlled forms and substances. Copies of all reports will be provided to the Director, EHS, the Controlled Substances Officer (CSO) and the Pharmacy Officer.

3. Director, Environmental Health and Occupational Safety Department, is responsible for:

a. Overall management, administration, and supervision of the Pharmacy Officer.

b. Appointing the CSO.

c. Ensuring that a temporary CSO is designated during any absence of the assigned CSO.

d. Reviewing and updating this instruction as required.

4. Controlled Substances Officer (CSO) is responsible for:

a. Overseeing and approving procedures within the Pharmacy for ordering, issuing, returning and destroying controlled substances.

b. Providing initial and periodic Controlled Substances training to Principal Investigators and Controlled Substance Custodians.

c. Assisting the Chair, CSAIB, in convening the CSAIB.

d. Investigating inventory discrepancies identified by the CSAIB and any incidents of attempts to obtain controlled substances in an unauthorized manner. Report of findings will be submitted to the Director, EHS.

e. Immediately reporting any lost or stolen controlled forms or substances to the Chief, Security Division; Chair, CSAIB; Director, EHS; and President, USUHS.

- f. Providing guidance to the Inventory Management Specialist (IMS) and Pharmacy Officer regarding the proper management of controlled substances.
- g. Participating as an ad hoc member of the CSAIB.

5. The Pharmacy Officer (PHO) is responsible for:

- a. Directly supervising the operations of the Pharmacy.
- b. Approving the purchase, issue, return, destruction and shipping of controlled substances.
- c. Reporting lost or stolen controlled substances to the CSO and the DEA.
- d. Reporting significant in-transit and inventory losses of alcohol (greater than 1% of total aggregate contents and greater than 5 proof gallons) to the ATF.
- e. Ensuring that the Pharmacy is in compliance with all DEA regulations regarding registration, ordering, storage, recordkeeping, and disposal of controlled substances.
- f. Ensuring that the Pharmacy is in compliance with all ATF regulations regarding permit, ordering, storage, recordkeeping and disposal of industrial alcohol.
- g. Approving orders for alcohol.
- h. Participating as an ad hoc member of the CSAIB.

6. The Inventory Management Specialist (IMS) is responsible for:

- a. Initiating orders for bulk-supplied controlled substances, regulated chemicals and alcohol using USUHS Pharmacy DEA registration and ATF permits.
- b. Ensuring that receipt and issue records for controlled forms, substances and alcohol are maintained so that accountability can be achieved.
- c. Maintaining and issuing stocks of the most commonly required controlled forms and substances.
- d. Maintaining the authorization master list of personnel authorized to purchase controlled substances for specifically approved protocols.
- e. Maintaining a master list of authorized controlled substance use for each PI after verifying that his/her protocol requires the use of the specific controlled substance.
- f. Maintaining a database for all personnel who receive Controlled Substances Training.
- g. Maintaining the Pharmacy's DEA Registration and ATF Industrial Alcohol Permits in a current status.
- h. Initiating purchase orders for controlled substances, regulated chemicals and alcohol.
- i. Storing, securing, and accounting for bulk stocks of controlled substances, alcohol and regulated chemicals.
- j. Issuing controlled substances and regulated chemicals only to authorized controlled substance custodians. For a controlled substance to be issued, the controlled substance custodian's and the principal investigator he/she represents must be current in their mandatory training.
- k. Providing the Pharmacy Officer with a history of controlled substances issues.
- l. Immediately reporting any lost or stolen controlled forms, substances, regulated chemicals and alcohol to the Pharmacy Officer.
- m. Performing biennial inventory of controlled substances and biannual inventory of industrial alcohol stored in Pharmacy Supply Center.
- n. Filing quarterly Acquisition/Distribution transaction reports with Automation of Reports and Consolidated Orders Systems (ARCOS).
- o. Notifying Logistics, the Receiving, Distribution and Records Branch Supervisor and Work Leader of the following information for Controlled Substance Orders:

- (1) Credit Card Order Number.
- (2) Vendor.
- (3) Carrier.
- (4) Tracking Number.
- (5) Approximate Delivery Date.

7. Department Chairs and Activity Heads are responsible for:

- a. Safeguarding and maintaining formal accountability of controlled substances and regulated chemicals, stored or used within their activity.
- b. Designating, in writing (Enclosure 5), a primary Controlled Substance Custodian (CSC) and an alternate CSC to order, dispense, and return controlled substances. It is recommended that each department assign a faculty member as either the primary or alternate CSC.
- c. Providing, in writing, all designations and appointments to the Pharmacy Officer. Copies of these appointment letters must be available for inspection during the annual CSAIB audits.
- d. Informing the Pharmacy Officer in writing when a controlled substance custodian or principle investigator is replaced, resigns, or leaves the university.
- e. Ensuring that departmental staff are prohibited from procuring controlled substances and alcohol other than through the University Pharmacy Supply Center.
- f. Assuming responsibility for controlled substances issued to non-Department of Defense principal investigators in their department.
- g. Reviewing and approving use of controlled substances requested under protocols that are not subject to Institutional Animal Care and Use Committee (IACUC) or Institutional Review Board (IRB) approval.

8. Principal Investigators (PIs) are responsible for:

- a. Ensuring that all controlled substances are purchased or obtained by the CSC through the Pharmacy.
- b. Obtaining supplies of controlled substances for daily use from the CSC.
- c. Returning unused controlled substances to the CSC for secure storage before close of the business day.
- d. Ensuring that all controlled substances in use are listed in an approved, funded protocol.
- e. Immediately reporting any lost or stolen controlled substances to the CSC, Pharmacy Officer, and if suspected theft, the Base Police Department.
- f. Completing initial and periodic training on the Management of Controlled Substances.
- g. Ensuring that he/she has a current, valid DEA registration if Schedule I controlled substances are employed.
- h. Ensuring that:
 - (1) He/she or one of the co-investigators on his/her approved protocol is a DoD employee who will assume responsibility for the controlled substances authorized under the protocol.
 - (2) If neither he/she nor any of the co-investigators on his/her approved protocol is a DoD employee, a letter from the department chair assuming responsibility for the controlled substances authorized in the protocol is on file with the Pharmacy Officer.
 - (3) If his/her protocol does not require IACUC or IRB approval, a memo from the department chair reviewing and approving the use of controlled substances is on file with the Pharmacy Officer.
- i. Providing the CSC copies of protocols and the IACUC, IRB or chair approval memo when controlled substances are initially issued by the Pharmacy or the protocol has been modified or

renewed.

9. Controlled Substances Custodians are responsible for:

- a. Taking custody of and responsibility for all controlled substances and forms used in his/her department.
- b. Purchasing or obtaining all controlled substances for use in his/her department through the Pharmacy.
- c. Safeguarding all controlled substances and forms in accordance with DEA and USUHS regulations.
- d. Completing initial and periodic training on the Management of Controlled Substances.
- e. Issuing controlled substances to PIs with current protocols on a daily basis.
- f. Ensuring that controlled substances are issued only to PIs whose annual controlled substance training is current.
- g. Recording amounts of all controlled substances dispensed to, or returned by, the PI on USUHS Form 6049, the Yellow Sheet (*Enclosure 6*).
- h. Submitting the completed USUHS Form 6049 to the Pharmacy, along with any unused controlled substances.
- i. Notifying the Pharmacy Officer, in writing, when controlled substances are brought into his/her department through channels other than the normal procurement system (e.g., from another university, or a different laboratory).
- j. Making available to the CSAIB, all records and substances on-hand for purpose of inventory.
- k. Immediately reporting any lost or stolen controlled forms or substances to their Principal Investigator, their department chairperson and the Pharmacy Officer.
- l. Returning to the Pharmacy, any controlled substances which are beyond their expiration dates.
- m. Maintaining copies, in the controlled substance safe, of the:
 - (1) Primary and Alternate Controlled Substance Custodian's appointment letters.
 - (2) Principle Investigator's and Controlled Substance Custodian's completion of annual training certificates.

11. Logistics Division is responsible for:

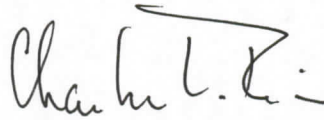
- a. Providing, upon request, all shipping and receiving documentation for controlled substances and alcohol from all sources to the Controlled Substance Officer.
- b. Maintaining a logbook of all incoming controlled substances and alcohol with the following information:
 - (1) Order number
 - (2) Time and date received
 - (3) Tracking number
 - (4) Printed name and signature of Pharmacy personnel receiving the item(s)
 - (5) Date received by Pharmacy personnel
- c. Monitoring E-mail from Pharmacy personnel of incoming controlled substance(s).
- d. Notifying Receiving personnel of incoming controlled substance shipments.
- e. Receiving personnel notifying the Pharmacy personnel that a controlled substance and/or alcohol has been delivered.
- f. Securing the shipment until it is signed for by the Pharmacy personnel.

H. Controlled Substance Authorization, Procurement and Control Procedures. *See Enclosure 7.*

I. Alcohol Management Procedures. *See Enclosure 8.*

J. Effective Date.

This instruction is effective immediately.

A handwritten signature in black ink, appearing to read "Charles L. Rice".

Charles L. Rice, MD
President

Enclosures:

1. References
2. Glossary
3. Pharmacy Chain of Command
4. Sample Controlled Substances and Alcohol Inventory Board (CSAIB) Inventory Audit Checklist
5. Controlled Substance Custodian Appointment Letter
6. USUHS Form 6409 "Yellow Sheet"
7. Controlled Substance Authorization, Procurement and Control Procedures
8. Alcohol Management Procedures

REFERENCES

- (1) USUHS Instruction 6404, "Management of Controlled Substances and Regulated Chemicals," May 15, 2009 (hereby canceled).
- (2) Title 21 Code of Federal Regulations (CFR) Food and Drugs, Parts 1300 to End, revised as of April 1, 2009.
- (3) Title 27 Code of Federal Regulations (CFR), ATF, parts 20-21.

GLOSSARY

Controlled Forms: Forms having registered numbers that are used to account for receiving, issuing, and administration of controlled substances by the Pharmacy, Departments, or responsible personnel (USUHS Form 6048, and USUHS 6049, DEA 222).

Controlled Substances: Items of narcotics and dangerous drugs identified by the DEA in the Regulations (Title 21, CFR, Food and Drug Chapter II) implementing the comprehensive Drug Abuse Prevention and Control Act of 1970. The items are divided into five schedules depending on the accepted medical use of the drug in the United States and its abuse potential.

CSC: Personnel designated by their department chairperson or activity head to be responsible for the departmental management of controlled substances and regulated chemicals.

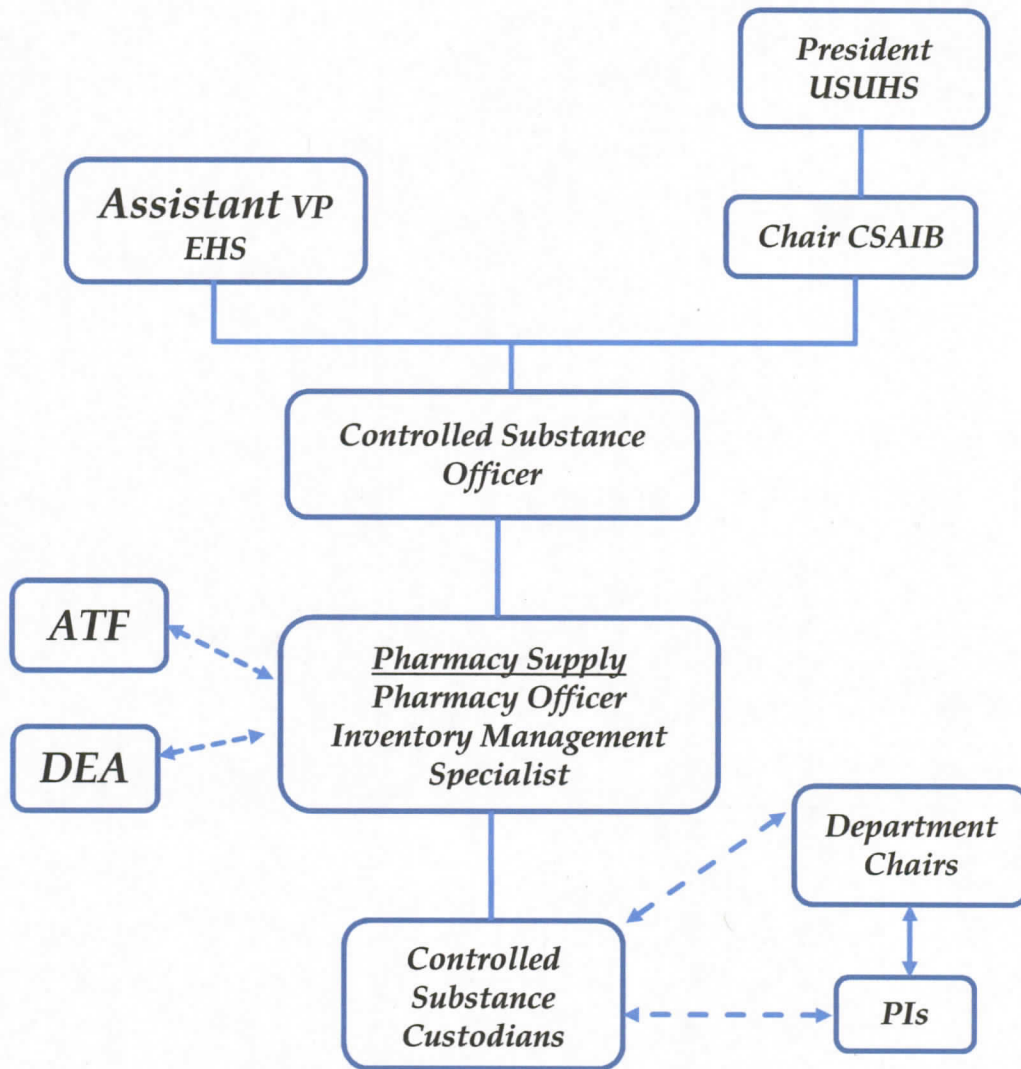
Regulated Chemicals: Items identified by the DEA in the regulations (21 CFR 1310-1313) implementing the Chemical Diversion and Trafficking Act of 1988. This act contains requirements for record keeping, importing and exporting of regulated chemicals.

IACUC: Institutional Animal Care and Use Committee reviews research and teaching protocols involving animals. Recommends approval or disapproval based in part on Title 9 CFR, parts 1, 2 and 3, PHS policy and the Guide for the Care and Use of Laboratory Animals.

IRB: Institutional Review Board reviews and provides approval for research and teaching protocols involving human subjects.

Tax-free alcohol: Tax-free alcohol is undenatured alcohol used for non-beverage purposes in scientific research and medicinal uses by educational organizations, hospitals, laboratories, etc. The use of alcohol free of tax is regulated to prevent illegal diversion to taxable beverage use.

Chain of Command



4. DISCREPANCIES NOTED

5. GENERAL COMMENTS

6. Copy of completed Inventory Audit Checklist provided to Department Chairman through CSC? YES NO

SIGNATURES OF AUDIT PARTICIPANTS:

CSAIB Member Assistant

CSC or Departmental representative

SAMPLE OF CSC APPOINTMENT LETTER

(Date)

**MEMORANDUM FOR PHARMACY OFFICER, PHARMACY SUPPLY
CENTER**

SUBJECT: Appointment of Departmental Controlled Substance Custodians

**The following personnel are appointed as my Departmental Controlled Substance
Custodians.**

	<u>Name</u>	<u>Protocol Cost Center #</u>
Primary	_____	_____
Alternate	_____	_____

**The above named individuals are aware of their responsibilities in the management
of controlled substances within the department.**

**The CSCs will maintain current CSC training in order to retain authorization as
Controlled Substances Custodians.**

**Name of Department Chair
Title, Department**

**Cc: All department PIs
Appointed CSCs**

Departmental Controlled Substances Form

[illegible]

CONTROLLED SUBSTANCES AUTHORIZATION, PROCUREMENT AND CONTROL PROCEDURES

1. Authorization

a. The Chair or Activity Head of each department will designate two individuals as Controlled Substances Custodians to monitor the use of controlled substances and forms within their department. Their appointment letters will be forwarded to the Pharmacy Officer. If the department is organized into divisions or branches in which controlled substances are utilized, the requirements of this paragraph also apply to the divisions and branches.

b. All controlled substances must be obtained through the USUHS Pharmacy Supply Center. Only drugs that are listed in approved, active protocols will be issued. All other controlled substances, for which there are no active protocols, must be returned to the Pharmacy Supply Center.

c. No authorization is required for the purchase of alcohol from the Pharmacy.

2. Procurement

a. The Pharmacy Supply Center will maintain a stock of the most commonly used controlled substances and regulated chemicals and purchase, at the request of a PI, other controlled substances and regulated chemicals that are not used frequently enough to be stocked.

b. All controlled substances, regulated chemicals and alcohol will be delivered to the USUHS warehouse or picked up at the WRNMMC Receiving area by the USUHS Pharmacy staff.

c. All controlled substances, regulated chemicals and alcohol received in the warehouse will be opened only by University Pharmacy staff. Upon arrival, the Pharmacy staff will take the substances to the Pharmacy to be secured, assign a (container number to the item and document its receipt on USUHS Form 6048 (Blue Sheet)).

d. Only CSCs, authorized in writing by their Department Chair, may be issued controlled substances, controlled substance forms, and regulated chemicals. The CSC will claim the controlled substances in person. If it is the initial issue of the controlled substance under a protocol or if the protocol has been renewed since the last issue, the CSC will provide the Pharmacy Inventory Management Specialist (IMS) with a copy of the protocol and the IACUC, IRB or department chair approval memo. The CSC must provide his/her Yellow Sheet (USUHS Form 6049) to the IMS to record the issue of the controlled substance. If the Yellow Sheet has expired, it must be turned in to the Pharmacy to be reissued. If it is an initial issue, the IMS will create a new Yellow Sheet for the drug. If a company or institution donates a controlled substance to a PI for use under an approved protocol, there will be no charge for the controlled substance. However, it must be delivered to, and processed through, the Pharmacy. The IMS will add the item to the inventory, create a Yellow Sheet and issue the controlled substance to the CSC. The CSC will acknowledge acceptance of the controlled substance by signing a receipt and providing a valid project number with available funds if there is a charge.

3. Control Procedures

a. Storage

(1) All controlled substances storage cabinets and safes must be located in an area with lockable door, which shall be locked when not in use. Keys to storage area must be limited and controlled. The combination or keys to the controlled substance storage container must be limited to authorized CSCs.

(2) Schedule I and II controlled substances must be stored in an approved security safe. The safe must meet the specifications described in CFR 21 Section 1301.72 with respect to surreptitious entry. It must weigh at least 750 pounds or be bolted to the floor or wall. Schedule III-IV controlled substances may be stored in a locked drawer or cabinet.

(3) Schedule I and II drugs and their forms must be stored separately from Schedule III-V drugs and forms. They may be in the same safe, but separated by shelf or divider.

(4) Bulk stocks of alcohol will be stored in a flammable storage locker.

b. Inventory and Audit Procedures

(1) Pharmacy

(a) The IMS will perform biennial audit of all controlled substances stored in the Pharmacy Supply Center on any date which is within two years of the previous inventory. The inventory must include date, time, name of substance, physical form of substance (i.e. tablets, powder, solution), and quantity of substance. For Schedule I and II substances, an exact measurement is required. For Schedule III-V substances, an exact count of unopened commercial containers is required. For opened Schedule III-V commercial containers, an estimated count or measurement of the contents is allowed unless the container initially held more than 1000 tablets, capsules or milliliters in which case, an exact count is required.

(b) The IMS will perform biannual inventories of all industrial alcohol stocked in the Pharmacy Supply Center. Records will identify the alcohol by quantity, proof, and purpose of removal (office, department, or location to which dispensed).

(2) CSAIB

a. The CSAIB will perform annual, announced inventories of departmental controlled substances and forms as follows:

(1) The inventory will be documented using the CSAIB Inventory Audit Checklist. *(Enclosure 4)*

(2) All controlled substances will be inventoried using grams for powders, milliliters for liquids, and count for tablets.

(3) For Schedule I and II substances, an exact count or measurement of the controlled substance is required; for Schedule III-V substances, an estimated count or measure of the contents is allowed, unless individual containers hold more than 1000 tablets, capsules or milliliters in which case, an exact count is required.

(4) Schedule I and II controlled substances and forms must be separated from schedule III-V forms and controlled substances.

(5) All on-hand controlled substances must be associated with an active protocol.

(6) All controlled substances must be purchased or obtained through USUHS Pharmacy.

(3) Logistics

a. Losses

(1) The apparent theft or other unaccountable disappearance of controlled substances, forms or regulated chemicals must be immediately reported to the Pharmacy Officer. The CSC or PI will submit a written report within 24 hours of the discovery of the loss, documenting the circumstances. The report will be submitted to the Pharmacy Officer, the Controlled Substance Officer through the Director, EHS, with copies to Chief, Security Division, Department Chairperson and Chairperson, CSAIB.

(2) If loss occurs through breakage or other accident, a written statement shall be submitted to the Pharmacy Officer through the CSC, by the responsible person, stating the quantities lost and the circumstances surrounding the incident. If schedule I or II substances are involved, an affidavit must be submitted. Assistance is available from the General Counsel when preparing such statements.

(3) For losses or apparent theft, the Pharmacy Officer will submit DEA Form 106 to the DEA within 24 hrs.

(4) "Small" spillages may be accounted for on USUHS Form 6049.

c. Returns

(1) If controlled substances have had their identities compromised or have exceeded their expiration dates or if no protocol supports their use, they must be returned to Pharmacy for reissue or destruction.

(2) Controlled substances being returned to the Pharmacy must be weighed, measured or counted by the CSC and accompanied by a Yellow Sheet (USUHS Form 6049). The Pharmacy will weigh, measure or count the substance to ensure totals are correct and document the return on the Yellow Sheet. In the case of a discrepancy between the totals, the CSC will provide written justification for the difference before the Pharmacy will accept the item.

(3) Pharmacy Supply Center will arrange for reissue or destruction by a licensed reverse distributor.

d. Forms Used in Controlled Substances Management.

(1) **Pharmacy Controlled Substances Form (USUHS Form 6048)** is maintained by the Pharmacy for accounting all substances received or issued.

(2) **Departmental Controlled Substances Form (USUHS Form 6049), "Yellow Sheet"** is maintained by the CSC for accounting of all substances received, administered, and on-hand balance.

(3) **Pharmacy/Departmental Controlled Substances Forms Register (USUHS Form 6047)** is maintained by the Pharmacy to record issuance of controlled USUHS Forms 6048 and 6049.

(4) **Pharmacy Controlled Substance Sealing Log (USUHS Form 6054)** is maintained by the Pharmacy for accountability of controlled substances sealed for storage.

(5) **Controlled Substance Temporary Issue Receipt (USUHS Form 6058)** will be prepared by the CSC for CSs leaving the physical facility of USUHS for use at a different location. A copy will be maintained in the CS storage cabinet or safe while the original will accompany the PI. After the CS has been used, the CSC will file the completed form with the controlled substance records. The copy is discarded.

(6) **Report of Theft or Loss of Controlled Substances (DEA Form 106)** will be submitted within 24 hours by the Pharmacy Supply Center to the DEA in the event of lost or stolen controlled substances.

(7) **DEA Form 222** is used by the Pharmacy to order all Schedule II controlled substances.

ALCOHOL MANAGEMENT PROCEDURES

1. The Bureau of Alcohol, Tobacco and Firearms (ATF) publishes regulations relating to the production, procurement, storage, use, and accounting for tax-free alcohol in Title 27, Code of Federal Regulations.
2. Industrial Alcohol Permit (given to USUHS as an institution) is required for procurement and use of tax-free alcohol (ethanol 190 proof and greater) and denatured alcohol.
3. Alcohol shall be considered as “used” when permanently removed from the Permittees supply storeroom. As the Permittee, the Pharmacy Supply Center is responsible for:
 - a. Ordering, receiving, and storing bulk supplies of alcohol.
 - b. Reporting significant in-transit and inventory losses (greater than 1% of total aggregate contents and greater than 5 proof gallons).
 - c. Maintaining records of usage that identify the tax-free alcohol by quantity, proof and purpose of removal (office, department or location where dispensed).
 - d. Performing bi-annual inventories of stock.
 - e. Ensuring secure and safe storage according to ATF and USUHS regulations.
4. All alcohol must be stored according to ATF and USUHS guidelines. Storerooms or cabinets shall be flameproof, constructed and secured as to prevent unauthorized access and will be equipped for locking. A flameproof locker kept inside a room which is locked when unattended is considered adequately secured.
5. All alcohol must be purchased from the Pharmacy Supply Center.
6. Questions pertaining to these procedures may be directed to the EHS.