USUHS
INSTRUCTION
6404

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

SUBJECT: Management of Controlled Substances and Regulated Chemicals

Instruction 6404

DEC 12 2003

(PHM)

ABSTRACT

This Instruction provides policy and guidance regarding the Management of Controlled Substances and Regulated Chemicals 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 the Pharmacy Supply personnel, custodians, 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 Pharmacy Supply to meet their needs.

B. References. *See Enclosure 1.*

C. Applicability. The provisions of this Instruction are applicable to all USUHS personnel to include Henry M. Jackson Foundation and Armed Forces Radiological Research Institute (AFRRI) personnel planning on, or engaging in work involving controlled substances and regulated chemicals.

D. Policy. It is USUHS policy that controlled substances and regulated chemicals 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; and,
5. Purchased only through the Pharmacy to ensure tracking and control is established upon receipt and distribution at USUHS.

E. Responsibilities.

1. President, USUHS, is responsible for setting policy for the internal control and management of 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 (CSAIB) is composed of:

a. The CSAIB, which is composed of at least three faculty or senior staff members appointed by the President, USUHS. 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; and,

b. The Board will:

(1) Inventory alcohol logs and controlled substances forms. An annual, announced inventory of controlled substances and

alcohol will be conducted as determined by the Chair, CSAIB. Random, unannounced spot-checks will be accomplished as needed;

(2) In cooperation with the Controlled Substance Officer (CSO), the Pharmacy Officer and the Inventory Management Specialist, ensure that seldom used, open lots of controlled substances are sealed in polyethylene bags closed with numbered tags/bands and disposed of as appropriate;

(3) During inventories, ensure that all Controlled Substance Custodians (CSC) have been approved by the Department Chairs and have attended the required training; and,

(4) The Chair, CSAIB, will provide a written report to the President, USUHS, through the Director, 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 Vice President, Teaching and Research Support, Director, EHS, the CSO and the Pharmacy Officer.

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

a. Overall management, administration, and supervision of the Pharmacy Officer, including review and update of this Instruction as required;

b. Appointing and supervising of the CSO; and,

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

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

a. Approving the issue, return, destruction and shipping of controlled substances to ensure all the appropriate forms are filled out, all controlled substances are properly secured, and that the DEA is properly notified;

b. Provide initial and periodic training to Controlled Substance Custodians;

c. Assist 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. Reports 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, or President, USUHS;

f. Providing guidance to the Inventory Management Specialist and Pharmacy Officer regarding the proper management of controlled substances; and,

g. Participating as an ad hoc member of the CSAIB.

5. The Pharmacy Officer is responsible for:

a. Directly supervising the operations of the Pharmacy;

b. Reporting lost or stolen controlled substances to the Controlled Substance Officer;

c. Identifying controlled substances that are not used or seldom used, for disposal/return, and obtaining the approval of the CSO before taking action;

d. Approving orders for controlled substances and alcohol;

e. Participating as an ad hoc member of the CSAIB;

f. Providing initial and periodic training for Alcohol Custodians; and,

g. Cradle-to-grave accountability for controlled substances and alcohol.

6. The Inventory Management Specialist is responsible for:

a. Initiating orders for bulk supplied controlled substances, sensitive items, and regulated chemicals using USUHS Schedule II-V and Alcohol, Tobacco, and Firearm licenses;

b. Ensuring that receipt and issue records for controlled forms, substances and alcohol are

maintained so that accountability can be achieved. The records will normally include the use of the Pharmacy/Departmental Controlled Substances Form Register (USUHS Form 6047); Pharmacy Controlled Substances Form (USUHS Form 6048); Departmental Controlled Substances Form (USUHS Form 6049); and Pharmacy Controlled Substance Sealing Log (USUHS Form 6054);

c. Maintaining and issuing stocks of the most commonly required controlled forms and substances;

d. Providing copies of documentation for stock issues of controlled substances to the Controlled Substance Officer;

e. Maintaining the authorization master list that contains key personnel authorized to purchase controlled substances and regulated chemicals for specifically approved protocols;

f. Maintaining a master list of authorized controlled substance use for each PI after verifying that his/her approved protocol requires the use of the specific controlled substance;

g. Initiating purchase orders for controlled substances and regulated chemicals;

h. Storing, securing, and accounting for bulk stocks of regulated chemicals;

i. Storing, securing, and accounting for bulk supplies of controlled substances;

j. Issuing controlled substances and regulated chemicals only to authorized custodians;

k. Providing the Pharmacy Officer with a history of controlled substances issues; and,

l. Immediately reporting any lost or stolen controlled forms or substances to the Pharmacy Officer, who will inform the CSO.

E-mail Receiving, Distribution and Records Branch Supervisor and Work Leader the following information on Controlled Substance Orders:

1. Credit Card Order Number;
2. Vendor;
3. Carrier;
4. Tracking Number; and,
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, 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 Controlled Substance Custodian;

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 audit;

d. Ensuring a CSC is available to receive and dispense controlled substances when PIs need them; and,

e. Ensuring that departmental staff is prohibited from procuring controlled substances other than through the University Pharmacy.

8. Principal Investigators (PIs) are responsible for:

a. Ensuring proper accountability of controlled substances received from the CSC;

b. Ensuring that a complete and accurate annotation of controlled substances administered to animals is entered in the animal record on Standard Form (SF) 600;

c. Delivering completed original or photocopies of the SF 600 to the Veterinary Medicine Division, Department of Laboratory Animal Medicine, upon expiration of the protocol or the final disposition of the animal;

d. Returning unused controlled substances to the CSC before close of business day;

e. Ensuring all regulated chemicals are properly stored, tracked, and used; and,

f. Ensuring that all controlled substances in use are listed in an approved, funded protocol.

9. Controlled Substances Custodians (CSC) are responsible for:

a. Monitoring the use of controlled forms, substances, and regulated chemicals in their department;

b. Reviewing all usage and storage practices for regulated chemicals in their department;

c. Reviewing for accuracy all use of Absolute Alcohol Storage Sheets (USUHS Form 6055), and 95% Alcohol Storage Sheets (USUHS Form 6056), which are kept in a logbook;

d. Safeguarding under lock and key all controlled substances and their USUHS Form 6049s;

e. Taking custody and responsibility for controlled substances issued to his or her Department, using the USUHS Form 6049;

f. Maintaining an accurate accounting of all controlled substances dispensed to authorized personnel using USUHS Form 6049;

g. Delivering completed USUHS Form 6049 to the Pharmacy, accompanied by any remaining substances;

h. Requesting Pharmacy Supply to purchase controlled substances not listed in the Pharmacy's formulary, using USUHS Form 6417, Request for New Supplies/Pharmaceutical. A copy of the approved, funded protocol (3206) must be provided to the Inventory Management Specialist with the order;

i. Notifying the Pharmacy Officer, in writing, when controlled substances or alcohol are brought into the University Departments 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 the Pharmacy Officer, the USUHS Security Officer, and the CSO;

l. Returning to the Pharmacy, any controlled substances which have not been used within a three-year period, or for which there is no approved protocol requiring such substances; and,

m. Maintaining a copy of the CSC's authorization letter in the controlled substances safe.

10. Regulated Chemical (Alcohol) Custodians are responsible for:

a. Taking custody of regulated chemicals from the Pharmacy;

b. Ensuring their proper security and storage;

c. Tracking receipt and dispensed quantities on the proper USUHS Forms; and,

d. Overseeing the safe and secure use and disposal of regulated chemicals on behalf of the PI.

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 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); and,

(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 shipment;

e. Receiving personnel notifying the Pharmacy personnel that a Controlled Substance has been received; and,

f. Securing the Controlled Substance shipment until it is signed for by the Pharmacy personnel.

12. Director, Contracting, is responsible for:

a. Providing copies of all purchase orders (Form 1155) to Pharmacy Supply;

b. Ensuring, with the assistance of the Pharmacy Officer, that only DEA forms initiated (all Schedule II through V agents) or approved (Schedule I agents only) by the Pharmacy are used for the procurement of controlled substances; and,
c. Ensuring that all purchase orders for controlled substances and alcohol are approved by the Pharmacy Officer and are appropriately processed.

13. Pharmacy Chain of Command. *See Enclosure 2.*

14. Additions and Deletions to Protocol Procedures:

a. Additions.

(1) PIs wishing to add controlled substances to a protocol must have an active, funded grant. The CSC must provide a copy of the 3206 to the Inventory Management Specialist; and,

(2) An amended USUHS Form 6007 must be submitted to the Office of Research (REA) for review by the Biohazards, Controlled Substances and Dangerous Materials (BCD) Committee.

b. Deletions.

(1) A memorandum must be submitted to the Pharmacy Officer, identifying the protocol, substance(s) to be deleted, and the disposition of the remaining totals of the substance(s) (i.e., destruction or storage); and,

(2) Items that are not currently listed on any active protocol are to be returned to the Pharmacy with the 6049 and an accompanying memorandum identifying the generic name, concentration, lot number, unit number, and remaining totals. This memorandum, signed by the Department Chairperson/Activity Head or the CSC, should also detail the disposition of the substance (i.e., destruction or storage).

F. <u>Effective Date.</u> This Instruction is effective immediately.

James A. Zimble, M.D.
President
Vice Admiral, USN (Ret.)

Enclosures:
1. References
2. Pharmacy Chain of Command
3. Procurement, Receiving, and Inventory Procedures
4. University Control Procedures
5. Controlled Substances and Alcohol Inventory Board (CSAIB) Inventory Audit Checklist
6. Request for Additions to Stock/Pharmaceuticals
7. Sample of an Appointment Letter of CSC and Alcohol Custodians Signed by Department Chair
8. 95% Alcohol Storage Record
9. Absolute Alcohol Storage Record
10. Glossary

REFERENCES

(1) USUHS Instruction 6404, "Management of Controlled Substances, Alcohol and Alcoholic Liquors, Syringes, and Hypodermic Needles," 28 June 1991 (hereby cancelled)

(2) DOD Instruction 5200.8, "Security of DoD Installations and Resources," 25 April 1991 (# replaced 5210.7-ALS)

(3) Executive Order 12564, "Drug-Free Federal Workplace," September 15, 1986

(4) USUHS Instruction 1012, "USUHS Drug-Free Workplace Program," 11 April 1990

(5) USUHS Instruction 6401, "Biohazards and Dangerous Materials Guide," 15 May 1987

(6) USUHS Instruction 5200, "Physical Security," 12 January 2000

(7) USUHS Instruction 5210, "Security Locks and Containers," 17 May 1989

(8) Title 21 Code of Federal Regulations (CFR) Food and Drugs, Chapters I and II, 1 April 1990

(9) Title 40 Code of Federal Regulations Protection of Environment 261, subpart D, 1 April 1990

(10) Public Law 91-513, Controlled Substance Act, October 27, 1970 (21 U.S.C. S202, 802(6), and (812))

(11) Chemical Diversion and Trafficking Act of 1988

(12) Anabolic Steroid Control Act of 1990

(13) US Navy. (nd). Virtual Naval Hospital – Manual of the Medical Department (MANMED): NAVMED P-117, Chapter 21. http://www.vnh.org.

(14) Department of Defense. DOD Instruction 5210.71, Security of Selected Sensitive Inventory Items Drugs, Drug Abuse Items, and Precious Metals, August 21, 1981

PHARMACY CHAIN OF COMMAND

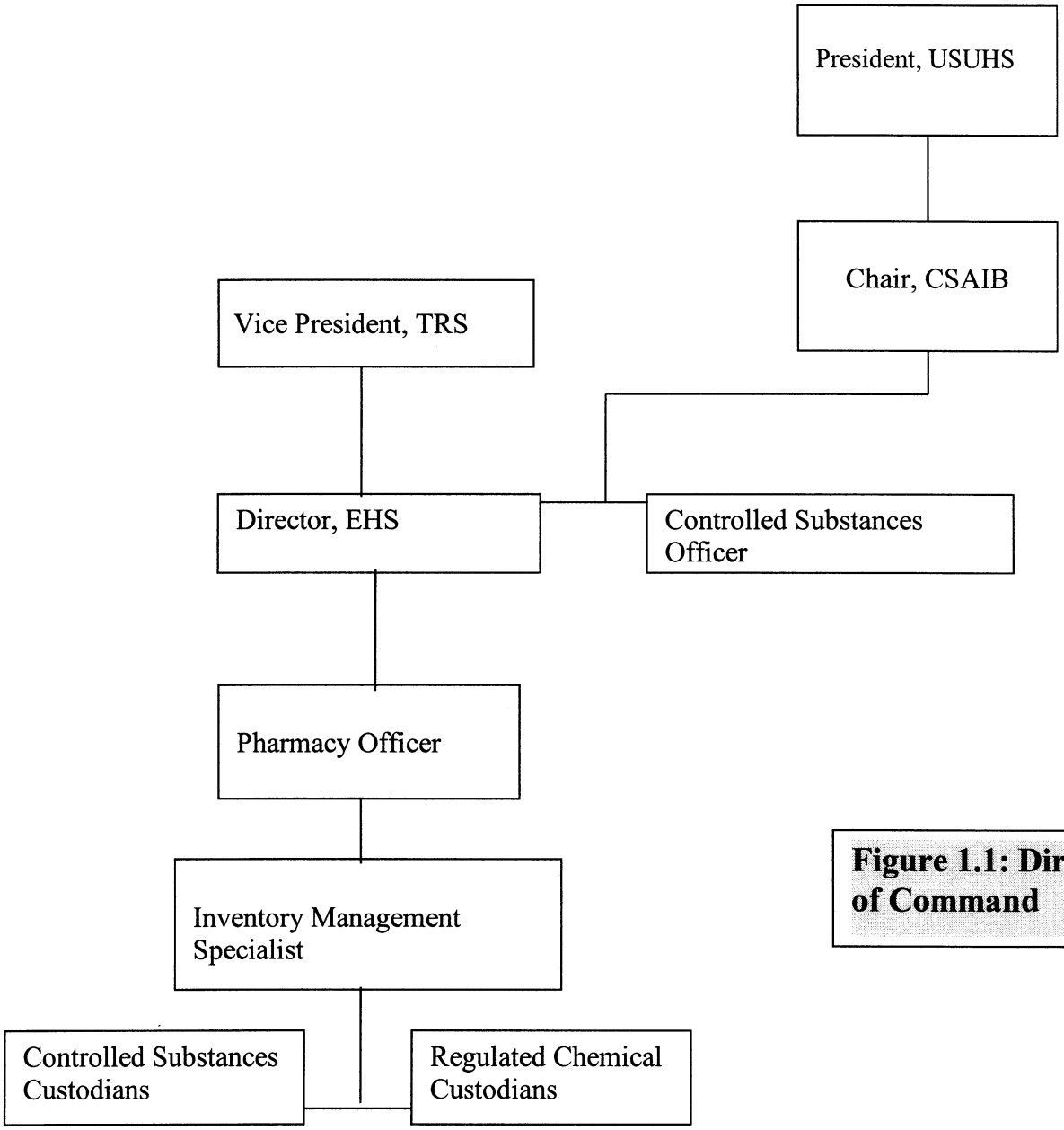

Figure 1.1: Direct Chain of Command

PROCUREMENT, RECEIVING, AND INVENTORY PROCEDURES

1. Procurement

a. Persons wishing to obtain controlled forms, substances, and regulated chemicals must be authorized, in writing, to do so by their department chairperson or activity head.

b. Departmental orders for controlled substances and regulated chemicals not stocked in the University Pharmacy must follow all guidelines for purchasing, identifying substances/chemicals by generic name, concentration, and quantity. Additionally, the delivery location must be specified as the University Pharmacy (GO58C).

c. The most commonly used controlled substances, and regulated chemicals are usually stocked in the Pharmacy; authorized custodians may obtain items at the Pharmacy.

d. Authorized persons wishing to obtain controlled substances and regulated chemicals not usually stocked in the Pharmacy will complete a request (USUHS Form 6417) for new Supplies/Pharmaceuticals. The CSC will submit the form to the Inventory Management Specialist, who will evaluate the usage of the item and either add it to Pharmacy stock or request it be purchased by departmental order.

e. The Inventory Management Specialist will initiate purchase requests for bulk alcohol and alcoholic liquors and submit them to the Pharmacy Officer for his/her approval.

f. The Inventory Management Specialist will initiate purchase requests for syringes, needles, and all other non-controlled items to be stocked in the Pharmacy.

g. The substance(s) will be logged in the pharmacy computer program and the requester will be notified upon the arrival of the substance.

h. The CSC will claim the controlled substance(s), and regulated chemicals in person and will acknowledge receipt of the substance(s) by recording his/her name, identification number, cost center number, and signing the computer-generated controlled substance issue form or USUHS Form 6412, USUHS/ Pharmacy Issue Form.

2. Receiving

a. All controlled substances, and regulated chemicals will be delivered to the USUHS warehouse or picked up at the Naval Medical Center Receiving area by the Inventory Management Specialist for accountability. Departments must order all controlled substances through the Pharmacy Supply Center.

b. All controlled substances received in the warehouse will be opened only by University Pharmacy staff. Upon arrival, the Pharmacy staff will take the substance to the Pharmacy to be added to the pharmacy computer program and secure it in the safe. The departments will be notified that the item is ready for pickup.

3. Inventory

a. Inventories of controlled forms and substances will be accomplished by the CSAIB as follows:

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

(2) All controlled forms will be inventoried using the consecutive, individual registry numbers;

(3) All alcohol will be inventoried using liquid measurements. Bulk stock amounts will be distinguished from small working volumes;

(4) Annually (scheduled in advance) - All Schedules III, IV, and V substances (in accordance with CFR 21, Section 1304.7, estimated counts are acceptable unless there are more than 1,000 tablets or capsules per container, in which case, exact counts are required), and alcohol log books will be reviewed for accountability; and,

(5) Annually (scheduled in advance) - All controlled forms and Schedule I and II substances (actual measurement required if original container is opened and CSAIB or the Controlled Substance Officer has reason to believe a discrepancy exists between the amount stated on the form and the actual content in the container). In addition, a random check of two or more substances is acceptable where the Department Stock is large enough to warrant weighing. This should be conducted at the discretion of the CSAIB.

b. Notify the Pharmacy Officer, in writing, when controlled substances or alcohol are brought into the University Departments through channels other than the normal procurement system (e.g., from another University, or a different laboratory).

c. The Chief of Logistics will, on a quarterly basis, provide the Pharmacy Officer with summary purchasing-issue histories of controlled substances procured by Government Services Agency (GSA) and Defense Logistics Agency (DLA). The CSAIB will use these reports to reconcile controlled substances accounts.

d. Controlled substances not obtained through procurement channels will be entered into the pharmacy computer program as follows:

(1) Anyone bringing controlled substances (Schedule I, II, III, IV, or V) into the University from other organizations (e.g., a new staff member bringing previously-owned supplies from a former place of employment) will provide a complete inventory of such items to the Pharmacy Officer within three working days after arrival of the material. Copies will be sent to the Controlled Substance Officer and the CSAIB; and,

(2) Appropriate accountability records for the drugs must be initiated within three working days after arrival of the drugs.

e. Questions pertaining to these procedures may be directed to the Pharmacy Officer by calling 295-3668.

UNIVERSITY CONTROL PROCEDURES

1. Controlled Substances Custodian (CSC) - Each department will have two individuals designated, in writing, to monitor the use of controlled forms within the department. The name of the primary and alternate custodian, in writing, 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.

2. Storage

a. Bulk stocks of alcohol (either unopened 5-gallon drums or sealed pint-size bottles) will be kept in secure storage at all times. Such storage must consist of a limited access fire retardant room or security fire cabinet secured by a University approved security lock. For controlled substances, all keys and/or combinations to storage areas or cabinets must be controlled.

b. Controlled forms will be stamped with a control number and controlled substances will be given a unit number. They must be stored in a metal, lockable cabinet or security safe that will be kept locked at all times.

c. All Schedule I drugs will be stored in an approved security safe weighing at least 750 pounds.

d. All storage cabinets or safes must be located in an area with a lockable door, which is kept locked when no one is present.

e. Controlled substances which have not been used within a three-year period, or for which there are no approved protocols requiring such substances, will be turned into the Pharmacy for storage, reissue, or destruction, accompanied by a memorandum requesting disposition of such items.

3. Losses

a. The apparent theft or other unaccountable disappearance of any controlled forms, substances, and regulated chemicals must be reported, in writing, immediately to the Pharmacy Officer; Controlled Substance Officer through the Director, EHS; with copies to Chief, Security Division; and Chairperson, CSAIB. The responsible CSC or user will submit a written report within 24 hours after the discovery of such a loss, documenting the circumstances surrounding the loss insofar as is known.

b. If loss occurs through breakage or other accident, an affidavit submitted to the Pharmacy Officer, through the CSC, by the responsible person stating the quantities lost and the circumstances shall be included in the report. If Schedule I and II substances are involved, the affidavit must be a sworn statement. Assistance is available from the General Counsel when preparing such statements.

4. Returns

a. Controlled Substances being returned to the Pharmacy must be weighed, measured, or counted by the department and accompanied by a memorandum signed by the CSC stating: generic name, quantity (in milliliters or grams) and lot number(s).

b. The Pharmacy will weigh, measure or count the substance to ensure the totals are correct. Should there be a discrepancy between the totals, prior to accepting the substance for disposition the Pharmacy will request from the CSC a written justification for the difference.

5. Destruction of Unusable Controlled Substances, and Regulated Chemicals

a. Controlled substances and alcohol that have had their identities compromised or have exceeded their shelf life will be returned to the Pharmacy for destruction. Destruction will be accomplished only after approval of the Pharmacy Officer and Controlled Substance Officer. A Controlled Substances and Alcohol Survey Request/Report (USUHS Form 6016), signed by the Controlled Substance Officer as the person responsible for the destruction and signed by the Officer(s) or civilian equivalent(s) witnessing the destruction, will be incorporated into the Pharmacy records. This certification will include the complete nomenclature and quantity of the substances destroyed, together with the method used to accomplish the destruction. After the certificate is completed, it will be retained in the Pharmacy files as authority for deleting those items from the appropriate records. Drug Enforcement Administration (DEA) Form 41 will then be submitted to serve as documentation of the destruction.

b. Items that are not currently listed on any active protocol are to be returned to the Pharmacy with the 6049 and an accompanying memorandum identifying the generic name, concentration lot number, unit number, and remaining totals. This memorandum, signed by the Department Chairperson/Activity Head, or the CSC, should detail the disposition of the substance (i.e., destruction or storage).

6. Forms Used in Controlled Substances Management

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

b. Departmental Controlled Substances Form (USUHS Form 6049, "yellow sheet") is maintained by CSC for accounting all substances received, administered, and on-hand balance.

c. List of Controlled Substances is maintained by the Drug Enforcement Agency. Modification and exemption in schedule of items change from time to time, and information is available through the University Pharmacy.

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

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

f. Controlled Substances and Alcohol Inventory Board Inventory Report (USUHS Form 6019) is used by the CSAIB to report the results of all inventory actions.

g. Standard Form 600 (SF 600) will be used by the PI to annotate the administration of controlled substances to animals. The PI will deliver a completed form to the Veterinary Medicine Division, Department of Laboratory Animal Medicine, to be placed in the animal's permanent health record.

h. Request for New Supplies/Pharmaceuticals (USUHS Form 6417) is used to request that a new item be added to those stocked in the Pharmacy.

i. Use of Biohazards, Controlled Substances, and Dangerous Materials (USUHS Form 6007, Sections 9 and 10) is used to list specific controlled substances involved in a protocol to permit evaluation. This form should include the following: generic name, concentration, container sizes, how the items will be handled

and accounted for, the physical location (both within and outside USUHS), how the items will be secured, and all precautions used to eliminate possible loss or abuse.

j. Controlled Substance Temporary Issue Receipt (USUHS Form 6058) will be prepared by the CSC for items leaving the physical facility of USUHS for use at a different location. The CSC will maintain a copy while the original will be given to the PI responsible for the items. The PI is required to immediately return the completed form to the CSC; the copy is then discarded, and the original is stored with the other controlled records. If a PI fails to obtain a Form 6058, he/she will be responsible for any lost or missing controlled substance.

k. Absolute Alcohol Storage Record (USUHS Form 6055) will be used by the alcohol custodians, PI, and staff to keep accountability of absolute alcohol stored in the Department fire cabinets. The sheet will be bound in the USUHS Pharmacy Alcohol logbook, issued by the Pharmacy Technician to the CSC/ Alcohol custodian.

l. 95% Alcohol Storage Record (USUHS Form 6056), will be used by the alcohol custodian, PI, and staff to keep accountability of 95% alcohol stored in the department hazardous material cabinets. The sheet will be bound in the USUHS Pharmacy Alcohol logbook issued by the Pharmacy Technician to the CSC/Alcohol custodian.

m. Department of Justice/Drug Enforcement Administration, Registrants Inventory of Drugs Surrendered DEA Form 41, will be prepared by the Controlled Substance Officer and submitted to DEA to account for the destruction of controlled substances.

Controlled Substances and Alcohol Inventory Board (CSAIB)
Inventory Audit Checklist

Date: _____

Dept.: _____ **Chair Name:** _____ **Safe Location:** _____

Controlled Substances Custodians (CSC):

Primary: _____

Alternate: _____ **Inventory Audit Team: CSAIB Member:** _____

Assistant (CSC): _____

	Circle One	
1. In-brief with the CSCs and Regulated Chemical (RC) Custodians.	YES	NO
2. Appointment letter for CSCs signed by Department Chairman.	YES	NO
3. CSC acknowledged appointment and received training.	YES	NO
4. Confirmed all alcohol security locations and their RC Custodians, and ensure their availability for this audit.	YES	NO
5. Storage area for controlled substances is secure and adequate.	YES	NO
6. Controlled Substances' "yellow" USUHS Form 6049s kept in safe.	YES	NO
A. There is an inventory sheet for each controlled substance with a unique logged registry number.	YES	NO
B. All notations are legible and properly entered for receipt, use, return and disposal (math correct, bottle # annotated,...)	YES	NO
C. The CSC has initialed all entries on the inventory sheets.	YES	NO
D. Contents of the controlled substance locker matches inventory pages.	YES	NO
E. All issued "yellow" sheets with last usage over 3 years ago have been returned to the Pharmacy with the unused substance (unless they have an active protocol showing the specific need for the CS).	YES	NO
7. Controlled Substances Custodians level of knowledge. Does the appointed CSC know the procedure for:		
A. Return of controlled substances for destruction.	YES	NO
B. Report lost or accidentally destroyed alcohol or controlled substances.	YES	NO

8. Discrepancies Noted: _____

_____

_____

_____

_____

9. General Comments: _____

_____

_____

10. Alcohol Inventory/Audit

Date: _____

Dept: _____ CSC Name: _____
Inventory Audit Team:
Controlled Substance and Alcohol Inventory Board (CSAIB) Member: _____
Assistant (CSC): _____

Flammable Cabinet Location: _____
Regulated Chemical (RC) Custodians:
Primary: _____
Alternate: _____

A. Storage area for alcohol is secure and adequate.	YES	NO
B. Alcohol log is maintained and notations are legible.	YES	NO
C. All log notations have been properly initialed.	YES	NO
D. Contents of the alcohol locker match the log entries.	YES	NO
E. Alcohol is maintained in labeled and capped containers.	YES	NO

F. DISCREPANCIES NOTED: _____

_____

G. GENERAL COMMENTS: _____

Flammable Cabinet Location: _____
Regulated Chemical (RC) Custodians:
Primary: _____
Alternate: _____

A. Storage area for alcohol is secure and adequate.	YES	NO
B. Alcohol log is maintained and notations are legible.	YES	NO
C. All log notations have been properly initialed.	YES	NO
D. Contents of the alcohol locker match the log entries.	YES	NO
E. Alcohol is maintained in labeled and capped containers.	YES	NO

F. Discrepancies Noted: _____

_____

G. General Comments: _____

_____

Signatures of Audit Team Members:

_____

CSAIB Member Assistant (CSC)

11. Out-brief with the Department Chairman, or representative, and CSC.	YES	NO
12. Copy of report provided to the Department Chairman.	YES	NO

REQUEST FOR ADDITIONS TO STOCK/PHARMACEUTICALS

Date:____ Requestor:_____ Telephone No.:_____

Product Requesting: GENERIC NAME_____
BRAND NAME_____

Manufacturer or Preferred Source:_____

Product Concentration:_____ Container Size:___

Number of Containers:____

Is this a one-time order? YES/ NO

Signature:_____ Protocol No.:_____

For Pharmacy Use Only

Order date:_____ Expected Arrival:_____

Order No.:_____

Figure 4.1: Form used when requesting items not in current formulary.

SAMPLE OF AN APPOINTMENT LETTER OF CSC AND ALCOHOL CUSTODIANS SIGNED BY DEPARTMENT CHAIR

MEMORANDUM FOR Pharmacy Officer, USUHS **[Date]**

SUBJECT: Appointment of Departmental Controlled Substance Custodians (CSC)

The following personnel are appointed as my Departmental CSCs (primary and alternate) and are the only individuals (besides myself) who are authorized to receive Controlled Substances and ATF-regulated alcohol. My primary CSC is listed first.

Name (Last, First)	**Phone #**	**Protocol Cost Center***	**Room Security Location**	**Date Trained**

The above individuals know they are responsible for the proper receipt of all Controlled Substances and ATF-regulated alcohol, tracking of all departmental use, and return of all unused excess or waste to the USUHS Pharmacy.

MAJ Edward J. Briand
Director, Department of Laboratory
Animal Medicine

Cc: *All Principal Investigators*
CSCs appointed above

PAGE NO. _____

95% ALCOHOL STORAGE RECORD

Balance forwarded from page #_____				Amount forwarded _____	
DATE	**CONTAINER NUMBER**	**AMOUNT RECEIVED**	**AMOUNT USED**	**BALANCE ON HAND**	**INITIAL**
Balance forwarded to page # _____				**Total**	

USUHS FORM 6056 (PHM) (12/03)

PAGE NO. _____

ABSOLUTE ALCOHOL STORAGE RECORD

Balance forwarded from page #_____			Amount forwarded _____		
DATE	**CONTAINER NUMBER**	**AMOUNT RECEIVED**	**AMOUNT USED**	**BALANCE ON HAND**	**INITIAL**
Balance forwarded to page # _____				**Total**	

USUHS FORM 6055 (PHM) (12/03)

GLOSSARY

Alcohol: 95 percent and absolute ethyl alcohol that has not been denatured to render it unfit for human consumption. Other alcohols (Methyl, Isopropyl, Methanol, etc.) are not included within this scope.

Alcoholic Liquors: Any substance containing more than 3.2 percent alcoholic content by volume and normally intended for beverage purposes.

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

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.

Controlled Substance Custodians (CSC): Personnel assigned in writing by the department chairperson and/or activity head to be responsible for the departmental management of controlled substances, alcohol, alcoholic liquors, needles, syringes, regulated chemicals and anabolic steroids.

Dangerous Materials: Substances or Materials not defined under biohazard and controlled substances that are capable of causing injury, illness, and/or death.

Prescription Drugs: Any drug identified by the Food and Drug Administration (FDA) contained in the Food, Drug and Cosmetic Act.

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.

Sensitive Items: Items identified by the University Pharmacy (needles and syringes, etc.) that have the potential for abuse.