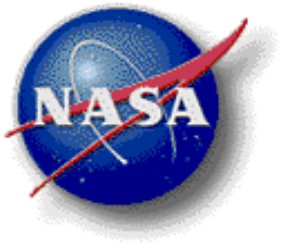
Storage and Handling of Dangerous Drugs and Controlled Substances Used for Research Purposes

Space Life Sciences Directorate

Basic

May 5, 2010

Verify that this is the correct version before use.



National Aeronautics and
Space Administration

Lyndon B. Johnson Space Center
Houston, Texas

Space Life Sciences Directorate

Storage and Handling of Dangerous Drugs, and Controlled Substances Used for Research Purposes

May 5, 2010

Approved by

Original signature on file. *6/16/2010*

Jeffrey R. Davis, M.D. Date
Director, Space Life Sciences Directorate

Approved by

Original signature on file. *6/14/2010*

J.D. Polk, D.O. Date
Chief, Space Medicine Division

Approved by

Original signature on file. *6/15/2010*

David Francisco Date
Chief, Human Adaptation and Countermeasures Division

Approved by

Original signature on file. *6/14/2010*

William Seitz Date
Chief, Habitability and Environmental Factors Division

Verify that this is the correct version before use.

REVIEW AND CHANGE PROCESS

This Work Instruction (WI) shall be reviewed, at a minimum, every two years by the Director, Space Life Science.

Document Change Record

Revision	Date	Originator / Phone	Description
Basic	5/5/2010	V. Daniels/ 281-483-6284	Approved per CR # SLSDCR-DCB-10-008

TABLE OF CONTENTS

1.0 PURPOSE

This document will provide guidance within the Space Life Sciences Directorate (SLSD) to ensure that all medications that the Drug Enforcement Agency (DEA) establishes as dangerous drugs, and controlled substances used for research purposes, including laboratory analysis, and human or animal research, are procured, handled, and stored in accordance with state and federal regulations.

2.0 SCOPE

This document is applicable to all SLSD personnel involved in laboratory research in a non-clinical setting with dangerous drugs or controlled substances.

3.0 DEFINITIONS

3.1 Dangerous (Legend) Drug: Device or drug that is unsafe for self-medication and that is not included in schedules I-V or penalty groups 1-4 of the Texas Health and Safety Code, Chapter 481 (Texas Controlled Substances Act). The term includes a device or a drug that bears, or is required to bear, either of the following legend or labels:

*”Caution: Federal law prohibits dispensing without prescription; or "Rx only" or another legend that complies with federal law”; or

*”Caution: Federal law restricts this drug to use by or on the order of a licensed Veterinarian.”

3.2 Controlled Substance: The Controlled Substances Act (CSA) places all substances that are in some manner regulated under existing federal law into one of five schedules (C-I through C-V). Schedules are established by the CSA based on specific findings concerning the drug or other substance’s medical use, potential for abuse, and safety or dependence liability. http://www.justice.gov/dea/pubs/scheduling.html

3.3 DEA: Federal Drug Enforcement Administration.

3.4 DPS: Texas Department of Public Safety.

3.5 Non-Clinical settings: A setting where a controlled substance or dangerous drug is used in research or education that is not a clinical usage of the controlled substance or dangerous drug.

3.6 Practitioner: Under the CSA, the term “practitioner” is defined as a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which the practitioner practices or performs research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

3.7 Registrant: Practitioner, physician, dentist, nurse, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, analyze, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in Texas.

3.8 NASA Institutional DEA Research Registrant: Space Medicine Division (SMD) Chief.

4.0 RECORDS AND FORMS

4.1 SMD Chief Or Delegate:

4.1.1 DEA Registration

4.1.2 DEA Form 222

4.1.2.1 Blank Prescriptions

4.1.2.2 File Copies

4.1.3 List of researcher names with DEA concurrent suffixes (Appendix Form: 14.1)

4.1.4 List of medications used in research with corresponding laboratory (Appendix Form: 14.2)

4.2 Research Laboratories Using Medications:

4.2.1 Perpetual Inventory Log for controlled substances (Appendix Form: 14.3)

4.2.2 Initial Inventory: Required for all controlled substances on hand on the date laboratory personnel first engage in conducting research with controlled substances.

4.2.3 Biennial Inventory: After the initial inventory is taken, the registrant or delegate is required to take an inventory of all controlled substances on hand, at least every 2 years (on any date which is within the 2 years of the previous biennial inventory date), in accordance with federal and state law.

4.2.4 Medication Accountability and Inventory Logs for Dangerous Drugs (Appendix Form: 14.4)

4.2.5 Controlled Substance Invoices: The original invoice is required to be maintained, in accordance with federal and state law.

4.2.6 List of personnel that have access to controlled substances or chemicals

4.2.6.1 Research Medication Authorized Users List – (Appendix Form: 14.5)

4.2.6.2 Application For Use of Dangerous Drugs or Controlled Substances for Research – (Appendix Form: 14.2)

5.0 SAFETY PRECAUTIONS AND WARNING NOTES

Dangerous drugs, and controlled substances shall be stored to provide minimal access to individuals in accordance with Code Of Federal Regulations (CFR) Title 21, Part 1301.

6.0 TOOLS, EQUIPMENT, AND MATERIALS

6.1 Storage Requirements:

6.1.1 Controlled substance medications, Schedules II-V (C-II - V), must be stored in a securely locked cabinet that meets the security standards as outlined in federal and state pharmacy laws.

6.1.2 The securely locked cabinet for controlled substance medication storage must be housed within a controlled, locked facility with limited access.

6.1.3 A log of all personnel with access to the limited-access facility will be documented and maintained.

7.0 PERSONNEL TRAINING AND CERTIFICATION

7.1 A NASA civil servant who meets DEA registrant qualifications must obtain the Institutional Research DEA registration.

7.2 The NASA Institutional Research DEA registrant delegate shall be a practitioner registered in the state of Texas.

8.0 RESPONSIBILITIES

All SLSD personnel involved in ordering, storing, handling, and dispensing of dangerous drug or controlled substance chemicals and medications must comply with all state and federal pharmacy laws.

8.1 SMD Chief –DEA Registrant:

The SMD Chief, a NASA practitioner shall maintain the NASA Institutional Research DEA Registration.

8.2 SMD Chief – Oversight:

The SMD Chief is the oversight authority and has the responsibility of ensuring the proper use, inventory accountability, record-keeping and security of all controlled substances.

8.2.1 The SMD Chief may delegate some or all authority/responsibility in writing to another practitioner licensed in the state of Texas

8.2.1.1 A list of controlled substance medications that must be reported upon DEA certificate renewal shall be maintained by the SMD Chief or delegate

8.2.1.2 A list of researchers and their assigned suffixes shall be maintained by the SMD Chief or delegate

8.3 Research Principal Investigator:

The Principal Investigator is responsible for all activities conducted under an approved Johnson Space Center (JSC) Committee for the Protection of Human Subjects (CPHS), Institutional Animal Care and Use Committee (IACUC) protocols, or analytical research protocol, to conduct analysis or experimentation with dangerous drugs, controlled substance medications, and / or chemicals.

8.3.1 The Research Principal Investigator may delegate some responsibilities (ordering, storage, handling, dispensing, disposal) for dangerous drugs and controlled substances used for research purposes to qualified laboratory personnel. All Research Investigators and lab personnel who work with dangerous drugs or controlled substances must read and comply with this work instruction.

8.4 Thefts / Losses:

Thefts, suspected thefts, unauthorized uses, or other losses of any controlled substance must be reported by primary investigator to the SMD Chief or delegate immediately upon discovery.

8.4.1 The SMD Chief or delegate will document the incident in writing per DEA Form 106, and submit the appropriate paperwork to the DEA within 72 hours, in accordance with 21 CFR Part 1301.76(b).

8.5 Medication Accountability Audits / Inspections:

The SMD Chief or delegate shall conduct periodic accountability audits of records in laboratories using medications / chemicals outlined in this work instruction.

8.5.1 Accountability Audits: Verify / document date(s) completed

8.5.2 Biennial Inventory: Verify / document date completed.

9.0 PROCUREMENT

Procurement of dangerous drugs, or controlled substances for research purposes are accomplished by completing the following steps:

9.1 Dangerous Drugs (Non-Controlled Prescription or Legend Drugs):

Prior to procurement of dangerous or legend drug from a vendor, the research investigator must submit to the SMD Chief or delegate:

9.1.1 A list of dangerous drug medications with quantities

9.1.2 A copy of the JSC CPHS, IACUC, or experimental approved research protocol

9.1.3 The name of the physician or veterinarian who will support the study with license and registration credentials

9.1.4 A completed and signed Medication Request Form (Appendix Form: 14.6)

9.1.4.1 If there is no physician or veterinarian affiliated with the study to provide the prescription order, a written request should be made to the laboratory's assigned Branch Chief to appoint one.

9.1.5 A completed and signed prescription order (Appendix Form: 14.7 – Requisition Local Purchase – Non-Controlled Medication, Chemicals, Medical Devices Used for Research Purposes)

9.1.6 The research investigator shall facilitate procurement through routine purchasing procedures

9.2 Controlled Substances:

Prior to purchasing controlled substances from vendor, the research investigator must submit the following information to the SMD Chief or delegate for review:

9.2.1 A list of controlled substance medications and their prospective quantities required to carry out the protocol (Appendix Form: 14.2 – Application for Use of Controlled Substances in Research)

9.2.2 A copy of the protocol approved by JSC CPHS for human research, or the JSC IACUC for animal research

9.2.3 The name of the physician or veterinarian who will support the study with license and registration credentials

9.2.4 A completed and signed prescription order: **C-III through C-V controlled substance**

9.2.4.1 The SMD Chief or delegate shall provide the NASA Research DEA number with an assigned suffix to the research investigator/requestor.

9.2.4.2 The study physician or veterinarian will populate and sign the prescription order (Appendix Form 14.8: Requisition (Local Purchase – Controlled Medication / Chemicals Used for Research Purposes).

9.2.4.3 The order for controlled substances may proceed through normal procurement procedures with the aid of the SMD Chief or delegate.

9.2.4.4 The DEA number with assigned suffix and any additional requested practitioner credential documentation is submitted to the vendor to complete the order.

9.2.5 **C-II controlled substance prescription order:**

9.2.5.1 The SMD Chief or delegate will prepare a Research DEA Form 222 prescription

9.2.5.2 The SMD Chief or delegate will submit the signed and dated Research DEA Form 222 prescription order to the pharmacy or chemical vendor in accordance with state and federal law

10.0 MEDICATION ACCOUNTABILITY AND RECORD KEEPING

Persons registered under the Federal and Texas Controlled Substances Acts to manufacture, distribute, analyze, or dispense controlled substances or dangerous drugs, or to conduct research with controlled substances or dangerous drugs must keep and maintain inventories and records required for 2 years from the date such inventories and records are made. A “record” is any notification, order form, statement, invoice, prescription, inventory information, or other document for the acquisition or disposal of controlled substances or dangerous drugs in conformance with record keeping and inventory requirements of federal law and the Texas Controlled Substances Act.

10.1 Dangerous Drugs and Controlled Substances:

Complete and accurate inventory records of all dangerous drug, controlled substance medications and chemicals must be maintained by the research investigator.

10.1.1 Documentation must be generated upon receipt of the initial inventory of any prescription medication, chemical or device received.

10.1.2 A Biennial inventory must be performed for all controlled substances every two years in accordance with 21 CFR Part 1304.11.

10.1.3 A copy of the prescription order and all invoice documents must be maintained in accordance with state and federal law.

10.1.3.1 Invoices must be annotated to document quantity and date received.

10.1.3.2 Original invoices for controlled substances / chemicals must be kept and filed in accordance with state and federal law.

10.1.3.3 The laboratory personnel handling the receipt of C-III – C-V controlled substances shall verify the quantities received and enter the quantities on a perpetual controlled drug inventory record.

10.1.3.4 The laboratory personnel verifying the receipt of C-III – C-V controlled substances shall place his/her signature or initials and the date of receipt on the invoice.

10.1.3.5 Copies of all invoices shall be provided to the SMD chief or delegate.

10.1.3.6 Dangerous drug or non-controlled prescription medication or device invoices must be filed separately from any controlled substance invoices.

10.1.3.7 C-II invoices must be filed separately from C-III through C-V invoices in accordance with state and federal law.

10.1.3.7.1 The C-II invoices with DEA-222 shall be retained for 2 years.

10.1.3.7.2 The C-III through C-V invoices shall be retained for 2 years.

10.1.4 Medication accountability logs must be maintained in accordance with state and federal law.

10.1.4.1 Dangerous drug medication and device accountability logs must be maintained separately from controlled substance medication accountability logs in accordance with state and federal law.

10.1.4.2 C-III - V controlled substance medication accountability logs must be maintained separately from dangerous drug medication and device accountability logs in accordance with state and federal law.

10.1.4.3 C-II controlled substance medication accountability logs must be maintained separately from C-III - V and dangerous drug medication and device accountability logs in accordance with state and federal law.

10.2 Scheduled II Controlled Substances:

SMD Chief or delegate shall handle the receipt of C-II Drugs for research use.

10.2.1 SMD Chief or delegate shall annotate the original invoice and DEA Form 222 to document quantity and date received.

10.2.2 SMD Chief or delegate shall verify the quantities received and enter the quantities on a perpetual controlled medication accountability log.

10.2.3 The Research DEA Form-222 shall be filed in the SMD office with a copy of the C-II invoice.

11.0 DISPOSITION FOR DANGEROUS DRUGS AND CONTROLLED SUBSTANCES

Expired or unusable dangerous drugs and / or controlled substances drugs in their whole dosage form must be properly disposed of as outlined in this work instruction.

11.1 The principal investigator or authorized delegate will contact the SMD Chief or Delegate when a medication is expired or can no longer be used.

11.2 All expired or unusable research medications shall be transferred to the SMD Chief or delegate for proper disposal (Appendix Form 14.9 –Research Medication Transfer of Custody).

11.2.1 C-III through C-V records shall be kept by the SMD Chief or delegate with a copy of the signed transfer form from the laboratory turned over to the SMD Chief or delegate.

11.3 If medication is a C-II medication, proper transfer of the medication using a DEA-222 Form shall be supplied by the SMD Chief or delegate to the reverse distributor disposition vendor.

11.3.1 The disposition vendor will provide documentation of the transfer for destruction to the SMD Chief or Delegate by providing a copy of the DEA Form 41.

11.3.2 C-II records shall be kept by the SMD Chief or delegate with the appropriate section of the DEA-222 turned over to the reverse distributor disposition vendor.

11.4 Incidents in which controlled substances and dangerous drugs are destroyed accidentally and cannot be recovered must be documented in detail and co-signed by a witness to the destruction. The documentation must indicate the date, name, strength, amount of substances destroyed, and method of disposal. This documentation must be filed in the laboratory with the perpetual inventory.

11.4.1 SMD Chief or delegate must be notified immediately if a controlled substance medication or chemical is accidentally destroyed.

11.4.2 In the event that a controlled substance is accidentally destroyed, lost or stolen, the SMD Chief or Delegate must execute a DEA Form 106 in accordance with Federal Law.

11.5 Dangerous drugs and controlled substances utilized for chemical analysis are considered “consumed by analysis.” Analytical waste or residue from these substances should be disposed of using medication waste receptacles and removed for destruction in accordance with vendor contract.

11.5.1 To obtain medication waste receptacles, contact the SMD Chief’s delegate or the Safety Officer assigned to the laboratory.

12.0 EMERGENCY PREPAREDNESS PLAN

The information provided in this section is intended only as a practical guideline and information source for SLSD laboratories conducting research with dangerous drugs and controlled substances in the event of a major disaster. Disaster events may be without warning (e.g. fire, explosion, earthquake) or may allow advance notification such as with a hurricane. In all events there may be damage to buildings and short-term or extended loss of power. Individuals may be away from their laboratory for several days in the event of mandatory evacuation. In the event of such a disaster, instructions for obtaining contact information, advanced preparation, and recovery / disposition for medications used for research purposes following a disaster event can be obtained by accessing the applicable NASA – JSC Division emergency preparedness plans document (SD-WI-005, SF-WI-004, SK-WI-002), found at the links below, and Appendix 14.10 of this work instruction. In addition to this specific information, all Principal Investigators and laboratory staff should be familiar with the emergency preparedness plans for the Center, Division and Branch offices; which offer a broader perspective of the issues faced and actions to be taken in the context of disaster management.
http://stic.jsc.nasa.gov/dbase/iso9000/docs/SD/master.htm

http://stic.jsc.nasa.gov/dbase/iso9000/docs/SF/master.htm

http://stic.jsc.nasa.gov/dbase/iso9000/docs/SK/master.htm

13.0 REFERENCES

13.1 Texas Health and Safety Code, Chapters 483 – Texas Dangerous Drug Act

13.2 Security Outline of the Controlled Substance Act of 1970; U.S. Dept. of Justice Drug Enforcement Administration: http://www.deadiversion.usdoj.gov/pubs/manuals/sec/sec_req.htm.

13.3 Texas Health and Safety Code, Chapters 481 – Texas Controlled Substance Act

13.4 Code of Federal Regulations, Title 21, Part 1300 – 1499. List of medications by DEA schedule: http://www.usdoj.gov/dea/pubs/scheduling.html

13.5 Crew and Thermal Systems Division Chemical Hygiene Plan (CTSD-SH-998). JSC Office of Emergency Management- Emergency Preparedness Plan, JPR 1040.4: http://www6.jsc.nasa.gov/ja/js/js7/jscepp.cfm

13.6 US Department of Homeland Security. National Response Plan. December 2004.Available at http://www.scd.state.hi.us/documents/nrp.pdf

13.7 US Public Health Service Commissioned Corps. The Mission of the Commissioned Corps. Available at http://www.usphs.gov/aboutus/mission.aspx

13.8 Centers for Disease Control and Prevention. Emergency Preparedness and Response, Strategic National Stockpile. Available at *www.bt.cdc.gov/stockpile/*

13.9 Georgia Pharmacy Foundation. *An Action Plan for State Pharmacy Associations to Respond to Natural or Man-Made Disasters*. March 1996.

13.10 US Department of Homeland Security. *Ready Business Mentoring Guide: Working with Small Business to Prepare for Emergencies: www.ready.gov/business/_downloads/mentor_guide.pdf.*

13.11 Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy August 2009

13.12 Emergency and Disaster Preparedness and Response Planning: *A Guide for Boards of Pharmacy*. National Association of Boards of Pharmacy November 2006

13.13 Medical University of South Carolina *Disaster Preparedness – Research Continuity*

14.0 FORMS AND APPENDICES

FORMS

14.1 Institutional Research DEA Assigned Suffix Log

14.2 Application For Use of Dangerous Drugs or Controlled Substances for Research

14.3 Research Laboratory Controlled Substance Inventory & Accountability Log

14.4 Research Laboratory Medication Accountability Form

14.5 Research Medication Authorized Users Form

14.6 Research Laboratory Medication Request Form

14.7 Requisition (Local Purchase – Non-Controlled Medication, Chemicals, Medical Devices Used for Research Purposes

14.8 Requisition Local Purchase Schedule III – V Chemical / Medication For Research Purposes

14.9 Research Medication Transfer of Custody Documentation

APPENDICES

14.10 Emergency Preparedness – Dangerous Drugs And Controlled Substances Used For Research Purposes

Appendix 14.10: Emergency Preparedness – Dangerous Drugs and Controlled Substances Used for Research Purposes

The information provided here is intended only as a practical guideline and information source for Space Life Sciences Directorate (SLSD) laboratories conducting research with dangerous drugs and controlled substances in the event of a major disaster. Disaster events may be without warning (e.g. fire, explosion, earthquake) or may allow advance notification such as with a hurricane. In all events there may be damage to buildings and short-term or extended loss of power. Individuals may be away from their laboratory for several days in the event of mandatory evacuation. These guidelines do not replace the official NASA – JSC Center or Division emergency preparedness plans or procedures, but will provide instruction for obtaining contact information, advanced preparation, and recovery / disposition of medications used for research purposes following a disaster event. In addition to the information provided below, all Principal Investigators and laboratory staff should be familiar with the emergency preparedness plans for the Center, Division and Branch offices; which offer a broader perspective of the issues faced and actions to be taken in the context of disaster management.

Contact Information:

- Each Principal Investigator must provide his / her contact information and provide that of two Points of Contact (POCs) for each laboratory to the Space Medicine Division (SMD) Chief or SMD Chief's Delegate in the event of disaster event:

  Name (POC)
  Phone information (*i.e. mobile, office, home, and alternate phone numbers*)
  Email address (*office and alternate*)
  Home and alternate (*evacuation***) addresses**

- Each principal investigator must maintain at both work and home, and submit to the SMD Chief or SMD Chief's Delegate a contact list for all laboratory Personnel.
  - The laboratory personnel contact list will be reviewed and updated no less than once annually to insure information is as current and accurate as possible.
- Each clinical trial group must maintain and submit to the SMD Chief or SMD Chief's Delegate a list of enrolled patients with remote contact information if evacuation is required.

Advanced Preparation:

- In the event of a disaster in which advanced notification is provided (at level 4 Hurricane alert), each laboratory using dangerous drugs or controlled substances for research must verify inventory and the accuracy of medication accountability logs in preparation for transfer.
- If the preparedness level escalates (Hurricane alert level 3), all dangerous drugs and controlled substances used for research purposes must be packaged and prepared for

transfer. Form 14.9, "Research Medication Transfer of Custody Documentation" must be completed and submitted along with the packaged medications, Material Safety Data Sheets (MSDS), and copies of accountability logs to the SMD Chief or SMD Chief's Delegate (a copy of the transfer documentation will be provided to the lab for their records).

- The SMD Chief or SMD Chief's Delegate will verify inventory and medication accountability documentation received from each laboratory transferring medication for temporary centralized storage in the Animal Care Facility (ACF), Building 37, Room 1033B.
    - Keys to the temporary centralized storage medication cabinet in the ACF will be maintained only by the SMD Chief and SMD Chief's Delegate.
        - ACF medications for emergency use, will be stored separately from the temporary centralized storage cabinet. An additional copy of the ACF emergency use cabinet key will be provided to the SMD Chief or his / her Delegate.
    - The original accountability and custody documentation received from the laboratories will be stored with the research medication in the ACF temporary centralized storage cabinet. A copy of that documentation will be compiled and transported with the SMD Chief or Chief's Delegate to their temporary evacuation site.
    - The medication will remain in the ACF centralized storage cabinet until a Center "all-clear" status has been issued, and the medications (for human or animal consumption only) have been deemed acceptable for use in accordance with State and Federal Law by the SMD Chief or SMD Chief's Delegate
- Medications requiring special temperature controlled storage conditions will remain in their current laboratory location or be transferred to a designated facility with temperature controlled storage if available.
    - If a SLSD laboratory has an active study using research medication that requires special temperature controlled storage, the name of the temporary storage facility selected will be submitted annually, in April, for inclusion in each SLSD Branch Severe Weather Plan.
    - If the medications are transferred to a designated facility with temperature controlled storage the name, address and Point-of-Contact for the temporary safe storage location, Form 14.9, "Research Medication Transfer of Custody Documentation," as well as other required documents described in item 10.3.2 must be submitted to the SMD Chief or SMD Chief's Delegate prior to transfer.
    - All storage and accountability requirements as described in this policy for storage and handling of dangerous drugs or controlled substances must be adhered to while in the temporary storage.

- In the event that power is lost and the medications are not stored in accordance with the manufacturer specified conditions, those medications will be destroyed as described in Section 11.0 of SA-WI-027, and subsequently replaced as needed.

Recovery:

The steps taken for recovery of the research mission following a major disaster will depend upon the nature of the event. In any event, Principal Investigators should follow their communication plan to keep track of laboratory personnel. Division heads should communicate with Laboratory Technical Monitors and Principal Investigators.

- In the event of a hurricane involving a mandatory evacuation or similar event, the SMD Chief will be responsible for assessing damage and contacting Research stakeholders and project administrative offices.
- There will also be direct communication with outside research funding sources where applicable. General information about the Center's business resumption will be communicated through a number of media: NASA Emergency telephone line, 877-470-5240, NASA Emergency website, www.nasa.gov/offices/eoc., and the JSC Offices of Emergency Management (OEM) Website, http://www.jscsos.com/go/site/2033/. OEM will also provide information on JSC Information Radio (AM1690), and other local radio and TV media to provide information to a broad area of the Bay Area. Information will also be provided through the Systematic Recall and Emergency Notification (SyREN) System for personnel registered to receive messages. The SMD Chief will work with OEM to post accurate information about plans and requirements for research personnel return.
- Once the Center "All-Clear" has been issued, and laboratories are clear to resume work, the SMD Chief or Chief's Delegate will assess condition of research medications and certify the inventory as fit for use in accordance with State and Federal pharmacy law.
    - If the medication inventory is deemed as fit for use, the SMD Chief or Chief's Delegate will transfer medication back to the applicable lab using Form 14.9, Research Medication Transfer of Custody Documentation
    - Should the centralized storage area for research medications sustain flood and/or fire damage, and the entire medication inventory becomes unfit for human or animal use, or the temperature controlled storage area for research medications requiring refrigeration / freezing experience a loss of power for an extended period of time, the medication will be destroyed as described in Section 11.0 of SA-WI-027, and subsequently replaced as needed.