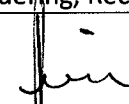


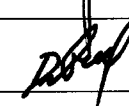


SOP #: 205.01

Title: SOP - Ordering, Receiving, Inspection and Tracking of Controlled Substances

Approvals:

Attending Veterinarian  **Date:** 10/11/12

Assistant Director LAR  **Date:** 10/11/12

1. Purpose

1.1 To delineate the procedures for ordering, receiving, and inspection of supplies and controlled substances

2. Responsibility

2.1 Receiving Animal Care Facility Personnel

3. Definitions

3.1 Controlled Substances (CS) – those chemical compounds for which manufacture, sale and use are subject to the provisions of the Controlled Substances Act of 1970.

4. Guidelines

4.1 Ordering Controlled Drugs:

4.1.1 All controlled substances category C-III to C-V would be ordered from the supplier using a purchase order. For items from category C-II, use the DEA Form 222 for ordering. Previous arrangements with the Attending Veterinarian need to be made for placing orders for CS.

4.2 Receiving Controlled Drugs:

4.2.1 When the controlled substances arrive the receiver will follow the following receiving procedures:

4.2.1.1 Inspection:

4.2.1.2 The person receiving the order will complete the controlled substances inspection form 901 current revision.

4.2.1.3 Items that did pass inspection (right drugs, intact packaging, within expiration limits) will be released for use and hand logged into the CS form and placed into the safe by the Animal Facility Manager or appropriate personnel, who are supplied with the combination to the safe.

4.3 Tracking

4.3.1 All controlled substances will be tracked following form 901 current revision with entries for the following:

4.3.1.1 Drug Name (Item), ML's Per Bottle, Concentration, Supplier and Manufacture.

4.3.1.2 Date received, Lot number, Container Number, Expiration date, Qualified, Date opened, Initials, Date closed, and Initials.

4.3.1.3 Once an item is opened and labeled appropriately on the tracking form, the drug name and lot number are then entered onto the Controlled Substance Log, form 902 current revision.

4.3.1.4 Amounts are then individually logged on a per use basis including the following information:

4.3.1.4.1 Initial amount of new bottle or carry over from previous page.

4.3.1.4.2 Containers or vials from one lot can be entered continuously sheet to sheet with amounts carried over.

4.3.1.4.3 As the last container or vial of a lot number is closed the final sheet will be closed. Empty spaces lined through, N/A, signed and dated.

4.3.1.4.4 Containers or vial with a new lot number must begin a new sheet.

4.3.1.4.5 Date used / initial, Audit date/initial, Vial (container) number, species, Identification number (ID) and or name of animal, amount used, amount remaining, and procedure/comments.

4.3.1.4.6 Audit date/initial –The Director and Assistant Director perform a monthly audit to confirm amount used.

4.3.1.4.7 Drugs used for anesthesia cocktails or diluted analgesia solutions preparation must also be entered on the Controlled Substance for the respective mix.

- 4.3.1.4.8 Vial number, Date prepared/Initial, Expiration date, and Lot and Vial number for each individual component, which makes up the solution has to be recorded on the label affixed to the bottle used to store the mix.
- 4.3.1.4.9 The solution expires after 30 days and is discarded. (Does not have to be officially disposed through the State Board of Pharmacy).
- 4.3.1.4.10 The solution is then stored upright in the safe with the controlled substances and is logged on a per use basis.
- 4.3.1.4.11 Date, initial, Audit date/initial, ID*, Species/Breed, number of animals used, dosage per animal, approximate amount used, amount remaining, and procedures/comments are recorded in the corresponding form.
- 4.3.1.4.12 ID* - not inclusive to individual rodents unless noted. Enter quantity of rodents used.
- 4.3.1.4.13 Due to the small amounts used per rodent during procedures and amounts potentially lost in the needle hub, approximate amounts of mixed or diluted solutions used are indicated.

4.4 Disposal:

- 4.4.1 For disposal of CS, contact person is Surendra Dua, Ph.D., CHP, MHP, CLSO (Radiation, Laser, Controlled Substances and Nanotechnology Safety Officer), Environmental Health & Safety. Phone: (305) 348-0489; e-mail: duas@fiu.edu who will provide instructions.

4.5 Contingencies:

- 4.5.1 Any inventory discrepancy must be reported immediately to the Director or Assistant Director, so the proper course of action can be determined.
- 4.5.2 Allow for 5 – 10% overfill in each vial determined by individual manufacture.

5. References

- 5.1 Drug Enforcement Agency – Practitioner’s Manual
(<http://www.deadiversion.usdoj.gov/pubs/manuals/pract/index.html>)