

Annex L - Safe keeping, storage, and transportation

(1)(a) The licensed operator shall ensure that the safekeeping, handling and transportation of the controlled substance are in accordance with the Fire Code of the Philippines and its implementing regulations, JOINT DTI-DENR-DA-DOF-DOH-DILG-DOLE-DOTC ADMINISTRATIVE ORDER NO. 01 Series of 2009 Subject: The Adoption and Implementation of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), and the Material Safety Data Sheet or Safety Data Sheet of the controlled substance concerned and this regulation:

(b) The storage area should be sheltered; fenced-up; under lock and key; provided with kerb/hump all round the storage area; provided with fire protection and safety facilities; equipped with leak detection and warning devices and emergency scrubbing systems for storage of toxic gases.

(c) The containers and storage tanks for the chemicals must be designed, manufactured and tested in accordance to acceptable standards.

(2)(a) Licensed holder must store raw materials and immediate controlled precursor, bulk materials awaiting further drug processing, and finished dangerous drug products in one of the following secure storage areas:

(i) a safe or steel cabinet where small quantities permit;

(1) Which safe or steel cabinet, if it weighs less than 350 kilograms, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed; and

(2) Which safe or steel cabinet, if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system which, upon attempted unauthorized entry, shall alert the company security force.

(ii) A vault of substantial construction with a steel door, combination or key lock, and an alarm system.

b) A building used for storage of controlled drugs, except with perimeter security which limits access during working hours and provides security after working hours and meets the following specifications:

(i) has an electronic alarm system.

(ii) Is equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided, however, a door which is kept closed and locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the registrant is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. Regarding hinged doors, where hinges are mounted on the outside, such hinges shall be sealed, welded or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination or key-lock type and:

(1) In the case of key locks, key control shall be required to limit access to a limited number of employees, or;

(2) In the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination;

(c) A cage, located within a building on the premises, shall meet the following specifications:

(i) Having walls constructed of not less than No. 10 gauge steel fabric mounted on steel posts, which posts are:

(1) At least one inch in diameter;

(2) Set in concrete or installed with lag bolts that are pinned or brazed; and

(3) Which are placed no more than ten feet apart with horizontal one and one-half inch reinforcements every sixty inches;

(ii) Having a mesh construction with openings of not more than two and one-half inches across the square,

(iii) Having a ceiling constructed of the same material, or in the alternative, a cage shall be erected which reaches and is securely attached to the structural ceiling of the building. A lighter gauge mesh may be used for the ceilings of large enclosed areas if walls are at least 14 feet in height,

(iv) Is equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and

(v) Is equipped with an alarm system which upon unauthorized entry shall transmit a signal directly to the company's security force.

(d) An enclosure of masonry or other material, as providing security comparable to a cage;

(e) A building or enclosure within a building which continues to provide adequate security against the diversion of Schedule 1 through 5 controlled substances, of which fact written acknowledgment has been made by the PDEA;

(f) The controlled substance storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through controlled substance storage areas, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

(3) Working stocks of dangerous drugs of a registered pharmacy shall be kept in a stationary, securely locked cabinet of substantial construction.

(4) Working stocks of dangerous drugs held by license holders engaging in research, instructional activities, and chemical analysis shall be securely kept as follows:

(a) The controlled substance must be kept only in a fixed and stationary, secure and substantially constructed locked cabinet or vault or other containment furniture. Access to the controlled substance cabinet is to be limited to individuals who are registrants.

(b) A permanently locked room accessible only to the authorized users may serve as a vault if the locked safe is placed in this room.

(c) In containment structures located in a room or office that is not accessible to the general public or students who are not involved in approved laboratory and research activities.

(d) Key locks or safe combinations should be changed whenever personnel changes occur, or on a prearranged schedule determined by the department chair.

(5) Hospitals/institutional dispensers shall safeguard drugs as follows:

(a) Storage of bulk controlled substances must be in the main pharmacy vault, or other limited access locked room or cabinet. Controlled substances must be stored separate from non-dangerous drugs stock.

(b) The working stock of controlled substances must be stored in a locked cabinet or secured cart; it must not be dispersed with general pharmacy stock.

(c) All outpatient controlled substances awaiting patient pickup must be stored in a locked area or cabinet. Employees having access to the locked area are to be limited and documentation of access must be maintained.

(d) Access control systems in pharmacies shall be provided to monitor access to controlled substances. This includes vaults or cabinets used for storage of controlled substances within pharmacies, and secured areas utilized for dispensing controlled substances within pharmacies.

(e) Facilities and equipment used to store drugs should be so designed that the drugs are accessible only to medical practitioners authorized to prescribe, to pharmacists authorized to dispense, or to nurses authorized to administer such drugs.

(f) Medication carts shall be provided with the following:

(i) double-keyed locks;

(ii) when not in use, anchored to a floor or wall device or maintained in another secure location;

(iii) locked drawer system;

(iv) independent locking device.

(6) Dangerous drugs for veterinary use shall be stored in a sturdy locked facility, fixed to the floor or wall. When transported for use in another location, dangerous drugs must be stored in a locked receptacle (e.g. toolbox) in the veterinary practitioner's possession. If the receptacle is necessarily out of the veterinary practitioner's possession (even for a brief period), it should be secured, out of sight, in a lockable facility (e.g. concealed in locked vehicle or locked cupboard) to prevent unauthorized access.

(7) Training aids for K-9 dangerous drugs detector dog program will comply with the following minimum security and control requirements:

(a) Controlled substance training aids will be stored in a location meeting the minimum criteria shown below.

(i) Vault in an enclosed area and/or room of sturdy construction for secure storage structures within the building;

(ii) The door(s) to the room in which controlled substance training aids are stored will be secured using approved locking devices. Lightweight doors will be replaced with solid metal or wood doors, or covered with 9-gauge to 12-gauge security screen or 16-gauge sheet steel. It will be fastened with smooth-headed bolts and nuts, and peened in place.

(iii) All windows providing access to a storage room that is not staffed 24 hours a day will be protected by a 9-gauge to 12-gauge security screen, or 3/8-inch or larger diameter steel bars spaced no more than 6 inches apart. The frames holding the screen or bars must be fastened to the window frame with smooth-headed bolts.

(b) Storage containers for dog training.

(i) Controlled substance training aids will be secured in a security container equipped with approved 3 position combination locks. If the security container weighs less than 350Kg it will be bolted, chained, or cemented to the floor or wall in such a way that it cannot be readily removed.

(ii) Heroin, cocaine, hashish, marijuana, ephedrine and pseudoephedrine will each be stored in a separate area, drawer, or container within the security container to prevent cross-contamination of the individual odor characteristics of each substance.

(iii) Heroin, hashish, cocaine, methamphetamine, ephedrine, marijuana and MDMA training aids shall be packaged in 5 to 20-gram containers.

(c) Access control. The controlled substances storage area shall be accessible to an absolute minimum number of specifically authorized personnel.

(i) Access to the controlled substance storage room will be limited to the primary and alternate custodians, and a very limited number of other individuals. These are persons who will require access for official purposes. A copy of access authorizations will be maintained on file in the storage area, but will not be posted in the area or on the container.

(d) The doors to the storage area will always be locked unless authorized personnel are physically present and have direct observation of the storage container.

(e) During normal duty hours or at other times when the storage room has been authorized to be opened, unauthorized personnel will not be allowed to enter the storage room. The storage container will not be opened except to issue, inventory, repackage, or return controlled substance training aids, or to perform other necessary and authorized functions. At all other times, the storage container will be secured.

(f). Weight checks.

(i) Each container of controlled substances will be weighed monthly and verified by a responsible person who will certify the exact weight of each controlled substance training aid/container in grams. Completed weight check recording will be filed in the controlled substances accountability folder.

(ii) Minor weight variation because of irretrievable loss resulting from breakage of training aids during dog team training exercises or any unexplained or suspicious loss of more than one gram of heroin, cocaine, or hashish, or two grams of marijuana will be reported immediately to the PDEA.

(g). Inventories.

(i) Inventories will be made

(1) Once during each calendar quarter.

(2) When a new primary controlled substance training aid custodian is appointed.

(3) When any controlled substances are lost from storage, or when there has been a breach in security of the storage room or storage container.

(ii) Change of primary custodian inventories will be joint inventories between the old and new custodian.

(iii) An inventory will completely account for all quantities of controlled substances maintained as training aids and will be a complete audit of the accountability records pertaining to those

substances. Only those records that are still active and those that have not been previously audited need to be audited. The person conducting the inventory will positively account for all quantities and types of substances by verifying the audit trail and the amount of the substances on hand.

(iv) The person conducting the inventory will prepare a report for the PDEA. A copy of the report will be maintained with the controlled substances accountability folders in a secure files storage area. Inventory reports will be maintained for at least two years from the date of the report

(h) Control of use

(i) Training aids will be issued, returned, and secured during the same duty day;

(ii) Control of training aids during use.

(1) All personnel authorized to conduct training using controlled substance training aids will be thoroughly briefed on the security requirements and personal responsibility for controlled substances before being allowed to participate in the training. Briefings will be conducted at least annually thereafter. A written record for these briefings will be made and will be maintained on file.

(2) The person who was issued and is using controlled substance training aids for training is responsible for the control and security of the training aids. This person will not leave the immediate area where training aids are being used, and is responsible for retrieving and returning all training aids to the custodian.

(3) Unauthorized personnel will not be allowed to handle training aids. However, different authorized personnel should be involved in placing training aids rather than the same person, so that the dog genuinely responds on the training aids rather than the scent of the person placing the training aids.

(8)(a). Registrants/licensees who store controlled substances in warehouses or terminal or depots are responsible for selecting a facility which meets the standard physical security requirement and controls, with the knowledge that it is the registrant/licensee, not the warehouseman, who is responsible for the security of the controlled substance. The PDEA shall determine if the overall security is adequate. The licensee shall notify PDEA in writing within fifteen (15) working days of any change in the warehouse inspected and approved by Director General, PDEA.

(b) Registrants/licensees are also responsible for utilizing a common or contract carrier that will provide adequate security of the controlled substances while they are in transit. Precautions such as securely wrapping and sealing packages containing controlled substances or utilizing unmarked or coded boxes or shipping containers are required for guarding against losses in storage or in transit.

(c) The responsibility for the safe custody of shipments of controlled substances rests with the supplier until the recipient acknowledges receipt, even if the supplier employs the services of contract carriers and parcel delivery companies to undertake its deliveries. It is also the responsibility of the supplier to report any discrepancy, loss or theft to the PDEA.

(d) When evaluating security of warehouses or terminal or depots Director General, PDEA will

consider the following aspects:

(i) warehouses or terminal or depots

(1) Adequacy of sturdy cage and/or walled compartmentalization, perimeter fence, lighting, electronic detection and monitored alarm system, checkpoints, and other perimeter controls;

(2) Use of order tracking or tracing system;

(3) Personnel screening, hiring, and control programs and adequate supervision, including pre-hire and random drug testing programs and routine conduct of criminal background checks of applicants

(4) Hours of operation;

(5) Employee reporting of knowledge of diversion

(6) Use of contract or proprietary guards;

(7) Procedures and systems to control in-bound and out-bound tractors, trailers, containers, vehicles, customers, visitors, maintenance personnel, outside contractors and other individuals in areas of the facility where controlled substances are stored, such as guarded entrance, roving security patrols and fencing surrounding the perimeter of the property;

(8) Yard control of customers, personnel, drivers, tractors, trailers, containers, vehicles;

(9) Compliant with the Fire Code of the Philippines;

(10) Controlled substance in tanks, sealed containers or totes are securely stored;

(11) Conduct of random inspection of packages or bags carried by individuals as they leave the facility;

(12) Periodic cycle counts to identify any possible discrepancy;

(13) All shipments and deliveries are inventoried prior to loading into trucks and verification of inventory is also conducted upon delivery to consignee;

(14) Trucks are sealed and the seal inspected before the truck leaves the warehouse/depot premise or compound and upon arrival at destination;

(15) Conduct of random checks of vehicles that are leaving and arriving the warehouse/depot compound;

(e) When evaluating security of common or contract carriers, including the company-owned or leased vehicles operated by company employees, PDEA will consider the following aspects:

(i) Physical security of the vehicles, e.g.:

(1) Adequate vehicle and trailer locks subject to proper key control, and locking of vehicles at all times when unattended;

(2) Vehicular alarm systems in use at all times when vehicles and trailers are unattended;

(3) Fuel lock alarm devices.;

(ii) Delivery men can communicate with local law enforcement agencies or the warehouse-or depot- or- terminal security unit in the event of an emergency or other condition

(iii) Driver screening, hiring and control programs including periodic drug testing.

(iv) Maintain its vehicles in good condition and in accordance with manufacturers' recommendations;

(v) Issue comprehensive instructions to its staff to deal with routine and emergency situations;

(vi) Provide its drivers with identity cards or other appropriate forms of identification;

(vii) Prohibit drivers from transporting unauthorised passengers and making visits to their homes and unauthorised locations;

(viii) whenever an accident occurs which requires the attendance of the emergency services, the PDEA or police should be made aware of the incident and the vehicle's contents;

(ix) Route variations to avoid patterns;

(x) Distributing and transporting or otherwise handling a controlled chemical is accompanied by an MSDS or SDS.

(xi) All drivers must be trained in the handling of accidental spills of hazardous controlled chemicals and have attended a special course for the purpose.

(8)(b) When transporting controlled substances:

(i) Transfer of controlled chemicals, except raw material of Table I precursor chemical used in the manufacture of pharmaceutical drug preparation from one licensed operator to another or from one address to another, shall be accompanied by documentation indicating

(1) the name and quantity of the controlled chemical;

(2) the name of the licensed dealer selling or providing the controlled chemical;

(3) the name of the person to whom the controlled chemical is being sent, transported or delivered;

(4) copy of the PDEA license,

(5) delivery or sales receipt and/or invoice receipt, and

(6) MSDS or Safety Data Sheet or latest version of the globally harmonized system-based (GHS-based) version of the chemicals, which shall be kept by the person in charge of making the delivery.

(7) the date the controlled chemical was sent.

(ii) transport of hazardous controlled chemicals shall also be in accordance to the JOINT DTI-DENR-DA-DOF-DOH-DILG-DOLE-DOTC ADMINISTRATIVE ORDER NO. 01 Series of 2009 Subject: The Adoption and Implementation of the Globally Harmonized System (GHS) of Classification and Labelling of Chemicals and regulations pertinent thereto that are issued by implementing agencies and this Regulation.

(iii) Key locks or safe combinations should be changed whenever personnel changes occur, or on a prearranged schedule determined by the department chair.