Sec. 21a-115-32. Minimum requirements for the storage and handling of drugs and for the establishment and maintenance of drug distribution records by wholesalers

(a) **Facilities.** All facilities at which drugs are stored, warehoused, handled, offered, markted, or displayed shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

(4) Be maintained in a clean and orderly condition; and

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) **Security**.

(1) All facilities operated by wholesalers shall be secure from unauthorized entry.

(2) Access from outside the premises shall be kept to a minimum and well controlled.

(3) The outside perimeter of the premises shall be well-lighted.

(4) Entry into areas where drugs are held shall be limited to authorized personnel.

(5) All facilities shall be equipped with an alarm system to detect entry after business hours.

(6) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(7) In the case of wholesalers who are also licensed as pharmacies in accordance with Chapter 382, Section 20-168 of the general statutes, subdivisions (2) and (4) of this subsection shall apply only to areas where legend drugs are stored.

(c) **Storage.**

(1) All drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United State Pharmacopoeia/National Formulary (USP/NF).

(2) If no storage requirements are established for a drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(3) Appropriate measures shall be undertaken to ensure that drugs are stored under conditions of proper temperature and humidity and that such storage conditions are adequately documented.

(4) The recordkeeping requirements in subsection (f) of this section shall be followed for all stored drugs.

(d) **Examination of materials.**

(1) Upon receipt each outside shipping container shall be visibly examined for identity and to prevent the acceptance of contaminated drugs or drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would

suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected for identity of the drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.

(3) The recordkeeping requirements in subsection (f) of this section shall be followed for all incoming and outgoing drugs.

(e) **Returned, damaged, and outdated drugs.**

(1) Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.

(2) Any drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesaler shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(4) The recordkeeping requirements in subsection (f) of this section shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated drugs.

(f) **Recordkeeping.**

(1) Wholesalers shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs. These records shall include the source of the drugs, including the name and principal address of the seller or transferor, the address of the location from which the drugs were shipped or in the case of distribution the name and address of the purchaser; the identity and quantity of the drugs received and distributed or disposed of; and the dates of receipt and distribution or other disposition of the drugs. In the case of registered wholesalers who are also licensed as pharmacies in accordance with Chapter 382, Section 20-168 of the general statutes, no records shall be required to be maintained for the receipt or disposition of over-the-counter drugs.

(2) Inventories and records shall be made available for inspection and photocopying by authorized Federal, State or local officials for a period of 3 years following disposition of the drugs.

(3) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within 2 working days of a request by an authorized official of a Federal, State, or local agency.

(g) **Written Policies and Procedures.** Wholesalers shall establish, maintain, and adhere

to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesalers shall include in their written policies and procedures the following:

(1) A procedure whereby the oldest approved stock of a drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate;

(2) A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to: any action initiated at the request of the U. S. Food and Drug Administration or other Federal, State, or local law enforcement or government agency; any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design;

(3) A procedure to ensure that the wholesaler prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency;

(4) A procedure to ensure that any outdated drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated drugs. This documentation shall be maintained for 3 years after disposition of the outdated drugs; and

(5) In the case of wholesalers who are also licensed as pharmacies in accordance with Chapter 382, Section 20-168 of the general statutes, the requirements of this subsection shall apply to legend drugs only.

(h) **Responsible Persons.** Wholesalers shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(Effective August 27, 1992)