



TEXAS DEPARTMENT OF STATE HEALTH SERVICES

DSHS Web Site: <http://www.tdh.state.tx.us/bfds/dmd/salvagerules.html>

RULES FOR REGULATION OF DEVICE SALVAGE ESTABLISHMENTS AND BROKERS

(25 Texas Administrative Code, §§229.601-229.614)

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§229.601. Purpose

These sections provide for the licensing and regulation of device salvage establishments and brokers to prevent the sale or distribution of adulterated or misbranded devices to consumers.

§229.602. Applicable Laws and Regulations

(a) A salvage establishment or salvage broker who is subject to these sections and who is also involved in the reconditioning, sale or distribution of distressed or salvaged food, drugs, or cosmetics must comply with the applicable requirements in Subchapter AA of this chapter (relating to Regulation of Food Salvage Establishments and Brokers), Subchapter BB of this

chapter (relating to Regulation of Drug Salvage Establishments and Brokers), and Subchapter DD of this chapter (relating to Regulation of Cosmetic Salvage Establishments and Brokers).

(b) The Department of State Health Services (department) adopts by reference the following federal laws and regulations:

(1) Fair Packaging and Labeling Act, 15 United States Code (U.S.C.), §1451 et seq., as amended;

(2) Federal Food, Drug, and Cosmetic Act, 21 U.S.C., §301 et seq., as amended;

(3) §501(c)(3), Internal Revenue Code of 1986, as amended;

(4) 21 Code of Federal Regulations (CFR), Part 801, as amended;

(5) 21 CFR, Subchapter J, Radiological Health, as amended; and

(6) 21 CFR, Part 820, Quality System Regulation, as amended.

(c) Copies of the laws and regulations referenced in subsection (b) are indexed and filed at the department, 1100 West 49th Street, Austin, Texas 78756, and are available for inspection during normal working hours. Electronic copies of these laws and regulations are available online at <http://www.dshs.state.tx.us/license.html>.

(d) Nothing in these sections shall relieve any person of the responsibility for compliance with other applicable state and federal laws and regulations.

§229.603. Definitions

The following words and terms, when used in these sections, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Act - The Texas Food, Drug, Device, and Cosmetic Salvage Act, Health and Safety Code, Chapter 432.

(2) Adulterated device - Has the meaning specified in the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431, §431.111.

(3) Authorized agent - an employee of the department who is designated by the commissioner to enforce the provisions of this chapter.

(4) Change of ownership - A sole proprietor who transfers all or part of the salvage establishment or salvage broker business to another person or persons; the removal, addition, or substitution of a person or persons as a partner in a salvage establishment or salvage broker business owned by a partnership; a corporate sale, transfer; reorganization; or merger of the corporation which owns the salvage establishment or salvage broker business if the sale, transfer,

reorganization, or merger causes a change in the salvage establishment's or salvage broker business's ownership to another person or persons; or if any other type of association, the removal, addition, or substitution of a person or persons as a principal of such association.

(5) Class I exempt device - A class I device not labeled or otherwise represented as sterile that has been determined by the U.S. Food and Drug Administration to be exempt from the current good manufacturing practice requirements in 21 CFR, Part 820 (quality system regulation), except for general requirements concerning records (21 CFR, §820.180) and complaint files (21 CFR, §820.198).

(6) Class I device - A device determined by the U.S. Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, §513, to be subject to only the general controls authorized by or under §§501 (adulteration), 502 (misbranding), 510 (registration), 516 (banned devices), 518 (notification and other remedies), 519 (records and reports), and 520 (general provisions) of the Federal Food, Drug, and Cosmetic Act.

(7) Class II device - A device determined by the U.S. Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, §513, to be subject to or eventually subject to special controls, such as performance standards, postmarket surveillance, patient registries, or guidance documents.

(8) Class III device - A device determined by the U.S. Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, §513, to be subject to or eventually subject to the premarket approval requirements in the Federal Food, Drug, and Cosmetic Act, §515.

(9) Commissioner - The Commissioner of Health or his successor.

(10) Cosmetic - Any article or substance intended to be rubbed, poured, sprinkled, or sprayed on or introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering appearances; or an article or substance for use as a component of such an article, except that the term does not include soap.

(11) Department - The Department of State Health Services.

(12) Device - An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component; part, or accessory; that is:

(A) recognized in the official United States Pharmacopoeia National Formulary or any supplement to it;

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals; or

(C) intended to affect the structure or any function of the body of man or other animals and that does not achieve any of its principal intended purposes through chemical action within or on

the body of man or other animals and is not dependent on metabolization for the achievement of any of its principal intended purposes.

(13) Device manufacturer - A person who manufactures, fabricates, assembles; or processes a finished device. The term includes a person who repackages or relabels a finished device. The term does not include a person who only distributes a finished device.

(14) Distressed device - Any device that is adulterated or misbranded within the meaning of the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, §§431.111 and 431.112. The term includes a device that:

(A) has lost its labeling or is otherwise unidentified;

(B) has been subjected to prolonged or improper storage, including insanitary conditions whereby the device may have been contaminated with filth or whereby it may have been rendered injurious to health;

(C) has been subjected for any reason to abnormal environmental conditions, including temperature extremes, humidity, smoke, water, fumes, pressure, or radiation;

(D) has been subjected to conditions that result in either its strength, purity, or quality falling below that which it purports or is represented to possess; or

(E) may have been rendered unsafe or unsuitable for its intended use according to the manufacturer's recommendations or specifications; or for any reason other than those specified by this paragraph.

(15) Drug -

(A) an article or substance recognized in the official United States Pharmacopoeia, the official Homeopathic Pharmacopoeia of the United States, the official National Formulary, or any supplement of them;

(B) an article or substance designed or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

(C) an article or substance, other than food, intended to affect the structure or any function of the body of man or other animals; or

(D) an article or substance intended for use as a component of any article or substance specified in this definition.

(16) Finished device - A device, or any accessory to a device, which is suitable for use, whether or not packaged or labeled for commercial distribution.

(17) Flea market - A location at which booths or similar spaces are rented or otherwise made available temporarily to two or more persons and at which the persons offer tangible personal property for sale.

(18) Food -

(A) any article of food or drink for man;

(B) chewing gum; or

(C) an article used for components of any such article.

(19) Labeling - All labels and other written, printed, or graphic matter:

(A) upon any article or any of its containers or wrappers; or

(B) accompanying such article.

(20) Misbranded device - Has the meaning specified in the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431, §431.112.

(21) Nonprofit organization - An organization that has received an exemption from federal taxation under 26 U.S.C., §501(c)(3).

(22) Nonsalvageable device - A distressed device, as defined in this section, which cannot be safely or practically reconditioned.

(23) Person - Includes individual, partnership, corporation, and association.

(24) Personnel - Any person employed by a salvage establishment or salvage broker who does or may in any manner handle or come in contact with the handling; storing; transporting; or selling and distributing of salvageable or salvaged devices.

(25) Place of business - Each location from which a salvage establishment or salvage broker operates. The term does not include a salvage warehouse.

(26) Practitioner - A person licensed by the Texas State Board of Medical Examiners, State Board of Dental Examiners, Texas State Board of Podiatric Medical Examiners, Texas Optometry Board, or State Board of Veterinary Medical Examiners to prescribe and administer prescription devices.

(27) Prescription device - A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which adequate directions for use cannot be prepared.

(28) Quality audit - An independent examination of a salvage establishment, including the organizational structure and responsibilities, procedures, and processes necessary to ensure that such resources and activities comply with the requirements of these sections and result in the adequate reconditioning of a distressed device.

(29) Reconditioning - Any appropriate process or procedure by which a distressed device can be brought into compliance with the standards of the department for use by the public. In addition, all reconditioned devices must be in compliance with the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431.

(30) Sale or distribution - The act of selling or distributing, whether for compensation or not; and includes delivery; holding; or offering for sale; transfer, auction; storage; or other means of handling or trafficking.

(31) Salvage broker - A person who engages in the business of selling, distributing, or otherwise trafficking in any distressed or salvaged food, drug, device, or cosmetic and who does not operate a salvage establishment.

(32) Salvage establishment - Any place of business engaged in reconditioning or by other means salvaging distressed food, drugs, devices, or cosmetics, or that sells, buys, or distributes for human use any salvaged food, drug, device, or cosmetic.

(33) Salvage operator - A person who is engaged in the business of operating a salvage establishment.

(34) Salvage warehouse - A separate storage facility used by a salvage broker or salvage establishment for the purpose of holding distressed or salvaged devices.

(35) Salvageable device - Any distressed device, as defined in this section, which can be reconditioned to departmental standards.

(36) Salvaged device - Any distressed device that has been reconditioned.

(37) Vehicle - Any truck, car, bus, or other means by which distressed, salvageable, or salvaged devices are transported from one location to another.

§229.604. Exemptions and Applicability

(a) A person is exempt from licensing under these sections if the person is:

(1) a manufacturer or distributor of a device who in the normal course of business engages in the activities of reconditioning the device manufactured or distributed by or for that person and not purchased by that person solely for the purpose of reconditioning and sale;

(2) a person who is a common carrier or the common carrier's agent, who disposes of or otherwise transfers an undamaged or distressed device to a person who is exempt under this section or to a licensed salvage broker or salvage operator; or

(3) a person who transfers a distressed device to a licensed salvage broker or salvage operator.

(b) An exemption from the licensing requirements under these sections does not constitute an exemption from other applicable provisions of the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431 or the rules adopted to administer and enforce the Act.

(c) A salvage establishment or salvage broker who is engaging in conduct within the scope of the license issued under §229.605 of this title (relating to Licensing Requirements and Procedures) is not required to also be licensed under Health and Safety Code, Chapter 431. An exemption from the licensing requirements under Health and Safety Code, Chapter 431, does not constitute an exemption from other applicable provisions of Health and Safety Code, Chapter 431, or the rules adopted to administer and enforce the chapter.

(d) These sections do not apply to the sale or distribution of previously used devices that are not distressed devices and have been determined to function properly and meet manufacturer's performance specifications. Acceptable determinations of functionality shall include at least one of the following:

(1) certification statements;

(2) reports of inspection, installation, or calibration; or

(3) product conformance affidavits.

(e) All certification statements, reports, and conformance affidavits referenced in subsection (d) of this section shall be completed, signed and dated no more than 14 days prior to the time of sale or distribution by:

(1) a qualified representative of the seller;

(2) a qualified representative of a hospital licensed under Health and Safety Code, Chapter 241;

(3) a person licensed under these sections; or

(4) a state or federal regulatory agency having knowledge or jurisdiction over the devices subject to any sale or distribution.

§229.605. Licensing Requirements and Procedures

(a) General. Except as provided by §229.604(a) of this title (relating to Exemptions and Applicability), it shall be unlawful for any person to operate a salvage establishment or act as a

salvage broker within this state, who does not possess a current and valid license issued by the department.

(b) Licensing of out-of-state salvage establishments and brokers. A person who operates a salvage establishment or acts as a salvage broker outside this state may not sell, distribute, or otherwise traffic in distressed or salvaged food, drugs, devices, or cosmetics within this state unless the person holds a license from the department.

(c) Reports from other jurisdictions. The department may accept reports from authorities in other jurisdictions to determine the extent of compliance with these sections and with the provisions of the Act.

(d) New place of business. Each person acquiring or establishing a place of business for the purpose of operating a salvage establishment or operating as a salvage broker shall apply for and obtain a license of such business prior to beginning operation.

(e) Two or more places of business. If the salvage establishment or salvage broker operates more than one place of business, the salvage establishment or salvage broker shall license each place of business separately.

(f) License application. License application forms may be obtained from the department, 1100 West 49th Street, Austin, Texas 78756 or online at <http://www.dshs.state.tx.us/license.shtm>.

(g) Contents of license application. The application for licensing as a salvage establishment or salvage broker shall be signed and verified, submitted on a license application form furnished by the department, and shall include the following information:

(1) the name of the legal entity to be licensed, including the name under which the business is conducted;

(2) the address of the place of business to be licensed and the mailing address or billing address if different;

(3) the name, residence address, and driver's license number of the responsible individual in charge at the place of business;

(4) the hours of operation of each place of business;

(5) the address of any salvage warehouse used by a salvage establishment or salvage broker;

(6) if a proprietorship, the name and residence address of the proprietor; if a partnership, the names and residence addresses of all partners; if a corporation, the date and place of incorporation and name and address of its registered agent in the state and corporation charter number; or if any other type of association, then the names of the principals of such association; and

(7) a statement signed and verified by the sole proprietor, managing partner, corporate officer, or person in a managerial capacity for an association that acknowledges the applicant has read, understood, and agrees to abide by the provisions of these sections and those of the Act.

(h) Issuance of license. In accordance with §229.281 of this title (Processing License/Permit Applications Relating to Food and Drug Operations), the department may license a salvage establishment or salvage broker who meets the requirements of these sections and pays all fees in compliance with §229.606 of this title (Licensing Fees).

(i) Transfer of license. Licenses shall not be transferable from one person to another or from one place of business to another.

(j) Display of license. The license shall be displayed in an open public area at each place of business and each salvage operator shall have a copy of a valid license in each vehicle used by the salvage operator to transport distressed devices.

(k) License term. Unless the license is amended as provided in subsection (o) of this section or revoked or suspended as provided in §229.614 of this title (relating to Enforcement and Penalties), the license is valid for one or two years as determined by the department.

(l) Renewal of license.

(1) The license application as outlined in subsections (f) and (g) of this section and nonrefundable licensing fee(s) as outlined in 229.606 of this title (relating to Licensing Fees) for each place of business shall be submitted to the department prior to the expiration date of the current license. A person who files a renewal application after the expiration date shall pay an additional \$100 as a delinquency fee.

(2) The department shall renew the license for a one or two-year term as determined by the department if the licensee is in compliance with these sections and has paid all required fees, including any past due and delinquency fees.

(m) Completeness of license applications. Failure to complete the license application form may result in the denial of a license.

(n) Report of changes. The license holder shall notify the department in writing within ten days of any change, including a change in location, name or ownership of a salvage establishment or salvage broker, which would render the information contained in the license application no longer accurate. Failure to inform the department within ten days of a change in the information required in the license application may result in enforcement action as described in §229.614 of this title.

(o) Amendment of license. A license that is amended, including a change of name, ownership, or a notification of a change in the location of a licensed place of business will require submission of an application as outlined in subsection (g) of this section and submission of fees as outlined in §229.606 of this title (relating to Licensing Fees).

(p) Return of license. A license issued under these sections shall be returned to the department if the place of business:

(1) ceases business or otherwise ceases operation on a permanent basis;

(2) relocates;

(3) changes the name of the business under which the salvage establishment or salvage broker operates; or

(4) changes ownership.

§229.606. Licensing Fees

(a) Licensing fees.

(1) All applicants for a license or a renewal license must pay a license fee. All fees are nonrefundable. The license fees are as follows:

(A) \$600 for a one-year license; or

(B) \$1,200 for a two-year license.

(2) Delinquency fee. A salvage establishment or salvage broker must pay a \$100 delinquency fee if:

(A) the renewal license application is submitted or the renewal license fee is paid after the expiration date of the current license; or

(B) the initial license application is submitted or the initial license fee is paid more than 30 days following the effective date of a change in location, name, or ownership of an existing salvage establishment or salvage broker as described in §229.605(o) of this title (relating to Licensing Requirements and Procedures).

(3) Reinspection fee. A salvage establishment or salvage broker who requests reinstatement of a license that has been denied, suspended, or revoked pursuant to §229.614 of this title (relating to Enforcement and Penalties), shall pay a nonrefundable inspection fee of \$600.

(4) Texas Online. Applicants may submit applications and renewal applications for a license under these sections electronically by the Internet through Texas Online at www.texasonline.state.tx.us. The department is authorized to collect fees, in amounts determined by the Texas Online Authority, to recover costs associated with license application and processing through Texas Online.

(b) Consolidation of license terms. The department may, upon receipt of a written request from a license holder, prorate a license fee for the purpose of consolidating the license renewal dates of multiple licenses issued in the name of the license holder.

(c) Exemption from licensing fees. A person is exempt from the licensing fees required by this section if the person is a nonprofit organization, as described in the Internal Revenue Code of 1986, §501(c)(3), as amended, or a nonprofit affiliate of the organization, to the extent otherwise permitted by law.

§229.607. Personnel

(a) Employee health requirements. No person known to be or suspected of being affected with any disease in a communicable form, or while a carrier of such disease, or while afflicted with boils, infected wounds, sores, or respiratory infection, shall work in an area of a salvage establishment or for a salvage broker in any capacity in which there is any possibility of such person contaminating salvageable or salvaged devices with pathogenic organisms, or transmitting disease to other individuals.

(b) Personal cleanliness.

(1) All personnel while working in direct contact with salvageable devices or while engaged in reconditioning, repacking, or otherwise handling any components or accessories of salvageable devices shall wear clean outer garments, maintain a high degree of personal cleanliness, and conform to hygienic practices while on duty.

(2) Personnel engaged in reconditioning salvageable devices shall wash their hands thoroughly in a department approved hand-washing facility before starting work, and as often as may be necessary to remove soil and contamination.

(3) No person shall resume work after visiting the toilet room without first washing their hands.

§229.608. Construction and Maintenance of Physical Facilities

(a) Buildings. Buildings used by salvage establishments and salvage brokers shall be of suitable design and contain sufficient space to perform necessary operations, prevent mix-ups, and assure orderly handling.

(b) Floor construction.

(1) The floor surfaces in all rooms and areas in which salvageable or salvaged devices are stored or processed and in which tools or equipment are washed, and walk-in refrigerators, dressing or locker rooms and toilet rooms, shall be constructed to be smooth and easily cleanable.

(2) Any floor that is exposed to water or liquids shall be constructed and maintained to be nonabsorbent.

(3) All floors shall be kept clean and in good repair.

(4) Floor drains shall be provided in all rooms where floors are subjected to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(c) Walls and ceilings. Walls and ceilings of all rooms shall be clean, smooth, and in good repair.

(d) Lighting. Adequate lighting shall be provided in handwashing areas, dressing and locker rooms, and toilet rooms and in all areas where salvageable or salvaged devices are examined, processed, or stored and where equipment or tools are cleaned.

(1) Where personnel are inspecting, sorting, or reconditioning distressed devices, at least 540 lux (50 foot candles) of light shall be provided at the work surface.

(2) At all other areas of the facility where light is required, at least 110 lux (10 foot candles) of light shall be provided when measured at a distance of 30 inches above the floor.

(e) Ventilation.

(1) All rooms, in which salvageable or salvaged devices are reconditioned or tools or equipment are washed, dressing or locker rooms, toilet rooms, and garbage and refuse storage areas shall be well ventilated.

(2) Ventilation hoods and related equipment when used shall be designed to prevent condensation from dripping onto salvageable devices or onto work surfaces.

(3) Filters, when used, shall be readily removable for cleaning or replacement.

(4) Ventilation systems shall comply with applicable federal, state, and local fire prevention and air pollution requirements.

(f) Locker area. Adequate facilities shall be provided for the orderly storage of personnel clothing and personal belongings.

(g) Cleanliness of facilities.

(1) All parts of the salvage establishment or salvage warehouse and its premises shall be kept neat, clean, and free of litter and refuse.

(2) Cleaning operations shall be conducted in such a manner as to prevent contamination of salvageable and salvaged devices.

(3) None of the operations connected with a salvage establishment or salvage warehouse shall be conducted in any room used as a personnel lounge or toilet facility, or living or sleeping quarters.

(4) Soiled coats and aprons shall be kept in suitable containers until removed for laundering.

(5) No birds or animals shall be allowed in any areas used for the conduct of salvage establishment operations or the storage of salvageable and salvaged devices, except that guide dogs accompanying blind persons shall be permitted in sales areas.

(h) Vehicles. Vehicles used to transport distressed, salvageable, or salvaged devices shall be maintained in a clean and sanitary condition to protect the product from contamination.

§229.609. Sanitary Facilities and Controls

(a) Water supply. The water supply shall be adequate, of a safe, sanitary quality, and from a source constructed and operated in accordance with the Minimum Standards of Sanitation and Health Protection, Health and Safety Code, Chapter 341, and rules promulgated under this chapter.

(b) Sewage. All sewage, including liquid waste, shall be disposed of in a public sewerage system or, in the absence thereof, in a manner applicable with the Minimum Standards of Sanitation and Health Protection, Health and Safety Code, Chapter 341, and rules promulgated under this chapter.

(c) Plumbing. Plumbing shall be sized, installed, and maintained in accordance with applicable state and local plumbing codes.

(d) Toilet facilities.

(1) Each salvage establishment shall provide its personnel with adequate and conveniently located toilet facilities.

(2) Toilet facilities, including rooms and fixtures, shall be kept in a clean condition and in good repair at all times.

(3) The doors of all toilet rooms shall be self-closing.

(4) Toilet tissue shall be provided.

(5) Easily cleanable receptacles shall be provided for waste materials, and such receptacles in toilet rooms for women shall be covered.

(6) Where the use of non-water-carried sewage disposal facilities are approved by the department they shall be located at least 100 linear feet from the salvage establishment and from any well or stream.

(e) Hand-washing facilities. Each salvage establishment shall be provided with adequate, conveniently located hand-washing facilities for its personnel, including a lavatory or lavatories equipped with hot and cold or tempered running water, hand-cleansing soap or detergent, and approved sanitary towels or other approved hand-drying devices. Such facilities shall be kept clean and in good repair.

(f) Garbage and refuse.

(1) All organic or organic-containing refuse shall be kept in leak proof, non-absorbent containers which shall be kept covered with tight-fitting lids when filled or stored, or not in continuous use. Such containers shall be covered when stored and stored in either a vermin-proof room or enclosure or in a waste refrigerator. Paper, cardboard, unused equipment, and non-organic refuse shall be stored in containers, rooms, or areas in such a manner to prevent it from becoming a source of contamination or pest harborage.

(2) Adequate cleaning facilities shall be provided, and each container, room, or area shall be thoroughly cleaned after the emptying or removal of refuse.

(3) All refuse shall be disposed of with sufficient frequency and in such a manner as to prevent contamination.

(4) All refuse shall be disposed of in accordance with all applicable state and local requirements, including requirements for solid waste disposal as referenced in Title 30, Texas Administrative Code, Chapters 330, 335, and 336.

(g) Insect and rodent control. Effective measures shall be taken to protect against the entrance into the salvage establishment or salvage warehouse, and the breeding or presence on the premises of rodents, insects, and other vermin.

§229.610. General Provisions for Handling and Movement of Distressed Devices

(a) Notice to the department.

(1) When the source of distressed devices is the result of a natural disaster, accident, power failure, or other emergency, the salvage establishment or salvage broker shall make contact with the department's Bureau of Food and Drug Safety within 24 hours after their initial awareness of the emergency and prior to any removal of distressed devices from the place at which it was located when it became distressed.

(2) If emergency removal of distressed devices referenced in subsection (a)(1) is required, notice to the department shall be made as soon thereafter as possible. It shall be the duty of the salvage establishment or salvage broker to make contact with the department's Bureau of Food and Drug Safety within 48 hours whenever distressed devices subject to the provisions of this subsection are obtained.

(3) Distressed devices referenced in subsection (a)(1) shall not be moved out of the State of Texas without the prior approval of the department and the responsible state agency in the state to receive the devices. Concurrence shall also be obtained from the U.S. Food and Drug Administration prior to interstate movement.

(b) Protection of salvageable and salvaged devices.

(1) All salvageable and salvaged devices stored by salvage establishments or salvage brokers shall be held at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such devices.

(2) All salvageable and salvaged devices, while being stored or processed at a salvage establishment, salvage warehouse, or during transportation, shall be protected from contamination.

(3) Poisonous and toxic materials shall be identified and handled under such conditions as will not contaminate other salvageable or salvaged devices, or constitute a hazard to personnel.

(c) Segregation of devices. All salvageable devices shall be promptly sorted and segregated from nonsalvageable devices to prevent further contamination of the distressed devices to be salvaged or offered for sale or distribution.

(d) Nonsalvageable devices.

(1) Containers, including metal and glass containers with press caps, screw caps, pull rings, or other types of openings which have been in contact with nonpotable water, liquid foam, or other deleterious substances, as a result of fire fighting efforts, flood, sewer backups, or similar mishaps, shall be deemed unfit for sale or distribution, i.e., nonsalvageable devices as defined in §229.603(23) of this title (relating to Definitions).

(2) Nonsalvageable devices shall be disposed of as in §229.609(f)(4) of this title (relating to Sanitary Facilities and Controls) or §229.611(o) of this title (relating to Reconditioning Distressed Devices); or by delivery to a waste reclamation (recycling) facility for destruction.

(3) Distressed devices which are deemed to be nonsalvageable by a duly authorized agent of the department shall, at the request of the agent, be destroyed under the supervision of that agent at the expense of the owner.

(e) Transporting of distressed devices.

(1) Distressed devices shall be moved from the site of a fire, flood, sewer backup, wreck, or other cause as expeditiously as possible after compliance with subsection (a) of this section, if applicable, so as not to become hazardous to public health.

(2) All distressed devices of a temperature sensitive nature shall, prior to reconditioning, be transported only in vehicles capable of maintaining adequate temperatures, if necessary, for product integrity.

(f) Handling of distressed articles other than devices. If distressed articles other than devices are also salvaged, they shall be handled separately so as to prevent contamination from poisonous and toxic materials or other contaminants.

(g) Cross-contamination protection. Sufficient precautions shall be taken to prevent cross-contamination among the various types of devices that are salvageable or salvaged.

§229.611. Reconditioning Distressed Devices

(a) Salvageable devices. All salvageable devices shall be reconditioned prior to sale or distribution except for such sale or distribution to a person holding a valid license to engage in a salvage operation or as provided for in subsection (o) of this section.

(b) Reconditioned devices. All reconditioned devices must be in compliance with the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431.

(c) General labeling. All salvaged devices must be labeled in accordance with the requirements of the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431; the Federal Food, Drug, and Cosmetic Act, 21 U.S.C., §301 et seq., as amended; the Fair Packaging and Labeling Act, 15 U.S.C., §1451 et seq., as amended; and the federal regulations promulgated under those Acts.

(d) Reconditioned Labeling. In addition to the general labeling requirements found in subsection (c) of this section, all reconditioned devices shall be labeled with the statement "Reconditioned by (name and business address of the salvage establishment responsible for the reconditioning of the device)."

(e) Salvage warehouses. A person may not use a salvage warehouse to recondition devices or sell to consumers.

(f) Personnel. Each salvage establishment that engages in the reconditioning of devices shall have sufficient personnel with the necessary education, background, training, and experience to assure that all reconditioning activities are correctly performed. With the exception of class I exempt devices, training of personnel engaged in the reconditioning of class I, II, or III devices shall be documented.

(g) Operating procedures. Each salvage establishment that engages in the reconditioning of devices shall establish, maintain, and implement written procedures for identifying devices during all stages of receipt, reconditioning, distribution, and installation to prevent mixups.

(h) Inspection, measuring, and test equipment.

(1) Each salvage establishment that engages in the reconditioning of devices shall ensure that all inspection, measuring, and test equipment used in the reconditioning of devices is:

- (A) suitable for its intended purpose and capable of producing valid results; and
- (B) routinely calibrated, inspected, checked, and maintained.

(2) Each salvage establishment that engages in the reconditioning of class II and III devices shall establish and maintain calibration records for inspection, measuring, and test equipment to include:

- (A) the equipment identification;
- (B) dates of calibration;
- (C) the person performing each calibration; and
- (D) the next scheduled calibration date.

(i) Device history record. With the exception of class I exempt devices, each salvage establishment that engages in the reconditioning of class I, II, or III devices shall establish and maintain a device history record for each batch, lot, or unit reconditioned to ensure that devices are reconditioned in accordance with manufacturer's specifications. The device history record shall include the following information:

- (1) the dates of reconditioning;
- (2) the quantity reconditioned;
- (3) the quantity released for distribution;
- (4) the acceptance records which demonstrate the device is reconditioned in accordance with the device master record;
- (5) copies of any labeling required by these sections; and
- (6) any device identification or control number used.

(j) Device master record. Each salvage establishment that engages in the reconditioning of class II or III devices shall establish and maintain device master records for each type of class II or III device reconditioned. The device master record shall include, or refer to the location of, the following information:

- (1) device specifications, including appropriate drawings, composition, formulation, component specifications, and software specifications;

(2) reconditioning process specifications, including the appropriate equipment specifications, reconditioning methods, reconditioning procedures, and reconditioning environment specifications;

(3) final acceptance procedures and specifications, including acceptance criteria and the inspection, measuring, and test equipment to be used;

(4) packaging and labeling specifications, including methods and processes used; and

(5) installation, maintenance, and servicing procedures and methods.

(k) Complaint files. Each salvage establishment and salvage broker that engages in the reconditioning or distribution of distressed or salvaged devices shall establish and maintain complaint files. Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated. All records of investigation shall include:

(1) the name of the device;

(2) the date the complaint was received;

(3) any device identification(s) and control number(s) used;

(4) the name, address, and phone number of the complainant;

(5) whether the complaint is associated with any illness or injury involving the device;

(6) the nature and details of the complaint;

(7) the dates and results of the investigation;

(8) any corrective action taken;

(9) any reply to the complainant; and

(10) the name and signature of the person formally designated by the salvage establishment or salvage broker as responsible for investigating all complaints.

(l) Internal audits. Each salvage establishment that engages in the reconditioning of class II or III devices shall establish, maintain, and implement written procedures for conducting an internal quality audit and shall conduct such an audit at least annually. The dates and results of the audit shall be documented, including any deficiencies found and the corrective action taken to address the deficiencies.

(m) Corrective and preventative action. Each salvage establishment that engages in the reconditioning of class II or III devices shall document any action taken by the salvage

establishment to correct or prevent any nonconformities relating to a salvaged class II or III device or to the reconditioning of a class II or III device.

(n) Device remanufacturers. Those salvage establishments who are also device remanufacturers shall comply with these sections and with the device manufacturer requirements in the Texas Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431, Subchapter L, including the applicable requirements in 21 CFR, Part 820 (quality system regulation).

(o) Sale or distribution of unreconditioned devices.

(1) A person licensed under §229.605 (a) of this title (relating to Licensing Requirements and Procedures) who is unable to recondition a salvageable device in accordance with this chapter may sell or distribute the device if such device:

(A) is sold or distributed to a person licensed under 229.605 (a) of this title (relating to Licensing Requirements and Procedures);

(B) is sold or distributed to a person located outside this state who is responsible for the reconditioning of the device prior to sale or distribution to the ultimate consumer located outside Texas. Each salvage establishment or salvage broker who sells or distributes a salvageable device to such a person shall maintain documentation that discloses the person is aware that the device requires reconditioning and that the person is authorized to perform such reconditioning under laws applicable to the state in which the person is located; or

(C) is a non-prescription device to be used solely for a non-medical purpose (e.g. research, teaching, or analysis) and not introduced into commercial distribution for use on man or other animals, provided these conditions of sale or distribution are disclosed to the purchaser in writing.

(2) At a minimum, all written disclosure records required in paragraph (1)(B) - (C) of this subsection shall:

(A) include the information required by §229.612(a) of this title (relating to Records);

(B) include a statement regarding the conditions of sale or distribution that is signed by both the seller and purchaser, and contains the address and telephone number of both the seller and purchaser; and

(C) be retained as required in §229.612(b) of this title (relating to Records).

(p) Sale or distribution of prescription devices.

(1) A prescription device in the possession of a salvage establishment or salvage broker licensed under these sections of this subchapter is exempt from Health and Safety Code, §431.112(f)(1), relating to labeling bearing adequate directions for use, providing it meets the requirements of 21 CFR, §801.109 (prescription devices) and 21 CFR, §801.110 (retail exemption for prescription devices).

(2) Each salvage establishment or salvage broker who sells or distributes a prescription device shall establish and maintain a record for every prescription device, showing the identity and quantity received, date of receipt, and the disposition of each device.

(3) Each salvage establishment or salvage broker who delivers a prescription device to the ultimate user shall maintain a record of any prescription or other order lawfully issued by a practitioner in connection with the device.

(q) Sale of contact lenses at flea markets. Persons at flea markets may not sell contact lens devices unless:

(1) the person selling the contact lenses has complied with the requirements of Business and Commerce Code, §35.55; and

(2) the person selling the contact lenses has complied with the requirements of the Texas Contact Lens Prescription Act, Texas Civil Statutes, Article 4552-A.

§229.612. Records

(a) Inventory Records. A written record or receipt of all distressed, salvageable, and salvaged devices shall be maintained by the salvage establishment or salvage broker and shall include:

(1) the common name, the brand name or manufacturer, and quantity of the device received;

(2) the source of the distressed device;

(3) the date received;

(4) a brief description of the type or cause of damage (fire, flood, wreck, prolonged storage, warehouse damage, etc.);

(5) the name of the individual or business that purchases any such device for the purpose of sale or distribution and the date of any such transaction; and

(6) the date and final disposition of the device (reconditioned, unreconditioned, destroyed, etc.).

(b) Retention of records. All records required in these sections shall be kept at the place of business of the salvage establishment or salvage broker for a period of two years following the completion of any transaction involving a device.

(c) Electronic records. Records required by these sections which are maintained by the salvage establishment or salvage broker on computer systems shall be regularly copied, at least monthly, and updated on storage media other than the hard drive of the computer. An electronic record must be retrievable as a printed copy.

§229.613. Inspection

(a) Inspection. To enforce these sections or the Act, the commissioner or an authorized agent may, on presenting appropriate credentials to the owner, operator, or agent in charge of a place of business:

(1) enter at reasonable times the place of business of a salvage establishment or salvage broker;

(2) enter a salvage warehouse used to store or hold distressed or salvaged devices;

(3) enter a vehicle being used to transport or hold distressed or salvaged devices; or

(4) inspect at reasonable times, any place of business of a salvage establishment or salvage broker, salvage warehouse, or vehicle and all equipment, finished and unfinished materials, containers, and labeling of any item and obtain samples necessary for the enforcement of these sections or the Act.

(b) Access to required records. A person who is required to maintain records referenced in these sections or under the Act or a person who is in charge or custody of those records shall, at the request of the commissioner or an authorized agent, permit the commissioner or authorized agent at all reasonable times access to review, copy, and verify the records.

(c) Access to records showing movement in commerce. A person who is subject to licensing under §229.605 of this title (relating to Licensing Requirements and Procedures) or a person, including a common carrier or the common carrier's agent, who disposes of or otherwise transfers distressed or salvaged devices shall, at the request of the commissioner or an authorized agent, permit the commissioner or authorized agent at all reasonable times access to review, copy, and verify all records showing:

(1) the movement in commerce of any distressed or salvaged device;

(2) the holding of any distressed or salvaged device after movement in commerce; and

(3) the quantity, shipper, and consignee of any distressed or salvaged device.

(d) Receipt for samples. The commissioner or an authorized agent who makes an inspection of a place of business, including any vehicle or salvage warehouse, and obtains a sample during or on completion of the inspection and before leaving the place of business, shall give to the owner, operator, or the owner's or operator's agent a receipt describing the sample.

(e) Detained or embargoed device. In accordance with Subchapter C, Chapter 431, the commissioner or an authorized agent may detain or embargo a distressed device that is in the possession of a person operating as a salvage establishment or acting as a salvage broker. The commissioner or authorized agent may not detain a distressed device in the possession of a

person licensed under §229.605 of this title and that is being held for the purpose of reconditioning unless the commissioner or authorized agent finds or has probable cause to believe that the device cannot be adequately reconditioned in accordance with the chapter and these sections.

§229.614. Enforcement and Penalties

(a) General license actions. The department may deny, suspend, or revoke the license of an applicant or licensee who fails to comply with any one of the following:

- (1) failure to comply with the Act or these sections;
- (2) falsification of information provided in an application for a license;
- (3) refusal to allow the department to conduct an inspection or collect samples;
- (4) interference with the department in the performance of its duties;

(5) removal or disposal of detained food in violation of the Texas, Food, Drug and Cosmetic Act, Health and Safety Code, §431.021; or

(6) failure to inform the department of any salvage warehouse(s) at the time of an inspection or when requested by the department.

(b) Emergency license suspensions.

(1) The department may suspend a license without notice when there is an imminent threat to the health or safety of the public.

(2) If an emergency suspension order is issued without a hearing, the department, not later than the 30th day after the date on which the emergency order was issued, shall determine a time and place for a hearing at which the emergency order will be affirmed, modified, or set aside. The hearing shall be held under departmental formal hearing rules governed by §§1.21, 1.23, 1.25, and 1.27 of this title (relating to Formal Hearing Procedures).

(c) Hearings.

(1) Any hearings for the denial, suspension, or revocation of a license are governed by §§1.21, 1.23, 1.25, and 1.27 of this title (relating to Formal Hearing Procedures).

(2) Within 20 days after the postmark date of the department's written notice of proposed denial, suspension, or revocation, the applicant or licensee may request a hearing in writing from the department. If the applicant or licensee does not request a hearing during the required time period, then the applicant or licensee is deemed to have waived his/her right to a hearing.

(d) Reinstatement of license.

(1) A person whose application for a license has been denied or whose license has been placed under an emergency suspension may request a reinspection for the purpose of granting or reinstating a license not later than the 30th day after the denial or emergency suspension. Not later than the 10th day after the receipt of a written request from the applicant or licensee, the department shall make a reinspection.

(2) As regards a nonemergency suspension or a revocation, the licensee may request at any time, an inspection for reinstating the license or for issuing a new license.

(3) If, after inspection, the department determines that the applicant or licensee meets the requirements of the Act or these sections, the department shall reinstate the license or issue a new license, as appropriate.

(4) Reinspection fee. Except as provided for in §229.606(c) of this title (relating to Licensing Fees), a salvage establishment or salvage broker who requests reinstatement of a license that has been denied, suspended, or revoked pursuant to this section shall pay a nonrefundable inspection fee of \$600.

(e) Emergency order.

(1) General. The commissioner or the commissioner's designee may issue an emergency order, either mandatory or prohibitory, concerning the sale or distribution of distressed devices in the department's jurisdiction if the commissioner or the commissioner's designee determines that:

(A) the sale or distribution of those devices creates or poses an immediate and serious threat to human life or health; and

(B) other procedures available to the department to remedy or prevent the threat will result in unreasonable delay.

(2) Absence of notice and hearing. The commissioner or the commissioner's designee may issue the emergency order without notice and hearing if the commissioner or the commissioner's designee determines it is necessary under the circumstances.

(3) Hearings. If an emergency order is issued without a hearing, the department, not later than the 30th day after the date on which the emergency order was issued, shall determine a time and place for a hearing at which the emergency order will be affirmed, modified, or set aside. The hearing shall be governed by §§1.21, 1.23, 1.25, and 1.27 of this title (relating to Formal Hearing Procedures).

(f) Administrative penalty. If a person violates these sections, or an order adopted or license issued under the Act, the commissioner may assess an administrative penalty against the person.

(1) The penalty may not exceed \$25,000 for each violation. Each day a violation continues is a separate violation.

(2) In determining the amount of the penalty, the commissioner shall consider the following criteria:

- (A) the person's previous violations;
- (B) the seriousness of the violation;
- (C) any hazard to the health and safety of the public;
- (D) the person's demonstrated good faith; and
- (E) other matters as justice may require.

(3) Violations subject to this subsection shall be categorized into severity levels as determined in §229.261 of this title (relating to Assessment of Administrative or Civil Penalties).

(4) Hearings, appeals from, and judicial review of final administrative decisions under this subsection shall be conducted according to the contested case provisions of the Government Code, Chapter 2001, and §§1.21, 1.23, 1.25, and 1.27 of this title (relating to Formal Hearing Procedures).

(5) An administrative penalty may be assessed only after a person charged with a violation is given an opportunity for a hearing.

(6) If a hearing is held, the commissioner shall make findings of fact and shall issue a written decision regarding the occurrence of the violation and the amount of the penalty.

(7) If the person charged with the violation does not request a hearing, the commissioner may assess a penalty after determining that a violation has occurred and the amount of the penalty.

(8) After making a determination under this subsection that a penalty is to be assessed, the commissioner shall issue an order requiring that the person pay the penalty.

(9) The commissioner may consolidate a hearing held under this subsection with another proceeding.

(10) Not later than the 30th day after the date of issuance of an order finding that a violation has occurred, the commissioner shall inform the person against whom the order is issued of the amount of the penalty.