DEPARTMENT OF TOXIC SUBSTANCES CONTROL

Our mission is to provide the highest level of safety, and to protect public health and the environment from toxic harm.

Fact Sheet, July, 2009

Dental, Medical and Veterinary Offices: Managing Your Hazardous Waste

Regulatory Assistance Officer's Note

The Regulatory Assistance Officers of the Department of Toxic Substances Control (DTSC) prepared this fact sheet to provide general information about the hazardous waste requirements for dental, medical and veterinary facilities. Clicking on highlighted text will take you to sites containing the described references, laws and regulations. If you generate hazardous waste, you should consult with your Certified Unified Program Agency (CUPA) for more detailed compliance requirements. Finally, DTSC strongly encourages all businesses generating hazardous waste to consider waste minimization, source reduction and pollution prevention.

Does DTSC regulate the disposal of sharps and expired pharmaceuticals?

Sharps are not regulated by DTSC. Sharps are regulated by the Medical Waste Management Act, not the Hazardous Waste Management Act. The California Department of Public Health (CDPH) Environmental Management Branch regulates the collection, storage, transportation and disposal of sharps and medical wastes from businesses. Sharps generated by residents are not classified as either medical waste or hazardous waste. Sharps are not to be disposed of in the solid waste but must be sent to an appropriate disposal location.

Expired pharmaceuticals may be regulated by DTSC if the active ingredient in the pharmaceutical in question is regulated by RCRA or if the compound contains some other ingredient that meets the definition of hazardous waste. (e.g. contains enough alcohol to be flammable). Otherwise most other pharmaceuticals from medical and veterinary offices are regulated as medical waste by CDPH. Pharmaceuticals generated by households are not classified as either medical waste or hazardous waste and may be disposed of in the solid waste stream or sanitary sewer. However, it is preferable for residents to dispose of pharmaceuticals at a pharmaceutical take back program operated by the local environmental agency.
For further information about medical waste management, contact the CDPH Medical Waste Management Program at (916) 449-5671, or email to MedWasteInfo@cdph.ca.gov.

What can I do with waste glutaraldehyde and OPA?

Glutaraldehyde and ortho-phthaldehyde (OPA) are the active ingredients in several brands of sterilizing solutions. Health and Safety Code section 25123.5(c) allows medical facilities to use glycine to neutralize waste glutaraldehyde and OPA disinfectant solutions onsite, without a permit or other authorization prior to disposal to the sanitary sewer.

If you prefer to dispose of your wastes rather than treat and dispose onsite, you will still need to characterize the waste as hazardous or non-hazardous. If characterized as hazardous the waste must be managed according to the Hazardous Waste Management Act. See the DTSC fact sheet "Accumulating Hazardous Wastes at Generator Sites" (Jan. 02) and Generator Fact Sheet http://www.dtsc.ca.gov/HazardousWaste/upload/HWM_FS_Generator_Requirements.pdf for more information regarding hazardous waste management requirements for generators.

The manufacturer of OPA has informed DTSC that the solution at use-dilution fails the California aquatic bioassay toxicity characteristic and thus is hazardous waste when discarded without treatment.

Generators of waste glutaraldehyde who wish to classify the waste as non hazardous, based on generator knowledge, must be able to show documentation upon which the waste classification was made. This information may be supplied by the vendor or chemical company producing the sterilant.
Solutions that do not use glutaraldehyde or OPA may or may not be toxic, depending on the cleaning and sterilizing agents used. Check with the manufacturer for guidance, and your sanitary district inspector who may be familiar with the products as well. Many manufacturers of ultrasonic and autoclave systems claim that the chemicals used in their systems are not toxic.

What can I do with formalin and other laboratory waste chemicals?

Formalin is commonly used as a tissue preservative and other chemicals are commonly used in a clinical setting. Health and Safety Code section 25200.3.1 allows the treatment of hazardous wastes without a permit generated in laboratories where relatively small quantities of hazardous chemicals are handled or used. The laboratory must meet the following conditions: The laboratory must be associated with education, research, chemical analysis, clinical testing, product development, testing or quality control.

Treatment of laboratory waste may be conducted without a permit, as long as the laboratory waste treatment methods used have been published in either a peer-reviewed scientific journal or the National Research Council's Prudent Practices in the Laboratory: Handling and Disposal of Chemicals. Please see Health and Safety Code section 25200.3.1 for further details.

DTSC has determined that pathology labs conduct activities that qualify as "clinical testing," and may treat waste formalin or formaldehyde generated from medical specimen preparation or preservation. When a preserved specimen is being disposed of, the formalin must be decanted off of the specimen. The specimen must be managed in accordance with medical waste management requirements, and the formalin as hazardous waste.

If you prefer to dispose of your wastes rather than treat them onsite, you will still need to characterize them as hazardous or non-hazardous, and handle them appropriately. Formalin solutions may vary in their toxicity, depending on the formulation. Some manufacturers have related to DTSC that formulations containing greater than 2.9% formaldehyde may fail the aquatic bioassay or acute toxicity tests. Generators may characterize their waste formalin by having it analyzed or by getting toxicity information from their supplier, if it is available. If toxicity information is not available for their brand of formalin, and the generator does not want to characterize it by laboratory analysis, it may be assumed to be hazardous and sent off for treatment and disposal as a hazardous waste.

How should I handle lead foil from x-ray film and scrap dental amalgam? Are they hazardous wastes?

The lead foil from dental x-ray film, lead blankets and lead film storage boxes are considered to be scrap metal if they are sent to a metal recycler, but they are hazardous wastes if you dispose of them. Most metal recyclers accept lead scrap. Dental amalgam is nearly 50% mercury, a metal that is a hazardous waste constituent and may be managed under the universal waste management standards or as fully regulated hazardous waste. Because amalgam contains mercury, copper and zinc, the amalgam cannot be considered an exempt silver-only waste.
Extracted teeth that have amalgam fillings will likely be hazardous waste. Many scrap amalgam recyclers accept teeth with amalgam as long as the sender certifies that they are not infectious wastes. Extracted teeth without attached tissue are considered non-infectious wastes, unless the extracted teeth are deemed infectious or biohazardous waste by the attending surgeon or dentist.

Changes to the universal waste regulations now allow unused mercury, scrap amalgam, extracted teeth with amalgam fillings, chair traps, sink traps and filters containing amalgam to be handled under the universal waste management standards rather than full hazardous wastes standards. Empty used amalgam capsules are not considered hazardous waste and may be disposed of with solid waste. Check the DTSC publication "Managing Universal Waste in California" for details on management standards for amalgam and other universal wastes.

What do I do with photofixer and other "silver-only wastes"?

For many dental, medical and veterinary establishments, the only hazardous waste you generate is x-ray fixer that is hazardous for the silver content. Health and Safety Code section 25143.13 contains the management standards for silver only wastes. DTSC has prepared a Fact Sheet, "Onsite Tiered Permitting: Changes in Regulation of Silver Wastes" (Jan. 2000)

In my office, photo fixer is the only waste. Can I treat it onsite without a permit and discharge to the sewer?

Health and Safety Code section 25143.13 regulates photofixer that is hazardous only for silver. If the silver is sent for recycling, you may treat the photo fixer waste onsite without a hazardous waste permit from DTSC or your local CUPA. Prior to beginning treatment, you must notify your local sanitation department if you discharge the treated photo fixer to the sewer.

You may not discharge untreated fixer directly to the sewer. You must treat it first to remove the silver by using a silver recovery unit. All recovered silver must be reclaimed. Furthermore, you may also take the waste fixer solution to a permitted recycler or have it hauled off by a service company. You do not need to use a hazardous waste manifest or a transporter registered with DTSC when shipping either the recovered silver or the fixer.

My office generates more than 100 kilograms (that is, about 220 pounds or 27 gallons) of federally-regulated (RCRA) hazardous waste per month. What are my options?

You must have an EPA ID Number for shipping those other hazardous wastes. Further those wastes must be transported offsite by a registered hazardous waste transporter under a hazardous waste manifest.

Again, you do not need a permit to treat the fixer before it is discharged but you will need a permit if you treat other hazardous wastes. Contact you local CUPA for permitting requirements for onsite treatment of hazardous wastes.

As in the previous examples above, you may not discharge untreated fixer directly to the sewer. You must first use a silver recovery unit to reduce the silver concentration to the discharge level allowed by your sanitation district. You must notify your local sanitation department if you discharge to the sewer after the treatment. Another option is to have the silver only waste taken to a permitted recycler. To fit this category, any recovered silver must be reclaimed.

I have been offered a chemical that solidifies my x-ray chemical wastes, and the salesperson claims that it can be disposed of to the municipal trash dumpster after it has been solidified. May this system be used in California without a permit or other authorization?

No, such a system cannot be used to treat hazardous waste without a permit. Conducting treatment for the purposes of disposal would require a treatment permit and the resulting waste would have to be sampled to determine if it is a hazardous waste or not.

I understand that electronic devices, batteries, fluorescent lamps and video terminal are now called "universal wastes." What does that mean for me?

Universal wastes include most consumer-type batteries (nickel-cadmium or Ni-Cad, lithium, silver button, mercury, alkaline, small sealed lead-acid batteries used for burglar alarms and emergency lights (but not auto batteries), as well as fluorescent lamps, electronics, which include electronic devices (CEDs), cathode ray tubes (CRTs) from TVs, computer monitors, and other devices, and mercury containing medical devices such as thermometers and dental amalgam (as discussed earlier), and spent aerosol cans that still contain hazardous materials. While all of these are classified as hazardous wastes, they may be managed under the universal waste management regulations.

The universal waste management regulations specify management standards in line with the risk presented by these waste. In general, you may take these wastes to a universal waste collector for management or to a recycler for recycling.

Please see DTSC's website for the management requirements for universal waste. http://www.dtsc.ca.gov/HazardousWaste/UniversalWaste/index.cfm.

As discussed earlier, nearly all mercury-containing wastes and devices may now be handled as "Universal Wastes", including dental amalgam, mercury switches, sphygmomanometers and other mercury-containing gauges. These may not be disposed of in municipal landfills, so cannot be discarded with your regular office trash.

A final word . . .

Remember that all businesses are required to determine whether the wastes that they generate are hazardous wastes. If you have unknown substances, it is your responsibility to determine whether they are hazardous or not. Wastes that have been determined to be hazardous must be labeled and managed as hazardous wastes, regardless of whether you are eligible to treat them onsite under exemptions, or send them away with a hazardous waste hauler for offsite treatment or disposal. If you generate less than 100 kilograms of hazardous waste per month, you may be eligible to take your waste to a small business/house-hold hazardous waste program, if your local agency has one. Call your county environmental health program (look under "Local Environmental Agencies" in the "Information Resources"section of the DTSC website) or your DTSC Regulatory Assistance Officer to determine whether you have a small business program in your area. If you cannot find the answer to your question in this fact sheet, please contact the Regulatory Assistance Officer directly. You can call them at 800-728-6942, or contact them via the Department of Toxic Substances Control website -- http://www.dtsc.ca.gov/ -- click on "Regulatory Assistance Officers" and you will go to a page with links to the Regulatory Assistance Officers' email.

DTSC Regulatory Assistance Officers provide informal guidance only regarding management of hazardous waste for the convenience of the public. Such advice is not binding upon DTSC, nor does it have the force of law. If you would like a formal opinion on a matter by DTSC, please contact the responsible program office directly. You should also refer to the statutes and regulations, DTSC Policies and Procedures, and other formal documents. If you believe that you have received incorrect information from a Regulatory Assistance Officer, please contact External Affairs, at 916-322-0476. We also encourage you to complete a Cal/EPA Customer Satisfaction survey (http://www.calepa.ca.gov/Customer/) so that we may improve our Regulatory Assistance Program.

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NOTE

Authority cited: Sections 208 and 25017, Health and Safety Code. Reference: Sections 25071, 25072, 25072.5, 25073, 25090 and 25092, Health and Safety Code.

HISTORY

1. New section filed 10-15-91 as an emergency; operative 10-15-91 (Register 92, No. 7). A Certificate of Compliance must be transmitted to OAL 2-12-92 or emergency language will be repealed by operation of law on the following day.
2. New section refiled 1-23-92 as an emergency; operative 2-12-92 (Register 92, No. 15). A Certificate of Compliance must be transmitted to OAL 6-11-92 or emergency language will be repealed by operation of law on the following day.
3. Certificate of Compliance as to 1-23-92 order including amendment of subsections (a)(5), (11), (12), (13), (15) and (17) transmitted to OAL 6-2-92 and filed 7-14-92 (Register 92, No. 29).
4. Editorial correction of subsection (a)(13) and History 2 (Register 95, No. 47).

Article 4. Fees

§65628. Application Fees.

- Note • History

(a) Each person submitting an offsite treatment facility permit application will be charged a processing fee of one hundred dollars ($100) per hour up to a maximum of fifty thousand dollars ($50,000). The processing fee is to cover costs for technology evaluation, construction inspections, and review of records relative to monitoring procedures and operation. The fee will be billed as follows:

(1) An initial deposit of twenty-five thousand dollars ($25,000) with the application.

(2) When the costs for processing the application reach 75 percent of the initial deposit, a second deposit amounting to one-half of the initial deposit shall be paid, and if processing costs exceed 75 percent of the second deposit, the remaining twelve thousand, five hundred dollars ($12,500) shall be charged.

(3) For subsequent deposits, after the first deposit, the Department shall give 30 days notice by registered mail of the further amount of fee due. If this amount is not received by the Department within the stated 30-day period, the application shall be denied, and there shall be no refund to the applicant.

NOTE

Authority cited: Sections 208 and 25017, Health and Safety Code. Reference: Sections 25036, 25079, 25079.1, 25079.2 and 25079.3(b), Health and Safety Code.

HISTORY

1. New section filed 10-15-91 as an emergency; operative 10-15-91 (Register 92, No. 7). A Certificate of Compliance must be transmitted to OAL 2-12-92 or emergency language will be repealed by operation of law on the following day.
2. New section refiled 1-23-92 as an emergency; operative 2-12-92 (Register 92, No. 15). A Certificate of Compliance must be transmitted to OAL 6-11-92 or emergency language will be repealed by operation of law on the following day.
3. Certificate of Compliance as to 1-23-92 order including amendment of section transmitted to OAL 6-2-92 and filed 7-14-92 (Register 92, No. 29).
4. Editorial correction of History 2 (Register 95, No. 47).

(8) A map extending one mile beyond the property boundary of the facility identifying access roads and the type of development in the area (i.e., residential, commercial, recreational, schools, etc.).

(9) A disclosure statement, as required in Section 25072 of the Health and Safety Code.

(10) A description of the security procedures required pursuant to Section 25086 of the Health and Safety Code.

(11) A copy of the general operation plan including a schedule for inspection and calibration of monitoring equipment, a description of disinfection procedures, location and type of safety and emergency equipment, location and type of security devices, and operating and structural equipment that are important in preventing or responding to medical-waste related environmental or human health hazards.

(12) A copy of the emergency action plan addressing equipment breakdowns, natural disasters, or other occurrences as required in Section 25092, Health and Safety Code.

(13) An outline of both the introductory and continuing training programs which will be provided by owners or operators to prepare employees to operate or maintain the medical waste treatment facility in a safe manner. A brief description of how training will be designed to meet actual job tasks.

(14) A copy of the closure plan including a written estimate of the cost of closing a facility. The estimate shall equal the cost of closure at the point in the facility's operating life when the extent and manner of its operation would make closure the most expensive, as indicated by its closure plan. The owner shall revise the closure cost estimate whenever a change in the closure plan increases the cost of closure.

(15) A description of the compliance history of the applicant under any local, state, or federal law or regulation governing the control of medical waste or pollution including, but not limited to, the Clean Air Act. Such description shall include all violations as specified in Section 25072.5 of the Health and Safety Code which have occurred at this or any other facility permitted and owned or operated by the applicant in the State for the three years prior to the date of this application.

(16) A schedule for the installation of monitoring equipment and a written statement of operating procedures covering the proper use, maintenance, and testing of such equipment.

(17) A monitoring schedule, including type of monitoring, intervals and frequency of monitoring sufficient to yield data which are representative of the monitored activity, including, when appropriate, continuous monitoring.

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§65624. Duration of Permits.

• Note • History

The term of a medical waste facility permit shall not exceed 5 years.

NOTE

Authority cited: Sections 208 and 25017, Health and Safety Code. Reference: Sections 25049, 25050, 25059 and 25074, Health and Safety Code.

HISTORY

1. New section filed 10-15-91 as an emergency; operative 10-15-91 (Register 92, No. 7). A Certificate of Compliance must be transmitted to OAL 2-12-92 or emergency language will be repealed by operation of law on the following day.
2. New section refiled 1-23-92 as an emergency; operative 2-12-92 (Register 92, No. 15). A Certificate of Compliance must be transmitted to OAL 6-11-92 or emergency language will be repealed by operation of law on the following day.
3. Certificate of Compliance as to 1-23-92 order transmitted to OAL 6-2-92 and filed 7-14-92 (Register 92, No. 29).
4. Editorial correction of History 2 (Register 95, No. 47).

§65625. Contents of a Medical Waste Treatment Facility Permit Application.

• Note • History

(a) The application shall include the following information:

(1) The name, business address, and telephone number of the owner and operator of the facility. Include ownership status as federal, state, local government or other public or private entity.

(2) The name, mailing address, and location of the facility for which the application is submitted.

(3) A description of the nature of the business and activities which require it to have a permit.

(4) An indication of whether the facility is new or existing and whether it is a first or revised application.

(5) A description of the process to be used for treating, storing, and disposing of medical waste (i.e. incinerator, autoclave, or other approved treatment technology as specified in Section 25090(d) Health and Safety Code).

(6) A description of the treatment and/or storage capacity of the facility, an estimate of the average monthly quantity of the waste to be treated and/or stored, and a general description of the process to be used for disposal of treated wastes.

(7) A scale drawing and general description of the facility showing location of all treatment and storage areas.

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(l) The following shall be included as information which shall be reported orally within 24 hours under subsection (j)(3) of this section:

(1) Information concerning release of any medical waste that may endanger the public health;

(2) Any information of a release or discharge of medical waste from or of a fire or explosion at a medical waste facility which could threaten the environment or human health outside the facility. The description of the occurrence and its cause shall include:

(A) Name, address, and telephone number of the owner or operator;

(B) Name, address, and telephone number of the facility;

(C) Date, time, and type of incident;

(D) Name and quantity of material(s) involved;

(E) The extent of injuries, if any;

(F) An assessment of actual or potential hazards to the environment and human health outside the facility, where this is applicable; and

(G) Estimated quantity and disposition of recovered material that resulted from the incident.

(m) The permittee shall attempt to reconcile any significant discrepancy in a tracking document. The permittee shall also report any medical waste received without a tracking document. In either case, the discrepancy with or without a tracking document shall be reported to the enforcement agency within 15 days.

NOTE

Authority cited: Sections 208 and 25017, Health and Safety Code. Reference: Sections 25040.5, 25050, 25062, 25063, 25064, 25070, 25071, 25072, 25072.5, 25074 and 25075, Health and Safety Code.

HISTORY

1. New section filed 10-15-91 as an emergency; operative 10-15-91 (Register 92, No. 7). A Certificate of Compliance must be transmitted to OAL 2-12-92 or emergency language will be repealed by operation of law on the following day.
2. New section refiled 1-23-92 as an emergency; operative 2-12-92 (Register 92, No. 15). A Certificate of Compliance must be transmitted to OAL 6-11-92 or emergency language will be repealed by operation of law on the following day.
3. Certificate of Compliance as to 1-23-92 order including amendment of section and Note transmitted to OAL 6-2-92 and filed 7-14-92 (Register 92, No. 29).
4. Editorial correction of History 2 (Register 95, No. 47).

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(i) All applications, reports, or information submitted to the enforcement agency shall be signed and certified (see Section 65622).

(j) The permittee shall meet all reporting requirements as required below:

(1) The permittee shall give notice to the enforcement agency as soon as possible and at least 30 days in advance of any planned physical alterations or additions to the permitted facility.

(2) Reports of compliance or noncompliance with, or any progress reports on, interim and final conditions contained in any compliance schedule of the permittee's permit shall be submitted no later than 14 days following each scheduled date.

(3) The permittee shall report any noncompliance with the Medical Waste Management Act (Health and Safety Code, Sections 25015 et seq.) or this chapter which may endanger health, safety, or the environment. Any information shall be provided orally within 24 hours from the time the permittee becomes aware of the circumstances. A written report shall also be provided within five days of the time the permittee becomes aware of the circumstances. The written report shall contain a description of the noncompliance as specified above, and its cause; the period of noncompliance, including exact starting and ending dates and time frames, and, if the noncompliance has not been corrected, the anticipated time it is expected to continue; and steps taken or planned to reduce, eliminate, and prevent recurrence.

(4) The permittee shall report all instances of noncompliance with permit conditions not reported under subsections (1), (2), and (3) of this Section, at the time the monitoring reports are submitted. The reports shall contain the information listed in subsections (1) and (3) of this section.

(5) Where the permittee becomes aware that it failed to submit any relevant facts in a permit application, or submitted incorrect information in a permit application or in any report to the enforcement agency, it shall promptly submit the relevant facts or correct information.

(k) For a new medical waste facility, the permittee may not commence treatment or storage of medical waste; and for a facility being modified, the permittee may not treat or store medical waste in the modified portion of the facility until:

(1) The permittee has submitted to the enforcement agency, by certified mail or hand delivery, a letter signed by the permittee and a professional engineer, registered in California, stating that the facility has been constructed or modified in compliance with the permit; and

(2) The enforcement agency has inspected the modified or newly constructed facility and finds it is in compliance with the conditions of the permit;

furnished within 30 days or as otherwise set by the enforcement agency if a longer duration is required.

(g) The permittee shall allow an authorized representative of the enforcement agency to:

(1) Enter, at reasonable times, the permittee's premises where a regulated facility or activity is located or conducted, or where records must be kept under the conditions of the permit;

(2) Have access to and copy, at reasonable times, any records that must be kept under the conditions of the permit;

(3) Inspect, at reasonable times, any facilities, equipment (including monitoring and control equipment), practices, or operations regulated or required under the permit; and

(4) Sample or monitor, at reasonable times, for the purposes of assuring permit compliance or as otherwise authorized by law, any substances or parameters at any location.

(h) The permittee shall establish and maintain a monitoring and sampling program.

(1) Samples and measurements taken for the purpose of monitoring shall be representative of the monitored activity.

(2) The permittee shall retain records of all monitoring information, including all calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation, copies of all reports required by the permit, and records of all data used to complete the application for the permit, for a period of at least three years from the date of the sample, measurement, report, or application. This period may be extended by request of the enforcement agency at any time.

(3) Records of monitoring information shall include:

(A) The date, exact place, and time of sampling or measurements;

(B) The individual(s) who performed the sampling or measurements;

(C) The date(s) analyses were performed;

(D) The individual(s) who performed the analyses;

(E) The analytical techniques or methods used; and

(F) The results of such analyses.

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NOTE

Authority cited: Sections 208 and 25017, Health and Safety Code. Reference: Sections 25072, 25098 and 25099.1, Health and Safety Code.

HISTORY

1. New section filed 10-15-91 as an emergency; operative 10-15-91 (Register 92, No. 7). A Certificate of Compliance must be transmitted to OAL 2-12-92 or emergency language will be repealed by operation of law on the following day.
2. New section refiled 1-23-92 as an emergency; operative 2-12-92 (Register 92, No. 15). A Certificate of Compliance must be transmitted to OAL 6-11-92 or emergency language will be repealed by operation of law on the following day.
3. Certificate of Compliance as to 1-23-92 order including amendment of subsections (a), (b), (b)(3), (c) and (d) transmitted to OAL 6-2-92 and filed 7-14-92 (Register 92, No. 29).
4. Editorial correction of History 2 (Register 95, No. 47).

§65623. Requirements Applicable to All Permits.

- Note • History

(a) The permittee shall comply with all requirements of this article and any specific conditions of the permit.

(b) No permittee shall continue an activity regulated by a medical waste facility permit after the expiration date of the permit. If the permittee fails to make a timely application for renewal, the medical waste permit shall expire on the expiration date.

(c) In an enforcement action, it shall not be a defense for a permittee to state or show that reducing or ceasing of the permitted activity would have been necessary in order to maintain compliance with the requirements of this article.

(d) The permittee shall take all reasonable steps to minimize or correct any adverse impact on the environment resulting from noncompliance with the conditions of the permit.

(e) The permittee shall at all times properly operate and maintain all facilities and systems of treatment and control (and related appurtenances) which are installed or used by the permittee to achieve compliance with the specific conditions of the permit and requirements of this article. Proper operation and maintenance shall include but not be limited to effective performance, adequate funding, adequate operator staffing and training, and adequate laboratory and process controls, including appropriate quality assurance procedures. Backup or auxiliary facilities or similar systems shall be operated only when necessary to achieve compliance with the requirements of this article.

(f) The permittee shall furnish to the enforcement agency any relevant information which the enforcement agency may request to determine whether cause exists for modifying, revoking and reissuing, or terminating the permit, or to determine compliance with the permit. The permittee shall also furnish to the enforcement agency upon request copies of records required to be kept by the permit. Such information shall be

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(1) For a corporation: By a responsible corporate officer authorized to make management decisions which govern the operation of the regulated facility.

(2) For a partnership or sole proprietorship: By a general partner or the proprietor, respectively; or

(3) For a municipality, state, federal or other public agency: By either a principal executive officer or ranking elected official.

(b) All reports required by permits and other information requested by the enforcement agency shall be signed by a person described in subsection (a) of this section, or by a duly authorized representative of that person. A person is a duly authorized representative only if:

(1) The authorization is made in writing by a person described in subsection (a) of this section;

(2) The authorization specifies either an individual or a position having responsibility for the overall operation of the regulated facility, such as the position of plant manager, superintendent or position of equivalent responsibility (a duly authorized person may be a named individual or any individual occupying a named position); and

(3) The written authorization is submitted to the enforcement agency.

(c) If an authorization under subsection (b) of this section is no longer accurate because a different individual or position has responsibility for the overall operation of the facility, a new authorization satisfying the requirements of subsection (b) of this section shall be submitted to the enforcement agency prior to or together with any reports, information or applications to be signed by an authorized representative.

(d) Any person signing a document under subsection (a) or (b) of this section shall make the following certification:

"I certify under penalty of perjury that this document and all attachments have been prepared under my direction and supervision in accordance with a system to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those directly responsible for gathering the information, the information is to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment.

City: _____ State: _____ Date: _____

Name: (Please print) _____

Signature: _____

application. The application shall be completed by the applicant pursuant to Sections 65610 through 65612, 65622, and 65625 and must be approved by the enforcement agency prior to a permit being issued. Failure to provide the renewal information required in these sections prior to January 1, 1992, shall result in a final permit not being issued.

(b) For new onsite medical waste facilities, the application shall be filed with the enforcement agency, and written approval by the enforcement agency shall be provided before construction can commence. For all offsite medical waste facilities, the applications shall be filed with the Department and written approval by the Department shall be provided before construction can commence.

(c) Any ongoing medical waste treatment facility or transfer station with a valid permit which is about to expire shall submit a new permit application at least 90 days before the expiration date of the effective permit.

(d) When a facility is owned by one person but is operated by another person, it is the operator's duty to obtain a permit. Both the owner and operator shall sign the application.

(e) No medical waste shall be treated until the applicant has fully complied with the application requirements for that permit and the permit has been issued by the enforcement agency.

(f) Applicants shall keep records of all data used to complete the permit application, along with any supplemental information submitted, for the life of the permit.

NOTE

Authority cited: Sections 208 and 25017, Health and Safety Code. Reference: Sections 25070, 25072, 25074, 25077 and 25097, Health and Safety Code.

HISTORY

1. New section filed 10-15-91 as an emergency; operative 10-15-91 (Register 92, No. 7). A Certificate of Compliance must be transmitted to OAL 2-12-92 or emergency language will be repealed by operation of law on the following day.
2. New section refiled 1-23-92 as an emergency; operative 2-12-92 (Register 92, No. 15). A Certificate of Compliance must be transmitted to OAL 6-11-92 or emergency language will be repealed by operation of law on the following day.
3. Certificate of Compliance as to 1-23-92 order including amendment of subsections (a), (b), (c) and (e) transmitted to OAL 6-2-92 and filed 7-14-92 (Register 92, No. 29).
4. Editorial correction of History 2 (Register 95, No. 47).

§65622. Signatories to Permit Applications and Reports.

- Note • History

(a) All permit applications shall be signed by both the owner and operator of the medical waste facility as follows:

2. New section refiled 1-23-92 as an emergency; operative 2-12-92 (Register 92, No. 15). A Certificate of Compliance must be transmittted to OAL 6-11-92 or emergency language will be repealed by operation of law on the following day.
3. Certificate of Compliance as to 1-23-92 order including amendment of section transmitted to OAL 6-2-92 and filed 7-14-92 (Register 92, No. 29).

§65620. Scope of Permit Requirement.

- Note • History

(a) Permits are required for storage and treatment of medical waste. Owners and operators of medical waste treatment facilities or transfer stations shall have a valid permit to operate while the facility is in operation. The period of operation includes cleanup and removal of medical waste prior to closure of the facility. The permit shall be terminated by the enforcement agency upon closure.

(b) The following persons are not required to obtain a permit pursuant to this article:

(1) Generators who accumulate their own medical waste on site for up to 7 days above 0 degrees Centigrade, or up to 90 days at or below 0 degrees Centigrade.

(2) A person is not required to obtain a permit for those activities carried out immediately to contain or treat a spill of biohazardous or sharps waste.

(3) Registered small quantity generators providing onsite treatment for their own waste.

NOTE

Authority cited: Sections 208 and 25017, Health and Safety Code. Reference: Sections 25040, 25040.5, 25062, 25070, 25081, 25084 and 25084.5, Health and Safety Code.

HISTORY

1. New section filed 10-15-91 as an emergency; operative 10-15-91 (Register 92, No. 7). A Certificate of Compliance must be transmitted to OAL 2-12-92 or emergency language will be repealed by operation of law on the following day.
2. New section refiled 1-23-92 as an emergency; operative 2-12-92 (Register 92, No. 15). A Certificate of Compliance must be transmitted to OAL 6-11-92 or emergency language will be repealed by operation of law on the following day.
3. Certificate of Compliance as to 1-23-92 order including amendment of subsections (a), (b) and (b)(1) and Note transmitted to OAL 6-2-92 and filed 7-14-92 (Register 92, No. 29).
4. Editorial correction of History 2 (Register 95, No. 47).

§65621. Application for a Permit.

- Note • History

(a) Any person who is required to have a medical waste facility permit (including new applicants and permittees with expiring permits) shall complete, sign, and submit an original application with two copies to the enforcement agency. In order to continue operations after January 1, 1992, persons authorized to operate under an interim status infectious waste facility permit effective January 1, 1991, shall comply with the provisions of this article in submitting a medical waste treatment facility permit

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§65614. Application Time Periods for Processing a Permit Based on Actual Performance.

- Note • History

(a) The Department's time periods for processing a medical waste facility permit, from receipt of the initial application to the final decision regarding the permit or registration, are as follows:

(1) The median time for processing is:
(A) 180 calendar days for a medical waste facility permit;
(2) The minimum time for processing is:
(A) 120 calendar days for a medical waste facility permit;
(3) The maximum time for processing is:
(A) 730 calendar days for a medical waste facility permit.

NOTE

Authority cited: Section 15376, Government Code; and sections 208 and 25017, Health and Safety Code. Reference: Section 15376, Government Code; and section 25077, Health and Safety Code.

HISTORY

1. New section filed 10-15-91 as an emergency; operative 10-15-91 (Register 92, No. 7). A Certificate of Compliance must be transmitted to OAL 2-12-92 or emergency language will be repealed by operation of law on the following day.
2. New section refiled 1-23-92 as an emergency; operative 2-12-92 (Register 92, No. 15). A Certificate of Compliance must be transmitted to OAL 6-11-92 or emergency language will be repealed by operation of law on the following day.
3. Certificate of Compliance as to 1-23-92 order transmitted to OAL 6-2-92 and filed 7-14-92 (Register 92, No. 29).
4. Editorial correction of History 2 (Register 95, No. 47).

Article 3. Medical Waste Treatment Facility Permits

§65619. Requirements for Medical Waste Facility Permit.

- Note • History

For a new medical waste facility, the permittee may not commence treatment or storage of medical waste; and for a facility being modified, the permittee may not treat or store medical waste in the modified portion of the facility until the permittee has submitted evidence of successful completion of a trial burn, if applicable.

NOTE

Authority cited: Sections 208 and 25017, Health and Safety Code. Reference: Sections 25072 and 25078, Health and Safety Code.

HISTORY

1. New section filed 10-15-91 as an emergency; operative 10-15-91 (Register 92, No. 7). A Certificate of Compliance must be transmitted to OAL 2-12-92 or emergency language will be repealed by operation of law on the following day.

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NOTE

Authority cited: Section 15376, Government Code; and sections 208 and 25017, Health and Safety Code. Reference: Sections 15376, 65940 and 65943, Government Code; and section 25079, Health and Safety Code.

HISTORY

1. New section filed 10-15-91 as an emergency; operative 10-15-91 (Register 92, No. 7). A Certificate of Compliance must be transmitted to OAL 2-12-92 or emergency language will be repealed by operation of law on the following day.
2. New section refiled 1-23-92 as an emergency; operative 2-12-92 (Register 92, No. 15). A Certificate of Compliance must be transmitted to OAL 6-11-92 or emergency language will be repealed by operation of law on the following day.
3. Certificate of Compliance as to 1-23-92 order including amendment of section transmitted to OAL 6-2-92 and filed 7-14-92 (Register 92, No. 29).
4. Editorial correction of History 2 (Register 95, No. 47).

§65613. Notice of Decision on Application.

• Note • History

(a) The notification of the enforcement agency's decision to grant or deny an application shall be mailed via certified mail to the applicant within 120 calendar days after the date on which the enforcement agency determines the application to be complete and accepted for filing.

(b) Within 20 days after the enforcement agency mails a notice of denial, the applicant may present a written petition for a hearing to the enforcement agency. Upon receipt of the petition, which shall clearly identify that it is an appeal, the petition shall be set for hearing.

(c) If the Department is the enforcement agency, the proceedings shall commence with the filing of a statement of issues and shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(d) If the Department is not the enforcement agency, the hearings shall be held in accordance with the ordinance or resolution adopting the medical waste management program.

NOTE

Authority cited: Sections 208 and 25017, Health and Safety Code; section 15376, Government Code; and section 21100.2, Public Resources Code. Reference: Section 15376, Government Code; sections 25077 and 25079, Health and Safety Code; and sections 21100.2 and 21151.5, Public Resources Code.

HISTORY

1. New section filed 10-15-91 as an emergency; operative 10-15-91 (Register 92, No. 7). A Certificate of Compliance must be transmitted to OAL 2-12-92 or emergency language will be repealed by operation of law on the following day.
2. New section refiled 1-23-92 as an emergency; operative 2-12-92 (Register 92, No. 15). A Certificate of Compliance must be transmitted to OAL 6-11-92 or emergency language will be repealed by operation of law on the following day.
3. Certificate of Compliance as to 1-23-92 order including amendment of subsections (c) and (d) transmitted to OAL 6-2-92 and filed 7-14-92 (Register 92, No. 29).
4. Editorial correction of History 2 (Register 95, No. 47).

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§65611. Application Procedures.

- Note • History

(a) Any person proposing to operate an offsite medical waste treatment facility or transfer station shall submit an application for a medical waste treatment facility or transfer station to the Department. Any person proposing to operate an onsite medical waste treatment facility shall submit an application for an onsite medical waste treatment facility permit to the enforcement agency. Submission of an application for an offsite medical waste treatment facility permit, or a modification or renewal thereof, shall be deemed to occur on the date the application is received by the Department. Submission of an application for an onsite medical waste treatment facility permit, or a modification or renewal thereof, shall be deemed to occur on the date the application is received by the enforcement agency.

(b) An application for a medical waste treatment facility or transfer station permit, or a modification or renewal thereof, is considered complete when the applicant has fully complied with the application requirements set forth in Sections 65610, 65621, and 65625 of this chapter.

NOTE

Authority cited: Section 15376, Government Code; and sections 208, 25017 and 25072, Health and Safety Code. Reference: Section 15376, Government Code; and sections 25070 and 25072, Health and Safety Code.

HISTORY
1. New section filed 10-15-91 as an emergency; operative 10-15-91 (Register 92, No. 7). A Certificate of Compliance must be transmitted to OAL 2-12-92 or emergency language will be repealed by operation of law on the following day.
2. New section refiled 1-23-92 as an emergency; operative 2-12-92 (Register 92, No. 15). A Certificate of Compliance must be transmitted to OAL 6-11-92 or emergency language will be repealed by operation of law on the following day.
3. Certificate of Compliance as to 1-23-92 order including amendment of section and Note transmitted to OAL 6-2-92 and filed 7-14-92 (Register 92, No. 29).
4. Editorial correction of History 2 (Register 95, No. 47).

§65612. Determination of Completeness and Notification.

(a) Within 30 calendar days of receipt of an application for a medical waste treatment facility or transfer station permit, or a request for permit modification pursuant to Section 25078, Health and Safety Code, the enforcement agency shall inform the applicant in writing either that the application is complete and accepted for filing, or that it is deficient and identify the additional specific information necessary for the application to be complete.

(b) The date on which the application is determined complete for filing, or on which the application is determined deficient, shall be the date on which the enforcement agency's written notification to the applicant is postmarked.

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NOTE

Authority cited: Sections 208 and 25017, Health and Safety Code. Reference: Section 25021.2, 25034.8 and 25040, Health and Safety Code.

HISTORY

1. New section filed 7-14-92; operative 7-14-92 (Register 92, No. 29).

Article 2. General Provisions

§65610. Compliance with the California Environmental Quality Act (CEQA).

- Note • History

(a) All medical waste treatment facility or transfer station permit applications, and applications for permit revisions, modifications, and amendments shall be accompanied by the following:

(1) Information necessary to enable the enforcement agency to comply with the requirements of the California Environmental Quality Act (Public Resources Code Sections 21000-21174). This information shall be either:

(A) A copy of any environmental impact report (EIR) or negative declaration prepared by a lead agency, evidence that a lead agency is preparing or will prepare environmental documentation, or other evidence deemed acceptable by the enforcement agency of showing compliance with the requirements of CEQA.

(B) Where the enforcement agency is required by law to be the lead agency, the applicant shall submit environmental information as set forth in the CEQA guidelines, Title 14, Division 6, Chapter 3, Sections 15000 through 15387 and Appendix H of the California Code of Regulations.

NOTE

Authority cited: Sections 208 and 25017, Health and Safety Code; and Section 65940, Government Code. Reference: Sections 25071, 25072 and 25077, Health and Safety Code; Sections 21100.2 and 21151.5, Public Resources Code; and Section 65940, Government Code.

HISTORY

1. New section filed 10-15-91 as an emergency; operative 10-15-91 (Register 92, No. 7). A Certificate of Compliance must be transmitted to OAL 2-12-92 or emergency language will be repealed by operation of law on the following day.
2. New section refiled 1-23-92 as an emergency; operative 2-12-92 (Register 92, No. 15). A Certificate of Compliance must be transmitted to OAL 6-11-92 or emergency language will be repealed by operation of law on the following day.
3. Certificate of Compliance as to 1-23-92 order including amendment of section transmitted to OAL 6-2-92 and filed 7-14-92 (Register 92, No. 29).
4. Editorial correction of History 2 (Register 95, No. 47).

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§65602. Transfer Station.

- Note • History

"Transfer station" means any offsite location where medical waste is loaded, unloaded, or stored during the normal course of transportation of the medical waste. "Transfer station" does not include common storage facilities, large quantity generators used for the purpose of consolidation, or onsite treatment facilities.

NOTE

Authority cited: Sections 208 and 25017, Health and Safety Code. Reference: Sections 25020.8, 25027.5, 25062, 25070.2 and 25070.3, Health and Safety Code.

HISTORY

1. New section filed 10-15-91 as an emergency; operative 10-15-91 (Register 92, No. 7). A Certificate of Compliance must be transmitted to OAL 2-12-92 or emergency language will be repealed by operation of law on the following day.
2. New section refiled 1-23-92 as an emergency; operative 2-12-92 (Register 92, No. 15). A Certificate of Compliance must be transmitted to OAL 6-11-92 or emergency language will be repealed by operation of law on the following day.
3. Certificate of Compliance as to 1-23-92 order including amendment of section transmitted to OAL 6-2-92 and filed 7-14-92 (Register 92, No. 29).
4. Editorial correction of History 2 (Register 95, No. 47).

§65603. Applicant.

- Note • History

"Applicant" means an owner, operator, or other person who applies to the enforcement agency for a permit pursuant to this chapter.

NOTE

Authority cited: Sections 208 and 25017, Health and Safety Code. Reference: Sections 25030, 25030.1, 25030.4 and 25072, Health and Safety Code.

HISTORY

1. New section filed 10-15-91 as an emergency; operative 10-15-91 (Register 92, No. 7). A Certificate of Compliance must be transmitted to OAL 2-12-92 or emergency language will be repealed by operation of law on the following day.
2. New section refiled 1-23-92 as an emergency; operative 2-12-92 (Register 92, No. 15). A Certificate of Compliance must be transmitted to OAL 6-11-92 or emergency language will be repealed by operation of law on the following day.
3. Certificate of Compliance as to 1-23-92 order including amendment of section transmitted to OAL 6-2-92 and filed 7-14-92 (Register 92, No. 29).
4. Editorial correction of History 2 (Register 95, No. 47).

§65604.

- Note • History

"Enforcement agency" means the Department of Health Services or the local agency administering the Medical Waste Management Act.

California Code of Regulations

TITLE 22. Social Security
Division 4. Environmental Health

Chapter 21. Minimum Standards for Permitting Medical Waste Facilities

Article 1. Definitions and Scope

§65600. Onsite.

- Note • History

(a) "Onsite" means a medical waste treatment facility on the same or adjacent property as the generator of the medical waste being treated.
(b) "Adjacent," for purposes of subdivision (a), means real property within 400 yards from the property boundary of the existing onsite medical waste treatment facility.

NOTE
Authority cited: Sections 208 and 25017, Health and Safety Code. Reference: Sections 25025.8, 25040.(d) and 25050.(d), Health and Safety Code.

HISTORY
1. New section filed 10-15-91 as an emergency; operative 10-15-91 (Register 92, No. 7). A Certificate of Compliance must be transmitted to OAL 2-12-92 or emergency language will be repealed by operation of law on the following day.
2. New section refiled 1-23-92 as an emergency; operative 2-12-92 (Register 92, No. 15). A Certificate of Compliance must be transmitted to OAL 6-11-92 or emergency language will be repealed by operation of law on the following day.
3. Certificate of Compliance as to 1-23-92 order including newly designated subsection (a), adoption of subsection (b) and amendment of Note transmitted to OAL 6-2-92 and filed 7-14-92 (Register 92, No. 29).
4. Editorial correction of History 2 (Register 95, No. 47).

§65601. Offsite.

- Note • History

"Offsite" means any location which is not onsite.

NOTE
Authority cited: Sections 208 and 25017, Health and Safety Code. Reference: Sections 25025.5 and 25070, Health and Safety Code.

HISTORY
1. New section filed 10-15-91 as an emergency; operative 10-15-91 (Register 92, No. 7). A Certificate of Compliance must be transmitted to OAL 2-12-92 or emergency language will be repealed by operation of law on the following day.
2. New section refiled 1-23-92 as an emergency; operative 2-12-92 (Register 92, No. 15). A Certificate of Compliance must be transmitted to OAL 6-11-92 or emergency language will be repealed by operation of law on the following day.
3. Certificate of Compliance as to 1-23-92 order transmitted to OAL 6-2-92 and filed 7-14-02 (Register 92, No. 29).
4. Editorial correction of History 2 (Register 95, No. 47).