



County of San Diego

DEPARTMENT OF ENVIRONMENTAL HEALTH
HAZARDOUS MATERIALS DIVISION
P.O. BOX 129261, SAN DIEGO, CA 92112-9261
(858) 505-6880 FAX (858) 505-6848
<http://www.sdcdeh.org>



SMALL QUANTITY MEDICAL WASTE GENERATOR REGISTRATION SELF-CERTIFICATION PROCESS

Dear Business Owner/Operator:

Thank you for your application. In order to approve your self-certification, you will need to demonstrate that the medical waste generated by your facility will be managed in accordance with the [California Medical Waste Management Act](#) (MWMA).

To fulfill this requirement, you can:

1. Complete and submit the attached Medical Waste Management Plan for Small Quantity Generators (MWMP SQG). Please see pages 3-4.
 2. Provide the following supporting documentation to verify compliance:
 - Copies of the last 2 years of medical waste disposal receipts. If you have not yet had a pick-up, please provide a copy of your contract with your registered medical waste hauler. If you are using a mail back service or encapsulation device (e.g., Isolyzer), please note that in your MWMP SQG.
 - Photos of your medical waste storage area(s) with required signage and security.
 - Photos of your medical waste container(s) with required labeling.
 - If you generate photographic/x-ray processing waste containing silver, provide evidence of your annual notification in CERS per San Diego County Code 68.909.5. If you need assistance with the CERS notification, please contact the CERS Help Desk at: (858) 505-6990.
- or -
3. In lieu of step 2, you can call the CERS Help Desk to schedule an onsite inspection of your facility. An hourly rate will be assessed for an onsite inspection.

Please refer to Chapters 2 and 9 of the MWMA for definitions and specific requirements for small quantity medical waste generators. A handout has also been included with this letter for additional assistance.

Once your documentation has been reviewed, an HMD representative will contact you with the status of your self-certification. If approved, an invoice will be sent for the registration fee. Upon payment of the invoice, the registration will be mailed and the period the registration is valid will be indicated. For questions, please call the HMD Permits Line at: 858-505-6661.

In accordance with the California Health and Safety Code §117940, you must notify the HMD within 30 days of any changes that occur. To submit changes or renew this permit you must submit an updated MWMP SQG **at least 30 days** prior to the expiration date on the current registration. A copy of your current MWMP SQG will be sent to you along with your invoice for confirmation.

Be advised: Failure to complete the Self-Certification Process and/or pay your invoice may result in an onsite verification and inspection fees. If you have any questions, please call the CERS Help Desk at (858) 505-6990 or email: Inbox.CERS@sdcounty.ca.gov.

"Environmental and public health through leadership, partnership and science"

MEDICAL WASTE – DEFINITION OF TERMS

“MEDICAL WASTE” means biohazardous, pathology, pharmaceutical, or trace chemotherapy waste not regulated by the federal Resource Conservation and Recovery Act; sharps and trace chemotherapy wastes generated in a health care setting in the diagnosis, treatment, immunization, or care of humans or animals; waste generated in autopsy or necropsy; waste generated during preparation of a body for final disposition such as cremation or interment; waste generated in research pertaining to the production or testing of microbiologicals; waste generated in research using human or animal pathogens; sharps and laboratory waste that poses a potential risk of infection to humans generated in the inoculation of animals in commercial farming operations; waste generated from the consolidation of home-generated sharps; and waste generated in the cleanup of trauma scenes.

“BIOHAZARDOUS WASTE” means all of the following (A-D):

(A) (i) Regulated medical waste, clinical waste, or biomedical waste that is a waste or reusable material derived from the medical treatment of a human or from an animal that is suspected by the attending veterinarian of being infected with a pathogen that is also infectious to humans, which includes diagnosis and immunization; or from biomedical research, which includes the production and testing of biological products.

(ii) Regulated medical waste or clinical waste or biomedical waste suspected of containing a highly communicable disease.

(B) Laboratory waste such as human specimen cultures or animal specimen cultures that are infected with pathogens that are also infectious to humans; cultures and stocks of infectious agents from research; wastes from the production of bacteria, viruses, spores, discarded live and attenuated vaccines used in human health care or research, discarded animal vaccines, including Brucellosis and Contagious Ecthyma, as defined by the department; culture dishes, devices used to transfer, inoculate, and mix cultures; and wastes identified by Section 173.134 of Title 49 of the Code of Federal Regulations as Category B “once wasted” for laboratory wastes.

(C) Waste that, at the point of transport from the generator’s site or at the point of disposal contains recognizable fluid human blood, fluid human blood products, containers, or equipment containing human blood that is fluid, or blood from animals suspected by the attending veterinarian of being contaminated with infectious agents known to be contagious to humans.

(D) Waste containing discarded materials contaminated with excretion, exudate, or secretions from humans or animals that are required to be isolated by the infection control staff, the attending physician and surgeon, the attending veterinarian, or the local health officer, to protect others from highly communicable diseases or diseases of animals that are communicable to humans.

“BIOHAZARD BAG” means a disposable film bag that is impervious to moisture. The film bags that are used for transport shall be marked and certified by the manufacturer as having passed the tests prescribed for tear resistance in the American Society for Testing Materials (ASTM) D1922, “Standard Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method” and for impact resistance in ASTM D1709, “Standard Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method,” as those documents were published in January 1, 2014. The film bag shall meet an impact resistance of 165 grams and a tearing resistance of 480 grams in both parallel and perpendicular planes with respect to the length of the bag. The color of the bag shall be red; except when yellow bags are used to further segregate trace chemotherapy waste and white bags are used to further segregate pathology waste.

“SHARPS WASTE” means a device that has acute rigid corners, edges, or protuberances capable of cutting or piercing, including, but not limited to, hypodermic needles, hypodermic needles with syringes, blades, needles with attached tubing, acupuncture needles, root canal files, broken glass items used in health care such as Pasteur pipettes and blood vials contaminated with biohazardous waste, and any item capable of cutting or piercing from trauma scene waste. **“SHARPS WASTE”** means a device that has acute rigid corners, edges, or protuberances capable of cutting or piercing, including, but not limited to, hypodermic needles, hypodermic needles with syringes, blades, needles with attached tubing, acupuncture needles, root canal files, broken glass items used in health care such as Pasteur pipettes and blood vials contaminated with biohazardous waste, and any item capable of cutting or piercing from trauma scene waste. Refer to the definition of sharps waste as it pertains to the definition of a medical waste in section 117690 of the Medical Waste Management Act.

“SHARPS CONTAINERS” means a rigid puncture-resistant container used in patient care or research activities meeting the standards of and receiving approval from the United States Food and Drug Administration as a medical device used for the collection of discarded medical needles or other sharps.

“PATHOLOGY WASTE” means human body parts, with the exception of teeth, removed at surgery and surgery specimens or tissues removed at surgery or autopsy that are suspected by the health care professional of being contaminated with infectious agents known to be contagious to humans or having been fixed in formaldehyde or another fixative. Pathology waste also means animal parts, tissues, fluids, or carcasses suspected by the attending veterinarian of being contaminated with infectious agents known to be contagious to humans.

“PHARMACEUTICAL WASTE” (a) means a pharmaceutical, as defined in Section 117747, including trace chemotherapy waste, that is a waste, as defined in Section 25124. (b) For purposes of this part, “pharmaceutical waste” does not include any pharmaceutical that meets either of the following criteria:

(1) The pharmaceutical is being sent out of the State of California to a reverse distributor, as defined in Section 4040.5 of the Business and Professions Code, that is licensed as a wholesaler of dangerous drugs by the California State Board of Pharmacy pursuant to Section 4161 of the Business and Professions Code.

(2) The pharmaceutical is being sent by a reverse distributor, as defined in Section 4040.5 of the Business and Professions Code, offsite for treatment and disposal in accordance with applicable laws, or to a reverse distributor that is licensed as a wholesaler of dangerous drugs by the California State Board of Pharmacy pursuant to Section 4160 of the Business and Professions Code and as a permitted transfer station if the reverse distributor is located within the State of California.

STORAGE AREA WARNING SIGN is: A sign posted at a designated accumulation area, visible for 25 feet, used to store medical waste which must read in English, “CAUTION—BIOHAZARDOUS WASTE STORAGE AREA—UNAUTHORIZED PERSONS KEEP OUT” and in Spanish, “CUIDADO-ZONA DE RESIDUOS—BIOLOGICOS PELIGROSOS—PROHIBIDA LA ENTRADA A PERSONAS NO AUTORIZADAS” or in another language determined to be appropriate. Intermediate storage areas shall be marked with the international biohazardous symbol or the signage noted above. These warning signs shall be readily legible from a distance of five feet.



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Medical Waste Management Plan for Small Quantity Generators

Facility Information

Business Name	Registration #
Type of Business	Date
Street Address	City/ZIP

Person Responsible for implementing the Medical Waste Management Plan (MWMP)

Name	
Title	Phone

Types of Medical Wastes (MW) Generated

Please check the box for all types of medical waste that will be generated by your facility. Also estimate the number of pounds (lbs.) that will be generated each month. Definitions are in Chapter 2 of the [Medical Waste Management Act](#) in the California Health and Safety Code (HSC) §117625-117780.

In order to approve your self-certification, a representative photo of EACH waste stream must also be submitted with your updated Medical Waste Management Plan.

Sharps waste - a device that has acute rigid corners, edges, or protuberances capable of cutting or piercing. (see page 2 for full definition from § 117690 of the MWMA)

Estimated monthly amount _____ lbs

Non RCRA Pharmaceutical waste - a prescription or over-the-counter human or veterinary drug that is not RCRA hazardous waste nor radiological waste.

Estimated monthly amount _____ lbs

Trace Chemotherapeutic waste - waste that is contaminated through contact or contained, chemotherapeutic agents. (e.g. gloves, disposable gowns, towels, and IV bags and attached tubing that are empty)

Estimated monthly amount _____ lbs

Pathology waste – human body parts or animal tissues suspected to be infectious to humans or have been fixed in formaldehyde or other fixative

Estimated monthly amount _____ lbs

Trauma Scene waste – waste that has been removed, is to be removed, or is in the process of being removed, from a trauma scene by a trauma scene waste management practitioner.

Estimated monthly amount _____ lbs

Biohazardous waste – regulated medical waste, clinical waste, or biomedical waste from the medical treatment of a human or from an animal that is suspected to be infected with a pathogen that is infectious to humans.

Biohazardous waste also includes:

Highly Communicable waste - waste contaminated with excretion, exudates or secretions from humans or animals who are isolated due to highly communicable diseases.

Laboratory waste – infectious specimens or microbiological cultures, stocks of infectious agents, live and attenuated vaccines, biologicals, and culture media.

Fluid Blood or Blood Products – recognizable fluid human blood or blood products, containers, equipment containing human blood or blood from animals

Estimated monthly amount _____ lbs

Liquid/Semi-liquid biohazardous waste - treated onsite by chemical disinfection and discharged to sewer.*

Estimated monthly amount _____ lbs

Other (specify):

Estimated monthly amount _____ lbs

Estimate of TOTAL monthly medical waste generated: _____ lbs

*Per HSC §118215(c), for liquid or semi-liquid biohazardous laboratory waste (§117690(b)(1)(B)), the treatment method must be recognized by the NIH, the CDC, or the American Biological Safety Association. If the chemical disinfection of the medical waste causes the waste to become a hazardous waste, the waste shall be managed in accordance with the requirements of HSC Chapter 6.5 (commencing with §25100) of Division 20.

Medical Waste Management Plan

Registered Medical Waste Hauler or Common Carrier

In accordance with HSC§117945, a small quantity of medical waste shall maintain on file in its office all of the following:

- (1) An information document stating how the generator contains, stores, treats, and disposes of any medical waste generated through any act or process of the generator.
- (2) Records required by the United States Postal Service of any medical waste shipped offsite for treatment and disposal. The small quantity generator shall maintain or have available electronically at the facility or from the medical waste hauler or common carrier, these **records for no less than three years**.

Documentation shall be made available to the enforcement agency onsite.

Primary Medical Waste Transporter	CA Registration #
Street Address	City/ZIP
Contact Person	Phone #
Secondary (backup) Medical Waste Transporter	CA Registration #
Street Address	City/ZIP
Contact Person	Phone #

How frequently will the waste be disposed? (e.g. weekly, monthly, quarterly):

Decontamination Procedure

In accordance with HSC§118295 and 118300, the following decontamination procedure is to be followed in the event of a biohazardous spill or contamination, to include but not limited to the reuse of rigid containers for medical waste.

Check the appropriate box indicating which method of disinfection you will use:

- Exposure to hot water 180°F for ≥ 15 seconds**

- Rinse/Immersion in hypochlorite solution for ≥ 3 minutes**
(500 ppm available chlorine)

- Rinse/Immersion in phenolic solution for ≥ 3 minutes**
(500 ppm active agent)

- Rinse/Immersion in Iodoform solution for ≥ 3 minutes**
(100 ppm available iodine)

- Rinse/Immersion in Quaternary ammonium solution for ≥ 3 minutes**
(400 ppm available active agent)

Acknowledgement

I have read and understood, as a small quantity medical waste generator, I am required to comply with the applicable requirements in the Medical Waste Management Act found in the California Health and Safety Code, Sections 117600-118360. **Yes**

Self-Certification Statement

I declare under penalty of law that to the best of my knowledge and belief, the statements made herein are correct and true. I hereby consent to all necessary inspections made pursuant to the California Medical Waste Management Act and incidental to the issuance of my registration and the operation of this business.

Name	
Title	
Signature	Date