



Medical waste can be divided into two basic types for treatment purposes: 1) infectious wastes like blood and body fluids; cultures and stocks; items that are capable of releasing blood or body fluids or are caked with dried blood or body fluids; pathological wastes; and sharps and 2) waste pharmaceuticals and trace chemotherapy waste. When selecting a treatment method for infectious medical waste, the load configuration, packing density, waste composition, type of packaging, moisture content, thermal properties, and volume of the waste must also be considered.

Treatment Methods and Standards for Infectious Wastes

Treatment Effectiveness

The Colorado Department of Public Health and Environment (the Department) does not pre-approve or recommend specific medical waste treatment technologies. Approval is provided on a site-specific basis during review of an application for a Certificate of Designation (permit).

The technology manufacturer and waste treater have shared responsibility in demonstrating the selected treatment technology's effectiveness through validation and verification testing to confirm for the Department that the medical waste will be adequately treated. Acceptable methods of treatment are methods that will render the waste non-infectious and not present a danger to facility personnel or the public. "Rendered non-infectious" means that the waste has been successfully treated to inactivate pathogens and other biologically active material to a level that will no longer present a potential hazard of infection when managed, stored or disposed of.

Infectious wastes must be treated to achieve a level of at least a 6 Log₁₀ reduction (i.e., a 99.9999% reduction) in the concentration of the biological indicator *Mycobacterium phlei* or *Mycobacterium bovis* AND a 4 Log₁₀ reduction (i.e., a 99.99% reduction) in the level of biological indicator *Bacillus stearothermophilus*, *Bacillus subtilis* or *Bacillus atrophaeus* endospores. Some treatment technologies may combine different methods or may include grinding or shredding of the waste to improve treatment efficiency, but in all cases the treated waste must be rendered non-infectious. Encapsulation, solidification, and/or compaction without rendering the waste non-infectious are not adequate forms of treatment for infectious wastes.

Treatment Technology Validation and Verification

Treatment technologies may be classified based on their method of rendering the waste noninfectious:

- Thermal (e.g., autoclaving, incineration, heat, micro- or macrowaving, pyrolysis, gasification).
- Chemical (e.g., chlorine or chlorine derivatives, ozone, enzymes, sodium hydroxide).
- Irradiation (e.g., ultraviolet, Cobalt 60, electron beam).
- Other mechanisms designed for specific medical waste categories (e.g., gas/vapor sterilization).

The treatment technology manufacturer must determine the methodology and protocols used to demonstrate their technology meets at least the minimum acceptable biological inactivation standards. This is a two step process that involves developing appropriate validation test methods used by the manufacturer to prove to the Department that the overall technology and specific equipment perform as

designed and are able to consistently render medical waste noninfectious. The manufacturer must also determine appropriate verification test methods that can be done on a routine and/or periodic basis by the waste treater to verify the effectiveness of the treatment process on-site under actual operating conditions. Protocols developed for validation testing should incorporate a systematic approach for identifying and effectively managing the critical control points in the treatment process.

The treatment technology manufacturer is responsible for identifying which medical waste compositions their technology is designed to handle as well as its technological limitations. As recommended in the 1998 Technical Assistance Manual: State Regulatory Oversight of Medical Waste Treatment Technologies (referred to as STAATT II), validation testing should involve the actual equipment using waste loads representing the typical composition and size the system is designed to handle. Testing should also include loads that vary in organic to non-organic and solid to liquid compositions, as well as testing the anticipated worst case scenario for that treatment method.

The technology manufacturer must develop verification test methods to be used on a routine basis by the waste treater under actual operating conditions that include the specific biological indicators. Parametric monitoring is the monitoring of measurement data (such as time and temperature) to control the operation of the equipment and to verify that certain performance criteria were met to assure compliance with appropriate treatment standards. Use of parametric monitoring may be allowed for certain technologies without using biological indicators if the manufacturer has completed validation studies that demonstrate that appropriate critical limits were met to achieve adequate biological inactivation and that biological inactivation is directly correlated to the parameters being monitored. In that case, the technology should include tamper-proof controls or automatic factory-set controllers, provide tamper-proof recording of all monitored parameters, provide for automatic shut-down of the unit if it isn't performing to standards, and provide for periodic re-calibration as specified by the technology manufacturer. The technology manufacturer should provide not only a written operating and maintenance manual for the waste treater, but also provide on-site training to ensure that the treatment unit is functioning properly at the site and that the waste treater is using the right operating procedures to achieve the required treatment standards. On-site verification testing must be completed on representative test loads before production start-up of a newly installed treatment system at the waste treater's facility.

On-Site or Off-site Treatment of Infectious Wastes

Medical waste may either be treated on-site by the generator or sent offsite to an approved commercial medical waste treatment facility. Facilities that treat medical waste cannot become a health or environmental hazard and must prevent the development of nuisance conditions. The medical waste treater is responsible for determining the most appropriate and effective treatment method(s) for the waste they will be treating. Based on the technology manufacturers' recommendations, the waste treater must have written standard operating procedures, written verification testing procedures including the use of biological indicators and/or parametric monitoring to confirm that an acceptable level of biological inactivation is achieved, an operator training plan, an emergency response plan, and a contingency plan for alternative waste handling and treatment in the event of equipment breakdown. For a medical waste generator treating their own waste on-site, this information must be included in their medical waste management plan. For a commercial medical waste treatment facility, this information must be included in their engineering design and operations plan.

On-Site Treatment by the Generator

Medical waste generators are not required to obtain a Certificate of Designation to treat their own medical waste on-site. They may also treat medical waste that is self-transported by private motor carrier from other locations operated by the same business and household-generated waste collected as a community service.

The most common on-site medical waste treatment method is steam disinfection (autoclaving). Although rare, generators can incinerate their medical waste provided the facility has the proper air and local permits. Other on-site medical waste treatment technologies include chemical disinfection, thermal inactivation, irradiation, and gas/vapor sterilization. These treatment technologies may require licensing or permitting from other regulatory programs such as air pollution control and local wastewater pretreatment programs.

Generators conducting on-site treatment of medical waste must include written standard operating procedures for implementation of the method, the type of monitoring or testing that will be performed to test the effectiveness of the treatment, verification data showing that the waste was rendered non-infectious, a contingency plan for spills or loss of containment, provisions for alternative waste handling and treatment in the event of equipment breakdown, and written operating records that will be maintained in their medical waste management plan. They should also include records of the type and quantity of waste treated and maintenance records appropriate for the type of technology used.

Treatment at an Off-Site Commercial Treatment Facility

A commercial medical waste treatment facility must obtain a Certificate of Designation from the county or municipality in which they are located. As part of their application, the facility must provide an engineering design and operations plan that includes, among other things: general information about the facility; a description of facility operations; a description of the incoming waste streams; on-site waste management plans; details of the treatment technology including equipment used, standard operating procedures, and type and frequency of verification monitoring; an operational safety plan, a fire prevention and emergency response plan; a personnel plan; an operator training plan, and a contingency plan for loss of containment, alternative waste treatment, or storage in the event of an equipment breakdown. Once the Certificate of Designation is issued, the facility must be operated in compliance with the procedures specified in the approved engineering design and operations plan and all other applicable requirements.

Commercial medical waste treatment facilities must maintain records of the volume of waste, type of waste, generator names and addresses, container types, treatment methods, dates of pick-up/drop-off/treatment/disposal, all verification testing and monitoring results as well as information regarding water discharges, if any. They must also maintain records of equipment maintenance, all variations from the approved standard operating procedures, any deviations from identified operating limits, and self-inspections conducted at the facility. These records must be made available to state and local inspectors and should be kept for at least three years from the date the treated waste was sent off-site for disposal.

Disposal of Treated Infectious Wastes

Medical waste that has been treated to achieve an acceptable level of biological inactivation is considered to have been rendered non-infectious and may be discharged into the sanitary sewer system or disposed of with other non-infectious solid wastes, as appropriate. Sewer disposal may require that the waste treater obtain approval from their wastewater treatment facility or the pretreatment authority

in charge of their wastewater discharge prior to disposing of treated waste to the sewer. Waste treaters that are on individual sewage disposal systems (septic tanks) should not dispose of waste in this manner.

Treated medical waste that is sent to a solid waste disposal facility must be clearly identified as treated waste, or the waste treater can provide the waste transporter and disposal facility with a written statement that its ordinary solid waste also includes appropriately treated medical waste. The waste treater's operating and monitoring records may be used to document to the sewer authority, transporter and/or disposal facility that the medical waste has been successfully rendered non-infectious.

Untreated medical waste from non-household sources may not be disposed of in a solid waste disposal facility unless the disposal facility has an approved Engineering Design and Operations plan that specifically allows these wastes. Contact the Department at comments.hmwmd@state.co.us if you have questions regarding approved disposal facilities.

Medical waste consisting of recognizable human anatomical remains must be disposed of by interment, cremation, incineration or other method consistent with the Mortuary Science Code (Title 12 Article 54 Parts 1 – 4), or by acceptance by a representative of the State Anatomical Board (5 CCR 1006-1).

Treatment and Disposal of Waste Pharmaceuticals and Trace Chemotherapy Waste

Medical waste generators must evaluate each pharmaceutical that has expired or is otherwise wasted to determine whether it is regulated as a hazardous waste, a controlled substance, or a solid waste. Waste pharmaceuticals that contain constituents that are P- or U-listed hazardous wastes or that exhibit one or more characteristics of hazardous waste (ignitable, corrosive, reactive, toxic) are hazardous waste and have specific requirements for on-site management, disposal methods and locations, manifesting, and record keeping under Colorado's Hazardous Waste Regulations (6 CCR 1007-3). The Department considers hazardous waste pharmaceuticals that are returned to a reverse distributor to be a waste and not a commodity. Therefore, pharmaceuticals that meet the definition of hazardous waste must be managed as a hazardous waste and generally cannot be returned to a reverse distributor. More information about these requirements can be obtained from the Department's web site at www.cdphe.state.co.us/hm/medicalwaste/.

Waste pharmaceuticals that contain controlled substances are regulated by the United States Drug Enforcement Administration (DEA). These wastes have specified management and disposal requirements under the Controlled Substances Act (Title 21 Chapter 13 Subchapter I Part B (USC)). Waste pharmaceuticals regulated as controlled substances must be disposed of per DEA regulations (21 CFR 1307.21). In cases where a waste pharmaceutical meets the definition of a hazardous waste and is also regulated as a controlled substance by the DEA, the Department allows the pharmaceutical to be sent to a DEA-registered reverse distributor. The local DEA Special Agent in Charge often instructs the facility to destroy controlled substances on-site, witnessed by two health care professionals. In the past, this meant disposal down the drain. The U.S. EPA and the Department strongly discourage the practice of sewer disposal for pharmaceuticals. The preferred alternative is to transfer control of the waste pharmaceutical to a DEA registrant that is specifically approved to destroy pharmaceuticals. In cases where a waste pharmaceutical meets the definition of a hazardous waste and is also regulated as a controlled substance by the DEA, the preferred alternative is to transfer control of the waste pharmaceutical to a DEA registrant that is specifically approved to destroy pharmaceuticals and that is also permitted to handle hazardous waste.

Waste pharmaceuticals that are not regulated as controlled substances or hazardous wastes are regulated as solid waste under Colorado's solid waste regulations (6 CCR 1007-2). These wastes may be sent to a reverse distributor or sent to a pharmaceutical mail-back service for proper disposal, treated to encapsulate or solidify the waste at an approved medical waste treatment facility prior to disposal at a solid waste disposal site, or incinerated at an approved solid or hazardous waste incinerator, or must be disposed of in an approved solid waste disposal site that has an approved Engineering Design and Operations Plan that specifically allows these wastes. Biological inactivation technologies (e.g., autoclaving) are ineffective in treating waste pharmaceuticals. Waste pharmaceuticals should not be disposed of down the drain, in the sewer, or in the regular trash.

Trace chemotherapy waste must be disposed of in an approved solid waste disposal site that has an approved Engineering Design and Operations Plant that specifically allows this waste, or may be incinerated at an approved solid or hazardous waste incinerator.

Radioactive Medical Waste

Persons who use radionuclides for medical purposes are required to obtain a radioactive materials license issued by the Department under the Rules and Regulations Pertaining to Radiation Control (6 CCR 1007-1). As a radioactive materials licensee, the waste generator may be able to hold the waste for decay-in-storage under the provisions of 6 CCR 1007-1 Section 7.29 until the radioactivity cannot be distinguished from background levels as described in the regulations. If these requirements are met, the waste generator may further manage the waste as medical waste without regard for its radioactivity. Wastes contaminated with radioactive material should not be put into a standard medical waste container unless or until the radioactivity has decayed to background levels. If decay-in-storage is not an option, the waste must be managed as radioactive waste.

For more information please contact:

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