ARIZONA MEDICAL WASTE SERVICES, LLC

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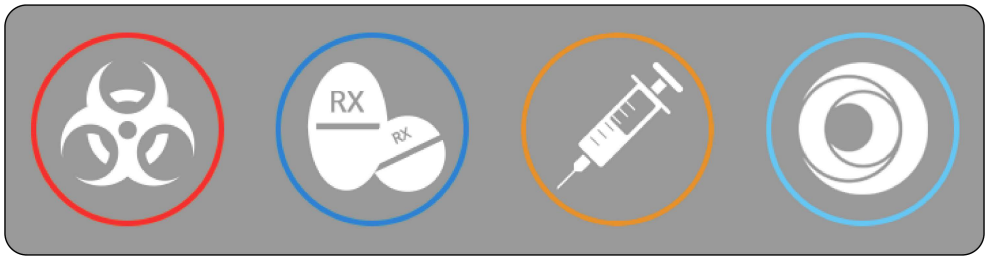

ARIZONA

OFFICIAL GUIDE FOR MEDICAL WASTE DISPOSAL

Arizona Administrative Code Article 14 (AAC R18-13-1401 to 1420)

Appendix B recodified from 18 A.A.C. 8, Article 3, filed in the Office of the Secretary of State September 29, 2000 (Supp. 00-3).

Contents

Overview

There are several regulations regarding handling and disposal of medical waste in the state of Arizona. These guidelines apply to institutions, businesses and facilities that produce medical waste, the waste collector that handles and collects waste, and facilities that treat or dispose of medical waste.

What is medical waste?

According to the Arizona Administrative Code Article 14 (AAC R18-13-1401 to 1420), biohazardous medical waste is any waste composed of one or more of the following:

> **Cultures and stocks**: Discarded cultures and stocks generated in the diagnosis, treatment or immunization of a human being or animal or in any research relating to that diagnosis, treatment or immunization, or in the production or testing of biologicals.
>
> **Human blood and blood products**: Discarded products and materials containing free-flowing blood or free-flowing blood components.
>
> **Human pathologic wastes**: Discarded organs and body parts removed during surgery. Human pathologic wastes do not include the head or spinal column.
>
> **Medical sharps**: Discarded sharps used in animal or human patient care, medical research, or clinical laboratories. This includes hypodermic needles; syringes; pipettes; scalpel blades; blood vials; needles attached to tubing; broken and unbroken glassware; and slides and coverslips.
>
> **Experimental and animal research wastes**: Animal carcasses, body parts, and bedding of animals that have been infected with agents that produce, or may produce, human infection.

This means that certain waste items generated by hospitals, health clinics and nursing homes, medical research labs and diagnostic labs, offices of physicians, dentists and veterinarians, as well as funeral homes are considered medical waste.

Who Should Follow These Guidelines? (R18-13-1402)

These regulations apply to the following:

A. Businesses and facilities that generate medical waste on site.

B. Businesses that contract with a medical waste facility for the purpose of treatment of waste.

C. Persons who transport medical waste for purpose of treatment.

D. Facilities and operators that treat medical waste.

E. Facilities and operators that provide alternative methods for treatment of medical waste.

F. Persons possessing biohazardous medical waste that does not meet treatment standards.

G. Operators and facilities that accept untreated medical waste.

H. Persons and businesses that generate medical sharps in preparation of human remains and the treatment of animals.

I. Institutions that generate discarded drugs not returned to the manufacturer.

Exemptions (R18-13-1403)

These guidelines may not apply to some entities, persons, or businesses.

The following are exempt from following these guidelines:

A. Law enforcement personnel handling biohazardous medical waste for law enforcement purposes.

B. Persons possessing materials that emit radiation.

C. Persons who return unused medical sharps to manufacturer.

D. Household medical waste generators residing in private, public, or semi-private residences in administration of self-care, or the agent of the household generator who administers the medical care. This does not apply to facilities licensed by the Arizona Department of Health Services.

E. Generators that separate medical devices from medical waste streams that are sent out for reprocessing and returned to the generator.

F. Persons in possession of human bodies regulated by Arizona Revised Statutes (A.R.S.) Title 36.

G. Persons who send used medical sharps via U.S Postal Service or private shipping agent to the treatment facility.

The following are conditionally exempt:

A. Persons who prepare human cadavers, remains and anatomical parts for internment or cremation. (But if medical sharps are generated during a procedure, they must be disposed of according to guidelines.)

B. Persons who operate emergency rescue vehicles, ambulances, or a blood service collection vehicle if the biohazardous medical waste is returned to the home facility for disposal. This facility is considered to be the point of generation for packaging, treatment, and disposal.

C. Persons who discard drugs, liquid and semi-liquid biohazardous substances, excluding stocks and cultures, into the sanitary sewer system with authorization, permit or approval of the operator of the wastewater sewer system.

D. Persons who possess hazardous waste regulated by A.R.S. Title 49, Chapter 5.

E. Health care workers who use multi-purpose vehicles in the conduct of routine business other than transporting waste, are exempt when they comply with all of the following requirements:

   a. Package the biohazardous medical waste according to R18-13-1407.

   b. Secure the packaged biohazardous medical waste within the vehicle so as to minimize spills.

   c. Transport the biohazardous medical waste to the place of business or to a medical waste treatment or disposal facility.

   d. Clean the vehicle when it shows visible signs of contamination.

   e. Secure the vehicle to prevent unauthorized contact with the biohazardous medical waste.

Transition and Compliance Dates (R18-13-1404)

This section is adopted and ruled effective on September 17, 1999 (Supp. 99-3).

A. Unless otherwise specified below, the date of compliance for generators, transporters and facilities that treat waste using conventional or alternative methods and other persons possessing biohazardous medical waste is effective at the date of this article.

B. Facilities using alternative medical waste treatment technology must register the technology with the Department, and must not use the technology unless the Department receives the registration certificate. The facility must provide a copy of the registration certificate and specifications of the technology used.

C. Generators utilizing alternative waste treatment technologies must obtain a Department registration number and equipment specifications within 180 days. If the documents in the Department are not on file with the generators, the waste treated with unregistered alternative waste treatment technology will be classified as untreated biohazardous medical waste.

D. Generators using incineration or autoclaving technology for on-site treatment of medical waste must comply with concerning regulations and requirements of such technologies.

E. Transporters of medical waste must register at the Department within 90 days after the effective date of this article.

F. Operators of medical waste transfer facilities must meet the requirements in R18-13-1410 within 180 days after the effective date of this article.

G. Operators of medical waste treatment facilities approved by the Department can operate as long as they meet the following requirements:

    a. Comply with treatment standards and recordkeeping requirements.

    b. If treater determines that waste treatment is not in keeping with standards, the Department must be informed within 2 days, and within 30 days must enter into an administrative consent to bring the facility into compliance.

H. Operators of a municipal solid waste landfill intending to accept untreated biohazardous medical waste must submit Type III change (in R18-13-1413) and an amended facility plan within 180 days after the effective date of this article.

I. If the Department has determined that an updated solid waste facility plan is required, the treater may continue to operate under conditions specified at subsection (G) while the Department conducts a review of the plan.

J. A solid waste plan approval is required for a new medical waste treatment or disposal facility before construction.

Treatment of Biohazard Waste On-Site (R18-13-1405)

These guidelines apply to treatment of medical waste on the site of its generation. Medical waste must be treated on the site of generation for containment and make it less hazardous. This section applies to businesses, institutions and facilities (generators) that have to treat their own generated medical waste for collection.

A. Treatment of biohazardous medical waste should use incineration, autoclaving or an alternative medical waste treatment method according to standards (more on this later).

B. Generators that burn/incinerate biohazardous medical waste must DO ALL of the following:

    a. Obtain a state or local air quality permit

    b. Reduce biohazardous waste to ash. This excludes metallic items

    c. Determine if the resulting ash is a hazardous waste

    d. Dispose of non-biohazardous resulting ash at a municipal waste facility

C. Generators that autoclave their medical waste must COMPLY WITH ALL of the following:

    a. Process biohazardous waste, including human and animal remains, by grinding or shredding to render it unrecognizable and ensure proper treatment.

b. Only operate the autoclave according to manufacturer's instructions, density and quantity of load.

c. Record operational performance levels for six months after each treatment cycle. Records should have the following:

    i. Duration of time for each treatment cycle.

    ii. Temperature and pressure maintained during each treatment.

    iii. Methods used to determine treatment parameters.

    iv. Methods used to confirm microbial inactivation and test results.

    v. Other treatment parameters in manufacturer's specifications for each cycle.

d. Records of equipment maintenance

D. Generators who use alternative treatment technology for treatment of medical waste must COMPLY WITH ALL of the following:

a. Use only alternative methods approved and registered by the Arizona Dept of State (more on this later)

b. Must also process biohazardous waste (including human and animal remains) by grinding or shredding to render them unrecognizable and ensure proper treatment.

c. Follow manufacturer's specifications for equipment operation.

d. Generators must supply the following upon request:

    i. Department registration number of the alternative medical waste treatment technology used for treatment

    ii. Equipment specifications including operating procedures and instructions to comply with treatment standards

e. Maintain training manuals for proper operation of equipment.

f. Maintain records of waste treated, the volume, schedule of calibration and maintenance, and maintain records for six months for each treated load.

g. Maintain equipment according to specifications during use.

E. Generators must DO ALL of the following:

a. Package medical waste in accordance to waste collection agency requirements

b. The package or container of treated medical waste must be labeled or tagged with the following words: "This medical waste has been treated as required by

Arizona Department of Environmental Quality standards" before placing the treated medical waste out for collection as general solid waste. Medical waste must be treated according to regulations in R18-13-1414.

F. Generators must dispose of medical sharps according to regulations in R18-13-1419.

G. Generators of chemotherapy waste, biohazardous cultures and stocks, and animal waste must handle waste according to regulations in R18-13-1420.

Transport of Biohazardous Medical Waste Off-Site for Treatment (R18-13-1406)

These guidelines must be followed when transporting medical waste from point of source for treatment.

A. Generators must package medical waste according to standards (using red bags, puncture-resistant containers for sharps, and using secondary containers as necessary as per R18-13-1407).

B. Transporters of medical waste must provide generators with a copy of a TRACKING DOCUMENT showing acceptance of the waste. This document must be kept for a year. The tracking document must contain all of the following:

   a. Name and address of the transporter, generator, and the facility for medical waste treatment, storage, transfer or disposal.

   b. Quantity (weight, volume and number of containers) of the medical waste.

   c. Identification number attached to the bags or containers.

   d. Date of medical waste collection.

C. Generators of chemotherapy waste, cultures and stocks, and medical sharps must handle the waste according to standards in R18-13-1419 and in R18-13-1420.

Packaging of Biohazardous Medical Waste (R18-13-1407)

These guidelines must be followed when packaging biohazardous medical waste for collection for treatment or disposal.

A. Red bags must be leak resistant, impervious to moisture, sufficiently strong to prevent tearing or bursting under normal use, and sealable.

B. Red bags must be puncture resistant for sharps and placed in a secondary container that prevent breakage of bags during storage and handling.

C. The secondary container for the red bag can be either disposable or reusable, and must bear a conspicuous biohazard symbol.

D. The secondary container, if reusable, must be leak-proof on all sides and bottom, closable with a fitted lid, cleanable and resistant to corrosion.

E. The secondary container must be cleaned unless there is an inner liner, bags or devices that contain the waste. The secondary container must be cleaned with hot water (at least 180 F) or EPA-approved disinfectant.

F. Secondary containers that cannot be cleaned thoroughly, or disposable containers, must be classified as medical waste.

G. Secondary containers must never be used for purposes other than storing biohazardous medical waste.

H. Liners, red bags and other disposable packaging must never be reused, and must be disposed as biohazardous medical waste.

Storage of Biohazardous Medical Waste (R18-13-1408)

These guidelines govern the storage of biohazardous medical waste.

A. Generators may place conspicuously marked biohazardous waste containers alongside solid waste containers. However, the room for waste storage must never be used to store substances like food or medical supplies.

B. Generators should provide a storage area for packaged medical waste for shipment off-site until waste is collected. The storage area must COMPLY WITH ALL of the following requirements:

    a. The area must be secure and must restrict contact by authorized persons to the waste.

    b. Must display universal biohazard symbols and warning signs. Warning signs must be worded as follows: “CAUTION — BIOHAZARDOUS MEDICAL WASTE STORAGE AREA — UNAUTHORIZED PERSONS KEEP OUT” (English), “PRECAUCION -- ZONA DE ALMACENAMIENTO DE DESPERDICIOS BIOLOGICOS PELIGROSOS — PROHIBIDA LA ENTRADA A PERSONAS NO AUTORIZADAS” (Spanish).

C. Generators must COMPLY WITH ALL of the following when storing medical waste:

    a. Putrescible medical waste can be left unrefrigerated if it does not cause undesirable odors. Otherwise, it must be refrigerated at 40 °F or below. If odors become a problem, the generator must minimize it. If the Department deems that the generator did not perform measures to adequately control the odors, refrigeration must be used.

    b. Biohazardous medical waste must be stored within 90 days or less, unless the generator has approved facilities in compliance with A.R.S. § 49-762.04 (rules governing waste regulation).

c. The area must be protected from contamination and contact with water, rain, wind, and animals. Generator must make sure that medical waste storage does not become a breeding ground to rodents and insects.

d. Medical waste containers that have spilled must be repackaged and re-labeled. Surfaces soiled by the spill must be thoroughly cleaned and disinfected.

Guidelines on Transportation, Transport License and Annual Fees (R18-13-1409)

A. Transporters of biohazardous medical waste must obtain a transporter license from the Arizona Department of State, as well as necessary permits and licenses from the local health department, environmental agency and other agencies within jurisdiction.

B. Transporters must pay $750 every year: transporters registered before July 2012 must pay until December 31st each year until expiration of registration, and must apply for a license no more than 60 days before expiration expires.

C. Those who want to apply for a transporter license must furnish the following:

   a. Name, address and telephone number of transportation company

   b. Names, addresses and telephone numbers of owner/s

   c. Names, addresses and telephone numbers of anyone authorized to act on the behalf of the owner/s

   d. Copy of certificates of disclosure required by A.R.S. § 49-109 or a written acknowledgment that this disclosure is not required.

   e. Photocopies of permits, licenses or other papers of approval from the local health department, environmental agency, or other governmental agency with jurisdiction.

   f. List of dedicated transporter vehicles.

   g. Application fee of $2,000

D. You can get a license, or renew a license, from the Department if:

   a. You comply with the requirements needed for the license

   b. The Department has already inspected the transporter vehicle\s

   c. The necessary fees are being

E. The transporter license is valid for 5 years.

F. If there is anything that needs to be amended regarding the license, it must be submitted to the Department within 30 days. Additional vehicles may only be added if in

compliance with requirements. Amendments will be only processed after payment of fees (a maximum of $5,000) including an application fee of $100.

G. Any disagreements with the bill must be written in a request sent to the Director for review, and the paying party may refuse to pay the bill in protest. The request must contain all matters in dispute, and must be received by the Department within 10 working days of the date of receipt of the final bill.

H. The review takes place within 30 days of request, and the Director will decide on whether the time and costs billed are correct and reasonable. This decision is emailed to the applicant in 10 working days.

I. Transporting vehicles must have a transporting management plan consisting of procedures to minimize exposure to waste during collection, transportation and handling, and emergency procedures in case of accidents or spills.

J. The transporter must leave a tracking document for the generator during acceptance of the waste. Upon delivery of the waste to the disposal/storage/treatment facility, the tracking document must be signed by persons representing the facility to signify acceptance of the medical waste.

K. The transporter must ensure that the cargo compartment for medical waste must be secured at all times. The cargo compartment can be constructed in one of the following:

    a. A fully enclosed compartment, with leak-proof floor, sides and roof made from non-porous materials. Must be completely separate from driver's compartment.

    b. A cargo box for hauling, with a waste compartment made from non-porous materials.

    c. Tow trailer, with waste compartment made from non-porous materials.

L. Persons using a vehicle not dedicated to medical waste transportation used longer than 30 consecutive days must obtain a license from the Department as well as follow regulations for dedicated vehicles, and clean the vehicle according to regulations before it is used for other purposes.

M. Transporters who accept medical waste must COMPLY WITH ALL of the following:

    a. Only accept properly packaged medical waste.

    b. Accept medical waste with tracking document.

    c. Deliver the waste within 24 hours, or if not possible, refrigerate it at 40 °F no longer than 90 days.

    d. The vehicle must not hold the medical waste longer than 96 hours refrigerated, unless parked at a Department-approved facility.

e. Persons must not reload, transfer or unload medical waste in any location other than in a Department-approved facility, except in emergency. Trailers can be coupled or uncoupled as long as the medical waste is not removed from the cargo compartment.

Storage, Transfer, Treatment, and Disposal Facilities; Facility Plan Approval (R18-13-1410)

A. Off-site facilities used to store, transfer, treat or dispose of medical waste must first obtain solid waste facility plan approval from the Department before they are constructed.

B. If an air quality permit is required for the facility, evidence of the air quality must be included in facility plan approval.

C. The facility approval plan must also include plans on how to comply with the State's Medical Waste Disposal Requirements.

Storage and Transfer Facilities; Design and Operation (R18-13-1411)

A. The facility must be designed so the biohazardous medical waste is handled and stored separately from other types of waste, if the facility has both types of waste.

B. The facility must display the universal biohazard symbol prominently as required in R18-13-1401.

C. The storage area for medical waste must be smooth, easily cleanable, impervious to liquids and resistant to corrosion.

D. The storage area for medical waste must be protected from water, rain, wind, and animals.

E. The application for facility plan approval must specify the maximum storage time that the medical waste will remain at the facility. If medical waste will be stored for 24 hours or more, the facility must be equipped with a refrigerator with a temperature at 40 °F or less.

F. The facility must only accept medical waste with accompanied tracking form. This tracking form must be signed by the facility operator and a copy must be kept for one year.

G. The facility must only accept medical waste packaged properly according to regulations in R18-13-1407. If the medical waste container is damaged or leaking, improperly labeled, or otherwise unacceptable, the facility must:

    a. Reject the waste and return it to the transporter.

    b. Accept the waste and immediately repackage it according to regulations.

H. The storage area of the facility must be cleaned daily and properly as prescribed in R18-13-1407(A) (2).

Treatment Facilities; Design and Operation (R18-13-1412)

These regulations apply to treatment facilities for medical waste.

A. Operators applying for approval of the facility plan must:

a. Submit to the Department documents for the following:

i. Equipment specifications that identify the type of medical waste to be treated in the equipment, and design and equipment restrictions.

ii. Manufacturer's specifications and operating procedures of the equipment, including type and volume of waste, monitoring, calibration and testing, and specifics on the capability of equipment to comply with regulations in R18-13-1415.

iii. Instructions for monitoring, calibration and testing.

iv. A written certification from the equipment manufacturer stating capability to comply with regulations in R18-13-1415.

b. Submit to the Department the operating procedures of the equipment including:

i. Operating procedures for treating medical waste within 24 hours of receipt, or the option for refrigeration for waste that will not be treated or disposed of within 24 hours.

ii. Contingency plans if ever the equipment will be out of service for an extended period of time.

iii. Procedures for handling chemicals, radioactive waste and chemotherapy waste. The plan must also provide for the use of a Geiger counter for detection of radioactive waste products.

c. Have handwritten procedures for acceptance of medical waste with an accompanying tracking document. When the accepted medical waste is damaged or leaking, there must be procedures for: rejecting and returning the waste; accepting and transferring waste to a treatment processing unit; and repacking the waste for storage.

B. The facility floors that come in contact with the medical waste must be smooth, easily cleanable and impervious to liquids. The floors of the storage and treatment area must have curbs of sufficient height to contain spills and slopes to a drain connected to an approved sewage system, septic tank or collection device.

C. Store medical waste as required in R18-13-1408.

D. For medical waste treated by incineration, the waste must be reduced to an ash; then it must be determined whether the ash is still biohazardous.

E. For medical waste treated by autoclave, the machine must be used only according to the manufacturer's specifications.

F. Medical waste to be treated with alternative treatment methods must be treated according to regulations in R18-13-1415(A).

G. Animal waste, chemotherapy waste, cultures and stocks must be treated according to regulations in R18-13-1420, and medical sharps according to regulations in R18-13-1419.

H. The facility must keep records of equipment maintenance and operational performance for 3 years. The records must also include equipment calibration and maintenance. Operational performance records must indicate the following:

    a. Duration of the treatment cycle.

    b. Temperature and pressure maintained during the treatment cycle for steam and microwave treatment.

    c. Solution used for chemical treatment.

    d. Temperature in the treatment unit for incineration.

    e. Any other operating parameters in the manufacturer's specifications.

    f. A description of the treatment used and a copy of maintenance test results.

I. Red bags must be never opened for any reason other than for treatment of contents, and when transferring contents as part of treatment.

J. All treatment records must be available for the Department upon request.

Changes to Approved Medical Waste Facility Plans (R18-13-1413)

These guidelines must be followed when implementing changes to medical waste facility plans that have already been approved by the Department.

A. Treatment facility owners or operators must submit a notice to the Department requesting changes to an approved facility plan. The changes are categorized as follows:

    a. Changes not described in subsections (b), (c) or (d) are termed as Type I.

    b. Changes in which the treatment equipment is replaced with equal or like equipment, which will neither increase nor add equipment not directly used in treatment process, are termed as Type II.

c. Changes which will result in less than a 25% increased treatment capacity, or less than 25% increased storage capacity, or changes in treatment technology, are termed as Type III.

d. Type IV changes are as follows:

i. Additional treatment equipment resulting in more than 25% increase in treatment capacity.

ii. Changes that result in more than 25% increase in storage capacity.

iii. Additional equipment that requires an environmental permit.

iv. Expansion of the treatment facility not described in the approved plan.

B. As required by A.R.S. § 49-762.06, facility operators identifying changes as described in subsection (A) must do the following:

a. Type I change can be implemented without notice or without securing approval from the Department.

b. Type II changes, before implementation, must first give written notification describing the change to the Department.

Note: The addition of refrigeration equipment in compliance to this article is considered a Type II change that does not require approval from the Department.

c. Type III and Type IV changes require approval from the Department. Operators must first submit an amended plan to the Department for approval.

Alternative Medical Waste Treatment Methods: Registration and Equipment Specifications (R18-13-1414)

Here are requirements for operators and persons who want to operate alternative medical waste treatment facilities.

A. Agents or manufacturers applying for alternative medical waste treatment methods must submit to the Department the following:

a. Contact name, address and company name of the manufacturer.

b. Contact name, address and telephone number of the person submitting the application.

c. Description of the alternative medical waste treatment method.

d. List of any other states in which the alternative medical waste treatment method is used, and copies of state approvals.

e. Description of byproducts produced by the alternative medical waste treatment method.

f. Certification statement from the applicant, i.e. *contents of this application are true and correct to my knowledge and belief*.

g. Written documentation demonstrating that the alternative medical waste treatment method can comply with rules and regulations for the type of waste treated. For this analysis, the manufacturer must also employ services of an independent laboratory as an oversight.

h. Equipment specifications of the alternative medical waste treatment method:

i. Unit model or serial number.

ii. Specifications about the type of medical waste to be treated by the equipment, and design and equipment restrictions.

iii. Operating procedures.

iv. Instructions for equipment maintenance, testing and calibration.

i. Registration documents as required by A.R.S. § 3-351.

B. The Department will decide whether to approve or reject the registration application. If approved, the Department will issue a certification of registration containing the alternative medical waste treatment method registration number to the applicant.

Treatment Standards, Quantification of Microbial Inactivation and Efficacy Testing Protocols (R18-13-1415)

These guidelines detail the standards for microbial inactivation used to determine efficiencies of medical waste treatment equipment. The efficiency of medical waste treatment technology is commonly based on the numbers of microbial microorganisms inactivated after treatment. The results detailed in the following must be used as standards for determining efficacies of medical waste treatment equipment.

A. Treaters using alternative medical waste technology will ensure treatment based on the following standards:

a. A 6 $\log_{10}$ inactivation in the concentration of vegetative microorganisms.

b. A 4 $\log_{10}$ inactivation in the concentration of Bacillus stearothermophilus or Bacillus subtilis.

B. Treaters using alternative medical waste technology must conduct efficiency studies and must achieve standards in the subsection (A) through one of the following:

a. Mycobacterial species Mycobacterium phlei or Mycobacterium bovis (BOG) (ATCC 35743).

b. Spore suspensions of Bacillus stearothermophilus (ATCC 7953) or Bacillus subtilis (ATCC 19659). The equipment must demonstrate 4 log $_{10}$ reduction of viable spores, from the initial suspension of 5 log $_{10}$ or greater.

C. Treaters using an alternative medical waste treatment method must quantify microbial inactivation as follows:

a. Microbial inactivation, or "kill" efficacy is equated to "Log 10 Kill" that is defined as the difference between the logarithms of the number of viable test microorganisms before and after treatment. This definition is stated as:

Log 10 Kill = Log 10 (cfu/g "I") - Log 10 (cfu/g "R")

where:

Log 10 Kill is equivalent to the term Log 10 reduction,

"I" is the number of viable test microorganisms introduced into the treatment unit,

"R" is the number of viable test microorganisms recovered from the treatment unit, and

"cfu/g" are colony forming units per gram of waste solids.

b. For those treatment processes that can maintain the integrity of the biological indicator carrier of the desired microbiological test strain, biological indicators of the required strain and concentration may be used to demonstrate microbial inactivation. Quantification is evaluated by growth or no growth of the cultured biological indicator.

c. For those treatment mechanisms that cannot ensure or provide integrity of the biological indicator, quantitative measurement of microbial inactivation requires a two-step approach: Step 1 "Control" and Step 2 "Test." The purpose of Step 1 is to account for the reduction of test microorganisms due to loss by dilution or physical entrapment.

i. Step 1:

i. Use microbial cultures of a predetermined concentration necessary to ensure a sufficient microbial recovery at the end of this step.

ii. Add suspension to a standardized medical waste load that is to be processed under normal operating conditions without the addition of the treatment agent (that is, heat, chemicals).

iii. Collect and wash waste samples after processing to recover the biological indicator organisms in the sample.

iv. Plate the recovered microorganism suspensions to quantify microbial recovery. The number of viable microorganisms recovered serves as a baseline quantity for comparison to the number of recovered microorganisms from wastes processed with the treatment agent.

v. The required number of recovered viable indicator microorganisms from Step 1 must be equal to or greater than the number of microorganisms required to demonstrate the prescribed Log reduction, either a 6 Log 10 reduction for vegetative microorganisms or a 4 Log 10 reduction for bacterial spores. This can be defined by the following equation:

Log 10 RC = Log 10 IC - Log 10 NR

or

Log 10 NR = Log 10 IC - Log 10 RC

where:

Log 10 RC is greater than 6 for vegetative microorganisms and greater than 4 for bacterial spores, and where:

Log 10 RC is the number of viable "control" microorganisms in colony forming units per gram of waste solids recovered in the non-treated, processed waste residue;

Log 10 IC is the number of viable "control" microorganisms in colony forming units per gram of waste solids introduced into the treatment unit;

Log 10 NR is the number of "control" microorganisms in colony forming units per gram of waste solids which were not recovered in the non-treated, processed waste residue. Log 10 NR represents an accountability factor for microbial loss.

ii. Step 2:

i. Use microbial cultures of the same concentration as in Step 1.

ii. Add suspension to the standardized medical waste load that is to be processed under normal operating conditions with the addition of the treatment agent.

iii. Collect and wash waste samples after processing to recover the biological indicator organisms in the sample.

iv. Plate recovered microorganism suspensions to quantify microbial recovery.

v. From data collected from Step 1 and Step 2, the level of microbial inactivation, “Log 10 Kill”, is calculated by employing the following equation:

Log 10 Kill = Log 10 IT - Log 10 NR - Log 10 RT

where:

Log 10 Kill is equivalent to the term Log 10 reduction;

Log 10 IT is the number of viable “Test” microorganisms in colony forming units per gram of waste solids introduced into the treatment unit. Log 10 IT = Log 10 IC;

Log 10 NR is the number of “Control” microorganisms in colony forming units per gram of waste solids which were not recovered in the non-treated, processed waste residue;

Log 10 RT is the number of viable “Test” microorganisms in colony forming units per gram of waste solids recovered in treated, processed waste residue.

d. A treater shall employ the appropriate methodology to determine efficacy of the treatment technology following the protocols in subsection (C) that are congruent with the treatment method.

Recycled Materials (R18-13-1416)

These guidelines must be followed whenever Treaters intend to recycle medical waste.

A. Medical waste from sealed red bags must not be removed from the bags until it is treated according to regulations in R18-13-1415.

B. Generators intending to recycle a portion of medical waste must first segregate that portion from the portion that will not be recycled. Generators must do one of the following:

a. Treat the portion of medical waste intended for recycling according to regulations in R18-13-1415 before sending the treated waste to a recycler.

b. Before sending the waste through a transporter or self-hauling it to the treatment facility, first follow regulations in R18-13-1406, R18-13-1407, and R18-13-1408. After the waste has been treated, it can be sent to the recycler.

Disposal Facilities: Operation (R18-13-1417)

These guidelines must be followed by disposal facilities that accept untreated medical waste.

A. Only accept properly packaged medical waste (see R18-13-1407).

B. The disposal area for medical waste must be separated from the general purpose disposal area.

C. The disposal area must be clearly labeled, and persons in the area must be informed that it contains untreated medical waste.

D. The area with medical waste deposited must not be directly driven over. A sufficiently thick layer of soil must be first applied to the area before the compacting equipment can drive over. This is to ensure that the waste does not come in contact with the compaction equipment.

E. At the end of the day, the area with compacted medical waste must be covered with at least 6 inches of compacted soil to prevent vector breeding and odors.

F. Salvaging is not allowed in a landfill with untreated medical waste.

Discarded Drugs (R18-13-1418)

These guidelines must be followed for disposing discarded drugs.

A. Generators must return discarded drugs to the manufacturer. If not possible, generators must destroy drugs on-site with methods that prevent drug use before placing the waste for collection. The destruction method for drugs must comply with applicable federal or state laws.

B. If allowed by the wastewater treatment authority, generators can dispose of discarded drugs by flushing them down a sanitary sewer.

Medical Sharps (R18-13-1419)

These guidelines must be followed for the handling and disposing of medical sharps.

A. Generators treating biohazardous medical waste on-site must place medical sharps in a rigid, sealed and clearly marked container that prevents stick hazard. Medical sharps processed in this manner are considered solid waste.

B. Generators shipping medical waste on-site must do one of the following:

    a. Place medical sharps in a rigid, sealed and clearly marked container and follow regulations in R18-13-1406, or

    b. Package and send medical sharps to a treatment facility via mail-back system. Treatment facilities in Arizona must process sharps by placing them in a rigid, sealed and clearly marked container.

C. Treatment facilities accepting medical sharps must encapsulate or process the sharps in a way that prevents stick hazard.

Additional Requirements for Certain Wastes (R18-13-1420)

Here are guidelines for handling certain types of medical wastes, like cultures and stocks, waste with chemotherapy agents, and waste generated from experimental and research animals.

Cultures and stocks

A. Cultures and stocks must be incinerated, autoclaved or treated with alternative medical waste treatment methods [as per R18-13-1415(A)]. Cultures and stocks must be placed in a primary container with absorbent lining if shipped off-site for disposal or treatment. This primary container must be placed inside a secondary inner container, which must be then placed inside an outer container.

B. If federal and state laws prescribe specific requirements for packaging and transporting cultures and stock waste, the treater must comply with those laws.

Waste with chemotherapy

A. Medical waste with chemotherapy agents must be incinerated or disposed of in either an approved solid waste or hazardous waste disposal facility.

Experimental or animal research waste

A. Waste from experimental sources or from animal research can be autoclaved or packaged (as per R18-13-1407) for off-site treatment or for landfilling.

B. Animal carcasses must be incinerated on-site for treatment in compliance with one of the following:

    a. Package the waste in a covered, labeled and leak-proof container, which must be sent to an incinerator or a Department-approved landfill.

    b. If not treated by incineration, the waste must be preprocessed by grinding and treated in compliance with the standards in R18-13-1415(A).

C. If waste is processed by grinding and other treatment methods, grinding must be done in a closed system that prevents release of waste into the environment. Medical sharps processed by grinding must be done in a manner that renders the waste incapable of creating a stick hazard.