TITLE 18. ENVIRONMENTAL QUALITY

CHAPTER 13. DEPARTMENT OF ENVIRONMENTAL QUALITY - SOLID WASTE MANAGEMENT

ARTICLE 14. BIOHAZARDOUS MEDICAL WASTE AND DISCARDED DRUGS

Section

ARTICLE 14. BIOHAZARDOUS MEDICAL WASTE AND DISCARDED DRUGS

R18-13-1401. Definitions

In addition to the definitions in A.R.S. § 49-701, the following definitions apply in this Article:

~~1. "Administrative consent order" means a bilateral agreement between the consenting party and the Department. A bilateral agreement is not subject to administrative appeal.~~

~~2.~~ "Alternative treatment technology" means a treatment method other than autoclaving or incineration, that achieves the treatment standards described in R18-13-1415.

~~3.~~ "Approved medical waste facility plan" means the document that has been approved by the Department under A.R.S. § 49-762.04, and that authorizes the operator to accept biohazardous medical waste at its solid waste facility.

~~4.~~ "Autoclaving," means using a combination of heat, steam, pressure, and time to achieve sterile conditions.

~~5.~~ "Biohazardous medical waste" includes the following wastes, which may contain human pathogens of sufficient virulence and in sufficient concentrations that exposure to them by a susceptible host could result in disease. Biohazardous medical waste is composed of one or more of the following:

a. 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.
b. Human blood and blood products: Discarded products and materials ~~containing free-flowing blood or free-flowing blood components.~~ saturated or dripping or both with human blood and items that were saturated or dripping or both with human blood that are now caked with dried human blood, including items that would release blood in a liquid or semi-liquid if compressed, including serum, plasma, and other blood components. An item would be considered caked if it could release flakes or particles when handled.
c. Human pathological wastes: Discarded organs, tissues, and body parts, including cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid and amniotic fluid, removed during surgery or other medical procedures, including autopsy, obstetrics, or emergency care. Human pathological wastes include wastes produced in the course of physically altering a human being including tattooing, ear piercing, or any other process where a foreign object is used to cut or pierce the skin; all sharps generated in this manner must be handled according to R18-13-1419. Crime scene/accident/trauma clean-up wastes generated by individuals or commercial entities hired to clean crime scenes or accidents that are saturated with human blood, sharps, or sharp objects contaminated with human blood are classified as human pathological wastes. Human pathological wastes do not include the head, ~~or~~ spinal column, hair, nails, or teeth.
d. 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.
e. Research animal wastes: Animal carcasses, body parts, and bedding of animals that have been infected with agents that produce, or may produce, human infection.

~~6.~~ "Biologicals" means preparations made from living organisms or their products, including vaccines, cultures, or other biological products intended for use in diagnosing, immunizing, or treating humans or animals or in research pertaining to these activities.

~~7.~~ "Biological indicator" means a representative microorganism used to evaluate treatment efficacy.

~~8.~~ "Blood and blood products" means discarded human blood and any product derived from human blood, including but not limited to blood plasma, platelets, red or white blood corpuscles, and other derived products.

~~9.~~ "CFR" means the Code of Federal Regulations.

~~10.~~ "Chemotherapy waste" means any discarded material that has come in contact with an agent that kills or prevents the reproduction of malignant cells.
a. Trace contaminated chemotherapy waste includes: masks, empty drug vials, gloves, gowns, IV tubing, empty IV bags/bottles, and spill clean-up materials.
b. Bulk chemotherapy waste, such as full expired vials of chemotherapy drugs, are not biohazardous medical waste; they are considered hazardous wastes and must be handled accordingly.

~~11~~. "Dedicated vehicle" means a motor vehicle or trailer that is pulled by a motor vehicle used by a transporter for the ~~sole~~ purpose of transporting biohazardous medical waste in conjunction with other compatible waste according to the USDOT requirements, listed at 49 CFR 176.83(b).

"Department-approved facility" means a storage, transfer, treatment, or disposal facility that has undergone plan approval as described in R18-13-1410.

~~12.~~ "Discarded drug" means any prescription medicine, over-the-counter medicine, or controlled substance, used in the diagnosis, treatment, or immunization of a human being or animal, that the generator intends to abandon. The term does not include hazardous waste or controlled substances regulated by the United States Drug Enforcement Agency.

~~13.~~ "Disposal facility" means a municipal solid waste landfill that has been approved by the Department under A.R.S. § 49-762.04 to accept untreated biohazardous medical waste for disposal.

"Emergency situations" include those situations where following location restrictions may result in an imminent threat to human health and the environment.

~~14.~~ "Facility plan" has the meaning given to it in A.R.S. § 49-701.

~~15. "Free flowing" means liquid that separates readily from any portion of a biohazardous medical waste under ambient temperature and pressure.~~

~~16.~~ "Generator" means a person whose act or process produces biohazardous medical waste, or a discarded drug, or whose act first causes medical waste or a discarded drug to become subject to regulation.

~~17.~~ "Hazardous waste" has the meaning prescribed in A.R.S. § 49-921.

~~18.~~ "Health care worker" means, with respect to R18-13-1403(B)(5), a person who provides health care services at an off-site location that is none of the following: a residence, a facility where health care is normally provided, or a facility licensed by the Arizona Department of Health Services.

~~19.~~ "Improper disposal of biohazardous medical waste" means the disposal by a person of untreated or inadequately treated biohazardous medical waste at any place that is not approved to accept untreated biohazardous medical waste.

~~20.~~ "Independent testing laboratory" means a testing laboratory independent of oversight activities by a provider of alternative treatment technology.

~~21.~~ "Medical sharps container" means a vessel that is rigid, puncture resistant, leak proof, and equipped with a locking cap.

~~22.~~ "Medical waste," as defined in A.R.S. § 49-701, means "*any solid waste which is 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, and includes discarded drugs but does not include hazardous waste as defined in A.R.S. § 49-921 other than conditionally exempt small quantity generator waste.*"

~~23.~~ "Medical waste treatment facility" or "treatment facility" means a solid waste facility approved by the Department under A.R.S. § 49-762.04 to accept and treat biohazardous medical waste from off-site generators.

~~24.~~ "Multi-purpose vehicle" means any motor vehicle operated by a health care worker in the course of providing health care services, where the general purpose is the non-commercial transporting of people and the hauling of goods and supplies, but not solid waste. A multi-purpose vehicle is limited to hauling biohazardous medical waste generated off site by health workers in the course of providing health care services. "Off site" for purposes of this definition means a location other than a hospital or clinic.

~~25.~~ "Off site" means a location that does not fall within the definition of "on site" contained in A.R.S. § 49-701.

~~26.~~ "Packaging" or "properly packaged" means the use of a container or a practice under R18-13-1407.

~~27.~~ "Putrescible waste" means waste materials capable of being decomposed rapidly by microorganisms.

~~28.~~ "Radioactive material" has the meaning under A.R.S. § 30-651.

~~29.~~ "Secure" means to lock out or otherwise restrict access to unauthorized personnel.
~~30.~~ "Spill" means either of the following:
a. Any release of biohazardous medical waste from its package while in the generator's storage area.
b. Any release of biohazardous medical waste from its package or the release of packaged biohazardous medical waste by the transporter at a place or site that is not a medical waste treatment or disposal facility.
~~31.~~ "Store" or "storage" means, in addition to the meaning under A.R.S. § 49-701, either of the following:
a. The temporary holding of properly packaged biohazardous medical waste by a generator in a designated accumulation area awaiting collection by a transporter.
b. The temporary holding of properly packaged biohazardous medical waste by a transporter or a treater at an approved medical waste storage facility or treatment facility.
~~32.~~ "Technology provider" means a person that manufactures, or a vendor who supplies alternative medical waste treatment technology.
~~33.~~ "Tracking document" means the written instrument that signifies acceptance of biohazardous medical waste by a transporter, or a transfer, storage, treatment, or disposal facility operator.
~~34.~~ "Transportation management plan" means the transporter's written plan consisting of both of the following:
a. The procedures used by the transporter to minimize the exposure to employees and the general public to biohazardous medical waste throughout the process of collecting, transporting, and handling.
b. The emergency procedures used by the transporter for handling spills or accidents.
~~35.~~ "Transporter" means a person engaged in the business of hauling ~~of~~ biohazardous medical waste from the point of generation to a Department-approved storage facility or to a Department-approved treatment or disposal facility.
~~36.~~ "Treat" or "treatment" means, with respect to the methods used to render biohazardous medical waste less infectious: incinerating, autoclaving, or using the alternative treatment technologies prescribed in this Article.
~~37.~~ "Treated medical waste" means biohazardous medical waste that has been treated and that meets the treatment standards of R18-13-1415. Treated medical waste that requires no further processing is considered solid waste.
~~38.~~ "Treater" means a person, also known as an operator, who receives solid waste facility plan approval for the purpose of operating a medical waste treatment facility to treat biohazardous medical waste that is generated off site.
~~39.~~ "Treatment certification statement" means the written document provided by either a generator who treats biohazardous medical waste on site or by a treater, to inform a solid waste disposal or recycling facility that biohazardous medical waste has been treated as prescribed in this Article, and therefore is no longer subject to regulation under this Article.
~~40.~~ "Treatment standards" mean the levels of microbial inactivation, prescribed in R18-13-1415, to be achieved for a specific type of biohazardous medical waste.
~~41.~~ "USDOT" means the United States Department of Transportation.
"Universal biohazard symbol" or "biohazard symbol" means a representation that conforms to the design shown in 29 CFR 1910.145(f)(8)(ii) (Office of the Federal Register, National Archives and Records Administration, July 1, 1998) and which is incorporated by reference in this rule. This incorporation does not include any later amendments or editions. Copies of the incorporated

material are available for inspection at the Department of Environmental Quality and the Office of the Secretary of State.

~~42.~~ "Vehicle not dedicated to the transportation of biohazardous medical waste but which is engaged in commerce" means a motor vehicle or a trailer pulled by a motor vehicle whose primary purpose is the transporting of goods that are not solid waste or biohazardous medical waste and that is used by a transporter for the temporary transportation of biohazardous medical waste.

R18-13-1402. Applicability

A. This Article applies to the following:

1. A generator who treats biohazardous medical waste on site, before disposing of it as treated medical waste, and to any equipment used for that purpose. Specific requirements for a generator who treats on site are prescribed in R18-13-1405.
2. A generator who contracts with a medical waste treatment facility for the purpose of treating biohazardous medical waste. Specific requirements for such a generator are prescribed in R18-13-1406.
3. A person who transports biohazardous medical waste and any motor vehicle used for that purpose.
4. A medical waste treatment facility operator, a medical waste treatment facility, and any equipment used for medical waste treatment.
5. A person who provides alternative medical waste treatment technology for the purpose of treatment, and to any technology used for treatment.
6. A person in possession of biohazardous medical waste if the waste does not meet the treatment standards in R18-13-1415.
7. An operator of a Department-approved disposal facility who accepts untreated biohazardous medical waste.
8. A person who generates medical sharps in the preparation of human remains.
9. A person who generates medical sharps in the treatment of humans or animals.
10. A generator of discarded drugs not returned to the manufacturer.

B. The requirements for biohazardous medical waste set out for collection do not apply to the manner in which the generator collects, or handles biohazardous medical waste inside the generator's place of business.

C. Provisions in this Article requiring placement in Department-approved facilities do not restrict the right to place materials in facilities that are out of state or in Indian Country.

R18-13-1403. Exemptions; Partial Exemptions

A. The following persons are exempt from the requirements of this Article:

1. Law enforcement personnel handling biohazardous medical waste for law enforcement purposes.
2. A person in possession of medical waste that is regulated by a state or federal agency due to its radioactive nature ~~materials~~.

~~3~~3. A person who returns unused medical sharps to the manufacturer.

4. A household generator residing in a private, public, or semi-public residence who generates biohazardous medical waste in the administration of self care or the agent of the household generator who administers the medical care. This exemption does not apply to the facility in which the person resides if that facility is licensed by the Arizona Department of Health Services.
5. A generator that separates medical devices from the medical waste stream that are sent out for re-processing and returned to the generator.
6. A person in possession of human bodies regulated by A.R.S. Title 36.
7. ~~A person who sends used medical sharps via the United States Postal Service or private shipping agent to a treatment facility.~~

B. The following are conditionally exempt from the requirements of this Article:

1. A person who prepares human corpses, remains, and anatomical parts that are intended for interment or cremation. However, ~~if~~ medical sharps ~~are generated during the preparation of the human remains, they~~ must be disposed of as prescribed by this Article.
2. A person who operates an emergency rescue vehicle, an ambulance, or a blood service collection vehicle in the course of providing medical services 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.
3. A person who discharges ~~discarded drugs and~~ liquid and semi-liquid biohazardous medical wastes, excluding cultures and stocks, to the sanitary sewer system if the operator of the wastewater sewer system and treatment facility allows, permits, authorizes, or otherwise approves of the discharges.
4. ~~A person who possesses h~~Hazardous waste regulated by A.R.S. Title 49, Chapter 5.
5. A health care worker who uses a multi-purpose vehicle in the conduct of routine health care business other than transporting waste, is exempt from the requirements of R18-13-1409 if the health care worker complies with all of the following:
   a. Packages the biohazardous medical waste according to R18-13-1407.
   b. Secures the packaged biohazardous medical waste within the vehicle so as to minimize spills.
   c. Transports the biohazardous medical waste to the place of business or to a medical waste treatment or disposal facility.
   d. Cleans the vehicle when it shows visible signs of contamination.
   e. Secures the vehicle to prevent unauthorized contact with the biohazardous medical waste.
6. A person who transports biohazardous medical waste between multiple properties separated by a public thoroughfare and which is owned or operated by the same owner or governmental entity is exempt from the requirements of R18-13-1409 if the person complies with R18-13-1403(B)(5)(a) through (e).
7. A hospital that chooses to accept medical sharps from staff physicians who generate medical sharps in a private practice is exempt from the requirement to obtain facility plan approval as long as the hospital collects medical sharps for off-site treatment or disposal.

C. The following are exempt from some of the requirements of this Article:

1. A generator who treats biohazardous medical waste on site and who accepts for treatment medical waste described in R18-13-1403(A)(4) is exempt from the requirement to obtain solid waste facility plan approval prescribed in R18-13-1410.
2. A generator who self hauls biohazardous medical waste to a Department-approved medical waste treatment, storage, transfer, or disposal facility is exempt from the requirements of R18 13 1409 if the generator complies with R18 13 1403(B)(5)(a) through (e).

R18-13-1404. ~~Transition and Compliance Dates~~ REPEAL

~~**A.** Unless otherwise specified in subsections (B) through (H), the date for compliance with this Article by generators, transporters, treaters, providers of alternative medical waste technology, and persons in possession of untreated biohazardous medical waste is the effective date of this Article.~~

~~**B.** A person who provides alternative medical waste treatment technology used by a generator before the effective date of this Article shall perform all of the following:~~

~~1. Register the alternative medical waste technology with the Department as prescribed in R18-13-1414 within 90 days after the effective date of this Article.~~
~~2. Not provide alternative technology 90 days after the effective date of this Article unless a Departmental registration certificate is received.~~

3. After receipt of the Departmental registration certificate, provide to all generators using the alternative treatment technology a copy of the registration certificate and the alternative technology manufacturer's specifications.

C. A generator who utilizes alternative medical waste treatment technology before the effective date of this Article shall obtain, within 180 days after the effective date of this Article, the Departmental registration number and equipment specifications, described in R18-13-1414, from the technology provider. If documentation of Departmental registration is not on file with the generator, the Department shall classify biohazardous medical waste treated 180 days after the effective date of this Article using the unregistered alternative treatment technology as untreated biohazardous medical waste.

D. A generator who utilizes incineration or autoclaving for onsite treatment of biohazardous medical waste before the effective date of this Article may continue to do so after the effective date if the treatment requirements of R18-13-1415 and the onsite treatment requirements of R18-13-1405 are met.

E. A transporter of biohazardous medical waste in business on the effective date of this Article shall register, within 90 days after the effective date of this Article, as required in R18-13-1409(A).

F. An operator of a medical waste storage facility, who has obtained approval for a solid waste facility under A.R.S. § 49-762.04 on or before the effective date of this Article, may continue to shall store biohazardous medical waste if the facility complies in compliance with the design and operation standards prescribed in R18-13-1411. The addition of a refrigeration unit is a Type II change as described in R18-13-1413(A)(2).

G. An operator of a medical waste transfer facility shall obtain solid waste facility plan approval that meets the requirements of R18-13-1410 within 180 days after the effective date of this Article.

H. An operator of a medical waste treatment facility who has obtained Departmental plan approval to operate a medical waste treatment facility on or before the effective date of this Article may continue to operate under that plan approval if both of the following are met:

1. Tthe treater complies with the treatment standards of R18-13-1415 and the recordkeeping requirements of R18-13-1412, except as noted in the subsection below.
2. If the treater determines that the waste is not being treated to the applicable treatment standards of R18-13-1415, the treater informs the Department within two working days after the date on the determination, and within 30 working days enters into an administrative consent order to bring the facility into compliance.

I. An operator of an existing municipal solid waste landfill who intends to accept untreated biohazardous medical waste shall submit a notice of a Type III change and an amended facility plan within 180 days after the effective date of this Article.

J. Notwithstanding subsection (H), iIf the Department determines that an updated solid waste facility plan is required, a treater shall submit an updated plan within 180 days after the date on the Department's determination. The treater may continue to operate under the conditions specified in subsection (H) of this Section while the Department reviews and determines whether to approve or deny the updated plan.

K. After the effective date of this Article, solid waste facility plan approval under A.R.S. § 49-762.04 is required for a new medical waste treatment or disposal facility before construction.

R18-13-1405. Biohazardous Medical Waste Treated On Site

A. A person who treats biohazardous medical waste on site shall use incineration, autoclaving, or an alternative medical waste treatment method that meets the treatment standards prescribed in R18-13-1415.

B. A generator who uses:

1. Incineration shall follow the requirements of subsections (C), (F), (G), and (H),
2. Autoclaving shall follow the requirements of subsections (D), (F), (G) and (H), or
3. An alternative treatment method shall follow the requirements of subsections (E), (F), (G), and (H).

C. A generator who incinerates biohazardous medical waste on site shall comply with all of the following requirements:
1. Obtain a permit if required by the local or state air quality agency having jurisdiction.
2. Reduce the biohazardous medical waste, excluding metallic items, into carbonized or mineralized ash.
3. Determine whether incinerator ash is hazardous waste as required by hazardous waste rules promulgated under A.R.S. Title 49, Chapter 5.
4. Dispose of the non-hazardous waste incinerator ash at a Department-approved municipal solid waste landfill.

D. A generator who autoclaves biohazardous medical waste on site shall comply with all of the following requirements:
1. Further process by grinding, shredding, or any other process, any recognizable animals and human tissue, organs, or body parts, to render such waste non-recognizable and ensure effective treatment.
2. Operate the autoclave at the manufacturer's specifications appropriate for the quantity and density of the load.
3. Keep records of operational performance levels for six months after each treatment cycle. Operational performance level recordkeeping includes all of the following:
   a. Duration of time for each treatment cycle.
   b. The temperature and pressure maintained in the treatment unit during each cycle.
   c. The method used to determine treatment parameters in the manufacturer's specifications.
   d. The method in manufacturer's specifications used to confirm microbial inactivation and the test results.
   e. Any other operating parameters in the manufacturer's specifications for each treatment cycle.
4. Keep records of equipment maintenance for the duration of equipment use that include the date and result of all equipment calibration and maintenance.

E. A generator who uses an alternative treatment method on site shall comply with all of the following requirements:
1. Use only alternative treatment methods registered under R18-13-1414.
2. Further process by grinding, shredding, or any other process, any recognizable animals and human tissue, organs, or body parts, to render this waste non-recognizable and ensure effective treatment.
3. Follow the manufacturer's specifications for equipment operation.
4. Supply upon request all of the following:
   a. The Departmental registration number for the alternative medical waste treatment technology and the type of biohazardous medical waste that the equipment is registered to treat.
   b. The equipment specifications that include all of the following:
      i. The operating procedures for the equipment that enable the treater to comply with the treatment standards described in this Article for the type of waste treated.
      ii. The instructions for equipment maintenance, testing, and calibration that enable the treater to comply with the treatment standards described in this Article for the type of waste treated.
5. Maintain a training manual regarding the proper operation of the equipment.
6. Maintain a treatment record consisting of a log of the volume of medical waste treated and a schedule of calibration and maintenance performed under the manufacturer's specifications.

7. Maintain treatment records for six months after the treatment date for each load treated.
8. Maintain the equipment specifications for the duration of equipment use.

F. A generator shall do all of the following:
1. Package the treated medical waste according to the waste collection agency's requirements;
2. Attach to the package or container a label, placard, or tag with the following words: "This medical waste has been treated as required by the Arizona Department of Environmental Quality standards" before placing the treated medical waste out for collection as a general solid waste. The generator shall ensure that the treated medical waste meets the standards of R18-13-1415.
3. Upon request of the solid waste collection agency or municipal solid waste landfill, provide a certification that the treated medical waste meets the standards of R18-13-1415.
4. Make treatment records available for Departmental inspection upon request.

G. A generator of medical sharps shall handle medical sharps as prescribed in R18-13-1419.

H. A generator of chemotherapy waste, cultures and stocks, or animal waste shall handle that waste as prescribed in R18-13-1420.

R18-13-1406. Biohazardous Medical Waste Transported Off Site for Treatment

A. A generator of biohazardous medical waste shall cause the waste to first be packaged ~~the waste~~ as prescribed in R18-13-1407 ~~before~~ and shall subsequently either self-haul~~ing~~ or ~~before~~ store the waste as provided under R18-13-1408 and set~~ting~~ the waste out for collection by a properly licensed transporter under R18-13-1409.

B. A generator shall obtain a copy of the tracking document signed by the transporter signifying acceptance of the biohazardous medical waste. A generator shall keep a copy of the tracking document for ~~one year from the date of acceptance by the transporter~~the period required under the USDOT requirements, as listed in 49 CFR 172.201. The tracking document shall contain all of the following information:
1. Name and address of the generator, transporter, and medical waste treatment, storage, transfer, or disposal facility, as applicable.
2. Quantity of biohazardous medical waste collected by weight, volume, or number of containers.
3. Identification number attached to bags or containers, as specified as by the USDOT requirements, as listed in 49 CFR 172.300 et seq.
4. Date the biohazardous medical waste is collected.

C. A generator of chemotherapy waste, cultures and stocks, or animal waste shall handle the waste as prescribed in R18-13-1420.

D. A generator of medical sharps shall handle the waste as prescribed in R18-13-1419.

R18-13-1407. Packaging

A. A generator who sets biohazardous medical waste that does not include sharps out for collection for off-site treatment or disposal shall package the biohazardous medical waste in either of the following:
1. A red disposable plastic bag that is:
   a. Leak resistant,
   b. Impervious to moisture,
   c. Of sufficient strength to prevent tearing or bursting under normal conditions of use and handling,
   d. Sealed to prevent leakage during transport,
   e. Puncture resistant for sharps, and
   f. Placed in a secondary container. This container shall be constructed of materials that will prevent breakage of the bag in storage and handling during collection and transportation and

bear the universal biohazard symbol. The secondary container may be either disposable or reusable.

2. A reusable container that bears the universal biohazard symbol and that is:
   a. Leak-proof on all sides and bottom, closed with a fitted lid, and constructed of smooth, easily cleanable materials that are impervious to liquids and resistant to corrosion by disinfection agents and hot water, and
   b. Used for the storage or transport of biohazardous medical waste and cleaned after each use unless the inner surfaces of the container have been protected by disposable liners, bags, or other devices removed with the waste. "Cleaning" means agitation to remove visible particles combined with one of the following:
      i. Exposure to hot water at a temperature of at least 180 degrees Fahrenheit for a minimum of 15 seconds.
      ii. Exposure to an EPA-approved chemical disinfectant used under established protocols and regulations.
      iii. Any other method that the Department determines is acceptable, if the determination of acceptability is made in advance of the cleaning.

B. A generator shall handle any container used for the storage or transport of biohazardous medical waste that is not capable of being cleaned as described in subsection (A)(2)(b), or that is disposable packaging, as biohazardous medical waste.

C. A generator shall not use reusable containers described in subsection (A)(2) for any purpose other than the storage of biohazardous medical waste.

D. A generator shall not reuse disposable packaging and liners and shall manage such items as biohazardous medical waste.

R18-13-1408. Storage

A. A generator may place a container of biohazardous medical waste alongside a container of solid waste if the biohazardous medical waste is identified and not allowed to co-mingle with the solid waste. The storage area shall not be used to store substances for human consumption or for medical supplies. Chemotherapy waste, including trace chemotherapy waste such as masks, empty drug vials, gloves, gowns, IV tubing, empty IV bags/bottles, and spill clean-up materials, shall be clearly identified as such by its label and shall be treated according to the standards in R18-13-1420.

B. Once biohazardous medical waste has been packaged for shipment off site, a generator shall provide a storage area for biohazardous medical waste until the waste is collected and shall comply with both of the following requirements:

1. Secure the storage area in a manner that restricts access to, or contact with the biohazardous medical waste to authorized persons.
2. Display the universal biohazard symbol and post warning signs worded as follows for medical waste storage areas: (in English) "CAUTION -- BIOHAZARDOUS MEDICAL WASTE STORAGE AREA -- UNAUTHORIZED PERSONS KEEP OUT" and (in Spanish) "PRECAUCION -- ZONA DE ALMACENAMIENTO DE DESPERDICIOS BIOLOGICOS PELIGROSOS -- PROHIBIDA LA ENTRADA A PERSONAS NO AUTORIZADAS."

C. Beginning at the time the waste is set out for collection, a generator who stores biohazardous medical waste shall comply with all of the following requirements:

1. ~~Keep p~~Putrescible biohazardous medical waste ~~unrefrigerated~~ may be kept unrefrigerated up to 72 hours if it ~~does not~~ would not otherwise create a nuisance. A nuisance is odor detectable beyond the property line or that attracts vermin. ~~However, refrigerate putrescible biohazardous medical waste kept more than seven days.~~

2. Refrigerate at 40° F. or less from hour 72 through day 90 putrescible biohazardous medical waste kept for up to 90 days.
3. Nonputrescible biohazardous medical waste may be kept unrefrigerated for up to 90 days.
~~2~~4. Store biohazardous medical waste for 90 days or less unless the generator has obtained facility plan approval under A.R.S. § 49-762.04 and is in compliance with the design and operational requirements prescribed in R18-13-1412.
~~3~~5. Keep the storage area free of visible contamination.
~~4~~6. Protect biohazardous medical waste from contact with water, precipitation, wind, or animals. A generator shall ensure that the waste does not provide a breeding place or a food source for insects or rodents.
~~5~~7. Handle spills by re-packaging the biohazardous medical waste, re-labeling the containers and cleaning any soiled surface as prescribed in R18-13-1407(A)(2)(b).
~~6~~8. Notwithstanding subsections (C)(1) and (2), ~~if odors become a problem,~~ a generator shall minimize ~~objectionable odors and~~ the off-site migration of odors and the presence of vermin. If the Department determines that a generator has not acted or adequately addressed odors or vermin~~the problem,~~ the Department shall require the waste to be removed or refrigerated at 40° F or less.

R18-13-1409. Transporter License; Fees; Transportation~~; Transporter License; Annual Fee~~

A. A transporter shall obtain a transporter license from the Department as provided under subsections (B)~~,~~ and (C)~~, and (D)~~ below in addition to possessing a permit, license, or approval if required by a local health department, environmental agency, or other governmental agency with jurisdiction.

B. A transporter license is valid for 5 years after issuance. To renew the license, the licensee shall submit an application under subsection (B)(1) no later than 60 days prior to the license's expiration and shall pay the fee provided in subsections (B)(2) and (3).With each application submitted for approval, the applicant shall remit an initial transporter license application fee in accordance with the Fee Table in subsection (B)(2). This subsection also lists the maximum fees that the Department will bill the applicant. All fees paid shall be payable to the state of Arizona. The Department shall deposit the fees paid into the Solid Waste Fee Fund established pursuant to A.R.S. § 49-881, unless otherwise authorized or required by law.

1. To apply for or to renew a transporter license, an applicant shall submit all of the following on a form approved by the Department:
    a. The name, address, and telephone number of the transportation company or entity.
    b. All owners' names, addresses, and telephone numbers.
    c. All names, addresses, and telephone numbers of any agents authorized to act on behalf of the owner.
    d. A copy of either the certificate of disclosure required by A.R.S. § 49-109 or a written acknowledgment that this disclosure is not required.
    e. Photocopies or other evidence of the issuance of a permit, license, or approval if required by a local health department, environmental agency, or other governmental agency with jurisdiction.
    f. A copy of the transportation management plan that meets the requirements in subsection (G).
    g. A list identifying each dedicated vehicle.
    h. The initial transporter application license fee indicated in the Fee Table in (B)(2) for Transporter License Fees.

2. The new or renewal application license fee shall be calculated by multiplying the hourly rate of $122 by the number of personnel hours involved in inspecting each transporting vehicle, evaluating the application, and approving the license, which amount shall be subtracted from the initial

application license fee on deposit. Any remaining surplus of the initial application license fee on deposit shall be returned to the applicant. Any cost that exceeds the initial application license fee on deposit shall be billed to the applicant, but shall not exceed the maximum.

Fee Table

Transporter License Fees

	Initial	Maximum
New Application	$2,000	$20,000
Renewal Application	$2,000	$20,000
Amendment Application	$100	$5,000

Frequency of Application for Transporter License

Year	Type of Application	Frequency
1	New	Once
6, 11, 16, etc.	Renewal	Every 5th Year

3. The Department may only issue a transporter license, including a renewal, if all of the items in subsection (~~C~~B(1)) have been received and determined to be correct and complete, and a Department inspection of each transporting vehicle shows that the vehicle is in compliance with this Article.

B~~B~~**C**.~~Beginning on July 1, 2012, a~~ T~~t~~ransporter~~s~~ shall pay by the invoice due date an annual fee of $750 for ~~every~~ each calendar year following payment of the new or renewal application license fee and subsequent years in which a renewal application license fee is not charged and paid, such as in the Fee Table below.~~according to the following schedule, except that no transporter shall pay more than one annual fee in any calendar year:~~

~~1. Transporters registered with the Department before July 1, 2012, shall pay byDecember 31st of each year until their registration expires and shall apply for a license according to subsections (C) and (D) of this Section no more than 60 days before their registration expires.~~

~~2. Transporters who have been issued a license or renewal of a license under this Section and have paid the licensing year fee as provided in subsection (D) shall pay the annual fee by December 31st of each year thereafter.~~

~~3. A transporter that has not been registered with the Department shall apply and obtain a license according to subsections (C) and (D) of this Section and pay an annual fee by December 31st of each year thereafter.~~

Fee Table

Transporter Annual Fee

Years	Amount

2,3,4,5,7,8,9,10, etc.	$750

~~C.~~To apply for or to renew a transporter license, an applicant shall submit all of the following on a form approved by the Department:

~~1. The name, address, and telephone number of the transportation company or entity.~~

~~2. All owners' names, addresses, and telephone numbers.~~

~~3. All names, addresses, and telephone numbers of any agents authorized to act on behalf of the owner.~~

~~4. A copy of either the certificate of disclosure required by A.R.S. § 49-109 or a written acknowledgment that this disclosure is not required.~~

~~5. Photocopies or other evidence of the issuance of a permit, license, or approval if required by a local health department, environmental agency, or other governmental agency with jurisdiction.~~

~~6. A copy of the transportation management plan that meets the requirements in subsection (I~~J).

~~7. A list identifying each dedicated vehicle.~~

~~8. An application fee of $2,000 which shall apply toward the licensing year fee in subsection (D)(3).~~

~~D.~~ The Department may only issue a transporter license, including a renewal, after all of the following:

~~1. All of the items in subsection (C) have been received and determined to be correct and complete;~~

~~2. A Department inspection of each transporting vehicle shows that the vehicle is in compliance with this Article; and~~

~~3. The applicant has paid a licensing year fee consisting of:~~

~~a. An amount based on the expenses associated with inspecting each transporting vehicle, evaluating the application, and approving the license, minus the application fee. The amount shall be calculated using a rate of $122 per hour, multiplied by the number of personnel hours used in these duties.~~

~~b. The annual fee of $750 for the year as provided for in subsection (B).~~

~~c. The maximum fee for both subsections (D)(3)(a) and (b) shall be $20,000.~~

~~E.~~ A transporter license is valid for five years after issuance. To renew the license, the licensee shall submit an application under subsection (C) no later than 60 days before expiration. Renewals shall be issued after payment of a licensing year fee as provided in subsection (D)(3).

~~F~~**D.** Amendments. After issuance, the licensee shall submit to the Department any change to the information listed in subsection (~~C~~B(1)) within 30 days of its occurrence. Vehicles may only be added to the license after a Department inspection shows that the vehicle is in compliance with this Article. Amendments to the transportation management plan or amendments adding vehicles shall be processed after payment of inspection fees and other expenses at the rate listed in subsection (~~d~~B)(2), except that the application fee shall be $100 and the maximum fee $5,000.

~~G~~**E.** An applicant who disagrees with the final bill received from the Department for the amendment, issuance, renewal or denial of a transporter license or vehicle inspections may make a written request to the Director for a review of the bill and may pay the bill under protest. The request for review shall specify the matters in dispute and shall be received by the Department within 10 working days of the date of receipt of the final bill.

~~H~~**F.** Unless the Department and applicant agree otherwise, the review shall take place within 30 days of receipt by the Department of the request. The Director shall make a final decision as to whether the time and costs billed are correct and reasonable. The final decision shall be mailed to the applicant within 10 working days after the date of the review and is subject to appeal pursuant to A.R.S. ~~§ 49-769~~ §§ 41-1092 through 1092.12.

~~I~~**G.** A person who transports biohazardous medical waste shall maintain in each transporting vehicle at all times a transportation management plan consisting of both of the following:

1. Routine procedures used to minimize the exposure of employees and the general public to biohazardous medical waste throughout the process of collecting, transporting, and handling.
2. Emergency procedures used for handling spills or accidents.

~~J~~**H.** A transporter who accepts biohazardous medical waste from a generator shall transmit electronically or leave a physical copy of the tracking document described in R18-13-1406(B) with the person from whom the waste is accepted. A transporter shall ensure that a copy of the tracking document accompanies the person who has physical possession of the biohazardous medical waste. Upon delivery to a Department-approved transfer, storage, treatment, or disposal facility, the transporter shall obtain a copy of the tracking document, signed by a person representing the receiving facility, signifying acceptance of the biohazardous medical waste.

~~K~~**I.** A transporter who transports biohazardous medical waste in a dedicated vehicle ~~dedicated to the transportation of biohazardous medical waste~~ shall ensure that the cargo box, trailer, or compartment can be secured to limit access to authorized persons at all times except during loading and unloading. In addition, the cargo box, trailer, or compartment shall be constructed in compliance with one of the following:

1. Have a fully enclosed, leak-proof cargo compartment consisting of a floor, sides, and a roof that are made of a non-porous material impervious to biohazardous medical waste and physically separated from the driver's compartment.
2. Haul a fully enclosed, leak-proof cargo box made of a non-porous material impervious to biohazardous medical waste.
3. Tow a fully enclosed leak-proof trailer made of a non-porous material impervious to biohazardous medical waste.

~~L~~**J.** A person who transports biohazardous medical waste in a vehicle not dedicated to the transportation of biohazardous medical waste, but that is used ~~longer than 30 consecutive days,~~ at least once weekly for a month shall comply with the following:

1. Subsections (A) and (~~I~~G) through (~~M~~K).
2. Clean the vehicle as prescribed in R18-13-1407(A)(2)(b) before it is used for another purpose.

~~M~~**K.** A ~~person who transports~~ transporter of biohazardous medical waste shall comply with all of the following:

1. Accept only biohazardous medical waste packaged as prescribed in R18-13-1407.
2. Accept biohazardous medical waste only after providing the generator with a signed tracking ~~form~~ document as prescribed in R18-13-1406(B), and keep a copy of the tracking document for the period required under the USDOT requirements, as listed in 49 CFR 172.201.~~one year.~~
3. Deliver biohazardous medical waste to a Department-approved biohazardous medical waste storage, transfer, treatment, or disposal facility within ~~24 hours of collection or refrigerate the waste for not more than 90 days at 40° F or less until delivery.~~ the following timeframes:
   a. 72 hours of collection, if putrescible and unrefrigerated; or
   b. 90 days of collection, if putrescible and refrigerated at 40° F or less from hour 72 through day 90; or
   c. 90 days of collection, if nonputrescible and unrefrigerated.
4. Not hold biohazardous medical waste longer than specified under subsection (K)(3)~~96 hours in a refrigerated vehicle~~ unless the vehicle is parked at a Department-approved facility.
5. Except in emergency situations, n~~N~~ot unload, reload, or transfer the biohazardous medical waste to another vehicle in any location other than a Department-approved facility ~~except in emergency situations~~. Combination vehicles or trailers may be uncoupled and coupled to another cargo vehicle

or truck trailer as long as the biohazardous medical waste is not removed from the cargo compartment.

~~**N.** As used in this Section, "licensing year" means the calendar year in which the Department issues a license or a renewal of a license under this Section.~~

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

A. A person shall obtain solid waste facility plan approval from the Department as prescribed in A.R.S. § 49-762.04 to construct any facility that will be used to store, transfer, treat, or dispose of biohazardous medical waste that was generated off site. Plan approval shall be obtained before starting construction of the medical waste treatment or disposal facility. This requirement also applies to solid waste facilities for which an operator self-certifies under A.R.S. § 49-762.05, if the facility also will receive biohazardous medical waste.

B. If an air quality permit is required for the facility under A.R.S. Title 49, Chapter 3, the person shall include evidence of that air quality permit, or evidence of an air quality permit application with the application for solid waste facility plan approval.

C. A person applying for facility plan approval shall ensure that the plan contains information demonstrating how the plan will comply with this Article.

R18-13-1411. Storage and Transfer Facilities; Design and Operation

An operator of a storage facility or transfer facility shall comply with all of the following design and operation requirements:

1. Design the facility so that biohazardous medical waste is always handled and stored separately from other types of solid waste if accepted at the facility.
2. Display prominently the universal biohazard symbol as prescribed in R18-13-1401.
3. Construct the storage area from smooth, easily cleanable non-porous material that is impervious to liquids and resistant to corrosion by disinfecting agents and hot water.
4. Protect biohazardous medical waste from contact with water, precipitation, wind, or animals.
5. Specify in the application for facility plan approval the maximum storage time that biohazardous medical waste will remain at the facility. If ~~the~~ putrescible biohazardous medical waste will be stored for more than 72 hours~~24 hours,~~ ~~t~~he operator shall equip the facility with a refrigerator to refrigerate ~~the~~ putresible biohazardous medical waste. The operator of the facility shall maintain the temperature in the refrigerator at 40° F. or less.
6. Accept biohazardous medical waste only if it is accompanied by the tracking ~~form~~document. The operator shall sign the tracking ~~form~~document and keep a copy of the acceptance documentation for one year;
7. Accept biohazardous medical waste if it is packaged as described in R18-13-1407. If a biohazardous medical waste container is damaged or leaking, improperly labeled, or otherwise unacceptable, a transfer facility operator shall do one of the following:
   a. Reject the waste and return it to the transporter or self-hauling generator.
   b. Accept the waste and immediately repackage it as prescribed in R18-13-1407(A).
8. Clean the storage area daily~~as prescribed in R18-13-1407(A)(2).~~ "Clean" means to remove visible particles combined with one of the following:
   a. Exposure to hot water at a temperature of at least 180 degrees Fahrenheit for a minimum of 15 seconds.
   b. Exposure to an EPA-approved chemical disinfectant used under established protocols and regulations.
   c. Any other method that the Department determines is acceptable, if the determination of acceptability is made in advance of the cleaning.

R18-13-1412. Treatment Facilities; Application Requirements; Design and Operation

A. An operator who applies for facility plan approval shall comply with 1 and 2 ~~all of the following~~ as well as all of the requirements in B:

1. Submit to the Department the following documentation:
   a. Equipment specifications that identify the proper type of medical waste to be treated in the equipment and any design or equipment restrictions.
   b. Manufacturer's specifications and operating procedures for the equipment that describe the type and volume of waste to be treated, monitoring data of the treatment process, and calibration and testing of the equipment, providing specific details about the capability of the equipment to achieve the treatment standards prescribed in R18-13-1415.
   c. Instructions for equipment maintenance, testing, and calibration that ensure the equipment achieves the treatment standards prescribed in R18-13-1415.
   d. Training manual for the equipment.
   e. Written certification from the manufacturer stating that the equipment, when operated properly, is capable of achieving the treatment standards prescribed in R18-13-1415.
2. Submit to the Department and have readily available at the facility, an operations procedure manual describing how the waste will be handled from the time it is accepted by the treater through the treatment process and final disposition of the treated waste. The operations procedure manual shall include all of the following:
   a. Provisions for treating biohazardous medical waste within ~~24~~72 hours of receipt or refrigerating ~~immediately~~ at 40° F. or less upon determination that treatment or disposal will not occur within ~~24~~72 hours. Nonputrescible biohazardous medical waste that is not immediately treated may be stored for up to 90 days unrefrigerated.
   b. A contingency plan if the treatment equipment is out of service for an extended period of time. The plan shall address the manner and length of time for storage of the waste. An operator shall not store biohazardous medical waste more than 90 days. The plan shall be based on the capacity of the treatment equipment to treat all waste at the facility, including any backlog of stored waste and any new waste intake. If the 90-day time-frame will be exceeded, the operator shall either stop accepting waste until the backlog is treated, or contract with another treatment facility for treating the waste.
   c. Procedures for handling hazardous chemicals, radioactive waste, and chemotherapy waste. The plan shall provide for scanning biohazardous medical waste with a Geiger counter and handling waste that measures above background level in a manner that complies with state and federal law.
3. ~~Have on hand written procedures stating that biohazardous medical waste is to be accepted from a transporter only if the waste is accompanied by a tracking form, and written procedures that require compliance with both of the following:~~
   a. ~~The treater or the treater's authorized agent shall sign the tracking document and keep a copy of the acceptance documentation for one year.~~
   b. ~~If a biohazardous medical waste container is damaged or leaking, improperly labeled, or otherwise unacceptable, a treater shall do one of the following:~~
      i. ~~Reject the waste and return it to the transporter.~~
      ii. ~~Accept the waste and transfer it directly from the transporting vehicle to the treatment processing unit.~~
      iii. ~~If the waste will not be treated immediately, repackage the waste for storage.~~
4. ~~Assure that the facility is designed to meet both of the following requirements:~~

~~a. Any floor or wall surface in the processing area of the facility which may come into contact with biohazardous medical waste is constructed of a smooth, easily cleanable non-porous material that is impervious to liquids.~~

~~b. The floor surface in the treatment and storage area either has a curb of sufficient height to contain spills or slopes to a drain that connects to an approved sanitary sewage system, septic tank system, or collection device.~~

~~5. Store biohazardous medical waste as required in R18-13-1408.~~

~~6. Comply with all of the following if the treatment method is incineration:~~

~~a. Reduce the incinerated medical waste, excluding metallic items, into carbonized or mineralized ash by incineration.~~

~~b. Determine whether the ash is hazardous waste as required under R18-8-262.~~

~~7. Conduct any autoclaving according to the manufacture's specifications for the unit.~~

~~8. Use only alternative medical waste treatment methods that achieve the treatment standards in R18-13-1415(A).~~

~~9. Treat animal waste, chemotherapy waste, and cultures and stocks as prescribed in R18-13-1420.~~

~~10. Treat medical sharps as prescribed in R18-13-1419.~~

~~11. Keep records of equipment maintenance and operational performance levels for three years. The records shall include the date and result of all equipment calibration and maintenance. Operational performance level records shall indicate the duration of time for each treatment cycle and:~~

~~a. For steam treatment and microwaving treatment records, both the temperature and pressure maintained in the treatment unit during each cycle and the method used for confirmation of temperature and pressure.~~

~~b. For chemical treatment, a description of the solution used.~~

~~c. For incineration, the temperature maintained in the treatment unit during operation.~~

~~d. Any other operating parameters in the manufacturer's specifications.~~

~~e. A description of the treatment method used and a copy of the maintenance test results.~~

~~12. Not open the red bag prior to treatment unless opening the bag is required to treat the contents. Transfer of the entire contents, when performed as part of the treatment process, is permitted.~~

B. An operator of a department approved facility shall comply with the following: ~~The treater shall make treatment records available for Departmental inspection upon request.~~

1. Have on hand written procedures stating that biohazardous medical waste is to be accepted from a transporter only if the waste is accompanied by a tracking document, and written procedures that require compliance with both of the following:
   a. The treater or the treater's authorized agent shall sign the tracking document and keep a copy of the acceptance documentation for one year.
   b. If a biohazardous medical waste container is damaged or leaking, improperly labeled, or otherwise unacceptable, a treater shall do one of the following:
      i. Reject the waste and return it to the transporter or self-hauling generator.
      ii. Accept the waste and transfer it directly from the transporting vehicle to the treatment processing unit.
      iii. If the waste will not be treated immediately, repackage the waste for storage.
2. Assure that the facility is designed to meet both of the following requirements:
   a. Any floor or wall surface in the processing area of the facility which may come into contact with biohazardous medical waste is constructed of a smooth, easily cleanable non-porous material that is impervious to liquids.

b. The floor surface in the treatment and storage area either has a curb of sufficient height to contain spills or slopes to a drain that connects to an approved sanitary sewage system, septic tank system, or collection device.

3. Store biohazardous medical waste as required in R18-13-1408.
4. Comply with all of the following if the treatment method is incineration:
   a. Reduce the incinerated medical waste, excluding metallic items, into carbonized or mineralized ash by incineration.
   b. Determine whether the ash is hazardous waste as required under R18-8-262.
5. Conduct any autoclaving according to the manufacturer's specifications for the unit.
6. Use only alternative medical waste treatment methods that achieve the treatment standards in R18-13-1415(A).
7. Treat animal waste, chemotherapy waste, and cultures and stocks as prescribed in R18-13-1420.
8. Render medical sharps incapable of creating a stick hazard by using an encapsulation agent or any other process that prevents a stick hazard.
9. Keep records of equipment maintenance and operational performance levels for three years. The records shall include the date and result of all equipment calibration and maintenance. Operational performance level records shall indicate the duration of time for each treatment cycle and:
   a. For steam treatment and microwaving treatment records, both the temperature and pressure maintained in the treatment unit during each cycle and the method used for confirmation of temperature and pressure.
   b. For chemical treatment, a description of the solution used.
   c. For incineration, the temperature is maintained in the treatment unit during operation.
   d. Any other operating parameters in the manufacturer's specifications.
   e. A description of the treatment method used and a copy of the maintenance test results.
10. Not open the red bag prior to treatment unless opening the bag is required to treat the contents. Transfer of the entire contents, when performed as part of the treatment process, is permitted.
11. Clean the storage and treatment areas as necessary to protect the public health and employee health and safety.

C. The treater shall make treatment records available for Departmental inspection upon request.

R18-13-1413. Changes to Approved Medical Waste Facility Plans

A. As required by A.R.S. § 49-762.06, before making any change to an approved facility plan, a ~~treatment~~ facility owner or operator shall submit a notice to the Department stating ~~which of~~ the ~~following categories~~ type of change ~~is~~ requested, including but not limited to:

1. A Type I change to an approved medical waste facility plan is a change not described in subsection (A)(2), (3), or (4).
2. A Type II change to an approved medical waste facility plan is a change in which treatment equipment is replaced with equal or like equipment, resulting in either no increase to treatment capacity or the addition of equipment that is not directly used in the treatment process.
3. A Type III change to an approved medical waste facility plan is a change described by one of the following:
   a. Treatment equipment is added, resulting in less than a 25% increase in treatment capacity.
   b. The storage area is enlarged resulting in less than a 25% increase in storage capacity.
   c. Treatment technology is changed.
4. A Type IV change to an approved medical waste facility plan is a change described by one of the following:
   a. Treatment equipment is added, resulting in a 25% or more increase in treatment capacity.

b. The storage area is enlarged resulting in a 25% or more increase in storage capacity.
c. Treatment equipment is added that requires an environmental permit.
d. An expansion of the treatment facility onto land not previously described in the approved plan.

B. As required by A.R.S. § 49-762.06, a treatment facility operator who has identified a change under subsection (A) shall comply with one of the following:

1. For a Type I change, make the change without notice to, or approval by the Department.
2. For a Type II change, before making any change, provide written notification that describes the change to the Department. The addition of refrigeration units only for compliance with this Article is a Type II change for which no Departmental approval is required.
3. For a Type III or Type IV change, submit an amended plan to the Department for approval before making any change. Departmental approval is required prior to making any change.

C. An owner or operator of an existing municipal solid waste landfill who intends to accept untreated biohazardous medical waste shall submit a notice of a Type III change and an amended facility plan.

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

A. A manufacturer or its agent who applies for alternative medical waste treatment method registration shall submit to the Department all of the following:

1. The manufacturer or company name and address.
2. The name, address, and telephone number of the person who submits the application.
3. A description of the alternative medical waste treatment method.
4. A list of any other states in which the treatment method is used, including a copy of any state approvals.
5. A description of by-products generated as result of the alternative treatment method.
6. A certification statement that the contents of the application are true and accurate to the knowledge and belief of the applicant.
7. Written documentation demonstrating that the alternative medical waste treatment method is capable of compliance with the treatment standards in this Article for the type of waste treated. The manufacturer shall employ a laboratory independent of any oversight activities by the manufacturer to provide this analysis.
8. The manufacturer's equipment specifications for the alternative medical waste treatment method being registered, including all of the following:
   a. Unit model number, or serial number.
   b. Equipment specifications that identify the proper type of biohazardous medical waste to be treated by the equipment and any design or equipment restrictions.
   c. Operating procedures for the equipment that ensure the equipment complies with the treatment standards prescribed in this Article for the type of waste treated.
   d. Instructions for equipment maintenance, testing, and calibration that ensure the equipment complies with the treatment standards prescribed in this Article for the type of waste treated.
9. Written documentation of registration if required by A.R.S. § 3-351.

B. The Department shall make a determination whether to approve the registration application. If the Department approves the application, it shall issue to the applicant a certification of registration containing an alternative medical waste treatment method registration number. Only an alternative technology method with a valid Department issued registration number meets the requirements of this Article.

C. If documentation of Departmental registration is not on file with a generator utilizing alternative medical waste treatment technology, the Department shall classify biohazardous medical waste treated using the unregistered alternative treatment technology as untreated biohazardous medical waste.

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

A. A treater using an alternative treatment technology shall ensure that treatment achieves either of the following treatment standards:
1. A 6 $\log_{10}$ inactivation in the concentration of vegetative microorganisms.
2. A 4 $\log_{10}$ inactivation in the concentration of Bacillus stearothermophilus or Bacillus subtilis as is appropriate to the technology.

B. A treater utilizing an alternative treatment method shall conduct efficacy studies to demonstrate that the treatment mechanisms are capable of achieving the standards in subsection (A) through either of the following:
1. Mycobacterial species used as indicators of vegetative microorganisms:
   a. *Mycobacterium phlei*, or
   b. *Mycobacterium bovis* (BOG) (ATCC 35743)
2. Spore suspensions of one of the following two bacterial species, as appropriate to the technology, used as biological indicators in efficacy tests of thermal, chemical, and irradiation treatment systems. Studies shall demonstrate a 4 $\log_{10}$ reduction in the concentration of viable spores, through the use of an initial inoculum suspension of 5 $\log_{10}$ or greater of:
   a. *Bacillus stearothermophilus* (ATCC 7953), or
   b. *Bacillus subtilis* (ATCC 19659).

C. A treater utilizing an alternative treatment method shall quantify microbial inactivation as follows:
1. 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:
   $\text{Log}_{10}\text{Kill} = \text{Log}_{10}(\text{cfu/g "I"}) - \text{Log}_{10}(\text{cfu/g "R"})$
   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.
2. 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.
3. 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.
   a. 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.

b. 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.

R18-13-1416. Recycled Materials

A. Once a generator places biohazardous medical waste in a red bag as required in R18-13-1407, a person shall not remove any of the biohazardous medical waste from the bag until the biohazardous medical waste has been treated as required in R18-13-1415.

B. A generator of biohazardous medical waste intending to recycle any portion of the biohazardous medical waste shall segregate that portion of biohazardous medical waste from the portion of biohazardous medical waste that will not be recycled. The generator shall do either of the following:

1. Treat the biohazardous medical waste intended for recycling as required in R18-13-1415 before sending the treated medical waste to a recycler.
2. Follow the requirements in R18-13-1406, R18-13-1407, and R18-13-1408, before either contracting with a transporter to haul or self-hauling the biohazardous medical waste to a treatment facility for treatment. After treatment, the treated medical waste may be sent to a recycler.

R18-13-1417. Disposal Facilities: Design and Operation

An operator of a municipal solid waste landfill that accepts untreated biohazardous medical waste shall comply with all the following in design and operational requirements:

1. Accept biohazardous medical waste only if packaged according to R18-13-1407.
2. Keep the biohazardous medical waste disposal area separate from the general purpose disposal area.
3. Clearly label the biohazardous medical waste disposal area, informing persons that the disposal area contains untreated medical waste.
4. Not drive directly over deposited medical waste. The operator shall achieve compaction by first spreading a layer of soil that is sufficiently thick to prevent compaction equipment from coming into direct contact with the waste, or dragging waste over the area.
5. Cover the biohazardous medical waste with 6 inches of compacted soil at the end of the working day or more often as necessary to prevent vector breeding and odors.
6. Not allow salvaging of untreated biohazardous medical waste from the landfill.

R18-13-1418. Discarded Drugs

A. ~~A generator of d~~Discarded drugs that are not hazardous waste, not returned to the manufacturer and not segregated and labeled on site for transport to a treatment facility shall be destroyed on site by the generator of such ~~the~~ drugs ~~on site~~ by any method that prevents the drugs' use prior to placing the waste out for collection~~. A generator shall destroy the discarded drugs by any method that prevents the drug's use~~. If federal or state law prescribes a specific method for destruction of discarded drugs, the generator shall comply with that law.

~~**B.** A generator of discarded drugs may flush them down a sanitary sewer if allowed by the wastewater treatment authority.~~

R18-13-1419. Medical Sharps

A. Medical sharps shall be handled as follows:

1. A generator who treats biohazardous medical waste on site shall place medical sharps in a sharps container after rendering them incapable of creating a stick hazard by using an encapsulation agent or any other process that prevents a stick hazard. Medical sharps encapsulated or processed in this manner are considered to be solid waste.
2. A generator who ships biohazardous medical waste off site for treatment shall either:
   a. Place medical sharps in a medical sharps container and follow the requirements of R18-13-1406, or
   b. Package and send medical sharps to a treatment facility via a mail-back system as prescribed by the instructions provided by the mail-back system operator. ~~An Arizona treatment facility shall render medical sharps incapable of creating a stick hazard by using an encapsulation agent or any other process that prevents a stick hazard~~. The generator shall retain proof of shipping.

~~3. A person operating a treatment facility who accepts medical sharps for treatment shall either:~~
~~a. Encapsulate medical sharps to prevent stick hazard, or~~

~~b. Use any other process that prevents a stick hazard.~~

B. Notwithstanding subsections (A)(1) and (A)(2), the following syringes do not have to be placed in a medical sharps container:

1. Syringes that have never had a needle (sharp) attached,
2. Syringes where a needle or sharp had been attached and has been separated from the syringe so that no stick or puncture hazard remains with the syringe.

C. Syringes that are exempted by subsection (B) from being placed in a medical sharps container are still subject to biohazardous medical waste determination in accordance with the definition of biohazardous medical waste.

R18-13-1420. Additional Handling Requirements for Certain Wastes

A. A person who treats the following biohazardous medical waste categories shall meet the following additional requirements:

1. Cultures and stocks shall be incinerated, autoclaved, or treated by an alternative medical waste treatment method that meets the treatment standards set forth in R18-13-1415(A). ~~and~~ If cultures and stocks are shipped off site for treatment or disposal, they shall be packaged inside a watertight primary container with absorbent packing materials ~~if shipped off site for treatment or disposal~~. The primary container shall be placed inside a watertight secondary inner container that is then placed inside an outer container with sufficient cushioning material to prevent shifting between the secondary inner container and the outer container. If federal or state law prescribes specific requirements for packaging and transporting this waste, the treater shall comply with that law.
2. Trace ~~C~~chemotherapy waste shall be incinerated or disposed of in either an approved solid waste or hazardous waste disposal facility.
3. Experimental or research animal waste shall be handled as follows:
   a. Autoclave bedding on site or package as described in R18-13-1407 for off-site treatment or landfilling.
   b. Incinerate animal carcasses on site, or if taken off site for treatment, comply with one of the following requirements:
      i. Package the waste in a leakproof, covered container, label the contents and send to an incinerator or a Department-approved landfill, or
      ii. If treated by a method other than incineration, pre-process by grinding, then treat by a method that achieves the standards of R18-13-1415(A).

B. If a treater uses grinding in combination with another treatment method described in this Article, the treater shall conduct it in a closed system to prevent humans from being exposed to the release of the waste into the environment. If grinding is used for medical sharps, the grinding shall render the medical sharps incapable of creating a stick hazard.