

**NOTICE OF PROPOSED RULEMAKING**  
**TITLE 18. ENVIRONMENTAL QUALITY**  
**CHAPTER 13. DEPARTMENT OF ENVIRONMENTAL QUALITY**  
**SOLID WASTE MANAGEMENT**

**PREAMBLE**

<b><u>1. Article, Part or Section Affected (as applicable)</u></b>	<b><u>Rulemaking Action</u></b>
R18-13-1401	Amend
R18-13-1402	Amend
R18-13-1403	Amend
R18-13-1404	Repeal
R18-13-1406	Amend
R18-13-1407	Amend
R18-13-1408	Amend
R18-13-1409	Amend
R18-13-1411	Amend
R18-13-1412	Amend
R18-13-1413	Amend
R18-13-1414	Amend
R18-13-1415	Amend
R18-13-1417	Amend
R18-13-1418	Amend
R18-13-1419	Amend
R18-13-1420	Amend
<b><u>2. Citations to the agency's statutory rulemaking authority to include the authorizing statutes (general) and the implementing statutes (specific):</u></b>	
Authorizing Statutes:	A.R.S. §§ 41-1003 and 49-104
Implementing Statute:	A.R.S. § 49-761

**3. Citations to all related notices published in the *Register* as specified in R1-1-409(A) that pertain to the record of the proposed rules:**

Notice of Rulemaking Docket Opening: 26 A.A.R. 2004, September 25, 2020

**4. The agency's contact person who can answer questions about the rulemaking:**

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**5. The agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:**

Summary. The Arizona Department of Environmental Quality (ADEQ) is proposing to amend the state's Biohazardous Medical Waste (BMW) rules within the Solid Waste (SW) area to improve clarity, bring the standards up to date, address stakeholder concerns, correct references and citations, and ensure adequate protection of human health and the environment.

Background. BMW is medical waste from regulated generators that is either soaked with blood or that has come into contact with infectious agents capable of transmitting disease to humans. Arizona's BMW rules were promulgated in 1999 after more than 6 years of stakeholder feedback and modifications. BMW generators and transporters have communicated to ADEQ over the years that updates are necessary to make the process of handling and transporting BMW more clear and protective of human health and the environment. The current COVID-19 epidemic has highlighted the need to make these changes now. Technical changes will also be made to fulfill a commitment to the Governor's Regulatory Review Council (GRRC). All of these changes would increase the health and safety of the community without imposing undue burdens on the regulated community

Background to this Notice of Proposed Rulemaking. ADEQ's current rulemaking process contains a significant stakeholder dialogue leading up to the formal proposed rule. From October 2020 through January 2021, ADEQ posted informational documents on its website and held two virtual public

stakeholder meetings prior to producing a draft rule in February 2021. An additional stakeholder meeting occurred in February seeking feedback on this draft language. Stakeholders also sent in comments for the duration of October 2020 through February 2021. These meetings were well attended and answered many early stakeholder questions, particularly with regard to the potential application of any changes to their businesses.

Effective date of rule. If these proposed rules are considered by the Governor's Regulatory Review Council (GRRC) in August 2021, they would be effective in October or November of 2021.

Subsections not amended listed as "No change". ADEQ has used the option in A.A.C. R1-1-502(B)(18)(f) to list most rule text subsections not amended by this rulemaking as "No change", rather than showing long sections of text that are not being changed. Occasionally, certain subsections of unchanged text are shown to provide context for nearby proposed changes.

**6. A reference to any study relevant to the rules that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rules, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:**

No such study was relied upon in this instance.

**7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:**

There would be no diminution of previous grants of authority under this rule.

**8. The preliminary summary of the economic, small business and consumer impact:**

Identification of the rulemaking: 18 A.A.C. 13, Article 14

Transport

- **Conduct & Frequency.** The current burden requires transporters to deposit BMW at a licensed facility within 24 hours if it is unrefrigerated and does not allow carriage of multiple waste streams on the same vehicle. Nonputrescible waste is currently subject to the same 24 hour rule, when it could be stored at room temperature safely for much longer.
- **Estimated Change.** Some of the proposed changes include allowance for 48 hours of additional unrefrigerated storage time of BMW and carrying multiple Department of Transportation

(DOT)-compatible wastes on the same vehicle. These changes would allow transporters, for instance, to carry larger amounts of waste unrefrigerated to maximize collection space, minimize inefficiency, improve customer relationships by collecting waste at one convenient time, and consolidate multiple trips.

- Cost Savings. From the self-reported transporter data gathered by 2/24/21, the cost savings ranges from \$0-5,000, with a mean savings of \$1,872.31 per month for each licensed transporter.

#### DOT Integration

- Conduct & Frequency. The current burden requires transporters to comply with dueling regulations for BMW from both DOT and ADEQ. For instance, DOT requires a longer records-retention period than ADEQ (2-3 years versus 1 year). This means administrative time is expended to keep track of compliance with both timeframes.
- Estimated Change. The proposed changes would mirror DOT requirements in the ADEQ rules, thus eliminating the additional administrative time and confusion required to comply with two different requirements. From the self-reported transporter data gathered by 2/24/21, the time savings ranges from 0 to 24 hours, with a mean low savings of 1.23 hours and a mean high savings of 6.46 hours .
- Cost Savings. The time savings would amount to administrative personnel cost savings. From the self-reported transporter data gathered by 2/24/21, 31% anticipated some cost savings, 15% were unsure of cost savings, and 54% did not see any cost savings in the record retention requirement. When responses were broken down by size (1-3 versus 4-10 transport vehicles), 36.3% of the smallest transporters (1-3 vehicles) reported a cost savings, 45.5% of the smallest transporters anticipated no savings, and 18.2% of the smallest transporters were unsure of potential savings. Of the larger transporters (4-10 vehicles), there were no anticipated savings.

#### Registration

- Conduct & Frequency. Currently, transporters are only subject to certain management and hygiene standards for a vehicle that is used to transport BMW for more than 30 consecutive days. However, this loophole has been exploited by rotating vehicles every 29 days and avoiding regulation that was intended to apply to those in business transporting to protect human health and environmental safety. This provision has also created frustration and confusion regarding compliance.

- **Estimated Change.** Modifying this provision such that the requirements apply to “at least once weekly for a month” should capture those in the business of transporting regularly while appropriately excluding those not intended for inclusion. This modification would eliminate confusion and frustration, allowing for even and fair application and avoiding counting the number of consecutive days- an administrative burden. From the self-reported transporter data gathered by 2/24/21, 84.6% of transporters spent time tracking the operation days of vehicles, with 38.5% spending between 1 and 3 hours per month and 46.2% spending between 4 and 24 hours per month. Survey data did not include estimates of additional time that would be expended complying with management and hygiene standards; further data is required to analyze this impact.
- **Cost Savings.** The modification in the rules would ameliorate frustration and time needed to count the exact number of days a vehicle is transporting BMW and save expenses involved in such tracking. From the self-reported transporter data gathered by 2/24/21, the tracking savings ranged from \$0 to \$5,000, with a mean savings of \$875.38 per month. Survey data did not include estimates of additional expenses required to comply with management and hygiene standards; further data is required to analyze this financial impact.

#### Sewering

- **Conduct & Frequency.** Due to the Hazardous Waste Pharmaceutical rule changes, effective November 3, 2020, that prohibit disposing of such substances in sewers (sewering), non-HW pharmaceuticals are now subject to different requirements from all HW pharmaceuticals, which may cause increased compliance costs incurred through training and sorting.
- **Estimated Change.** Removing the provisions that allow for non-HW pharmaceutical sewerage would match EPA recommendations for non-HW pharmaceuticals, stakeholder requests for such removal, streamline disposal, and therefore minimize sorting and training time needed for the different types of pharmaceuticals.
- **Cost Savings.** The modification in the rules would allow for fewer hours spent sorting and training at the generator level. Although there is not a precise measure localized to Arizona generators for non-hazardous waste pharmaceuticals at this point, training for the hazardous waste pharmaceuticals sewerage ban is already being conducted as necessitated by the incorporation of the sewerage ban into the hazardous waste rules. Therefore, no additional training is likely to be necessary and any time previously spent differentiating the types of pharmaceuticals for sewerage purposes can now be used more productively.

## Mail-back Records Retention

- **Conduct & Frequency.** The current rules do not provide clarity for requirements of records retention for mail-back sharps, thus creating confusion and concern about appropriate compliance.
- **Estimated Change.** The proposed change would clarify that requirement is to retain documentation that is already required under United States Postal Service mailing guidelines. There is no increase in burden other than placing the paper into a location it can be found later. This avoids any time spent discussing what the compliance requirements are during inspections and maximizes efficiency.
- **Cost Savings.** This modification helps avoid extra time spent discussing what the compliance requirements are during inspections and maximizes efficiency. There may be no cost savings, but there should also be no added cost.

### **9. The agency's contact person who can answer questions about the economic, small business and consumer impact statement:**

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### **10. The time, place, and nature of the proceedings to make, amend, repeal, or renumber the rules, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rules:**

Date: May 18, 2021

Time: 1:30 p.m.

Location: GoToWebinar hosted by Arizona Department of Environmental Quality at:  
<https://attendee.gotowebinar.com/register/5845659535557299728>

Nature: Public hearing on the proposed rules, with opportunity for formal comments on the record. Please call (602) 771-4795 for special accommodations pursuant to the Americans with Disabilities Act.

The close of the written comment period will be 5:00 p.m., May 17, 2021. Submit comments to [wasterulemaking@azdeq.gov](mailto:wasterulemaking@azdeq.gov).

**11. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:**

**a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:**

See A.R.S. § 41-1037(A)(2). This rulemaking would amend an existing rule that requires a regulatory permit. This rulemaking does not require a general permit because A.R.S. § 761(D)(2) specifically requires rules for payment for transporter licensure. A.R.S. § 49-762(A)(3) requires solid waste facility plans for medical waste facilities. Taken together, these statutory provisions require specific plan approval and licensure requirements for biohazardous medical waste transporters and facilities. Therefore, it is not possible to utilize a general permit for these activities.

**b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:**

There are no federal laws that are applicable to the subject of this rule, therefore the rule is not more stringent than federal law. A.R.S § 49-761 (D) provides authorization for ADEQ to “regulate biohazardous medical waste and medical sharps” and ADEQ has taken into account specific areas where United States Department of Transportation rules may intersect with ADEQ regulations and harmonized as much as possible.

**c. Whether a person submitted an analysis to the agency regarding the rule’s impact on the competitiveness of businesses in this state as compared to the competitiveness of businesses in other states:**

No person has submitted a competitiveness analysis under A.R.S. § 41-1055(I).

**12. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rule:**

<u>Incorporated Federal Citation</u>	<u>Location</u>
49 CFR 176.83(b)	R18-13-1401
29 CFR 1910.145(f)(8)(ii)	R18-13-1401
49 CFR 172.201	R18-13-1406(B); R18-13-1409(K)
49 CFR 172.300 et seq	R18-13-1406(B)(3)

**13. The full text of the rules follows:**



## TITLE 18. ENVIRONMENTAL QUALITY

### CHAPTER 13. DEPARTMENT OF ENVIRONMENTAL QUALITY - SOLID WASTE MANAGEMENT

#### ARTICLE 14. BIOHAZARDOUS MEDICAL WASTE AND DISCARDED DRUGS

##### Section

- R18-13-1401. Definitions
- R18-13-1402. Applicability
- R18-13-1403. Exemptions; Partial Exemptions
- R18-13-1404. Transition and Compliance Dates
- R18-13-1406. Biohazardous Medical Waste Transported Off Site for Treatment
- R18-13-1407. Packaging
- R18-13-1408. Storage
- R18-13-1409. Transportation; Transporter License; Annual Fee
- R18-13-1411. Storage and Transfer Facilities; Design and Operation
- R18-13-1412. Treatment Facilities; Design and Operation
- R18-13-1413. Changes to Approved Medical Waste Facility Plans
- R18-13-1414. Alternative Medical Waste Treatment Methods: Registration and Equipment Specifications
- R18-13-1415. Treatment Standards, Quantification of Microbial Inactivation and Efficacy Testing Protocols
- R18-13-1417. Disposal Facilities: Operation
- R18-13-1418. Discarded Drugs
- R18-13-1419. Medical Sharps
- R18-13-1420. Additional Handling Requirements for Certain Wastes

#### 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. 1. “Alternative treatment technology” means a treatment method other than autoclaving or incineration that achieves the treatment standards described in R18-13-1415.
3. 2. “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. 3. “Autoclaving,” means using a combination of heat, steam, pressure, and time to achieve sterile conditions.
5. 4. “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.~~ that are saturated and/or dripping with human

- blood or caked with dried human blood, including items that would release blood in a liquid or semi-liquid form 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 do not include the head, 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.
  - f. Tattoo and body modification waste: any waste generated during 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.
  - g. Trauma scene waste: any crime scene, accident, or trauma clean-up wastes generated by individuals or commercial entities hired to clean crime scenes or accidents, such as sharps and materials that contain human blood and blood products.
- ~~6.~~ 4. “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.~~ 5. “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.~~ 6. “C-F-R:” means the Code of Federal Regulations.
- ~~10.~~ 7. “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, is not biohazardous medical waste. Bulk chemotherapy waste may be considered hazardous wastes and must be handled according to the hazardous waste regulations if deemed a hazardous waste by the generator.
- ~~11.~~ 8. “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).
- ~~9.~~ “Department-approved facility” means a storage, transfer, treatment, or disposal facility that has undergone plan approval as described in R18-13-1410.
- ~~12.~~ 10. “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. ~~11.~~ “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. ~~12.~~ “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. ~~13.~~ “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. ~~14.~~ “Hazardous waste” has the meaning prescribed in A.R.S. § 49-921.
18. ~~15.~~ “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. ~~16.~~ “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. ~~17.~~ “Independent testing laboratory” means a testing laboratory independent of oversight activities by a provider of alternative treatment technology.
21. ~~18.~~ “Medical sharps container” means a vessel that is rigid, puncture resistant, leak proof, and equipped with a locking cap.
22. ~~19.~~ “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. ~~20.~~ “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. ~~21.~~ “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 providing services.~~ “Off site” for purposes of this definition means a location other than a hospital or clinic, at a location other than a hospital or clinic.
25. ~~22.~~ “Off site” means a location that does not fall within the definition of “on site” contained in A.R.S. § 49-701.
26. ~~23.~~ “Packaging” or “properly packaged” means the use of a container or a practice under R18-13-1407.
27. ~~24.~~ “Putrescible waste” means waste materials capable of being decomposed rapidly by microorganisms.
28. ~~25.~~ “Radioactive material” has the meaning under A.R.S. § 30-651.
29. ~~26.~~ “Secure” means to lock out or otherwise restrict access to unauthorized personnel.
30. ~~27.~~ “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.~~ 28. “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.~~ 29. “Technology provider” means a person that manufactures, or a vendor who supplies alternative medical waste treatment technology.
- ~~33.~~ 30. “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.~~ 31. “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.~~ 32. “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.~~ 33. “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.~~ 34. “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.~~ 35. “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.~~ 36. “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.~~ 37. “Treatment standards” mean the levels of microbial inactivation, prescribed in R18-13-1415, to be achieved for a specific type of biohazardous medical waste.
- ~~38.~~ “USDOT” means the United States Department of Transportation.
- ~~41.~~ 39. “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.~~ 40. “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. No change
  - 1. No change
  - 2. No change
  - 3. No change
  - 4. No change
  - 5. No change
  - 6. No change
  - 7. No change
  - 8. No change
  - 9. A person who generates medical sharps in the treatment of humans or animals.
  - 10. No change
- B. No change
- 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. No change
  - 2. A person in possession of medical waste that is regulated by a state or federal agency due to its radioactive materials nature.
  - ~~3.~~ 3. A person who returns unused medical sharps to the manufacturer.
  - 4. No change
  - 5. No change
  - 6. No change
  - 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 hazardous~~ 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. No change
    - b. No change
    - c. No change

- d. No change
- e. No change
- 6. No change
- 7. No change
- C. No change
  - 1. No change
  - 2. No change

**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. The 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), if 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.~~

#### **R18-13-1406. 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 this article R18-13-1407 before and shall subsequently either self-hauling or before store the waste as provided under R18-13-1408 and setting 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. No change~~
  - ~~2. No change~~
  - ~~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. No change~~
- ~~C. No change~~
- ~~D. No change~~

#### **R18-13-1407. Non-Sharps 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. No change~~
    - ~~a. No change~~
    - ~~b. No change~~
    - ~~c. No change~~
    - ~~d. Sealed to prevent leakage during transport, and~~
    - ~~e. Puncture resistant for sharps, and~~
    - ~~fe. 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. No change~~
    - ~~a. No change~~
    - ~~b. No change~~
      - ~~i. No change~~

- ii. No change
- iii. No change

- B. No change
- C. No change
- D. No change

**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.
- B. No change
  - 1. No change
  - 2. No change
- 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 may be kept unrefrigerated up to 72 hours if it does not create a nuisance. However, refrigerate putrescible biohazardous medical waste kept more than seven days. would not otherwise cause odor detectable beyond the property line or attract vermin.
  - 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) ~~if odors become a problem, and (2),~~ 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 ~~the problem, odors or vermin,~~ the Department shall require the waste to be removed or refrigerated at 40° F or less.
- D. Trace chemotherapy waste shall be clearly identified as such by its label.

**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). 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 in a Department-approved format:
  - 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

	<u>Initial</u>	<u>Maximum</u>
<u>New Application</u>	<u>\$2,000</u>	<u>\$20,000</u>
<u>Renewal Application</u>	<u>\$2,000</u>	<u>\$20,000</u>
<u>Amendment Application</u>	<u>\$100</u>	<u>\$5,000</u>

Frequency of Application for Transporter License

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

3. The Department may only issue a transporter license, including a renewal, if all of the items in subsection (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. C. Beginning on July 1, 2012, a transporter~~ Transporters shall pay by the invoice due date an annual fee of \$750 for every each calendar year according to the following schedule, ~~except that no transporter shall pay more than one annual fee in any 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.

- ~~1. Transporters registered with the Department before July 1, 2012, shall pay by December 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

<u>Transporter Annual Fee</u>	
<u>Years</u>	<u>Amount</u>
2,3,4,5,7,8,9,10, etc.	<u>\$750</u>

~~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).~~
- ~~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)(3)~~ (32), 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.~~ A.R.S. §§ 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 ~~(H)(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 ~~one year~~ the period required under the USDOT requirements, as listed in 49 CFR 172.201.
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. ~~Not~~ Except in emergency situations, not 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.

#### **R18-13-1411. 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. No change
2. No change
3. No change
4. No change
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 ~~24 hours,~~ 72 hours, the operator shall equip the facility with a refrigerator to refrigerate the putrescible 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~~ the period required under the USDOT requirements, as listed in 49 CFR 172.201.
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. No change
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 ~~all of the following: 1 and 2 as well as all of the requirements in B:~~

1. No change
  - a. No change
  - b. No change
  - c. No change
  - d. No change
  - e. No change
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. No change
  - c. No change
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. The treater shall make treatment records available for Departmental inspection upon request. An operator of a department approved facility shall comply with all of the following:**
1. Have readily accessible 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 the period required under the USDOT requirements, as listed in 49 CFR 172.201.
    - 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 a sealed biohazardous medical waste container prior to treatment unless opening the container 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. No change
2. No change
3. No change
  - a. No change
  - b. No change
  - c. No change.
4. No change
  - a. No change
  - b. No change
  - c. No change
  - d. No change

B. No change

1. No change
2. No change
3. No 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. No change

1. No change
2. No change

- 3. No change
- 4. No change
- 5. No change
- 6. No change
- 7. No change
- 8. No change
  - a. No change
  - b. No change
  - c. No change
  - d. No change
- 9. No change.

**B.** No change

**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.** No change

- 1. No change
- 2. A 4 log<sub>10</sub> inactivation in the concentration of ~~Bacillus stearothermophilus~~ *Bacillus stearothermophilus* or ~~Bacillus subtilis~~ *Bacillus subtilis* as is appropriate to the technology.

**B.** No change

- 1. No change
  - a. No change
  - b. No change
- 2. No change
  - a. No change
  - b. No change

**C.** No change

- 1. No change
- 2. No change
- 3. No change
  - a. No change
    - i. No change
    - ii. No change
    - iii. No change
    - iv. No change
    - v. No change
  - b. No change
    - i. No change
    - ii. No change
    - iii. No change
    - iv. No change
    - v. No change

**D.** No change



**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 of the following in design and operational requirements:

1. No change
2. No change
3. No change
4. No change
5. No change
6. No change

**R18-13-1418. Discarded Drugs**

- ~~A. A generator of discarded 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 destroy the drugs on site~~ be destroyed on site by the generator of such drugs 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. ~~Chemotherapy~~ Trace chemotherapy waste shall be incinerated or disposed of in either an approved solid waste or hazardous waste disposal facility.
  3. No change
    - a. No change
    - b. No change
      - i. No change
      - ii. No change
- B.** No change