(as submitted to GRRC)

NOTICE OF FINAL RULEMAKING

TITLE 18. ENVIRONMENTAL QUALITY

CHAPTER 13. DEPARTMENT OF ENVIRONMENTAL QUALITY

SOLID WASTE MANAGEMENT

PREAMBLE

1. Article, Part or Section Affected (as applicable)	**Rulemaking Action**
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

2. Citations to the agency's statutory rulemaking authority to include the authorizing statutes(general) and the implementing statutes (specific):

Authorizing Statutes: A.R.S. §§ 41-1003 and 49-104

Implementing Statute: A.R.S. § 49-761(D)

3. The effective date of the rules:

The rules will be effective 60 days after the date filed with the Secretary of State.

4. 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

Notice of Proposed Rulemaking: 27 A.A.R. 535, April 09, 2021

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

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6. The agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking: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) has amended 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 communicated to ADEQ over the years that updates were necessary to make the process of handling and transporting BMW more clear and protective of human health and the environment. The COVID-19 epidemic further highlighted the need to make these changes. Technical changes were also made to fulfill a commitment to the Governor's Regulatory Review Council (GRRC). All of these changes increase the health and safety of the community without imposing undue burdens on the regulated community

Background to this Notice of Final Rulemaking. ADEQ's rulemaking process contained significant stakeholder dialogue leading up to the formal final 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 the draft language. Stakeholders sent in comments throughout the October 2020 to February 2021 period. These meetings were well attended and answered many early stakeholder questions, particularly with regard to the potential application of any changes to their businesses. ADEQ also consulted with members of the Arizona Department of Health Services during the rulemaking process to ensure consistency.

Effective date of rule. Contingent upon approval by the Governor's Regulatory Review Council (GRRC) on August 3, 2021, these rules would be effective 60 days after the date filed with the Secretary of State.

Subsections not amended listed as "No change". ADEQ exercised 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 were not changed. Occasionally, certain subsections of unchanged text were shown to provide context for nearby changes.

7. 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.

8. 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 is no diminution of previous grants of authority under this rule.

9. A summary of the economic, small business and consumer impact:

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

   Brief summary of Economic Impact Statement (EIS) rule information, by rule topic:

   Transport

   - Conduct & Frequency. The previous rule burden required transporters to deposit BMW at a licensed facility within 24 hours if it was unrefrigerated and did not allow carriage of multiple waste streams on the same vehicle. Nonputrescible waste was subject to the same 24-hour rule, even though it can be stored at room temperature safely for much longer.
   - Estimated Change. One change included allowing 48 hours of additional unrefrigerated storage time and carrying multiple U.S. Department of Transportation (DOT)-compatible wastes on the same vehicle. These changes allow transporters 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 estimate ranged from $0 to $5,000, with a mean savings of $1,872.31 per month for each licensed transporter.

   DOT Integration

- Conduct & Frequency. The previous burden required transporters to comply with overlapping regulations for BMW from both USDOT and ADEQ. For instance, USDOT requires a longer records-retention period than ADEQ (2 to 3 years versus 1 year). Therefore, transports expended administrative time keeping track of compliance with both timeframes.
- Estimated Change. The changes mirrored USDOT 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 estimates ranged from 0 to 24 hours per month, with a mean low savings of 1.23 hours per month and a mean high savings of 6.46 hours per month.
- Cost Savings. The time savings amounted 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 business size (1 to 3 versus 4 to 10 transport vehicles), 36.3% of the smallest transporters (1 to 3 vehicles) anticipated a cost savings, 45.5% of the smallest transporters anticipated no savings, and 18.2% of the smallest transporters were unsure of potential savings. The larger transporters (4 to10 vehicles) reported no anticipated savings.

Registration

- Conduct & Frequency. Previously, transporters were only subject to management and hygiene standards for a vehicle that was used to transport BMW for more than 30 consecutive days. However, some businesses exploited that loophole by rotating vehicles every 29 days and avoiding regulation that was intended to apply to BMW transporters in order to protect human health and the environment. That provision also created frustration and confusion regarding compliance.
- Estimated Change. The requirement now requires a license for vehicles that transport BMW "at least once weekly for a month." This revision captured those in the business of transporting BMW regularly while excluding those not intended for inclusion. This modification eliminated confusion and frustration, allowed for even and fair application of the requirements, and avoided counting the number of consecutive days, which can be 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. Estimates of time expended to comply with the management and hygiene standard ranged from 15 to 30 minutes per vehicle (average of 22.5 minutes), at a rate of one to two times per week (average of 1.5 used); this weekly cleaning amount averaged 33.75 minutes per week per vehicle. For transporters with 1-3 vehicles, this amounted to 33.75 to 101.25 minutes, on average, of total cleaning time weekly. For transporters with 4 to 10 vehicles, this amounted to 135 to 337.5 minutes, on average, of total cleaning time weekly. Depending upon size, transporters spent from 60 to 1,440 minutes per month tracking (a general average of 750 minutes) versus 135 to1,350 minutes cleaning (a general average of 742.5 minutes), yielding a break-even or small time savings.

- Cost Savings. The modification in the rules ameliorated frustration and time needed to count the exact number of days a vehicle transported BMW and saved expenses involved in such tracking. From the self-reported transporter data gathered by 2/24/21, the tracking savings estimates ranged from $0 to $5,000, with a mean savings of $875.38 per month. From survey data, the chemical used to clean was typically diluted bleach or a similarly priced product. A typical 121-ounce jug of bleach ranges in price from $2.97 to $21.99 ($12.48 as a general average of these 2), depending on formulation, brand, and retailer, with the strongest concentration the CDC recommends (for bleach to water ratio) being 8 ounces of bleach to 1 gallon of water; this allows for 15.125 cleanings per 121-ounce jug of bleach, which is a material cost of around $0.83 per cleaning. Given the above data regarding time, the employee time expended was anticipated to be the same or slightly less. Given the price per cleaning and employee time factors, tracking costs likely break even with cleaning costs. However, some stakeholders who retained insurance apprised ADEQ that their insurer required cleaning after each pick up and required picture submissions and logging; typically, this resulted in trucks being cleaned one or twice per week. One stakeholder said they were “happy to clean the truck” because they got paid for it, through an insurance program called “Xactimate.” The amount of cost savings was not disclosed to ADEQ by the stakeholder, but is an additional factor in cost savings for the cleaning requirement.

Sewering

- Conduct & Frequency. Due to the Hazardous Waste (HW) Pharmaceutical rule changes (effective November 3, 2020) that prohibit disposing of such substances in sewers (sewering), non-HW pharmaceuticals were subject to different requirements than HW pharmaceuticals, which caused increased compliance costs incurred through training and sorting.
- Estimated Change. The removal of the provisions that allowed for non-HW pharmaceutical sewering matched EPA recommendations for non-HW pharmaceuticals and stakeholder requests for such removal. The removal also streamlined disposal and eliminated sorting and training time needed for the different types of pharmaceuticals.
- Cost Savings. The modification in the rules equated to fewer hours spent sorting and training at the generator level. Although there was not a precise measure localized to Arizona generators for non-hazardous waste pharmaceuticals available, training for the hazardous waste pharmaceuticals sewering ban had already been conducted as necessitated by the incorporation of the sewering 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 sewering purposes can be used more productively.

Mail-back Records Retention

- Conduct & Frequency. The previous rules did not provide clear records retention requirements for mail-back sharps and created confusion and concern about compliance.
- Estimated Change. The change clarified that the requirement is to retain documentation that is already required under United States Postal Service mailing guidelines. There is no increase in burden other than filing.
- Cost Savings. This change minimizes discussions about basic compliance requirements during inspections and maximizes efficiency. There are no cost savings, nor any added cost.

2. Identification of persons who will be directly affected by, bear the costs of, or directly benefit from the rules:

Parties Affected:

- Arizona Department of Environmental Quality (ADEQ)

- County agencies acting as regulatory authorities
- Exempt businesses
- Licensed BMW Transporters
- BMW Generators
- Small businesses regulated
- Community members living near transporter's places of business (residential areas)

3. Cost/Benefit Analysis:

   a. Part I- Cost/Benefit Stakeholder Matrix

Description of Affected Groups	Description of Effect	Increased Cost/Decreased Revenue	Decreased Cost/Increased Revenue
A. State and Local Government Agencies			
ADEQ	Clarity of the new rule	None	None
County agencies acting as regulatory authorities	Clarity of the new rule	None	None
B. Privately Owned Businesses			
Exempt businesses	Clarity of the new rule	None	None
Licensed BMW transporters	Clarity of the new rule	Minimal to Moderate	Minimal to Moderate
BMW Generators	Clarity of the new rule	Minimal	Minimal

Small businesses regulated	Clarity of the new rule	Minimal	Minimal to Moderate
C. Community			
Individual community members	Clarity of the new rule, protection of human health	None	None

Minimal	Moderate	Substantial	Significant
$1,000 or less	$1,000 to $10,000	$10,001 or more	Cost/Burden cannot be calculated, but ADEQ expects it to be significant.

b. Part II- Individual Stakeholder Summaries/Calculations

ADEQ

1. Staffing levels will not change. No new employees need to be hired or laid off. Current staff will update their inspection procedures to meet the new rules. Minimal time is needed for these small updates.
2. Cash flow will not change as a result of the rules. There will be no delay in receipts or increase in expenses. There are no fee increases or decreases impacting ADEQ.
3. Barriers to industry entry will not be affected; this is an existing regulatory program so there are no startup costs for ADEQ. Business start-up costs already in existence for the regulated community will remain the same, and no additional burden is created on ADEQ for processing.

County agencies acting as regulatory authorities

1. Staffing levels will not change. No new employees need to be hired or laid off. Current staff will update their inspection procedures to meet the new rules. Minimal time is needed for these small updates.
2. Cash flow will not change as a result of the rules. There will be no delay in receipts or increase in expenses. There are no fee increases or decreases impacting the agency either way.
3. Barriers to industry entry will not be affected; this is an existing regulatory program so there are no startup costs for county agencies. Business start-up costs already in existence for the regulated community will remain the same, thus no additional burden is created on county agencies for processing.

Exempt businesses

1. Staffing levels of both small and large businesses exempt from the provisions in these rules will not change, as they are not affected. In this rulemaking, there are no additional obligations or costs for those who are exempt, nor should there be any staffing changes as a result of these rules.
2. Cash flow for exempt businesses will not be impacted, as there are no changes to these rules for exempt businesses. There would be no expected delay in receipts or increased expenses as a result of this rulemaking for businesses exempt from these rules.
3. Barriers to industry entry would not be increased for businesses exempt from these rules, as there is no change that affects those businesses under these rules. Start-up costs for exempt businesses would not change based on this rulemaking.

Licensed BMW Transporters

1. Staffing levels could vary slightly for larger businesses but are not expected to change for small businesses. The only potential increase in staffing could come from cleaning requirements. This increase would not

have an impact on those small businesses with fewer vehicles as the time required to clean appears not to require additional staff. Larger transporters who do not now comply but begin complying will need to budget some additional time, although it is unlikely there will be a need to hire people for this task. It is unlikely anyone will need to be laid off.

2. Cash flow change could occur if a transporter adds a vehicle via License Modification due to the update in R18-13-1409(J). A vehicle is required to be included on a license if used at least once each week for a month under the amended rule as opposed to the previous requirement for licensing occurring after 30 consecutive days of use. Small transporters in particular commented that they wished to see such a modification in order to level the playing field competitively. Those with additional vehicles used for transport will need to comply with proper licensing and cleaning protocols, which will allow smaller transporters with properly licensed vehicles and cleaning procedures to compete. The additional cost that could be incurred for these vehicles will vary according to R18-13-1409(D), with a license modification application fee of $100 and fees up to $5,000 based upon a formula in the rule that considers the number of vehicles and the actual hours spent by ADEQ. There should be no delay in receipts, however.
3. Barriers to industry entry should not change with these rule updates, and no additional business start-up costs will be imposed. No new fees are being added, and current fees are not being increased.

<u>BMW Generators</u>

1. Staffing levels will likely not be impacted for generators of various sizes under these rules. It is unlikely there would be a need for either additional employees or a reduction in employees, as responsibilities are largely remaining the same.

2. Cash flow is unlikely to be altered for generators of all sizes under these rules. Nothing in these rules should delay receipts or increase expenses. The practices in place for these generators will remain largely the same.
3. Barriers to industry entry will not increase. The requirements are largely the same under this rulemaking as under the previous rules for generators, so no increase in start-up costs is anticipated due to these rules.

Small businesses regulated

1. Staffing levels for small businesses regulated under these rules will be largely the same both before and after the updated rules go into effect. As examined in the previous industry-specific sections, it is unlikely small businesses will need to hire or lay off staff due to this rulemaking.
2. Cash flow for small businesses regulated under these rules should not delay receipts or increase expenses. Although some requirements, such as cleaning, will take a small amount of additional staff time, other requirements, such as increase in storage times, should result in less staff time expended. The net effect would be no change.
3. Barriers to industry entry are unlikely to increase under these rules. Regardless of business size, no additional start-up costs are imposed on businesses in this rulemaking.

4. Probable Impact on Employment: There is likely no impact on employment, as noted in the above sections with industry-specific discussions. There is the potential for increased hours or hiring should a stakeholder decide to expand their business to address additional COVID-19 waste. There will be no change to state employment as a result of this rule.

5. Probable Impact on Small Businesses: A.R.S. § 41-1035 requires agencies to consider reducing the rule's impact on small businesses. ADEQ has considered the feasibility of A.R.S. § 41-1035 methods (1)-(5) along with ADEQ's statutory mandate and has weighed the benefits of each against the need to protect human health and the environment. ADEQ is already allowing the regulated community to use the least stringent requirements necessary to maintain the appropriate levels of human safety and environmental protection. Due to the statutory mandate,

the nature of these regulations, and the potential impact to the community if businesses generating or transporting BMW are not regulated, it is not possible to exempt small businesses from these requirements. However, ADEQ has employed less stringent standards when doing so would not compromise human health and safety, such as increasing putrescible waste non-refrigeration time frames up to 72 hours. This extension allows small businesses more time to gather waste and deposit the waste at an appropriate facility, thus reducing trips and associated costs. ADEQ has also simplified record-keeping requirements to align with federal requirements so there is a unified retention schedule and documentation required. These simplified requirements should reduce training time and administrative burden.

a. Identification of Small Businesses subject to the rules: Directly affected small businesses include transporters and generators of BMW, like dentists, doctors, and veterinarians. Sharps provisions apply to tattoo shops. Individuals in their own homes will not be affected by these regulations.

b. Compliance Costs: Additional administrative costs required for compliance with the rules are not necessary, as no provision is anticipated to increase personnel hours or outside expenses. Additional compliance costs are likely to be minor, such as the time to clean vehicles, mentioned above; since many are already providing this cleaning to comply with insurance policies, little change is anticipated, if any. Since rule provisions have been redrafted for clarity, these rules should be easier to follow than in their previous form, particularly when it comes to the licensing requirements, which have not changed. It is not anticipated that counsel will be required, although all parties are encouraged to consult with an attorney if they wish.

c. Methods to Reduce Impact: In the beginning of the "Probable Impact on Small Businesses" section, ADEQ elaborates on its work to reduce the impact on small businesses. The rules have the least burden on business while accomplishing the regulatory objective provided in statute. ADEQ's robust stakeholder process has allowed for unique insights into the challenges and opinions of our business community. These insights have demonstrated opportunities where ADEQ could lessen regulations while remaining appropriately protective of human health and environment. This effort also

highlighted areas where the small business owners felt strongly that regulations were necessary. ADEQ thanks its stakeholders for their collaboration and honesty.

d. Cost/Benefit Analysis to Private Persons: ADEQ is conscious of the variation in business sizes and interests involved in this rulemaking and has worked to build consensus among stakeholders such that the rules provide a balanced benefit to all. ADEQ believes the rules may increase costs minimally, while decreasing costs elsewhere. The regulations are appropriately protective of human health and the environment while allowing for discretion. This will advance the goal of keeping Arizona an enjoyable place to live and work. Please see the above sections for additional details on costs. Various business sizes are analyzed above, as well as farther up in the EIS where impacts from specific changes are discussed.

6. Effect on Revenues to State Agencies. There will be no additional or reduced costs to ADEQ or other state agencies, nor will there be any change in state tax revenues, resulting from changes to these rules. No fee changes and no increase in business costs or decrease in business revenues are expected; therefore, no reduction in business activity that could lower state tax revenues should result from these rule changes. However, should the volume of transporters increase proportionate to COVID-19 waste volumes, the state would expect increased tax revenues due to increased business activity. In that scenario, businesses would also be increasing revenues and, incrementally, costs as they expand. However, these changes are not due to rule changes, but supply and demand in the market.

7. Less Intrusive/Costly Alternatives: ADEQ has examined as many potentially less intrusive or less costly alternatives as possible, but concludes most of these measures are untenable due to unique Arizona factors. For example, increasing unrefrigerated storage time frames for putrescible waste beyond 72 hours is not recommended in Arizona despite being utilized in other states, primarily because recommendations for safety indicate that the Arizona heat, especially in the summer months, could speed up decomposition of the putrescible waste more rapidly, thus creating potential disease vectors or nuisance odors. Additionally, the fee structure has been examined for available reduction; however, the current fees are as low as possible to account for program operational costs. The fees have been in place since 2012 without increase, despite increasing staff wages. These fees were also developed with extensive stakeholder feedback. So,

while ADEQ is not able to lower fees, ADEQ also will not increase fees. Thus, the burden on stakeholders will not increase. ADEQ has allowed maximum flexibility for storage times for non-putrescible waste (90 days), in order to allow transporters and generators to make the determinations for wastes that take refrigeration space versus those that may be safely stored elsewhere. ADEQ is balancing the least intrusive and most cost-effective approach with the need to protect the public and environment from potential disease vectors.

8. Data Basis: Searches on Lexis were conducted to compare various states' medical waste rules for comparison, including storage timeframes. State regulations from that database were used for comparison and modeling. All relevant information was summarized for stakeholders and opened for discussion prior to rule drafting, so all rules incorporate the stakeholder-preferred provisions and language. Data for impact on stakeholders was gathered via a simple anonymous online survey of transporters, wherein the link was available prior to and during the final stakeholder meeting. Participants were assured their data would be anonymous. Additional data was collected from transporters as to cleaning costs through program staff outreach to better understand current industry practices. This data comes directly from stakeholder responses targeted to specific areas and captures a small amount of their daily practices in an anonymous way so that trade secrets are not publicly shared. ADEQ thanks our stakeholders for their participation, feedback, and involvement in this rulemaking.

10. A description of any changes between the proposed rulemaking, including supplemental notices, and the final rulemaking:

The proper Code of Federal Regulations (CFR) effective date and the corrected citation for 49 CFR 177.848 (instead of 49 CFR 176.83(b)) were omitted in the proposed rule and have been inserted into the final rule. This insertion does not change the impact of the rules and was done for administrative reasons. Additionally, stakeholder comments indicated areas where the rule conflicted with federal regulations. ADEQ addressed these conflicts through removal of contradictory language regarding a "controlled substance" being regulated under these rules, appropriate cap security for medical sharps containers ("securely closed" instead of "locking), and elimination of the phrase "transportation management plan" when used in a manner that was inaccurate. Further, ADEQ was able to remove a redundant sentence, thanks to stakeholder input. A previous addition to the definition of biohazardous medical waste in R18-13-1401(4) that required an interpretation of what

was "sufficient virulence" was removed in favor of relying on specific examples of biohazardous medical waste. A clarification was made to the medical sharp section R18-13-1419 that states sharp-less syringes are not biohazardous medical waste if they are not composed of items listed in the biohazardous medical waste definition. Finally, ADEQ clarified that only biohazardous medical waste is regulated under these rules, so biohazardous medical items that were not yet waste would not be covered by these regulations.

11. Agency's summary of the public or stakeholder comments or objections made about the rulemaking and the agency response to the comments:

ADEQ thanks all commenters for their input. Although ADEQ in the rulemaking process is unable to address criticisms regarding how enforcement is carried out, these concerns have been shared with the appropriate staff. Additionally, ADEQ heard stakeholder concerns about landfill non-acceptance of certain wastes. ADEQ cannot require landfills to accept specific wastes; waste acceptance decisions are made at the discretion of the landfill operator. No comments were received on the following rules: R18-13-1403, 1404, 1413, 1414, 1415, 1417, 1419, 1420.

Rule	Comments	Agency Response
R18-13-1401(3)	Stericycle: The description of autoclaving is incorrect. Autoclaving is a process that relies on steam at high temperature and pressure to kill pathogens and render materials non-infectious. Autoclaving is not intended to achieve sterile conditions, nor are sterile conditions required for disposal of BMW.	The definition of "sterile" in Merriam-Webster includes "failing to bear or incapable of producing fruit or spores… [or]offspring…" Killing pathogens and avoiding pathogen reproductivity is consistent with the intent. Merriam-Webster defines "autoclave (verb)" as "to treat in an autoclave. Autoclave (noun) is defined as "*especially*: an apparatus (as for sterilizing) using steam under high pressure." The current definition for "autoclave" in the rules is consistent with the dictionary meanings of these words.
R18-13-1401(4)(c)	Stericycle: Cerebrospinal, synovial, pleural, peritoneal, pericardial and amniotic fluid are not typically characterized as pathological wastes. To maximize protection of human health and the environment,	ADEQ shared several state definitions with stakeholders for pathological wastes and feedback was received. Among them was South Carolina's definition that includes the mentioned "body fluids", which "may be infectious due to bloodborne pathogens." A stakeholder provided the following information

	ADEQ should also require that such human pathological wastes be incinerated. Human pathological wastes pose unique challenges compared to other BMW. For instance, autoclave treatment does not usually change the physical appearance of most pathological wastes, which often raises concerns with landfills. In addition, some generators of pathological wastes keep the material frozen or at very low temperatures, which can affect applicable treatment standards / methods. For these and other reasons, many states currently require that pathological waste be segregated from other BMW and treated by incineration. This is also a practice followed by Stericycle's customers per the company's waste acceptance policy.	during one of the stakeholder meetings: "OSHA from BBP Standard: Regulated Waste means liquid or semi-liquid blood or other potentially infectious materials … and pathological and microbiological wastes containing blood or other potentially infectious materials." Another stakeholder provided: "pathological means disease-related". A third stated, "any and all bodily fluids and substances [are] Biohazardous". In light of the comments received by our stakeholders, ADEQ integrated fluids into the pathological waste definition. The rules do not specify the method of destruction in order to allow for flexibility. There is nothing in these rules that prevents compliance with other regulations or company policies.
R18-13-1401(4)(f)	Stericycle: The proposed definition is too broad. Tattoo parlors and ear piercing operations likely generate multiple waste streams, but only those that contain human blood or blood products should be regulated as BMW. Similarly, "waste generated during the course of physically altering a human being … where a foreign object is used to cut or pierce the skin…" is too broad, and unnecessarily captures activities that are already covered by other sections of the BMW definition. For clarity, Stericycle recommends limiting the definition to tattoo and ear piercing-related wastes that contain human blood.	ADEQ's authority to regulate tattoo parlors is found in A.R.S. § 44-1342(A): "A tattoo needle and any waste exposed to human blood that is generated in the creation of a tattoo shall be disposed of in the same manner as biohazardous medical waste pursuant to § 49-761." A.R.S. § 49-761(D)(1) and (2) specifically mentions both biohazardous medical waste and medical sharps as areas to be regulated. The commenter misstates the standard as "contain human blood" when in fact the standard is "any waste exposed to human blood that is generated in the creation of a tattoo." ADEQ has clear authority to regulate both BMW and tattoo waste specifically. During stakeholder meetings, one commenter noted: "it is a good idea to include the language for body modification as they do not feel they are

		included in this regulation but they generate a lot of sharps and most states are now including body modification businesses". As stated, body modification and tattooing often occur on the same premises, so clarifying the regulations to cover both settings is appropriate.
R18-13-1401(8)	Stericycle: The regulations at 49 CFR Part 176 govern the carriage of hazardous materials by vessel and are inapplicable to motor vehicle transportation.	Transporters may comply with appropriate segregation as required by USDOT requirements under 49 CFR 177.848. ADEQ has corrected the citation such that it refers to "Carriage by Public Highway" rather than by vessel. ADEQ thanks the commenter for noticing this incorrect citation.
R18-13-1401(11)	Sharps Compliance: "Discarded drug": The definition is confusing as in the initial sentence you state that controlled substances are included as a "discarded drug", then in the second sentence you state that controlled substances regulated by the DEA are exempt. Additionally, you exclude "hazardous waste" however this definition is specific to discarded drugs so should say "hazardous waste pharmaceuticals".	ADEQ has removed "controlled substances" from the definitional term, keeping it in the exception to allow for maximum clarity surrounding the regulation of these substances. Although ADEQ's Proposed Rule indicated no changes to the definition of "discarded drug" beyond renumbering, ADEQ has made this new correction to address any confusion. Duplicative regulation is to be avoided, as stated in A.R.S § 49-1002. Certain types of discarded drugs could also be classified as hazardous waste pharmaceuticals or DEA-regulated substances; therefore, ADEQ has specifically mentioned these exceptions to allow regulations in those areas to continue to govern these types of wastes. Further, "hazardous waste" as referred to in this provision is not limited to "hazardous waste pharmaceuticals"; it includes other types of "hazardous waste" regulated elsewhere in ADEQ's rules.
R18-13-1401(18)	Sharps Compliance: "Medical sharps container": this definition is too general, and given the definitions are for regulated entities, we feel a more	The commenter has pointed out that OSHA, FDA, USPS, and USDOT all provide specific requirements for sharps containers. Due to the various regulations already applicable to these containers,

	specific definition is required.	ADEQ has no reason to increase stringency and complicate compliance. ADEQ's definition provides adequate guidance while still allowing for compliance with other regulatory entities' requirements.
R18-13-1401(18)	Stericycle: USDOT requires that a sharps container be: • "securely closed" • "registered under the Medical Device Regulations of FDA" • "made of puncture resistant plastic" See 49 C.F.R. §173.134 Similarly, OSHA requires that a sharps container be "puncture resistant" "leakproof" and "closed." See 29 C.F.R. § 1910.1030. A "locking cap" is not required by USDOT, OSHA or any other state where Stericycle currently operates. Stericycle operates nationwide, and its ability to efficiently serve its customers is compromised if it is required to design and use a specific sharps container only for customers in Arizona. In addition, requiring a "locking cap" is contrary to ADEQ's stated goal of protecting human health. For example, OSHA requires that sharps containers be "easily accessible to personnel." See 29 C.F.R. § 1910.1030(d)(4)(iii)(A)(2)(i). A locking cap can render a sharps container difficult to access, which is inconsistent with OSHA's standard and may cause additional sharps-related injuries for generators.	ADEQ thanks the commenter for noticing the inconsistency. ADEQ removed the "locking cap" requirement and replaced it with a provision requiring a cap that allows for secure closure. This change allows for increased compatibility with federal regulations.

	State and local regulations concerning the transportation of hazardous materials must be "substantively the same" as the USDOT requirements. The "locking cap" rule does not meet that standard and is unduly burdensome.	
R18-13-1402(B)	For clarity, this language [in R18-13-1402(B)] should be removed from ADEQ's BMW regulations. First, it is inaccurate. Several provisions within the BMW regulations do impose requirements on how a generator is to collect and handle BMW. See, e.g., R18-13-1406(A), R18-13-1408 and R18-13-1419. Second, to maximize protection of human health and the environment, it is important that all parties involved with handling BMW (including generators, transporters, treaters and disposers) are familiar with and follow applicable requirements related to proper classification, separation, labeling and storage. A generator that does not follow ADEQ's regulations puts both its and Stericycle's employees at risk.	ADEQ understands that the provision could cause confusion and has provided qualification to clarify that an item must first become waste before it is subject to the biohazardous medical waste regulations. Prior to becoming waste, such an item is not considered a biohazardous medical waste under these rules.
R18-13-1406(B)(3)	The reference is nonsensical. The regulations at 49 C.F.R. §§ 172.200 – 172.205 contain the requirements for shipping papers (or "tracking documents"). The regulations at 49 C.F.R §§ 172.300 – 172.338 relate to marking requirements. The shipping paper provisions do not cross-reference or otherwise incorporate the marking requirements. As such, under USDOT regulations, a tracking	For consistency and clarity, the tracking document should refer to the packaged waste in some manner to allow for identification. Under 49 CFR §172.201(a)(4), the regulations provide permissive authority to include additional information: "A shipping paper may contain additional information concerning the material provided the information is not inconsistent with the required description. Unless otherwise permitted or required by this subpart, additional information must be placed

	document prepared per 49 CFR 172.201 would not contain an identification number specified by 172.300. State and local regulations concerning the transportation of hazardous materials must be "substantively the same" as the USDOT requirements. The proposed identification number rule does not meet that standard.	after the basic description required by § 172.202(a)." Additionally, it is required under 49 CFR 172.300(b) that packaging be appropriately marked: "When assigned the function by this subpart, each carrier that transports a hazardous material shall mark each package, freight container, and transport vehicle containing the hazardous material in the manner required by this subpart." ADEQ is linking this information in order to provide quicker comprehension for those reviewing shipping papers while also complying with USDOT regulations.
R18-13-1407	Kenneth Bauer: This is focused on non-sharps packaging. What about waste that contains sharps containers? Not loose sharps but containerized ones that are generally processed with the waste and sealed in red bags?	Medical sharps are addressed directly in R18-13-1419 rather than in R18-13-1407.
R18-13-1408	Sharps Compliance: Most RMW generators, except for large generators, do not have the ability to refrigerate their waste. A 72-hour limit for storage places an undue burden and expense on small to medium waste generators to have to get rid of their waste basically immediately upon full. This would be one of the strictest storage time limits of all 50 states. The majority have 30-day limit.	The previous rule included a 7-day accumulation limit for both putrescible and nonputrescible waste. However, putrescible waste was subject to refrigeration at any point if it would "create a nuisance." ADEQ sought to clarify expectations for this vague provision on putrescible waste refrigeration by creating clear timelines for refrigeration (72 hours). The International Committee of the Red Cross recommends unrefrigerated storage for putrescible waste for up to 72 hours and refrigerated storage at 37-46 degrees Fahrenheit for up to one week for putrescible waste, depending on ambient temperatures. Due to Arizona's high temperatures, longer limits may be unsafe for putrescible waste due to the more rapid decomposition and creation of dangerous conditions. The revised regulations make compliance simpler for non-putrescible waste since

		the potential for harm while unrefrigerated is much less. These revised regulations clarify that non-putrescible waste may be kept unrefrigerated for up to 90 days, an increase of 83 days from the previous 7-day maximum. Although some states, such as Florida, may allow for 30 days of storage, during that time the biohazardous medical waste must be kept in a "sanitary condition". Dictionary definitions of "sanitary" indicate the meaning is synonymous with "aseptic, germfree, hygienic, sterile." In this sense, ADEQ has clarified something that Florida left vague: guidelines for proper sanitation for putrescible waste. ADEQ's rules allow a timeline triple that of Florida (90 days) for nonputrescible waste, while providing appropriate clarity for storage of putrescible waste (as indicated above). Texas, for instance, requires that such wastes are "not to create nuisances" and indicates the facility should "Maintain at a temperature of 45 degrees Fahrenheit or less any putrescible or untreated medical waste stored for longer than 72 hours after collection". Utah allows up to 7 days unrefrigerated for infectious waste, with a maximum on-site storage of 60 days. Comparisons of the most populous areas in Utah and Arizona indicate that Arizona is, on average, at least 12 degrees warmer than Utah, with an average of 2.5 hours per day more sunlight. In these conditions, it is reasonable to estimate that putrescible waste will decay faster in Arizona, thus making the 7-day period of Utah too long to be appropriate.
R18-13-1408	Kenneth Bauer: Just clarifying. Since the portion for the processor always referenced this section for storage requirements, does this mean that	R18-13-1412(A)(2)(a) directly addresses permitted treatment facilities and storage times. This requirement has not been changed.

	processors now have 90 days to process materials also?	
R18-13-1409	Kenneth Bauer: If these changes go into effect, everyone will have to update their plans. Will that require everyone to pay for an amendment?	The changes in R18-13-1409 are a reorganization of current provisions to improve clarity. Additional changes were meant to add flexibility (such as allowing electronic submittal and explicitly allowing for the use of trailers). The expansion from 24 hours to 72 hours aims to provide small businesses additional time and reduce unnecessary burden. ADEQ is aware that some updates may be needed where changes have been made to the "30 consecutive days" rule. However, these changes will only affect those who were exploiting the provisions in a manner not intended by the rules in order to avoid compliance. An amendment to address such changes will cost $100 for the application to add these vehicles onto the license. ADEQ has received no other comments that licenses or facility plans may need to be updated, so it appears that only a small number of stakeholders may need to pay for an amendment.
R18-13-1409(B)(1)(f) & 1409(G)	Stericycle: The requirement to submit a transportation management plan in a "department-approved format" should be removed. Stericycle is already required to prepare a transportation management plan per USDOT regulations. The obligation to prepare a similar but separate plan for ADEQ is duplicative and unnecessary. State and local regulations concerning the transportation of hazardous materials must be "substantively the same" as the USDOT requirements. The transportation management plan	Subsection (G) states that the transporter must have a transportation management plan, but leaves the requirements open such that a transporter may easily comply with both ADEQ and USDOT regulations using the same document. The commenter misstates the requirement regarding "department-approved format." The term "department-approved format" does not appear in regard to transportation management plans. The phrase "department-approved format" appears only in regard to a transporter license, in R18-13-1409(B). While an application for a transporter license is required to be submitted in a "department-approved format" in (B)(1), there is no similar requirement for a

	requirement does not meet that standard.	transportation management plan. In reviewing the document for transportation management plan information, ADEQ noted a few areas that needed to be clarified. First, 1409(D) has been corrected to clarify that adding vehicles to the license via amendment will incur a fee, rather than adding a transportation management plan. Second, ADEQ noticed the redundancy in R18-13-1409(G)(1) and (2), given that both components (1) and (2) are already accounted for in the definition of "transportation management plan" at R18-13-1401(33). Therefore, ADEQ eliminated (1) and (2) from 1409(G) to remove the redundancy.
R18-13-1409(B)(3)	Stericycle: The requirement to submit all transportation vehicles for inspection by ADEQ should be removed. Stericycle is already required to submit its vehicles for annual inspection by USDOT. See 49 C.F.R. Part 396. The obligation to undergo a similar but separate inspection by ADEQ is duplicative and unnecessary. State and local regulations concerning the transportation of hazardous materials must be "substantively the same" as the USDOT requirements. The inspection requirement does not meet that standard.	Under 49 CFR Part 396, the Federal Motor Carrier Safety Administration (FMCSA) has clarified in guidance on § 396.17 (Periodic inspection) that: "If the State requires all vehicles registered in the State to be inspected through its mandatory program, then the motor carrier must use the State program to satisfy the Federal requirements." Under 49 CFR § 396.3 (Inspection, repair, and maintenance), there is no specified inspection interval "because such intervals are fleet specific and, in some instances, vehicle specific" and "[t]he requirements of §396.11, 396.13, and § 396.17 are in addition to the systematic inspection, repair, and maintenance required by §396.3." FMCSA language clarifies that state inspections are allowed and, if state inspections are mandated, the transporter "must use the State program to satisfy the Federal requirements." Therefore, it is evident that USDOT did not preempt state inspections, and in fact contemplated them as the appropriate means to meet federal requirements. ADEQ also notes that the purpose of the respective USDOT regulations and

		ADEQ regulations differ, so state inspections may account for this to ensure compliance with ADEQ rules.
R18-13-1409(K)(3)	Stericycle: A transporter is not prohibited from delivering BMW to a medical waste storage, transfer, treatment or disposal facility located outside of Arizona, in which case such facility would not be "Department-approved." ADEQ has no authority to regulate or otherwise approve facilities that are not located in Arizona.	ADEQ explicitly provides in R18-13-1402(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." ADEQ does not purport to regulate or approve facilities located outside of Arizona, nor does ADEQ prohibit delivering BMW to an out of state facility. Rather, ADEQ regulates in-state facilities by requiring they be approved by the department.
R18-13-1411(6)	Stericycle: Stericycle is a transporter of BMW in Arizona and operates transfer facilities in Arizona. To clarify, Stericycle requests that the Proposed Rule be revised to indicate that a storage or transfer facility operator need not sign the tracking document if that operator is also the transporter.	To indicate the appropriate custodial record and responsibility for the waste, ADEQ requires that each party accepting the waste indicate their acceptance by signing. If ADEQ were to make an exception, the records could appear incomplete such that there is not appropriate documentation of the acceptance of waste by the treating facility. Although Stericycle contends that its role as both transporter and operator indicates the need for only one signature on behalf of Stericycle, this proposal does not provide for a complete record. Under the commenter's proposed circumstance, the individual transporter signing on behalf of Stericycle and the individual operator signing on behalf of Stericycle would not both sign, therefore the record would only show transmittal to the transporter with no indication of receipt at the operating facility. Both signatures attesting to acceptance by the transporter and acceptance at the facility are necessary to show appropriate waste chain of custody.
R18-13-1411(8)	The requirement to clean storage areas daily is unduly burdensome and should be removed. Other	The cleaning requirement is not new and should require no change in the procedures currently being used. The

	requirements throughout the BMW regulations, including the obligation to use containers that are leakproof, help ensure that spills are rare. In the absence of a spill (a release of BMW from its package) the cleaning procedures described in the Proposed Rule, including applying disinfectant and removing visible particles, are unnecessary. Such extreme cleaning procedures are only appropriate in the event of a spill. Reasonable housekeeping practices as necessary to protect the public health and employee health and safety should otherwise be sufficient for a BMW storage area.	change in this rule language merely replaces the citation to R18-13-1407(A)(2) with the language located in R18-13-1407(A)(2). The reason for this is that R18-13-1407(A)(2) uses language regarding containers, whereas R18-13-1411 refers to storage areas. The removal of the cross-citation and the inclusion of explicitly spelled out requirements should help avoid confusion. Protection of human health and the environment via the use of an approved disinfectant and removal of visible particles is necessary to prevent the spread of disease from biohazardous medical waste. Since putrescible waste may now be stored for 72 hours unrefrigerated, there is a potential for disease vectors if the area is not appropriately cleaned.
R18-13-1412(A)(1)(e) & B(5)	Stericycle: An autoclave may have many potential applications and an autoclave manufacturer is not typically aware of, and does not always design or build according to, particular treatment standards. Operators perform efficacy testing and are often in a better position than manufacturers to certify that the equipment can meet the required treatment standards. The regulations should therefore offer the option for operators to attest that the equipment can achieve the treatment standards. As discussed above, an autoclave may have many potential applications and an autoclave manufacturer may not have specifications that are relevant to BMW treatment operations. The text should therefore be revised to clarify that only applicable manufacturer specifications need	ADEQ specifies “according to the manufacturer’s specifications for the unit” in order to ensure uniformity and conformity with appropriately tested uses for autoclaves. Although an operator may certainly have more specified knowledge in their field than a manufacturer of an autoclave, the manufacturer has conducted strict testing to ensure the device complies with appropriate safety standards, as set by the FDA or other appropriate governmental entities. It is ADEQ’s goal to avoid risks to the public health, which necessarily involves ensuring that autoclaves are not operated in a way inappropriate to their specifications so as to avoid explosions and dispersion of infectious materials.

	be consulted.	
R18-13-1412(B)(10)	Kenneth Bauer: You have changed the verbage from red bag to container. The way it is worded would mean that we would have to take our reusable barrels and put them in the autoclave. That might be a tad expensive. Please identify what containers you mean. What is the purpose of the change from Red Bag to container?	Stakeholders pointed out in ADEQ's stakeholder meetings that red bags are not the only type of container that may be utilized, and therefore the word "container" seeks to be more inclusive of BMW storage. Sharps collected in puncture resistant containers, for instance, would be more clearly included in this provision than previously. ADEQ uses "container" in the Merriam-Webster definitional sense to mean "a receptacle."
R18-13-1418	Sharps Compliance: We believe there needs to be a stronger statement about medication disposal that should not include on-site destruction given the dangers improperly disposed medications pose to both humans and the environment. As of August 2019, hazardous waste pharmaceuticals can no longer be flushed. As of 2014, DEA has stated that flushing controlled substances does not meet their non-retrievable requirement. Drug degradation/decomposition products utilizing carbon or charcoal-based formulas (typically pouches or bottles) cannot be placed into the trash by RMW generators. Use of drug degradation products increase medication disposal costs since generators pay for both the products themselves as well as hazardous waste pickup fees, since the resulting concoction of medications cannot be profiled as non-hazardous. The degradation pouches have not been proven to meet the DEA's non-retrievable standard. The environmental dangers posed by the improper	ADEQ's rule addresses these concerns by including the requirement to comply with federal or state laws (including the EPA and DEA) prescribing methods of destruction. This rule also indicates segregation and labeling for transport to an appropriate treatment facility is an option. However, if none of the criteria are met, the minimum requirement is some form of destruction to prevent the drugs' use. The rules do not specify the method of destruction in order to allow for flexibility. There is nothing in this provision that prevents compliance with other regulations.

	disposal of any medication, not just hazardous or controlled medications, have been well-documented and give further cause to ensure all medications are disposed of in a regulated manner.	
R18-13-1418	Stericycle: Stericycle supports the Proposed Rule's prohibition on flushing discarded drugs down a sanitary sewer. To maximize protection of human health and the environment, ADEQ should also require that such discarded drugs be incinerated.	The rules do not specify the method of destruction in order to allow for flexibility.

12. 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:

A.R.S. § 41-1037(A)(3), "The issuance of a general permit is not technically feasible or would not meet the applicable statutory requirements," applies in this case. This rulemaking amends two existing rules that require a license or permit, R18-13-1409 and 1410. ADEQ cannot use a general permit in R18-13-1409 because transporters meet the requirements for licensing through criteria and information specific to their vehicles. Therefore, individual processing is required in order to issue licenses and conduct inspections. The transporters pay fees according to that processing, capped at a maximum fee. The vehicle-dependent nature of this license makes it impossible to use a general permit. Regarding the R18-13-1410 license, A.R.S. §49-762(A)(3) requires individual solid waste facility plans for medical waste facilities. Therefore, it is not possible to utilize a general permit for a license under R18-13-1410 either.

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 specifically to biohazardous medical waste, 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 considered specific areas where United States Department of Transportation (USDOT) 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).

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

Incorporated Federal Citation	Location
49 CFR 177.848	R18-13-1401(9)
29 CFR 1910.145(f)(8)(ii)	R18-13-1401(41)
49 CFR 172.201	R18-13-1406(B); R18-13-1409(K)
49 CFR 172.300-172.338	R18-13-1406(B)(3)

14. Whether the rule was previously made, amended, or repealed as an emergency rule. If so, cite the notice published in the Register as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages:

The rule was not previously made, amended, or repealed as an emergency rule.

15. 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

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" 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 or broken, and items that contain serum, plasma, and other blood

components. An item would be considered caked if it could release flakes or particles when handled.

c. Human ~~pathologic~~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 ~~pathologic~~pathological wastes do not include the head~~, or~~ spinal column~~.~~, hair, nails, or teeth.

d. Medical sharps: Discarded sharps that pose a stick hazard that have come into contact with blood, blood products, or pathological waste. ~~or human patient~~ care~~, medical research, or clinical laboratories.~~ Examples include ~~This includes~~ hypodermic needles; ~~syringes; pipettes;~~ scalpel blades; ~~blood vials;~~ and needles attached to tubing or syringes.~~; 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.~~ 5. "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.~~ 6. "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.~~ 7. "C~~.~~F~~.~~R~~.~~" means the Code of Federal Regulations.

~~10.~~ 8. "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~~. 9. "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 177.848, revised as of October 1, 2020, and no future editions or later amendments, is incorporated by reference in this rule and on file with ADEQ.

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

~~12.~~ 11. "Discarded drug" means any prescription medicine~~,~~ or 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.~~ 12. "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.

13. "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.~~ 15. "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.~~ 16. "Hazardous waste" has the meaning prescribed in A.R.S. § 49-921.

~~18.~~ 17. "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.~~ 18. "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.~~ 19. "Independent testing laboratory" means a testing laboratory independent of oversight activities by a provider of alternative treatment technology.

~~21.~~ 20. "Medical sharps container" means a vessel that is rigid, puncture resistant, leak proof, and equipped with a ~~locking~~ cap capable of being securely closed.

~~22.~~ 21. "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.~~ 22. "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.~~ 23. "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.~~ 24. "Off site" means a location that does not fall within the definition of "on site" contained in A.R.S. § 49-701.

~~26.~~ 25. "Packaging" or "properly packaged" means the use of a container or a practice under R18-13-1407.

~~27.~~ 26. "Putrescible waste" means waste materials capable of being decomposed rapidly by microorganisms.

~~28.~~ 27. "Radioactive material" has the meaning under A.R.S. § 30-651.

~~29.~~ 28. "Secure" means to lock out or otherwise restrict access to unauthorized personnel.

~~30.~~ 29. "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.~~ 30. "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.~~ 31. "Technology provider" means a person that manufactures~~,~~ or a vendor who supplies alternative medical waste treatment technology.

~~33.~~ 32. "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.~~ 33. "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.~~ 34. "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.~~ 35. "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.~~ 36. "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.~~ 37. "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.~~ 38. "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.~~ 39. "Treatment standards" mean the levels of microbial inactivation, prescribed in R18-13-1415, to be achieved for a specific type of biohazardous medical waste.

40. "USDOT" means the United States Department of Transportation.

41. "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. 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. The requirements for biohazardous medical waste set out for collection do not apply to the manner in which the generator collects~~,~~ or handles material prior to that material becoming 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. 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 ~~package~~ packaged ~~the waste~~ as prescribed in this article ~~R18-13-1407 before~~ and shall subsequently either ~~self-hauling~~ self-haul or ~~before~~ store the waste as provided under R18-13-1408 and ~~setting~~ set 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. 49 CFR 172.201, revised as of October 1, 2020, and no future editions or later amendments, is incorporated by reference in this rule and on file with ADEQ. 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 - 172.338. 49 CFR 172.300 - 172.338, revised as of October 1, 2020, and no future editions or later amendments, is incorporated by reference in this rule and on file with ADEQ.
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~~
   ~~f~~e. 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 putrescible~~ 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~~ complies with 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 (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 Transporters Annual Fee table.

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

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 (IJ).
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 to the license shall be processed after payment of inspection fees and other expenses at the rate listed in subsection (~~D~~B)(~~3~~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.~~ 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 ~~(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 ~~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:~~ subsections (1) and (2) as well as all of the requirements in subsection (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 $\log_{10}$ 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 not biohazardous medical waste, and may be treated as a solid waste, if they are not composed of

biohazardous items listed in R18-13-1401(4) and do not contain discarded drugs or another regulated substance.

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